



Government of Malawi

Ministry of Health

Guidelines for Safe Blood Transfusion



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PREFACE

The Government of Malawi is committed to ensuring adequacy, accessibility and the safety of the country's blood supplies as well as appropriate systems and infrastructure for blood transfusion safety. In this vein the Government of Malawi has established the Malawi Blood Transfusion Service as a nationally coordinated service with the mandate to ensure availability of safe blood supplies. The MBTS collects blood from voluntary non-remunerated blood donors, processes it for hospital blood banks to collect, transport, store, issue and administer to individual patients. As such the Malawi Blood Service includes the MBTS and the hospital blood banks. These hospital blood banks are owned by Government, Christian Health Association of Malawi (CHAM) and private hospitals. However, the overall responsibility of ensuring blood transfusion safety, in other words the safety of all the processes outlined above, is with the Government of Malawi through the Ministry of Health.

These guidelines were first published in 1997. This revised version will provide an updated framework through which the Ministry of Health guides blood transfusion in the Country. They are binding to all institutions and individuals involved in the blood transfusion chain from the vein of the blood donor to that of the patient (from vein to vein). They are practical simple to use and affordable in our resource-constrained environment. They shall be the basis for compliance auditing by regulatory bodies and other quality audits. These guidelines are not intended to replace standard operating procedures (SOPs) or detailed specifications. Instead they provide the broad outlines for which SOPs and detailed specifications must always conform to.

These guidelines have been developed in participation of and consultation with the Malawi Blood Transfusion Service, College of Medicine, Malawi and Malamulo Colleges of Health Sciences, hospital transfusion committees of Kamuzu and Queen Elizabeth Central Hospitals, the Medical Council of Malawi and partners.



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Secretary for Health


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1. CARE AND SELECTION OF BLOOD DONORS

1.1 Introduction

There is much data internationally and locally that confirms that regular voluntary, non-remunerated blood donors are the safest as they have the lowest prevalence of transfusion transmissible infections (TTIs). In accordance with internationally accepted guidelines and ethics, all blood for transfusion should be collected from voluntary non-remunerated blood donors from low risk population groups and strategies should be implemented to encourage regular voluntary non-remunerated blood donation. According to the International Society of Blood Transfusion (ISBT) Code of Ethics (which was also adopted by the World Health Organisation (WHO), a donation is considered voluntary and non-remunerated if the person gives his/her blood of his/her own free will, without any coercion, and receives no payment for it either in the form of cash or in kind, which could be considered a substitute for money. This would include time off work other than that reasonably needed for the donation and travel. Small tokens, refreshments and re-imbursment of direct travel costs are compatible with voluntary non-remunerated blood donation. Family replacement blood donation (where family or other community members donate blood for the patient or to replace that provided to the patient) will be gradually phased out to achieve 100% voluntary non-remunerated blood donation in the country.

Blood must never be collected from paid donors. Other forms of blood donation such as directed donation (where blood is donated for a specific patient and must be used by that patient only) and pre-deposit autologous blood donation (where patients donate their own blood in advance of planned surgery are generally discouraged. Autologous donation is encouraged as part of intra-operative cell salvage. Directed donations are acceptable only where medically indicated such as in patients with allo-antibodies. Where indicated, directed donations must fulfill the same blood donation criteria of voluntary non-remunerated blood donors and

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the ABO and RhD group from the potential donors and recipient should be determined by the unit requesting directed donation prior to donor venesection.

Malawi Blood Transfusion service (MBTS) is the only mandated body to collect blood from donors for transfusion. Hospitals may collect blood from donors under the authority of MBTS when blood is not available from the MBTS and they have all the mandatory screening tests available. The guidelines of this chapter are developed to protect both the blood donor and the recipient.

1.2 Blood Donor Education

The potential donor must be educated and provided with information on blood donation to enable him/her make an informed decision on blood donation. This should include the following:

- a) Who is eligible to donate
- b) Reasons for giving blood
- c) How much blood will be collected
- d) Tests to be carried out
- e) Risks of blood donation
- f) Potential donors must sign a consent form for taking blood, testing and use by patients and must understand that once donated the blood becomes property of the blood bank and cannot be returned to the blood donor.

1.3 Assessment of Fitness for Donation

Clinical assessment of the donor's fitness for donation should be conducted at each donation session.

Potential donors should complete a questionnaire with standard questions

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on general health, social, past medical and drug history. Donors must understand all the information on the donor questionnaire. Assessment should be confidential and in private to ensure that donors understand the importance of honesty; how non disclosure of certain information can put blood donors themselves as well as recipients of the blood at risk and be given an opportunity to self exclude from donating blood. Blood donors must only be allowed to donate blood if they meet the minimum donation criteria specified below:

Donor Age

Donors should be of age from 16 to 65 years.
Regular donors between 65 and 70 year can be allowed to donate if medically fit

Frequency of Donation

Blood can be donated every 3 months for males and 4 months for females.

