



Republic of Malawi

THE NATIONAL BLOOD POLICY

Ministry of Health
January 2012



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Foreword

The Government of Malawi recognises the importance of adequate and safe blood for all in need. As such it continues to improve blood services for its people. It established the Malawi Blood Transfusion Service (MBTS) and champions various improvements in hospital blood banks nationally. This policy provides guidance to all institutions that are involved in the blood transfusion process. It is a major platform for the goal of making safe, quality blood available to all who may need it. It forms the foundation for the development of relevant legislation and guidelines. This policy also underscores the role of individual citizens and grass root structures in donating blood on a voluntary non-remunerated basis.

This policy is in line with the Malawi Growth Development Strategy and it specifically supports implementation of the Health Sector Strategic Plan (HSSP).

Successful implementation of this policy shall require close collaboration of all blood transfusion stakeholders. In addition this policy will specifically require a change in mindset of all citizens to regularly donate blood on a voluntary, unpaid basis. Each one of us can donate blood and save a life.



Right Honourable, KHUMBO KACHALI

Minister of Health & Vice-President of Republic of Malawi

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Preface

Malawi is one of a few African countries that, in line with international best practices, has successfully established a nationally coordinated blood transfusion service, the Malawi Blood Transfusion Service. Malawi is also a signatory to key resolutions such as the World Health Assembly resolution WHA28.72 (1975) and the Afro-Regional Resolution AFR/RC51/R2 (2001). Malawi also enjoys support from various development partners, both local and international, in implementing blood safety activities.

The stage is therefore set for a successful national blood service that would adequately contribute towards reduction of child and maternal mortality as well as prevention of HIV and other blood transmissible infections. Blood donation from the recommended voluntary non-remunerated donors has substantially increased, but remains inadequate to meet the national blood requirements.

Development of this policy was led by the Department of Health Technical Support Services in the Ministry of Health and involved consultations with various stakeholders, including the Malawi Blood Transfusion Service, the National AIDS Commission, Howard University Technical Assistance Project, Medical and Nurses Councils of Malawi, Christian Health Association of Malawi, College of Medicine, Malawi College of Health Sciences, Central and district Hospitals, faith-based organisations, the Malawi Red Cross Society, the Ministry of Education and the Ministry of Youth Development and Sports. Contributions from all these institutions are kindly acknowledged.

This Policy will provide sustained motivation for more concerted efforts towards ensuring the right to health for all.



Willie Samute

Secretary for Health

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List of Acronyms and Abbreviations

AIDS	Acquired Immunodeficiency Syndrome
CHAM	Christian Health Association of Malawi
EHP	Essential Health Package
IFRCRCS	International Federation of the Red Cross and Red Crescent Societies
ISBT	International Society of Blood Transfusion
MBTS	Malawi Blood Transfusion Service
MDGs	Millennium Development Goals
MoH	Ministry of Health
TTIs	Transfusion Transmissible Infections
WHO	World Health Organisation

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1. Introduction

Blood is an important component of every country's health delivery system. It is used in all clinical disciplines to save lives. Availability and accessibility of adequate and safe blood supplies is important in achieving Millennium Development Goals 4, 5 and 6 which deal with reducing child and maternal mortality and combating HIV/AIDS, malaria and other diseases. On the other hand, unsafe blood spreads serious infections such as HIV, malaria, hepatitis, syphilis and others. Also weak systems in the blood transfusion chain are responsible for immune and non-immune transfusion reactions some of which are fatal. Efforts to improve blood safety should therefore, not only be restricted to the availability of adequate quantities of safe blood and blood products but should also target systems to improve the transfusion process.

Towards the end of the last century and the beginning of this century considerable efforts were made to improve the availability of safe blood supplies in Sub-Saharan Africa. Many international bodies such as the World Health Organisation (WHO), the International Federation of the Red Cross and Red Crescent Societies (IFRCRCS) and the International Society of Blood Transfusion (ISBT) have played a key role in providing guidance on blood transfusion safety. Of particular note is the WHO resolution WHA 28.72 which puts the responsibility of ensuring the safety and adequacy of a country's blood supply in the hands of national governments through their ministries of health.

On account of worldwide data that has consistently shown the safety of voluntary non-remunerated blood donors, this resolution further recommends that blood donation should be voluntary and non-remunerated.

Previous efforts by the Ministry of Health (MoH) resulted in the development of guidelines for the practice of blood transfusions in 1997 and formal establishment of the Malawi Blood Transfusion Service (MBTS) in 2003 as a nationally coordinated blood service with 3 regional centres in Blantyre, Lilongwe and Mzuzu.

