



MINISTRY OF HEALTH

**POLICY GUIDELINES
ON
BLOOD TRANSFUSION
IN KENYA**

**THE NATIONAL BLOOD
TRANSFUSION SERVICE OF KENYA**

NOVEMBER, 2001

TABLE OF CONTENTS

FOREWORD	(ii)
PREFACE	(iii)
ACKNOWLEDGEMENTS	(iv)
INTRODUCTION	1
SITUATION ANALYSIS	2
POLICY STATEMENT	3
Goal	3
Strategies	3
GENERAL RULES AND GUIDELINES	5
THE NATIONAL BLOOD TRANSFUSION SERVICE (NBTS)...	6
Institutional Framework and Organisation of the NBTS.....	6
The National Blood Transfusion Board.....	
Functions of the Board	
The National Blood Transfusion Centre	
Regional Blood Transfusion Centre	
Satellite Centre/District and Primary Hosp	
Financing of the NBTS.....	12
Legislation	12
GUIDELINES.....	13
Blood Donor	13
Recipient	14
Laboratory Testing of Donated Blood	16

FOREWORD

It is with great pride and privilege that I introduce Kenya's first ever blood safety policy.

The Government of Kenya has long recognised the importance of maintaining a safe and adequate blood supply throughout this country. Kenya is a signatory to the World Health Assembly declaration of 1975 and the Regional Commonwealth Ministers of Health declaration of 1989, two major global blood safety statements supporting the establishment of safe blood transfusion services. Despite Kenya's support, we have been unable to sustain the current blood transfusion service due to an increase in the demand for and a diminishing supply of quality blood and blood products.

The Ministry of Health is currently going through a comprehensive health-sector reform to identify priorities and strategies to meet the health demands of this country and has identified blood safety as one such priority. As a result, the MOH has been working to establish a comprehensive system for blood transfusion capable of meeting all the needs of the country.

Adopting a national policy is an important step forward in ensuring the demand for safe blood transfusions is met throughout Kenya. A strong policy ensures the technical excellence of the national blood transfusion service, confirms the commitment of the Government of Kenya, and guides policymakers and implementers in making the new blood service sustainable.

I would like to acknowledge the contributions of the many stakeholders, particularly the technical experts and local and international partners, in the development and adoption on the national policy. We sincerely appreciate their dedication and commitment.

Above all, I would like to thank the thousands of the Kenyans who voluntarily come forward to give their own blood in order to save the lives of other fellow Kenyans.



HON. HUSSEIN MAALIM MOHAMED, E.G.H., M.P.
MINISTER FOR MEDICAL SERVICES

(ii)

PREFACE

Provision of safe and adequate supplies of blood is dependent on a well-organised blood transfusion service, with dedicated, well-trained manpower and resources for the service. As part of the effort by the Ministry of Health to reform the health sector, there will be a reorganisation of departments and divisions within the ministry. The reorganisation of the blood transfusion service is one such consideration and it is our hope that following this change there will be better safer and more efficient provision of blood nation-wide.

Kenya is a signatory to the World Health Assembly Resolution (WHA 28.72 of 1975) which requires each member state to develop a comprehensive, well co-ordinated blood transfusion service, based on voluntary, non-remunerated blood donation. Kenya is also a signatory to the Regional Commonwealth Ministers of Health Resolution of 1989 requiring that each member country make the provision of safe blood to the people a national priority. Although this has not yet been fulfilled, the several recent mass disasters in the country have brought home an intensified commitment by the government to accelerate the process and ensure the implementation of the national plan.

The development of the national policy guidelines is the first step forward. This will guide the country towards better practices in blood transfusion and will assist all the participating institutions to use common, standard, and harmonised guidelines. The Ministry of Health is happy that there is consensus amongst health providers to participate effectively in this regard. A nation-wide, consultative process, followed by a consensus workshop, has led to the development of the policy guidelines. We are happy and grateful to all those who contributed to this effort.



DR. RICHARD MUGA
DIRECTOR OF MEDICAL SERVICES

(iii)

ACKNOWLEDGEMENTS

The development of these policy guidelines has been possible through the efforts of many people and organisations. The Ministry of Health specifically acknowledges the United States Agency for International Development (USAID) for providing funding and Family Health International for facilitating in the preparation of this document.