Weight

Potential blood donors must weigh at least 42 kg
a) 250mls of blood shall be drawn from donors weighing 42 – 44 kg
b) 450 ml shall be drawn from donors weighing 45 kg and above.

Medical and Social History

Blood donors with the following conditions shall be permanently deferred:

- a) Cardiovascular disease
- b) Epilepsy
- c) Mental illness
- d) Malignancy
- e) Diabetes (on insulin)
- f) HIV
- g) Hepatitis B
- h) Hepatitis C
- i) Syphilis

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Blood donors with the following conditions shall be temporarily deferred (period of deferral shown in brackets);

- a) Antibiotic use (7 days from the day of completing short acting antibiotics)
- b) Pregnancy (6 months post delivery if not lactating)
- c) Lactation (can donate after one year of lactation)
- d) Abortion (6 months)
- e) Major surgery (12 months)
- f) Minor surgery (6 months)
- g) Malaria (3 weeks after getting well)
- h) Blood transfusion (12 months)
- i) Jaundice (6 months)
- j) Hormonal contraceptives (acceptable at all times)
- k) On aspirin (acceptable for all blood components except for platelet production)
- l) Unwell and/or under any medical investigation (defer until condition is known to decide subsequent periods of deferral)

Potential blood donors who practice any of the following must be permanently deferred:

- a) Have multiple sexual partners;
- b) Have received payment for or have paid for sex;
- c) Men who have sex with men;
- d) Abuse intravenous drugs

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Potential blood donors with conditions not highlighted above shall be discussed with a trained medical officer before accepting their donations.

Haemoglobin

Haemoglobin must be at least 12g/dl.

Blood Pressure

At rest blood pressure should fall within the following range: 100/60 mmHg to 160/ 100 mmHg.

Pulse Rate

At rest pulse rate should be within the following range is 50 -100 beats per minute.

Very fit blood donors (such as long distance runners) may be allowed to donate blood with a lower pulse rate.

1.4 Premises for Blood Donation

A place suitable for carrying out a blood donation clinic must meet the following minimum requirements:

- a) Sufficient space to cater for donor registration, health check and drawing of blood.
- b) A private area for confidential counseling
- c) A separate area for provision of refreshments
- d) Non slippery floor
- e) Adequate lighting
- f) Toilet facilities for staff and donors
- g) Waste disposal facilities

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2. BLOOD COLLECTION

2.1 Introduction

Blood must be collected in a manner that is safe for the blood donor and the phlebotomist. Proper procedures for blood mixing to avoid clot formation and low platelets yield are also important for patient safety and the efficacy of the transfused blood product.

2.2 Preparation of Blood Pack

The pack shall be inspected for the presence of any defects and should not be used if the following defects are present including:

- a) Moisture on the surface of the pack
- b) Anticoagulant solution that is not clear
- c) Holes or broken tubing

2.3 Blood Donation

- a) Aseptic technique and infection prevention measures must be adhered to during phlebotomy.
- b) Strict sterile procedures, using disposable single use pyrogen free blood bags must be adhered to at all times.
- c) Blood must be collected from a suitable vein in the ante-cubital fossa which is free of skin lesions
- d) Veins may be made prominent by appropriate venous occlusion
- e) Blood of volume 450 ml may be collected from donors who weigh 45 kg and above;
- f) Blood of volume 250 ml from donors who weigh between 42 and 44kg.

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- g) The blood and anticoagulant must be gently mixed together every minute during collection by manual inversion of the blood pack.
- h) The donor may be given a stress ball to squeeze through out phlebotomy to facilitate blood flow.
- i) Blood flow must not be interrupted and must be completed within 15 minutes.
- j) During collection, the blood pack must be on a scale to monitor the weight / volume of blood collected.
- k) On completion of donation, the pressure cuff must be deflated, the needle removed from the arm and immediate pressure applied to the vein puncture site. .
- l) The donor must be monitored regularly during the donation by a medically qualified person.
- m) The arm and well being of the donor should be assessed before leaving the premises.
- n) Blood unit and specimen labels must be labeled with a unique donation (pack) number.

2.4 Post Donation Advice

The donor must be offered post donation advice on fluid intake, vein puncture site care and physical activity.

2.5 Donor Adverse Reactions

All adverse reactions should be noted, managed, documented and reported to the manager.

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2.6 Blood Donor Records

Blood donor records must be kept confidentially. The records must be kept in such a way as to allow transfusion audit trail in case of an adverse transfusion reaction Records must be kept for 5 years at the site and sent to National Archives thereafter.

2.7 Blood Storage and Transportation from Blood Donor Clinics

Blood must be allowed to cool to ambient temperature before putting in the refrigerator or cold chain box for transportation. Once collected, blood should be transported to the laboratory within 6 -10 hours. The blood cold chain must be maintained at all times.

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3. TESTING AND PROCESSING BLOOD

3.1 Introduction

The purpose of laboratory testing is to ensure that blood and blood products meet specified standards of safety and efficacy. All laboratory tests must be conducted according to well validated and documented techniques and in accordance with national standards and policy.

