Development: Studies and Research

Safe blood in developing countries

Principles and organisation

EUROPEAN COMMISSION

EUROPEAN COMMISSION

Safe blood in developing countries

Principles and organisation

Luxembourg:
Office for Official Publications of the European Communities, 1995
Second printing: January 1997

European Commission
Directorate-General for Development
Health and family planning, AIDS Unit.
Rue de la Loi, 200
B-1049 Brussels
Tel: (32-2) 296 36 98
Fax: (32-2) 296 36 97

Design and printing, Lannoo-Drukkerij, Tielt, Belgium

Safe blood in developing countries

Principles and organisation

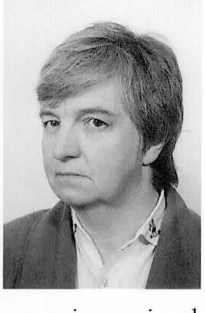
Written and edited by
C. Gerard
D. Sondag-Thull
E. J. Watson-Williams
L. Fransen

Final editing by
M. Bontinck
R.W. Beal

Contributors
A. Nuñes Brandao, W. Brünger, M. Chassaigne,
P. Conte, J. C. Emmanuel, P. Fontaine,
J. Goddard, D. Grodos, P. Kataaha, J. Koistinen,
D. A. Mvere, J. Ntibanyiha, P. Rao,
G. Van der Groen

Written & edited by

Christiane GERARD (MSc, PhD, Clin. Path.), has been a collaborator of the Department of Clinical Biology of the Liège University Hospital at the Service of Immuno-Haematology since 1972. She has been working at the HIV/AIDS Reference Laboratory of Liège since 1985. Owing to her function and expertise, her daily task is to ensure the connection between Biology and Clinical practice. Besides her numerous studies in the field of blood group serology, she is particularly experienced in the technology used to diagnose blood transmissible diseases (HIV, HCV...) as well as in the epidemiological and semiological aspects of these diseases among blood donors from Europe and from Central Africa.



Danièle SONDAG-THULL (MD, PhD, Clin.Path.) is currently Director of the Blood Transfusion Services of the Belgian Red Cross in the French-speaking part of the country. Even before she got her MD degree, she was active in Blood Transfusion and Immuno-Haematology, two scientific disciplines she is now teaching at the University of Liège. As Head of one of the 7 HIV/AIDS Reference Laboratories in Belgium since 1985, she has gained large experience in the study of safe blood programmes. Because of her skill and efficiency, she has often been entrusted with missions to African countries with a view to organizing local transfusion services and safe blood collection.

E. John WATSON-WILLIAMS (MB FRCP, FRCPath) is a graduate of Cambridge and of the Bristol Medical School. After training in Edinburgh as a haematologist, he spent five years as head of the Haematology division of University College Ibadan, Nigeria. The next seven years were spent at the University of Manchester. In 1969 he directed blood banks in California and joined the University of California at Davis, from where he retired, in 1987, as professor in Haematology and Oncology. After a short spell in a mission hospital in Kenya, he went to Uganda. From 1988 until 1994 he under-

took several missions for the EC to assist in the development of the national blood transfusion services of Uganda and Zambia.

Lieve FRANSEN (PhD, BA, MD, Dip. Tropical Medicine, Dip. Venereology) is public health adviser at the European Commission's Directorate General for Development since 1993. Before joining the Commission's newly created Health/AIDS Unit she was the Director of the AIDS Task Force. Between 1984 and 1987 she was a Medical Assistant and Researcher at the Institute of Tropical Medicine, Antwerp, Belgium, and since 1975 has variously been adviser and medical manager in Cabo Verde, Mozambique, Rwanda and Kenya.

Final editing by

M. Bontinck	EC AIDS Task Force Documentalist & Editor, ***Belgium***
R.W. Beal	Director Red Cross Blood Transfusion Service, ***South Australian*** Division (WHO collaborating Centre).

Contributors

A. Nuñes Brandao	EC Technical Assistant, ***Angola***
W. Brünger	EC AIDS Task Force Project Manager, ***Belgium***
M. Chassaigne	Director Regional Blood Transfusion Service, Tours, ***France***
P. Conte	Director Regional Blood Transfusion Service, Orléans, ***France***
J.C. Emmanuel	Blood Transfusion Medicine Specialist, World Health Organisation, ***Switzerland***
P. Fontaine	EC AIDS Task Force Legal Adviser, ***Belgium***
J. Goddard	EC Technical Assistant, ***Uganda***
D. Grodos	Consultancy Firm, ***Belgium***

P. Kataaha	Director, National Blood Transfusion Service, ***Uganda***
J. Koistinen	Director, Total Quality Management, ***Finnish*** Red Cross Blood Transfusion Service
D.A. Mvere	Director, National Blood Transfusion Service, ***Zimbabwe***
J. Ntibanyiha	Director, National Blood Transfusion Service, ***Burundi***
P. Rao	EC Consultant, ***India***
G. Van der Groen	Institute of tropical Medicine, Microbiology, ***Belgium***

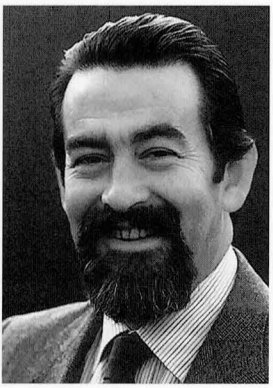
Contact addresses

Commission of European Communities
Directorate General for Development
Health, Family Planning & AIDS Unit
200, rue de la Loi
B-1049 Brussels, Belgium
Tel: (32.2) 296.37.01
Fax: (32.2) 296.36.97

AIDS Task Force
Technical Assistance Programme
10, rue de Genève, Box 7
B-1140 Brussels, Belgium
Tel: (32.2) 705.43.90
Fax: (32.2) 705.25.46

Blood Transfusion Centre
Red Cross - University of Liège
41, rue Dos Fanchon
B-4020 Liège, Belgium
Tel: (32.41) 66.75.39
Fax: (32.41) 66.75.47

Foreword by Commissioner Professor Pinheiro



HIV is one of the major social issues of the end of this century. Despite a major effort of the developing countries, supported by the international community over the last 9 years, the epidemic continues to spread rapidly, especially in the developing world.

Already in 1987 the European Union launched a support programme to limit the spread of the epidemic and mitigate its social impact. Interventions developed at both Community and bilateral levels since then make the Europe of the 15 the most important donor in the field of HIV/AIDS actions today. In order to mobilize the highest political support and to improve the efficacy of our technical and financial support, coordination between all members of the Community is being improved and the Council of Ministers adopted an important resolution on HIV/AIDS actions in the developing world. This resolution defines the European strategies and principles for the next 5 years.

One of the priority strategies in countries where the epidemic is already widespread is to ensure the safety of blood donations. Since 1987 the Community, with its partners, has accumulated an experience and developed an approach which was discussed in a first workshop in March 1991 and reviewed at a second safe blood workshop in July 1994. The results of this workshop are brought together in this new edition of the report which explains the strategy and shares some of the crucial lessons from the ongoing experiences.

I hope that this report will give readers a measure of the work already undertaken and motivate many to organize further support in the most efficient way possible to counter this social and public health threat.

Acknowledgements

This publication on safe blood in developing countries emanates from the activities of the European Communities' HIV/AIDS programme for developing countries. Fieldwork as well as discussions organized during two workshops held in Brussels in March 1991 and July 1994 led to a crystallization of the EC's thinking around safe blood.

The two workshops brought together professionals specialized in public health, sociology, haematology, virology, laboratory management and health system administration residing and working in various countries in Europe and the developing world. The group focused mainly on Sub-saharan Africa because that is where countries experience the most difficulties with the health systems and where the HIV/AIDS epidemic is already widespread.

The members of the group reported on their work experiences and study results and a writing and editorial group finalised the contributions into a coherent text. One member of the group, Dr John Watson-Williams, has been a highly motivated, very well informed and pragmatic collaborator, as well as a prolific writer. We want to pay tribute to his long years of dedication in this field. Special thanks also go to Dr Danièle Sondag-Thull and Christiane Gérard for their dedicated and beautiful work. The book would not have been possible without them. We also thank Michelle Dimora who ensured the smooth running of the second workshop.

The book aims to reach out to audiences interested in, and concerned about the issue of safe blood and public health as an international issue of human rights and as an area for support in the developing world. In the book the group advocates a more holistic and comprehensive approach to safe blood within the various countries' health systems in order to better meet the needs of individuals, the medical corps and public health authorities in the developing world, as well as to help aid agencies to contribute to the process.

Dr Lieve FRANSEN

Brief overview

In the introduction *to the book the EC's policies, strategies and methodologies concerning safe blood in developing countries are briefly reviewed.*

The first chapter *proposes how to best organize safe blood in a country taking into account its different components. A case is made for considering the Blood Transfusion Service as an entity by itself rather than a secondary medical activity.*

Chapter two *shares thoughts and experiences about the recruitment and the selection of blood donors. Too often donor recruitment is left to organisations without any policy or capacities while it should be an integral part of the strategy. Sometimes blood donations are forced or bought but there are numerous reasons why this should be avoided. The chapter also discusses issues such as the right of donors to know their test results and to be fully informed. Some successful and encouraging examples in the third world have shown that it can be done.*

Chapter three *discusses the concepts, definitions and parameters for blood screening procedures for infectious diseases, an aspect of blood safety that has very much come to the foreground since the HIV/AIDS epidemic has emerged. In the developed world public opinion and consequently, political bodies, are demanding foolproof blood safety. What is being done in developing countries ?*

Chapter four *reminds the reader about the preparation and the use of blood components in the context of blood safety.*

Chapter five *develops the main indications for the use of blood and blood products and the actual management of blood transfusions. This chapter is a reminder to all about the potential risk to the patient and waste of the donation if precious blood is not used appropriately. Examples of guidelines are included. The implementation of those guidelines should be monitored carefully so as not to be left to form the weakest part of the chain in safe blood provision.*

Chapter six *introduces the issues around equipment, storage, consumables and buildings as related to safety of blood provision.*

Chapter seven *on safe blood management indicators is a new chapter and has been developed in order to facilitate monitoring and evaluation of safe blood support in developing countries.*

Chapter eight *discusses quality assurance and auditing in relation to safe blood. Further work on costing and financing has been included in* chapter nine. *Training and human resource development is reviewed in* chapter ten.

The new, and final chapter eleven *raises ethical considerations and orientations around blood safety, opening up a crucial human rights debate and discussing some of the experiences and some of the instruments that can support the application of the ethical context.*

INTRODUCTION

In 1986, the international community reacted to the new and then little known HIV/AIDS epidemic by setting up, under the World Health Organisation (WHO), a global programme on AIDS. Around the same time, the late Lorenzo Natali, Vice President of the European Commission, invited all ACP (African, Caribbean and Pacific) states who had signed the 2nd Lomé Convention on European aid to developing countries, to take part immediately in an EC/ACP HIV/AIDS programme. Almost all ACP states responded and 6 months later, the programme was extended to all developing countries.

Over the last years, a process of collaboration between the Commission and the EC Member States led to the development of common HIV/AIDS policy principles and strategic priorities. The following policy principles, guiding all HIV/AIDS activities, were adopted:

1. *Adaptation to risk environments.* Interventions should focus not only on the behaviour of individuals that puts them at risk, but also on the social and structural determinants of exposure to risk. This is particularly important when dealing with specific target groups such as women, children, young people, people in high-risk situations.

2. *Gender sensitivity and specificity.* Analysis, planning and intervention must all show special sensitivity and specificity to gender. Long-term objectives such as the political and economic empowerment, formal education and legal protection of women must go hand-in-hand with short-term interventions focused on specific groups of women and men.

3. *Social learning and human dignity.* History has shown that measures based on coercion of individuals are counter-productive. They drive epidemics undergound and make interventions unsustainable. So it is no use just trying

to identify the individuals at risk or infected by HIV, and then isolating them from their social environment. Instead, there has to be a process of social learning, the aim of which is to enable individuals and society to avoid the risk of infection wherever possible, and to prevent discrimination against those already infected through respect for their human rights and dignity.

4. *Empowerment and responsibility*. Most HIV/AIDS activity cannot be just administered. It needs the motivation and support of individuals and communities. They in turn have to have the power to take responsibility for their own behaviours, risks and choices. Similarly, governments and others in positions of power have to take the responsibility for limiting the risks run by those over whom they have authority.

5. *Integration in a wider framework*. HIV/AIDS work must be integrated with other community activities, other health and education problems and other medical care strategies, at least where there are organisations and activities in these other areas. Integration also requires a national HIV/AIDS policy which includes all major participants, a multi-sectoral approach that involves all the main departments of state, and open policy dialogue between public and private sectors.

6. *Adaptation to the stage of the epidemic and rapid response*. The HIV epidemic takes time to spread over a region, and is at different stages in different regions of the world. So responses to HIV/AIDS also vary over time. But denial, and political and administrative delays have often meant that HIV prevention campaigns, needed before the epidemic becomes widespread, have come too late. So the timelag should be shortened, and every response should come at an appropriate stage in the progress of the epidemic.

The *strategic priorities* chosen for European action are:
- to minimize both the spread of the epidemic and the discrimination against those infected
- to strengthen the health sector to cope
- to measure and reduce the social and economic impact of the epidemic
- to promote better scientific understanding, both biomedical and socio-economic.

The second strategy, to support the health sector to cope with the epidemic, includes support for safe blood interventions.

The EC has devoted great efforts to safer blood supplies, mainly on the African continent, and to a lesser extent in Latin America and the Caribbean and, to date, has supported safe blood programmes in a total of 29 countries, ranging from Cameroon to Guyana, Mexico and Zimbabwe, for a total amount of 35 million ECU.

In industrialized countries, acquisition of HIV infection through transfusion of infected blood is now virtually nil, thanks to universal screening of blood before use. Moreover, screening adds only about 5 % to the cost of a unit of transfused blood.

But in the developing world, between 5 % and 10 % of HIV infections are still due to transfusion of infected blood. In Africa, most countries lack the type of Blood Transfusion Service needed for comprehensive screening of blood. Indeed, supply of safe blood has frequently been neglected in developing countries. On the one hand, blood transfusions are often used in an attempt to save life; on the other hand, the blood may not be safe, and to make it safe is relatively more expensive than in industrialized countries because it implies instituting a comprehensive safe blood strategy.

However, the pressure now to make it safe from HIV can be summed up in one simple statistic. The efficiency of HIV transmission through sexual intercourse (vaginal and anal) is between 0.1 % and 1 %. But the efficiency of transmission through blood transfusion is over 90 %. In other words, infected blood is lethal.

For the medical service, there is yet another dimension: in blood transfusion, the recipient often cannot individually decide and therefore the responsibility lies entirely with the medical services.

So in developing countries, HIV has raised complex issues about strategy and objectives, organisation and management, law and ethics, equipment and financing for the provision of safe blood.

A basic tenet of the safe blood policy of the Commission's programme is that simple testing for HIV is not enough and that provision of safe blood in itself is a life saving act. Other planks to the policy are:

- blood donors need to be selected more carefully, and then actively retained
- blood donors should be voluntary, not paid, to avoid (for example) infected people selling blood under different names in different places to make money

- blood and blood substitutes must be better used and available
- prevention or earlier detection of other diseases reduces the need for blood transfusions and therefore the risk of infection by this route
- screening of blood for other diseases as well as HIV is a basic requirement: failure to do this could render the whole programme absurd
- sophisticated testing laboratories are of little use if collection of blood is badly organized and produces either too little blood for testing or too many infected units because donors have been badly selected, or fails to produce enough blood for a reserve supply so that, for emergency operations, untested blood still has to be used.

LIST OF EC INTERVENTIONS IN THE AREA OF SAFE BLOOD IN DEVELOPING COUNTRIES

The EC has provided technical and financial support to 47 safe blood projects in 29 developing countries for a total amount of 35 million ECU. Support for safety of blood was given in the past to: Burundi, Chad, Costa Rica, Djibouti, Dominican Republic, Equatorial Guinea, Gabon, Grenada, Honduras, Mali, Mexico, Niger and Zaire.

At present further safe blood interventions are ongoing in:

Angola

In an initial phase EC support was given to strengthen safe blood activities in the blood transfusion centres at provincial level. Following the period of civil war these activities are starting up again via the strengthening of the role of the National Blood Transfusion Service in Luanda as well as the services at provincial level.

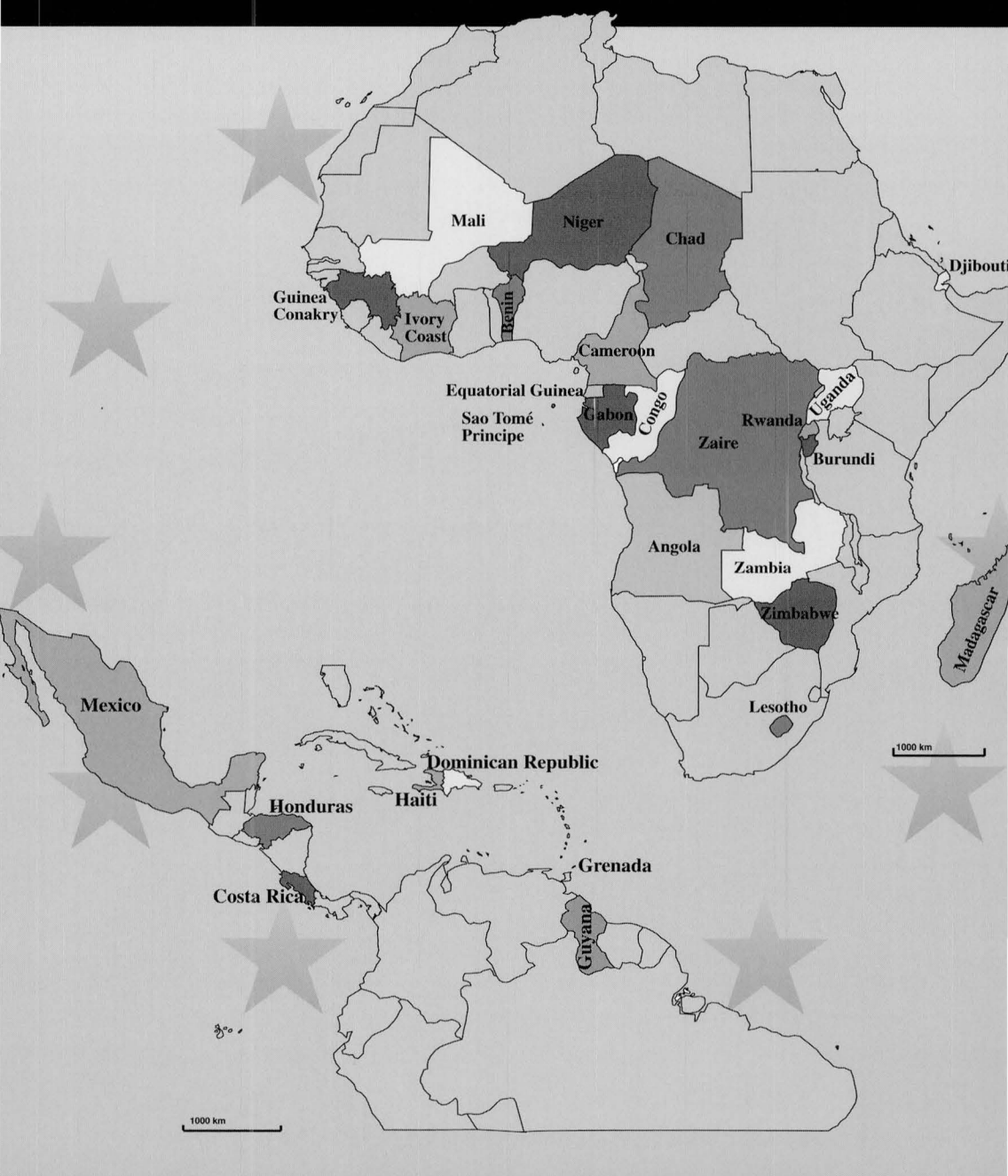
Benin

The EC supports government measures to strengthen the facilities and capabilities of the public health services in the southern departments of Benin. This includes support for the development of a national blood policy of the Ministry of Health, the creation or upgrading of regional blood banks in the three departments, Atlantique, Mono and Oueme, and the training of health staff in charge of blood transfusion in Benin.

Cameroon

Support was given to develop a national policy and to strengthen two regional blood transfusion centres in Yaoundé and in Douala, the country's main urban centres. These centres were refurbished and blood collection, screening and storage facilities and procedures were improved. Blood donor recruitment was expanded and reoriented towards blood collection among students and enterprises.

EC and HIV/AIDS SAFE BLOOD INTERVENTIO



EC safe blood interventions i developing countries

Congo

The objective of EC support is to assist the government in the development of a national blood policy and to establish a regional blood transfusion centre in Pointe Noire, the country's second largest town, to collect, test and supply safe blood for the the hospitals in town and the region around. The premises were rehabilitated, staff has been trained, equipment and supplies were provided. A national legislation on voluntary blood donation and blood transfusion was adopted.

Guinea Conakry

The goal of EC support to safe blood activities in Guinea Conakry, carried out with the support of the Belgian Red Cross Society, is the installation of a National Blood Transfusion Service in Conakry as well as blood banks in the prefectures and the training of the personnel of these structures. Considerable efforts have been made regarding the selection of blood donors among school students, the military and the private sector.

Guyana

With EC support, a National Blood Transfusion Service has been set up with a blood bank and testing laboratory for HIV and other infections in Georgetown, using voluntary donors. Testing is done on blood from New Amsterdam, Linden and Suddie hospitals.

Haiti

With the technical support of the French Red Cross Society, the European Commission supports the safe blood activities established by the Haitian Red Cross Society as well as by the public hospitals in the country.

Ivory Coast

Following support given to the safe blood activities of the National Blood Transfusion Service in Abidjan and the Regional Blood Transfusion Services in Korhogo and Bonaké, coverage has been extended to all transfusion services in the country's hospitals. The role played by the NBTS and the RBTS in training and supervision is crucial for this development.

Lesotho
Support is given to the national health budget to sustain the safe blood services which have been put in place, with particular attention for the promotion of regular donations of blood by voluntary donors.

Madagascar
EC support consists of strengthening the National Blood Transfusion Service in order to ensure blood provision for the hospitals in Antananarivo (needs amounting to 8,000 blood units per year). Support is also provided to strengthen its role of supervision, training and participation in the definition of a national blood transfusion policy.

Mauritius
EC support is provided for essential equipment for blood safety, supervision and quality control, and the improvement of the utilization of blood.

Rwanda
EC support (joint action with Belgian Cooperation and Belgian Red Cross) has strengthened the screening capacity of the National Blood Transfusion Service and the organisation of counselling. Following the political conflict all support has been suspended but hopefully will resume soon.

Sao Tomé
The EC supports the rehabilitation and reorganisation of the blood bank of the main government hospital of Sao Tomé by training of laboratory technicians and the provision of equipment and laboratory supplies. The provision of safe blood to health centres outside the capital is envisaged for the near future.

Uganda
EC assistance enabled the Ugandan government to develop a nationwide blood transfusion service. Following the rehabilitation of Nakasero Blood Bank (NBB) in Kampala and the reorganisation of donor recruitment and safe blood supply to hospitals in and around the capital, four regional blood banks and two collecting and screening centres were created, operating under the direction of the Uganda Blood Transfusion Service based at NBB. The UBTS collects, tests and distributes to the country's 92 hospitals all the blood and materials needed for transfusion of patients in Uganda. A national blood

policy has been developed and standard procedures for donor recruitment, selection and counselling and for all blood tests have been introduced in all hospitals through training of health staff and quality assurance.

Zambia

The EC supported Zambia to establish a national blood transfusion service, to reactivate voluntary donor recruitment and to improve safe blood facilities and practice throughout the country. A national blood policy has been formulated within the government's health system reform. The ZNBTS is directed by a core team and consists of two central blood centres serving Zambia's most populated regions around Lusaka and the Copperbelt, and 7 regional blood centres which serve the major provincial hospitals and provide training and support for the staff responsible for blood transfusion at the district hospitals in their area.

Zimbabwe

The Zimbabwe Blood Transfusion Service decided to extend donor recruitment and the provision of safe blood to hospitals by creating regional blood transfusion centres. So the EC assisted to create new transfusion centres in three regions (Gweru, Masvingo and Mutare), to improve capacities at the Harare centre through support for staff training, transport and laboratory supplies, and to develop a policy for blood use.

Chapter 1

ORGANISATION OF SAFE BLOOD

Introduction

1. Safe blood policy and strategy
   - 1.1. Level I: National Blood Transfusion Advisory Committee
     - 1.1.1. National Blood Transfusion Advisory Committee
       - – Members
       - – Objectives
     - 1.1.2. Policy
     - 1.1.3. Instruments
   - 1.2. Level II: Direction of Blood Transfusion Services
   - 1.3. Level III: Organization of Blood Transfusion
     - 1.3.1. Centralized structures
     - 1.3.2. Regionalized system
     - 1.3.3. Hospital based organisation
     - 1.3.4. Mixed organisation

2. Examples

3. Recommendations on blood policy

4. Recommendations on the organisation of blood transfusion services

Introduction

Blood transfusions are given in every country where there is emergency medical care. Thus at least some resources do exist for that purpose. However, in many developing countries, public health problems are serious and ongoing public health reforms are not taking the specific problems of safe blood into account. This is unfortunate since by better organizing safe blood, higher effectiveness could be achieved.

Key factors for the creation of an effective blood transfusion service system are: acceptance of transfusion medicine as a distinct sector in the health care system, establishment of a national blood policy, well trained and dedicated professionals as well as broadly based national advisory bodies. Indeed, transfusion medicine is not only collecting and testing of blood, it is a major therapeutic art requiring: recruitment and retention of blood donors, blood collection, laboratory testing, blood processing and storage as well as training of physicians in appropriate use of blood. A discipline of such diversity must be recognized as a distinct entity in the health system. It is often lack of this recognition that contributes to poor organisation and functioning of blood transfusion services (BTS).

The organisation and degree of development of the BTS should be part of the national health plan. Ultimately, the government bears the responsibility for organizing and backing up the BTS system regardless of the organisation which is responsible for the implementation. Safe blood implies the responsibility to be assumed either by national health authorities or to be partly delegated to a para-statal agency or NGOs such as the Red Cross or the Red Crescent.

As illustrated in ***Figure 1A*** *and* ***1B****, a national blood policy has been adopted in 81 % of the developed but only in 64 % of the developing and in 32 % of the least developed countries which have reported to WHO. Since only 58 % of the developing and 66 % of the least developed countries have reported, it is conceivable that in reality even fewer countries in the developing world have a national blood policy. (****Figure 1A****). A national blood transfusion service committee exists in 47 % of developing and in 42 % of least developed countries reporting to WHO, and 50 % and 60 %, respectively, have a national director. In 48 % of the least developed and in 46 % of the developing countries, which reported to WHO, the BTS are hospital based usually meaning also lack of national coordination (****Figure 1B****).*

Figure 1A

Percentage of developed, developing and least developed countries (which have reported to WHO), which have a *national director, national policy and national advisory committee* for Blood Transfusion Service.

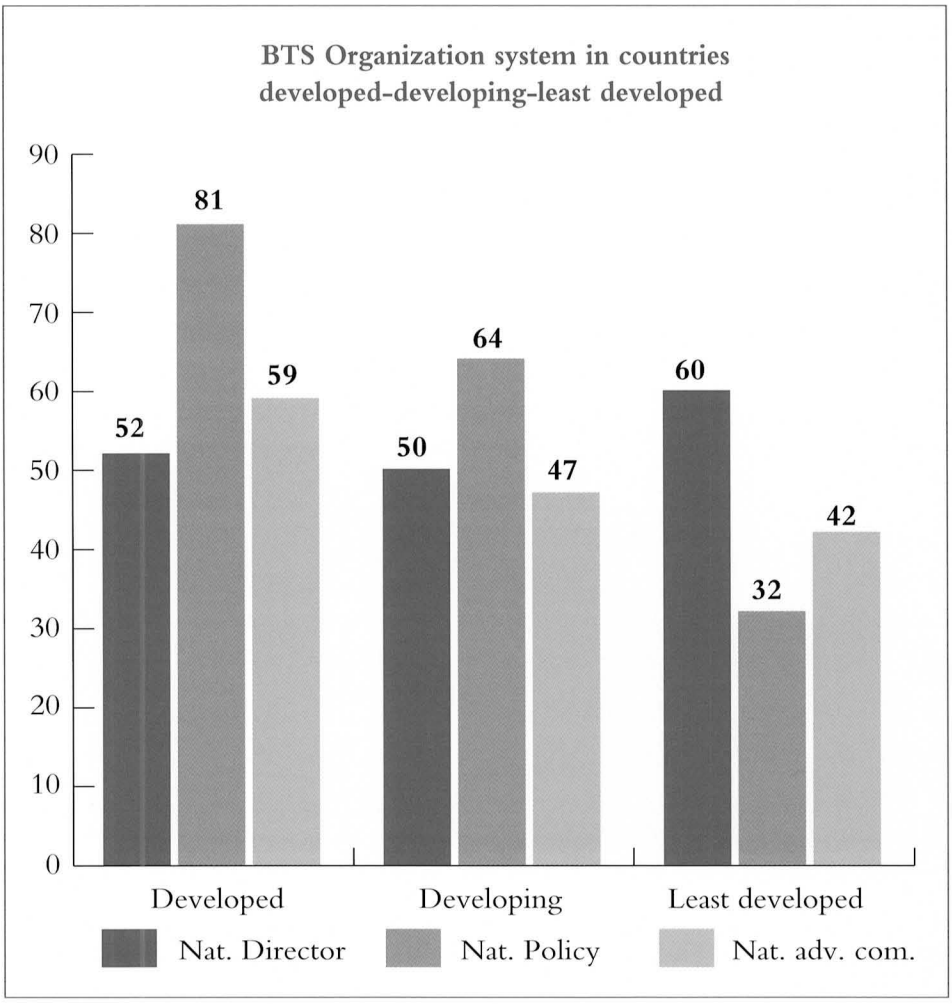
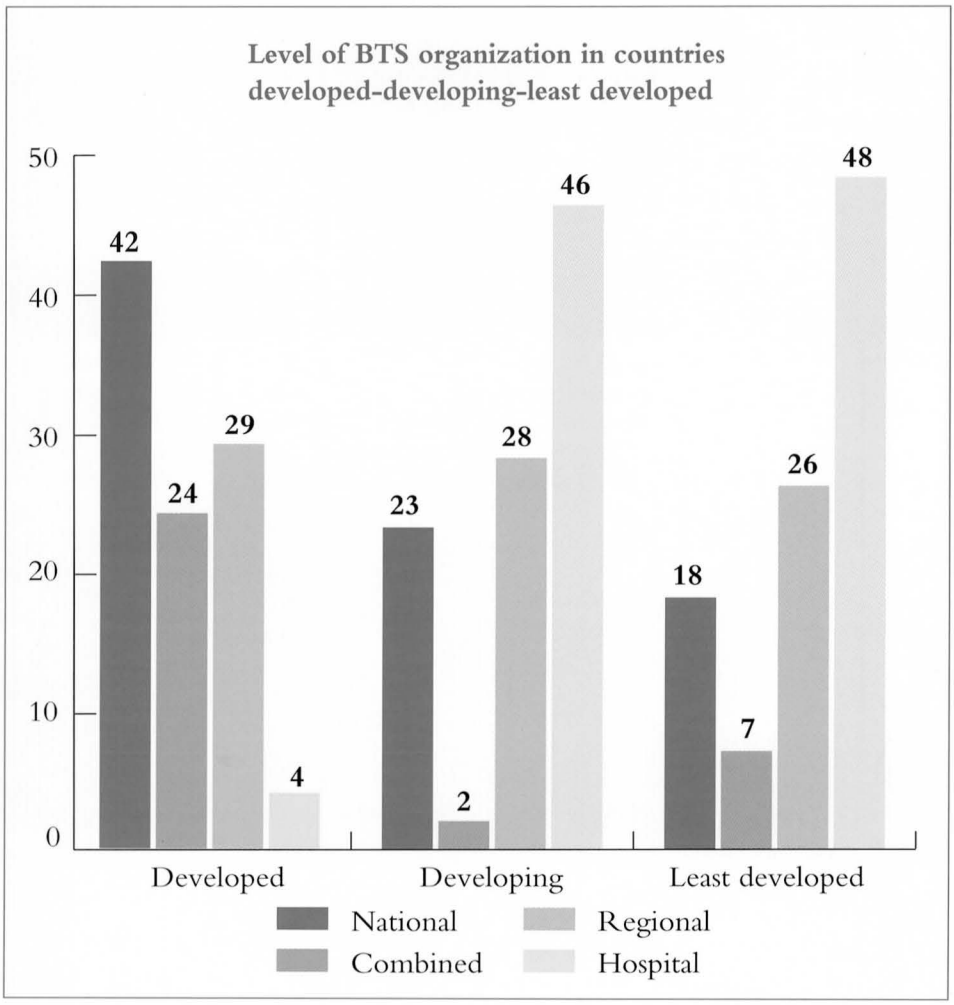


Figure 1B

Percentage of developed, developing and least developed countries (which have reported to WHO), which have either a *national, regional or hospital transfusion system or a combination* of these. (Less than 10 % of countries did not report).



