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## Strategies for Safe Blood Transfusion



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# Preface

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*The growing problem of transfusion-associated infections has been appreciated globally. Some of the major infectious diseases, including HIV/AIDS, hepatitis B, syphilis and malaria, are transmissible through blood. A reduction in their incidence can be guaranteed by ensuring transfusion of safe blood, which encompasses improved donor selection, screening of blood and reduction of unnecessary transfusions.*

*Developing countries have striven hard and achieved considerable success in reducing the incidence of transfusion-associated infections. In many developing countries, particularly in the South-East Asia Region, there is an urgent need to develop strategies for safe blood transfusion. A well-organized national blood transfusion policy and programme are the prerequisites to ensure effective and efficient implementation of these strategies.*

*The first step towards blood safety is to encourage blood donations that are voluntary, non-remunerated and obtained from low-risk and regular donors. Despite careful donor selection, some donors may be seropositive for HIV or other infectious agents. Rigorous screening of all donated blood is, therefore, required to ensure the supply of safe blood.*

*Optimal utilization of blood also helps in reducing or eliminating the use of allogeneic blood and often prevents unnecessary exposure of a patient to the risk of blood-borne infections.*

*Effective quality assurance is essential to ensure transfusion of high quality blood and blood components which carry maximum efficacy and minimum risk to both donors and recipients.*

*Persistent shortage of blood and increased public and professional concern over the risk of transfusion-associated infections have substantiated the need to have a fresh look at the existing services as well as available infrastructure and strengthening them to meet the ever-increasing need for blood and blood products.*

*Ensuring the availability of adequate quantities of safe blood requires political will, administrative commitment and unqualified support in terms of resources - both human and financial. The technical knowledge to achieve the objective of safe blood transfusion has been presented briefly in this book, which is addressed to national health authorities and transfusion specialists, particularly those in developing countries, in order to assist them in establishing national blood transfusion programmes and create an organized structure of blood transfusion service (BTS) to deliver quality services in this vital field.*

# 1

## Introduction

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**B**LOOD TRANSFUSION is the most efficient mode of transmission of infectious agents, such as HIV and hepatitis B and C. Transmission-transmitted infections are also the most easily preventable and can be substantially reduced by the following strategies:

- â Establishment of an organized blood transfusion service
- â Careful selection of donors to ensure that blood is collected only from low-risk, voluntary non-remunerated donors
- â Screening of donated blood for presence of infectious agents such as HIV, HBV, HCV, etc.
- â Appropriate use of blood

Blood transfusion service (BTS) is an essential component of the health care system. The primary objective

of this service is to ensure safety, adequacy, accessibility and efficiency of blood supply in an efficient, cost-effective and coordinated manner. Blood and blood products must be made available wherever and whenever they are required. It is necessary to plan blood collection after assessing the demands, including contingencies. It is imperative to observe high technological and clinical standards and provide assurance of safety to both donors and recipients through good manufacturing, laboratory and hospital practices as well as good clinical approach. In addition, blood and blood components should be appropriately utilized to ensure their availability for patients in need as well as to avoid unnecessary risk of transfusion-transmitted diseases.

A well-organized national blood transfusion programme is needed in all Member Countries to ensure effective and efficient implementation of these strategies to provide safe blood to all those who need it.

**Provision of safe blood to the community is one of the responsibilities of the government. Ensuring blood safety requires government commitment and support in terms of resources, both human and financial.**

## **1.1 TRANSFUSION-ASSOCIATED INFECTIONS IN SOUTH-EAST ASIA**

Transfusion of blood and blood products accounts for approximately 5-10% of the global HIV infection. In some countries of the South-East Asia Region, blood transfusion contributes substantially to HIV infection and AIDS. For

example, nearly 7% of AIDS patients reported to the National AIDS Programme in India acquired infection following transfusion of infected blood and blood products.

Much progress has been made in all countries in the provision of safe blood through appreciable increase in the proportion of donated blood tested prior to transfusion, the safety and quality of blood still varies greatly among countries in South-East Asia. Almost all donated blood is screened for HIV in many countries, including Thailand, Indonesia, Maldives, Nepal and Sri Lanka. However, for other countries in the Region, particularly India, Bangladesh and Myanmar, safe blood transfusion still remains an issue of major concern needing commitment and support both at national and international levels.

## **1.2 DEVELOPING BLOOD TRANSFUSION SERVICE**

In many developing countries, particularly in the South-East Asia Region, little importance has been given to the subject of transfusion medicine. Keeping in view, however, the risk of transfusion-transmitted infections that is appreciable in many countries, there is an urgent need for developing strategies for safe blood transfusion in the Region. Moreover, with the advances in medical and surgical specialities, the demand for blood and blood components has also increased throughout the world, and South-East Asia is no exception. The absence of a coordinated national blood transfusion programme in some countries can make it difficult for the BTS to meet these requirements.

The basic strategic priorities in the development of BTS and of the national blood transfusion programme are:

- â Education, recruitment and retention of low-risk donors
- â Testing of donated blood for transmissible agents
- â Rational use of blood
- â Capacity building and training of staff

To implement these strategies effectively, government commitment is necessary. The governments should recognize their responsibility to fully support national blood transfusion programmes which could include:

- â Developing a national policy and a plan for blood transfusion services
- â Establishing a national blood transfusion programme
- â Identifying the responsible authority and building partnerships
- â Appointing a management structure and assigning responsibilities

**In order to ensure an effective and efficient blood transfusion service, national blood transfusion programmes should be established in all countries and full support provided to it.**

There is also a need to develop guidelines for appropriate use of blood, autologous transfusion, use of recombinant blood products, pharmacological options and simple blood substitutes i.e. crystalloid/colloids. The option of contract fractionation should be considered where plasma derivatives are required.

# 2

## Motivation, Recruitment and Retention of Blood Donors

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**T**HE MOST important strategy to ensure a safe and adequate supply of blood and blood products is motivation, recruitment, selection and retention of voluntary non-remunerated blood donors.

**The first step towards blood safety is to encourage blood donations which are voluntary, non-remunerated and obtained from low-risk and regular donors. A regular donor is one who donates blood two to three times a year and continues to donate at least once a year.**

Internationally, voluntary non-remunerated regular blood donors who donate blood out of altruism are considered safe blood donors. In many countries, continuous efforts are needed to achieve 100% voluntary blood

donation. It is well established that paid donors constitute a group with high-risk behaviour leading to greater chances of transfusion-transmitted infections in the recipients. If the blood replacement system is in use, it is necessary to impose strict vigilance to identify paid donors who may masquerade as relatives and friends. Compulsion to donate blood for getting a driver's licence or university entrance is also an unacceptable approach and should be discouraged.

***Activities to ensure safe and regular blood donation***

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â	Identify low-risk donors and encourage self-exclusion by donors with risk behaviour
â	Estimate blood requirements
â	Develop effective education and motivation campaign to recruit voluntary donors
â	Develop and maintain effective donor selection procedure
â	Provide high standard of comprehensive donor care
â	Maintain efficient donor records
â	Develop system to retain voluntary and non-remunerated donors

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## **2.1 MOTIVATING AND EDUCATING DONORS**

Motivating people to donate is perhaps one of the most important aspects of a national blood transfusion programme.

It is also a major challenge in many countries of the Region. While planning donor education and motivation campaign, the following should be kept in mind:

- â People do not donate blood unless they are asked to
- â There are sufficient potential donors available
- â There are several myths and misconceptions about blood donation in public

Education therefore is an important bridge between awareness and recruitment. Donor education is essential to ensure recruitment of safe donors in the wake of possibility of false-negative test result, window phase infection or uncertainty of testing due to the non-availability of the testing facility.