Test equipment and reagents must be validated before being introduced into routine use. Procedures must be in place to ensure that test systems, reagents and equipment are able to produce consistent and valid results.

3.2 Reception

All specimens of blood received in the laboratory for testing and processing must be clearly labeled and documented. Each donation pack and connected satellite pack must be identified by a unique donation (pack) number applied at the time of donation.

3.3 Quarantine

Units of blood and blood components which have not yet been tested or are being tested must be kept in a well labeled area completely separate from the area designated for issuable units. This area is called quarantine.

Storage in quarantine

- a) Whole blood, which are intended for processing components (platelets; fresh frozen plasma; cryo-precipitate) must be stored at ambient temperature and processed within 6 hours of collection.

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- b) The blood components made from these must also be kept in the appropriate quarantine as follows:
 - i) *Platelet concentrates in quarantine platelet agitator at 20-24 °C;*
 - ii) *Fresh frozen plasma in blood bank deep freezers/freezer rooms at -25 °C or below.*
- ii) *Units earmarked for red cell and whole blood production must be stored in quarantine blood bank fridges or cold rooms at 2 - 6°C.*

Storage after testing

A designated storage area, appropriate for each type of blood component, must be provided for units that have passed the mandatory tests and can be issued. Consequently, those that have failed the test(s) must be labeled and separated in quarantine in readiness for disposal.

3.4 Testing

Mandatory Donor Testing

Laboratory tests must be performed on samples taken from the blood donor which have been labeled with a unique donation (pack) number. The results of the tests are used to ensure safety and correct labeling of all units of blood intended for transfusion and for compatibility testing purposes.

The following are mandatory and must be carried out before blood is transfused:

- a) ABO and RhD grouping
- b) Transfusion transmissible infections testing (TTIs) and
- c) Compatibility testing.

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ABO Grouping

The ABO blood group must be determined on each blood donation using the results obtained by testing the red blood cells with standardized antisera and testing the serum or plasma with known A, B and O cells for the reverse grouping.

RhD Grouping

The RhD blood group must be determined on each blood donation based on the results of testing for the D red cell antigen using standardized antisera. Those units which are negative for this test must be investigated for D variant.

Transfusion Transmissible Infection Testing

A Transfusion Transmissible Infection (TTI) is a blood borne infection that is capable of being transmitted by blood transfusion. Therefore, each donation of blood must be subjected to government approved test methods for the following infectious markers.

Human Immunodeficiency Virus (HIV)

Each donation must be screened for HIV I & II using tests which will determine both antibody and antigen.

HBV

Each donation must be screened for Hepatitis B surface antigen.

HCV

Each donation must be screened for Hepatitis C antibodies.

Syphilis

Each donation must be screened for syphilis antibodies.

Malaria

Each donation must be screened for malaria parasites.

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Use of Test Results

- a) Any unit of blood found positive for any of the mandatory serological tests must not be issued and must be disposed of using recommended means.
(SEE: *INFECTION PREVENTION GUIDELINES*).
- b) For the purposes of informing the donor about results of the above infections (except for HIV), when units are found serologically positive, each unit must be retested in duplicate.
- c) In accordance with the national HIV policy, supplementary or confirmatory testing must be carried out for HIV, before test results are disclosed to blood donors.
- d) Malaria positive (1+) units should be labeled and stored. Such blood may be transfused to non-high risk patients.

A Note on HCV Testing

Care must be taken when interpreting and using HCV ELISA test results as the available tests tend to produce a high false positive rate in low prevalence populations such as the Malawi population.

Tested donor samples must be kept frozen for 5 years before final disposal. This will help in case of later investigations or approved research.

Specialized Testing

Specialized immunohaematological tests such as antibody screening and identification may be carried out by the MBTS upon request by a specialist.

3.5 Labeling

Only units which have been tested and passed as issuable must be labeled. Units which have not passed must be discarded with a biohazard sticker label only. The label must specify the following:

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- a) Name of component
- b) Blood group
- c) Expiry date
- d) Unique donation (pack) number
- e) Storage conditions

Any other relevant information may be added. Labels containing any additional information must not be superimposed on other labels.

3.6 Blood Components: Preparation and Storage

The following blood components can be prepared and issued for clinical use. There must be quality control procedures in place to demonstrate the meeting of blood product specifications, storage and transportation conditions.

Platelet Concentrates

Random donor platelet concentrates are made from the buffy coats of single donor whole blood donations.

They must meet the following minimum specifications:

- a) Volume: 50-70ml
- b) Platelet yield: $\geq 55 \times 10^9$
- c) They must be stored at 20 - 24°C in a platelet agitator. There is no alternative piece of equipment for the storage of platelets.
- d) They must never be refrigerated nor frozen.
- e) They must be transported at ambient temperatures and used up to 5 days after production.