Ref: Improving safety of blood transfusion in developing countries
W.N. GIBBS and Patricia CORCORAN; *Vox Sanguinis* 67.S3.94, pp 61-66, 1994.

1. Safe blood policy and strategy

In a safe blood policy and strategy for a given country, several levels of responsibility and activity should be considered as proposed and illustrated in **Figure 2**. This chapter will try to propose the baselines of an organisation likely to be applicable in the field in any country, and which could be helpful for decision makers to implement an effective safe blood strategy. The three proposed levels are, of course, schematic; they represent in fact three levels of responsibility that have to be adapted according to the local environment. For each level, we will define: the responsibility, the purpose, who is in charge and with what means.

Figure 2: Levels of responsibility to be considered for safe blood policy and strategy in developing countries.

Level	Function	Responsibility	Executive body	Instruments
Level I	*Strategy and Policy*	*Ministry of Health*	*National Committee for Blood Transfusion*	*Legislation Recommendation Regulation*
Level II	*Implementation of Legislation & Recommendations*	*Governmental agency, MOH Department or NGO (Red Cross)*	*National Director of BTS*	*Quality Assurance/Standard Operating Procedures*
Level III	*Blood collection Testing Distribution*	*Direction of BTS*	*BTS*	

1.1. Level I: National Blood Transfusion Advisory Committee

In the proposed scheme, the Ministry of Health is responsible for the highest decision level and defines both Safe Blood *strategy* and *policy*. It is also the MOH's responsibility to find financial support. In practice, to achieve these tasks, it is recommended to the MOH to constitute a National Committee of Blood Transfusion. This National Committee has to formulate the policy in a written document that will be integrated as legislation, regulations or recommendations, in agreement with the national health legislation.

The members and the objectives of this National Committee as well as the policy content are described briefly below:

1.1.1. National Blood Transfusion Advisory Committee

– *Members*:
  1. Ministry of Health: (or representatives)
     including heads of the several health departments concerned
  2. National Blood Transfusion Service (representatives)
  3. Blood prescribers (including hospital and faculty representatives)
  4. Blood Donor Associations
  5. Others: – Press
     – Legal representatives
     – Ministry of Finance
     – Medical or scientific associations
     – Representatives of the Military Medical Services
     – Ethical committee

– *Objectives*:
  - to formulate policy and design strategies for Ministry of Health's approval
  - to promote voluntary non-remunerated blood donation
  - to ensure that ethical issues concerning both the donor and the recipient are respected
  - on request of the Ministry as well as on its own initiative, advise the Ministry about issues regarding safe blood.

1.1.2. Policy

The main principles on which the safe blood policy should be based must take into account the essential ethical principles (informed consent, confidentiality, medical secrecy...) (see chapter 11: *Ethical orientations for blood safety*) and encourage voluntary and non-remunerated blood donation.

Provided these principles are respected, each government decides, in the light of the country situation (financial, epidemiological ...), how to best adapt the safe blood policy.

The policy content should give clear specifications and guidelines about the main activities of blood transfusion i.e.

– donor selection
– blood collection
– testing procedures
– processing and storage of blood
– use of blood
– quality assurance

1.1.3. Instruments

The transfusion policy could be written as a legal text or any other form of regulation or recommendation. The need for legislation and/or regulations is obvious, but it is a matter for the country concerned to select the most appropriate form.

1.2. Level II: Direction of Blood Transfusion Services

The *expertise level* (see **Figure 2**), is responsible for all technical expertise. This level of responsibility can be left either to a governmental agency, or to a specialized department of the MOH or to an NGO such as Red Cross or Red Crescent.

– *objective and tasks:*
  - to organize the Blood Transfusion Service
  - to collect, monitor and analyze data
  - to organize quality control and assurance
  - to ensure training of staff
  - to edit guidelines and Standard Operating Procedures for: blood collection, donor counselling, testing procedures and blood use

The effective development of the organisation of the blood transfusion service requires an appointed director. In countries with a national BTS, a national director can be appointed. In large countries, regional organisation could be more suitable but at least a national advisory committee should be established. A national director or coordinator could however play an important role in creation of overall consistency and coherence so as to ensure the provision of safe blood for the whole country.

1.3. Level III: Organisation of Blood Transfusion

Level III directly concerns all "in the field" activities and how they can be organized and carried out practically. At level III, the director as well as staff members of the BTS are directly concerned in the application of the recommendations. Blood collection, testing and distribution should ideally be standardized whatever the type of BTS structure: centralized, regionalized, hospital based or mixed.

1.3.1. Centralized structure:

It consists of one national blood transfusion centre which operates the services for the whole country, with or without regional centres. This is more feasible in small countries.

In principle, a centralized National Blood Transfusion Service may offer better guarantees for blood safety than hospital based centres especially in the areas hereafter mentioned:

- Recruitment of voluntary and non-remunerated blood donors: a single centralized system is less dependent on local contingencies or emergencies.
- Regularity in blood supply: a centralized system is more able to manage and to guarantee a sufficient stock in a sustained way.
- Use of techniques respecting minimal safety standards: a centralized system is more often able to ensure the following minimum criteria of safety i.e. ABO grouping, compatibility testing, screening for infectious diseases, record keeping and quality control.
- Improved training of personnel, economies of scale (bulk purchase), efficiency of automation and selection of donors with rare red cell antigens.

In this type of system it is easier to obtain coordination at national level, which in turn results in higher cost-effectiveness. It also increases capacity to provide blood in emergencies, gives the possibility for a balanced and uniform national quality assurance as well as standardized training of personnel.

In a national system, it may also be less difficult to create a national blood transfusion service centre which can provide wide expertise for clinical service and for further development of the BTS. National reference laboratories in the field of transfusion medicine (e.g. blood group serology, haematology, tissue typing, coagulation) and support of scientific research are easier to arrange in a national centre.

It is also easier to develop a high profile among the medical establishment, as well as in the community at large, by means of a national BTS than if the blood transfusion service system is fragmented. This is important in recruitment of blood donors and in creating trust and confidence in the operation.

Need for good communication (e.g. telephone and telefax for laboratory results) and transportation (e.g. for laboratory samples and blood products) systems are disadvantages of a centralized BTS organisation. There may also be delays in the provision of laboratory results and blood components, if these are organized centrally. A greater distance between a national BTS centre and hospitals and blood donors may create difficulties in relations with the users of blood as well as with the blood donor population.

1.3.2. Regionalized system

A regionalized system is organized as follows: the country is divided into regions with varying degrees of autonomy, but with different mechanisms for achieving national control and coordination. However, even in this case, the regulations and policy coordination should be done on a national level with sufficient input from the regions.

A regional blood transfusion service system is preferred in larger countries, where the size of one region may allow for the creation of a system which corresponds to a national blood transfusion service of a smaller nation. The advantages and disadvantages have to be evaluated taking into account the special conditions and political realities in the country.

1.3.3. Hospital based organisation

Each hospital runs its own blood transfusion service with or without national coordination.

Organizationally this system is problematic and coordination at national level has been difficult to reach even in developed, industrialized nations. Because the national supervision and regulatory role are crucial, it is in general not recommended to leave the organisation of blood transfusion services totally to the individual hospitals.

However, blood banks integrated into hospitals theoretically present some minor advantages:

- hospitals are in close relation with patients and analyses can be performed for donors and for patients in the same laboratory;

– hospital blood banks are closer to prescribers so that blood indications can be discussed more easily.

1.3.4. Mixed organisation

Combinations of hospital based and national/regional blood centres exist in 28 % and 26 % of the reporting developing and least developed countries, respectively (see **Figure 1B**). Usually, there is a national BTS, but many hospitals find its coverage unsatisfactory and run their own blood banks. Sometimes the local blood centre in the capital carries the word "national" in its title. This organisation is not very often efficient and usually is more costly than national or regional blood transfusion services.

2. Example

2.1. Example of National Blood Policy

Summarized content of the
draft National Blood Policy of Zambia

1. National Blood Transfusion Advisory Committee

Members:
- Ministry of Health
  - Permanent Secretary or his representative
  - Director (head) of Clinical Services (MOH)
  - National AIDS, TB and leprosy manager
  - Chief Health Planner
- Zambian National Blood Transfusion Service:
  - Medical director
  - Assistant director
  - Donor service manager
- Blood prescribers (including hospital representatives)
- Blood Donor Associations (and Red Cross representatives)
- Others:
  - Press
  - Legal representatives

– Ministry of Finance / Chamber of Commerce
– Mine hospitals
– Any medical association

2. Specific structures of the Zambian National BTS

For each specific structure, functions and staffing are defined.
– Core programme
– Lusaka central blood bank
– Kitwe central blood bank
– Regional transfusion centre
– District hospital and private hospital based blood banks

3. Collection and processing of blood

– Premises: laboratory areas, donor room, phlebotomy rooms, etc.
– Donor selection criteria: voluntary and non-remunerated blood gift
information, counselling of donors
selection, minimum medical examination of donors
frequency of blood donation...
– Testing procedures: required sensitivity and specificity of tests used
ABO and Rhesus phenotyping
...

4. Blood Products

– Labelling: minimum information required
– Blood products: storage condition, expiration date, indications, ...
  – Whole Blood
  – Red Blood Cell concentrates
  – Fresh Frozen Plasma
  – Platelets
  – Cryoprecipitate

5. Use of Blood: guidelines on appropriate use of blood and blood products.

6. *Import and export of blood and blood products:* MOH approval.

7. *Quality assurance:* recording and validation of documents.

2.2. Example of BTS organigram

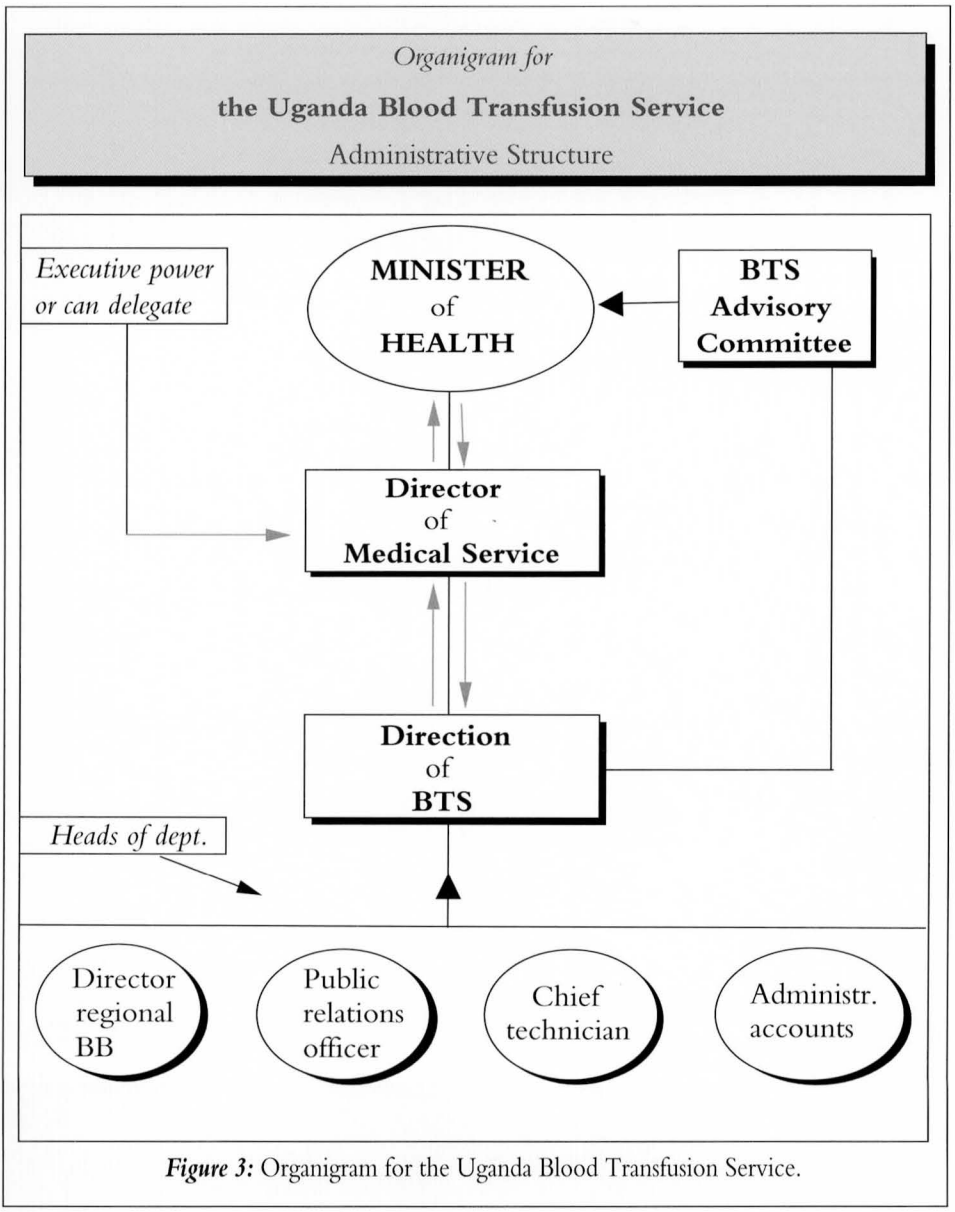


Figure 3: Organigram for the Uganda Blood Transfusion Service.

3. Recommendations on blood policy

A policy framework is supposed at least to specify some issues such as:
- The objective of the blood programme
- The chain of authority from government to safe blood services
- The advisory system
- The financial responsibility
  - sources of income
  - mode of disbursement
  - budgeting and approval processes
- Principles that are adopted:
  - organisation of blood collection depending mainly on voluntary non remunerated donors,
  - full compliance with nationally approved safe blood policies as determined by government,
- Monitoring of performance at all levels of activity.

4. Recommendations on the organisation of blood transfusion services

Three levels of organization could be proposed:

– **Level I.** Definition of policy and strategies by a National Committee of Blood Transfusion under the responsibility of the Ministry of Health through legislation, regulation and recommendations.
– **Level II.** A National Committee designated by the Ministry of Health which has the responsibility for the implementation of the legislation and recommendations stated at level I. The Director of the NBTS (or the board of directors) would be the executive body using Standard Operating Procedures (SOP) and quality assurance.
– **Level III.** At the "in the field level", all staff members of the BTS, under the responsibility of the director work and fulfil all the activities (blood collection, testing, distribution...) according to the guidelines (Standard Operating Procedures) defined by level II.

Chapter 2

BLOOD DONOR INFORMATION AND SELECTION

Introduction

1. Blood donor motivation, recruitment and retention
   - 1.1. Need for specific recruitment programmes
   - 1.2. There are three categories of blood donors
     - 1.2.1. Voluntary
     - 1.2.2. Family replacement
     - 1.2.3. Paid
   - 1.3. The aim of recruitment is to enrol "regular" blood donors
   - 1.4. How to ensure blood donor loyalty ?
2. Call for donors and blood collection
   - 2.1. Standard Operating Procedures
   - 2.2. Sites of blood collection
3. Information given to blood donors
4. Counselling of blood donors
   - 4.1. Right of blood donors to know results and responsibility of the BTS
   - 4.2. What about pretesting ?
5. Considerations about "high risk" and "low risk" blood donors
6. Examples
   - 6.1. Blood donation projects
   - 6.2. Information given to donors
7. Recommendations for blood donor recruitment
8. Recommendations for blood donor counselling

COLLECTION of SAFE BLOOD

It is necessary to develop systems based on:

- ❒ *non remunerated*
- ❒ *voluntary* — ***blood donations***
- ❒ *anonymous*

in order to obtain:

- ❒ *safe blood*
- ❒ *from selected donors*
- ❒ *in quantities adapted to the need*
- ❒ *whilst preserving the donor's health*
- ❒ *whilst preserving the recipient's health*

Prerequisites are:

❍ a good organisation with regard to:

❒ *information*		❒ ***blood***
❒ *education*	about	❒ ***its needs***
❒ *sensitization*		❒ ***its risks***
❒ *communication*		❒ ***its hazards***

❍ encouragement to:

- ❒ *self deferral*
- ❒ *motivation*
- ❒ *regular donations*

❍ warranted confidentiality:

- ❒ *the effectiveness of which must be proven and known*

Introduction

Everywhere in the world, transfusion of human blood is an essential therapeutic procedure for which there is no genuine substitute. If blood can save human lives in some instances, it can also transmit infectious diseases and, sometimes, death. The two main problems encountered in the field of blood transfusion are:

- *the collection of blood in sufficient amounts*
- *the collection of blood as safe as possible for the recipient's health.*

Being of human origin, blood collection depends solely on individual decision. Ideally, as is the case in most developed countries, blood should be collected only from voluntary, unpaid donors and the blood gift should be anonymous. It is widely known that blood donors who give blood for cash are more likely than unpaid ones to be carriers of infectious diseases. Blood collection based on voluntary decision allows for a selection of blood donors, which guarantees better transfusion safety. The major difficulty encountered is therefore to encourage the healthy population to give blood and to become regular blood donors.

Effective and efficient blood donation and collection procedures are an essential part of the provision of safe blood in any country or region. In view of the HIV/AIDS epidemic, however, screening of blood products for HIV has been given highest priority by many interested parties. As a consequence, several countries or regions now have sophisticated testing procedures for HIV, but either no blood available for testing, or blood available that is highly infected, either because donors are wrongly selected or because the minimum requirements for safe blood are not met at all.

Due to lack of reserves of tested blood and the need for emergency transfusion, blood is sometimes given before tests can be completed. Therefore, the Communities' Programme insisted from the beginning on the importance of a well organized blood collection service for blood transfusion services in general and for HIV control in particular. However, when the programme started in 1987, very few developing countries had a proper blood collection service which usually had to be built from scratch.

A few principles about blood collection and donation are discussed. Some examples also demonstrate how some countries have already improved their blood collection system.

1. Blood donor motivation, recruitment and retention

- need for specific recruitment programmes
- three categories of blood donors:
  voluntary, non-remunerated donors
  family replacement donors
  paid donors
- aim of recruitment: to enrol regular blood donors
- how to ensure blood donor loyalty ?

1.1. Need for specific recruitment programmes:

In the national programme, it is important that the protocol for dealing with blood donors and transfusion practices is organized by a medical officer. It is important that national authorities be aware of the overall need for a *specific donor recruitment programme* under the direct supervision of a donor recruiter.

In order to reach *altruistic, voluntary donors*, low risk populations such as school students and young adults in rural populations are targeted, informed and educated during a meeting. Following the initial meeting, a manager, sometimes advised by a committee, determines if there is a wish of the participants to invite the blood transfusion service to collect blood. A session is arranged usually 7-14 days later. If this is a first session, a donor recruiter accompanies the collecting team. Donors are reminded that their blood will be tested for HIV, hepatitis and other transmissible infections. Two weeks later, the same donor recruiter meets the voluntary donors by appointment to discuss and give results confidentially. At this follow-up visit, a tentative date is scheduled for the next cycle of information, collection and counselling. Other possibilities to organise collection also exist, depending on the region and its opportunities.

1.2. There are three categories of donors:

- voluntary donors,
- family donors
- remunerated donors.

1.2.1. Voluntary non-remunerated blood donors:

The best definition of a voluntary non-remunerated blood donor is given by the EC:

"A voluntary non-remunerated donor is a person who gives blood, plasma or cellular components of his/her own free will and receives no payment for it, either in the form of cash, or in kind which could be considered as substitute for money. This includes time off work other than that reasonably needed for the donation and travel. Small tokens, refreshments and reimbursement of direct travel costs are compatible with voluntary, non-remunerated donation". A blood transfusion service should aim at collecting all blood from altruistic, voluntary and unpaid donors. For moral and ethical reasons, the blood gift should remain anonymous.

The advantages of recruiting voluntary non-remunerated donors are that lower risk populations can be targeted, services are based on ethical and humanitarian principles and blood donors can be informed, counselled and monitored regularly.

1.2.2. Family replacement donor:

It is admitted that in some countries, *family replacement donors* continue to fulfil the need for blood and blood products. Efforts must be undertaken to educate family donors so that they are converted to regular donors, and to ensure that the standard donor screening procedure is used in evaluating their suitability. A staff member, or perhaps a volunteer, is responsible to ensure that when visitors and patients' relatives are asked to donate blood, they get information and are adequately counselled.

1.2.3. Paid blood donors

In a number of countries, paid donors are still providing the bulk of the available blood. Owing to potential danger to the recipient, this process is undesirable (but to change it will probably take years).

1.3. The aim of recruitment is to enrol "regular" blood donors

The "ideal" blood donor is a regular blood donor who gives blood three to four times a year, who has had information about risky behaviours and who has proved to take care of his health. Because they are regularly tested, regular blood donors constitute a population characterized by seroprevalence of infectious markers lower than that of the general population.

1.4. How to ensure blood donor loyalty ?

A main difficulty for a Blood Transfusion Service is to encourage the donor's loyalty. If the donor is accepted as a safe blood donor, a letter can be sent three months later, reminding him/her of the time to return so as to increase the pool of regular safe donors. Problems in arranging for blood donors to return on a regular basis arise mainly from lack of communication, organisational facilities or funds.

> *In Uganda an average of 2.4 ECU is spent on the recruitment of a first-time donor, and 1.5 ECU on a returning donor.*

On the other hand, it is also important for the donor to feel his/her gift is useful for the community and appreciated. He/she should be received warmly at the BTS by qualified personnel who pay attention to his/her well-being.
It is also possible to organize meetings to recognize regular blood donors by a medal or a diploma or another small gift.

2. Call for donors and blood collection

2.1. Standard Operating Procedures:

Written procedures about how to call for and how to manage blood donors should be clearly defined and explained to nurses and/or any people in charge of the donor session. They should contain essentials about how to care for the blood donor before, during and after donation and for referral when necessary.

Selection criteria for blood donors should be listed and defined while taking into account the epidemiological characteristics of the country for the various transmissible infectious agents.

Prior to the blood gift, a short medical examination is helpful for physicians to decide whether a donor can be bled or not. It should be oriented towards the search for the possibility of infectious disease carrier status and would also aim to make the physician sure that blood donation will not affect donor's health.

The typical aims and contents of medical examinations should be defined, listed and included in guidelines distributed country wide.

A questionnaire should be constructed which would be completed by all blood donors after they receive information focused on: the need for blood, blood donation, blood transmissible diseases, risk behaviours etc...

There should be a labelling system indicating that testing has been done on all blood units and that those units issued meet the agreed criteria.

Records should be held containing the main data: administrative, medical and transfusional. A manual or computerized file containing these data should always be up-to-date.

2.2. Sites of blood collection

- mobile transfusion centres
- permanent sites of blood collection

Blood donors may be invited to donate at a mobile transfusion centre or at a permanent site housing the transfusion service. In most developing countries, the mobile centres organized in schools, factories and communities in general, are popular and productive.

However, permanent sites provide for more reliable collection of blood and other special blood products such as platelets, and samples for research, and also for improved information, and confidentiality and counselling.

3. Information given to blood donors

It is the responsibility of the Blood Transfusion Service to research and prepare appropriate information on two major aspects of blood donation: on the one

hand, the need for blood in sufficient amounts, its therapeutic necessity, the blood donation process, post-donation procedures and follow-up, and on the other hand, the absolute necessity that blood will not transmit disease to recipients.

This information may be provided through written, oral or electronic media and by person to person contact.

This information needs to be strengthened at the predonation stage, thus enabling the potential donor to be informed fully on the donation, the tests to be performed and the procedures followed after donation. Consent to give blood under these circumstances must be obtained.

Potential donors are to be *informed* in a full and comprehensive way about how and why some infectious diseases are transmissible by blood, about the main modes of transmission of these infectious agents, the corresponding risk behaviours, about the tests which will be performed and the possibility to obtain results.

One of the main purposes of the information given to donors is to allow them to identify their own risk factors in order to encourage appropriate *self-deferral* from blood donation.

Information received from donors should be kept completely *confidential* and if this is not assured, names of donors should not be recorded at all and/or an alternative record identification should be used.

The results of tests performed on the donor's blood should be available for the donor, and for him only, *provided he has opted to know the results*, he has been thoroughly counselled before donation and will again be individually counselled when receiving the results.

4. Counselling of blood donors

After the laboratory tests are performed, the service must follow the prescribed procedure for informing donors in order to assess whether they are suitable to give blood again or not. Seronegative blood donors will be encouraged to give blood again (and become regular blood donors) and informed on how to continue to prevent infections. Seropositive donors will obviously not be allowed to give blood again. It is the duty of the service to inform them of their seropositive status in compliance with local counselling procedures. These

may, for example, be that such donors are referred to a doctor or approved counsellor or, when resources permit, the service gives the donor the results with the necessary counselling support.

Counselling may also be necessary for relatives, at a later stage, after the donor has received the results. This is an important and time-consuming activity which becomes difficult to organize in countries where seroprevalence among donors is high. It is therefore a service that has to be provided progressively and in coordination with other health services or structures in the region.

4.1. Right of blood donors to know results and responsibility of the BTS.

When individuals are invited to give blood, (either as an altruistic action or to replace blood used for a friend or relative) the blood programme authorities must decide whether and how they will make the test results known to the donor. However, *the individual has a right to have access to those results, but is not required to be forced to receive the information.* Various options, the advantages and disadvantages of which have to be taken into account, are possible.

4.2. What about pretesting ?

In most cases, *pretesting* of donors is not regarded as an appropriate method for selection because a similar purpose can be achieved by giving information, on the basis of which a process of self-selection is induced.

The disadvantages of pretesting are: an increased need for individual counselling, the inconvenience for the donor to return later and the risk of the blood transfusion service being used as a screening centre. The cost of pretest or of improving self-selection should be estimated in view of the HIV epidemiological situation, the type of available tests and the problems of ensuring confidentiality. Rapid tests would avoid the necessity of returning but make confirmation and counselling more difficult.

The advantages are that fewer infected units will be collected so that the risk of contamination within the blood transfusion centre is reduced. However, the same objective can be reached by supplying appropriate information and careful selection of blood donors.

5. Considerations about "high risk" and "low risk" blood donors

In most developing countries, HIV is spread predominantly through heterosexual contacts. The high risk groups in the U.S.A. and Europe (homosexuals, intravenous drug users and blood component recipients) are therefore of much less significance. Instead it is sometimes stated that *all sexually active persons* form a high risk group. Studies need to be carried out to identify low risk groups in the population.

Characteristics associated with high HIV seropositivity need to be identified at a national level in order that characteristics with a high predictive value for HIV seropositivity be used in donor selection. Efforts are directed to exclude donors with high risk as determined by age, sexual activity and social parameters. For these reasons, and because of easy access, better education and physiological status, blood collection strategies presently focus on the 17-21 year old senior school and college students. However, it is this age group of unmarried youth which is at greatest risk of acquiring infection through sexual intercourse. Increasing attention is now directed to retaining, as regular blood donors, those whose knowledge of HIV epidemiology and concern for their own health and that of potential recipients is likely to maintain them in a low risk behaviour group. Some observations illustrate the relevancy of these considerations on "high" and "low" risk populations:

1. *HIV seropositivity rate varies with age:* it increases from 17 years to 35 years (in some African countries, it is higher than 30 % in 30 year old females), and then declines to less than 5 % in women over 50 years and men over 60 years.
2. Persons with *itinerant and fluctuating activity*, such as military forces, truck drivers, market traders and commercial sexworkers have a higher frequency of HIV than others of the same age. It can be anticipated that wars in countries will have dramatic consequences on the spread of sexually transmitted diseases.
3. The lowest rate of infection is found in *school boys* between 17 and 21 years old, who have been informed about HIV infectivity and declare themselves not to have taken any risks.

Once a blood donor has met the criteria of low risk and is found to be HIV negative, every effort is made to encourage a risk-free life style with repeated blood donations every three to four months.

6. Examples

6.1. Example of blood donation projects.

6.1.1. in Guinea Conakry

Family donors were the only source for blood till May 1990 when the Commission's AIDS control programme started implementation of its support. In May 1990, the programme held a national training seminar prompting blood donor recruiters to organise a pool of regular voluntary donors in Guinea Conakry for the first time. Since then the activity has been spreading from the capital to the rest of the country. One year later, May 1991, blood was collected from 656 voluntary donors and from 1958 relatives. 85 % of the voluntary donors were youngsters (students and members of youth organisations). This made it possible to test all blood before it was used and since May 1990 no HIV or HBs antigen positive blood has been used. All donors have been informed and counselled, and have received some health education.

At present the following strategies are being developed:

- strategies to have donors return regularly;
- recognition of voluntary donor associations in the capital;
- elaboration of strategies and guidelines to advise seropositives among the blood donors.

6.1.2. in Rwanda

In Rwanda, blood transfusion services have been at work for more then 15 years. Since the AIDS epidemic became fully evident in 1987, the Commission's support, in cooperation with the Belgian Red Cross, made it possible to provide safe blood rapidly. At national level, a medical assistant in charge of blood donor recruitment plans and organizes blood collection. This person, in cooperation with the Rwandan Red Cross, also encourages repeat, voluntary blood donors. At regional level, the person in charge of the blood transfusion centre is also responsible for recruiting as many donors as are necessary to answer the region's needs. At the local level the recruitment is organized in collaboration with the local Red Cross representative who contacts the voluntary donors.

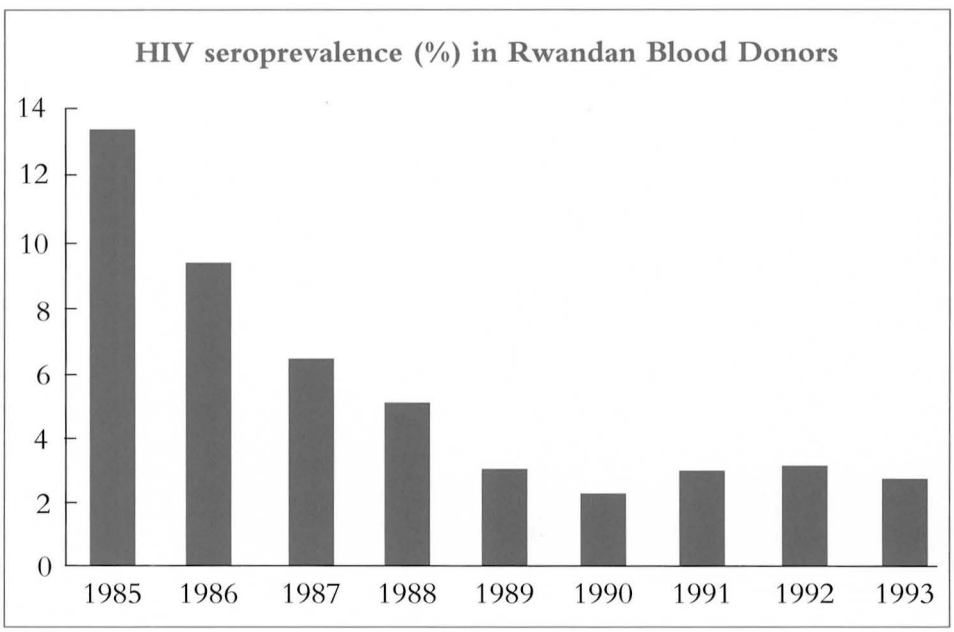
In view of the high HIV incidence in many parts of Rwanda and in order to diminish the risk for HIV transmission as much as possible, nearly all blood collected comes from campaigns in schools (94 % in 1990). Other strategies have also been combined to limit the risk of collecting infected blood:

- recruitment of donors among younger people (18-25 years);
- elimination of donors for further blood collection once found to be positive;
- medical consultation before blood collection with questionnaire about STDs and AIDS;
- follow up of donors to encourage them to become regular donors;
- change in collection sites (less in urban areas, more in schools).

The results confirmed the usefulness of these strategies since seroprevalence among blood donors fell from 13.5 % in 1985 to around 3 % in 1990's. (see **Figure 4**).

Figure 4

The efficiency of strategies applied in Rwanda to diminish the risk for HIV transmission by blood is illustrated by the continuous decrease of HIV seroprevalence among blood donors between 1985 and 1990. In 1991, on account of a war context in the country, massive blood collections were organized, making it much more difficult to select blood donors.



In Rwanda all blood is collected on a voluntary basis and relatives are no longer requested to give blood. All blood is safe and the needs are satisfied. Confidentiality is assured. With regard to HIV tests, the donors are informed about the results only if they want to be. This is not an ideal solution, but the result of the fact that most units are collected from donors who live far away from the blood transfusion centre and because pre- and post-test counselling is not fully guaranteed at the moment.

In 1993-1994, before the war in Rwanda, a lot of work had been produced to improve this situation which was really progressing. It is feared that the situation after the war will be different, and will necessitate many efforts to reach the level of the previous situation again.

6.2. Examples of information given to donors

6.2.1. Uganda programme

Uganda
Blood transfusion service
"saving life with safe blood"
information for the blood donor

Thank you for volunteering to donate blood.

To make sure that it is safe for you to give blood and that your blood is safe to give to a patient, and to safeguard your privacy, we follow these procedures:

1. Your name will not be used in registration at the blood bank. Instead, we use your mother's unmarried name, your birthplace and your date of birth.
2. You will be assigned a code number which is placed on all samples and records of your blood.
3. You will be asked some questions about your health and activities to make sure giving blood will not harm you.
4. You will also be asked questions about your private life to make sure the tests we perform will more accurately determine risk.
5. A small sample of your blood will be taken by finger pricking and tested to make sure you have enough blood to spare for a donation.
6. After your blood donation is drawn, we ask you to remain with us for a few moments to rest and to take some refreshment to replace the fluids you have lost. We will also give you some iron pills to help your body replace the donated blood quickly.