The Ministry sincerely appreciates Dr. M. S. Abdullah, who acted as the lead consultant throughout this process, for his input and the National Health Research and Development Centre for the logistical support provided throughout this exercise.

We are grateful for the input from various public and non-governmental hospitals, the United Nations, international development partners, professional organisations, religious bodies, individuals, and heads of various other health institutions and for all those who took time to respond to questionnaires or to be interviewed. They have all made invaluable contributions to the preparation of this document. The hard work put in by the national planning committee, who also steered the national consensus workshop and the writer's group, who each wrote various sections and did so in the required time, are all gratefully acknowledged.

Many other people have contributed directly or indirectly to the entire process and while we may not be able to acknowledge each individual, we would like all of them to know that we appreciate their inputs in this exercise.

Finally, we would like to thank the secretarial and support staff who worked hard to ensure that the document was prepared, typed, printed, and bound on time.

INTRODUCTION

Transfusion of blood and its products is an internationally established way of managing patients who are deficient in one or more blood constituents, and is therefore an essential part of healthcare.

The World Health Assembly and the Regional Commonwealth Ministers of Health recommend that their member states develop comprehensive and well co-ordinated blood transfusion services based on voluntary, non-remunerated blood donation (resolution WHA 28.72 of 1972 and resolution of 1989 respectively). Additionally, the International Society of Blood Transfusion and the International Federation of the Red Cross Society have also urged member states to enact effective legislative policies governing operations of blood transfusion and to take any other necessary action to protect and to promote the health of blood donors and recipients.

In recognition of the above recommendations and of the increasing demand for a safe blood supply and blood transfusion service in this country, the Ministry of Health has developed this policy for blood transfusion in Kenya. The policy will serve to ensure the technical excellence of the blood transfusion services, confirm the commitment of the Government of Kenya, and guide policymakers and implementers in making the new blood service sustainable.

SITUATION ANALYSIS

Despite the many improvements and advancements made in health in this country, Kenya continues to exhibit negative trends concerning the health of her people. The population continues to grow at an average rate of 2.9 percent. After years of improvement, life expectancy has recently decreased largely due to the AIDS pandemic. Negative trends are also apparent in both the infant and under-five mortality rates. To a very large extent this is due to the increase in malaria and consequent severe anaemia.

Kenya is also experiencing an ever-increasing demand for blood transfusions that can not be sustained by the blood transfusion services in its present state. While the demand has increased, the supply of blood in Kenya has diminished. This is due to a decrease in donations (the number of donations in 1998 was one tenth of what it was in 1990); a high prevalence of HIV and other blood-borne infections in the populations thereby rendering a large amount of donate blood unsuitable for use; and a decrease in resources and funding allocated to blood transfusion services.

Currently, blood transfusion services (BTS) are hospital-based and run as part of the hospital laboratory services. This arrangement has proved cumbersome to supervise and ensure quality and safety. Additionally, there have been logistics problems in the distribution of reagents and other supplies. Being part of the general laboratory, it has also become difficult to dedicate staff and equipment to BTS.

Running BTS is a costly affair. It is estimated that it costs between Kshs.2,000 and 4,000/= to provide one unit of safe blood in Africa. Because of low health per capital in many countries, BTS have remained grossly under-funded. Kenya is no exception to this. Indeed, the Ministry of Health does not have a dedicated budgetary vote for the services, which have continued to be supported by the general laboratory budget. This has tended to hurt the service at times, when funds are utilised for laboratory services in preference to BTS.

POLICY STATEMENT

The Ministry of Health has identified blood safety as a public health priority in Kenya and has developed the blood safety policy as a major strategy in delivering this service efficiently, efficiently, and safely. The MOH will ensure that the policy is responsive to current needs and issues throughout the country, and that it will continue to respond to emerging issues.

Goal

To provide safe blood whenever it is needed, through creating a strong, efficient, and self-sustaining national blood transfusion service capable of meeting all the needs of the country.

Strategies

Ensure the provision of adequate supplies of safe blood for the whole country.

Ensure that each recipient receives the most appropriate therapy compatible with maximum possible safety.

Ensure that blood and blood products are administered for genuine therapeutic needs only, and with no financial motivation on the part of either the prescriber or the health institution.

