

**FEDERAL DEMOCRATIC REPUBLIC
OF ETHIOPIA**

MINISTRY OF HEALTH



**NATIONAL BLOOD
TRANSFUSION SERVICES
STRATEGY**

February 2005
Addis Ababa
Ethiopia

Acknowledgement

The Ministry of Health of the Federal Democratic Republic of Ethiopia would like to acknowledge the technical support of the Ethiopian Red Cross Society, the Ethiopian Health and Nutrition Research Institute, Addis Ababa University Faculty of Medicine, World Health Organization – Geneva, AFRO and Country Office, and Centers for Disease Control and Prevention (CDC) – Ethiopia for the preparation and finalization of this National Blood Transfusion Service Strategy.

We are grateful to the WHO Country Office for the financial support provided to the MOH to organize blood transfusion service strategy workshop and for covering the printing expenses of this strategy.

Finally, the Ministry would like to thank members of the Health Services and Training Department and Health Services Team for their valuable contribution to the preparation of this document and for the efforts made to coordinate all stakeholders to finalize this Blood Transfusion Service Strategy.

ACRONYMS

<i>AIDS</i>	=	<i>Acquired Immuno-Deficiency Syndrome</i>
<i>BB</i>	=	<i>Blood Bank</i>
<i>BTS</i>	=	<i>Blood Transfusion Services</i>
<i>ERCS</i>	=	<i>Ethiopian Red Cross Society</i>
<i>HFBB</i>	=	<i>Health Facility-Based Blood Bank</i>
<i>HBV</i>	=	<i>Hepatitis B Virus</i>
<i>HIV</i>	=	<i>Human Immune Deficiency Virus</i>
<i>HMIS</i>	=	<i>Health Management Information System</i>
<i>ISBT</i>	=	<i>International Society of Blood Transfusion</i>
<i>MOH</i>	=	<i>Ministry Of Health</i>
<i>RBB</i>	=	<i>Regional Blood Bank</i>
<i>RHB</i>	=	<i>Regional Health Bureau</i>
<i>SOP</i>	=	<i>Standard Operating Procedures</i>
<i>TTLs</i>	=	<i>Transfusion Transmissible Infections</i>

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I. INTRODUCTION

Ethiopia is one of the developing countries in Africa, and 85% of its population lives in rural settlements with the major economic activity being subsistence farming. The National Health Service coverage is low (61.3%) and is compounded by poor quality of service. The number of health facilities and ratio of health personnel to population are still very low. An estimated 60-80 percent of health problems are due to communicable diseases and nutritional deficiencies. Life expectancy at birth is relatively low at 54 years and is further expected to decline to 46.5 years if present HIV infections rates are not maintained. Maternal, Infant and under 5 mortality rates are still high (850/100,000, 97/1000 and 140/1000 live births respectively). Currently the epidemic of HIV is becoming one of serious social, economic and public health problems in the country.

The World Health Organization estimates that 5-10 % of all HIV transmissions are attributable to unsafe blood transfusions. Transmission of HIV and other blood-borne pathogens via blood transfusion is preventable by establishing an adequate supply of safe blood through a systematized BTS and minimizing unnecessary transfusion. In the era of HIV/AIDS, it is crucial that all donated blood should be screened for HIV as well as the other transfusion-transmitted infections such as Hepatitis B, Hepatitis C, and syphilis before they are used.

The ERCS blood banks and Government Hospital based blood transfusion services in Ethiopia rely on family and replacement donors, and because of resource constraints

and lack of clear blood services strategy, the blood transfusion services encountered a serious challenge to reach to the expected standard.

The Ethiopian Red Cross Society has been the pioneer organization in developing blood banking services in the country. The first blood transfusion center was established in 1969. The service has since expanded into a network covering some major hospitals in the country. However, the Ethiopian Red Cross Blood Bank can only meet part of the country's blood demand.

Safe blood comes from safe voluntary non-remunerated blood donors. Research done in several countries has proved that blood collected from voluntary non-remunerated donors is much safer than blood collected from paid or replacement donors.

Although the efforts of the ERCS Blood Bank in recruiting voluntary regular donors and standardization of the quality of service is encouraging, much needs to be done to develop the same excellence in the Regions.