7. The blood you have donated will be tested for hepatitis and the HIV viruses, which cause hepatitis and AIDS, respectively.
   Note: HIV cannot be detected immediately after infection. It is possible for blood to test negative for two months or more after becoming infected.
8. The results of these tests will be available to you (and no one else) in two weeks, if you choose to know them.

Please turn over for important information about when you should not give blood

---

Uganda
Blood transfusion service
"saving life with safe blood"
information for the blood donor

Please do not give blood if:

A. In the last six months you have had sex with someone you are unsure about.
B. In the last two months you have had an illness such as a bad cold.
C. In the last year you have had:
   i) an injection except at a hospital or clinic; or
   ii) skin scarring or cutting by a traditional healer; or
   iii) a surgical operation.
D. You have ever had hepatitis (jaundice causing yellow coloration of the eyes).

Please do give blood again if:

A. If your blood has been found to be safe after testing.
B. If you continue to practice a healthy and safe lifestyle.
C. When three months have passed since your last donation.

Healthy blood donors are always needed to save lives. Patients who need blood can get it only if enough healthy people donate their blood. Of course, you and your blood will be checked every time to make sure you are healthy and your blood is safe.

6.2.2. Rwanda programme

RWANDA

Information for blood donors

BTS ***"Confidential"***

Information sheet on AIDS

Dear Blood Donor, we wish to inform you that since December 1985 we test each blood donation for AIDS before it is used. At present we communicate all the results (positive or negative) to the donors who wish to know.

In spite of systematic testing for AIDS on every unit of blood collected, there still remains a minimal risk of transmission of AIDS through blood transfusion. This risk is due to the fact that the tests that are used are made to detect the presence of antibodies to the AIDS virus. Now, these antibodies can only be discovered in the blood 2 to 6 months after infection, while the blood itself is contagious from the moment of contamination onwards.

Facing this situation, *the honest contribution of the donors is essential* to eliminate definitively the risk to transmit AIDS and other infectious diseases via this blood.

By giving an *honest* answer to the following questions you will have made your contribution.

Everything you say here will remain a secret between You and the person who receives you

YES / NO

1. Are you at present in good health ?
2. Have you suffered moments of physical feebleness without apparent cause ?
3. Did you have sexual intercourse with another person than your regular partner (your wife or husband) during the last six months ?
4. Did you contract any sexually transmissible disease during the last 12 months ?
5. Have you had shingles ?
6. Did you lose a lot of weight without apparent cause this year ?
7. Has it happened to you during the last year to have had drug injections from a Magendu ?
8. Were you subject to scarification practices for medical treatment or for aesthetic reasons during the last 12 months ?
9. Have you received blood ?
10. Have you had any skin diseases during the last two years ?
11. Do you have abnormally swollen glands ?
12. Have you noticed anything abnormal about your state of health lately ?
13. Do you wish to be informed about the results of the AIDS test performed on your blood ?

Note:

* Please, if it is your habit to have frequent sexual relations with several people, we advise you to abstain from donating blood.
* If you simply want to have an AIDS test performed on your blood, this can be done in all discretion without your having to donate blood for that matter.

We thank you for your consideration

7. Recommendations for blood donor recruitment

- There should be a National Blood Donor Recruitment Officer (NBDRO) who has the overall responsibility to develop voluntary blood donor recruitment strategies, within the guidelines of the National Safe Blood Policy and with the agreement of the National Blood Transfusion Advisory Committee (NBTAC).
- The NBDRO, with the assistance of trained, full-time blood donor recruiters, will ensure a sufficient supply of blood for the national requirements.
- Volunteers to assist in organisation may be recruited within schools, factories, churches and other suitable organisations. The volunteers will act as liaison with donors within each organisation.
- A dedicated budget is needed for donor recruitment and follow-up activities. Sufficient transport will be provided. The BDRO's duties include donor and public education and the establishment of a record system to provide data for donor statistics and recall procedures.
- The donor records will be confidential and protected, as much as possible under national law, from disclosure to any third party.
- Procedures and donor selection methods will be made known to potential donors before phlebotomy and conform to recognized standards approved by the National Advisory Committee.
- Whilst every effort will be made to achieve an all volunteer donor panel, the value of relatives willingly replacing blood used must be recognized and supported. These donors should benefit from the same information and courtesy as volunteer donors. No cash or financial benefit should be allowed.
- Counselling should be available to all donors.

8. Recommendations for counselling

- The donation process and post-donation procedures must be discussed with the donor *before* blood is collected.

- Donors must be advised *before* their next donation whether or not they are acceptable as blood donors. Such information is best given with appropriate counselling support.
- The results should be available to the donor, who should be given the *option* of knowing the results.
- Counselling is essential once the results are made available to the donor. Counselling may also be needed for *relatives*.
- Seronegative blood donors must be encouraged to lead a risk-free life and to continue to donate. Seropositive donors must be encouraged to live positively with the infection.
- It is essential to protect the *confidentiality* of donor test results and related information.

Chapter 3

SCREENING FOR INFECTIOUS DISEASES

Introduction

1. Concepts and definitions

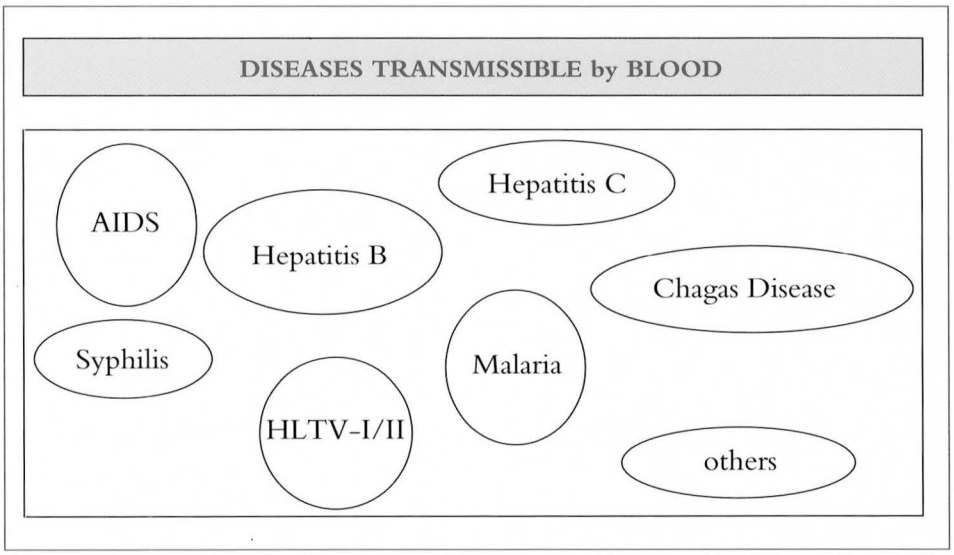
2. Levels of screening strategy
   2.1. Screening tests applied to blood units
   2.2. Testing carried out to diagnose an infection
   2.3. Test results as indicators of effective prevention

3. Parameters influencing the screening strategy

4. Which are the best tests to use ?
   4.1. Screening for HIV antibodies
   4.2. Screening for Hepatitis B surface antigen
   4.3. Screening for Syphilis
   4.4. Screening for Malaria
   4.5. Screening for Hepatitis C antibodies
   4.6. Screening for HTLVI/II antibodies
   4.7. Screening for Chagas disease

5. Example

6. Recommendations for testing procedures


DISEASES TRANSMISSIBLE by BLOOD
AIDS
Hepatitis B
Hepatitis C
Chagas Disease
Syphilis
Malaria
HLTV-I/II
others

Introduction

Blood transfusion is known to be an efficient way for transmitting infectious diseases. It is therefore important to screen blood before its potential therapeutic use in order to discard any blood unit capable of infecting a recipient.

Sometimes, infectious agents can be detected directly in blood (for example: HBs antigen detection reflects directly an HBV infection). More often blood is analyzed in order to detect specific antibodies. For some infectious diseases, the presence of antibodies may reflect a past infection and does not mean that the blood is infectious; in other cases, on the contrary, antibodies may reflect a current transmissible infection (for example: anti-HIV antibodies).

The notion of latency characterizing some infections has also to be taken into account for two main reasons: first, the latent phase is often infectious; secondly, tests detecting viral antigens before antibodies become detectable are not always available (for example: HCV).

In many developing countries the prevalence of infectious diseases in the general population is high. For that reason, high rates of infected blood donors can be expected and, proportionally, a high rate of co-infections.

> *In developing countries, transfusion of unscreened blood is an important route of transmission for five serious infections: HIV, HBV, HCV, syphilis and malaria.*

Laboratory testing of blood donors for infectious diseases is therefore an essential phase in assessing blood safety.

1. Concepts and definitions

Populations at risk for an infectious agent can be divided into two sub-populations: *infected* and *not infected*. An ideal laboratory test would separate these two sub-populations without any possible error. This ideal test, which would be described as 100 % sensitive and 100 % specific, does not exist.

Sensitivity is defined as the probability (usually expressed as a percentage) that the test result will be positive when infection is present.

Specificity is the probability that the test result will be negative if infection is

not present. Since an absolute standard is rarely available, sensitivity and specificity cannot be calculated precisely.

The *predictive value* of a test is a measure of how well the test performs in a given population. The predictive value of a positive test is the probability (usually expressed as a percentage) that the person is actually infected when the test result is positive. The predictive value of a negative test is the probability that the person is actually not infected when the test result is negative.

Unlike the sensitivity and specificity, which are relatively fixed for a given test, the predictive values change, depending on the *prevalence* of the marker that is being measured in the population. This latter parameter is the most important for choosing "the best test" i.e. the test best adapted to the concerned population.

2. Levels of screening strategy

Laboratory testing should be considered at least at three levels, the viewpoint and the consequences of each of which are different:

- *Screening tests* applied to blood units
- Testing carried out to *diagnose* an infection
- Test results as *indicators* of effective prevention of transmission of diseases by transfusion

2.1. *Screening tests applied to blood units.* To be useful in the improvement of blood safety, screening tests have to be applied systematically on all blood units in order to identify any potentially dangerous blood. In this context, a positive test result is by itself a sufficient reason to discard the blood unit from therapeutic use. Therefore, for the purpose of blood safety, the most sensitive test should be recommended for the screening of blood units.

2.2. Laboratory testing may acquire a role of *diagnosis* when blood donors ask for the results obtained by analyzing their blood for infectious agents. In this context, the results of screening tests have to be confirmed by confirmatory methods with high *specificity*. For example, HIV seropositivity

cannot be concluded, and should not be announced to the donor, from the sole basis of a "positive" screening assay; it must be confirmed by further testing.

2.3. Test results performed in blood banks can also be used as indicators of the effectiveness of the selection criteria applied to blood donors. Indeed, the rate of samples found to be "reactive" with the screening test will give information about the prevalence in the selected population and may help to revise and re-orient the criteria used in order to recruit and select "safer" blood donors.

3. Parameters influencing the screening strategy

Before dealing with technical considerations, one should keep in mind that environmental parameters as well as some intrinsic characteristics of the infectious agents themselves are likely to have an effect on the prevention of transmissible diseases in developing countries.

- Ideally, any blood for transfusion purposes should be tested for the presence of all those agents which are *prevalent in a given population* and, if transmitted, can cause serious disease in the recipient.
- In endemic areas (for example, HBV infection in Africa), the probability for an adult recipient to have been infected prior to transfusion and to have achieved *immunity*, depends on the prevalence of the disease in the population. However, such a consideration should be carefully revised as far as young children are concerned.
- Some infectious agents are present only in cells and are not transmitted by cell-free blood components such as plasma.
- On the contrary, some others will be present and infectious in either cell or cell-free blood components (for example, HIV infection as well as HCV and HBV can be transmitted by both cellular and plasma blood components).
- Some infectious agents are killed or at least their virulence attenuated, after blood storage for 72 hours at 4 to 7°C (syphilis). This could be kept in mind if there is insufficient financial support to test for all infectious agents.
- Information given to blood donors in order to teach them about at-risk behaviour and to encourage them to "self-deferral" is less expensive than

and probably as useful as testing to discard dangerous blood units. This is most relevant as far as sexually transmitted diseases are concerned.

- When financial support is limited, local priority should be given to the various screening tests (e.g. HIV ≥ HBV ≥ syphilis ≥ HCV ≥ HTLV) according to the prevalence of the carrier state in the general population, the consequences of infection for the recepient's health, and the age of the recipient.

4. Which are the best "tests" to use ?

4.1. Screening for HIV

Blood transfusion is an efficient mode of HIV transmission. HIV infection is characterized by a long term asymptomatic phase. It is common knowledge that most people are likely to develop HIV antibodies within a few weeks after infection but individuals are very infectious immediately after contamination.

The tests usually used for HIV1&2 antibody screening have a specificity and sensitivity higher than 95 %, which is excellent in comparison with most clinical laboratory tests. Similar performances were obtained in the field.

The characteristics essential for screening tests for HIV antibodies to be used in safe blood programmes in developing countries are high sensitivity, low cost, ease of performance and appropriate technology. As long as the test result is not used to inform the donor, a false-positive result is not a problem other than that of cost-effectiveness. False-negative tests have to be avoided when providing for safe blood.

However, more and more testing procedures are used to inform the donor. The consequences, especially of false-positive results, are of extreme importance with regard to the donor and his/her environment. Confirmation tests with a sensitivity similar to the screening test, but with a specificity as high as is technically possible, are therefore necessary.

Therefore, a single positive screening test for HIV is sufficient to determine the unsuitability for transfusion but if the donor is to be informed, a positive test result should lead to performance of another test to confirm the first result.

Different testing procedures *are available that can be classified into:*
simple tests = *immuno-dot screening assay with visual reading*
EIAs = *conventional Enzyme Linked Immuno Sorbant Assays*
The sensitivity of both simple tests and conventional EIA methods has been proved to be similar.

Different testing strategies *can be proposed (see* ***Figure 5****):*
1. Assay A + Western Blot *conventional algorithm*
2. Assay A + Assay B + LIA *alternative algorithm + a supplementary assay*
3. Assay A + Assay B *alternative algorithm using two screening assays*

It has been shown that there is no gain in accuracy from repeating initial reactive results with the same assay because results are generally reproducible. The combination of two different screening tests *(third strategy)* has been evaluated and proved to give reliable results with 100 % of sensitivity and specificity; it is also 5 times faster and 6 times less expensive than the conventional algorithm utilizing Western Blot. Utilization of Line Immuno Assay (LIA) as a confirmatory method presents, compared to conventional Western Blot, the advantage of allowing for HIV1 and/or HIV2 diagnosis in a one-step manipulation and of giving a lower rate of indeterminate results.

Although there are differences in sensitivity between HIV antibody tests when used during the seroconversion phase, these differences are small, and do not represent a significant threat to public health or to the blood supply.

What about HIV1 group O viruses ?
HIV1 subgroup O virus, which results in antibody not detected by all EIA tests using synthetic peptides or recombinant antigens, was first dicovered in Cameroon, where estimated O virus infections represent less than 1 % of total HIV infections.

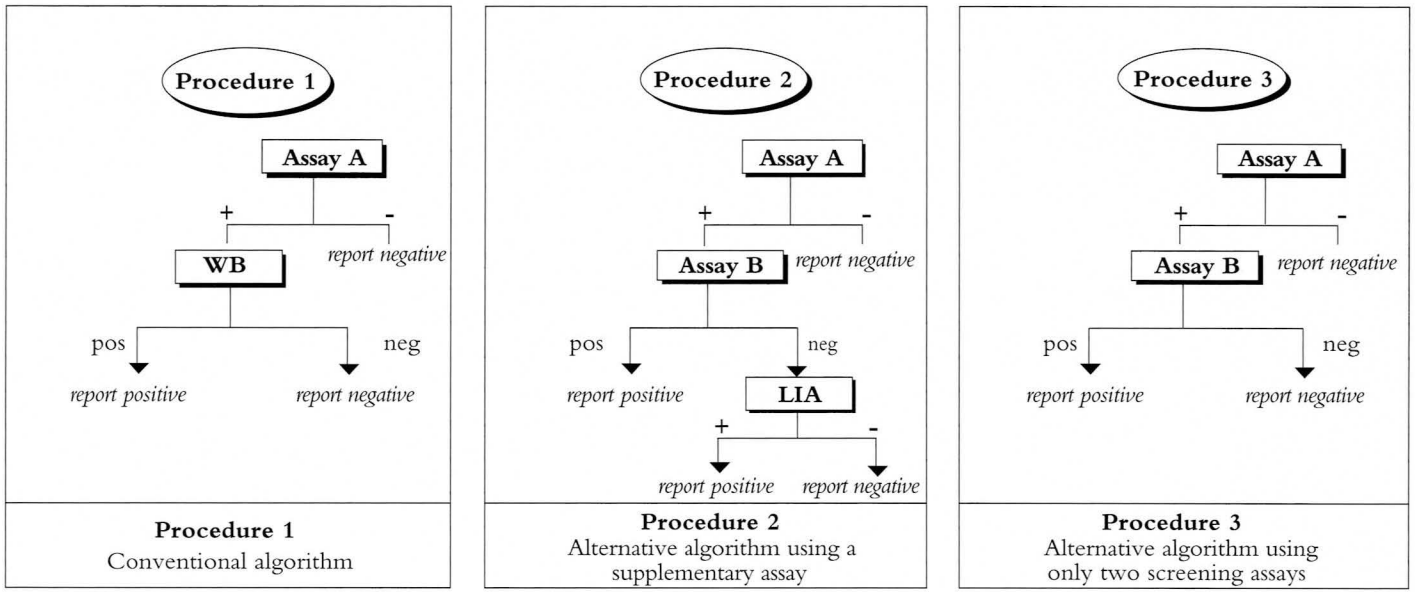


Figure 5 Schematic representation of the conventional (**Procedure 1**) and alternative confirmatory algorithms (**Procedures 2 and 3**) for HIV seropositivity.

In general, failure to detect HIV infection is more likely to result from the absence of antibodies in the seroconversion window phase than from infection with a highly divergent subgroup O HIV-1 strain. The existence of subgroup O HIV1 viruses is likely to have little – if any – impact on HIV diagnosis and blood safety outside the area where they are prevalent (Cameroon). Furthermore, in 1995, most commercial screening tests have been improved so that they are able to detect HIV-1 O infections.

4.2. Screening for Hepatitis B surface antigen: HBs Ag

Hepatitis B is an important transfusion hazard since it is established that blood infected with hepatitis B virus is infectious in almost 100 % of cases. In developing countries, the rate of people infected with HBV is very high and may reach 90 % in adults. It is essential that every blood unit should be screened for HBsAg for the following reasons: a great number of transfusion indications refer to paediatric patients who have not been immunized; besides, the consequences of transfusing blood infected with hepatitis B to immunized individuals are not known.

The most reliable method for preventing HBV transmission is to screen blood donors for HB surface antigen (HBsAg). The viral surface antigen HBs produced in great quantities by cells infected by HBV is a good marker of current infection.

The sensitivity and specificity of screening tests are quite good and the positive predictive value is high when enzyme-linked immunosorbent assays (EIAs) are used. Other techniques exist, e.g. latex agglutination, but are less sensitive.

4.3. Screening for Syphilis

Syphilis, a disease caused by the bacterium *Treponema pallidum* is essentially sexually transmitted. However, fresh blood is potentially infectious. The mean cost of Syphilis tests is cheap, less expensive than HIV or HBV assays. As this micro-organism is very sensitive to low temperature, storage of blood for 24-48 hours at 4°C significanly reduces the risk.

Although the risk of post-transfusion syphilis is quite low, the screening of infected donors may be used as a marker of individuals at risk of HIV infection on account of their sexual behaviour. The screening of blood donors can be performed by using two main serological methods:

VDRL: *search for antibodies against cardiolipin, characterized by a low specificity since 1 % of normal adults produce non-specific antibodies which may lead to false positive reactions.*
TPHA: *allows for the detection of specific antibodies. Particle agglutination tests that are cheap, specific and sensitive have been developed. They may be adapted in micro-well plates technology for large scale screening.*

4.4. Screening for Malaria

Malaria is caused by a protozoon. Approximately 150 million individuals each year are infected with malaria, of whom 2 million will die. Infection is transmitted through the bite of an infected female Anopheles mosquito. Humans themselves are the reservoirs of infection. Four species of sporozoa are causative agents of malaria: *Plasmodium vivax, Plasmodium ovale, Plasmodium malariae* and *Plasmodium falciparum*. In the course of the life cycle in the human host, merozoites infect red blood cells.

The best method for diagnosis of malaria is to search a thick blood film for parasites in the red blood cells. However, since this method requires microscopic examination of each sample, it is not suitable for large scale screening.

The extent to which transmission by transfusion is a problem depends on the incidence of malaria among the recipients. In areas where malaria is epidemic, most recipients are likely to have been infected during childhood. Screening for malaria is therefore important in countries with a low incidence of the disease.

4.5. Screening for Hepatitis C

HCV is responsible for more than 90 % of post-transfusional hepatitis if HBV has been excluded. Estimates are that 80 % of the persons receiving a transfusion with blood infected with HCV will seroconvert, and that probably more than 50 % of the persons who seroconvert will develop chronic liver disease with possible serious complications 10 to 20 years after infection (liver cirrhosis, hepatocellular carcinoma).

From 1989 to 1994, the efficiency of EIA HCV serology significantly improved: third generation tests are now available which are more sensitive and more specific than earlier ones. However, the problem related to the confirmation of EIA reactivi-

ties still remains because there is no true confirmatory method: no viral lysate is available (such as those used for Western Blots in HIV confirmation) and all complementary methods are very expensive.

The few epidemiological data available in Africa indicate high seroprevalence of anti-HCV antibodies but those data were obtained with tests of the first and second generation, which gave a high rate of *false positive* results and many discrepancies between screening (EIA) and confirmation (RIBA) results. In the field of HCV serology, as in the case of HIV, a distinction should be made between two different problems: that of blood safety and that of diagnosing the donor's HCV infection. On one hand, all EIA reactive blood units should be discarded. On the other hand, diagnosis of the donor's HCV infection should be referred to specialized laboratories (as is the case for HIV infection).

4.6. Screening for HTLV-I & II

The risk of developing HTLV-I disease, adult T-cell leukemia/lymphoma (ATLL) or tropical spastic paraparesis (TSP), is estimated to be 1 or 2 per 1,000 HTLV-I positive cases per year after an incubation period averaging 20 years. The actual estimates are that about 60 % of the persons receiving blood containing HTLV-I will seroconvert.

There are three known high prevalence areas: Central and South America and the Caribbean, southern Japan and sub-Saharan Africa but epidemiological data are incomplete. The tests (EIA test and Particle Agglutination Assay) give many false positive results. The available confirmation by Western Blot (WB) lacks sensitivity for the anti-envelope antibodies and consequently it is necessary to use additional more sophisticated techniques (RIPA). Actual screening tests do not distinguish HTLV-I and HTLV-II and it is not certain that HTLV-II is a pathogenic virus.

The relevance of screening for HTLV-I/II antibodies in developing countries remains questionable and needs to be documented further; at the present time, it seems not to represent a major problem of transfusion safety.

4.7. Screening for Chagas disease

Chagas disease, also known as American Trypanosomiasis, is caused by infection with the protozoon *Trypanosoma cruzi*. These protozoa are transmitted to

humans by the bites of infected insects; the disease can be severe and fatal. Trypanosomes can also be acquired by blood transfusion when blood is collected from an asymptomatic infected donor with parasitaemia.

As far as blood transmission of Chagas disease by blood is concerned, the problem is most serious in South America, where the disease is endemic. However, migration of people from endemic to non-endemic areas has resulted in the presence of infectious individuals in previously non-endemic areas.

Laboratory testing in the early phase of infection is by examination of a blood film in order to detect the protozoa. In the acute phase, the micro-organism can be cultured from blood samples. Neither of these two methods is applicable to the screening of blood donors. Several serological tests (IF, CF, EIA, PH) are available for the detection of antibodies that are produced in 50 % of acute phase patients, and in 95 % with chronic infection, but their sensitivity and specificity remain questionable.

5. Example

Serosurvey conducted in Rwanda in 1991

– Blood donors tested:		n = 437	
– Age of blood donors:		from 17 to 29 years.	
– Occupation:	cultivators	n = 329	mean age: 21.7 ± 1.57 years
	students	n = 108	mean age: 18.8 ± 0.63 years

Distribution of infectious markers:

	pos	neg	tot	%
– HIV	15	411	427	3.51 %
– HBs Ag	25	409	434	5.76 %
– Syphilis	10	424	434	2.30 %
– Malaria	8	426	434	1.88 %
– HCV	10	418	428	2.34 %
Total	68		434	

As much as 16 % of blood units collected must be discarded and not transfused.

Co-infections:

HIV	HBV	HCV	Syph	Malaria	N	(co)-infections	Percent
+	-	-	-	-	13	HIV	3.08 %
+	-	-	+	-	2	HIV + Syphilis*	0.47 %
-	+	-	-	-	24	HBV	5.69 %
-	+	+	-	-	1	HBV + HCV**	0.24 %
-	-	+	-	-	9	HCV	2.13 %
-	-	-	+	-	8	Syphilis	1.90 %
-	-	-	-	+	8	Malaria	1.90 %
-	-	-	-	-	357	uninfected individuals	
				Total	422		

65 infected individuals (15.4 %): 62 with one infection and 3 with dual infections

* HIV was found with Syphilis, suggesting sexual modes of transmission;

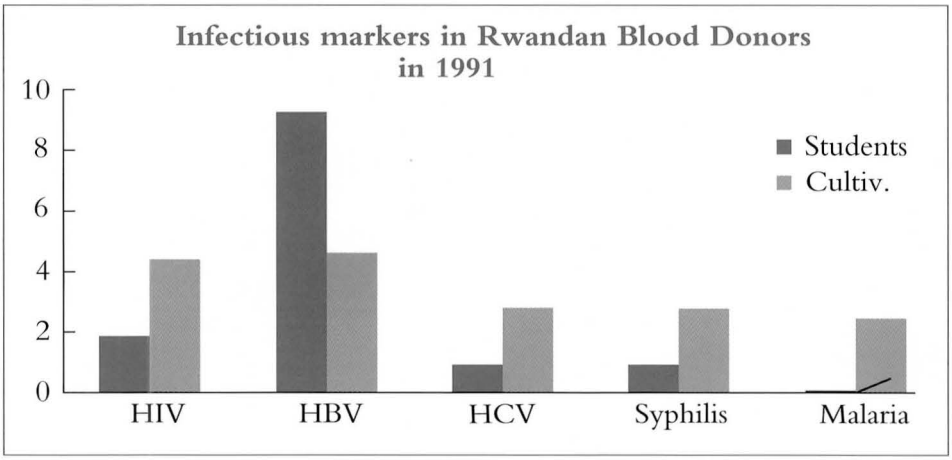
** HCV was found alone or in association with HBV, suggesting blood borne contaminations.

Distribution of infectious markers among the two categories of blood donors:

Occupational	Number	HIV	HBV	HCV	Syphilis	Malaria
		%	%	%	%	%
Students	n = 108	1.87	9.26	0.93	0.93	0.0
Cultivators	n = 329	4.40	4.63	2.82	2.78	2.47

Younger people are significantly less infected than older people as shown by **Figure 6.**

Figure 6: Prevalence of infectious markers (HIV, HBV, HCV, Syphilis, Malaria) among Rwandan blood donors (students and cultivators) in 1991. Younger people are less infected than older people.



6. Recommendations for testing procedures

About screening for transmissible diseases in general:
– has to be performed taking into account epidemiological data in the local population (donors and recipients)

About screening for particular transmissible diseases:
– **HIV**
  – HIV1&2 screening tests are preferred to HIV1 only. (Most HIV tests are also able to detect antibodies against HIV 0).
  – A single positive screening test result is sufficient to decide to discard the *blood unit* from therapeutic use.
  – If the *donor* is to be informed, all precautions should be taken: the positive test result should lead to performance of an alternative test (or a confirmatory test). The choice of the alternative test will depend on availability and specificity. Ideally, a *second* blood sample should be required for HIV analysis *before* the donor is informed of his HIV status.

- The choice of an appropriate screening and testing procedure will be determined by several parameters, among which: the *number* of tests to be performed, the *specificity*, the *sensitivity* under the operational conditions of the laboratory, the (positive and negative) *predictive value* in the local population and the *cost* of the procedures available.

- **HBV**
  - The decision to test for Hepatitis B is dependent upon many factors but should be given a high priority.
  - If testing is adopted, it is important that a *sensitive* test be used and that all blood donations giving a positive result be discarded.
  - HBs Ag testing is a *priority* for blood transfused to non-immune *infants* and *children*.
- **Syphilis**
  - Testing for syphilis is recommended. However, a positive test does not always mean that the blood unit is infectious. Besides, retention of blood for 3 days at 4°C inactivates the infecting agent.
  - If the result is used for diagnostic purposes, a confirmation should be performed with other specific tests.
  - Testing for syphilis has advantages of suggesting intervention for donor health and in suggesting a sexually active individual who might have increased risk of acquiring HIV infection.
- **Malaria**
  - In endemic areas, a medical history seeking evidence of recent fever and illness is essential.
  - In epidemic and other areas, examination of a thick film is advised.
  - The use of prophylactic anti-malarial therapy for transfusion recipients remains controversial.
- **HCV**
  - Epidemiological data in Africa report between 2 and 20 HCV carriers per thousand, but need to be further documented.
  - Screening for HCV antibodies is actually three times as expensive as that for HIV. Financial resources are therefore a major criterion for the decision on HCV screening.
- **Chagas disease and HTLV-I.**
  - No systematic screening recommended except in areas where the diseases are frequent.

Chapter 4

PREPARATION AND USE OF BLOOD COMPONENTS

Introduction

1. Whole blood

2. Blood components
   2.1. Red Blood Cell concentrates
   2.2. Platelets
   2.3. Fresh and Fresh Frozen Plasma
   2.4. Cryoprecipitated Factor VIII

3. Recommendations for preparation and storage of blood components

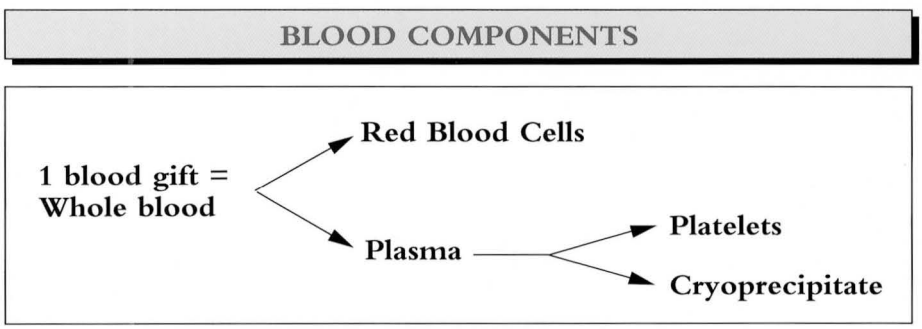


Figure 7 Main blood products that can be prepared from one whole blood unit: Red Blood Cells, Plasma, Platelets and Cryoprecipitate.

Introduction

In developing countries, due to a lack of equipment, blood component preparation is most often limited to red blood cell concentrates (RBC) and plasma (P). However, some procedures which are simple to perform and which require few means can be carried out to provide the patient with the specific needed fraction. To ensure optimal biological activity of the transfused products, it is important to know and to respect their specific storage conditions. Separation of blood components permits storage under optimal conditions which are different from one component to another. For example, fresh frozen plasma, red blood cell concentrates and platelets should not be stored at the same temperature.

Preparation of blood components should only be done if and where the safety of blood is satisfactory. Indeed, if the residual risk for HIV or any other blood transmissible disease remains high, preparation of blood components (red blood cell concentrates and plasma) will multiply twice the number of potentially infected recipients. An interesting strategy could be to prepare blood components only from regular blood donors who have been proved several consecutive times to be free of viral infections.

Moreover, blood components should only be prepared in sterile conditions. In this sense, multiple bag systems are preferred to single bag systems.

Blood components are prepared through separation of elements on the basis of their different densities. Separation is carried out at 4 °C (except that 20 to 24 °C is used when platelets are to be conserved), and can be achieved by sedimentation or, more quickly, by centrifugation.

As shown in ***Figure 7****, the basic blood components to be considered are:*
- *Whole Blood*
- *Red Blood Cells (RBC)*
- *Platelets (Plt)*
- *Plasma (P): Fresh Plasma (FP) and Fresh Frozen Plasma (FFP)*
- *Cryoprecipitate (Factor VIII + Fibrinogen)*

1. Whole blood

Definition

One whole blood unit corresponds to approximately 450 ml (350 to 500 ml) volume of blood collected from one blood donor, in a plastic bag containing an anticoagulant solution (**Figure 8**).