Improve and strengthen the procurement, supply, processing, distribution, and surveillance systems for blood transfusion through policy guidelines.

Establish a comprehensive and well co-ordinated National Blood Transfusion Service(NBTS) under the general guidance of the Ministry of Health.

Establish a National Blood Transfusion Management Board, appointed by the Minister of Health, which will have wide representation to advise the NBTS on the running and management of the services.

Define the roles and responsibilities of all stakeholders, who will play their part in ensuring the proper running of the service.

Ensure high standards of operations and safety through appropriate regulatory and supervisory mechanisms.

Provide guidelines for a blood donor recruitment system through public education and advertising. This shall be based on voluntary, non-remunerated, potential blood donors.

Create a self-sustaining financial mechanism that would run the service throughout the country. The government will provide direct funding as well as create an enabling environment for the NBTS to acquire funding from other sources, including local and international development partners and well-wishers. An agreed user fee will also be levied to recover part of the costs of providing safe blood products.

Enact legislation providing a legal framework for the running of the NBTS.

Phase out the current hospital-based blood bank systems and replace them with the new NBTS, which will have a network of regional and zonal blood transfusion centres. These will provide adequate and safe blood, and blood products to all hospitals both public and private, within their catchment areas.

Provide modality for manpower development, training, and retention to satisfy the needs of the service.

Establish a system for data collection and management of blood transfusion, which will form part of the national comprehensive BTS surveillance system.

Ensure active basic, operational, and developmental research into all aspects of blood transfusion.

GENERAL RULES AND GUIDELINES

Blood donation shall in all circumstances be voluntary and non-remunerated. No coercion of any kind shall be brought to bear on the donor. Financial profit must never be a motive either for the donor or for those responsible for collecting the donation.

Blood donation must not entail discrimination of any kind, whether by race, creed, nationality, religion, or otherwise. Whatever their financial resources, all patients must be able to benefit from the administration of human blood or blood products. In some circumstances, a small fee may be charged to administer the blood transfusion. Where applicable, this cost will be used exclusively to recover costs incurred by the blood transfusion centre.

In order to ensure quality blood preservation, blood and blood products must be stored in accordance with temperature, shelf life, and packaging requirements. Additionally, the "cold chain" must be maintained during transport of blood and blood products. Blood provided to hospital wards for transfusion must not be kept at room temperature for more than thirty minutes prior to beginning the transfusion.

The safety of the donor and the recipient is the highest priority, and all processes and procedures must be followed to ensure this safety.

Autologous blood transfusion shall be encouraged wherever possible for elective surgery.

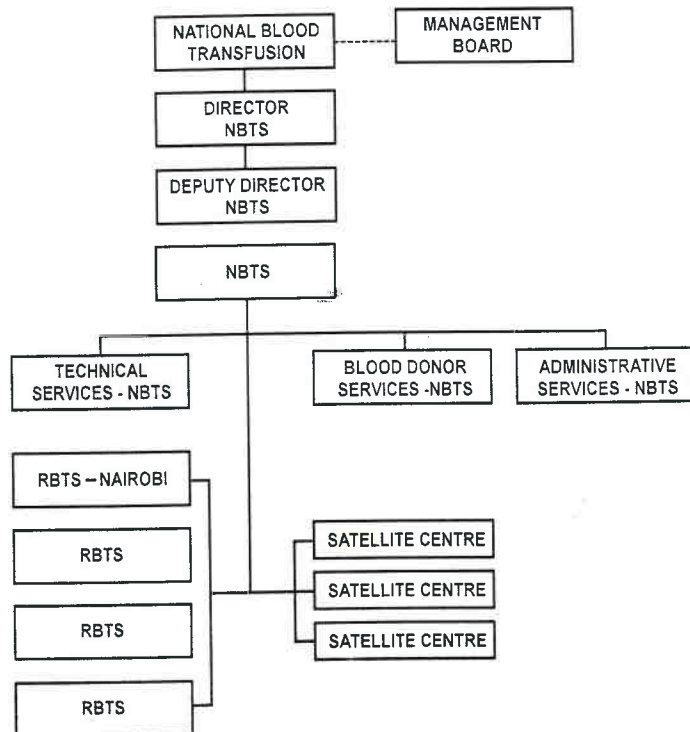
THE NATIONAL BLOOD TRANSFUSION SERVICE (NBTS)

Institutional Framework and Organisation of the NBTS

The NBTS shall operate as a separate and identifiable unit of the National Public Health Laboratories Service (NPHLS). It is proposed that as the service grows, it shall evolve to become independent and semi-autonomous with its own Board of Management, its own secretariat, and its own funding and accounting systems.