***Essential steps in donor motivation***

<b>Steps</b>	<b>Approach</b>
Awareness, information and education	School and public education, Media
Appeal and interest	Lectures and focused group discussion
Aspiration	Organized group or individual recruitment
Action	Organizing and providing infrastructure by BTS

Donor education and information materials, donor questionnaires and consent forms should be prepared in simple language and translated for use according to regional

variations. Picture presentations or flip charts can be used to educate donors who cannot read printed educational material.

## **2.2 ASSESSING NEEDS AND SETTING RECRUITMENT GOALS**

The requirement of blood and blood products in a country depends on the population, health care structure, prevalence of conditions requiring regular transfusions, such as haemophilia and thalassaemia, availability of surgical centres using modern sophisticated techniques, and awareness amongst clinicians regarding judicious use of blood.

This information is useful to assess and meet the demand for blood/blood products through blood donor recruitment, and planned production of blood components and plasma derivatives. It can also help in estimating the budget for national blood programme.

There are many different ways to estimate the total need for blood. The requirement of blood is assessed in relation to:

- â Total population
- â Acute hospital beds
- â Medical facilities available in the area
- â Annual blood usage (past, present and future)

Ideally, if 2% of the population donates blood, it will be sufficient to meet the need of the developing countries. The requirement of blood is usually calculated in terms of requirement of red cells, which very often falls short of the

requirement of plasma for fractionation. The need for blood varies from 7-15 units per acute bed per year depending on the type of medical care available. In a primary health care unit, the need is estimated at 5-7 units/bed/year whereas in a specialized institution the need may be 25-30 units/bed/year.

An appropriate component preparation programme must be instituted to allow optimum utilization of blood, tailored to meet the needs according to resources available in a given country. These may vary in different regions of the country and in different institutions in the same region depending on the clinical use.

## 2.3 RECRUITMENT OF DONORS

Recruitment of donors entails identification, education and motivation of potential donors in the community, training and motivation of blood donor organizers and recruiters as well as donor record maintenance and confidentiality.

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An investment in human and material resources for an effective donor recruitment programme can help by:

- ensuring adequate supply of blood through enhanced voluntary and regular non-remunerated donations, and
  - increasing safety of blood donations through regular blood donors who are well-informed about risk behaviour.
-

For satisfactory donor recruitment, the first essential step is to initiate Knowledge, Attitude and Practice (KAP) studies among a sample of donors and non-donors. The objective of KAP studies is to understand donor demographic profiles as well as the prevailing misconceptions, beliefs and fears leading to a negative attitude towards blood donation. This should also cover socio-economic and cultural factors relating to blood donations, such as asking donors how they decided to donate or learnt about the donation centres. The information so obtained could be helpful in developing appropriate messages to be used during recruitment campaigns, creating and strengthening positive attitudes towards blood donation, and developing and implementing focused awareness programmes for target populations.

***Principles of donor recruitment***

â	Highlighting the importance of voluntary non-remunerated donations
â	Continued motivation and education of potential donors
â	Involving important public figures and community leaders in education programmes
â	Retention of safe donors
â	Organizing donor recruitment campaigns on a continuous basis

## ***Effective Communication Programme***

Public relations are built on the foundation of good communication. A communication strategy should be developed depending on the messages to be conveyed and the communication channels to be used to reach the target population with these messages.

### ***Developing Messages***

A clear and simple message conveyed in a local language is most effective. A garbled or distorted message confuses the target. All health education or communication materials e.g. posters, leaflets, flip charts, etc., once prepared, should be field-tested among a subset of target population and suitably modified based on the feedback from the field test. Educational material suitable for the target group should then be prepared and used for the purpose of motivating potential donors. Traditional media, such as songs, folk dance, street plays, puppetry, etc. can prove valuable, especially in rural settings. In fact, the local community groups and youth groups can participate actively in preparation as well as in the use of such promotional material.

Target populations to be addressed may include:

- â Youth –in schools and colleges
- â People at work places i.e., factory workers, office workers, etc.
- â General population
- â Organizers of blood donation campaigns
- â Religious and community leaders

Planning of education and motivation campaigns should take into consideration the profile of the target audience in terms of socioeconomic and cultural background, age group, sex, level of education as well as physical, environmental and other factors.

### **Communication Approaches**

Methods and approaches to be employed for communication or awareness programme could include the use of mass media – newspapers, radio and television; interpersonal communication through person-to-person interaction; group educational workshops, e.g., lectures, exhibition – posters, banners and hoarding; use of celebrities to convey messages; regular contact with potential donors through greeting cards, phone calls, use of pagers, blood donation drives on important national days, recognition of blood donors, etc. Choosing a wrong and inappropriate medium may be counterproductive.

**Proper and effective communication strategy can help motivate potential donors to become donors, encourage suitable donors to be regular donors, and deter unsuitable individuals from donating blood, thus reducing the chances of transmitting infections through blood transfusion.**

The main messages which the communication programme should highlight include the following:

- â Importance of voluntary blood donation by the general population

- â Need for preventing transfusion-transmitted infections and risk associated with blood collected from paid blood donors
- â Assuring harmlessness of blood donation, safety of blood donors through their pre-donation medical check up and use of disposable equipment for blood collection
- â Community responsibility for blood donation
- â Emotional appeals regarding haemotherapy required to manage blood-related disorders
- â Information about collection, processing and distribution of blood

### ***Ensuring Safety during Blood Donations***

During blood donation campaigns, it is crucial to ensure the safety of both the donors and the recipients. The donor should willingly consent to donate blood without being pressurised. The organizers of donation campaigns should be dissuaded from offering expensive incentives to blood donors. Information and counselling are essential for enhancing donor awareness, perception, motivation, self-deferral and recall. The donor should be assured of absolute confidentiality. Moreover, the procedure for blood collection should be made completely safe, e.g., by using disposable needles, syringes and blood collection packs to instil confidence in the donors about their own safety.

## **2.4 SELECTING SAFE DONORS**

Considering the spread of HIV infection and AIDS, together with the limitations in the process of testing blood for transmissible diseases, blood donor programme should develop stringent criteria for selection of safe donors. In the interest of blood safety, blood donations from individuals with high-risk behaviour, such as those having multiple sex partners, intravenous drug users and prisoners should be avoided.

A detailed questionnaire is essential for donor selection. The donor should be aware that correct and honest answers to the questionnaire would ensure both his/her safety and that of the recipient. Leaflets for donor awareness and education are necessary to make the donors understand the importance of providing as accurate answers as possible. Facilities for interviewing in privacy should be provided.

## **2.5 COUNSELLING AND TESTING**

The policy for donor information and counselling should be precise and clear. Proper implementation of donor education and counselling programme reduces the number of units discarded, which improves cost-efficiency, reduces HIV prevalence amongst donors and helps in developing a safe donor pool. The donor should be asked whether he/she would like to be informed of the results of HIV testing. The HIV test result should be conveyed maintaining full confidentiality to those who wish to know, after confirming the test result, but only where counselling facilities are

available. As a general rule, all HIV testing where the test results are to be conveyed to the donor, must be accompanied by pre- and post- counselling.

Specific guidelines and facilities for counselling should be made available to blood centres by the national blood transfusion service; BTS staff should be trained to prevent serious medical and psychological implications which are likely at the time of revealing a positive test result. Counselling and psychosocial support helps in preparing donors to accept HIV test results and increases AIDS awareness amongst the general population.