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The MBTS has the delegated mandate (by MoH) to provide safe and adequate blood supplies, promote appropriate clinical use of blood and blood products and to spearhead improvement of blood transfusion systems within hospital blood banks.

A situational analysis of blood safety in Malawi was conducted in 2008 and it reported some encouraging results. These include the fact that almost all (98%) laboratories were manned by at least one qualified staff member and that 100% of blood donations were screened for at least HIV before transfusion. However, the survey also showed several gaps that need to be addressed. It showed that there was no policy or legislation; the regulatory and supervisory environment was weak with outdated guidelines on the practice of blood transfusions; no guidelines on the clinical use of blood and blood products. It further showed that:

- The proportion of donated blood from voluntary non-remunerated blood donors, who are the safest source, was low at 42%;
- There was widespread use of inappropriate cross-match techniques;
- There were weak systems for maintaining an uninterrupted supply of essential reagents and supplies;
- Essential pieces of equipment for blood cold chain as well as for issuing blood were not available in some hospitals and were poorly maintained in others; and
- Laboratory staffing levels were low with 24% of the hospitals being manned by only one qualified laboratory staff member.

These findings underscored the urgent need for the MoH to put in place formal supervisory and regulatory tools for improving blood transfusion safety in the country. This policy is being developed in response to that need and it forms the foundation for the development of key blood transfusion guidelines and legislation.

This policy is being developed to operate in line with other existing policies at different levels which include:

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- The AFR/RC441/R12 (1994) which urges African countries to strengthen blood services by developing the necessary policies and mobilising resources to support those policies;
- ISBT Code of Ethics (2006) which addresses ethics and code of conduct in voluntary non-remunerated blood donation;
- Malawi Growth and Development Strategy which sets development priorities for the nation and includes targets in the health sector;
- Health Sector Strategic Plan's Essential Health Package which includes several diseases and conditions that require blood transfusion;
- The National HIV Policy which recognises blood safety as one of the key strategic areas in HIV prevention;
- The National Laboratory Policy which recognises the role of laboratories and the MBTS in achieving blood safety and addresses laboratory human resource constraints; and
- The Road Map to Accelerating the Reduction of Maternal Mortality in Malawi which spells out the role of safe blood transfusion in reducing maternal and neonatal deaths.

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2. Broad Policy Directions

2.1 Policy Goal

Contribute towards a healthy nation free from deaths and suffering arising from lack of safe blood.

2.2 Policy Outcomes

A blood service that meets the needs of the population and complies with national and international standards.

2.3 Policy Objectives

- (i) To mobilise adequate voluntary non-remunerated blood donors to meet the national blood requirements;
- (ii) To improve and sustain quality blood services to national and international standards;
- (iii) To support development of legislation on blood transfusion;
- (iv) To strengthen organisational and infrastructural capacity for blood safety; and
- (v) To facilitate collaboration with stakeholders.

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3. Policy Priority Areas

3.1 Selection and Recruitment of Blood Donors

Choice of safe blood donors is critical in achieving blood safety. Of the various types of blood donors, regular voluntary non remunerated blood donors have been proven to be the safest.

Recent improvements in blood service organisation have led to an increase in the proportion of voluntary non-remunerated blood donation. However, voluntary non-remunerated blood donations remain inadequate.

The policy will ensure that:

- (i) The MBTS is the only mandated body to collect blood from blood donors;
- (ii) Health facilities are only permitted to collect blood from donors under conditions as specified in the national guidelines for safe blood transfusion;
- (iii) Blood donations are voluntary and non-remunerated from low risk population groups;
- (iv) Regular blood donation is actively promoted;
- (v) Paid blood donation is prohibited;
- (vi) The family replacement donation system is gradually phased out as voluntary donation programs become established;
- (vii) Directed donations are discouraged unless medically indicated;
- (viii) Autologous pre-deposit donations is discouraged, while intra-operative cell salvage is promoted; and
- (ix) Partners such as faith-based organisations, non-governmental organisations, and local communities actively participate in motivating and mobilising voluntary donors for subsequent blood collection by MBTS.

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3.2 Blood Collection

Blood collection (phlebotomy) is a medical procedure with possible adverse effects. Regular voluntary non-remunerated blood donation succeeds if the blood donation process is safe, ethical and properly supervised.