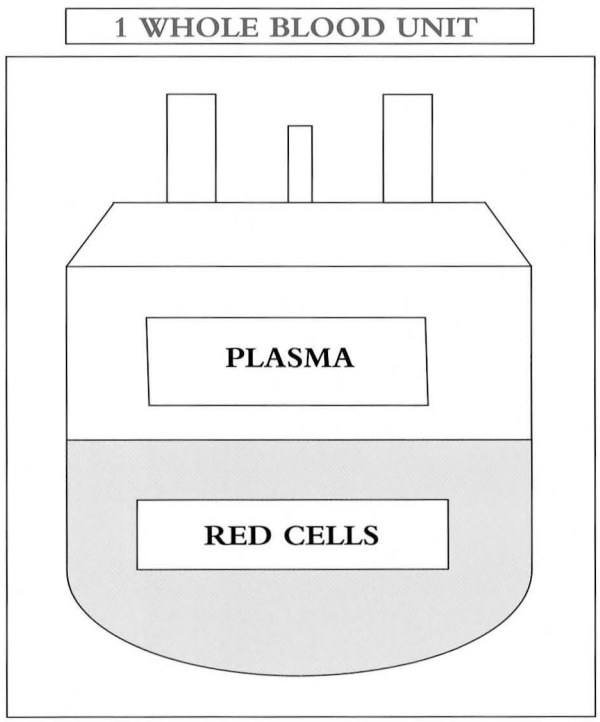


Figure 8 Plastic bag used to collect one blood unit

Preparation

In order to prevent bacterial contamination of the blood unit, it is of greatest importance to ensure skin disinfection before venipuncture of the donor.

There is no "preparation" of whole blood since it is the direct product of the donor's bleeding and serves as raw material for the preparation of blood components. The acidification of whole blood by the anticoagulant solution has a beneficial effect on the synthesis of adenine nucleotides which are vital for the maintenance of cellular structure and integrity. CPDA1 (Citrate-

Phosphate-Dextrose) is generally preferred to ACD (Acid-Citrate-Dextrose) as anticoagulant. The choice of anticoagulant is important in determining the acceptable duration of storage of blood before transfusion.

Storage

The optimal storage temperature of whole blood is 1 to 5 °C. However, according to the anticoagulant used, the optimal duration of storage differs, longer for CPD-A (35 days) than for ACD (21 days).

Precautions

Whenever possible, it is preferable to collect whole blood into a multiple bag system which enables the preparation of blood components in a closed sterile system.

The ABO compatibility between donor and recipient should be respected when transfusing whole blood (see **Figure 9**). However, special attention should be paid when transfusing whole blood of the so-called universal group O because of possible anti-A and anti-B high titer haemolytic antibodies (see below: *Group O: universal but dangerous donor*).

Whole blood, because it is unprocessed, is highly efficient in transmitting infectious diseases.

2. Blood components

2.1. Red Blood Cell concentrate (RBC)

Definition

Concentrated red blood cells result from the removal from whole blood of sufficient plasma to obtain a final concentration (haematocrit) of 60 to 70 %.

Preparation

Plasma can be removed from whole blood by using a *closed system* when the blood collection set includes one or more satellite bags. If the closed system is used, plasma may be separated at any time and the red cells continue to be stored at 1 to 5 °C for up to the *normal period* for that anticoagulant/preservative solution. A closed system offers the important advantage of avoiding microbial contamination from the environment.

In practice, when the equipment (centrifuge, plasma extractor etc) required to fractionate blood is not available, a convenient method is to hang the blood

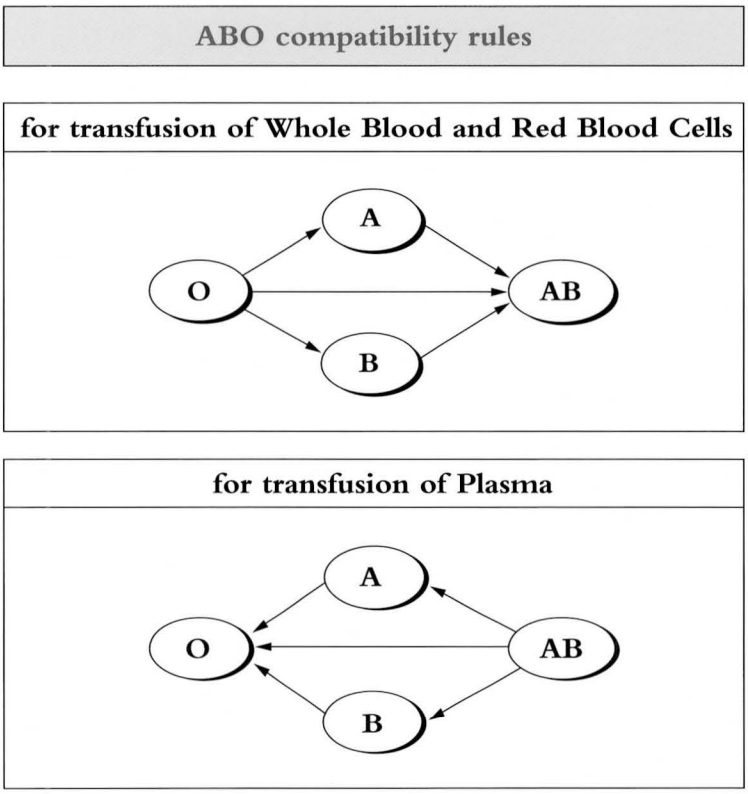


Figure 9 ABO compatibility rules that have to be respected for Red Blood Cells and Plasma transfusions.

bag from its base in the blood bank, make sure that the contents are not mixed before administration and stop the transfusion when plasma enters the drip chamber.

Storage

at 1 to 5 °C for no more than 35 days, depending upon storage conditions and the quality of the cold chain.

Precautions

The ABO compatibility between donor and recipient must be respected when transfusing concentrated red blood cells.

Red Blood Cell concentrates are efficient in transmitting infectious diseases.

Group O donors: universal but potentially dangerous donor

Group O individuals are generally considered as universal donors, whose blood can

be transfused to any recipient, whatever his own blood group A, B or AB. However, some group O individuals possess high titer anti-A or anti-B antibodies that can produce haemolysis in vivo. When transfused in large amounts, as may be the case when whole blood is administered, these antibodies are potentially damaging for group A, B or AB erythrocytes. But when whole blood is fractionated into concentrated red blood cells and plasma, the volume of plasma remaining in the RBC concentrate is much smaller and generally does not entail any adverse effects against the recipient's erythrocytes. Therefore, the use of fractionated blood consistently reduces the risk of haemolytic reaction due to ABO antibodies.

2.2. Platelets

Definition

One Platelet Unit is the number of platelets extracted from one unit of whole blood = $(0.6 \pm 0.2) \times 10^{11}$ platelets.

Preparation

Platelets are prepared from freshly collected whole blood (within 6-12 hours from bleeding) as:

– platelet concentrate
– platelet rich plasma

1. Preparation of *platelet concentrates* requires special equipment and expensive blood collection sets that are likely to be needed only at tertiary care facilities. When adequate equipment is available, preparation of platelet concentrates requires a two step centrifugation. A first (low speed) centrifugation allows for the separation of *platelet rich plasma* and packed red blood cells. After a second (high speed) centrifugation allowing extraction of a large volume of plasma, the sedimented platelets are resuspended in a small volume of plasma (about 50 ml).
2. When adequate equipment is not available, *platelet rich plasma* (PRP) can be prepared by allowing fresh blood to sediment with the bag supported vertically for six hours at room temperature. The plasma is then transferred to a satellite bag (closed system) or to a transfer pack (open system). The red cells are stored refrigerated and the platelet rich plasma mixed by gentle agitation every four hours whilst stored for up to 24 hours at room temperature.

Storage

Platelet concentrates may be stored in an agitator at room temperature (RT = theoretically 20 ± 2 °C) for up to *72 hours* from the time of the blood collection.

In developing countries, platelet needs can be achieved by giving "fresh" blood or platelet rich plasma (PRP) provided the whole blood has remained *at room temperature* until separation is made. "Fresh" blood is blood that has been kept at room temperature for not more than 12 hours.

Precaution

Although it may be possible to complete the required serological testing within 12 hours, it is safer to prepare platelets from blood collected from regular donors known to be negative for markers of transmissible disease and compatible with the intended recipient: this does not replace the need for screening and laboratory testing.

Platelet transfusion usually includes some of the donor's red cells and therefore requires demonstrated ABO compatibility between recipient serum and donor red cells.

2.3. Fresh and Fresh Frozen Plasma

Definition

Plasma is the supernatant of red blood cells that contains proteins; it can be recovered from whole blood by centrifugation or sedimentation of red blood cells. One whole blood unit allows for the recovery of approximately 250 ml of plasma.

Preparation

Plasma may be prepared as a byproduct of the preparation of a red cell concentrate. If this is done *within 6 hours* of collection it can be presumed to have retained labile coagulation factors (V and VIII) and can be frozen and used as fresh frozen plasma. Otherwise the plasma, stored either as liquid or frozen, will retain all proteins except factor V and VIII.

Storage

The best storage conditions for plasma are to be kept frozen at –25 °C or lower. Frozen plasma can be conserved for up to 1 year.

Liquid refrigerated (4 to 8 °C) plasma may be used within 35 days of collection if separated from red cells in a closed system.

Thawed frozen plasma must not be refrozen.

Precaution

The indications for the use of plasma in developing countries are limited by the recognition that it has the same risk of disease transmission as does whole blood.

Transfusion of plasma requires ABO compatibility with recipient's red cells.

2.4. Cryoprecipitated Factor VIII

Definition

Cryoprecipitate is a preparation of plasma which is particularly rich in coagulation factors (fibrinogen, Factor VIII, X and XIII).

Preparation

Cryoprecipitate is prepared from snap-frozen fresh plasma which then thaws slowly at 4 to 6 °C. After thawing, the supernatant plasma is removed (cryoprecipitate-poor plasma) and the precipitate is resuspended in about 20 ml of plasma.

Storage

It can be frozen and kept for one year at -65 °C. It contains about 50 % of the whole blood content of fibrinogen and factors VIII, IX and XIII.

Precaution

Transfusion of cryoprecipitate requires ABO compatibility.

Cryoprecipitate has to be infused as soon as possible after thawing.

3. Recommendations for preparation and storage of blood components

- Whenever possible, a closed system should be preferred to an open system to avoid microbial contamination.
- Whenever possible, whole blood should be fractionated into RBC concentrates and plasma.
- For each transfused blood product, there is a risk of infectious disease transmission, plus a risk of immunological adverse reaction.
- Specific *storage conditions* (time, temperature) should be respected for each blood component.
- Any discoloration, sign of haemolysis, precipitate or abnormality indicates that the fraction must not be used.
- Conservation of optimal biological activity during storage of whole blood, red blood cells and plasma strongly depends on the quality of the cold chain. Variation between 1 and 10 °C is acceptable for whole blood, provided the period above 6 °C is no more than six hours.

Blood Component	Main Indications	Storage T°	ABO compatibility
Whole Blood	*Acute blood loss*	**4°C**	yes
RBC concentrate	*Anemia*	**4°C**	yes
	Haemorrhage		
Plasma	*Burns*	**4°C**	yes
Fresh Frozen Plasma	*Severe blood loss*	**- 25°C**	yes
	Coagulopathy		
Platelets	*Massive haemorrhage*	**room T°**	when possible
	Coagulation disorders		
Cryoprecipitate	*Haemophilia A*	**- 65°C**	when possible
	Von Willebrand		

Chapter 5

USE OF BLOOD AND BLOOD COMPONENTS

Introduction

1. Main indications for blood and blood products
   - 1.1. Acute blood loss
   - 1.2. Anaemia
   - 1.3. Elective surgery
2. Alternative to homologous blood transfusion
   - 2.1. Prevention of anaemia
     - 2.1.1. For pregnant women
     - 2.1.2. For infants
   - 2.2. Autologous transfusion
     - 2.2.1. Preoperative deposit
     - 2.2.2. Immediate preoperative haemodilution
     - 2.2.3. Intraoperative blood salvage
   - 2.3. Blood substitutes
     - 2.3.1. Crystalloid solutions
     - 2.3.2. Colloid solutions
3. Management of transfusions
   - 3.1. Blood grouping
   - 3.2. Compatibility testing (cross-matching)
   - 3.3. Technical alternatives to cross-matching
     - 3.3.1. Direct saline proof
     - 3.2.2. Importance of temperature
     - 3.3.3. Enhancement of sensitivity
     - 3.3.4. Minimum alternative to cross-matching
     - 3.3.5. Type and screen strategy
   - 3.3. Transfusion reactions
4. Examples
5. Recommendations for the use of blood
6. Recommendations for the use of blood substitutes

Introduction

The pattern of blood use in developing countries is quite different from that in developed countries.

> *In developing countries, a high proportion of blood transfusions are given to children and to women, respectively in relation to anaemia and complications of pregnancies.*

As an example, a study carried out in Kenya in 1994 reports that 67 % of transfusions were ordered for children under 15 years, 27 % were for adult women and 6 % for adult men (J.R. Zucker et al. 1994).

The risk of viral diseases transmitted through transfusion is of great concern in general but more particularly in children who have a potentially longer life span and are often otherwise not exposed as yet. In developing countries with high prevalence of infectious diseases (HIV, HVB...), the risk of transmitting infections by blood is high. Therefore, testing of blood for serological markers (of HIV, HBV... infections) is one part of the strategy. However, this is not sufficient since a mathematical formula estimated, in 1993, that...

> *... in a donor population incidence of HIV of 10 %, 2 out of every 1000 transfusions of blood, although tested seronegative for anti-HIV, will transmit the virus.*

Therefore, another way to reduce the spread of infectious diseases by transfusion is to prescribe blood or blood components only when they are clearly and strictly indicated, after a careful assessment of the relative benefits and risks for the recipient. Ideally, every transfusion should always be strictly evaluated and the decision to transfuse must take into account both the therapeutic advantages and the infectious risk encountered.

On account of the difficulty to recruit "safe" blood donors, it is a priority to optimize the use of blood and blood components, to perform all tests, analyses and manipulations so as to enhance or maintain their therapeutic benefit.

Other strategies such as those of preventing anaemia in children and in pregnant women, or to promote administration of blood substitutes whenever possible or to develop alternative procedures such as autologous transfusions should also be implemented since they are also likely to reduce the rate of blood borne infections.

J.R. Zucker, E.M. Lackritz, T.K. Ruebush, A.W. Hightower, J.E. Adungosi, J.B.O. Were and C.C. Campbell. Anaemia, blood transfusion practices, HIV and mortality among women of reproductive age in western Kenya; *Transactions of the Royal Society of Tropical Medicine and Hygiene (1994), 88; 173-176.*

Another main feature of blood transfusion in developing countries is the absence of guidelines about appropriate use of blood. Very few well designed studies about the use of and the need for blood in developed and developing countries are available. Also, the benefit of blood transfusion has always been accepted in medical practice but it has rarely been evaluated precisely, and data for developing countries are not available at all. Unless more studies become available, only current practice and knowledge can be used and reported on.

In many developing countries mainly in Africa, there is little demand or need for blood for elective surgery. Furthermore, the rate of blood consumption for elective surgery chiefly depends on the degree of sophistication of hospitals. Most often, emergencies are the major indications for blood transfusion. However, in all the programmes there is an important shortage of information about the real basic needs *which, in some instances, are quite different from the* demand *for blood transfusions.*

It is also often difficult for the authorities in charge of the transfusion services to obtain reliable data about the use of blood in the hospitals. Unlike for developed countries elective surgery should not be the major indication governing the demand for blood. Therefore, each country is encouraged to convene a meeting of a panel of experts to draw up national guidelines for blood transfusion indications. As a global estimation, the number of blood transfusions required annually in the regions reported on is less than 1,000 per 100,000 population, which is lower than in developed countries (in Belgium ± 1 per 10). Experience suggests that it is between 2 and 10 transfusion episodes of an average of 1.6 units per thousand population per year.

Use of blood

In most cases, blood must be immediately available to have an optimal effect. Thus, as well as ensuring a supply of safe blood, blood typing and compatibility testing as well as clinical monitoring procedures must be simple and not time-consuming.

1. Main indications for blood and blood components

The major indications for transfusion are: *severe anaemia* (in children and in adults, for example due to sickle cell or malnutrition...) and *acute blood loss* during pregnancy, delivery or accident, and the two groups most concerned as blood recipients are *children* and *women*. However, minor indications such as elective surgery as well as alternative management will also be discussed.

1.1. Acute Blood Loss:

- Acute blood loss is a major indication for blood transfusion in developing countries. Life threatening *haemorrhages* are most frequently a complication of pregnancy (ectopic pregnancy, delivery) and trauma (road accidents, war or weapon accidents). In some cases, acute blood loss may happen during an emergency or elective surgery.
- The management of acute *haemorrhage* relies on three main principles: identification of the bleeding site, restoration of circulating volume and restoration of oxygen transport.
- *Volume* can be restored by infusion of crystalloid, synthetic colloid solutions or proteins of human origin (albumin).
- Depending upon the patient's haemoglobin level before haemorrhage, red blood cells should only be transfused after 25 % of volume loss. Indeed, normally, a healthy adult can tolerate acute loss of up to 20 % of the circulating blood volume without requiring intraveinous fluid replacement. Acute blood loss is a major cause of female mortality in developing countries. In a normal pregnacy, 10 g/dl of haemoglobin may be within normal range, with lowest Hb levels at 30-34 weeks of gestation. In pregnancy, transfusion is not indicated unless the Hb is below 6 g/dl, or below 7 g/dl at the onset of labour, and there is evidence of respiratory and/or circulatory compromise.
- Unfortunately, in developing countries, such management of acute blood loss is made difficult, partly due to the heavy cost of the replacement crystalloid solutions, or due to their unavailability. In these conditions and paradoxically, blood is used as volume expander, which should not be recommended.

1.2. Anaemia:

- Anaemia is a frequent pathology in developing countries, due to several factors: malnutrition and poor dietary intake, chronic blood loss related to parasitic diseases (such as malaria, gastro-intestinal diseases...) or hereditary haemolytic disorders (G6PD deficiency, sickle cell anaemia, thalassemia...).
- Chronic anaemia is generally well tolerated and blood transfusion is not necessary as long as the haemoglobin remains stable. However, in case of "aplastic crisis" or acute haemolysis crisis, when haemoglobin level falls rapidly and the patient exhibits clinical symptoms, red blood cell transfusion may be indicated. Although the level and rate of decrease of haemoglobin can serve as a criterion for blood transfusion, severe anaemia associated with cardiac failure is a clear indication for red cell transfusion. Children up to age of 6 ought to have a haemoglobin level < 5g/100 ml and show breathlessness or other signs of hypoxia to justify a blood transfusion.
- For paediatric patients, in order to use blood optimally, one blood unit can be divided by sterile technique into 3 units of 80 ml of packed red blood cells. Such blood is best collected from known HIV and HBV negative voluntary repeating blood donors.

1.3. Elective surgery:

- Indications for blood transfusion as well as the *number* of blood bags needed for a given elective operation should be discussed locally and be the result of a consensus between clinicians. As far as elective surgery is concerned, the use of autologous blood should be preferred to homologous blood transfusion whenever it is possible.

2. Alternative to homologous blood transfusion

2.1. Prevention of anaemia:

2.1.1. For pregnant women.

Prevention of iron-deficiency anaemia by counselling pregnant women

through the organisation of open consultation systems and/or training of midwives. Iron and folate supplementation and/or antimalarial prophylaxis or therapy could be part of the ante-natal care in order to reduce the risk and the severity of anaemia.

- Ensuring a follow-up of pregnant women at risk of problem delivery in order to transfer them as soon as possible to an adequate hospital environment.

2.1.2. For infants.

Prevention of the spread of malaria in children by preventing mosquito bites, by environmental cleaning, and the use of anti-malaria therapy.

2.2. Autologous transfusion

Autologous transfusion is the collection and subsequent re-infusion of the patient's own blood or blood components. Blood transfusion in general, whether autologous or homologous, should only be used when clearly indicated. Autologous blood transfusion is most useful in elective or planned surgical procedures where blood normally is needed.

- A programme for autologous transfusion requires precise record keeping and labelling, and adequate facilities for the collection and storage of blood; a well organized blood transfusion service is therefore essential. Costs of these services have generally been shown to be higher than for homologous blood transfusion and should be weighed against those of long-term morbidity and mortality of transfusion related diseases.
- In situations where homologous blood is in short supply, expensive or carries a risk of transmission of serious infection, the use of the patient's own blood must be considered before ordering other blood for the care of patients undergoing surgery.
- Three methods exist to collect blood and reinfuse it during or after surgery.
  1. Preoperative deposit
  2. Immediate preoperative haemodilution (perioperative collection)
  3. Intraoperative blood salvage

2.2.1. Preoperative deposit

- Must be *previously* arranged with the BTS.
- Suitable for some elective procedures in which blood loss is expected to be greater than 30 ml/kg.

- Needs careful planning.
- Is at least as expensive as homologous blood.
- Every seven days, from 35 to 7 days before surgery, 10 ml/kg can be collected into CPDA1.
- Autologous blood has to be typed (ABO & Rhesus) and screened for infectious disease according to the national policy.
- Haematinics, such as ferrous sulphate, are given orally starting 50 days before surgery.

2.2.2. Immediate preoperative haemodilution

- 10 to 20 ml/kg of blood are collected into anticoagulant and with replacement of crystalloid or colloid solution, immediately before the start of surgery. It is kept in the operating room and unrefrigerated until reinfusion within 6 hours, at the end of surgery, or at time when blood loss is enough to demand replacement.
- Adequate labelling of blood bags is of greatest importance.
- Blood does not need to be tested if it is to be given only in the operating room.
- If not used, it must be destroyed when the patient leaves the operating room.
- Suitable for all elective, and many emergency, surgical procedures where blood loss is expected to be greater than 15 ml/kg.
- Contra-indications: haemoglobinopathy, sepsis or severe cardiac, liver or renal disease.
- Haemoglobin should not drop below 9 g/dl before surgery.

2.2.3. Intraoperative blood salvage

- Blood collected from a sterile uncontaminted abdominal or thoracic cavity may be reinfused (after filtration if clots are present), during or immediately after surgery.
- The most common indication is ruptured ectopic pregnancy.
- Blood can be collected by inserting the needle of a blood collection set through the cavity wall before incision or by scooping and filtering blood after the cavity is opened.
- The cavity is examined to exclude possible contamination from bowel contents, urine, bile infection or malignancy before blood is reinfused.

2.3. Blood substitutes

- It is clear that very often, substitutes could be used instead of blood products but that because of their unavailability, an unknown percentage of transfusions are not indicated but still performed.
- The rapid administration of sufficient volume of crystalloid solution will maintain circulation in most patients until the blood loss ceases.
- Patients who need volume expanders can benefit from gelatin solution (for example Gelacil®) which is cheaper than other colloids like albumin or Dextran, and is very effective. This would save a lot of transfusions, especially in management of trauma.

2.3.1.- Crystalloid solution

- A considerable proportion of blood used in developing countries (e.g. 20 % in Uganda) is for women with post-partum haemorrhage. Most of these patients receive less than 1 litre of whole blood. Experts think many patients could be managed successfully with intravenous saline solution. Similarly, most recipients of blood following trauma get less than one litre and could also be managed with saline. However, saline is not available in a lot of developing countries in sufficient supply at the time needed.
- Doctors usually underestimate the volume required and the duration of continued IV fluid. For a loss of 30 ml/kg it is necessary to administer 100 ml/kg acutely and to continue at a similar level in the subsequent 24 hours.

2.3.2.- Colloid solutions

- Colloid solutions, such as albumin 5 % or 20 %, or substitutes such as Dextran, hydroxyethyl starch (HES), or gelatin solutions are often considered to manage acute blood loss. However, these solutions are much more expensive than saline, even though about half the volume is needed, and they are therefore not included in the first priority for treatment. Compared with saline, Dextran is 5-10 times (and HES 20 times) more expensive.
- 5 % albumin is very expensive. Most of the BTS programmes have human plasma available but the use of untreated plasma from a population with a high seroprevalence of HIV and hepatitis virus is unjustified.

3. Management of transfusions

To respect ABO compatibility rules is the major preoccupation since transfusion of ABO incompatible blood may have adverse effects with potentially fatal outcome for the recipient. In order to prevent such accidents, extreme care has to be used to ensure correct identification of *patient* and of *specimen*. However, it is worth noting that problems of ABO incompatible transfusions are not only due to laboratory errors; most often, transfusion accidents are due to a mistake in the identification of patients.

3.1. Blood grouping

- *ABO and Rhesus typing*. Pre-transfusion testing includes blood grouping (ABO and Rhesus) of the *patient*. Blood samples from patients should be typed using anti-A and anti-B (+ eventually anti-A+B) for red cells and, when possible, A and B red cells for serum typing. Any discrepancies between cell and serum grouping should be re-investigated until the correct group is determined.
- All blood *units* are previously phenotyped for both ABO (cell and serum proofs) and Rhesus (D) systems.
- Whenever possible, Rh negative recipients should not be transfused with Rh positive blood. However when the Rh negative blood is in short supply it may be necessary to reserve it for Rh negative females with potential for child bearing.
- ABO compatibility rules have to be respected strictly for transfusion of whole blood, concentrated RBC and plasma (see **Figure 9**)

3.2. Compatibility testing (cross-matching)

- Compatibility testing uses laboratory methods allowing verification that the recipient's serum does not contain any antibody likely to react with donor's red blood cell antigens.
- Compatibility testing requires the provision of a sample of the recipient's clotted blood (10 ml). Patients who have never been transfused nor pregnant can be expected to have only naturally occurring antibodies. ABO compatible blood is assured by an immediate room temperature saline cross-match: the cells to be transfused are tested against the recipient's serum.

(Compatibility testing also serves as a valuable tool to reinforce the identification of the patient and the blood unit).

3.3. Technical alternatives for cross-matching

3.3.1. The Direct proof in Saline.

- Donor red cells are added to patient's serum and examined, after centrifugation, for haemolysis and for agglutination. *If neither has occurred the blood is compatible.* If even a hand operated centrifuge is not available, red cells should sediment through serum in a tube for 30 minutes and then be inspected.
- In practice, *a tube technique* compatibility test must be performed and found to be negative before transfusion. The most convenient method is to add 1 drop of 5 % donor cells to 1 drop of recipient serum in a 12 x 10 mm tube, at room temperature. Centrifuge for 1 minute and examine by visual inspection the red cell button as it releases from the tube bottom when it is gently rotated. The complete procedure can be completed within 5 minutes.
- A microscopic examination is not required.
- Tile or slide cross-matching without centrifuging is NOT acceptable.

3.3.2. Importance of temperature

The saline cross-match performed *at room temperature* will avoid most problems of ABO incompatibility since most ABO as well as cold agglutinins are more potent at lower temperature. However, a lot of clinically significant antibodies will react only at temperatures closer to 37 °C. Therefore, cross-match performed at 37 °C will result in enhancing the sensitivity for the detection of clinically significant antibodies.

3.3.3. Enhancement of sensitivity:

- Other techniques can also be applied in order to enhance the sensitivity of the compatibility testing. For example: use Low Ionic Strength Solution (LISS); use of proteolytic enzymes (papain, trypsin, bromelin), use of *Coombs' reagent...*
- *The Indirect proof: anti-human globulin (AHG) in case of Immunized patients.* Patients who have been previously transfused or who have had a pregnancy may have developed allo-antibodies. Therefore, for all recipients who might

have been *immunized*, by pregnancy or by previous transfusion, and who might have produced IgG against red blood cell antigens, it is advisable to exclude "coating" (or sensitizing) antibodies. These antibodies have to be detected with other techniques such as a Coombs' test (AHG). This is reliable only in experienced hands.

- To achieve this further compatibility analysis, the same tube used for the saline room temperature test can be used. The cells are resuspended by mixing and incubated for a minimum of 15 minutes in a water bath or in an incubator at 37 °C. The tube is centrifuged and the button washed four times with saline. Two drops of anti-human-immunoglobulin (AHG) are added and the tube centrifuged again. The tube is then gently rotated to look for agglutination.
  - If agglutination takes place, the blood is not compatible and should not be transfused.
  - If agglutination is not seen, the test should be completed by adding pre-sensitized red cells, and, after centrifuging, confirm that there are agglutinates.

3.3.4. Minimum alternative to cross-matching.

A *minimum* alternative to cross-matching consists in re-checking the ABO blood group of both the donor and the receiver. Ideally, each result of grouping should be checked by two different staff members. For example: technician A determines the patient's ABO group whereas, independently, technician B tests for the ABO groups of all blood units selected.

3.3.5. Type and Screen strategy.

This strategy consists in searching for irregular antibodies in recipient serum by using standard phenotyped red blood cells as reagents. The type and screen strategy can be applied with two levels of sensitivity: the lowest one is the direct saline proof and the highest one, which should be recommended when possible, with the AHG reagent.

3.4. Transfusion reactions:

- The first 20 ml (less for infants) of each transfusion are the most critical. If there is pain, either remote or spreading from the site of the needle, sudden

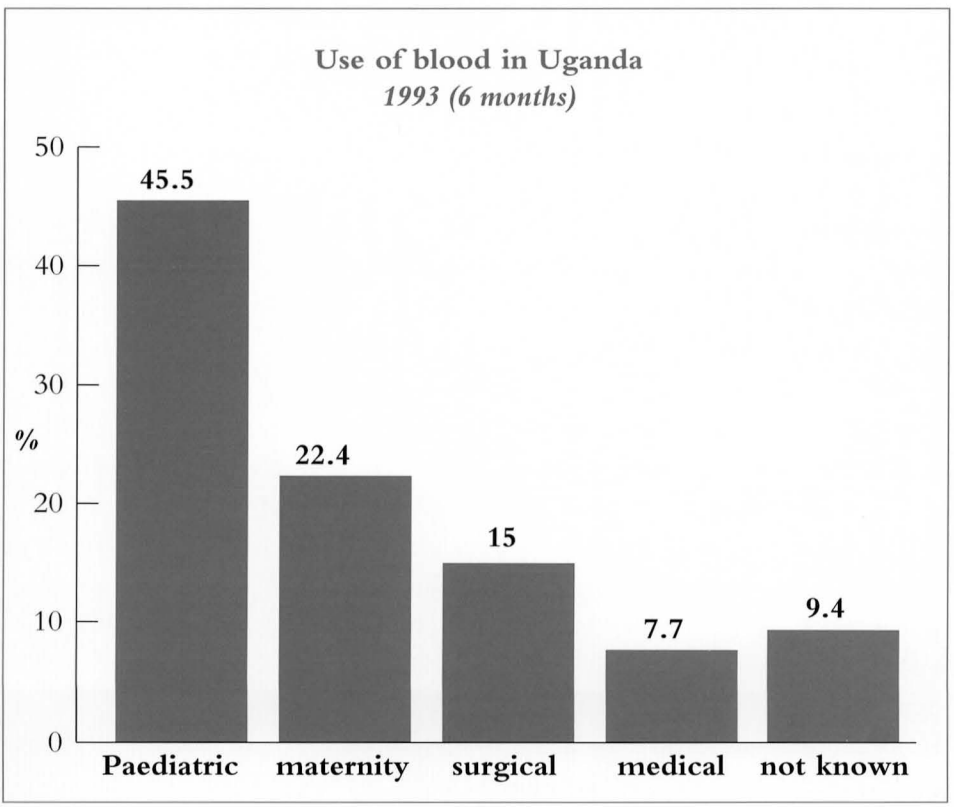
fever or shaking chills, a transfusion reaction has occurred. This must be noted in the patient's chart. The patient should be monitored at regular intervals until 12 hours after the transfusion is finished.

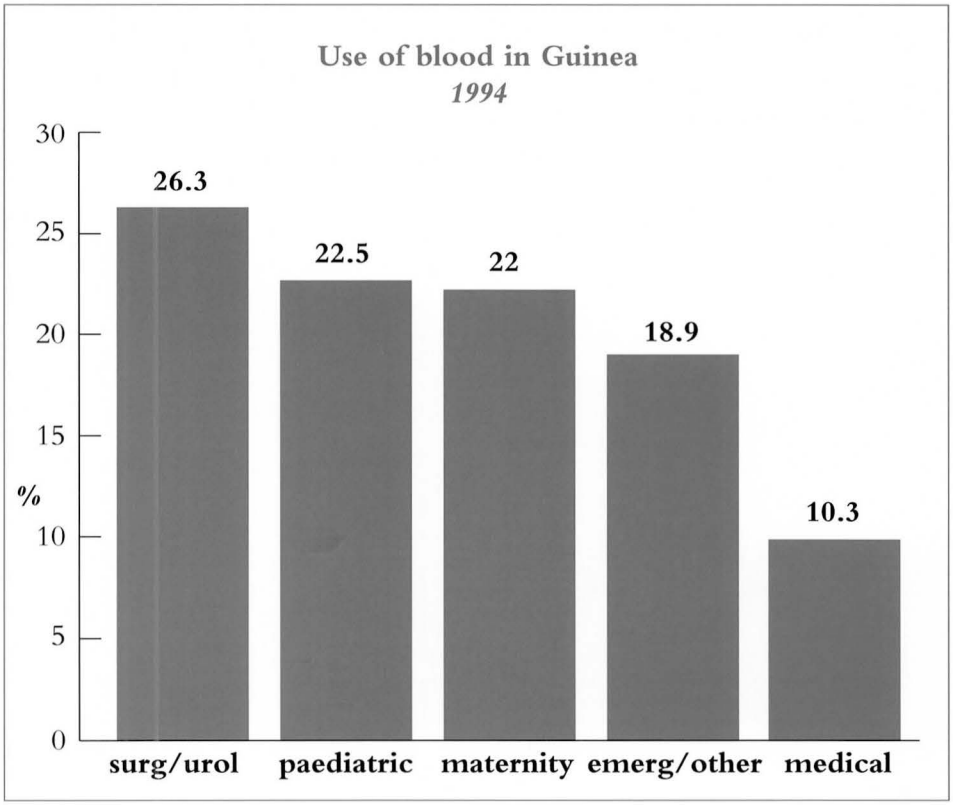
- Accurate records must be kept allowing identification of (1) the transfused patient and (2) the blood given.
- The presence of allo-antibodies in the serum of an immunized patient is a finding which must be kept in mind and taken into account in case of future transfusion.