**It should be kept in mind that individuals wanting to know their HIV status might be posing as donors with an idea of getting tested and thereby endangering blood safety. Voluntary and anonymous alternative testing sites should be established in the area so that those wishing to know their HIV status could avail of this facility and not come to the blood bank.**

In some countries, where counselling facilities are not well developed, the policy decision is to screen donated blood for HIV and discard the blood units that test initially reactive. In such situations, facilities for post-donation counselling should also be established as soon as possible so that the service of providing test results to the donors could be provided, if asked for.

Those who test positive should be referred to existing government and non-government counselling centres for counselling and medical support.

## **2.6 RETAINING DONORS**

Sustained efforts are required through a systematic donor retention programme to increase the number of blood donors and retain them as regular donors. This is important because the prevalence of infections in regular donors is known to be much lower than in new donors. Recruiting regular blood donors will help in increasing the yield of plasma for therapeutic and fractionation purposes. The regular donors are tested each time they donate, which further increases the safety of blood.

For an effective donor retention programme, building a long-term relationship with donors is crucial.

Some of the measures that may help in donor retention include a clean and easily accessible location for blood donation and a time schedule convenient to most of the donors. Donors should be given personal attention and they should not be made to wait long. Staff behaviour is perhaps the most important; the staff should therefore be courteous, trained and experienced in providing proper donor care to make the procedure of blood donation a pleasant and comfortable experience. The donors must be appreciated and thanked for their contribution and assured of total confidentiality. Finally, appropriate follow up and medical support, if needed, would go a long way in donor retention.

## **2.7 RECORD MAINTENANCE**

A well-maintained donor record, kept in strict confidentiality, is an essential part of the programme. It is helpful in donor

retention as well as in tracing the donor for any specific needs, such as requirement of rare blood group, donor recall in case of post-transfusion infection, confirmation of test results and counselling.

## **2.8 MONITORING AND EVALUATION**

The effectiveness of a donor education, motivation and recruitment programme should be monitored and evaluated to assess whether activities are being carried out properly or not and to ascertain whether communication strategies are having the desired impact.

### *Indicators of effectiveness*

â	Increase in the total number of voluntary non-paid donors
â	Decrease in the number of permanently excluded donors
â	Increase in the number of regular donors
â	Increase in the number of organizations and/or communities involved in motivating voluntary blood donation

# 3

## Screening of Blood

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**S**CREENING OF blood is mandatory for providing safe blood. This includes blood grouping, ensuring compatibility of the donor and the recipient as well as testing for transfusion-transmitted agents. Despite a careful donor selection programme, some donors may be seropositive for HIV or other infectious agents; rigorous screening of all donated blood is therefore required to ensure the safety of the blood supply.

The transmission of infection through transfusion of infected blood and blood products can be easily prevented through screening of blood. The policy for screening blood for HIV should be determined at the national level, taking into consideration the availability of resources and the local prevalence. The extent and range of the screening performed as well as the effectiveness of screening programme varies

greatly based on the difference in the countries' needs as well as financial constraints.

### **3.1 SCREENING FOR HIV ANTIBODIES**

WHO recommends three testing strategies for HIV screening to maximise accuracy while minimising the cost. The use of appropriate strategy will depend on the objectives of testing, estimated HIV prevalence and sensitivity and specificity of the test being used.

For the objective of transfusion safety, strategy I is to be used. However, if a blood donor is to be notified of a test result, testing strategies II and III must be applied and donors counselled before and after testing (see Table). The test selected for donated blood should be a combined HIV-1/HIV-2 assay, which is highly sensitive and specific. All serum/plasma is tested with one ELISA or simple/rapid assay. Units of blood yielding reactive or indeterminate test results must be considered as probably infected with HIV and should be discarded using universal safety instructions. The non-reactive units may be taken on blood inventory for use.

For the purpose of notification of donors, strategy II is employed, i.e., any serum found reactive on the first assay, is retested with a second ELISA or simple/rapid assay based on a different antigen preparation and/or different test principle. Serum that is reactive on both tests is considered HIV antibody positive. Donors should be counselled before and after testing. This strategy is applicable in areas where prevalence of HIV infection in general population is greater than 10%.

**Requirements of a screening programme**

â	Adequately trained staff
â	Availability of equipment and reagents
â	Supply of assay kits
â	Availability of testing kits

Strategy III requires a third test if the serum is found reactive on the second assay. The three tests in this strategy should be based on different antigens and/or different test principles. Serum reactive on all three tests is considered HIV antibody positive. This strategy is applicable in areas such as SEA Region where prevalence of HIV infection in general population is less than 10%.

**WHO recommendations for HIV testing strategies according to test objective and prevalence of infection in the sample population**

	Prevalence of infection	Testing strategy	
Transfusion/ transplant safety	All prevalence	I	One
Surveillance	> 10%	I	One
	≤ 10%	II	Two
Diagnostic Clinical signs/ Symptoms of HIV Infection	>30%	I	One
	≤ 30%	II	Two
Asymptomatic	> 10%	II	Two
	≤ 10%	III	Three

## 3.2 SCREENING FOR OTHER TRANSMISSIBLE AGENTS

### *Hepatitis B*

To reduce the occurrence of post-transfusion hepatitis, it is essential to screen all blood donations for hepatitis B surface antigen by the most sensitive and specific assays.

### *Hepatitis C*

HCV can also be transmitted through blood transfusion. Third generation ELISA kit is available to detect antibodies to HCV. Screening blood for HCV antibodies is recommended but the cost of these is presently prohibitive for many resource-constrained countries.

### *Syphilis*

Serum samples from all blood units must be subjected to either the VDRL (Venereal Disease Research Laboratory) test or a treponemal test, such as Treponema Pallidum Haemagglutination (TPHA) test before transfusion. Any unit found positive should be discarded as per standard safety procedures.

### *Malaria*

Presently, sensitive screening tests for malaria are not available. The most effective way of screening donors is to take proper history of malaria or of fever that could be due to malaria. Donor selection criteria should be designed to

exclude potentially infectious individuals from donating red cells for transfusion. However, there is a need to develop suitable screening tests, especially for use in the endemic area.

### **3.3 RED CELL SEROLOGY**

The donated blood unit should be routinely tested for ABO and Rh (D) grouping and red cell antibody screening employing standardized procedures with adequate control. Pre-transfusion antibody screening of patients and cross-matching with donors' blood using sensitive techniques should be done to avoid immunological transfusion reactions. Compatibility testing must be carried out on all whole blood and red cell transfusions.

### **3.4 BIOSAFETY PRECAUTIONS**

It is necessary to include a safety programme for all categories of staff. Staff working in the blood transfusion department must be educated and motivated to follow universal safety precautions. Necessary training and facilities must be made available to enable health workers to practise these safety precautions, including action to be taken in the event of exposure. All staff members should be vaccinated for HBV according to national guidelines. In case of a penetrating injury, the individual should be administered HBIG as well as HBV vaccine and provided antiviral prophylaxis for HIV according to national guidelines.

### **3.5 QUALITY ASSURANCE**

All laboratories should have a quality assurance programme. It is important to stringently comply with the quality control procedures and to maximise the accuracy of laboratory results. Procedures for detecting and preventing both technical and clerical errors must be included in all protocols. It is recommended that all laboratories submit to an external quality assessment at least once a year. Quarantine procedures that guarantee correct identification of initially reactive units of donated blood, which must be discarded, are essential to maintain a safe blood supply.

### **3.6 ROLE OF REFERENCE CENTRES**

It is necessary to establish reference centres at various sites which could assist blood centres in solving any technical problems, selecting consumables, reagents and test kits; carrying out an external assessment programme; and training of technical staff.