Cryo-precipitate

- a) Cryo-precipitate must be made by separating the precipitate that forms when plasma freshly frozen at -65°C or below is thawed overnight for 24 hours.

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- b) It must meet the following minimum specifications:
 - i. Volume 30-40ml
 - ii. Factor viii yield: 80iu/pack.
- c) It must be stored at - 25-30°C in a plasma freezer or freezer room for a maximum of one year.
- d) Freezer compartments of domestic fridges are not suitable for the storage of cryoprecipitate as their temperature rarely goes below -20°C.
- e) It must be transported frozen at least at -18°C, and returned to storage temperature within 24 hours. .

Fresh frozen plasma

- a) Fresh frozen plasma is made by rapidly freezing plasma at -30°C or below.
- b) It must meet the following minimum specifications:
 - i. Volume 200-300ml
 - ii. Factor viii yield 0.7iu/ml
- c) It must be stored at - 25-30°C in a plasma freezer or freezer room for a maximum of one year.
- d) Freezer compartments of domestic fridges are not suitable for the storage of cryoprecipitate as their temperature rarely goes below -20°C.
- e) It must be transported frozen at least at -18°C, and returned to storage temperature within 24 hours.

Red Cell Suspensions

- a) Red cell suspensions are made by adding an additive solution to packed cells.
- b) The haematocrit must be between 50-70%.

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- c) It must be stored at 2 - 6°C in a blood bank fridge or cold room for up to 42days.
- d) They must be transported at between 2 - 10°C and returned to storage temperature within 24 hrs.
- e) Red cell suspensions are also referred to as red cells in additive solution.

Whole Blood

- a) Whole blood is made by collecting blood in an anticoagulant-preservative solution.
- b) The expiry date depends on the solution used.
- c) Most current blood bags contain CPDA1, conferring the longest storage period of 35 days.
- d) Whole blood must be stored at 2-6°C in a blood bank fridge or cold room.
- e) It must be transported, at a maximum 10°C and returned to 2-6°C within 24hrs.

3.7 Arrangement of Blood Products in Storage Facility

Blood components must be stored in an orderly manner such as according to blood groups and/or cross-match status. Blood components must be arranged in a manner that allows for air circulation in cubicles or trays.

3.8 Use of Household (Domestic) Fridge

- a) Domestic refrigerators are not intended for blood component storage.
- b) They have no fan for uniform air circulation, have no alarm for warning when temperature is outside range and have no temperature display.

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- c) Red cell products may only be stored in domestic refrigerators in exceptional circumstances.
- d) They must be placed in the middle of the fridge compartment,
- e) Blood must not be placed near the back as the temperature may be lower than 2°C and not near the door, as the temperature may be higher than 6°C.
- f) Blood stored in domestic refrigerators may only be stored for a maximum of 7 days.
- g) A thermometer should be placed in the middle compartment of the fridge to monitor the temperature. The temperature must be documented at least twice per day.
- h) Fresh frozen plasma and cryoprecipitate must never be stored in the freezer compartment of a household fridge.

3.9 Cross-Border Movement of Blood

Cross-border movement or exchange of blood and components shall be with the explicit approval of the Ministry of Health and in line with international health regulations.

4. HOSPITAL BLOOD BANK PROCESSES

4.1 Introduction

Health facility blood banks collect blood from the MBTS, store, prepare for issue, issue for transfusion and carry out transfusions in individual patients. Proper hospital blood bank processes are important for blood transfusion safety.

4.2 Requirements for a Health Facility Blood Bank

The following are minimum requirements for operations of a blood bank:

- a) Room with at least 3 x 3 meters of space
- b) At least a 3 meter bench
- c) Adequate lighting
- d) Proper ventilation
- e) Provision of a sink
- f) Blood grouping and cross matching equipment and reagents.
- g) Storage facilities for reagents, specimens and blood components.
- h) Qualified laboratory medical and nursing personnel registered with the relevant regulatory bodies
- i) If a refrigerator/deep freezer (as opposed to a cold/freezer room) is used to store blood components, make provision for an air conditioner.
- j) Blood cold chain box
- k) Back-up power source

4.3 Management of Hospital Blood Bank Stock

Ordering of blood from MBTS

- a) Blood should be obtained from MBTS as the first priority source.
- b) Individual healthcare facilities should order blood in order to maintain agreed minimum stock levels and to cover known demand such as for planned surgery).
- c) A minimum stock level of the daily average demand+25% should ensure that blood is available roughly 90% of the time.
- d) The quantity of blood ordered should reflect actual demand as described above rather than existing MBTS blood stocks.
- e) Blood must only be ordered by approved blood banks.
- f) A formal order must be issued from the blood bank before blood will be released from MBTS.
- g) Following collection, healthcare units are responsible for tracking the subsequent use or disposal of all blood products.
- h) Both MBTS and health facility blood banks must keep written records of all blood products ordered.