The emergence of transfusion transmissible diseases, of which HIV is prominent, has been a challenge in the preparation of safe blood & blood products. Accordingly, the World Health Assembly, the International Federation of Red Cross and Red Crescent Societies and the International Society of Blood Transfusion, having recognized the need, have urged member states to enact effective legislative policies governing operations of blood transfusion services.

In response to this challenge, the Government of the Federal Democratic Republic of Ethiopia Ministry of Health therefore,

Realizing the huge demand for safe blood and blood products in health institutions,

Understanding the role of blood centers in the prevention of transfusion transmissible diseases,

Aware of the need to establish a national blood transfusion safety program,

Aware of the need to mobilize voluntary non-remunerated blood donors,

Considering the need to standardize the quality of service provided by blood transfusion centers,

And

Recognizing the need to strengthen and expand the service to the regions,

Hereby, demonstrates its commitment to the provision of safe and adequate blood and blood products, and has issued as part of its overall health policy this national blood transfusion services strategy.

In this strategy,

Safe blood means blood that is free from transfusion transmissible diseases, drugs, alcohol, chemical substances, or other extraneous factors that might cause harm or danger to the recipient.

Voluntary non-remunerated donation means free donation of blood by volunteers out of humanitarian concern.

Replacement donation means donation of blood for relatives or friends to replace blood used from blood bank stocks.

Paid donors are donors who are paid or remunerated otherwise for their donation.

Quality assurance means a process through which the quality of blood transfusion services is checked continually

II. SCOPE OF THE STRATEGY

1. Establishment of a nationally coordinated blood transfusion services (NBTS)
2. Recruitment and retention of voluntary non-remunerated blood donors and blood collection
3. Testing of blood and blood products for transfusion transmissible infections (TTIs) and appropriate blood grouping and compatibility.
4. Promotion of appropriate use of blood and blood products in a safe manner.
5. Comprehensive quality management system to cover the entire transfusion process
6. Establishment of data management and monitoring and evaluation system for NBTS

7. Collaboration with national and international partners supporting the service.

III. THE GOAL OF BLOOD TRANSFUSION SERVICES STRATEGY

The goal of the Ministry of Health regarding blood safety is to ensure a comprehensive national blood transfusion service that:

1. Ensures the provision of safe and adequate blood and blood products
2. Ensures the appropriate use of blood and blood products.
3. Expands access to blood transfusion service
4. Ensures sustainability and cost-effectiveness of blood transfusion service

IV. PRIORITY INTERVENTION AREAS

1. Create and sustain awareness on blood transfusion service.
2. Promote voluntary non-remunerated blood donation
3. Strengthen existing and establish new RBBs & HFBBBs at different levels.
4. Develop and mobilize human and financial resources for blood transfusion service
5. Implement quality assurance standards at all levels
6. Design and implement management information system
7. Undertake operational research

V. MAJOR COMPONENTS OF THE BLOOD TRANSFUSION SERVICES STRATEGY

1. Ensure professional ethics in transfusion services
 - 1.1 The safety of blood donors and recipients shall be given at most consideration.
 - 1.2 Standard operational procedures (SOP) shall be prepared and adherence to these SOP shall be ensured at all times in all blood transfusion centers.
 - 1.3 All Blood shall be screened for transfusion transmissible diseases before it is issued for transfusion.
 - 1.4 Strict safety measures shall be taken in the collection processing, preserving and issuing of blood and blood products to protect health personnel, donors and recipients.
 - 1.5 All aspects of blood donation including donor laboratory results shall be confidential.
 - 1.6 All other ethical issues adopted by the ISBT (Annex I) shall be ensured in all blood transfusion centers.

2. Enacting legislation pertinent to BTS
 - 2.1 Appropriate legislation and guideline shall be enacted to safeguard the donor, recipient and to ensure quality of blood transfusion services.