The National Blood Transfusion Service shall use a network of regional blood transfusion centres in order to ensure complete coverage throughout Kenya. The regional and satellite centres shall be manned by staff of the NBTS.

Organisation of the National Blood Transfusion Service



The National Blood Transfusion Board

The National Blood Transfusion Board will serve as the management body for the NBTS. Members of the board shall be appointed by the Minister of Health for a renewable term of three years. The composition of the board shall be as follows:

- Chairperson - an independent and prominent Kenyan scientist
- Secretary - Head of NBTC

Members representing the following positions and institutions:

- Permanent Secretary, Ministry of Health
- Director, Medical Services
- Permanent Secretary, Ministry of Finance and Planning
- Permanent Secretary, Ministry of Education
- Permanent Secretary, Ministry of Local Government
- Officer in charge, Office of the President (State Corporations)
- Chief Laboratory Technologist, Ministry of Health
- Secretary General, Kenya Red Cross Society
- Chief Executive Officer, National AIDS Control Council
- Chief Executive Officer, KEMRI
- Representative, Attorney General's Office
- Two private hospital representatives
- Haematologist with knowledge of blood transfusion services
- Clinical specialist
- One regular blood donor representative
- One representative from the business sector
- Two representatives from philanthropic organisations
- One representative from a co-ordinating research organisation

Functions of the Board

- Ensure the realisation of the National Blood Transfusion Service policy objectives within the national health structure.
- Secure government commitment in the articulation, implementation, and evaluation of the national blood transfusion policy.
- Advise and approve the plans and development programmes for the National Blood Transfusion Service appropriate for the country.
- Encourage collaboration between the NBTC and other relevant national and international organisations and professional associations.
- Ensure professional, technical, and administrative excellence in the NBTS.
- Promote pre/in-service education of all NBTS personnel and other health staff on blood transfusion practice, and encourage sharing of information with all end users and members of the public on proper use of the NBTS.
- Audit the National Blood Transfusion Service activities (at least every two years).
- Review the blood policy guidelines regularly to accommodate any new and relevant developments.
- Perform any other tasks as prescribed by the Minister of Health.

The National Blood Transfusion Centre (NBTC)

The National Blood Transfusion Service, as established by the Ministry of Health, shall be entrusted with the responsibility of managing the blood programme through the National Blood Transfusion Centre. The National Blood Transfusion Centre shall be situated in Nairobi.

and will be a distinct and separate unit from the general laboratory functions. The Centre shall house the National Secretariat of the Blood Transfusion Service, in addition to performing blood transfusion functions. It shall be charged with the responsibility of accomplishing the objectives of the national policy on blood transfusion. The Centre shall collaborate with all the relevant stakeholders, including the Kenya Red Cross Society, non-governmental organisations, and the private sector on issues pertaining to blood transfusion and blood supply.

The objective of the NBTC is to ensure adequate and safe supply of blood and products. To achieve this, the centre shall perform the following functions:

- Supervise and monitor all collections, processing, and distribution of blood and its products in the country.
 - Implement the national policies and guidelines regarding blood transfusion in Kenya.
 - Operationalise the services centrally, in the regions, and in the peripherals units.
 - Ensure adequate blood donor requirement and efficient distribution of safe blood wherever it is needed.
 - Collect adequate data, which will guide and improve the services.
- Disseminate appropriate information to all end users, including health care providers, prescribers of blood, the general public, and policymakers.
- Procure, stock, and distribute relevant reagents and supplies needed for collection of blood and blood products.
 - Develop and operate a cost-recovery system as part of the self-financing mechanism.
 - Develop and monitor implementation of standard operating procedures for the entire NBTS.

- Develop and establish organised quality assurance systems for the NBTS.
- Participate in the formulation and implementation of guidelines on appropriate use of blood and blood products.
- Organise and participate in the training and development of manpower nationally and regionally.