Documentation on Receipt

On reception of blood and blood products, laboratory must check and document the following:

- a) Date and time of reception
- b) Pack number
- c) Blood group
- d) Temperature of (transportation) blood cold chain box (as specified in chapter 2)
- e) Integrity of pack and contents (*refer to appendix 1*)

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- f) Expiry date
- g) A declaration that blood has been screened for TTIs
- h) Name and signature of person registering receipt of blood

Blood must not be used if all of the above information is not available.

Storage/ Stock Control

After reception, blood and blood products must be stored according to specifications given in chapter 2. Individual healthcare facilities should have SOPs detailing: management of blood storage. These should include:

- a) Temperature records.
- b) Recording of stock levels.
- c) Arrangement of blood products in storage facility
- d) Separate storage of directed/.replacement donor blood
- e) De-reserving unused cross-matched blood
- f) Crossover of unused directed donor blood

Mandatory documentation should include daily temperature records and stock levels.

Blood banks should be able to account for every unit received and its fate (used or disposed of).

Disposal

Blood which is unsuitable for transfusion must be disposed of according to the national Infection Prevention Guidelines.

The date of disposal, pack number and reason for disposal must be recorded.

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4.4 Pre-Transfusion Testing

The purpose of pre-transfusion testing is to ensure transfused blood is safe for the intended recipient. This includes serological compatibility, microbiological safety, product integrity and prevention of misidentification errors. The commonest cause of serious transfusion reactions is the recipient receiving incompatible blood meant for another patient.

It is essential that procedures for ensuring correct identification are followed strictly at all points of the transfusion process. The requirements for identification and documentation are an integral part of the safety system

4.5 Ordering of Blood from the Hospital Blood Bank

Blood must be ordered under the authority of a registered clinician. All samples should be accompanied by a request form specifying the tests or investigation required and the signature and name of person requesting the test. A recommended hospital blood ordering form is attached in appendix 2.

All requests must contain the following minimum information

- a) Surname and first name of the intended recipient
- b) A second point of identification (date of birth or hospital number).
- c) Ward Blood product required
- d) Time blood products are needed
- e) Date and time of blood specimen collection
- f) Name and signature of person ordering the test
- g) Name and signature of person taking the blood sample, if this is different from the person ordering the test.

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Health facility blood banks should not process requests which do not have all of the above information.

Health facilities should have written procedures for communicating and dealing with incomplete hospital blood requests.

It is good practice to include the following when ordering blood from the blood bank:

- a) Reason for request
- b) Hb level of the patient
- c) Details of any previous transfusions if known
- d) Patient's blood group if known
- e) If there is a directed donation for the patient

Sample Requirements

Potential recipients require a blood sample for ABO and RhD grouping and cross-matching. Samples must have the following minimum information written on the tube:

- a) First name and surname
- b) A second point of identification (see 3.2.1 above)
- c) Ward

Healthcare facilities should develop written procedures for communicating and dealing with inadequately labeled samples.

Individual laboratories should have SOPs to cover specimen reception.

These should include:

- a) Documentation of time and date of specimen receipt.
- b) Issuing a unique specimen identification number for each sample.

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- c) Checking that identification information is adequate and consistent with the request form.
- d) Visual inspection of sample to determine unsuitability for testing.
- e) Incorrect or damaged specimen tube.
- f) Presence of haemolysis/lipaemia/clots.
- g) Low sample volume.
- h) Procedure for dealing with unsuitable specimens or requests.

4.6 Compatibility Testing (Cross-Matching)

- a) Compatibility testing is the set of procedures required to ensure that there are no antibodies in the patient's serum that could cause a haemolytic transfusion reaction.
- b) ABO blood group compatibility is the most important determinant of compatibility but there are other antibodies that can cause transfusion reactions even where the ABO groups are compatible.
- c) Cross-matching between donor red cells and recipient serum/plasma is therefore necessary in addition to blood group determination to ensure safety.
- d) Tests must be performed using donor red cells from the originally attached pilot tube on the blood bag, and recipient's serum/plasma sample no older than 48 hours.
- e) A fresh sample must be taken from the patient if the patient has been transfused more than 48 hours previously.
- f) Cross-match samples should be stored at 4°C for 7 days after sampling for investigation of transfusion reactions.

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Routine Cross-Matching

Minimum mandatory cross-matching processes must include:

- a) Review of readily available transfusion records
- b) Forward ABO grouping on recipient and donor specimens
- c) Confirmation of recipient ABO group by reverse grouping
- d) RhD determination by a reagent insensitive to DVI
- e) Saline cross-match will detect IGM incompatibility only and offers a second check that blood is ABO compatible. (take note that there are other IgM antibodies which are not clinically significant which can cause a positive reaction with saline cross-matching)
- f) Indirect antiglobulin Test (IAT) allows for detection of many clinically significant (IgG) antibodies which cannot be detected with a saline cross match.