3. Voluntary non-remunerated blood donor program
 - 3.1 The blood units collected every year should be based on the patients' needs and the level of health care service.
 - 3.2 Voluntary non-remunerated blood donors shall be recruited from low risk population groups in all blood centers.
 - 3.3 More focus shall be given to students and youth associations in order to strengthen the donor base and retain long time donors.
 - 3.4 Due recognition and appreciation shall be given to regular voluntary non-remunerated blood donors for their humanitarian act.
 - 3.5 Replacement donation shall be discouraged and gradually be replaced with voluntary donation
 - 3.6 The establishment of blood donor associations shall be encouraged in each region.
 - 3.7 Blood donor association representatives shall be encouraged to participate in the planning and decision-making process of the blood transfusion services.
 - 3.8 The community at large will be mobilized and participate actively in recruitment and retention of voluntary blood donors using different mechanisms such as the mass media, forms of youth associations, women's associations, blood donor clubs, professional associations, and community forums.
 - 3.9 Donor recruitment and retention guideline will be developed.

4. Screening Blood and Blood Products for Transfusion transmissible diseases.
 - 4.1 All blood shall be screened for transfusion transmissible diseases such as HIV, Syphilis and Hepatitis.
 - 4.2 More reliable and cost effective tests shall be introduced in blood transfusion centers.
 - 4.3 Laboratory safety procedures shall be ensured in all blood centers.

5. Developing and implementing SOP for each step of blood transfusion service
 - 5.1 SOP shall be developed for every activity of the blood transfusion service.
 - 5.2 Adherence to SOP shall be ensured in blood centers.
 - 5.3 SOP shall be revised regularly based on new scientific findings.

6. Establishing QA system in the NBTS
 - 6.1 Quality assurance system shall be established in the NBTS.
 - 6.2 The quality of service of each unit in the BTS shall be checked regularly
 - 6.3 Appropriate measures shall be taken based on the findings of quality check
 - 6.4 MOH will ensure the quality of BTS through establishing QA systems (internal and external) at national and regional level.

- 6.5 Regular review of all the activities to assess the overall effectiveness of the quality system shall be done to ensure continuous improvement.
 - 6.6 QA system will include all elements of quality according to WHO recommendations including organizational management, national standards for quality system, training, documentation and ongoing assessment.
7. Establish national blood data management and monitoring and evaluation system for NBTS
 - 7.1 MOH shall be responsible for the design of blood data management and monitoring and evaluation system as part of the national HMIS.
 - 7.2 MOH shall develop indicators for monitoring and evaluating the NBTS.
 - 7.3 Standard formats shall be applied for recording and reporting BTS activities
 - 7.4 Blood banks and hospitals shall establish reporting mechanisms to jointly monitor utilization of blood and blood products.
 - 7.5 Regular reporting and information exchange system shall be established between the HFBB, RBB, the NBTS and the MOH.
 8. Establish new and strengthen existing blood banks

Existing blood banks shall be strengthened with the necessary equipment and human resources.

New blood banks shall be established at appropriate locations in the country.

Training shall be given to blood bank personnel to upgrade their skill and to acquaint them with new scientific techniques and findings.

Cost effective utilization of resources shall be ensured in all blood centers.

Measures shall be taken to ensure the availability of necessary resources in blood centers.

External support shall be mobilized as needed to strengthen the blood transfusion service.

9. Conduct research on blood transfusion service

9.1 The activities of the NBTS shall be supported by relevant research.

9.2 Priority shall be accorded to research that contributes towards service quality improvement.

VI. INSTITUTIONAL ARRANGEMENT

The national BTS plans for the recruitment and retention of voluntary blood donors, ensures that all activities in all the blood banks are done according to standard operational procedures, facilitates procurement of equipment and supplies, recruits BTS staff and provides technical support to RBBs and HFBBs. The National Blood Center will serve the whole country (71.07 million).

The RBBs ensure a safe, stable and cost-effective supply of blood and blood products and assist health facilities in their appropriate use of blood. RBBs will plan regional blood transfusion service activities and supervise HFBBs. One RBB serves about to 2-3 million people.

The HFBBs are located in health facilities such as hospitals and health centers that undertake surgery and obstetrics. Each HFBB will serve 25,000 (Health Center) to one million (Zonal Hospital) population depending on the catchment's population. The role of HFBBs is to provide readily available blood and blood products in adequate amounts and of suitable quality. To this end they must recruit donors, establish blood donor panels and arrange blood collecting programs.