# 4

## Promoting and Practising Rational Use of Blood

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**O**PTIMAL UTILIZATION of blood helps in reducing or eliminating the use of allogeneic blood and often prevents unnecessary exposure of a patient to the risk of blood-borne endogenous infections. Appropriate and rational use of blood/blood components is required to ensure their availability to needy patients as well as to avoid the unnecessary risk of transfusion-transmitted diseases.

Rational use of blood means providing the right blood product, in the right quantity, for the right patient. It can help

in bridging the gap between demand and supply of the precious blood or blood products in many countries.

***Strategies ensuring rational use of blood***

â	Developing guidelines for rational use of blood
â	Organizing clinician awareness training programmes
â	Setting up hospital transfusion committees (HTC) to promote strategies for rational use of blood
â	Ensuring availability and accessibility of blood/ plasma substitutes
â	Promoting blood component therapy
â	Encouraging autologous transfusions
â	Managing inventory of blood
â	Providing orientation to transfusion medicine experts

Patients who require blood or blood products, whether in life-threatening acute situations or as a supportive therapy in chronic haematological disorders, must receive the required component only. The safety, adequacy and effectiveness of blood supply can only be achieved if there are no unnecessary transfusions.

The involvement of the officer-in-charge of transfusion service is generally restricted to procurement and supply of blood. The attending physicians rarely, if at all, consult them to decide on the use of whole blood or blood components. To enhance their motivation and interest, the transfusion specialist should be involved in patient care. The primary responsibility for deciding on transfusion of blood or the

components/products is of the treating physician; however, it would be very desirable if the decision to do so is made in consultation with the transfusion specialist.

Strategies for ensuring appropriate use of blood are as follows:

#### **4.1 DEVELOPING GUIDELINES FOR USE OF BLOOD/BLOOD PRODUCTS**

- â Indications and guidelines for appropriate use of blood should be developed and disseminated to various levels of health care, such as physicians and surgeons; medical college faculty; resident doctors and medical officers in blood centres.
- â Organizing clinician awareness and training sessions, including CME programmes in the form of lectures, seminars and symposia held in various hospitals.
- â Patients should be given blood transfusion only when there is a definite indication to do so and its benefit outweighs the risk associated with it.
- â Use of whole blood should be discouraged. Instead, patients can be treated with the specific components e.g., red cells, plasma or platelets. Crystalloid or colloid solutions (dextrose-saline, ringer lactate, dextran, etc.) may be used for mild to moderate blood loss and red cell transfusions

may be limited only for patients with acute blood loss of > 20% of blood volume.

- â Use of blood less than three days old should preferably be avoided as there is an increased risk of transmission of viral infections from fresh blood which may get inactivated on storage. Organization of efficient and adequate blood inventory system prevents wastage and helps to minimise transfusion of untested or improperly screened blood.
- â Single unit transfusions raise the haemoglobin by 1 g/dl only, which is therapeutically insignificant. The use of a single unit of blood should therefore be strongly discouraged.

**Each unit of allogeneic blood transfused carries an inherent risk of disease transmission and transfusion reactions.**

- â Autotransfusion (autologous blood transfusion) is a unique approach of providing the patients with their own blood and it helps to avoid the use of allogeneic blood.
- â Reducing the exposure of patient to different donors will also decrease the risk of transfusion-transmitted diseases. This is of importance in a paediatric patient requiring 30-50 ml of blood every day or on alternate days, who may be transfused with small quantities of blood separated from a single donor blood unit.

Apheresis blood products prepared from single donors also help in reducing number of donor exposures to a particular patient. Apheresis is the selective removal of one or more specific components of blood, returning the remaining elements to the donor. Apheresis procedure can be carried out using a cell separator (apheresis) machine with the main objective of harvesting sufficient amount of cells from a single donor to allow adequate transfusion therapy.

- â Other related strategies include the use of pharmacological agents for patients with bleeding diathesis, e.g. DDAVP or desmopressin is useful in the treatment of mild haemophilia. Similarly, vasoconstrictor agent aprotinin can be used to reduce loss of blood from the operative site during surgery.

***Blood sparing strategies***

â	Pharmacological agents for patients with bleeding diathesis
â	Crystalloid/colloids
â	Haematinics for patients with anaemia
â	Genetically engineered recombinant products – rFVIII, rFIX, rGF, rEpo
â	Blood substitutes – perfluorocarbons, modified haemoglobin solutions

## **4.2 ENSURING AVAILABILITY OF BLOOD/BLOOD PRODUCTS**

Procedures for availability and accessibility of plasma substitutes such as crystalloids and colloids should be developed. For management of mild to moderate blood loss, plasma substitutes should be used as volume expanders. Preparation and storage of sufficient quantity of blood components would ensure that these are readily available for the use of clinicians. The inventory should be managed in order to minimise wastage and outdating of blood units.

## **4.3 ROLE OF HOSPITAL TRANSFUSION COMMITTEE**

It is almost imperative for each hospital to constitute a Hospital Transfusion Committee (HTC) consisting of blood users (such as representatives from surgical disciplines, internists, haematologists and anaesthesiologists), representatives from administration and nursing staff and blood transfusion specialist.

Review of blood usage, blood ordering strategies and active interaction amongst blood transfusion service and clinicians will definitely help in appropriate utilization of blood, promotion of autologous blood transfusion and avoidance of unnecessary transfusions.

***Functions of a hospital transfusion committee***

â	Formulating policies for use of blood and blood components
â	Developing guidelines for use of blood/plasma substitutes
â	Establishing Standard Surgical Blood Ordering Schedules (SSBOS)
â	Monitoring source and supply of blood components
â	Monitoring adverse effects of blood transfusion
â	Auditing blood transfusion practices

#### **4.4 MEDICAL AUDIT**

The goals of a medical audit in a blood transfusion centre are to improve the processes introduced in the ordering, distribution, handling, and administration of blood as well as to monitor the response to transfusion. As a management tool for rationalising blood usage and an important part of quality assurance programme in a transfusion centre, medical audit can provide necessary information for improving transfusion medicine practice.

For rational use of blood, it is essential to look into the existing blood transfusion practices and collect background information about the type of existing blood transfusion practices e.g. requests for single unit transfusion, fresh blood transfusion, use of blood component therapy, use of

autologous blood transfusion, etc. and modify these practices for appropriate utilization of blood in the hospital setting.

Guidelines for transfusion can be utilized to assess the appropriateness of transfusion during a medical audit. A transfusion audit serves to identify areas of practice that can be improved by follow-up education. It has been shown that the implementation of audit with monitoring can significantly reduce the use of blood products with considerable cost-saving.

# 5

## Formulation and Adoption of National Blood Policy

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**H**IV/AIDS pandemic has greatly increased public awareness of blood transfusion, thereby generating great interest in the safety and adequacy of the nation's blood supply. The persistent shortage of blood and heightened public and professional concern over the risk of transfusion-transmitted diseases has substantiated the need to have a fresh look into the existing services. Many constraints are faced by blood transfusion services in some countries of the Region due to the lack of an adequate infrastructure.

In some countries of the Region, blood transfusion is not considered an integral part of the health care system. The system of blood banking is fragmented and a planned system

of donor motivation, recruitment and retention is non-existent. Sufficient blood to meet the transfusion needs of the community is still not available and system of professional blood donation is not uncommon. Blood transfusion services are not properly organized. Adequate financial resources are lacking, besides the shortage of adequate and trained manpower, and the absence of a cadre for blood transfusion personnel. Quality assurance and accreditation system is still in the stage of infancy in many countries of the Region.