Emergency Cross-matching

- a) In emergency situations where there is insufficient time to perform an IAT cross-match, blood may be released after the saline cross-match only. This should make the blood available after 15 minutes.
- b) The IAT cross-match should still be performed and positive results actively notified to the clinicians.
- c) In extreme emergencies, where there is insufficient time to perform, the emergency cross-match, uncross-matched group O Rh (D) negative blood may be issued, clearly labeled as uncross-matched blood.
- d) In this case a signed declaration from the clinician accepting responsibility for the transfusion should be obtained. Full compatibility testing should be performed while the blood is being transfused and positive results actively notified to the clinicians.

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4.7 Post Cross-Match Labeling

Compatible blood must be labeled with the following as a minimum.

- a) First name and surname of recipient.
- b) A second point of identification (see 3.2.1 above).
- c) Pack number.
- d) Laboratory number.
- e) Blood group of unit.
- f) Blood group of recipient.
- g) Ward.
- h) Name of person cross-matching blood.
- i) Date and time of cross-matching.
- j) Expiry date.
- k) Any special information (for example if recipient and unit have different blood groups) {a recommended cross-match label is attached in appendix 3}.

Uncross-matched blood issued in extreme emergencies can be released marked as such without further labeling. The laboratory compatibility records should include all of the above information.

4.8 Issuing of Blood and Blood Products

4.8.1 Product selection

Red cell suspension /Whole blood

- a) Whole blood and red cell suspension can be issued interchangeably for treatment of anaemia. For paediatric patients where blood is prescribed by volume, an equivalent red cell dose should be issued (10ml red cell suspension is equivalent to 15 ml whole blood)

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- b) RhD negative recipients should receive RhD negative products.
- c) An uncertain RhD result (“weak D expression”) in the recipient should be treated as RhD negative.
- d) In life threatening emergencies where RhD negative products are unavailable, RhD positive products may be issued upon request from a senior clinician.
- e) IAT cross-match must be performed either prospectively or retrospectively.

Fresh Frozen Plasma

- a) FFP should be ABO group compatible with the patient.
- b) Because plasma is being transfused, compatibility is opposite to red cell transfusion (Group AB plasma may be given to recipients of all groups; Group O should only be given to group O).
- c) FFP must be thawed before transfusion.
- d) Once thawed, FFP must never be refrozen for storage. It can be stored at 2-6°C. For 24 hours only for fibrinogen replacement therapy as most labile clotting factors (factor viii & v) will have deteriorated.
- e) Water baths at 30-35°C. Can be used to thaw FFP. This is fast and takes about 15 minutes to thaw one unit.
- f) Where this is not feasible tap water in plastic pails/basins can be used. This is slower and takes about 30-40 minutes to thaw 1 unit.
- g) Care must be taken to avoid contact of the transfusion ports with thawing water (particularly water bath water) as this can lead to bacterial contamination of the plasma and septicaemia in the recipient.

Guidelines for Safe Blood Transfusion

Cryo-precipitate

- a) If possible, it should be ABO group compatible with the patient as for FFP but this is not necessary.
- b) Cryo-precipitate must be thawed before transfusion.
- c) Once thawed it must never be refrozen for storage.
- d) It can be stored at 2-6°C. for 24 hours only for fibrinogen replacement therapy as factor viii will have deteriorated.
- e) Water baths at 30-35°C can be used to thaw FFP.
- f) Where this is not feasible tap water in plastic pails/basins can be used. As units of cryoprecipitate have smaller volume, they thaw much faster than FFPs.

Platelet Concentrates

- a) These should be of the same ABO group as the patient and RhD compatible.
- b) ABO mismatched platelets may be given if ABO compatible platelets are unavailable but may be less effective.
- c) RhD positive platelets should not be given to RhD negative women of childbearing age.
- d) Avoid giving group O platelets to non-O infants.

4.8.2 Procedures for Issuing Blood

- a) The person collecting the blood from the blood bank should bring documentation to identify the patient including full name and a second unique identifier.
- b) Both blood bank staff and individual collecting blood should check that the patients name and other identification information agree with the blood request form, compatibility label and laboratory record.

Guidelines for Safe Blood Transfusion

Checks must be made to ensure that:

- a) All required tests for transfusion transmissible infections have been performed and are negative
- b) Blood is compatible by checking the blood group on the request form, compatibility label and compatibility register
- c) Blood is not expired.
- d) Blood has no signs of deterioration or loss of integrity (see WHO guideline in appendix 1)
- e) The date and time of issue must be written in the laboratory record.
- f) The technician issuing blood and individual collecting blood should sign the laboratory record.

4.9 Blood Administration

There should be national guidelines on the appropriate clinical use of blood and blood products guiding all the clinical aspects of blood transfusion including indications for use, maximal blood ordering schedules, the role of hospital transfusion committees, patient monitoring and management of transfusion reactions.

4.10 Non-Transfusion Use of Blood and Blood Products

Acceptable non transfusion use of blood and blood products shall include: preparation of controls, reagent cells and approved research. Ministry of Health approval must be sought if blood is going to be used for purposes other than those outlined above.