Regional Blood Transfusion Centres (RBTC)

Several Regional Blood Transfusion Centres are to be strategically located throughout the country. These centres decentralise the blood transfusion services to more effectively meet the regional needs.

The functions of the Regional Blood Transfusion Centres include the following:

- Implement national policies and guidelines regarding blood transfusion in Kenya.
- Operationalise and supervise the services in the regions and in the peripheral units.
- Collect adequate data, which will guide and improve the services.
- Disseminate appropriate information to all end users, including health care provider prescribers of blood, the general public, and policymakers.
- Participate in the cost-recovery system as part of the self-financing mechanism.
- Monitor implementation of standard operating procedures in the districts.
- Implement quality assurance systems developed by the NBTS.
- Participate in the training and development of manpower in the regions.

- Participate in the standardisation of techniques and procedures.
- Co-ordinate activities between the National Blood Transfusion Centre and the district and primary hospital blood banks.
- Ensure adequate blood donor recruitment and efficient distribution of safe blood in the regions.
- Monitor and co-ordinate recruitment of donors and collection of blood from blood donors in the regions.
- Ensure maximum health standards and safety at the transfusion points in the regions.
- Supervise implementation of guidelines on appropriate use of blood and blood products in the districts.
- Assist and participate in research and publication in blood transfusion practice.

Satellite Centres/District and Primary Hospital Blood Banks

The satellite centres and district and primary hospital blood banks shall be established under the directions of the National Blood Transfusion Centre and regional centres. The functions are as follows:

- Participate in the cost recovery system as part of the self-financing mechanism.
- Supervise implementation of guidelines on the appropriate use of blood and blood products in the wards.

Financing of the NBTS

The National Blood Transfusion Service will be a non-profit, semi-autonomous service, providing organisation. Initial start-up capital from the government will be required. The NBTS is, however, expected to be self-sustaining. The Board will identify sources of funds for the running of the NBTS. Such sources may be from:

- Subventions from the Treasury
- Operation of a cost recovery scheme
- Medical insurance schemes
- Private organisations and individuals
- External sources
- Marketing of products

Legislation

In support of the World Health Organisation recommendations and as a result of this policy, the Government of Kenya will enact legislation to address the collection, processing, preservation, distribution, supply of blood and blood products, and approve the policy on blood transfusion in Kenya.

GUIDELINES

The following guidelines serve to supplement the policy regulations outlined above, and provide specific guidance on requirements for blood donation, testing, storage and transfusion.

Blood Donor

- Any healthy person between 16-65 years of age(inclusive), may become a blood donor. However, blood can be collected from fit, regular blood donors who are above the age of 65 years. Where it is necessary to request blood donation from some below the age of 18 prior consent shall be obtained from parents or guardians. Donors above the age of 65 must be thoroughly examined by competent physicians with good knowledge of blood transfusion procedures.
- Fifty kilograms (50 kg) body weight shall be the minimum acceptable weight for a blood donor; blood donors weighing between 45 kg -50 kg may, in exceptional circumstances, be allowed donate blood at the discretion of the medical officer.
- The volume of blood collected from a donor shall not exceed 500 ml per visit.
- The blood haemoglobin level accepted for blood donation shall be a minimum of 12.5 g/dl for both female and male donors. For autologous donation, a minimum of 10 g/dl will be accepted.
- Prior to the donation, the donor shall complete a questionnaire that declares his/her identity as well as present and past health status. A donor with an identified risk factor will be temporarily or permanently excluded from donating blood.
- The donor must acknowledge that he/she has been made aware of socio-behavioural risk factors associated with an increased risk of transmitting an infection through transfusion. Pre-donation, individual counselling shall be used to defer donors who are at risk of transmitting an infection if they do not elect to defer themselves.
- Only donors who agree to be informed of their sero-status of notifiable diseases through appropriate counselling facilities shall be accepted as regular donors.