In view of these, and in order to develop a comprehensive blood transfusion programme, it is necessary to formulate a national blood policy which would provide a strategy framework and directions for the management of BTS integrated into the national health programme.

**A national blood policy can be defined as the clearly expressed view of the national health authority on how blood donation and transfusion should be arranged in a particular country.**

A national blood policy should address the following issues:

***(1) Consideration of Blood Transfusion as an Integral Part of Health Programme***

The government has the full responsibility for the blood programme even though, in some countries, the management of blood transfusion service may be delegated fully or partly to an appropriate non-governmental organization (NGO) working on a no-profit basis, e.g., Red

Cross and Red Crescent Society. When an NGO is assigned this responsibility, the government should formally recognize it, and give a clear mandate with necessary support to facilitate the service to be rendered.

### ***(2) Funding of National Blood Transfusion Service (NBTS)***

Strengthening blood transfusion service should be accorded high priority and adequate provision made for NBTS in the national health budget. An independent budget will improve motivation, efficiency and accountability of the blood transfusion personnel.

Government support, whether through regular budgetary allocation or the development of a cost recovery system, is essential to ensure a sustainable programme.

Besides governmental support, other sources of funding such as multinational or bilateral donor support, sponsorship from industrial houses and philanthropic organizations and annual fund raising drives, should be explored. The government should also support educational and training programmes related to transfusion medicine and increase the opportunities for training professionals.

### ***(3) Organization and Management of NBTS***

It is necessary to ensure that safe blood is provided to all government, semi-government and private hospitals throughout the country.

Pre-requisites for improving the country's blood safety include the following:

- â Strong national leadership
- â Government support and commitment from NGOs
- â Sustainability
- â Adequate infrastructure
- â Formation of a National Transfusion Committee

***(4) Promotion of the Concept of Total Voluntary, Non-Remunerated Blood Donation***

A voluntary, non-remunerated donor recruitment programme must be considered as the topmost priority to ensure safe and adequate blood supply.

***(5) Policy Decisions on Relevant Issues***

While formulating the national blood policy, it is important to consider policy decisions on relevant issues such as:

- â Testing policy for transfusion-transmitted diseases
- â Information and counselling of donors
- â Notification
- â Confidentiality
- â Legal implications and compensation, etc.

**(6) Legislative and Regulatory Control**

Implementing and enforcing appropriate regulations are necessary functions of health service to ensure high quality service and safe blood. Evaluation and monitoring of the national blood programme is also the responsibility of the Ministry of Health.

**(7) Technical Procedures**

There is a need to develop technical guidelines and standard operating procedures (SOP) comprising various aspects of BTS,

- â Donor recruitment and retention
- â Blood collection, storage and transport
- â Testing and processing of blood and blood products
- â Quality assurance and accreditation
- â Appropriate clinical use
- â Disposal of infected waste – blood and other disposables
- â Universal safety precautions
- â Products, reagents and consumables required in the service

**(8) Human Resource Development**

The government should support educational and training programmes related to transfusion medicine and increase opportunities for training professionals.

**(9) Research and Development**

The national blood policy should promote:

- â Introduction of advanced technology
- â Indigenisation of equipment, reagents, test kits and blood substitutes
- â Development of a uniform management information system MIS for blood programmes in all transfusion centres.

# 6

## Organization and Management of National Blood Transfusion Service

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**S**AFETY AND adequacy of the nation's blood supply largely depends on the national blood policy which should identify the organizations responsible for the programme, the source of funding, the type of blood donation and the outline of the regulations that ensure the safety of blood. After formulating the national blood policy, it is necessary to establish a management structure at the national level, which would be responsible for planning the finance, data management and routine operations as well as for coordinating the overall programme in the country.

**A good management structure is the key for ensuring safe and adequate blood supply. An inefficient and poorly managed blood service not only misuses scarce blood supply, but also costs more in terms of the total national budget than a well-organized service.**

## 6.1 NATIONAL LEVEL

### *National Blood Committee*

At the national level, a national blood committee should advise the government on national blood programme. The latter has the responsibility to implement the national blood policy and coordinate all activities relating to blood transfusion services. The Ministry of Health should constitute a national blood committee or commission (NBC) to advise and assist in planning and monitoring transfusion services of a uniform standard throughout the country. The committee should include transfusion medicine experts, representatives from the government, blood donor organizers, NGOs, such as Red Cross, and clinicians who prescribe and use blood.

The responsibilities of the NBC should be:

- â To guide the Ministry of Health in formulating a national blood policy (NBP).
- â To provide advice and guidance to the government on national blood transfusion programme.
- â To monitor progress in ensuring the availability of safe blood and blood components/products in the country, keeping in view regional variations, population density, availability and sophistication of medical care.
- â To assist the programme in developing a standardized format for building a national database of blood transfusion services.

It is necessary to establish appropriate sub-committees that can meet more often, such as sub-committees on:

*Donor Services*—to assist and advise NBC on strategies related to voluntary blood donor recruitment and efficient blood collection.

*Technical Aspects*—to advise NBC pertaining to technical aspects, such as testing strategies, training, biosafety, quality management, rational use of blood, etc.

*Advocacy and Resource Mobilization*—to advise on advocacy and fund-raising strategies.

***National Blood Programme/National Blood Transfusion Service (NBTS)***

National blood programmes should be established in all countries, if not already done, under the Ministry of Health. Even if the management of NBTS/national blood programme is delegated to a non-profit or nongovernmental organization, such as Red Cross, the overall responsibility for blood safety still remains with the government. The national blood programme, with adequate staff and budget, has the overall authority and responsibility for implementing the national blood transfusion service with guidance from the national blood committee.

The government should promote and support centralized organization and management, introduction of advanced technology, development of indigenous equipment, reagents, test kits and blood substitutes; and development of a uniform management information system for the blood programme in all centres.

The national programme should be coordinated and managed through a national blood directorate, with appropriate and competent staff, adequate office space and supplies. Some of the important roles of the national blood programme are as follows:

- â Advocacy and resource mobilization
- â Collaboration with state, regional centres, NGOs
- â Development of technical guidelines and standard operating procedures
- â Institution of a monitoring and evaluation mechanism, and ensuring quality management
- â Identification of referral centres
- â Promotion of research and development
- â Development of a plan for disaster management
- â Establishment of fractionation policies.

The organizational structure should consist of various units which are responsible for managing specific programme areas, such as blood donation, technical matters, advocacy and resource mobilization. The staff should have adequate experience, managerial skills and orientation in the programme.

## **6.2 STATE OR PROVINCE LEVEL**

### ***State or Provincial Blood Committee***

It is necessary to establish committees at the state/provincial level to guide activities at the peripheral level and to provide

policy advice. These committees should monitor activities at state and province levels and support the districts. Sufficient staff is therefore required at various state levels for effective administration and monitoring of the blood programme.

### ***Organization of Blood Transfusion Service***

Various types of organizational structure may be used for blood transfusion services depending on the size, population, and geographic and socioeconomic structure of the country. Accordingly, the services can be centralized or decentralized.

#### ***Centralized System***

Centralization of the service brings planning, coordination and management of all aspects of national blood supply under a single organization. Although centralization is viewed as the most cost-efficient system optimising all requirements, it may require a large inventory and face transport problems.

#### ***Decentralized System***

Although decentralized system is thought to be more practical, such a system may lead to problems related to uniformity of services, costefficiency and quality management. It will be unrealistic to change over to total centralization immediately in countries where a hospital based system is already established and functioning. In such a situation, it is advantageous to introduce a mixed system through development of centres in the region where the requirement of blood cannot be met by the existing hospital-based centres.