The policy will ensure that:

- (i) Blood donation is carried out under the responsibility of a suitably qualified and registered medical practitioner;
- (ii) Blood donation is carried out with informed consent of the prospective donor;
- (iii) Donor safety, selection, deferral and counselling is as specified in the national guidelines for safe blood transfusion;
- (iv) Donor information, confidentiality and appropriate record keeping is as specified in the national guidelines for safe blood transfusion; and
- (v) Once donated, the blood becomes a national resource and ceases to belong to the blood donor such that it cannot be reclaimed.

3.3 Blood Processing

Blood undergoes several processes from the time it has been collected from the blood donor to the time that it is transfused to the recipient.

These processes include transportation, testing, component preparation and storage. Improper processing can compromise safety of blood and blood products.

This policy will ensure that:

- (i) The blood cold chain is maintained from the vein of the blood donor to that of the patient - 'vein to vein';

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- (ii) All donor blood for transfusion is screened for Transfusion-Transmissible Infections as specified in the guidelines for safe blood transfusion;
- (iii) The blood donor and the patient has their blood appropriately grouped and cross-matched before transfusion;
- (iv) Blood may be processed into blood components; and
- (v) Cross-border movement or exchange of blood and blood products occurs with the explicit approval of the Ministry of Health and in line with international health regulations.

3.4 Blood Utilisation

In spite of all the processes that blood goes through, there is still a residual risk of transmitting a TTI. Furthermore, there are many other adverse effects of blood transfusion which may occur. Some of these are life-threatening and fatal. It is important that every effort be made to avoid unnecessarily exposing patients to blood transfusion risk.

This policy will ensure that:

- (i) The prescription and administration of blood and blood products is under the authority of a registered clinician;
- (ii) Blood and blood products are used in accordance with the national guidelines on the clinical use of blood and blood products;
- (iii) Anonymity between donor and recipient is ensured except in medically indicated directed donations;
- (iv) Unscreened blood or blood components are not transfused and
- (v) Preparation of controls, reagent cells and approved research are the only other acceptable non transfusion uses of blood.

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3.5 Quality Assurance

Blood transfusion saves lives. However blood transfusion can also cause serious morbidity and mortality if not properly managed. In addition, improper waste handling and disposal can lead to adverse effects on those working with blood and the environment. As such it is important that the quality of all activities and processes carried out in blood transfusion from blood donor selection to blood utilisation is assured.

This policy shall ensure that:

- (i) Quality assurance is implemented for all blood transfusion processes from vein to vein;
- (ii) Blood services are accredited by recognised bodies and comply with quality standards;
- (iii) Regulatory bodies are involved in quality assurance programs for blood services;
- (iv) Premises and pieces of equipment conform to the established standards and specifications applicable for the various processes in the blood transfusion service;
- (v) Appropriate systems are in place for ensuring maintenance of premises and pieces of equipment;
- (vi) Infection prevention principles apply in all activities carried out in the blood transfusion processes in accordance with national infection prevention (IP) guidelines; and
- (vii) Blood specimens and blood products that cannot be used for whatever reasons and other forms of waste are disposed of in an environmentally friendly manner and in keeping with the national IP Guidelines.

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4. Implementation Arrangements

4.1 Institutional Arrangements

The Malawi blood service includes several institutions owned by government, Christian Health Association of Malawi (CHAM) and private individuals or institutions. The WHO resolution WHA 28.72 places the responsibility of ensuring blood transfusion safety in the hands of national governments through their Ministries of Health. This is in line with the Ministry of Health's legal mandate and mission to provide health services to all citizens. This policy shall guide the organisation and management of blood services in the country.

The Ministry of Health

The Minister of Health has the overall responsibility for blood transfusion safety. The Minister shall delegate the responsibility of ensuring the safety and adequacy of blood and blood products to the not-for-profit MBTS Trust that operates semi-autonomous of the civil service. S/he shall take every measure to secure Government commitment and support towards achieving blood transfusion safety.

Specifically, the Minister of Health shall appoint an MBTS Board of Trustees to supervise the MBTS and carry out their tasks as per the constitution of the Board of Trustees of the MBTS. S/he shall ensure that the Ministry of Health has up to date policy, legislation and guidelines to regulate and guide all institutions and processes in the blood transfusion chain, regardless of ownership of the institutions involved.

The MBTS Board of Trustees

The MBTS Board of Trustees shall appoint directors and staff to fulfill its mandate, as delegated by the Minister of Health and to oversee the operations of the MBTS in accordance with its constitution and conditions of service. The MBTS shall be registered as a welfare trust established by the Ministry of Health with its own constitution, premises, staff members and conditions of service.