4. Examples

4.1. Example of use of blood in two African countries

Figure 10: Use of Blood in Uganda in 1993, and in Guinea in 1994.





4.2. Example of indications for blood transfusion

Indications for Blood Transfusion in Uganda

Summary statement of *"Indications for Blood Transfusion in Uganda"*, prepared by the AIDS Control Programme of the Ministry of Health of the Republic of Uganda. Published July 1989.

Blood transfusion may have major consequences for good or bad in patient care. Indications and contra-indications are different from those in developed countries and are not available in textbooks. The spread of the HIV epidemic in the population has increased dramatically the risks of transfusing blood. In some urban areas, more than 20 % of the blood donors have been found to be anti-HIV positive. If this blood had not been tested and instead used to transfuse patients, all recipients would have become infected with the AIDS virus. In fact, even when testing is done and HIV positive blood discarded, a few donors will be virus positive but antibody negative (the window period) and HIV transmission will occur. Thus severely limiting transfusions to only the most unavoidable situations is indicated.

INDICATIONS FOR TRANSFUSION IN UGANDA prepared by the AIDS Control Programme of the Ministry of Health of the republic of Uganda (1989).

1. *Anaemia in infants:* Transfusion may be necessary if:

- Hgb is less than 3 g/dl without complications.
- Hgb is less than 4 g/dl and complicated by malaria (positive blood smear) or bacterial infection, even without cardiac failure.
- Hgb is less than 5 g/dl and is complicated by cardiac failure (air hunger, increased venous pressure, hypotension = systolic BP less than 80 mm hg., tachycardia = pulse rate more than 140/minute, and general or dependent oedema).
- Transfusion is NOT necessary if Hgb. is more than 5 g/dl.

2. *Anaemia in pregnancy*

- Hgb levels less than 7 g/dl may need treatment if near term, but transfusions are essential only when cardiac failure results from anaemia. In addition, diuretics should be concurrently administered.
- In case of postpartum haemorrhage, blood transfusion is indicated only if hypotension and reduced cerebral function persist after at least 50 ml/kg of fluid has been given intravenously, and all measures have been taken to stop blood loss.

3. *Anaemia: other*

- Blood transfusion is indicated only in cases where symptoms of anaemia progress and Hgb. is less than 4 g/dl or if haemolysis or haemorrhage occurs.

4. *Haemorrhage:* the first effort is to stop blood loss.

- Haemorrhage from any cause requires replacement of volume rather than of red cells. Initially this should be with crystalloid (saline or Ringer's lactate) solutions up to 50 ml/kg followed by colloid (5 % Dextran or

5 % hydroxyethyl-starch) in the same amount during the first 12 hours. Only if shock is worsening or persisting after the above measures should blood be given. After each 250 mls of blood the condition of the patient should be evaluated before the risk of more transfusion is accepted.

5. Emergency surgery:

- The guidelines for haemorrhage apply.

6. Elective surgery

- It must be an exception to use donor blood in case of elective surgery. Any such instance is cause for a full evaluation and subsequent report to the District Medical Service by the hospital superintendant.

7. Other indications:

- Chronic anaemia etc. guidelines are being compiled.

5. Recommendations for the use of blood

- It is recommended that in each country a survey is performed about the actual use of blood and this survey should be repeated at regular intervals to monitor the use of blood.
- Each blood transfusion programme in a country should also have an approximate idea about minimum and realistic needs for blood, blood products and substitutes.
- In collaboration with hospital clinicians, each transfusion service should develop guidelines for the best use of blood, blood substitutes and blood products and monitor the daily practice.

6. Recommendations for the use of blood substitutes

- Whenever possible, blood transfusion should be avoided for infants and pregnant women and replaced by safer blood substitutes.
- Promote crystalloids as the first choice as volume expander.
- Facilitate the distribution and the availability of saline.
- Plasma has limited indications and must be used carefully.
- Plasma is NOT recommended for volume expansion.
- Promote autologous transfusion for elective surgery.
- Blood transfusion services should determine the amount of IV saline required and develop procedures to ensure supply, distribution and correct use. In Uganda it is, for example, estimated that to provide sufficient saline to treat acute blood loss by volume replacement will require 800,000 L/year.

Chapter 6.

EQUIPMENT, STORAGE, CONSUMABLES AND BUILDINGS

Introduction

1. Buildings

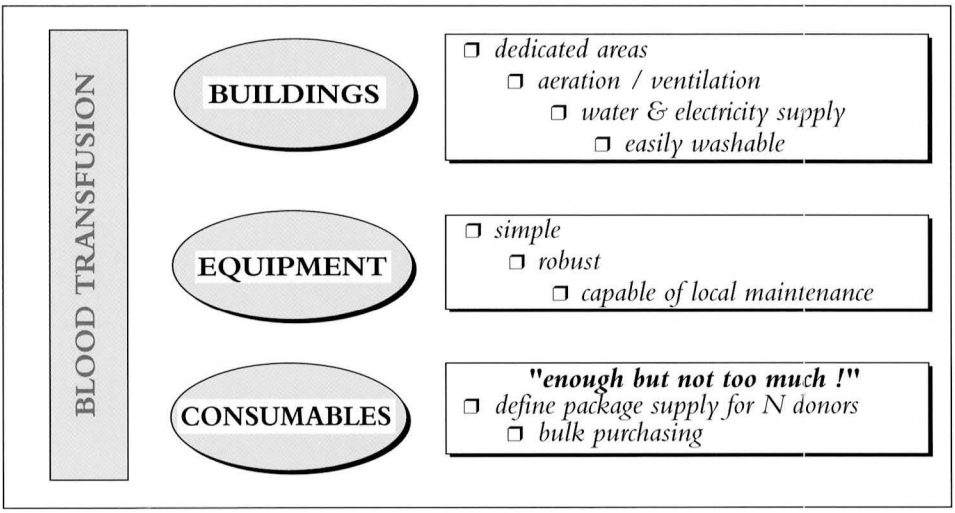
2. Equipment
   2.1. Major equipment
   2.2. Other equipment needed

3. Consumables

4. Storage of blood
   4.1. Electricity available
   4.2. Unreliable or no mains electricity service

5. Example

6. Recommendations for equipment


BLOOD TRANSFUSION
BUILDINGS
❒ dedicated areas
❒ aeration / ventilation
❒ water & electricity supply
❒ easily washable
EQUIPMENT
❒ simple
❒ robust
❒ capable of local maintenance
CONSUMABLES
"enough but not too much !"
❒ define package supply for N donors
❒ bulk purchasing

Introduction

Equipment required to provide blood and blood components for transfusion in a tertiary care hospital in developing countries is much the same as would be needed in a developed country. In a primary care setting, however, emphasis should be placed on providing the minimum essential, rugged and easily maintained and replaced equipment. When electrical supply is available only during a limited time, or not at all, it is important for the laboratory to be able to perform all essential tasks without it.

Storage facilities should be equipped with a security system to prevent disappearance of stock as well as to protect stock from humidity, insects, rodents, etc. Another security measure is to insure stock which is cheaper than it seems when looked at on a long-term basis. Reliability of delivery dates is an important issue to take into account.

Monthly records of number of donors, collection, blood products production and distribution, are necessary in order to organize consumable ordering and purchasing. It is clear that the best price is not always the lowest one and the choice should be made taking into account the quality of the product, the quality of the service and maintenance, and the delivery facilities, sometimes even the training facilities.

Bulk purchasing between different programmes is suggested to the EC's HIV/AIDS programme to get a lower price, better standardization and better adaptation to the blood programmes in developing countries. However, this is usually found to be impossible due to variation in installation, maintenance and delivery requirements as well as individual preferences.

1. Buildings

In determining how a building should be constructed several important principles apply, including:

- selection of suitable local materials
- integrity of electricity and water supply
- application of ergonomic principles in all areas
- donor privacy
- security
- physical separation of donor and laboratory areas
- ventilation and air-conditioning
- space requirements should be based on 8-10 square meters per donor bed,

and sufficient pre- and post-donation area should be provided to allow privacy and refreshments at interview
- planning of capital investment should be done together with that of operational costs
- all possibilities in the construction to assure easier maintenance of the work spaces should be applied, for example:
  - the walls and the floors should be easily washable and covered by materials not susceptible to be changed by the use of detergents (daily cleaning with hypochlorite solutions is necessary)
  - plinths should be rounded so as not to accumulate dust
  - especially in the laboratory and blood handling spaces, tiles should be used as much as possible
  - cupboards should be elevated so as to make cleaning easier
  - plumbing and electricity should not be walled in but they should be reduced to the minimum in the technical spaces and preferably run through hallways, under the roof or outside
  - washbasins should be easy to clean by non-professional people
- in climates with heavy rains, rain water pipes should be large enough and easy to maintain. Containers can be placed to organize a water reserve for the dry season.
- electrical wiring, laboratorial plumbing, air-conditioning should be appropriate and not too sophisticated and priority should always be given to materials locally produced or available.

2. Equipment

It is essential that equipment for a blood transfusion service in a developing country be simple, robust and capable of local maintenance. In selection of such equipment, the availability of a locally based distributor and maintenance service should have a high priority. Within the blood transfusion service, staff members are the maintenance persons, who will look after the building, vehicles and non-specialized equipment.

2.1. Major equipment

- donor beds
- scales for controlling the blood collection procedure
- bench centrifuges
- microscopes
- incubators/water baths
- refrigerators
- freezers
- generator
- voltage stabilizer
- containers
- laboratory scales
- autoclaves
- still; deionizer
- laboratory furniture
- office furniture, equipment
- workshop furniture, equipment
- refrigerated centrifuge

Major equipment should also include vehicles *for transport.* Transport of blood and blood products but also transport of staff members who are in charge of mobile sites of blood collection.

2.2. Other equipement needed includes:

- three or more insulated *boxes* for holding blood between issue and administration. These are very useful if blood is required on standby for surgery
- spring *balances* to determine the optimum filling of blood bags and for separating blood units into smaller amounts
- tube *strippers* and hand punches to clip blood tubing in segments
- strong plastic crocodile *forceps* to occlude tubing temporarily whilst filling the sample tube
- *weighing scales* to determine donor's weight
- maximum and minimum *thermometers*
- spring loaded and release *holders* for lancets to pretest donors for haemoglobin etc. from finger prick blood samples.

3. Consumables

"Enough but not too much"
is a rule to adapt to each item.

The definition of a package supply for *50 donors*, which includes everything necessary for recruitment, collection, treatment, etc. was discussed and seemed to be a good solution to organize stock management.
(see *"List of supplies for collecting blood from 50 donors"* as an example at the end of the chapter).

4. Storage of blood

- Ideally, blood should be stored in refrigerators having automatically cycled, dual compressors, special insulation, external maximum and minimum temperature recording and alarm systems. If blood is collected and stored in disposable (closed) plastic bags, the risk of introduced infection germ is minimized. This allows some leniency on storage temperatures. Blood may be safely stored for 21 days in a well functioning domestic refrigerator which is dedicated only to blood. The door must be opened rarely and a maximum/minimum thermometer is used and monitored at least daily.
- Variations from 2 to 10°C are acceptable. Blood must never be frozen. Before transfusion it is essential that the bag be carefully inspected. Any discoloration or sign of haemolysis at the cell/plasma junction indicates that it must not be given.
- The only acceptable storage system is a closed system, plastic based.
- In developing countries, it may occur that electrical supply is unreliable. It is therefore important to have some notions about alternative practical strategies and procedures that can be adopted.

4.1. Electricity available and reasonably reliable:

- *Refrigerator*: a simple laboratory refrigerator with 60 unit capacity can be obtained for under 200 ECU. At this price it is reasonable to reserve it for

blood bank use only. The door should be opended for the shortest possible time and inventory control is less difficult if a lock is fitted.

For laboratories providing more than 50 transfusions a week, two refrigerators should be available: one for processed and the other for unprocessed blood. This is better than providing one large refrigerator for which there is no back up should a compressor need replacement.

Temperature may be monitored by a laboratory thermometer in a water container and by a maximum/minimum thermometer. Care is needed to ensure that the area nearest to the cooling mechanism is insulated to prevent blood from freezing.

- *Centrifuge*: The blood bank needs only the simplest centrifuge. It should have space for twelve tubes (12 x 100 mm) and on/off switch but no brake and no timer. Such a centrifuge can be obtained for less than 200 ECU.

4.2. Unreliable or no mains electricity service:

- *Refrigerator.* Butane gas in cylinders is expensive and difficult to transport. Paraffin has the same problems. Solar or 12 Volt rechargeable batteries may be the best solution. Refrigerators suitable for storing blood with these power sources are necessarily small (about 12 units of blood) and must be well insulated and used conservatively so the door is opended only for the minimum time. An alternative as a standby when electricity is available at least part of every 24 hours period, is the use of a well insulated picnic box with precoated ice containers. Such a cold box will maintain 12 units of blood at less than 10 °C for 48 hours.
- *Centrifuge*: a hand operated unit is adequate.

5. Example

List of supplies for collecting blood from 50 donors.

The following list are the supplies required to collect, process and administer blood from 50 donors. The numbers assume 20 % wastage of collected units, and 30 % of units will be used for transfusion of smaller aliquots of blood.

❒	single CPDA1 blood bags (450 ml) Usually 40/10 split
❒	double CPDA1 blood bags (450 ml) (multiple packs for component preparation).

Fifty of:

❒	disposable lancets	
❒	sterile 5 x 5 cm gauze squares	
❒	hibitane 2% in water	20 ml
❒	liquid soap solution 5% in water	20 ml
❒	preprinted sets of six identical adhesive number labels	
❒	donor record cards	
❒	adhesive plaster strips	
❒	supplies for donor refreshment	
❒	thank you letters / instructions for future blood donations	
❒	packets of iron tablets with instructions	40
❒	vacutainers tubes	

For reagents and analyses:

❒	test tubes	
❒	anti-A, anti-B, anti-AB, anti-D; all monoclonal	10 ml of each
❒	anti-human globulin (polyclonal)	2 ml
❒	anti-HIV, HBsAg, RPR	75 of each
❒	lab glassware	
❒	disinfectant and detergent	
❒	sharps containers	
❒	protective clothing, gloves	
❒	timers	
❒	aspirator bottles	

For administration of transfusions and stationery:

❒	transfusion administration sets	50
❒	biohazard disposable bags	50
❒	transfer packs	20
❒	blood group labels	
❒	compatibility report forms in triplicate	60
❒	blood transfusion request forms in duplicate	100
❒	blood crossmatched or available reports	100
❒	blood donor register	
❒	confidential laboratory register	
❒	blood donor recruiting posters and leaflets.	as available

6. Recommendations for buildings, equipment and consumables

- Buildings:
  Appropriate buildings should be designed and made available for BTS.

- Equipment:
  - Equipment should be appropriate, simple and robust.
  - Local maintenance by the manufacturers should be available and the manufacturer should be asked to train local people for maintenance.

- Consumables:
  - It is recommended to define a package supply for 50 or 100 donors which includes everything necessary for recruitment, collection, treatment etc.
  - Monthly records should be kept.
  - Bulk purchasing of products adapted to developing countries to get a lower price should be organized if possible.
  - The technical assistance or programme manager appointed to the project should be involved, at the decision stage, in the design of buildings and the purchase of equipment and supplies when and if possible.

Chapter 7

SAFE BLOOD MANAGEMENT INDICATORS

Introduction

1. Useful definitions

2. Indicators
   - 2.1. Categories of indicators
   - 2.2. Criteria for selecting indicators
   - 2.3. Process of indicator selection
   - 2.4. For whom are the indicators ?

3. Safe blood
   - 3.1. Stage 1: Blood donor recruitment and retention
   - 3.2. Stage 2: Screening
   - 3.3. Stage 3: Storage and stock management
   - 3.4. Stage 4: Distribution
   - 3.5. Stage 5: Use of blood

4. Example

5. Recommendations on the use of process indicators to monitor safe blood projects

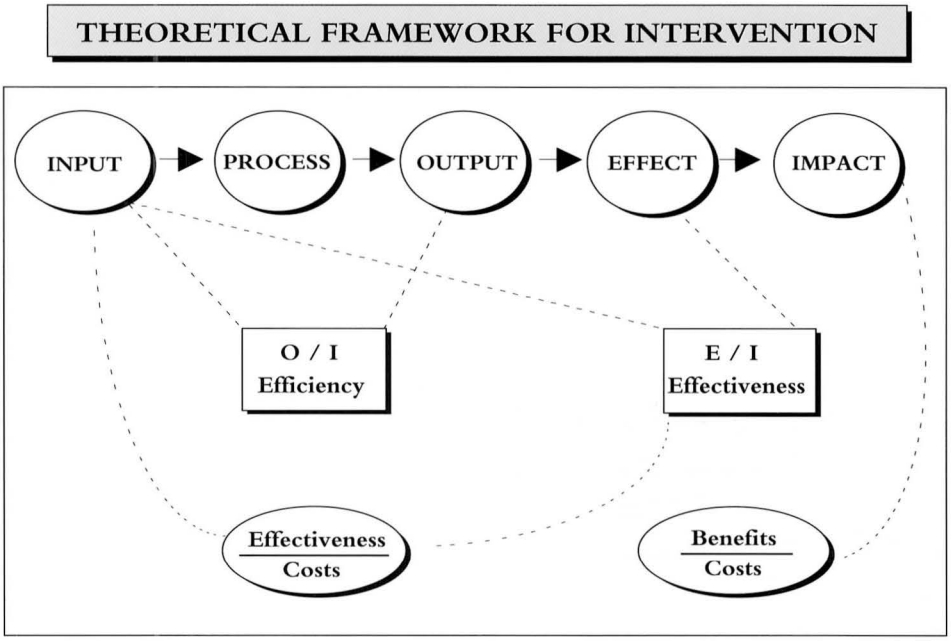


Figure 11: Diagram illustrating the various parameters and their interaction, to be taken into account in defining an indicator model

The ***inputs*** when processed using methods give a certain amount of ***output***.

This output results in ***effects*** which create an ***impact***. *The* ***efficiency*** of the health service could be assessed by the proportion of output to input **(E1 = O/I)**.

The ***effectiveness*** could be assessed by the proportion of effect to input (**E2 = E/I**).The impact could be assessed by carrying out cost / benefit studies and evaluation on a larger scale.

Introduction

Health Management Indicators are variables which help to measure change in a given situation. They may be a partial reflection of the "real situation" because often the situation is complex. They may also be only indirect measures of a situation. If measured sequentially over time, they can indicate the direction and speed of change. They can also be used to compare different geographical areas and different groups of people at the same moment of time.

In summary, indicators provide a standard against which we can measure, assess or show progress in an activity or objectives where targets have been stated.

> *Indicators can only be used in a situation where aims and objectives have been clearly stated in advance.*

There is some variation in the understanding of what constitutes an indicator. The above definition seems to restrict the term to the epidemiological and service coverage types of information. Indicators should not be restricted only to those which can be drawn from existing records, but should include other types of information that can be obtained through observation, supervision visits and community contacts.

The development of the methodology to assure safe blood in view of the HIV/AIDS epidemic in developing countries is not limited to testing for HIV. Targeted and better procedures to select and retain donors and collect blood, as well as to improve and make optimal use of blood and blood substitutes, are important parts of the total strategy.

Therefore, in all projects, the intervention is analysed and designed in a comprehensive way. Education of donors, counselling of seropositive and seronegative persons, rationalization of the use of blood, training and management are integrated components of the programmes that are supported.

1. Useful definitions

For a better understanding of the use of indicators and monitoring, the diagram given in **Figure 11** is useful. In order to have a clear idea of diagram, the following definitions are given:

Indicator

A variable which helps to measure change, directly or indirectly. The main

characteristic of an indicator is that it contains a well defined numerator and denominator. Indicators are not synonymous with objectives or targets but are measures of the extent to which targets are being reached.

Activity

A set of actions required to carry out an intervention.

Activity indicator

A measure of the extent of implementation of an activity. Monitoring of activity indicators can show how work is progressing on the activities needed to achieve a programme target.

Activity target

Quantified goals for achievement of specific activities within an intervention. They are targets specific to target population or aspects of activities needed to carry out the intervention. The achievement of activity targets contributes to the achievement of programme targets.

Monitoring

The process of collecting and analyzing information about implementation of the programme. It involves regular checking to see whether programme activities are being carried out as planned so that problems can be discussed and dealt with. Monitoring helps to follow progress of planned activities, identify problems, and give feedback to staff and solve problems before they cause delays.

Output

The product of a given set of service activities.

Effectiveness

The degree to which a plan, a programme or a project has achieved its objectives.

Objectives

In management terms, an objective is a statement of purpose or the condition desired in some stated future. A well formulated objective has criteria defining:

– acceptable level of performance (state which is desired)
– extent to which it is desired (quantification)
– when it is expected to be attained.

2. Indicators

2.1. Categories of indicators

Indicators can be classified using a variety of categories. A widely used approach is to group indicators according to the conventional description of a programme. Thus, there are:

- *input* indicators
- *output* indicators
- *process* indicators
- *effect* indicators
- *impact* indicators

2.2. Criteria for selecting indicators

In selecting indicators, certain qualities should be sought:

Validity

An indicator has high validity if it measures what it is supposed to measure. In other words, the figure obtained is the nearest reflection of the true situation.

Reliable

If used under different situations, the indicator should yield consistent results and different observers using it should come to the same conclusions.

Relevant

The indicator should relate to the project objectives (in terms of time frame, inputs, environments etc.)

Sensitive

Indicators should reflect change in the situation as soon as it occurs.

Specific

Indicators should reflect changes in the situation and be free from other confounding variables.

2.3. Process of indicator selection

In order to select indicators, a process of questioning is proposed. For example:

- "is the nature of the health problem clearly defined ?"
- "is there a clear model of service delivery ?"

– "are there generally accepted strategies for achieving results ?"
– "are the expected health results clearly stated ?"

2.4. Who are the indicators for ?

Indicators should be developed based on the level of the people who use these indicators, the level of operation of the programme they would supervise, and what aspect of the programme they are concerned with. The table below gives a clear idea of the focus of study of indicators.

User of indicators	Operational level	Concerned with
Programme Director	Programme	Policy / strategies
Project Managers	Projects	Objectives
Field Managers	Field projects	Activities

Indicators could be developed to match the interventions. The critical value for each of the indicators could depend on the initial status of a situation at the beginning of intervention.
With this analysis on indicators as a background, the interventions on "Safe Blood" (see **Figure 12**) can be analysed.

3. Safe blood

There are several activities that are carried out in each of these stages of the BTS. Each stage adds value to the unit(s) of blood that are collected and used, hence the title *Value Chain* of the BTS. Refer to the diagram (see **Figure 12**) which gives a clear picture of the Value Chain of the BTS.
The Value Chain of safe blood comprises the following stages (see **Figure 12**):
Stage 1. Blood donor recruitment & retention
Stage 2. Screening
Stage 3. Storage & stock management
Stage 4. Distribution
Stage 5. Use of Blood

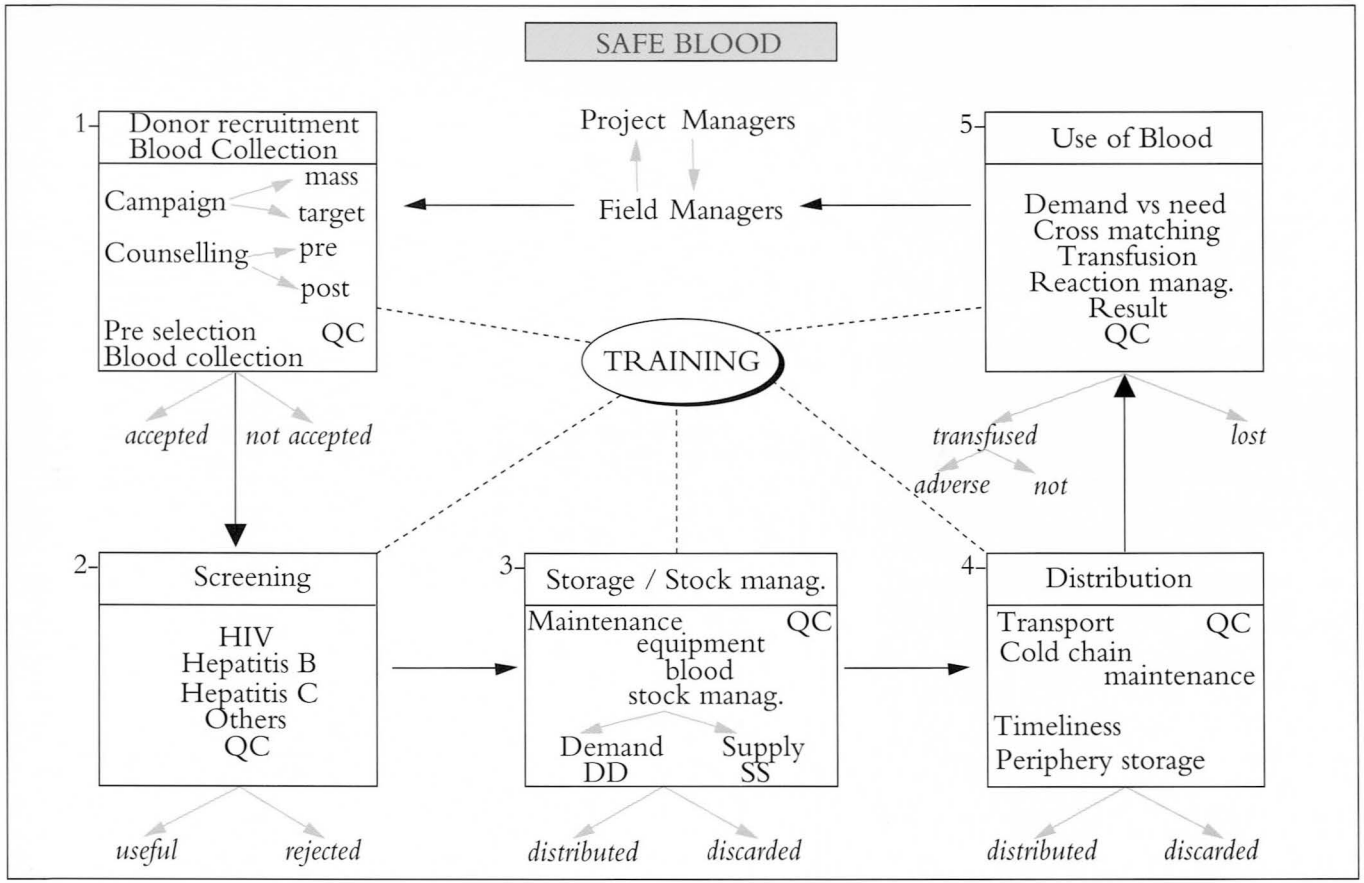


Figure 12: Different stages of the 'Value Chain' of the BTS, from blood collection to use of blood.

QC = Quality Control

3.1. Stage 1: Blood donor recruitment & retention / Blood collection

Effective and efficient blood donation and collection procedures are essential parts of the Safe Blood projects in all the developing countries which EC supports. The programme stresses the importance of well organized blood collection for the BTS. A set of activities is conducted to achieve this.

Altruistic, voluntary donors, low risk populations, such as school students and young adults in rural populations are targeted, informed and instructed during a meeting. Following the initial campaign, it is determined if it is a wish of the attendees to invite the BTS team to collect blood. A session is arranged, usually 7-14 days later. Donors are reminded that their blood would be tested for HIV, hepatitis and other transmissible infections. Two weeks later, the same donor recruiter meets the donors, who have asked for results, to discuss and give results confidentially. At this follow-up visit, a tentative date is scheduled for the next cycle of information, collection and counselling. Other possibilities to organize collection also exist and depend on the region and its opportunities. Thus, one can see that a recruitment campaign is followed by counselling and preselection after which blood is collected.

This is one of the important steps of the BTS activities and the outcome of these activities could be measured in terms of output and effect. For example, if a set of campaigns were to be conducted in a region, the number of campaigns carried out during the year could be an indicator in terms of output. The effect of the campaigns could be measured by the increase of altruistic, voluntary donors, from the low risk population that are willing to donate blood. Several indicators can thus be developed for this step in the Value Chain of the BTS.

Managers could use these indicators for this stage of the value chain:

$$1 = \frac{\textit{Number of donors accepted}}{\textit{Number of donors assessed}}$$

What does this indicate?

Many inferences could be made from this indicator, although primarily it measures the effectiveness of the selection procedure.

- If the number of deferred persons is high, there will be a need for better messages to be given during the campaign for donor recruitment.

- If the number of deferred persons is high, it could also be that the selection procedure may be required to be examined.
- On the other hand, if the number of donors accepted is high but the number of usable blood units is low, this definitely reflects the ineffectiveness of the selection procedure.

$$2 = \frac{\textit{Number of voluntary donors accepted}}{\textit{Number of donors accepted}}$$

What does this indicate ?

Three categories of donors are recognized: voluntary donors, family/replacement donors and paid donors. A BTS should aim to collect only from altruistic voluntary donors among the low risk population. In order to find out if this aim is being reached the above indicator could be useful, provided the classification of donors is well understood and systematically recorded at the time of blood donation.

$$3 = \frac{\textit{Number of blood units collected}}{\textit{Number of donors bled}}$$

What does this indicate ?

Needless to say, the number of units of blood collected is important to record. This third indicator helps to estimate the competence of the team involved.

The reporting format that has been designed, generates necessary data to calculate these indicators and more if need be. Examples of reporting formats are found at the end of this chapter.

3.2. Stage 2: Screening

At this stage of the value chain of the BTS, another set of activities is carried out. Blood units collected during blood campaigns are screened for infections. The essential characteristics for screening tests for HIV antibodies are: highly sensitive, low cost and easy to perform. Blood is screened as per national guidelines prepared for the BTS. Blood is screened for HIV, hepatitis B, eventually for syphilis and others in function of the local epidemiological status.

The danger of false negative results in HIV screening is well known. Testing

procedures are used not only to screen but also to inform the donor of the result and its consequences. Therefore quality control of screening is an important component of the BTS. There are several factors such as well trained laboratory technicians, well maintained and equipped laboratories, screening procedures adopted etc. which contribute to the success of this stage of the value chain of the BTS.

Several indicators can be developed for this stage of the value chain of the BTS, however the key indicators have been selected as per the consensus of managers and given below:

$$4 = \frac{\textit{Number of units screened 'negative'}}{\textit{Number of blood units collected}}$$

What does this indicate ?

The end product of the value chain of the BTS is to produce blood which is safe for transfusion. This indicator measures:

- the effectiveness of the BTS in terms of the adequacy in meeting the need for safe blood in that region
- the effectiveness of the selection procedure adopted for accepting the donors
- to an extent, the health status of certain populations of the region could be evaluated
- if the number of units discarded during screening is high, it reflects the amount of resources wasted in order to produce safe blood.
- it also reflects the effectiveness of the donor selection procedure in question which should be investigated and improved.

$$5 = \frac{\textit{Number of units screened 'positive' for HIV}}{\textit{Number of units collected}}$$

What does this indicate ?

Control of HIV transmission via blood and blood products is one of the primary aims of the comprehensive strategy of safe blood programmes. Therefore, it is interesting to note the number of units discarded due to positivity of HIV screen test.

$$6 = \frac{\textit{Number of units discarded due to other infection}}{\textit{Number of units collected}}$$

What does this indicate ?

As mentioned earlier, safe blood is looked at in a comprehensive way and screening is done for infections other than HIV as per the guidelines adopted by the blood policy. It would be interesting to note the percentage of loss due to this factor and the infectious agents involved.

$$7 = \frac{\textit{Number of samples with right result}}{\textit{Number of samples sent for Quality Control}}$$

What does this indicate ?

Quality Control forms an integral part of the BTS, and an indicator to measure the performance of the screening activities of the BTS is essential. In the absence of this component of the BTS, one is not assured of the quality of safe blood that is produced and used in the region.

This indicator indirectly measures the quality of training of the laboratory technicians of the blood bank or in other words, it reflects the performance of the laboratories that perform the screening.

Screening is the heart of the value chain of the BTS. Many output indicators can be introduced to assess the performances of the screening activities in the field according to the region and the infrastructure of BTS. The above are the essential ones.

3.3. Stage 3: Storage and stock management

The principal function of the BTS is to provide the required quantity of safe blood that has been collected in sterile plastic bags and has been stored at 1 to 6 °C.