Depending on the area, population and the medical facilities available, each state should plan its own transfusion service within the framework of the national blood policy and plans. Taking into consideration the needs of each state, one or more centres could be established where many activities could be centralized for costeffectiveness and reliability, such as laboratory testing, staff training, quality assurance, research and development, and procurement of supplies.

The blood donor programme should be centralized to have uniform policies and functions of motivation, education, and recruitment of donors. However the following activities may be decentralized in various district areas, based on the agreed national policy and plan:

- â Donor recruitment
- â Blood collection
- â Blood processing
- â Distribution of blood and blood products

All blood samples from district areas should reach the major centres for testing and blood should be moved from quarantine to inventory only on receipt of test reports. Those testing positive for transfusion-associated infections should be sent to major centres for disposal.

Specialized functions of histocompatibility and bone marrow registry may be entrusted either to major centres or major hospitals where transplant facilities are available.

### **Organization of a Blood Centre**

Blood centre is defined as a building or location specifically dedicated to blood collection, component production, testing, storage, distribution, etc. In a blood centre, the place allocation, type and number of equipment, amount of consumables and the number and category of staff will vary with the quantum of blood collected and processed per annum. The scope of the centre will also depend on the size, local requirements and modus operandi.

Large hospitals with attached medical colleges or specialized medical institutions should have centres with all facilities to ensure adequate and efficient provision of blood. The small hospital-based centres can receive the blood from regional or larger hospital centres in the area and may be provided only basic laboratory facilities with controlled storage of whole blood and blood components.

Basic functions of a blood transfusion centre are:
â Organizing the services
â Recruitment of donors
â Collection, processing, storage and distribution o blood and blood components
â Laboratory investigations
â Participation in clinical use of blood and blood components
â Teaching and training
â Research and development

Organization of a blood centre involves designing the premises, procurement of equipment, reagents and consumables, personnel management and continuing medical education. The blood centres should develop an interface with those involved in clinical transfusion practice. Adherence to biosafety precaution and provision of good working environment should also form an essential part of the organization of a blood centre.

Collection of blood can be done either at a static donor session at the blood centre or at outdoor mobile donor sessions. In addition to guidelines for indoor collection of blood, standard operating procedures should also be provided for outdoor donor sessions, which should be monitored. Outdoor collections organized at railway platforms, in open grounds and other places with unclean environment, may lead to contamination of blood and should therefore be discouraged.

### **6.3 MONITORING AND EVALUATION**

It is important to set up a specific mechanism for monitoring and evaluation of the blood programme. Blood is considered a drug, as per many pharmacopoeias, and hence in those countries the drug control authority would regulate the blood programme.

In most countries, only the plasma industry is regulated by the drug control authority and blood is not considered a drug. In these countries, there is a need to determine mechanisms to accredit the blood centres based on standards

of manufacturing, quality control and assessment as per the technical guidelines provided. The inspectors appointed for the accreditation programme should be trained in transfusion medicine and must have experience of having worked in the blood centre.

There is a need for local, national and global coordinated effort to streamline regulations and explore changes beneficial to the entire transfusion medicine community including recipients of blood.

# 7

## Quality Management in Blood Transfusion Service

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**Q**UALITY MANAGEMENT in blood transfusion service is concerned with every aspect of transfusion practice and applies to all activities of a blood transfusion service. It involves identification and selection of prospective blood donors, adequate collection of blood, preparation of blood components, quality laboratory testing and ensuring the safest and most appropriate use of blood/blood components.

A simple definition of quality is 'fitness for a purpose'. In a blood transfusion service, the primary goal of quality is 'transfusion of safe unit of blood.' The objective is to ensure availability of a sufficient supply of high quality blood and blood components for transfusion with maximum efficacy and minimum risk to both donors and recipients.

Quality management can be achieved by adopting good manufacturing practice, good laboratory practice, good hospital practice and good clinical approach by establishing a comprehensive and co-ordinated approach of total quality management. All those who are involved in blood transfusion-related activity must be aware of the importance of quality management for its successful implementation. To maintain a high level of performance in most of the laboratory techniques, it is essential to monitor the functioning of reagent, equipment, techniques and procedures in the laboratory.

Good record-keeping and documentation, use of standard operating procedures and laboratory worksheets, and implementation of safety guidelines further improve the quality performance of the services.

Quality management may consist of:
â Quality in procurement (donor, material, reagent)
â Quality in preparation (efficient and effective blood component preparation)
â Quality in design and development (improved techniques and procedures)
â Quality in supply (transportation and service)

Quality management system includes:

- (1) Quality planning
- (2) Quality assurance and quality control

## 7.1 QUALITY PLANNING

To create quality consciousness and build an environment that facilitates practices relating to quality, the following steps should be taken:

- (a) The national blood committee should take a lead by formulating a policy statement relating to total commitment to quality. This statement should then be displayed at all blood centres.
- (b) In addition, each blood centre should produce/adapt:
  - â Quality manual and procedures
  - â Standard operating procedures (SOP)
  - â Work instructions
  - â Records

The technical committee should review the legal requirements and frame the guidelines that can help the centres in developing their quality manual. The manual should describe the procedure of implementing quality system and SOP for systemwide operations, such as training, auditing, document preparation and corrective action besides routine work being carried out.

The guidelines for system-specific work should include:

- â policy decisions
- â details of routine procedures in blood centres
- â specifications of all blood products
- â information regarding documentation and record management

- â training of personnel
- â control of material and equipment
- â special procedures.

The regulatory authority should also be involved in the preparation of these guidelines as the same should be acceptable for accreditation/licensing of blood centres.

## **7.2 QUALITY ASSURANCE AND QUALITY CONTROL**

*Quality assurance (QA)* deals with the maintenance of a system to ensure that the performance in a laboratory is of the required quality. In a blood transfusion centre, it means that a management system should exist to look into provision of a safe unit of blood and, if any errors are identified, these should be corrected.

*Quality control (QC)* is the inspection system, which involves specific actions performed to monitor the effectiveness of the system and checks that no mistakes have occurred.

### ***Quality Assurance Programme***

A Quality Assurance Programme is concerned with sampling, specifications and testing as well as with organization, documentation and release procedures that ensure that the necessary and relevant steps have been taken to ensure satisfactory quality.

The accuracy and clinical value of the laboratory analysis of the clinical specimen depends upon a quality assurance programme that

- â assesses the quality of the specimen;
- â documents the validity of the test method;
- â monitors the performance of the test procedures, reagents, instruments and personnel; and
- â reviews test results for errors and clinical relevance.

An effective QA programme is dependent on a continuous process of assessment and improvement. It has two broad components – Internal Quality Control (IQC) and External Quality Assessment (EQA)

### ***Internal Quality Control (IQC)***

Internal quality control is the set of procedures undertaken by the staff of a laboratory for continuously and concurrently assessing laboratory work and the emergent results, to decide whether they are reliable enough to be released. It is meant to allow laboratory technicians to check their own performance and help them to monitor the reliability of their technique.

**IQC includes procedures designed for continuous evaluation of the work of the laboratory concerned and it aims at achieving high level of safety and efficiency.**

### ***External Quality Assessment (EQA)***

External quality assessment, which was earlier known as proficiency testing, refers to a system of objectively assessing the laboratory performance by an outside agency. EQA is a system whereby a set of reagents and techniques are assessed by an external source and the results of the testing laboratory are compared with those of an approved reference laboratory.

The main objective of external quality assessment is to establish inter-laboratory compatibility. This will influence the reliability of future testing. In contrast, the main objective of internal quality control is to ensure day-to-day consistency. Hence, both internal quality control and external quality assessment are complementary in ensuring the reliability of procedures, their results and, finally, the quality of the product.