- Before blood is collected, the donor must pass a medical examination, including a personal medical history and physical examination. Blood pressure will be recorded, and haemoglobin or haematocrit values must be determined by a reliable technique. The standard operating procedures for donor assessment must be followed precisely. However, donations may be acceptable from certain donors, subject approval of the medical person in charge of the centre.
- The interval of blood donations shall not be less than 3 months. In special circumstances, blood may be donated at 2-month intervals. The standard operating procedures must be followed precisely.
- Potential donors who are either temporarily or permanently deferred shall be referred to appropriate medical and/or counselling facilities of their choice.
- Sterile, disposable blood collection sets must be used for blood collection. Strict aseptic conditions must be ensured during blood collection. Steps must be taken to ensure that blood and blood products for transfusion are as safe as possible.
- All blood for transfusion must pass the infectious diseases screening tests agreed upon by the Ministry of Health, before being made available to the recipient.
- Confidentiality in blood donor records shall be maintained.

Recipient

- It is the service provider's responsibility to inform the recipient of the blood transfusion process, that the success of the process cannot be guaranteed, and that there is the slight possibility of inadvertent risk, either reactive or ineffective, from blood transfusion.
- Transfusion of blood or any blood product must be based on a careful assessment by the clinician to determine the necessity for such transfusion.
- There shall be no age limit for a person who needs blood transfusion. The judgement that blood transfusion is required by a recipient will be made by the attending clinician.

- Plasma expanders (crystalloid and colloids) should be considered for restoring blood volume before resorting to blood transfusion, except when oxygen carrying capacity is compromised.
- As much as possible, the patient should receive only the needed component of blood (cells, plasma or plasma derivatives).
- The actual transfusion must be given under the responsibility of a doctor.
- Patients receiving blood transfusion must be under continuous observation for the first 15 minutes, and thereafter they must be observed at half-hour intervals until the unit being transfused has ended, and finally at 24 hours after the last transfusion.
- Any observation of abnormal signs or symptoms should lead to immediate stoppage of the transfusion. The doctor in charge of the patient and the officer in charge of the blood bank shall be informed immediately for necessary intervention and investigation. Immediate or delayed transfusion reactions must be reported to the laboratory providing the blood.
- Pulse rate, blood pressure, temperature and respiratory rate must be recorded before, during, and after transfusion according to the Transfusion Monitoring Chart. The beginning and end of each transfusion must be recorded on the chart. The Transfusion Monitoring Chart should be carefully kept in the patient's case file.
- Except for the emergency use of group "O" blood or red cells, every red cell transfusion necessitates preliminary blood-grouping tests on the recipient and compatibility tests between the donated blood and the recipient.
- All patients' samples shall have recipient ABO grouping and Rhesus D typing. A direct antiglobulin test shall be performed on the recipient's blood as part of the compatibility testing and screening for irregular antibodies in the recipient's serum.
- Compatibility testing (by appropriate techniques) shall be performed in order to eliminate the risk of transfusion reactions.
- Before any transfusion of blood or a blood product, a written request signed by a doctor (or issued under his responsibility) must be made which specifies the identity of the

recipient, the clinical indication, and the nature and quantity of the blood or product to be administered.

- Before dispatch and administration, it must be verified that the blood or blood product is correctly identified and appears normal on inspection, and that the expiry date has not passed.

The recipient's identity must be verified using all of the following:

- Hospital identification number
- Full names
- Ward
- Date of birth

Laboratory Testing of Donated Blood

The following tests shall be performed by the NBTS on each blood unit collected, according to current standard operating procedures:

- ABO grouping using cell and serum (reverse) grouping techniques
- Rhesus D and Dⁿ grouping
- Screening for allo- and autoantibodies by standard techniques
- Screening by nationally-approved, appropriate techniques for transfusion transmissible infections will be identified and agreed upon by the Ministry of Health. Only blood that is non-reactive to these approved infections will be issued for transfusion.
- Records of all individual tests must be maintained for at least seven years as required by the law.
- All serum samples of donated blood, including autologous donations, must be stored for at least seven days as required by the law, and thereafter may be frozen individually to enable tests to be done at the discretion of the NBTS.

*I'm big hearted
I give blood*



NATIONAL BLOOD TRANSFUSION SERVICES
P.O. BOx 20750, Nairobi, Kenya Telephone: (254-2)723569

Preparation and printing of this document was made possible with funding from the United States Agency for International Development (USAID) under the cooperative agreement 623-A-00-99-00057-00 with Family Health International