The above mentioned conditions require proper storage and stock management. The fact that blood units have to be stored in sterile plastic bags with anticoagulant and stored at 1 to 6 °C makes storage of blood an important component of the BTS. This implies that the equipment used for storage

should be well maintained, the maintenance staff trained, and that there should be an uninterrupted supply of the goods needed for proper storage. If any of these conditions is not met, this would result in a high discard rate of usable blood, the value of which is high as the amount of effort put into the donor recruitment, collection and screening is all wasted.

On the other hand, assuming the conditions for proper maintenance are met, it would be a pity if safe blood units were discarded due to excess stock as blood has limited life. At the same time, if stock is not available when it is needed, the purpose of the entire BTS is defeated. Therefore, stock management is also crucial for the success of the BTS. This requires a lot of planning and is directly linked to the distribution activities of the BTS. Planning to hold the right stock according to the predicted demand is important. This means that the planning of blood collection has to be scheduled in such a way that it does not result in excess or shortage of stock.

$$8 = \frac{\textit{Number of units discarded}}{\textit{Total Number of units produced}}$$

What does this indicate ?

This indicator is chosen after a consensus to indicate the discard rate due to improper storage and inadequate stock management.

$$9 = \frac{\textit{Number of safe blood units produced}}{\textit{Total Number of units requested}}$$

What does this indicate ?

This indicator denotes whether the supply of blood units meets the demand, provided the system of assessing the demand is established. Even if this is not established there are ways and means to estimate the demand. It must be noted that demand does not necessarily indicate the need for blood in that region.

3.4. Stage 4: Distribution

Blood has to be transported from the main blood bank to regional blood banks in some cases, and it has to be further transported to the peripheral hospitals where it would be used. Throughout this transportation, the cold chain has to

be maintained. This again implies good maintenance of the transportation system and the other factors that go into it. A sound distribution network is a crucial function of the BTS so that any damage in this area directly affects the efficiency of the BTS.

Here again, the outcome of this stage of the BTS is the total number of units successfully distributed and the number of units discarded due to bad transportation.

$$10 = \frac{\textit{Number of units distributed}}{\textit{Total Number of units transfused}}$$

What does this indicate ?
The above indicator also measures the effectiveness of distribution.

3.5. Stage 5: Use of Blood

This topic of the BTS is subject to a lot of discussion in the context that "demand denotes need". Of course, to a certain extent this depends on the decisions that the medical officers make on whether or not transfusion of blood could help, or what alternatives to blood could be used given a particular situation. This largely depends on the training the medical officers have had. For the purpose of monitoring, a consensus is arrived to use the following two indicators:

$$11 = \frac{\textit{Number of blood units transfused}}{\textit{Number of units distributed}}$$

What does this indicate ?
This indicator is an estimate of the adequacy of the demand by blood prescribers.

$$12 = \frac{\textit{Number of units cross-matched}}{\textit{Number of units transfused}}$$

What does this indicate ?

Cross-matching forms an important activity of the BTS as extreme care is necessary to ensure correct identification of the patient and specimen to avoid complications due to transfusion.

The above indicators have been chosen based on the value chain as shown in the diagram. The indicators as can be seen are primarily activity based.

4. Example for reporting format

4.1. Blood Donors' Recruitment & Blood Collection

Code	Categories	Family[1] Donors		Voluntary[2] Donors		Total	
		M	F	M	F	FD	VD
101	No. donors accepted[3]						
102	No. donors unaccepted						
103	No. donors evaluated[4] (101+102)						
104	No. new donors accepted						
105	No. regular donors bled[5]						
106	No. other donors bled						
107	Total No. donors (104+105+106=107)						
108	Total No. blood units collected						

1	Family donors / Replacement donors / Paid donors: blood donors who are relatives of patients, donors donating blood either as replacement or on emergency basis.

2	Voluntary donors: people who give blood of their own will and receive no payment either in the form of cash or in kind which could be considered a substitute for money.

3	A donor is evaluated prior to collecting his/her blood as a preliminary step to prevent collection of unsafe blood. Several methods of assessment are used e.g.; donor interview, physical examination etc. Some methods promote self-deferral. Based on this a donor is accepted or not to donate blood.

4	See footnote 3

5	Regular donors: A donor is classified as regular if he/she donates blood two times during a period of 12 months and if he/she is registered.

4.2. Screening

Code	Categories	Blood units Family Donors	Blood units Volunt. Donors	Total units
109	No. of *transfusable* Blood Units produced[1]			
110	No. of Blood Units discarded due to HIV infection[2]			
111	No. of Blood Units discarded due to HBV infection			
112	No. of Blood Units discarded due to other reasons[3]			
113	Total No. of Blood Units discarded during screening			
114	No. of Blood Units used for preparation of blood components			

1	*Transfusable* blood units produced: when a blood unit is screened for HIV and other infections as per the National guidelines adopted for the Blood Transfusion Service and found safe for transfusion, it is called *Transfusable* blood produced.

2	When there are blood units with double infection (HIV & HBV) this should be entered under code 110.

3	Sometimes some blood units collected are discarded due to reasons other than infection e.g. air in the bag etc. Units discarded due to these reasons should be entered in this row.

Quality Control of the screening

Code	Categories	Blood units Family Donors	Blood units Volunt. Donors	Total units
115	No. of samples tested HIV *positive* sent for retest.			
116	No. of samples tested HIV *positive* with right results			
117	No. of samples tested HIV *negative* sent for retest.			
118	No. of samples tested HIV *negative* with right results			
119	No. of Units HIV *(positive & negative)* with right results (116+118)			

4.3. Stock management and distribution

Code	Categories	Blood Units
120	Total No. of Blood Units requested[1]	
121	Opening stock of Blood Units as on 1/01/19.....	
122	No. of transfusable Blood Units produced[2]	
123	No. of Units discarded *due to poor storage & expiry*	
124	No. of Units discarded *due to poor transportation*	
125	No. of Units discarded *due to other reasons*	
126	Total Units discarded *during storage & transportation* (123 + 124 + 125)	
127	No. of Units delivered for use	
128	Balance stock as on 31/12/19..... (121 + 122 - 126) - 127 = 128	

1	Blood Units requested: the Central Hospitals and peripheral hospitals would send their requirement of Blood Units to the Blood Banks. The number of units requested needs to be recorded to know the total quantity of blood units demanded in one year.

2	This code is the same code 109. This is brought forward again under stock management and distribution to tally or cross check the figures mentioned.

4.4. Use of Blood

Code	Categories	Blood Units
129	No. of Blood Units transfused	
130	No. of Blood Units cross-matched[1]	

Code	Category of Patient	No. of Pts who received Tf
	Male	
	Female	
	Children mths - 6 yrs	
	Children 7 - 13 yrs	
131	Total No. of patients transfused	
132	No. of autologous transfusions done	

[1]	Cross-matching - compatibility testing. Care must be taken to ensure compatibility between donor and recipient blood before transfusion.

5. Recommendations on the use of Process indicators to monitor safe blood projects

- It is recommended that all projects should set annual operational targets in line with the project objectives. Targets for the activities to be conducted over a year period help to measure the efficiency of the programme. Quantifiable targets stated in the objective are good tools to measure the effectiveness of the programme.
- The management indicators of Safe Blood help to measure efficiency and effectiveness of the Blood Transfusion Services. These indicators could be used to monitor the BTS at the national level and regional level. The use of these indicators is recommended.
- A data collecting tool has been designed. The proposed format could be used to generate data allowing to calculate the indicators for better monitoring.
- The concept of *"Value Chain of BTS"* is recommended to be used in the field to assess the performance of the Blood Transfusion Service stage-wise. This helps to strengthen the areas of weakness for better performance of each unit of a BTS.
- The management indicators presented here are not exhaustive, field managers are urged to develop related indicators following the scheme proposed in this chapter.
- Indicators measuring cost effectiveness can also be calculated. Cost details have to be gathered to do this exercise. Financial managers of the Blood Transfusion Services are encouraged to do this and give feedback to managers in charge of the operations.

Chapter 8

QUALITY ASSURANCE

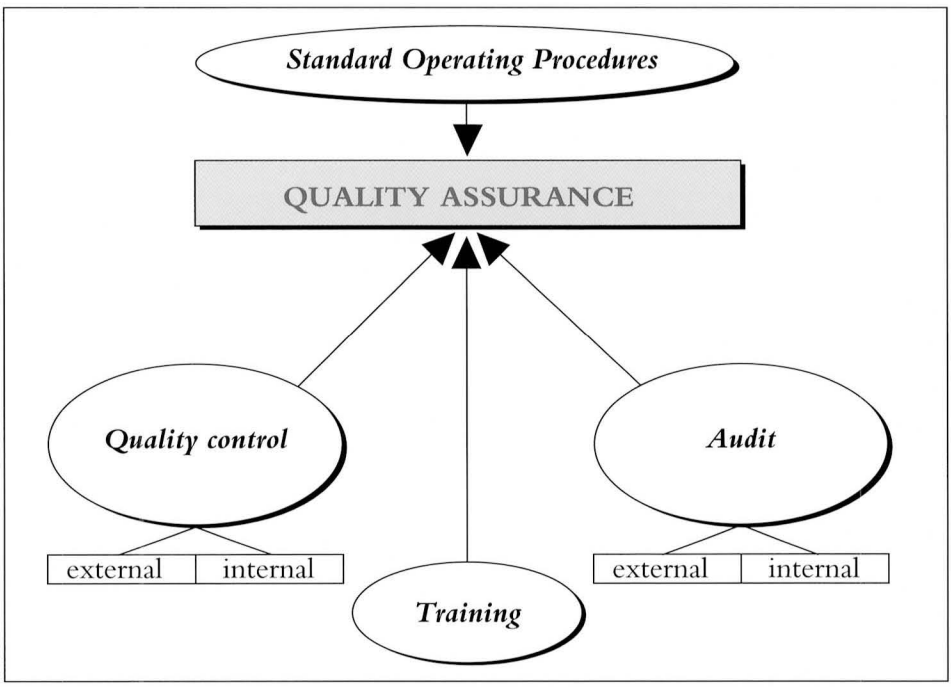
Introduction

1. Definition of concepts

2. Quality assurance implementation
   - 2.1. Standard Operating Procedures
   - 2.2. Quality Control
     - 2.2.1. Internal Quality Control
     - 2.2.1. External Quality Control
   - 2.3. Training
   - 2.4. Audit

3. Example

4. Recommendations on Quality Assurance


Standard Operating Procedures
QUALITY ASSURANCE
Quality control
external
internal
Training
Audit
external
internal

Introduction

The mission of any BTS is to provide blood and blood products that are as safe and effective as possible, when and where they are required for therapy.

Not only blood products *(red blood cells, plasma...) but also* services *(towards donors, recipients, physicians, clinics ...) are affected by quality assurance. The goal of quality assurance is to prevent, or to detect any possibility of errors in the processes carried out to produce blood or blood products from the time of blood donation to that of blood transfusion.*

Quality assurance is a concept made of a set of measures indispensable for guaranteeing safety and quality of blood transfusion. In fact, this concept covers several practical fields such as: written guidelines containing detailed Standard Operating Procedures, quality control procedures, implementation of an audit, training of staff members, design of activity organigrams and job description. Other important issues of quality assurance are: facilities, equipment, testing procedures and record keeping.

The impossibility or difficulty to maintain quality is generally due to human errors, misunderstanding or negligence rather than technical problems. That is the reason why it is the responsibility of the medical director of BTS and/or the managerial staff to inform and explain to all staff members at each level of activity, the importance of a quality assurance system. Misunderstanding of the importance of the quality assurance is likely to make it appear as too heavy to apply in the routine work and too expensive from the financial viewpoint.

In developing countries, BTS are more particularly concerned by the following aspects of blood transfusion i.e.: recruitment and selection of blood donors, blood collection, serological testing for blood transmissible diseases, compatibility testing, storage, distribution and indications for blood products.

1. Definition of concepts

Standard Operating Procedures.
Written guidelines explaining in detail how a task should be conducted. All activities carried out in a BTS, from the recruitment of blood donors to the distribution of tested and compatible blood products, can be divided into individualized tasks to which correspond proper SOP. SOP provide the means of compliance with generally admitted international standards.
Record.
Each task carried out following its SOP should be registered and all records should be kept in an organized manner. Records are the proof of compliance with SOP.
Quality Control.
All techniques and activities used to fulfil requirements for quality. The quality control can be external or internal or both.
Audit.
A quality audit is a means (internal or external) of monitoring compliance with a particular standard or guideline, allowing for a reliable evaluation of the quality assurance.
Quality Assurance.
Implemented systems or actions necessary to provide adequate confidence that a product or a service will satisfy given requirements for quality. For BTS, the objective is to give recipients the best adapted product which will be as safe as possible.

2. Quality assurance implementation

2.1. Standard Operating Procedures

A manual containing standard operating procedures (SOP) should cover all actions and all procedures carried out in the BTS, including: records, validation and establishment of documents. This manual, which should be very well documented from a technical point of view, could also serve as a management tool. It allows the BTS to avoid bias and errors liable to occur when pro-

cedures are explained or transmitted orally to staff members. It also allows for a more accurate evaluation of the work produced by each staff member as well as by the whole service. Furthermore, it can serve as learning material for new staff members. Ideally, all staff members concerned by the application of a SOP should be invited to participate in its elaboration.

SOP content:
The content of SOP should answer the following questions: *"who does what, how, when and where ?"*. It should cover the following items:
- a short title
- a brief description of the objectives and the basic scientific principles used
- conditions required for staff members who will carry out the procedure
- details concerning: materials, reagents, preparation of reagents, etc
- operating procedures recommended by the manufacturer; all manipulations should be described step by step and numbered
- notes concerning how to handle safely potentially dangerous materials
- explanation on how to interpret, to record and to notify results
- what is to be done in case of problem

Any modification of SOP has to be recorded, dated and agreed on by the person responsible for the concerned activity or process.

2.2. Quality Control

A quality control scheme is conceived to verify that a specific activity is carried out in agreement with SOP. BTS can adhere to internal or external quality control or both.

2.2.1. In practice, *internal quality control* samples (unrecognizable as quality control) have to be processed by laboratory workers without special attention, by using the same method and the same way as for routine samples. Results will be examined by the supervisor or by the person who is locally in charge of the implementation of quality control in order to evaluate the accuracy, precision of the method, its reproducibility.

2.2.2. The organisation of *external quality control* at a regional or a national scale requires a *reference* laboratory which takes charge of carrying out the relevant procedures (sending out of samples for testing to other laboratories and collecting the results) and subsequently analyses the results. Provided communi-

cation of results is clear and informative while preserving confidentiality, the external quality control is an excellent tool which provides each laboratory with precious information about: their adherence or deviation from the mean or norm calculated from the total results from all participants. The exercise provides each participating laboratory with a tool which allows it to detect and, eventually, remedy any deviation or bias in their working methods so that that quality assurance is met.

2.3. Training

- A training programme should be designed and implemented (see *Chapter 10*). It should address all new employees but also, as a matter of continuing education, all staff members.
- For each task workers have to be chosen taking into account not only their *curriculum vitae* but also their own affinity, talents and comprehensive experience in the operational and practical aspects of the system.
- It is important that each staff member be fully trained and motivated. Although good working depends upon personal characteristics and mentality, motivation of personnel can also be achieved through information and *recognition* of individual work.
- Ideally, all workers should be convinced that each working step of the activity chain is important and that the quality of the final product (i.e. safe blood) depends on how they have performed their task. Managers need to be familiar with the Quality assurance concept and it is their responsibility to transmit this approach to other staff members as well as to motivate them. Therefore, training and education programmes should be systematically planned and implemented into the BTS activities.

2.4. Audit

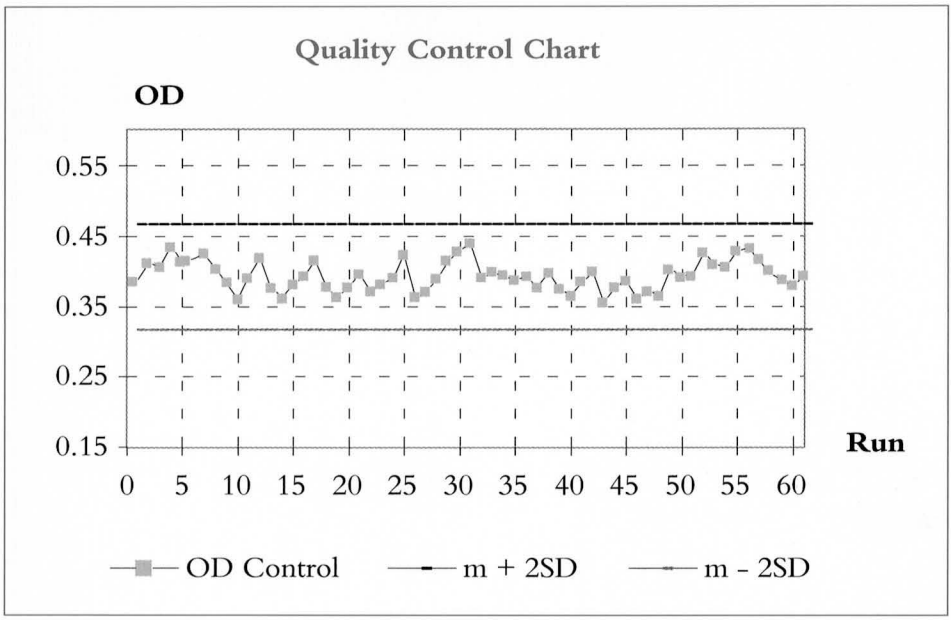
An audit is a management tool designed to monitor compliance with standards previously defined by local or national authorities. It can be *external* or *internal*, or both. An audit concerns all factors liable to affect the quality assurance of a product or a service. Ideally, audit should be realized by experienced internal people of the BTS. However, in developing countries, organisations which give the project financial support generally play the role of external audit.

The audit concerns not only technical aspects of BTS but should also aim to

verify that blood and blood products are optimally used for the benefit of the patient. In the latter aspect, hospital transfusion committees should be consulted.

3. Example

Figure 13: Quality Control Chart for HIV EIA testing



A QC graph is easy to perform: the **Optical Density** (OD) value measured from the control is plotted on the vertical axis (**Y**); the (**X**) axis indicates the **run number** or the **run date**. After testing at least 15 to 30 runs, calculate the **mean** value (**m**) and the **Standard Deviation (SD)**. A **range** of two standard deviations above and below the mean is recommanded (m ± 2SD). Thus, any control OD value falling ***within*** this range will be ***accepted*** with a level of confidence of at least **95 %**. Any control OD value falling **outside** this range must be ***rejected*** and the run repeated.

4. Recommendations on quality assurance

- The responsibilities of a Quality Assurance programme should include the following areas:
  - Standard Operating Procedures
  - Training and education with competence evaluation
  - Proficiency testing with process validation
  - Record management
  - Quality Assurance audit
- As far as the organigram of a BTS is concerned, each *function* should be clearly defined and each *task* fully described.
- At an individual level, each staff member should be fully informed, motivated and conscious of the importance of his/her own work in the *value chain* of the BTS.

Chapter 9

COST EVALUATION AND FINANCING OF BTS

Introduction

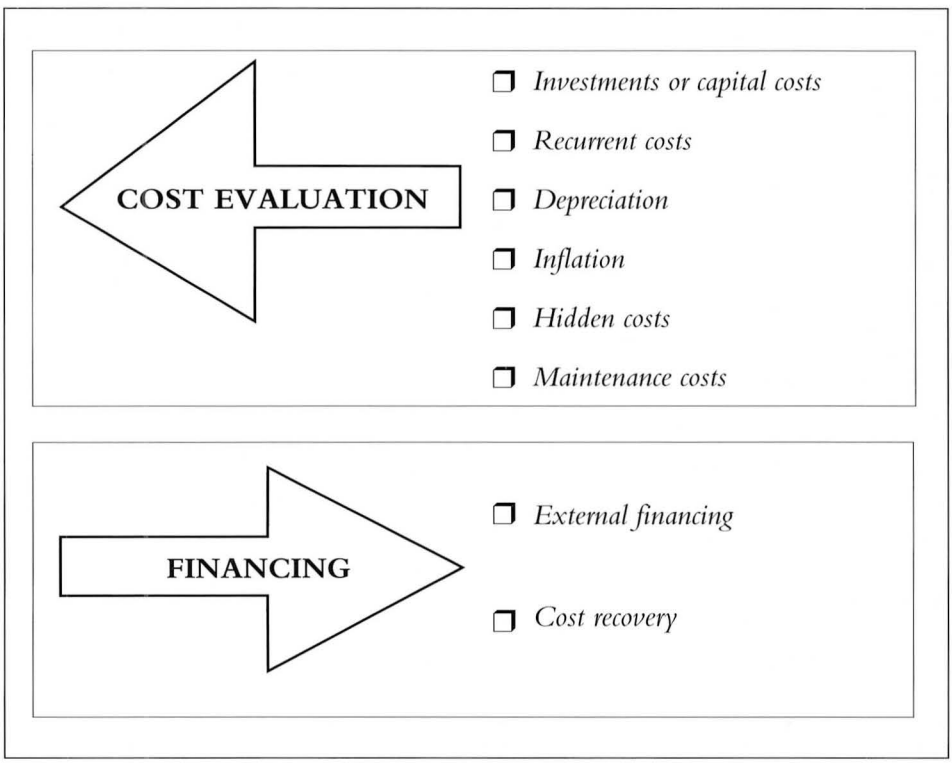
1. Cost evaluation
   - 1.1. Concepts and definitions
     - 1.1.1. Investments or capital costs
     - 1.1.2. Recurrent Costs
     - 1.1.3. Depreciation
     - 1.1.4. Inflation
     - 1.1.5. Hidden costs
     - 1.1.6. Current price
     - 1.1.7. Unit cost
     - 1.1.8. Maintenance cost
   - 1.2. Format for cost data reporting of BTS
     - 1.2.1. Specific comments

2. Financing
   - 2.1. External financing
   - 2.2. Cost recovery
     - 2.2.1. What and who to charge for ?
     - 2.2.2. Proposal
     - 2.2.3. How much to charge for ?

3. Example

4. Recommendations on cost analysis

5. Recommendations on cost recovery


COST EVALUATION
❒ Investments or capital costs
❒ Recurrent costs
❒ Depreciation
❒ Inflation
❒ Hidden costs
❒ Maintenance costs
FINANCING
❒ External financing
❒ Cost recovery

1. Cost evaluation

Introduction
Financial data are generally difficult to compare from one programme to another. Therefore, a model was developed to improve reporting of cost data by non-economists. The lists proposed are meant to help avoiding the omission of relevant cost data, to analyse what costs are more important in the running of a BTS and to standardise the reporting of data.
It is not the purpose to go into "in-depth economic jargon" but for the benefit of completing the cost data as required, some definitions are unavoidable and will ensure the comparison of like with like.

1.1. Concepts and definitions

1.1.1. Investments or capital (or equipment) costs are associated with the establishment of productive capacity and physical infrastructures; most of these costs are concentrated at the beginning of a project. They include the costs of:
- construction or repairing of buildings
- purchase of vehicles
- installation of major equipment necessary for the function of BTS
- investment in human capital (i.e. initial training of staff who run the BTS; e.g. basic training of laboratory technicians)
- technical assistance.

Note that the cost related to the basic initial training of personnel as well as of its technical assistance are included in the investment.

1.1.2. Recurrent (or operating) costs are those costs associated with the operation or maintenance of facilities or assets. These costs are likely to recur over the life of a project and may even increase at the end of the project as maintenance costs increase. Typically, they include the costs of:
- salaries and wages (of all personnel involved in BTS activities and additional workers such as cleaners, security guards, etc.)
- equipment maintenance and spare parts
- plastic blood bags
- supplies such as drugs, dressings, bandages and laboratory reagents and supplies

– utilities, such as electricity, water, fuel
– maintenance of human capital (i.e. on-the-job continuous training of technicians)

In practice there are often considerable difficulties in distinguishing between *capital* and *recurrent* costs. Their timing or periodicity is often used to classify costs, with recurrent costs defined as those which occur with at least annual frequency; and capital costs those which occur at intervals greater than one year.

1.1.3. Depreciation is the decrease in value of a capital good because of passage of time, wear and tear, etc.
For example, a generator, being an essential part of BTS equipment, has no eternal life. It has a certain life-span, depending on its quality, proper maintenance and intensity of use, estimated at between five and ten years. This means that every five to ten years this equipment has to be renewed, and for this purpose it is better to put some money aside every year.
– An allowance for depreciation may be included as an operating cost in the accounts. In the proposed format for cost-analysis of BTS, depreciation costs have been included as part of the recurrent costs (recurring on an annual basis).
– The depreciation of an investment will be considered by taking into account, as a recurrent cost, an annual sum equal to its initial value divided by the number of years foreseen for this depreciation.
For example, a 10,000 ECU investment redeemable over 20 years, will entail an annual cost of 500 ECU (without taking inflation into account).

1.1.4. Inflation has an effect on the depreciation cost. It has for example to be taken into account that the lifetime of buildings is generally estimated at 20 years, and at 5 years for equipment and vehicles.
Depreciation costs have to be adjusted for inflation especially in developing countries were inflation rates can be very high.

1.1.5. Hidden costs. It is important to remember that whatever activity is taking place in BTS, it costs somebody some money. Even if some activities, such as training of laboratory technicians or salaries of staff, have been taken care of by other sources (e.g. the MOH), those costs have to be reported on because without those activities the BTS would not operate. Therefore, those activities

sponsored from outside and not directly represented in the budget have to be reported on. Usually these are salaries, wages, allowances, some equipment, training, etc. The cost data have to be retrieved at the source of finance, such as the MOH. Basic training costs however are difficult to identify and for those costs the same amount will be used for all reporting countries. Only the filled posts have to be reported on by each country.

1.1.6. Current price is today's cost of a certain item, that is, what it would cost if a refrigerator was bought today and delivered to the blood collection centre.

1.1.7. Unit cost is the cost of one produced unit (for example: one transfused blood unit). The unit cost represents the total cost of an activity divided by the number of output units produced. This is also known as average cost. For example, the unit cost of a suitable blood unit is the total cost of producing the yearly amount of suitable blood units (including costs of donor screening and motivation, blood collection, wastage, etc.) divided by the yearly amount of suitable blood units produced.

$$\textit{Unit cost} = \frac{\textit{Total cost of production}}{\textit{Number of suitable units produced}}$$

These "Units" can be: collected blood units, treated blood units, produced blood units, transfused blood units... Since there is a progressive loss from one stage to the other among these different items, the denominator of the ratio will differ as well.

1.1.8. Maintenance cost is the cost of maintaining buildings and equipment. For example, the lifetime of centrifuges or refrigerators can be substantially extended if they are properly and regularly maintained.

These explanations might help in completing the reporting format as required.

1.2. Format for cost data reporting of BTS

1.Capital costs			
1.1	Capital costs of existing buildings at current value:	.....	
1.2	Costs of new planned building at current value:	.....	
	(remark: only complete 1.1 or 1.2)	**total**	.....
1.3	Capital costs of major equipment (current price) as per list:		
	– donor beds	.....	
	– scales for controlling the blood collection procedure	.....	
	– bench centrifuges	.....	
	– microscopes	.....	
	– incubator/water baths	.....	
	– refrigerators	.....	
	– freezers	.....	
	– generator	.....	
	– voltage stabilizer	.....	
	– containers	.....	
	– laboratory scales	.....	
	– autoclaves	.....	
	– still; deionizer	.....	
	– laboratory furniture	.....	
	– office furniture, equipment	.....	
	– workshop furniture, equipment	.....	
	– refrigerated centrifuge	.....	
	– any other major equipment not mentioned above.	.....	
		total	.....
1.4	Capital cost of transport (vehicles):	**total**	.....

1. Capital costs (continued)

1.5 Training cost of staff

1.5.1 basic *in-country* training:

	Number	***Years***
Medical doctor	.....	.....
Senior laboratory technician	.....	.....
Laboratory technician	.....	.....
Nurse	.....	.....
-....	.....	.....

total .....

1.5.2 training *outside* of the country:

	Number	***Cost/yr***
Medical doctor	.....	.....
Senior laboratory technician	.....	.....
Laboratory technician	.....	.....
Nurse	.....	.....
-....	.....	.....

total .....

1.6 Total amount for technical assistance
(foreseen over project lifetime) **total** .....

Total capital cost - training .....

Total capital cost + training .....

2. Recurrent costs

2.1 Salaries, honoraria, allowances, benefits
total costs for 1 year:

- administrative staff .....
- clinic staff .....
- laboratory staff .....
- pension fund .....
- Medical & dental aid .....
- manual staff wages .....
- cash in lieu of leave .....

2. Recurrent costs (continued)

2.1	Salaries, honoraria, allowances, benefits total costs for 1 year: – training expenses ..... – staff uniforms ..... – other benefits ..... – honoraria ..... – miscellaneous	
	total	.....
2.2	Transport: total costs for 1 year – allowances ..... – visits, supervision ..... – vehicle repair & maintenance (1) ..... – vehicle petrol, oil, lubricants (2) ..... *(1) + (2) = 20% of purchasing cost* ..... – vehicle licences	
	total	.....
2.3	Minor equipment as per list (minor equipment lasts 1 year or less) – domestic scales ..... – miscellaneous equipment and surgical items ..... (scissors, forceps, sphygmomanometers, tourniquets, stethoscopes, thermometers) ..... – necessary equipment for donor refreshment ..... – plasma extractors, hand sealers, tube strippers ..... – plastic/cardboard holders for blood units ..... – laboratory thermometers ..... – (eventually mobile team equipment) ..... – other minor equipment	
	total	.....
2.4	Consumables 2.4.1 for blood collection & blood administration – disposable lancets ..... – disinfectants and dressings ..... – materials/supplies for Hb concentration and packed cell volume ..... – blood collection single packs	

2. Recurrent costs (continued)

2.4	Consumables		
	2.4.1 for blood collection & blood administration		
	– multiple packs for component preparation	.....	
	– test tubes	.....	
	– transfusion administration sets	.....	
	– labels	.....	
	– supplies for donor refreshment	.....	
	2.4.2 for laboratory		
	– test tubes, slides, tiles	.....	
	– reagents + supplies for:		
	blood grouping,	.....	
	compatibility testing,	.....	
	screening of infections	.....	
	– lab glassware	.....	
	– disinfectant and detergent	.....	
	– sharps containers	.....	
	– protective clothing, gloves	.....	
	– timers	.....	
	– aspirator bottles	.....	
		total	.....
2.5	Cost of publicity		
		total	.....
2.6	Cost of administration		
	– stationery and material	.....	
	– printing	.....	
	– postage	.....	
	– cleaning materials	.....	
	– audit fees	.....	
	– insurance fees	.....	
	– security (e.g. night guards)	.....	
	– bank charges	.....	
	– interest payable	.....	
	– transport charges	.....	
	– sub-contracts	.....	

2. Recurrent costs (continued)

2.6	Cost of administration		
	– presentation & entertainment	.....	
	– rentals	.....	
	– other	.....	
		total	.....
2.7-	Utilities for one year		
	– water	.....	
	– electricity	.....	
	– gas	.....	
	– fuel	.....	
	– telephone, fax	.....	
	– other	.....	
		total	.....
2.8	Maintenance for one year of		
	– buildings (= 2% of capital cost per year)	**total**	.....
	– major equipment (10% of capital cost/yr)	**total**	.....
		total	.....
2.9	In service training cost per year	**total**	.....
2.10	Depreciation cost of buildings, major equipment and vehicles:		
	– buildings	**total**	.....
	– major equipment	**total**	.....
	– vehicles	**total**	.....
	Total recurrent cost - depreciation		.....
	Total recurrent cost + depreciation		.....

3. Income

3.1	Fee for service for blood transfusion	**total**	.....
3.2	Fee for service for other laboratory services	**total**	.....
3.3	Contract services	**total**	.....

3. Income (continued)			
3.4	Funding from: – Ministry of Health – other ministries – Hospital budgets – outside agencies – other (specify)	**total** **total** **total** **total**	....
3.5	Other sources of income (specify)	**total**	.....
	Total annual income		.....

1.2.1. Specific comments and explanations:

Capital costs: (see *"Format for cost data reporting"*: **1.**)

– *Capital costs of building at current value: (see "Format for cost data reporting":* **1.1.**)
  – either the original building costs can be retrieved and adjusted to current value by the following formula:

$$c = a\,(1 + r)^n$$

c = current value
a = previous or original value
r = basic interest rate
n = number of years since building was established

  – or the current cost of building a similar building can be estimated:

$$c = S \times P$$

P = cost/m^2: can easily be obtained from any building
S = surface area

– *New building:* (see *"Format for cost data reporting"*: **1.2**)
If the current building is inadequate and plans exist to build a new building or renovate the existing building, the costs of the new building can be used for capital cost.

– *Major equipment:* (see *"Format for cost data reporting":* **1.3**)
  capital costs of *major equipment* (current price) as per list: (*major equipment* = equipment that normally lasts 5 years or longer; this list is not meant to be exhaustive but major cost items have been identified; other items can be put under "any other main equipment" not mentioned above)

The *current price* of an item is the price which would have to be paid today to get this item installed at the BTS (e.g. cost of a refrigerator + cost of eventual transport, freight, insurance, customs clearance); the easiest way of knowing those prices is to enquire at local companies/shops or to use the UNIPAC price-list (available at UNICEF's Country Office).