### ***Standard Operating Procedure (SOPs)***

Each blood bank must have written SOPs for each procedure to prevent errors which may arise from verbal communication only.

It should provide a complete set of instructions to perform a certain task and contain accurate written description of the procedure. It should also specify the way one should perform the assay in the laboratory within its constraints and limitations. The manufacturer's instructions should also be incorporated in the SOP.

### ***Laboratory Record Documentation and Maintenance***

Blood transfusion service should develop and maintain documents for achievement of specified quality standards. Documentation enables one to trace prospectively and retrospectively every step in all procedures that are necessary for monitoring the techniques, component preparation, laboratory testing, etc.

Records and documents help to identify the possible sources of error. Recording of the assay results is important to ensure that the right results are linked to the right sample. A sequence of events can be followed from collection of a unit, passing through all the processes till it is issued, by checking all the necessary documentation.

### ***Laboratory Worksheet***

The results of manually performed assays should be recorded carefully in a format that expresses the results in a clear and understandable way, i.e. as the laboratory worksheet. At the end of a particular procedure or test, the correctly completed worksheet can be used as a quality statement.

Worksheet gives a clear plan of investigation and helps in organized sample dispensing. It can also act as a permanent detailed record of the test performed and the readings.

### ***Quality Monitoring and Quality Audit***

A regular quality monitoring is essential to ensure that a full quality assurance system has been implemented and is effective.

The purpose of quality monitoring is to check the integrity of the QA programme. For example, during screening for viral markers, data other than just the final screening results must be recorded. If during quality monitoring, problems are identified, they must be resolved as soon as possible. A follow-up audit is required later to ensure that changes have actually been incorporated.

**To improve the quality it is necessary to build quality consciousness among all employees through appropriate training in total quality management. It will also necessitate familiarising all categories of staff with quality system through introduction of special lectures and short courses in total quality management.**

Audit is a management tool for monitoring the quality assurance system. It is essential to set up audit teams to ensure compliance. Preferably, the national or regional/provincial blood committee should set up an audit team. A feedback should be given to all centres after the exercise of external quality assessment is carried out.

National and state directorates as well as all blood centres should be committed to quality and continuous quality improvements—a commitment that cannot be abrogated.

# 8

## Capacity Building and Resource Mobilization

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**A**N ESSENTIAL component of the organization and its efficient functioning will depend upon the availability of resources, both human and non-human. For efficient management of blood transfusion services and ensuring safety of blood supply, availability of adequately trained manpower and of infrastructural facilities, including supplies and equipment, is essential.

### 8.1 HUMAN RESOURCE DEVELOPMENT

Lack of manpower is often one of the major constraints in the development and strengthening of blood transfusion services. This in part is due to the lack of training opportunities, and

the lack of defined career structures and clearly defined job descriptions for the professionals in transfusion medicine. Appropriate training programmes will help to meet manpower requirements, and in the development of skills leading to improved career prospects.

Planning training programmes and refresher courses for all categories of health workers presently working in blood centres is also of great importance. Participation in periodic CME programmes and symposia would, in addition, help workers keep abreast with the latest developments, bring uniformity in operations and update their knowledge and impart appropriate skills. In order to avail of the training facilities within the Region and to have an exchange of experiences, a mechanism for information sharing and intercountry collaboration should be developed by facilitating study tours and fellowships.

***Why training in transfusion medicine is important?***

â	Transfusion practices are becoming increasingly complex
â	Blood donations are inadequate to meet the needs in some countries
â	Rapid technological advances in transfusion medicine necessitate continued training
â	Strong interrelationship is required with several other disciplines
â	Capacity building in terms of additional trained staff is required to ensure blood safety

While there is a need for all types of trained personnel for raising the standard of transfusion services, urgency for the medical experts who have to play the pivotal role in development of BTS, cannot be overemphasized. This can be achieved by conducting short-term orientation courses for medical staff already working in this area and by starting a postgraduate degree course (M.D.) in Transfusion Medicine. The leadership for the programme can only be provided by medical experts, including postgraduate specialists who could train various categories of blood transfusion workers, manage the blood transfusion centre as director, and play a key role in formulating and promoting national and local-level policies regarding blood transfusion.

Provision should also be made for a special Ph.D. course, both for medical as well as basic scientists to specialize in the subject. Such a course would especially provide opportunities for career promotion to non-medical scientists who render invaluable service for research and development.

Technologist training would include B.Sc./M.Sc. technology in Transfusion Medicine. These courses would train workers who would be entrusted with the responsibility of management, financial and administrative aspects of blood centre operations. This group will also help in the development of appropriate educational and donor motivational material. In addition, a certificate course for donor recruiters and social workers will also equip them with skills in public relations, recruitment of donors, donor room procedures and organization of blood donation camps.

Other staff requiring training includes nursing staff, donor room assistants, drug inspectors, computer assistants and clinical residents.

## **8.2 INFRASTRUCTURE/MATERIAL SUPPORT**

Appropriate buildings and facilities are required so that the national blood programme can function effectively. Each blood centre requires adequate, planned sites providing the desired environmental setup. Provision of necessary equipment, consumables, and laboratory reagents at various blood centres is important to fulfil the essential requirements for processing and screening of blood and blood components with effective quality assurance

### ***Equipment and Related Supplies***

All equipment needed, whether indigenous or imported, should be made available. These should be procured according to correct specifications. Necessary accessories and spares should be ordered at the time of initial purchase.

The number and specifications of any equipment being ordered must be needbased. Unless the requirement is properly assessed, it is likely that the equipment which is ordered may remain unused leading to unnecessary diversion of scarce resources. Centralized purchase through a technical committee may help in reviewing specifications and costs

The equipment should be calibrated after installation and checked regularly during use. For troublefree maintenance, it

is necessary to ensure the availability of spares and a service contract from the supplier to avoid the equipment remaining idle. A penalty clause applied in service contract in the event of failure to maintain continuous working of instrument may prevent prolonged breakdown.

### ***Reagents and Consumables***

A national institute dealing with biologicals that could be a part of the regulatory body, should control validity of the material in use, including test kits. These institutes should be designated to evaluate the kits before distribution to various testing centres.

Approved quality control specifications and approved or certified suppliers' list should be made available to all centres for purchase. A record of receipt of all material, including the name of the manufacturer, batch number, manufacturing and expiry date, type and quantity of the material and the date of receipt should be documented. The centres should also maintain a check on the material to assure that it complies with requirements of good manufacturing practice. Any material showing deviation or discrepancy in the quality should be rejected, and steps should be taken to avoid its use. A record of material issued for use and rejected should be maintained.

All equipment, consumables and reagents should be purchased preferably from ISO 9000 accredited manufacturers

An HIV test kit bulk purchase programme has been established by WHO in collaboration with UNAIDS in order

to provide national AIDS control programmes with tests which give the most accurate result at the lowest possible cost. The list of HIV test kits is updated annually. Tests other than those purchased under the bulk purchase programme, but meeting the maximum standards in terms of sensitivity and specificity are also suitable for use according to the testing strategies. Whenever possible, facilities for screening other appropriate transfusion-transmitted infections should be made available i.e., Hepatitis C.

### **8.3 FINANCIAL RESOURCES**

A careful planning of budget is necessary for adequate financial support for academic, research and service components. The limited resources necessitate optimising the cost of delivering quality service. Therefore it is important to carry out a cost analysis for BTS which will help in the planning of a budget. This analysis will justify the funding and help in evaluating and monitoring cost effectiveness.