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The MBTS

The MBTS shall provide safe and adequate blood supplies for all patients in need and promote their appropriate clinical use. It shall collect blood from blood donors, process and store blood and blood components for approved health facilities to collect and transfuse to individual patients.

Health Regulatory Authorities

Health regulatory authorities, in accordance with their mandate, shall ensure that only appropriately qualified health personnel carry out blood transfusion activities. Inspection and licensure of the MBTS and health facilities to carry out blood transfusion activities shall be conducted by the Medical Council of Malawi.

Health Facilities

Health facilities that are licensed to provide blood transfusions shall collect blood from the MBTS premises, transport, store, prepare for issue, issue, transfuse, monitor the blood transfusions and manage any adverse transfusion reactions that may occur. Each health facility involved in blood and blood product transfusions shall have a hospital transfusion committee.

4.2 Implementation Plan

- (i) Implementation of this policy shall be guided by the Health Sector Strategic Plan from which other specific institutional and program plans are derived.
- (ii) Funding of the MBTS Trust shall primarily be the responsibility of the Government of Malawi through the Ministry of Health and local councils.
- (iii) The MBTS may access additional funds and other forms of assistance from international donor agencies, multilateral agreements, non-governmental organisations, and others in an open and accountable manner.

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- (iv) The MBTS Trust may levy a fee for blood services on an accountable cost-recovery basis only.
- (v) The MBTS Trust shall conduct its operations with a view towards cost-effectiveness and sustainability.
- (vi) All health facilities which provide blood transfusion services shall make available adequate resources to comply with this policy.

4.3 Monitoring and Evaluation

Monitoring and evaluation (M&E) of this policy is the responsibility of all institutions involved in the blood transfusion process. Nonetheless, the overall responsibility for M&E remains with the Ministry of Health.

Blood transfusion data shall form part of the Health Management Information System (HMIS). The MBTS and hospital blood banks shall keep blood transfusion records in a confidential manner, provide regular reports and support all other M & E processes according to guidelines. Relevant research initiatives shall be promoted to provide evidence for blood safety programming.

4.4 Policy Review

The policy shall be reviewed every 5 years and when the need arises.

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Annex 2: Definitions

Approved health facilities are all institutions that are registered by regulatory bodies to manage patients and administer blood and blood products.

Autologous blood donors 'donate' blood for use by themselves. (refer to pre-deposit autologous blood donation, intra-operative cell salvage)

Blood refers to human whole blood which is un-separated and has been collected into an approved container with an anticoagulant preservative solution.

Blood Cold Chain refers to the optimal storage and transportation conditions that ensure that blood and blood products remain efficacious and safe.

Blood Component is a part of whole blood that can be used therapeutically e.g. red cell suspensions, platelet concentrates, fresh frozen plasma, cryoprecipitate, etc

Blood Product is any product separated from blood [blood components and plasma derivatives].

Blood Safety refers to all processes that are carried out to achieve a defined level of standard of safety of the blood and blood products that are available for transfusion.

Commercial or Paid Blood Donors (paid blood donation) are people who receive money or other awards which can be exchanged for money for the blood they donate.

Directed Blood Donors are people who donate blood for a particular person. The patient can only receive the blood donated by that person.

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Family Replacement Blood Donors are people who donate blood for use by a family member, friend or community member. The donated blood is either transfused into the intended patient or is used to replace the blood which the patient may have received already.

Intraoperative cell salvage refers to the collection of the patient's own lost blood for use by the same patient during surgery.

Plasma Derivatives are human plasma proteins prepared from plasma under pharmaceutical manufacturing conditions such as albumin, factor ix, factor Viii, immunoglobulin etc.

Pre-deposit autologous blood donation (PAD) occurs when patients donate blood in advance of their own scheduled surgery.

Reagent cells are red cells prepared for use in laboratory testing. These include but are not limited to cells for reverse grouping; screening cells and panel cells.

Voluntary Non-Remunerated Blood Donors are people who donate blood of their own free will and receive no money or other form of payment, which can be considered a substitute for money such as time off work except that reasonably needed for the donation and travel.

'Vein to vein' is used to emphasise the need for maintaining the blood cold chain and other quality assurance protocols from the time of blood collection (from the 'vein' of a blood donor) to the time of transfusing the blood (into the 'vein' of a patient).