– *Training cost of staff:* (see *"Format for cost data reporting":* **1.5**)
  – *basic in-country training:* (see *"Format for cost data reporting"*: **1.5.1**)
    Costs are calculated on the basis of internationally accepted average costs to train specific managers; the same costs will be used for all countries. The only information required is the number of staff in each category and the number of years initial training takes in the reporting country; for example, it might take 3 years to train a laboratory technician, but 5 years to train a technologist; (primary/secondary school education is not taken into account).
    It should be clear that often these training costs are taken care of by Ministry of Health (MOH) or Ministry of Education (MOE), but have to be taken into account because without trained staff blood transfusion services would not function up to required standards.
  – training *outside* of the country: (see *"Format for cost data reporting":* **1.5.2**)
    If staff get their basic training as part of the project costs (e.g. staff are trained in Europe during a specific period), annual cost estimates of this training should be submitted separately.

The technical assistance is considered a capital investment. The total cost over the project lifetime will be spread over a period of ten years. Note that there is no depreciation applicable to technical assistance cost.

Recurrent cost: (see *"Format for cost data reporting":* **2**)
Hidden cost related to work and services done free of charge should also be evaluated and considered as a recurrent cost. The corresponding benefit should also be considered under the "other sources of income" section.

– *Minor equipment:* (see *"Format for cost data reporting"*: **2.3**)
lasts one year or less; may differ by country and the lists presented are only a framework.
– *Maintenance* for one year of (see *"Format for cost data reporting"*: **2.8**)
  – buildings (2 % of capital cost per year)
  – major equipment (10 % of capital cost/year)

2. Financing

The cost data are useful tools to finalize a budget for a given programme. Frequently, in developing countries, the budget is divided in two parts: the first one dedicated to buildings and investment and a second one for recurrent costs (functioning, salaries...). After the exercise of cost evaluation, it is necessary to proceed to an exhaustive listing of all inputs. These latter include: external financing by international grants, bilateral financial support, budget from the local Ministry of Health etc.

2.1. External financing

– International financing of Blood Transfusion Programmes can either be dedicated to investments (heavy equipment, buildings...) or to outside training. This can be help given once as a whole, or alternatively, it can be allocated over a longer period of time. In this latter case, it provides a financial support for the function and/or technical assistance.
– Financing support to Transfusion Programmes originating from the Ministry of Health should be submitted to the same management rules as the whole Public Health budget. The diversity of financial support to transfusion programmes explains why "cost recovery" has to be discussed.

2.2. Cost recovery

– If the technical implementation of a Safe Blood Programme is of greatest importance from a practical viewpoint, it is also as important to determine accurately the costs of such programmes in order to evaluate their cost-effectiveness. At the end of this chapter, an example of calculation of cost-effectiveness, that could be considered as a model, will be illustrated.

– Possibilities for cost recovery mechanisms may be different from one country to another, depending on the local economic, financial and organisational set-up, and on political acceptability of the idea of cost-recovery. It is therefore impossible to work out an all-round solution and the meeting as well as the report only discussed some of the possibilities. Practical operational solutions will have to be developed for specific countries. Nevertheless, in terms of sustainability of BTS services, it is extremely important to develop local mechanisms of cost-recovery.

The four important questions on recovery of costs are:
– *what to charge for ?*
– *who and who not to charge ?*
– *how to charge ?*
– *how much to charge ?*

2.2.1. What and who to charge for ?

Which services should, or could, be charged for and which not ?

First, only those BTS activities directly related to blood transfusion are considered.

– Producing a suitable and safe blood unit costs money. Although blood is given free, there are the costs of recruitment, collection, screening, testing, production, distribution, health education, etc. As a matter of fact, blood transfusion has an "externality": transfusing infected blood (e.g., HIV infected) would not only affect the consumer (the patient who has been transfused), but also the community (spreading the infection). This could be an argument not to charge for blood transfusion. On the other hand, the activities that are essential for ensuring suitable safe blood are the activities that increase substantially the cost of production. Somebody has to pay for it, whether it be the MOH, the hospital budget, the patient, the community, donor aid, etc.
– From an ethical point of view it would be defendable not to charge the individual patient, as blood is given free by the donor and is only transfused to a critically ill patient, carefully selected and in need of blood. Whether this means that a patient could not even be charged a nominal fee is open to debate. In terms of cost-recovery, it would be defendable to charge the individual patient a nominal fee for this activity (as compared with other charges for X-rays, surgery, etc.), or to earmark part of the in-patient fee for

blood transfusion activities. However, if patients pay for blood transfusion it should be made clear to them that they do not pay for the blood (that was given free) but for the whole service or process ensuring suitable blood.

- There are of course other methods of cost recovery than charging the individual patient. Depending on the specific situation of each country, some might be more feasible, more acceptable and/or more effective:
  - *private patients* could be charged for all services (and could be charged at a price higher than the economic price)
  - *public patients* could be charged for blood transfusion services, but at a price lower than the economic price.

The full costs could be shared by:
- charging the hospital budget directly
- charging the total number of patients admitted over one year (cost of all blood units/number of in-patients per year)
- idem, but charging adults only
- charging the user (the patient transfused) only; this would be inequitable, as the user is the one in need.

Other mechanisms could be:
- cross-subsidization by charging private in-patients
- cross-subsidization from other activities carried out by BTS (e.g. HIV and other laboratory testing)
- local insurance mechanisms such as pre-payment schemes
- community financing
- donor aid.

- Which mix of sources would be acceptable, feasible and efficient, and what would be the extent of their relative contribution, is a question that has to be looked into by the individual countries and by community authorities and experts.
- Another issue is, who should be exempted from payment if a fee were to be introduced ? Would it be acceptable to charge children in need for blood transfusion ? What about poor people, and on the basis of which criteria would persons be exempted ?
- In countries where the most common indication for transfusion would be anaemia in infants/children, and where the decision would be taken not to charge children, the price of a blood unit charged to adults directly could

be high, and a better solution could be to charge the hospital directly or the total of adult in-patients instead of the individual patient.

- An interesting method of cost-recovery is cross-subsidisation of the cost of blood transfusion by the profit made on contract services. Some laboratories in developing countries run a reasonably lucrative business by, for example, testing blood for Syphilis or for HIV. One national BTS engages in private laboratory activities during night-time and by so doing makes some money for cross-subsidizing more essential activities such as blood transfusion. The feasibility and efficiency of this cost-recovery mechanism should be looked into by the individual countries' authorities.

2.2.2. Proposal.

A possible and maybe feasible way for cost recovery of BTS in developing countries could be to combine the following sources:

- the Government, by charging the hospital budget directly
- the international community, through donor aid, by asking for continuous support for some operational costs of the national BTS, and
- the patient, by charging the collectivity of in-patients, excluding children, for the service of having a continuous availability of safe blood.

Exemption from paying would follow the national exemption criteria for in-patient hospital services.

2.2.3. How much to charge for ?

- In determining the cost-recovery formula, the cost per unit needs to reflect the number of units (including components) used, rather than collected. Herein lies a problem - an efficient and effective service will have minimal outdating, and so the difference in cost determined by total operating costs/number collected and total operating costs/number used will not be great, whereas in an inefficient service there will be a significant difference. Whatever the formula, it should take into account both inflation and a provision for future capital outlay, if MOH is in agreement.
- The first step would be to define what the full economic price of a blood unit is in a specific country. The full economic price would be the total recurrent costs (including depreciation costs) divided by the total number of units transfused over one year, increased by a mark-up to cover inflation.

– This would be the cost to be recovered over, for example, the 3 sources mentioned above. How much to charge each of the three sources would be a decision to be taken nationally. A possible way of deciding this could be:
What is reasonable and fair to charge the adult patient for having the security of having blood available for him/her and the family at any time ?

This is extremely difficult to answer, but one could compare with other charges or costs of services, for example:
– The cost/charge of a chest X-ray ?
– The cost/charge of a delivery ?
– The cost/charge of an in-patient day ?
– The cost/charge of a hernia operation ?
– The local daily wage of an agricultural labourer ?

– If 5 % of all adult in-patient fees (or maybe 5 % of the total hospital budget ?) would be earmarked for BTS, how much of the cost of having safe blood available would be covered ?
– If a hospital budget for blood transfusion services exists, how much of the total need could be covered by this budget ?

Countries that have no hospital charges and are reluctant to introduce them, would have to focus on hospital budgets, the international community and possible cross-subsidization from private to public patients.

3. Example

Cost-Effectiveness of Uganda Blood Programme

Background:
Uganda has a population of 16 million and a gross national product of 170 USD per capita. Total health budget is about 2 USD per capita per annum. More than 25 % of young adults have antibodies to HIV1 and 6 % are carriers of Hepatitis B virus.

Blood donors:
volunteer blood donors recruited + patients' relatives as replacement donors.

All blood units are tested for HIV and HBs Ag. The mean seroprevalence was: 5.5 % for HIV and 6.3 % for HBs Ag. In 1993, out of 32,100 units collected, 26,194 (81.6 %) were transfused and distributed in 92 hospitals. 15.6 % of blood units collected were discarded because of HIV, HBV or any other reason.

Cost effectiveness: to answer 4 questions.

1. How many patients' lives were saved by blood transfusion ?

	Children	Adults	Total
Number transfused	11515	8641	20156
Expected to die without	5758 (50 %)	3898 (45 %)	9656
Die despite transfusion	3801 (33 %)	2592 (40 %)	6393
Number of deaths prevented	1957	1296	3253

➪ Half of the children who met the criteria (Hb < 5g/dl + respiratory compromise) would die from the primary illness.

2. How many HIV infections are prevented by screening blood ?

	Children	Adults	Total
Infected if 16.1 % donors are carriers	1854	2226	4080
Of above recipients already infected	167 (9 %)	890 (40 %)	1057
Non-surviving infected recipients	562 (33 %)	401 (30 %)	963
Infected if 0.8 % donors are carriers★	92	105	197
Total corrections to be substracted	821	1396	2217
HIV infections prevented	1033	830	1863

★i.e. donors during the window period of HIV infection.

➪ 1863 new infections were prevented in the survivors of the episode for which blood was given.

3. How many HBV infections are prevented by screening blood ?

	Children	Adults	Total
Infected if 5.7 % donors are carriers	656	747	1403
Of above recipients already infected	66 (10 %)	635 (85 %)	701
Non-surviving infected recipients	197 (33 %)	34 (30 %)	231
Total corrections to be substracted	263	669	932
HBV infections prevented	393	78	471

➪ 471 new HBV infections were prevented.

4. What is the cost of each prevention ?

	USD	USD
Total cost of BTS in 1993		929,900
Recruiting, counselling and care of 18,297 donors	167,300	
HIV screening of 32,100 units	130,800	
HBs Ag screening of 32,100 units	103,100	
Cost of supplies & staff for 1782 HIV positive units	21,794	
Cost of supplies & staff for 2025 HBs Ag positive units	24,766	
		-447,760
Cost to transfuse 26,200 units if screening was not done		482,140
Additional cost of HIV screening	319,894	
Additional cost of HBV screening	127,866	

➪ The cost of HIV screening was 319,894 USD (10 USD per unit collected)

➪ The cost of HBV screening was 127,866 USD (4 USD per unit collected)

Conclusions:

	Number	Cost	cost/case
		USD	USD
Deaths prevented by transfusion	3253	482,140	**148**
HIV infections by transfusion prevented	1863	319,894	**172**
Hepatitis B infections by transfusion prevented	471	127,866	**271**

➪ **148** USD per prevented death is cost-effective health care

➪ **172** USD per HIV infection prevented is the most cost-effective of AIDS prevention interventions

➪ **271** USD per hepatitis B infection prevented is good value.

1 ECU = 1.2 USD

4. Recommendations on cost analysis

- An effective safe blood programme will have an impact on the health of the population as well as on the health system in general. Although they are difficult to evaluate with accuracy, these benefits exist and have to be considered as well.
- Reporting of cost data is useful in order:
  - to determine the *total cost* of BTS in a specific country;
  - to identify the major *cost components* in the total cost. In trying to reduce the overall cost of a BTS it is important to focus on these cost components.
  - to evaluate the *cost-effectiveness* of the BTS;
  - *to monitor* the cost of the service on the basis of standardised reporting of yearly cost data;
  - to *compare the BTS of different countries* in terms of the importance of different cost components as parts of the overall costs, and to determine cheaper strategies (and in combination with indicators of effectiveness, more cost-effective strategies);
  - to *facilitate the decision* on which costs or which part of the total costs one wants to *recover* by, for example, cost-sharing.

5. Recommendations on cost recovery

- The first step is to determine the actual cost of one blood unit.
- Once this cost has been determined, decisions should be taken as to how much of the cost of this service the individual and/or the community are able to bear.
- Additional revenue can be generated through testing for patients and by selling by-products such as test sera ...

Chapter 10

TRAINING

Introduction

1. Training modules

2. Training must be conceived as a continuous activity

3. Organization of training

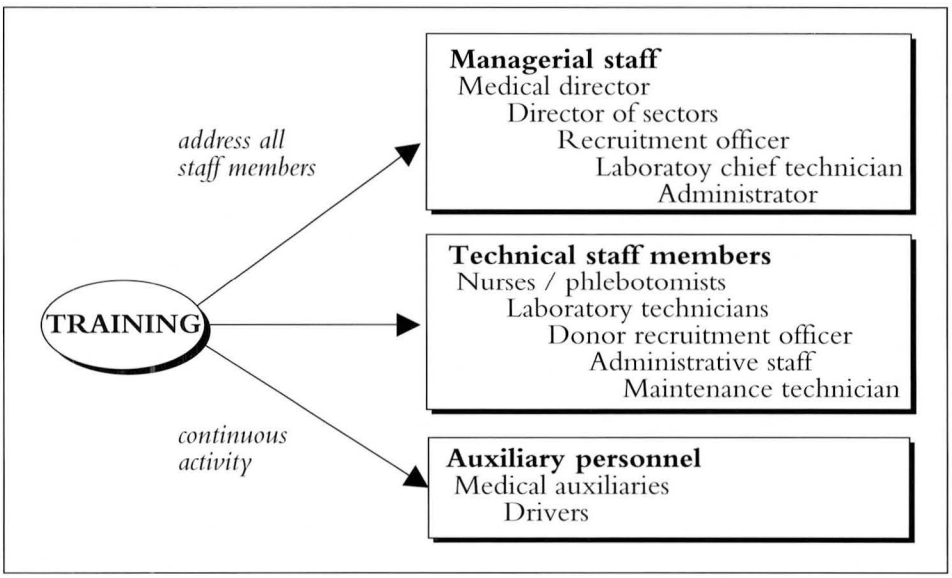
4. Specific training
   - 4.1. Medical director
   - 4.2. Donor recruitment officer
   - 4.3. Administrator
   - 4.4. Chief technologist/ laboratory technicians
   - 4.5. Nurses / Phlebotomists
   - 4.6. Maintenance technicians

5. Technical assistance

6. Example

7. Recommendations on training

8. Annexes


TRAINING
address all staff members
continuous activity
Managerial staff
Medical director
Director of sectors
Recruitment officer
Laboratoy chief technician
Administrator
Technical staff members
Nurses / phlebotomists
Laboratory technicians
Donor recruitment officer
Administrative staff
Maintenance technician
Auxiliary personnel
Medical auxiliaries
Drivers

Introduction

The successful implementation of a safe blood strategy will largely depend on the knowledge, skills and commitment of the people working in every Blood Transfusion Service and/or Hospital Blood Bank.

To be efficient, training strategies should be integrated as much as possible into a human resources policy which is appropriate to the country's public health policy and more particularly, to the blood policy.

Training of personnel for blood transfusion services (BTS) is required to ensure, improve and sustain efficient functioning of the services.

1. Training modules

should be addressing persons at different stages of experience:

- *personnel with many years of service* at a BTS who need to refresh and upgrade their knowledge and often re-orient their practices;
- *new staff members*, entering the service after having just completed their professional training, who need a proper introduction into the operations of the BTS and into their own tasks.

Appropriate and professional training has to be provided for all staff of BTS, i.e. the doctors in charge, nurses and paramedical staff, the laboratory technicians, the donor recruitment officers, the maintenance technicians and the counsellors.

2. Training: a regular and continuous activity

The training of personnel must be conceived and carried out as a regular and continuous activity for a BTS.

It must be based on:

- an analysis of the BTS operations and functions
- a detailed job description for each task
- an assessment of the individual training needs of each staff member

– the definition of priorities for the training
– identification of appropriate training methods, facilities and timing
– sufficient funds on a sustained basis

The training programme should include a regular evaluation of its results in terms both of improved qualification and skills of the staff member and of improved functioning of the BTS as a whole.

3. Organization of training

different kinds of training can be organised

– *locally* at the BTS (using appropriate support where necessary) or in other institutions in the country;
– in appropriate *training centres* or institutions in the region;
– in blood transfusion (training) services out of the region;
– through *Distance Learning Material* (see Annex 1).

It is demonstrated to be more effective in developing countries if training starts with in-service training, organised at the BTS - with external technical assistance if required - related to the day-to-day practice of the staff. Training courses outside, in specialised institutions or in-service training in comparable services in the country or abroad should be organised only after a reasonable period of working experience after the initial in-service training.

4. Specific training

Training for the different functions of the staff of blood transfusion services:

4.1. Medical Director

Sound knowledge of all aspects and techniques of blood transfusion services is the first priority. Management and administrative tasks are frequently underestimated and often the doctors selected for this function do not have any training in this field. Competence in all relevant aspects of organisation,

management and administration of a blood bank are equally important for the medical director.

4.2. Donor Recruitment Officer

- Donor recruitment requires, in particular, social and communication skills. A university training in psychology or social science may be a good basis but it is stressed the function depends essentially on personality, reliability, charisma and organisational capabilities. It is agreed that any training for such officers in BTS must be carried out in an appropriate environment.
- *For example,* WHO and FRCRCS developed such a training course for donor recruitment officers in Harare for Anglophone candidates.

4.3. Administrator

- BTS administration involves a specific mix of organisation and control of supplies and stocks, financial management and accounting, personnel administration, transport, etc. The administration of several facilities in a large region requires more managerial skills than for one blood bank only.
- Initial in-service training must introduce and adapt administrators who should have a training obtained in other sectors of public or business administration. It is usually possible to find training opportunities in the country. There are some institutions in Europe offering appropriate courses.

4.4. Chief Technologist / Laboratory Technicians

It is often possible to organise refresher and upgrading training for laboratory technicians in the country or in regional training institutions. The training should address all relevant techniques of serological analysis and testing and the proper handling of technical equipment.

4.5. Nurses / Phlebotomists

Nurses/phlebotomists are the officers with most contact with the donors. They need training not only in the technical aspects and organisation of bleeding, but also regarding an appropriate behaviour towards the donors. Their social skills are very important for donor retention and must be developed.

4.6. Maintenance Technicians

- Good maintenance of the laboratory equipment, vehicles, etc. is a backbone of an efficient BTS. Training of maintenance technicians must develop also skills for minor repairs.
- In case of absence of local servicing facilities for laboratory and other equipment, training for maintenance technicians should be organised at the manufacturing companies.

5. Technical assistance

- Technical assistance and inter-institutional support and cooperation are very often needed to develop and support safe blood initiatives in developing countries. However, worldwide, very few experts and institutes are available with the necessary expertise, the managerial and programming skills, and the developmental experience to take up this task in an effective and appropriate way.
- Discussion revealed that more regular expert meetings organised to exchange and analyse experiences, set up guidelines, and elaborate checklists etc., are beneficial and could be supported by organisations such as the European Community jointly with the International Federation of the Red Cross. This would greatly benefit the strengthening of the blood transfusion services for the sake of public health and as a means to improve HIV-AIDS prevention.

6. Example

Experiences of the EC HIV/AIDS Programme in supporting safe blood initiatives in Developing Countries have highlighted the need for a training of BTS professionals which addresses the specific problems of establishing safe blood transfusion services under conditions of developing countries where little organisation exists. Training in blood transfusion in industrialised coun-

tries generally does not address these aspects. These skills can best be acquired through a training programme based on the actual experiences of a developing country that faces such problems and has implemented a successful national safe blood programme.

The creation of the Uganda Blood Transfusion Service (UBTS) was a major project of the safe blood programme supported by the EC. Since its start in 1988, with the rehabilitation of Nakasero Blood Bank in Kampala, the development of UBTS has passed through the different stages of building a comprehensive nationwide blood transfusion service and developing a national safe blood policy.

Based on the experiences of the UBTS, a training programme for BTS staff from English-speaking developing countries is being organised at Nakasero Blood Bank starting in 1996.

Two specific training programmes will be developed and conducted, in English, by the UBTS, one for *senior BTS* staff and one for technicians from developing countries.

1. Training course for senior BTS staff

This 10 weeks training course is for those expected to be the professionals acting as leaders in the National Blood Transfusion Programme or in Regional Blood Transfusion Centres. It will be conducted ideally for teams from different countries including the medical director, chief technologist, administrator and senior donor recruiter and/or nurse in charge of such programmes. Each will have the general and professional education required to be employed in a senior position, and will have had at least two years experience in blood transfusion practice or in a leadership role in the administration or provision of health care. The training will provide senior BTS professionals with the knowledge and ability to:

- Write National Guidelines and Policies
- Develop a blood donor recruitment programme
- Organise a core group responsible for the management of the different aspects of the BTS
- Determine needs and arrange tenders and purchase of all blood transfusion related supplies
- Train blood bank and other hospital staff in efficient safe blood transfusion practice

- Plan a secure record system and data analysis programme
- Monitor and provide quality assurance for the various elements of a safe blood programme

This training course will consist of:

- A six week course of lectures, seminars and group work based on practical case studies covering the relevant subjects of donor recruitment, blood transfusion medicine and the technical organisation, management and administration of a national or regional blood transfusion service. Participants will at the end develop policies for implementation in their own country.
- A four week training attachment for doctors and technologists, including two weeks providing extensive experience of actually performing laboratory testing of blood with both manual and automated methods, a one week training attachment at a major hospital focusing on blood use procedures, record systems and evaluation of need for blood, and a one week attachment in a Regional Blood Bank where participants will actually perform the roles of their respective counterparts.

  This training course will be given once a year.

2. Training course for Technicians

This 12 week training course is for technicians in charge of larger blood transfusion laboratories serving more than one hospital and responsible for the collection, testing, storage, compatibility testing and issuing of blood for a patient. These need a complete knowledge of the essentials of blood bank practice and the ability to teach these essentials to others and to train junior staff to improve the quality of blood transfusion medicine in their hospitals.

Candidates must have completed at least a two year structured professional training in a school of medical laboratory technology.

The training will consist of theoretical courses and practical exercises. It will cover all relevant subjects of blood transfusion laboratory procedures, blood screening and grouping techniques, blood bank organisation, data recording, personnel management, quality assurance and control, and training methods.

At least 60 % of the time will be spent gaining practical experience at a regional blood bank or a hospital blood transfusion service.

This training will be given twice a year.

3. Other training

In addition to these two training courses, a short information and study visit

programme on safe blood policies, strategies, and organisation of blood transfusion services will be developed by the UBTS for senior health sector policy makers and planners of developing countries.

This programme will provide such national decision makers and planners with the information to determine the needs, the options and the resources and measures required to establish a National Blood Policy and effective blood transfusion services in their country.

This short (approx. 3-5 days) information programme will be organised by UBTS upon request. It can be tailored to the specific needs and interests of the participants.

Address: Uganda Blood Transfusion Service
Nakasero Blood Bank, Director UBTS
P.O. Box 1772, Kampala, Uganda
Fax Nr. (256-41) 257484

4. Training in Blood Transfusion in the Tropics

A three month training course in blood transfusion for medical staff and laboratory technicians from francophone countries in Africa and the Indian Ocean has been developed by the French Red Cross (FRC) in collaboration with specialists in blood transfusion from Africa and France.

This training course, consisting of theoretical lectures and practical laboratory and blood bank training, aims at providing the key medical staff and laboratory technicians with the knowledge and skills in blood donor recruitment, blood transfusion medicine, laboratory techniques and blood bank practice to enable them to improve the organisation and quality standards of their blood transfusion and to train their colleagues and junior staff.

Pilot courses were organised by the FRC in Yaoundé in collaboration with the Medical Faculty of the University of Yaoundé/Cameroon in 1991 and 1992. They were supported by the French government, the EC, WHO and the International Red Cross and Red Crescent Societies. It is envisaged that future courses will be held in Abidjan /Ivory Coast.

Address: Croix Rouge Française
1 Place Henry Dunant
75008 Paris, France
Fax (33-1) 44.43.11.01

7. Recommendations on training

- Training within a National Blood Service must involve an assessment of existing human resources and of existing skills.
- Annual planning must necessarily include a mapping of the training activities directed at the various professional groups as well as the resources to be allocated. Planning must also take into consideration the promotion of the most adequate use of blood and its components.
- At each level of blood transfusion practice (local, national and regional) the presence of a specialist in Transfusion Medicine remains a key requisite.
- Training must involve measures of enhancement of qualifications and skills as well as operational improvements.
- Training activities should preferably be carried out in the blood transfusion services or in the hospital blood banks, if necessary with technical assistance from abroad. Regional exchanges of personnel for courses is to be encouraged.
- Training activities on the spot should only be carried out after a reasonable period of practice by the staff involved and the setting up of realistic priorities.
- Technical assistance should be called in whenever necessary. It is recommended that it should be carried out by experts in blood transfusion.

8. Annex

8.1. Distance Learning Material (DLM): a WHO project.

WHO has developed a set of Distance Learning Material (DLM) for Safe Blood and Blood Products. The aim of this project is to contribute to the global preventive strategy on HIV and AIDS through the provision of safe blood and blood products. DLM has been specifically designed to make training more accessible and effective for laboratory technicians.

Background:
It is essential that all those involved in the collection, processing and use of blood and blood products use all possible means to ensure its safety, particularly in relation to HIV and other infectious agents. The training of laboratory technicians is a particular priority, especially since in many countries a large proportion of them work under limited supervision. World-wide, the need for the training and continual updating of technicians is so great that it will be impossible to meet it within the foreseeable future using existing approaches. The distance learning approach is designed to help overcome some of the practical problems that trainers throughout the world are currently facing by offering a practical and cost-effective means of making the best possible use of limited training resources.

Evaluation of the distance learning project:
The DL project started in 1991 and was completed in 1994. The primary audience will be laboratory technicians and the secondary audience will be blood transfusion technologists who have responsibility for training. In order to ensure regional evaluation, two participants from each WHO region were invited to attend an evaluation course in 1992. The evaluation formed part of the project and will form the basis of continuing evaluation and modification where necessary.

The Distance Learning Materials comprises:
- Study Guide (for trainees)
- Three modules of learning material
  Module 1: Safe Blood Donation

Module 2: Screening for HIV and other infectious agents
Module 3: Blood Transfusion Technology
– Trainers' Guide

Trainers will be able to provide uniformly high quality training to all technicians in their countries because they will all study the same learning material prepared by international experts. *Trainees* will have control over the pace at which they work on the materials; this means that those who are slower learners or who are less knowledgeable or experienced can spread their study over a longer period than those who are more familiar with the subject. The distance learning approach is interactive. As the trainees study, they should be able to relate their theoretical knowledge directly to their own work.

Module contents and learning objectives:

Module 1: Safe Blood Donation
section 1 Identification of safe blood donors
section 2 Education, motivation and recruitment
section 3 Selection of donors
section 4 Organising donor sessions
section 5 Care for the blood donor
section 6 Blood donor retention

Module 2: Screening for HIV and other infectious agents
section 1 Introduction to transfusion microbiology
section 2 The Human Immunodeficiency Virus
section 3 HIV screening assays and factors affecting their use
section 4 HIV-Ab screening of donated blood
section 5 Quality assurance
section 6 Screening for other transmissible infectious agents

Module 3: Blood Transfusion Technology
Part I: Blood group serology
section 1 Immunology
section 2 ABO blood grouping
section 3 Rh blood grouping
section 4 Compatibility testing

section 5 Techniques in blood group serology
Part II: The storage, transportation and stock control of blood and blood products.
section 6 Storage and transportation
section 7 Stock control

8.2. Distance Learning Material

– Transfusion Medicine; A European course in blood transfusion:
Coordinators: B. Genetet & W. Van Aken.
Edited by Centre Nationale d'Enseignement à Distance,
supported by: Ministère de l'Education Nationale, Vanves, France.

This bilingual English/French European course was initiated by the Blood Transfusion Expert Committee of the Council of Europe. A system of written tutorials leads to a certificate issued by the Louis Pasteur University of Strasbourg following written examination.

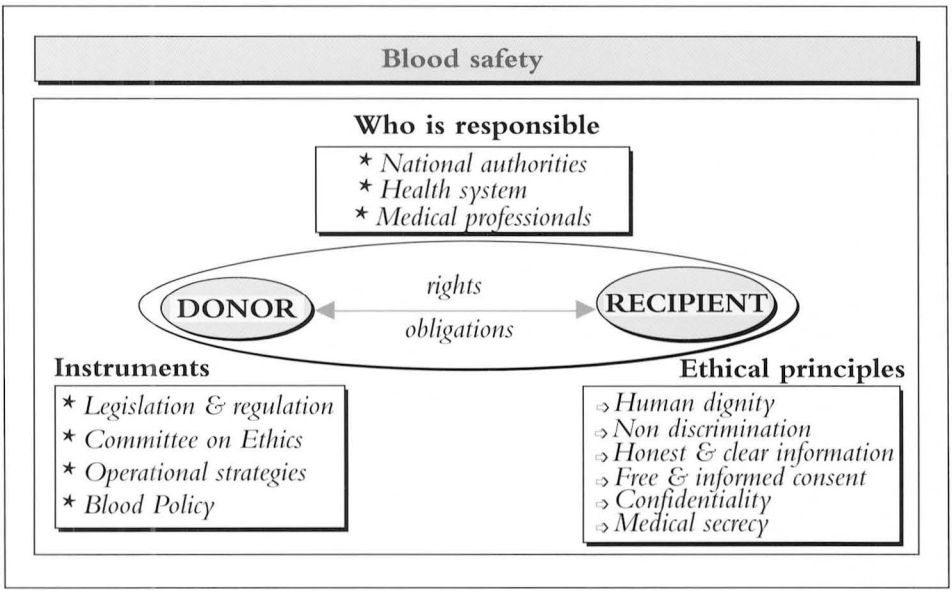
Address: Centre Nationale d'Enseignement à Distance
60, boulevard du Lycée
92170 Vanves Cedex
France

Chapter 11

ETHICAL ORIENTATIONS FOR BLOOD SAFETY

Introduction

1. Rights and obligations within the context of blood safety
   - 1.1. Basic ethical principles: universal rights
     - 1.1.1. Confidentiality
     - 1.1.2. Medical secrecy
     - 1.1.3. Non-discrimination
     - 1.1.4. Honest and clear information
     - 1.1.5. Free and informed consent
     - 1.1.6. Human dignity
   - 1.2. Specific rights and obligations
     - 1.2.1. The donor: rights and obligations
     - 1.2.2. The recipient: rights and obligations
     - 1.2.3. The population: rights and obligations
2. Commitment of all those responsible for blood safety
   - 2.1. Public and national authorities
   - 2.2. The medical profession and health system
3. Instruments of application and ethical context
   - 3.1. Legislative texts and/or regulations
   - 3.2. Committee on Ethics
   - 3.3. Judiciary system
   - 3.4. Operational strategies
   - 3.5. Official structures
   - 3.6. Associations
   - 3.7. Ethical charter
4. Example: Code of Ethics for blood donation & transfusion (ISBT)
5. Recommendations on ethical issues


Blood safety
Who is responsible
* National authorities
* Health system
* Medical professionals
DONOR
rights
obligations
RECIPIENT
Instruments
* Legislation & regulation
* Committee on Ethics
* Operational strategies
* Blood Policy
Ethical principles
Human dignity
Non discrimination
Honest & clear information
Free & informed consent
Confidentiality
Medical secrecy

Introduction

The quality of blood safety in a country or a region will be determined by several factors. High among those factors is the broad acceptance of a civic and medical ethic to guide action around safe blood. It is our viewpoint that without this ethic at all levels concerned, frictions and tensions related to priorities, rights, responsibilities and costs will not be resolved appropriately.

The ethical framework we propose with regard to safe blood is a step towards recognition of basic values and principles, related to solidarity between potential and actual donors and recipients, which are guiding medical practice and ensured by state rules and regulations on a blood policy. Although this is true for a lot of other topics, blood safety is here especially considered.

We wish to draw the reader's attention to three essential points:
1. At this stage, we present only a reminder of rights and obligations and give orientations as to how these could be taken into consideration and respected. The text has neither the pretention nor the mandate to represent an official or regulatory viewpoint.
2. Furthermore, the text does not have the intention to regulate blood safety, for example, it does not give indications (it is not meant to do that) as to structure (private or public), who will be responsible for blood collection, for transfusion, who will communicate test results, etc...
3. The proposals concern all countries although we know that realities are different from one country to another. However, the goal and general rules are similar and are focused upon here.

The two main partners in safe blood are the donor and the recipient with between them the blood (product) and the facilitators, the medical personnel and the health system. The total sum of interactions take place in a district, state, and international context.

All partners in the interaction have rights and responsibilities in order to ensure the safety of blood transfusion as a medical, life saving act. Those responsibilities and rights can be defined through consideration of civic, moral and ethical rules and principles.