Guidelines for Safe Blood Transfusion

5. QUALITY ASSURANCE

The quality assurance program should cover all health institutions involved in the blood transfusion process. The following should be implemented as a minimum:

- a) Standard operating procedures must be available for all processes from blood collection up to issuing of blood.
- b) All laboratory tests must be conducted according to well validated and documented techniques using appropriate controls.
- c) Laboratories shall have quality control procedures for monitoring the validity of results including the daily use of internal controls.
- d) Blood collection venues, testing and processing laboratories as well as blood banks must conform to minimum required standards.
- e) Equipment shall be operated by authorized personnel in accordance with written instructions.
- f) Records shall be maintained for key items of equipment and shall include details of maintenance carried out.
- g) Defective equipment must be taken out of service and identified as such or be isolated to prevent its use.
- h) All blood and blood products must be handled using aseptic techniques.
- i) There should be a documented quality audit program to ensure safety and efficacy of the blood/ blood products.
- j) All mandatory documentation should be easily accessible to enable audit, external review, and look back.
- k) All institutions should participate in an approved external quality assurance schemes.

Guidelines for Safe Blood Transfusion

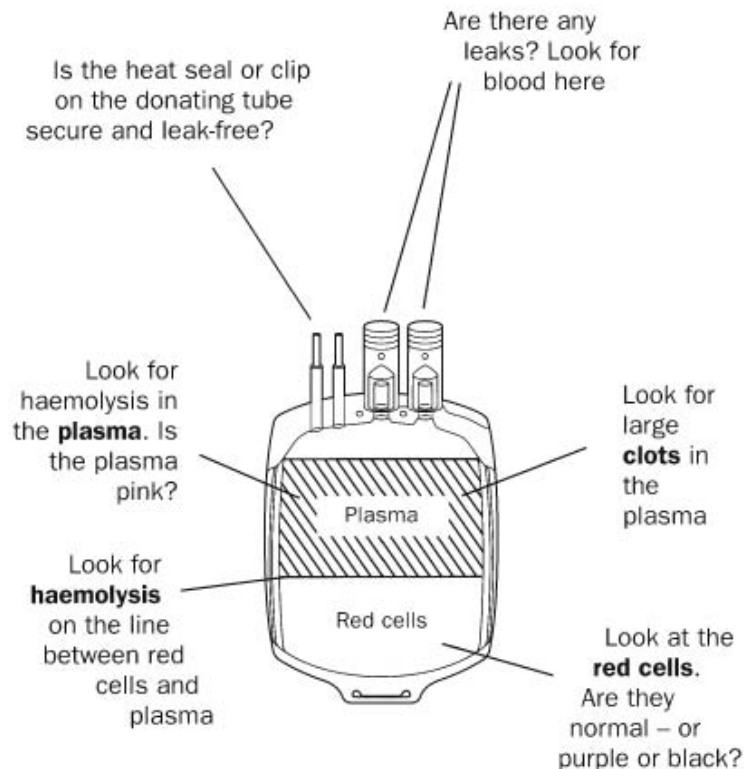
Guidelines for Safe Blood Transfusion

6. APPENDICES

6.1 Appendix 1: Checklist for Signs of Deterioration in Blood and Plasma

(courtesy of the World Health Organisation)

CHECKLIST FOR SIGNS OF DETERIORATION IN BLOOD AND PLASMA



6.2 Appendix 2: Recommended Hospital Blood Request Form

MINISTRY OF HEALTH ORDERING FORM FOR BLOOD & BLOOD PRODUCTS

PLEASE USE CAPITAL LETTERS Blood will not be issued unless this form is **completed in every detail** by the CLINICIAN. The particulars on the form and on the specimen label **must** agree in every detail.

Patient details:

Hospital Details:		Clinical details:	
SURNAME: _____	Hospital Number Specific to Patient _____	Diagnosis: _____	
FIRST NAME: _____	WARD _____	Haemoglobin: _____ g/dL	
Other names: _____ SEX MALE/FEMALE	Hospital _____	Hct/PCV _____ %	
TITLE Mr/Mrs/Ms/Baby RACE African/Caucasian/Asian			
Date of birth: ____/____/____ age if DOB unknown _____			

BLOOD REQUIREMENTS

Urgency Please Circle Standard (~ 1 hr) Emergency (5-10min) Un cross-matched (0 Rh neg)

Day & Date Blood Required _____ Time Required _____

Any previous transfusions? Circle YES/NO/NOT KNOWN Has patient ever been pregnant? Yes/No/Not Known/NA

If yes: Where _____ When _____ Is patient pregnant now? Yes/No

Clinician's Name: _____	Clinician's Signature _____	Time _____	Date _____
DATE collected _____	Sample _____		

AMOUNT OF BLOOD REQUIRED (& guidelines for ordering)