Funding of the BTS system is ultimately the responsibility of the national authorities regardless of the method of implementation of the blood programme. Nongovernmental organizations, such as Red Cross, must also be supported with funds so that they can carry out their functions within the framework of the national blood transfusion programme. Where possible, cost recovery or cost sharing strategies should be implemented to lighten the burden on the government.

For carrying out cost analysis and budget requirements, data must be available for cost indicators. The broad

categories for which costs could be itemised include costs of organizing blood donation campaigns, including material development and printing; collection, storage and processing of blood units; cost of testing and screening of blood; and distribution and transportation charges. Other costs would include managing the programme at national, state and local levels; staff salaries; costs of training health care workers and blood transfusion personnel; office supplies and equipment; maintenance of a quality assurance programme; and support for research and development in the area of blood transfusion services. These resources will be crucial to ensure that blood which is transfused is safe.

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## Annex 1

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## Annex 2

# AIDE-MEMOIRE

## *for National Blood Programmes*

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A well-organized blood transfusion service (BTS) is a prerequisite for the safe and effective use of blood and blood products.

The HIV/AIDS pandemic has focussed particular attention on the importance of preventing transfusion-transmitted infections (TTIs). Between 5% and 10% of HIV infections worldwide are transmitted through the transfusion of contaminated blood and blood products. Many more recipients of blood products are infected by hepatitis B and C viruses, syphilis and other infectious agents, such as Chagas disease.

Transfusion-transmitted infections can be eliminated or substantially reduced through an integrated strategy for blood safety which includes:

- â Establishment of a blood transfusion service
- â Collection of blood only from voluntary non-remunerated blood donors from low-risk populations
- â Screening of all donated blood for transfusion-transmissible infections including HIV, hepatitis viruses, syphilis and other infectious agents

- â Reduction in unnecessary transfusions through the effective clinical use of blood, including the use of simple alternatives to transfusion (crystalloids and colloids), wherever possible.

## **KEY ELEMENTS**

### ***Establish a blood transfusion service***

It is the responsibility of governments to ensure a safe and adequate supply of blood. This responsibility may be delegated to a Non-profit non-government organization, but the BTS should be developed within the framework of the country's health care infrastructure.

The BTS requires government commitment and support and recognition as a separate unit with an adequate budget, management team and trained staff.

Important activities in establishing a blood transfusion service include:

- â Formalization of government commitment and support
- â Development of a national blood policy and plan
- â Development of necessary legislation/regulation for the BTS
- â Formation of an organization with responsibility and authority for the BTS
- â Formation of a BTS management committee
- â Appointment of a medical director

- â Appointment of a quality manager
- â Appointment, when necessary, of specialist BTS advisory groups
- â Appointment and training of staff experienced in each key aspect of the BTS
- â Development and implementation of a budgeting and finance system to ensure a sustainable blood programme through cost recovery and/or annual budget allocation
- â Establishment of national quality system, including guidelines, standard operating procedures (SOPs), accurate records, monitoring and evaluation.

***Educate, motivate, recruit and retain low -risk blood donors***

High priority should be given to the elimination of family/replacement and paid blood donor systems, which are associated with a significantly higher prevalence of TTIs. Voluntary non-remunerated blood donors from low-risk populations who give blood regularly are the foundation of a safe and adequate blood supply.

Important activities include:

- â Appointment of an officer responsible for the national blood donor programme
- â Establishment of a BTS unit responsible for donor education, motivation, recruitment and retention
- â Appointment of a designated blood donor recruitment officer

- â Preparation of SOPs in accordance with BTS guidelines
- â Training of staff in the blood donor unit
- â Identification of donor populations at low risk for TTIs
- â Development of educational materials
- â Establishment of a register of voluntary non-remunerated blood donors
- â Assurance of safe blood collection procedures, including donor selection and deferral, donor care and confidentiality
- â Donor notification and referral for counselling
- â Monitoring of TTIs in the donor population.

### ***Screen all donated blood for infectious agents***

The BTS should develop and maintain a national strategy for the screening of donated blood and blood products for TTIs, using the most appropriate and effective tests, and for good laboratory practice in all areas of blood grouping, compatibility testing, component preparation, storage and transportation of blood products.

Important activities include:

- â Appointment of a designated technical officer
- â Development of protocols for the testing, selection and evaluation of appropriate screening assays to be used at each site
- â Training of BTS laboratory technical staff

- â Screening of all donated blood for TTIs, including HIV, hepatitis viruses, syphilis and other infectious agents, such as Chagas disease
- â Good laboratory practice, including the preparation of SOPs in accordance with BTS guidelines
- â Procurement, supply, central storage and distribution of reagents and materials to ensure continuity in screening at all sites
- â Maintenance of an effective blood cold chain for the storage and transportation of blood and blood products.

***Reduce unnecessary transfusions by effective clinical use of blood***

Blood transfusion has the potential for acute or delayed complications and the transmission of infection. The risks associated with transfusion can be reduced by minimizing unnecessary transfusions through the effective clinical use of blood and blood products and the appropriate use of simple alternatives to transfusion which are safer and more cost effective.

Important activities include:

- â Development of a national policy and guidelines on the clinical use of blood
- â Training in the clinical use of blood for all clinicians involved in the transfusion process and for BTS staff
- â Commitment to the prevention, early diagnosis and treatment of conditions that could result in the need for

transfusion (obstetrical complications, trauma and other causes of anaemia)

- â Availability of intravenous replacement fluids (crystalloids and colloids) for the correction of hypovolaemia, and pharmaceuticals and devices to minimize the need for blood
- â Effective clinical use of blood and blood products in accordance with national guidelines
- â Monitoring and evaluation of the clinical use of blood.

### **Words of Advice**

- â Secure government commitment and support for the national blood programme
- â Establish a blood transfusion service as a separate unit with responsibility and authority, an adequate budget, a management team and trained staff
- â Educate, motivate, recruit and retain voluntary non remunerated blood donors from lowrisk populations
- â Screen all donated blood for HIV and other transfusion Transmissible agents and ensure good laboratory practice in blood grouping, compatibility testing component preparation and the storage and transportation of blood products
- â Reduce unnecessary transfusions through the effective clinical use of blood, including alternatives to transfusion
- â Establish a quality system for the BTS
- â Train all BTS and clinical staff to ensure the provision of safe blood and its effective clinical use



## CHECKLIST

### ***Blood Transfusion Service***

- q Government commitment and support
- q National blood policy/plan
- q Legislation/regulation
- q Organization with responsibility and authority for the BTS
- q BTS management committee
- q BTS medical director
- q BTS quality manager
- q Specialist BTS advisory groups
- q Trained BTS administrative and technical staff
- q Adequate budget
- q National quality system

### ***Blood Donors***

- q National blood donor programme officer
- q Blood donor unit
- q Blood donor recruitment officer
- q Standard operating procedures
- q Training of staff in blood donor unit
- q Low-risk donor populations

- q Educational materials
- q Register of voluntary non-remunerated blood donors
- q Donor selection, deferral, care and confidentiality
- q Donor notification and referral
- q Monitoring of TTIs

### ***Blood Screening***

- q Technical officer
- q Screening strategies and protocols
- q Training of laboratory technical staff
- q Screening of all donated blood for TTIs
- q Good laboratory practice, including standard operating procedures
- q Continuity in screening
- q Effective blood cold chain

### ***Clinical Use of Blood***

- q National policy and guidelines on the clinical use
- q Training of clinicians and BTS staff
- q Prevention, early diagnosis and treatment
- q Alternatives to transfusion (crystalloids and colloids)
- q Effective clinical use of blood
- q Monitoring and evaluation