In this chapter we try to define the most important of these ethical principles, rules and responsibilities. We further discuss some of the instruments and conclude that a charter at national and international level for blood safety could be a step forward to clarify ethical principles and guide policy practice for safe blood initiatives.

1. Rights and obligations within the context of blood safety

1.1. Basic ethical principles: universal rights

Some basic ethical principles in relation to safe blood are hereby enumerated in order to enunciate and encourage commitment to core values concerned with the quality of safe blood and blood transfusion within medical practice, and strengthen the sense of common responsibility at all levels of society.

1.1.1. Confidentiality.

Obligation for all personnel (not only medical and paramedical) not to disclose any data on the health and private life of the individual obtained from questionnaires and/or medical examinations, which he/she has come to know in the context of his/her duties.

1.1.2. Medical secrecy.

Ethical obligation of the medical and paramedical staff not to disclose any medical and personal data concerning his/her patient in the context of their mutual relationship.

1.1.3. Non-discrimination.

Equitable treatment, irrespective of race, nationality, religion, illness, sex, social and financial status of the person.

1.1.4. Honest and clear information.

Accurate, comprehensive explanations given to the person concerned on the reasons for, and the method and consequences of, an administrative or medical act (questionnaire to be completed, test to undergo etc...)

1.1.5. Free and informed consent.

Clear and full agreement by the person concerned to undergo a medical act, having previously received honest and clear information concerning this act.

1.1.6. Respect of Human dignity.

Accomplishment of the medical or administrative act while ensuring moral and physical respect for the individual.

1.2. Specific rights and obligations

- Firstly, rights and duties are almost entirely defined in terms of the relationship between people and governments. We believe that it is crucial to think about rights and duties in broad terms when discussing safe blood because of the great interdependence of all partners. This means that all citizens, as individuals and as members of groups and associations, should recognize and help protect the rights of others.
- Secondly, the rights need to be paired with responsibilities. Over the long run, in relation to safe blood, the rights of the recipient are the obligation of the donor, and roles are interchangeable.

1.2.1. The donor

Rights:
- to be informed of the use made of the blood donated
- to refuse the commercialization of his/her donation
- to be accepted as a donor and screened with respect to the basic ethical principles given earlier
- to receive test results, orientation, advice, follow-up and care
- to respect the anonymity of his/her donation
- to a professional environment and to a (para)medical supervision when donating blood, which is a medical act.

Obligations:
- to give blood without remuneration (by refusing any financial reward)
- to be honest with respect to personal information given at interview
- to only use the official circuits, established and supervised by the health authorities, when giving blood.

1.2.2. The recipient

Rights:
- to receive a blood transfusion when it is deemed necessary on medical grounds
- to receive transfusion of safe blood (knowing that it is not possible to ensure 100 % safety)
- to a professional environment and to (para)medical supervision when receiving a transfusion, which is a medical act
- to receive blood collected, stored and supplied in accordance with the applicable safety standards
- to receive a transfusion irrespective of race, nationality, religion, sex, social and financial status

Obligations:
- to use the official circuits established and supervised by the health authorities for receiving blood
- to inform the doctor responsible for the blood transfusion of any reactions the recipient may have noticed after the transfusion.

1.2.3. The population

Rights:
- to the existence of a public health system which takes into account blood safety
- to obtain information on blood safety (donation or reception)
- to have access to blood of the quality and in the quantities required
- to have access to a blood supply, stored and transfused in ethical and safe conditions

Obligations:
- to encourage the population to participate actively in voluntary non-remunerated blood donations
- to make the population aware of the fact that donating blood is an act of human solidarity and moral responsibility
- to participate in the implementation of a safe blood policy (screening, transfusion, therapy, research etc.) in order to protect the members of the population

- to resist and protest against ethical misconduct
- not to create unofficial and commercial circuits, either for blood donation or for blood transfusion
- to circulate to its members information on blood safety

2. Commitment of all those responsible for blood safety in a country

2.1. Public authorities and national authorities of the state concerned.

The public and national authorities of the state concerned are responsible for recognizing the rights and obligations of the population.

2.2. The medical profession and the health system.

The medical profession in the country concerned is responsible for taking into account the rights and obligations of donors and recipients and must be willing to implement these.

Blood collection and transfusion organisations, together with all health structures in the country concerned, have a responsibility to ensure that everyone within the organisation (staff, donor, recipient...) is fully informed about, and respects, the rights and obligations of donors and recipients.

3. Instruments to ensure the ethical context of blood safety

The following instruments can help to ensure the development of the ethical context of blood safety within countries and unite people around common rights and shared responsibilities which would provide the moral foundation for constructing and watching over an effective system of blood safety. Over time, those principles, rights and responsibilities can be developed into national and international charter(s) for blood safety that could provide guidance.

3.1. Legislative texts and/or regulations adopted by the public authorities to define a coherent blood policy within the framework of a public health policy.

These texts should, in particular, establish:

- the conditions governing safety of blood, particularly through defining and attributing the roles and responsibilities of the health system and the professional and medical nature of such interventions
- the conditions governing blood safety, particularly by setting parameters measuring the transfusion risks and the margins beyond which transfusion is not authorized
- the obligation of voluntary non-remunerated, non-commercialised, anonymous blood donation
- the obligation of non-discrimination regarding blood distribution
- the obligation to distribute 'non perishable' blood products
- selection criteria of blood donation (age, frequency, etc)
- the intervention of official bodies and non-profit making organisations entitled to carry out blood collection and transfusion
- a supply policy (self-sufficiency or imports with the appropriate guarantees)
- a policy on blood collection, storage and delivery meeting the ethical and safety requirements for everyone and in everybody's interest
- a policy aiming at rationalizing the use of blood donations so as to prevent waste
- means (notably financial and structural) allowing implementation of the above mentioned policies.

3.2. Committee on Ethics and the protection of human rights established by the public authorities with consultative status (binding opinion).

This committee brings together all those concerned in a multidisciplinary partnership (recipient, donor, the medical profession, health authority representatives, national authority representatives, ethicists, etc) and through the diversity of its membership, guarantees its impartiality and thereby its effectiveness.

3.3. *An independent judiciary system* which must guarantee rights and obligations of the various parties as regards transfusion safety.

3.4. Operational strategies devised and applied by the medical profession to take action in an area in which legislative texts and regulation are often still lacking.

The operational strategies must take better account of the rights and obligations of the donor and the recipient, particularly by:
- systematically using appropriate methods and means to ensure reliable results
- forwarding results to the donor and systematically taking care of donors discovered to be HIV infected (orientation, follow-up, counselling, care)
- strengthening and creating a protection system for data which are considered confidential (protection of private life, limited access to data of individual, non-disclosure of medical results, etc).

All these operational strategies are essential, as they must be the driving force behind the adoption of legislative texts and regulations, by providing the technical, scientific and ethical basis.

3.5. Blood policy for official structures entitled to collect and/or to transfuse blood.

These structures should adopt a blood policy in order to ensure recognition of the operational strategies and the ethical principles.

This blood policy should be elaborated with the assistance of the medical profession and through consultation with associations of people concerned (donors, recipients, patients, staff, etc).

This policy should be applicable to everyone and by everyone (staff and patients) within the organisation.

3.6. Associations established within the society by and for people with a common interest (recipients, donors, haemophiliacs, HIV-infected people, patients etc).

Through such associations, the population and society are taking steps to ensure that they are properly represented and will be recognized as responsible partners for the public authorities.

3.7. Ethical charter for blood safety: declaration of intention

Within the context of actions supported by the European Commission in the matter of blood safety, it seems opportune as much for the Commission as its partners, the beneficiary countries, to recognize the ethical guidelines in the matter of blood safety.

Over a certain time period and after further discussion a charter could be developed. This charter could be a national and international moral commitment for all parties concerned by blood safety.

4. Example

Code of Ethics for blood donation and transfusion (1980). International Society of Blood Transfusion

The object of this code is to define the principles and rules to be observed in the field of Blood Transfusion: these should form the basis of national legislation or regulation.

I. The Donor

1. Blood donation shall, in all circumstances, be voluntary: no pressure of any kind must be brought to bear upon the donor.
2. The donor should be advised of the risks connected with the procedure: the donor's health and safety must be a constant concern.
3. Financial profit must never be a motive either for the donor or for those responsible for collecting the donation. Voluntary non-remunerated donors should always be encouraged.
4. Anonymity between donor and recipient must be respected except in special cases.
5. Blood donation must not entail discrimination of any kind, either of race, nationality or religion.
6. Blood must be collected under the responsibility of a physician.

7. The frequency of donations and the total volume of the blood collected according to the sex and weight of the individual, as well as the upper and lower age limits for blood donation, should be defined by regulations.
8. Suitable testing of each donor and blood donation must be performed in an attempt to detect any abnormalities:
   a) that would make the donation dangerous for the donor,
   b) that would be likely to be harmful to the recipient.
9. Donation by plasmapheresis should be the subject of special regulations that would specify:
   a) the nature of additional tests to be carried out on the donor,
   b) the maximum volume of plasma to be taken during one session,
   c) the minimum time interval between two consecutive sessions,
   d) the maximum volume of plasma to be taken in one year.
10. Donations of leukocytes or platelets by cytapheresis should be the subject of special regulations that specify:
    a) the information to be given to the donor about any drugs injected and about the risks connected with the procedure,
    b) the nature of any additional tests to be carried out on the donor,
    c) the number of sessions within a given time frame.
11. Deliberate immunisation of donors by any foreign antigen with the aim of obtaining products with a specific diagnostic or therapeutic activity should be the subject of special regulations that would specify:
    a) the information to be given to the donor about the substance injected and the risks involved
    b) the nature of any additional tests which have to be carried out on the donor.

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

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

II. The Recipient

13. The object of transfusion is to ensure for the recipient the most effective therapy compatible with maximum safety.
14. Before any transfusion of blood or blood products, a written request, signed by a physician or issued under his responsibility must be made, which specifies the identity of the recipient and the nature and quantity of the substances to be administered.
15. Except for the emergency use of the type O blood or red blood cells, every red cell transfusion necessitates preliminary blood grouping tests on the recipient, and compatibility tests between the donor and the recipient.
16. Before administration, one must verify that blood and blood products are correctly indentified and that the expiry date has not been passed. The recipient's identity must be verified.
17. The actual transfusion must be given under the responsibility of a physician.
18. In case of a reaction during or after the injection of blood or blood products, appropriate investigations may be required to ascertain the origin of the reaction and to prevent its recurrence. A reaction may require the interruption of the transfusion.
19. Blood and blood products must not be given unless there is a genuine therapeutic need. There must be no financial motivation on the part of either the prescriber or of the establishment where the patient is treated.
20. Whatever their financial resources, all patients must be able to benefit from the administration of human blood or blood products, subject only to their availability.
21. As far as possible the patient should receive only that particular component (cells, plasma, or plasma derivatives) that is needed. To transfuse whole blood into a patient who requires only part of it may deprive other patients of necessary components, and may carry some additonal risks to the recipient.
22. Owing to the human origin of blood and to the limited quantities available, it is important to safeguard the interests of both recipient and donor by avoiding abuse or waste.
23. The optimal use of blood and blood products requires regular contact between the physicians who prescribe and those who work in blood tranfusion centres.

III. Controls

24. Appropriate controls should be required by the Health Authorities to verify that blood transfusion practices meet internationally accepted standards and that the guidelines or regulations issued in accordance with this code are effectively respected.
25. The following should be regularly checked:
    a) the proficiency of the staff,
    b) the adequacy of the equipment and premises,
    c) the quality of methods and reagents, source material and finished products.

5. Recommendations on ethical issues

In all national safe blood programmes supported by the EC, it has also been recommended to the national authorities:

- to pass legislation and regulation to ensure the concept of voluntary, non-remunerated and anonymous donation of blood, of voluntary and informed testing, and of the protection of personal information
- to set up a legal statute for Blood Transfusion Services
- to take into account the blood transfusion scheme and then to define the function and the operational rules of this structure at each level
- to ensure optimal blood collection, processing, storage and distribution under safest conditions possible. This latter strategy is seen as a medical responsibility and dealt with as such
- to inform all personnel on matters related to ethical principles such as: confidentiality, anonymity, protection of personal information
- to create an ethics committee to watch over the application of these ethical principles.

GLOSSARY

&

MEANING OF ABBREVIATIONS

ABO	Human blood group system comprising 4 main blood groups: A, B, AB and O.
ACD	Acid Citrate Dextrose: preservative and anticoagulant solution used to conserve blood in plastic bags.
Agglutination	Immunological reaction between cellular antigens (for example, those at the surface of red blood cells) and antibodies (in serum or plasma) bringing cells close together (agglutinates).
Agglutinin	another name for "antibody".
AHG	Anti-Human Immunoglobulin.
AIDS	Acquired Immune Deficiency Syndrome due to HIV infection.
Albumin	The most abundant plasmatic protein the role of which is to retain plasmatic water in blood vessels.
Anaemia	Insufficient number of red blood cells (under 3,000,000/mL) due to a blood loss or to a lack of erythrocytes production
Antigen	Substance able to induce antibody production.
Asymptomatic	In transfusion practice, a donor is called "asymptomatic" when he/she is infected while presenting no clinical sign of this infection (for example: in the course of HIV and/or HCV infections).
ATLL	Adult T-cell Leukemia Lymphoma.

Audit	Procedure carried out within a quality assurance programme in order to depict problems and to find solutions
Autologous transfusion	donor giving blood for him / herself.
Blood grouping	Generally designates the ABO and Rhesus phenotyping of red blood cells.
Blood and blood products	These terms include all therapeutic substances derived from whole blood i.e. cellular components (red blood cells, platelets, white blood cells) and plasma derivatives.
Blood substitutes	Any substance which can replace blood or blood products.
Blood Unit	1 Blood Unit = 450 ml of whole blood collected by venipuncture.
BTS	Blood Transfusion Service
CF	Complement Fixation
Chagas disease	A disease transmissible by blood, due to Trypanosoma cruzi and frequent in South America.
Coagulation	Phenomenon resulting in the transformation of blood from a liquid to a solid phase (clot).
Cold Chain	A way to designate the optimal storage conservation (2 to 10 °C) of whole blood units collected; the cold chain should never be disrupted.
Compatibility	A laboratory test (cross-match) which aims to make sure that compatibility rules are respected between antibodies (natural or irregular) in recipient serum and antigens at the surface of the donors' red cells.
Coombs reagent	Anti-human immunoglobulin reagent.
Counselling	Overall information and advice given to blood donors about one particular subject such as, for example, HIV seropositivity.
CPD	Citrate Phosphate Dextrose; anticoagulant solution.
Cross-Matching	Compatibility testing.
Cryoprecipitate	Product of plasma obtained by freezing and thawing fresh plasma, which is particularly rich in coagulation Factor VIII.

D	D antigen (Rho) is the major Rhesus antigen. D positive cells are Rhesus positive; D negative cells are Rhesus negative.
Dextran	Crystalloid solution of glucose; can be used as blood substitute.
DLM	Distance Learning Material.
EC	European Communities.
ECU	European Currency Unit.
EIA	Enzyme Immuno Assay: a laboratory method allowing the search for antigens or antibodies by using an enzyme/substrate system as indicator (generally peroxidase).
Erythrocytes	Red blood cells.
Factor VIII	Coagulation factor particularly abundant in the cryoprecipitate.
FP	Fresh Plasma.
FFP	Fresh Frozen Plasma.
Fibrinogen	Plasmatic protein playing a role in blood coagulation.
G-6-PD	Glucose-6-Phosphate Dehydrogenase.
Haemolysis	Red blood cell destruction that can occur in vitro or in vivo when specific antibodies meet the corresponding antigen.
Haemorrhage	Blood loss.
Haemoglobin	(Hb) protein inside red blood cells, which carries oxygen.
Haemophilia	Hereditary acquired coagulation disorder due to a deficit in coagulation Factor VIII (haemophilia A) or IX (haemophilia B).
HAV	Hepatitis A virus.
HBV	Hepatitis B virus.
HBs Ag	Hepatitis B surface antigen.
HCV	Hepatitis C virus.
HDN	Haemolytic Disease of the Neonate; disease due to the destruction (haemolysis) of new-born's red blood cells by maternal allo-antibodies (for example: anti-Rhesus) that have crossed placenta.

HES	Hydroxy Ethyl Starch: colloid solution which can be used as blood substitute.
Hb, Hgb	Haemoglobin.
HIV	Human Immunodeficiency Virus.
HTLV	Human T-cell Leukemia Virus.
IF	Immuno Fluorescence.
IgG	Class G immunoglobulin.
Immunization	Production of antibodies following introduction of an antigen in organism.
Immunized	People who have developed antibodies after transfusion or after pregnancies. In transfusion, alloantibodies (for example: anti-Rhesus antibodies) are likely to hamper the beneficiary effects of blood transfusion.
IV	Intra-venous.
Latency	Silent phase of a disease, for example, HIV. During this phase, there are no clinical signs.
LIA	Line Immuno Assay: one confirmatory method to verify the specificity of antibodies.
LISS	Low Ionic Strength Solution.
MOE	Ministry of Education.
MOH	Ministry of Health
NBDRO	National Blood Donor Recruitment Officer.
NBTAC	National Blood Transfusion Advisory Committee.
NBTC	National Blood Transfusion Centre / Committee.
NGO	Non Governmental Organization.
PH	Phyto Haemagglutination.
Phenotype	Hereditary character of an individual that can be deduced from laboratory analyses (for example: blood group A is defined by agglutination of red blood cells with anti-A reagents).
Plasma	Biologic fluid composed of water, salts and proteins.
Plt	Abbreviation of Platelet.
Platelet	Small cellular blood component playing a major role in the coagulation phenomenon.
Prevalence	Number of cases (of a given disease) observed at a given time.

PRP	Platelet Rich Plasma.
RBC	Red Blood Cell - Red Blood Cell Concentrate - Erythocytes.
Rhesus	Human blood group system, the main antigen of which is D (Rho). Rhesus positive individuals are "D pos" whereas Rhsesus negative individuals do not posess D antigen and are "D neg".
RIPA	Radio Immuno Precipitation Assay.
Risk Factor	Exposure factor determining the probability for a health phenomenon to occur but which can be changed by an intervention.
Room Temperature	Theoretically, room temperature (RT) = 22° ± 2 °C.
RPR	Rapid Plasma Reagin test for Syphilis.
Saline	Liquid solution containing 9 gr of NaCl per L of water; mimicking the physiological liquid (plasma).
Screening	Search for supposed carriers of a disease by means of tests or any method that can be applied rapidly.
Self deferral	Encouragement to not give blood, to blood donors who have had risky behaviour(s) for blood transmissible diseases.
SOP	Standard Operating Procedures: written guidelines explaining in detail how a task should be conducted.
STD	Sexually Transmitted Disease.
TPHA	Treponema Pallidum Haemagglutination Assay: a laboratory method to confirm syphilis carriers.
Transfusion reaction	Any adverse effect that occurs in course of a transfusion.
Transmissible disease	A disease which among other modes of transmission, can be transmitted by blood from a donor to a recipient (for example: HIV, HBV, syphilis, malaria...).
Thrombopenia	Lack of platelets due to massive haemorrhage or to a defect of production.

Universal "dangerous" blood donor	Blood group O donor whose serum contains immune and haemolytic anti-A and anti-B. This blood from "dangerous" blood donors can only be transfused to group O recipients.
VDRL	Veneral Disease Research Laboratory: a method to search for syphilis carriers.
Von Willebrand	Genetic disease due to a coagulation disorder (abnormality of Factor VIII).
WB	Western Blot (Immuno Transfert): a method used to confirm the specificity of (HIV) antibodies.
WHO	World Health Organization.

LIST OF RECOMMENDATIONS

		page
Chapter 1	on blood policy	38
Chapter 1	on the organisation of Blood Transfusion Services	38
Chapter 2	for blood donor recruitment	55
Chapter 2	for counselling	55
Chapter 3	for testing procedures	70
Chapter 4	for preparation and storage of blood components	81
Chapter 5	for the use of blood	98
Chapter 5	for the use of blood substitutes	99
Chapter 6	for buildings, equipment and consumables	109
Chapter 7	on the use of process indicators to monitor safe blood projects	129
Chapter 8	on quality assurance	138
Chapter 9	on cost analysis	158
Chapter 9	on cost recovery	158
Chapter 10	on training	168
Chapter 11	on ethical issues	185

LIST OF RECOMMENDED READING

1. Safe blood in developing countries – a report of the EC's expert meeting
R.W. Beal, W. Brünger, E. Delaporte, L. Devillé, J. C. Emmanuel, P. Fontaine, J. J. Fournel, L. Fransen, P. Laso, J. Lockyer, D. Sondag, F. Van der Veen, E. J. Watson-Williams.
Edited by R.W. Beal, M. Bontinck, L. Fransen.
Published by EC AIDS Task Force, 1992.

2. Blood transfusion services for the developing world
Official Journal of the International Society of Blood Transfusion.
Vox sanguinis; volume 67, Supplement 5, 1994.
Guest editors: J. Leikola; M. Contreras; Karger editor.

3. Blood transfusion in clinical medicine
P. L. Mollison, C. P. Engelfriet and Marcella Contreras.
Ninth edition, Blackwell Scientific Publication.

4. Safe blood in developing countries – The lessons from Uganda
Editor: Rex Winsbury
Contributors: Marijke Bontinck, Wolfram Brünger, Dr Lieve Fransen, Dr Peter Kataaha, Dr Sam Okware, Dr John Watson-Williams, Rex Winsbury.
Office for Official Publications of the European Communities, 1995.
ISBN 92-827-5281-X
CN CF-91-95-342-EN-C

Training courses

5. The laboratory in the control of HIV infection in developing countries
A course for laboratory technicians
Peter M. Ndumbe, MD, PhD;
Associate Professor in Immunology
Faculty of Medicine and Biochemical Sciences
University of Yaoundé 1, Cameroon.

6. Transfusion medicine
A European course on blood transfusion
Coordinators: W. Van Aken and B. Genetet
Ministère de l'Education Nationale; Centre Nationale d'Enseignement à Distance, 1994.
60, boulevard du Lycée
92170 Vanves Cedex, France.

7. Safe blood and blood products
Distance learning material
Guidelines and principles for safe blood transfusion practice
Safe blood donation
Screening for HIV and other infectious agents
Blood group serology.
World Health Organization, Global Programme on AIDS, Geneva.

LIST OF FIGURES

page

Figure 1A 28
Percentage of developed, developing and least developed countries (which have reported to WHO), which have *a national director, national policy* and *national advisory committee* for Blood Transfusion Service. *(Chapter 1)*

Figure 1B 29
Percentage of developed, developing and least developed countries (which have reported to WHO), which have either a *national, regional* or *hospital based* transfusion system or a *combination* of these. (Less than 10 % of countries did not report). *(Chapter 1)*

Figure 2 30
Levels of responsibility to be considered for safe blood policy and strategy in developing countries. *(Chapter 1)*

Figure 3 37
Organigram for the Uganda Blood Transfusion Service; administrative structure *(Chapter 1)*

Figure 4 50
The efficiency of strategies applied in Rwanda to diminish the risk for HIV transmission by blood is illustrated by the continuous decrease of HIV seroprevalence among blood donors between 1985 and 1990. In 1991, on account of a war context in the country, massive blood collections were organized, making it much more difficult to select blood donors.*(Chapter 2)*

Figure 5 64
Schematic representation of the conventional (Procedure 1) and alternative confirmatory algorithms (Procedure 2 & 3) for HIV seropositivity. *(Chapter 3)*

Figure 6 70
Prevalence of infectious markers (HIV, HBV, HCV, Syphilis, Malaria) among Rwandan blood donors (students and cultivators) in 1991. Younger people are less infected than older people.*(Chapter 3)*
Figure 7 74
Main blood products that can be prepared from one whole blood unit: Red Blood Cells, Plasma, Platelets and Cryoprecipitate. *(Chapter 4)*
Figure 8 76
Plastic bag used to collect one whole blood unit. *(Chapter 4)*
Figure 9 78
ABO compatibility rules that have to be respected for Red Blood Cells and Plasma transfusions *(Chapter 4)*
Figure 10 95
Use of blood in Uganda (1993) and in Guinea (1994).*(Chapter 5)*
Figure 11 112
Diagram illustrating the various parameters and their interaction, to be taken into account in defining an indicator model.*(Chapter 7)*
Figure 12 117
Different stages of the Value Chain of the BTS, from blood collection to use of blood.*(Chapter 7)*
Figure 13 137
Quality Control chart for HIV EIA testing. *(Chapter 8)*

TABLE OF CONTENT

Foreword by Commissioner Professor Pinheiro 9
Acknowledgements 11
Brief overview 13
Introduction 15
List of EC interventions 19

Chapter 1.
ORGANISATION OF SAFE BLOOD 25

Introduction 27
1. Safe blood policy and strategy 30
   1.1. Level I: National Blood Transfusion Advisory Committee 30
      1.1.1. National Blood Transfusion Advisory Committee 31
         – Members 31
         – Objectives 31
      1.1.2. Policy 31
      1.1.3. Instruments 32
   1.2. Level II: Direction of Blood Transfusion Services 32
   1.3. Level III: Organisation of Blood Transfusion 33
      1.3.1. Centralized structures 33
      1.3.2. Regionalized system 34
      1.3.3. Hospital based organisation 34
      1.3.4. Mixed organisation 35
2. Examples 35
3. Recommendations on blood policy 38
4. Recommendations on the organisation of blood transfusion services 38

Chapter 2.
BLOOD DONOR INFORMATION AND SELECTION 39

Introduction 41
1. Blood donor motivation, recruitment and retention 42
   1.1. Need for specific recruitment programmes 42
   1.2. There are three categories of blood donors 42
      1.2.1. Voluntary 43
      1.2.2. Family replacement 43
      1.2.3. Paid 43
   1.3. The aim of recruitment is to enrol "regular" blood donors 44
   1.4. How to ensure blood donor loyalty ? 44
2. Call for donors and blood collection 44
   2.1. Standard Operating Procedures 44
   2.2. Sites of blood collection 45
3. Information given to blood donors 45
4. Counselling of blood donors 46
   4.1. Right of blood donors to know results and responsibility of the BTS 47
   4.2. What about pretesting ? 47
5. Considerations about "high risk" and "low risk" blood donors 48
6. Examples 49
   6.1. Blood donation projects 49
   6.2. Information given to donors 51
7. Recommendations for blood donor recruitment 55
8. Recommendations for blood donor counselling 55

Chapter 3.
SCREENING FOR INFECTIOUS DISEASES 57

Introduction 59
1. Concepts and definitions 59
2. Levels of screening strategy 60
   2.1. Screening tests applied to blood units 60
   2.2. Testing carried out to diagnose an infection 60
   2.3. Test results as indicators of effective prevention 61
3. Parameters influencing the screening strategy 61
4. Which are the best tests to use ? 62

4.1. Screening for HIV antibodies 62
4.2. Screening for Hepatitis B surface antigen 65
4.3. Screening for Syphilis 65
4.4. Screening for Malaria 66
4.5. Screening for Hepatitis C antibodies 66
4.6. Screening for HTLVI/II antibodies 67
4.7. Screening for Chagas disease 67
5. Example 68
6. Recommendations for testing procedures 70

Chapter 4.
PREPARATION AND USE OF BLOOD COMPONENTS 73

Introduction 75
1.Whole blood 76
2. Blood components 77
2.1. Red Blood Cell concentrates 77
2.2. Platelets 79
2.3. Fresh and Fresh Frozen Plasma 80
2.4. Cryoprecipitated Factor VIII 81
3. Recommendations for preparation and storage of blood components 81

Chapter 5.
USE OF BLOOD AND BLOOD COMPONENTS 83

Introduction 85
1.Main indications for blood and blood products 87
1.1. Acute blood loss 87
1.2. Anaemia 88
1.3. Elective surgery 88
2. Alternative to homologous blood transfusion 88
2.1. Prevention of anaemia 88
2.1.1. For pregnant women 88
2.1.2. For infants 89
2.2. Autologous transfusion 89
2.2.1. Preoperative deposit 89
2.2.2. Immediate preoperative haemodilution 90
2.2.3. Intraoperative blood salvage 90

2.3. Blood substitutes 91
2.3.1. Crystalloid solutions 91
2.3.2. Colloid solutions 91
3. Management of transfusions 92
3.1. Blood grouping 92
3.2. Compatibility testing (cross-matching) 92
3.3. Technical alternatives to cross-matching 93
3.3.1. Direct saline proof 93
3.2.2. Importance of temperature 93
3.3.3. Enhancement of sensitivity 93
3.3.4. Minimum alternative to cross-matching 94
3.3.5. Type and screen strategy 94
3.3. Transfusion reactions 94
4. Examples 95
5. Recommendations for the use of blood 98
6. Recommendations for the use of blood substitutes 99

Chapter 6.
EQUIPMENT, STORAGE, CONSUMABLES AND BUILDINGS 101

Introduction 103
1. Buildings 103
2. Equipment 104
2.1. Major equipment 105
2.2. Other equipment needed 105
3. Consumables 106
4. Storage of blood 106
4.1. Electricity available 106
4.2. Unreliable or no mains electricity service 107
5. Example 108
6. Recommendations for equipment 109

Chapter 7.
SAFE BLOOD MANAGEMENT INDICATORS 111

Introduction 113
1. Useful definitions 113
2. Indicators 115

2.1. Categories of indicators 115
2.2. Criteria for selecting indicators 115
2.3. Process of indicator selection 115
2.4. For whom are the indicators ? 116
3. Safe blood 116
3.1. Stage 1: Blood donor recruitment and retention 118
3.2. Stage 2: Screening 119
3.3. Stage 3: Storage and stock management 121
3.4. Stage 4: Distribution 122
3.5. Stage 5: Use of blood 123
4. Example 124
5. Recommendations on the use of process indicators to monitor safe blood projects 129

Chapter 8.
QUALITY ASSURANCE 131

Introduction 133
1. Definition of concepts 134
2. Quality assurance implementation 134
2.1. Standard Operating Procedures 134
2.2. Quality Control 135
2.2.1. Internal Quality Control 135
2.2.1. External Quality Control 135
2.3. Training 136
2.4. Audit 136
3. Example 137
4. Recommendations on Quality Assurance 138

Chapter 9.
COST EVALUATION AND FINANCING OF BTS 139

Introduction 141
1. Cost evaluation 141
1.1. Concepts and definitions 141
1.1.1. Investments or capital costs 141
1.1.2. Recurrent Costs 141
1.1.3. Depreciation 142

1.1.4. Inflation 142
1.1.5. Hidden costs 142
1.1.6. Current price 143
1.1.7. Unit cost 143
1.1.8. Maintenance cost 143
1.2. Format for cost data reporting of BTS 144
1.2.1. Specific comments 149
2. Financing 151
2.1. External financing 151
2.2. Cost recovery 151
2.2.1. What and who to charge for ? 152
2.2.2. Proposal 154
2.2.3. How much to charge for ? 154
3. Example 155
4. Recommendations on cost analysis 158
5. Recommendations on cost recovery 158

Chapter 10.
TRAINING 159

Introduction 161
1. Training modules 161
2. Training must be conceived as a continuous activity 161
3. Organisation of training 162
4. Specific training 162
4.1. Medical director 162
4.2. Donor recruitment officer 163
4.3. Administrator 163
4.4. Chief technologist/ laboratory technicians 163
4.5. Nurses / Phlebotomists 163
4.6. Maintenance technicians 164
5. Technical assistance 164
6. Example 164
7. Recommendations on training 168
8. Annexes 169

Chapter 11.
ETHICAL ORIENTATIONS FOR BLOOD SAFETY 173

Introduction 175
1. Rights and obligations within the context of blood safety 176
1.1. Basic ethical principles: universal rights 176
1.1.1. Confidentiality 176
1.1.2. Medical secrecy 176
1.1.3. Non-discrimination 176
1.1.4. Honest and clear information 176
1.1.5. Free and informed consent 176
1.1.6. Human dignity 177
1.2. Specific rights and obligations 177
1.2.1. The donor: rights and obligations 177
1.2.2. The recipient: rights and obligations 178
1.2.3. The population: rights and obligations 178
2. Commitment of all those responsible for blood safety 179
2.1. Public and national authorities 179
2.2. The medical profession and health system 179
3. Instruments of application and ethical context 179
3.1. Legislative texts and/or regulations 180
3.2. Committee on Ethics 180
3.3. Judiciary system 181
3.4. Operational strategies 181
3.5. Official structures 181
3.6. Associations 181
3.7. Ethical charter 182
4. Example: Code of Ethics for blood donation & transfusion (ISBT) 182
5. Recommendations on ethical issues 185

Glossary 187

List of Recommendations 193

List of Recommended Reading 195

List of Figures 197

European Commission
Safe blood in developing countries – Principles and organisation

Office for Official Publications of the European Communities
L-2985 Luxembourg

1995 – 206 pages – 16.5 x 24 cm

ISBN 92-827-5279-8

Catalogue number: CF-91-95-334-EN-C

EUROPEAN COMMISSION

DIRECTORATE-GENERAL
FOR DEVELOPMENT

Office for Official Publications of the European Communities
L-2985 Luxembourg

Catalogue number: CF-91-95-334-EN-C

ISBN 92-827-5279-8