Human blood Products	Unit Vol. (ml)	Units required	Clinical Condition	Guidelines for Transfusion
Standard Packed Cells (HCT 50-70%) with SAGM	300/325		(i) General Surgery (ii) Cardiac, pulmonary or vascular surgery (iii) Low Hb (iv) Significant Anaemia	Hb < 8g/dl Hb < 10g/dl Not indicated Adults – See Clinical use of Blood Guideline Children 10ml/kg 10ml/kg
Paediatric Packed Cells (Hct 50-70%) with SAGM	125-150		(i) Significant Anaemia	Platelet Count < 50 x 10 ⁹ /L Not indicated Not indicated if no evidence of bleed except if too low ~20x10 in all ages Not indicated unless bleeding INR > 1.4 or PT > 24 seconds
Platelet concentrates single donor (approx 5.5 x 10 ⁹ /L platelets)	50-70		Neurosurgery or blind invasive procedures ITP Low Platelet count HIV thrombocytopenia Massive transfusion	Reversal of Warfarin Effect
Fresh Frozen Plasma	250		Haemorrhage Haemorrhage Warfarin Effect General Surgery Massive Transfusion Haemophilia B Liver disease	Indicated only in cases of known coagulopathy e.g. DIC
Cryoprecipitate (80 i.u./Bag)	30		DIC Massive transfusion Haemophilia A Van willebrands disease	Indicated
Whole blood (for children blood should be ≤ 7 days old) Whole blood (for neonates blood should be ≤ 5 days old)	500		Severe anaemia plus shock Haemolytic disease of the new born	20 ml/kg in children. Adults see guidelines Exchange transfusion in neonates

essential for All private patients with respect to Medical Insurance

PRIVATE PATIENTS
Address details:
Medical Aid Society & Membership No. _____

CAUTION: All blood is donated to the Malawi Blood Transfusion Service (MBTS) by voluntary non-remunerated blood donors. Every unit is routinely tested for markers of transmissible disease viz: HIV p24 Antigen; anti-HIV 1 & II; anti-HCV; Syphilis and malaria. There is, never the less, a risk of transmitting these and other diseases by blood transfusion even though the blood is tested and found negative for these markers. The prescribing doctor must take this into consideration and consider possible alternatives, as appropriate.

Guidelines for Safe Blood Transfusion

FOR LABORATORY USE ONLY

(Details on specimen agree with those on request form)

Yes No

Routine Cross-match set up on (date/day):Time:.....
By:.....

Date Cross Match	Product type	Pack No.	ABO & RhD	Expiry Date	Compatible By: Routine /Emergency	Signature	Date & Time of issuing	Issued by	taken by

*The signature of the person issuing the blood certifies that:
1. Haemolysis is slight or absent.
2. The expiry date has not been reached.
3. No discrepancies exist between the labels on the packs and this form

Any comments:

OTHER PRODUCTS ISSUED

Product type	Pack No.	ABO & RhD gp	Expiry Date	Signature	Date & Time of issuing	Issued by	Taken by:

Lab Ref. No.:.....

Guidelines for Safe Blood Transfusion

6.3 Appendix 3: Recommended Cross-Match Label

PLEASE RETURN TO BLOOD BANK IMMEDIATELY IF THE BLOOD IS NOT USED

Pack Number
Blood group

THIS BLOOD IS COMPATIBLE WITH

Name.....
Age.....Sex.....
Ward..... Blood Group

Date Xmatched...../...../.....
Date expires...../...../.....
SALINE..... ALBUMIN.....COOMBS.....
FFP.....CRYO.....PLT.....
Unit amount

PLEASE RETURN TO BLOOD BANK IMMEDIATELY IF THE BLOOD IS NOT USED

Pack Number
Blood group

THIS BLOOD IS COMPATIBLE WITH

Name.....
Age.....Sex.....
Ward..... Blood Group

Date Xmatched...../...../.....
Date expires...../...../.....
SALINE..... ALBUMIN.....COOMBS.....
FFP.....CRYO.....PLT.....
Unit amount

PLEASE RETURN TO BLOOD BANK IMMEDIATELY IF THE BLOOD IS NOT USED

Pack Number
Blood group

PLEASE RETURN TO BLOOD BANK IMMEDIATELY IF THE BLOOD IS NOT USED

Pack Number
Blood group

THIS BLOOD IS COMPATIBLE WITH

Name.....
Age.....Sex.....
Ward..... Blood Group

Date Xmatched...../...../.....
Date expires...../...../.....
SALINE..... ALBUMIN.....COOMBS.....
FFP.....CRYO.....PLT.....
Unit amount

PLEASE RETURN TO BLOOD BANK IMMEDIATELY IF THE BLOOD IS NOT USED

Pack Number
Blood group

THIS BLOOD IS COMPATIBLE WITH

Name.....
Age.....Sex.....
Ward..... Blood Group

Date Xmatched...../...../.....
Date expires...../...../.....
SALINE..... ALBUMIN.....COOMBS.....
FFP.....CRYO.....PLT.....
Unit amount

PLEASE RETURN TO BLOOD BANK IMMEDIATELY IF THE BLOOD IS NOT USED

Pack Number
Blood group

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