- 1 The MOH will be responsible for regulating the delivery, access and quality of blood transfusion services.
- 2 The MOH shall continue providing all necessary support to ERCS to operate the NBTS in the interim.

- 3 The RHB are responsible for the sustainability and monitoring of the quality of service given by blood banks in their respective areas.
- 4 National Blood Transfusion Advisory Committee shall be established. This committee functions as an advisory body for MOH & the NBTS. The committee shall constitute members from relevant stakeholders and would advise MOH and NBTS on strategic issues.
- 5 Health facility transfusion committees shall be established to ensure the appropriate use of blood and blood products.

VII. IMPLEMENTATION OF THE NBTS STRATEGY

- 1 This blood transfusion services strategy may be amended as needed.
- 2 This strategy shall enter into force starting from February 2005.

Ministry of Health
February 2005
Addis Ababa

ANNEX I

ETHICAL ISSUES FOR BLOOD DONATION AND TRANSFUSION as adopted by the General Assembly of the International Society of Blood Transfusion (ISBT), 12 July 2000

The object of this principle is to define the ethical issues and rules to be observed in the field of transfusion medicine.

1. Blood donation including hematopoietic tissues for transplantation shall, in all circumstances be voluntary and non-remunerated; no coercion should be brought to bear upon the donor. The donor should provide informed consent to the donation of blood or blood components and to the subsequent (legitimate) use of the blood by the transfusion service.
2. Patients should be informed of the known risks and benefits of blood transfusion and/or alternative therapies and have the right to accept or refuse the procedure. Any valid advance directive should be respected.
3. In the event that the patient is unable to give prior informed consent, the basis for treatment must be in the best interest of the patient.
4. A profit motive shouldn't be the basis for the establishment and running of a blood service.

5. The donor should be advised of the risks connected with the procedure; the donor's health and safety must be protected. Any procedures relating to the administration to a donor of any substance for increasing the concentration of specific blood components should be in compliance with internationally accepted standards.
6. Anonymity between donor and recipient must be ensured except in special situations and the confidentiality of donor information assured.
7. The donor should understand the risks to others of donating infected blood and his or her ethical responsibility to the patient.
8. Blood donation must be based on regularly reviewed medical selection criteria and not entail discrimination of any kind, including gender, race, nationality or religion. Neither donor nor potential recipient has the right to require that any such discrimination be practiced.
9. Blood must be collected under the overall responsibility of a suitably qualified, registered medical practitioner.
10. All matters related to whole blood donation and hemapheresis should be in compliance with appropriately defined and internationally accepted standards.

11. Donors and recipients should be informed if they have been harmed.
12. Transfusion therapy must be given under the overall responsibility of a registered medical practitioner.
13. Genuine clinical need should be the only basis for transfusion therapy.
14. There should be no financial incentive to prescribe a blood transfusion.
15. Blood is a public resource and access should not be restricted.
16. As far as possible the patient should receive only those particular components (cells, plasma, or plasma derivatives) that are clinically appropriate and afford optimal safety.
17. Wastage should be avoided in order to safeguard the interests of all potential recipients and the donor.
18. Blood transfusion practices established by national or international health bodies and other agencies competent and authorized to do so should be in compliance with these principles of ethics.

ANNEX II

Governing Principles of the National Blood Transfusion Service

The following articles shall govern blood transfusion services in Ethiopia:

Article 1:

There shall be an established National Blood Transfusion Service

Article 2:

Blood and its products must be used under medical supervision strictly for medical therapeutics.

Article 3:

Blood and its products must be collected from a donor:

- a) With his/her free and conscious consent
- b) By or under the direction and responsibility of a qualified health worker
- c) Without compensation.

Article 4:

Any healthy person aged from 18-65 and weighing not less than 45 kilograms may become a donor.

Article 5:

Blood Transfusion Center shall effect the collection, processing, preservation and distribution of blood and blood products.

Article 6:

Blood and blood products shall be preserved under the supervision of a registered and trained medical doctor or a blood transfusion specialist.

Article 7:

The actual cost of processing, analyzing or preserving blood and blood components (products) shall be recoverable and shall not occasion any profit.

Article 8:

The MOH shall set and enforce standards on blood transfusion services.