National Blood Service Zimbabwe

Standards for Blood Donation, Processing & Clinical Transfusion in Zimbabwe

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Revision 00

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GLOSSARY OF TERMS

Allogeneic donation Blood donation from one individual to another of different genetic make-up within the same species.

Apheresis A method of collection where whole blood is removed from a donor or patient and separated into components; one or more of the components are retained, and the remainder is returned to the donor/patient during the same procedure.

Audit Trail Record-keeping system that re-creates every step in the manufacturing processes.

Audit Systematic investigation to determine whether policies and procedures are being performed and supported properly.

Autologous Donation Blood donated by a donor-patient for use on him/herself.

Blood Donor A person whose blood is collected for possible allogeneic transfusion to another person.

Blood Product Any therapeutic product derived from blood or plasma.

Blood Warmer Medical equipment that pre-warms donor blood to 37^{o}C before transfusion.

Change Control System to plan and implement changes in procedures, equipment, policies, and methods to increase effectiveness and/or prevent problems.

Clinically significant antibody An antibody obtained from a donor (allogeneic antibody) or recipient (autologous antibody) that is capable of producing an adverse reaction to transfused blood or blood product in the recipient. .

Closed system An airtight and sterile system in which the blood is not exposed to air or outside elements during collection and processing, including separation of components (e.g. platelets) if required prior to transfusion.

Compatibility testing All steps in the identification and testing of a potential transfusion recipient and donor blood before transfusion in an attempt to provide a blood product that survives in vivo and provides its therapeutic effect in the recipient.

Cross-match Procedure that combines the donor's RBCs and patient's serum to determine the serologic compatibility between donor and patient.

Donor-Recipient A person whose own blood is collected for possible transfusion to her/himself (autologous transfusion).

External Quality Assessment Scheme (EQAS) A scheme whereby samples are received from an outside agency for assessment and the results returned to the outside agency for evaluation. To be effective, the samples should be assessed in precisely the same way as routine samples.

Fresh Frozen Plasma Plasma separated from whole blood by centrifugation or apheresis and frozen within 6 hours of collection. It contains all of the plasma coagulation factors and labile factors V and VIII.

Hospital Blood Bank Hospital laboratory unit in charge of ordering, storage and performing compatibility testing of blood and blood products on behalf of the hospital.

Look back system Process of identifying and notifying persons who have received blood transfusions from donors who are subsequently found to have infections with HCV, HIV, HBV, Syphilis or other TTI and notifying them as appropriate.

Plasmapheresis The method used to remove plasma from the blood by separating and retaining the plasma whilst returning the red blood cells suspended in saline or other solution back into the donor's circulation system.

Proficiency Testing (PT) Surveys performed to ensure that a laboratory's test methods and equipment are working as expected.

Quality Assurance (QA) This is programme of procedures, controls, audits and corrective actions implemented to provide adequate confidence that a procedure, structure, component or system will function as expected and deliver results that meet or exceed predefined specifications.

Quality Control (QC) Testing to determine the accuracy and precision of the equipment, products, reagents and procedures.

Recipient A person who receives blood or blood components for therapeutic purposes.

Transfusion reaction Adverse reaction of a patient (recipient) to infused blood or blood products.

Unit of blood Sterile plastic bag in which a fixed volume of blood is collected in a suitable amount of anticoagulant. (The collections system should be a closed system, usually consisting of a sterile hypodermic needle connected by tubing to a collection bag that has one or more sterile ports for inserting a sterile administration set).

Weak D Weak form of the D antigen that requires IAT for its detection.

GLOSSARY OF ABBREVIATIONS

BTS	Blood Transfusion Service
CEO	Chief Executive Officer
FFP	Fresh Frozen Plasma
HBV	Hepatitis B Virus
HCV	Hepatitis C Virus
HIV	Human Immunodeficiency Virus
MoHCW	Ministry of Health and Child Welfare
NBSZ	National Blood Service Zimbabwe
PC	Packed Cells
PLT	Platelet
QMS	Quality Management System
RBC	Red Blood Cell
Rh	Rhesus
SOP	Standard Operating Procedure
WB	Whole Blood
WBC	White Blood Cell

INTRODUCTION

The aim of this document is to set out minimum standards for the collection, storage, processing, issuing of human blood and blood products in Zimbabwe and transfusion thereof. Human Blood and Blood Products used in the Republic of Zimbabwe are provided by a registered Service which derives its authority and mandate from the Minister of Health and Child Welfare (MoHCW). The Service operates in accordance with the National Blood Policy and regulations of the Anatomical Donations and Post Mortem Examinations Act [Chapter 15:01] of 1976, Health Professions Act [Chapter 27.19) of 2000 and other relevant Statutes of Zimbabwe. While such minimum standards must be regarded as obligatory for all establishments, it remains the prerogative of the registered Service and hospital blood banks to introduce standards and criteria over-and-above those laid down herein, provided that they do not modify or conflict with them. They are therefore, not intended to replace detailed specifications and standard operating procedures (SOPs), but provide a basic guideline on the minimum requirements under which the discipline of blood donation, processing and transfusion may be practised in Zimbabwe. The words "shall" or "must" or equivalent words are used to indicate a mandatory statement. Failure to meet the specified requirements is deemed to be a deficiency. The words "should" or "may" or equivalent wording are used to indicate a recommendation.

If the head of the Service or the head of a health institution is not a registered medical practitioner, the responsibility for all medical matters must be delegated to a registered medical practitioner, who is qualified by training and/or by experience in blood transfusion and related matters, who shall have the responsibility and authority for all medical policies and procedures. The head of the Service or the head of a health institution has overall responsibility to ensure the provision of adequate resources and day to day management necessary to ensure the goals and objectives of the organization are met.

Strict confidentiality must be observed by all employees of the Service and health institutions with regard to all information pertaining to blood donors and recipients of blood products.

Suggestions for amendments to these Standards should be addressed to the chairman of the National Blood Council. The chairman will, in consultation with the MoHCW (Minister), establish a Working Committee to review Version 1 of these standards and to continuously update them. Formal review of the Standards will be carried out at least every two years. The new versions will be published as appropriate.

In the event of any significant developments in the field of blood transfusion that will require urgent amendment of these Standards, recommendations for such amendments must be made to the chairman of the National Blood Council without delay. If the Council accepts the recommendations, it will recommend the changes to the Minister who will inform all health institutions for immediate implementation.

Failure to meet any of these minimum requirements will lead to the issue being referred to National Blood Council.

Arrangement of Sections:

These Standards are divided into four sections. Section 1 covers Quality, Safety and Environmental Management issues for all health institutions practising blood transfusion. Section 2 covers the activities that should be carried out by the Service mandated to collect, test, process and distribute blood, blood components and blood products. Section 3 covers laboratory and hospital-related activities, that link the Service and the patient while Section 4 stipulates the issues to be covered under Monitoring and Evaluation.

SECTION 1: QUALITY MANAGEMENT SYSTEMS

1.1 Introduction

This section covers quality management systems as it should apply to all organisations involved in blood transfusion. The section presents the minimum requirements that should be met by the Services and blood banks.

1.2 Structure and organisation

1.2.1 The Service shall have a defined structure that clearly identifies and documents the parties responsible for donor recruitment and the collection, testing, storage, and provision/issue of blood, blood components, blood products and related services. The roles of each position shall be clearly stated. Functional units must be established for Blood Donors and Blood Collection, Testing of Blood, Component Production and Compatibility Testing.

1.2.2 The Service shall have a fulltime medical director who is qualified in blood transfusion medicine.

1.2.3 The CEO of the Service shall have overall responsibility and authority for the day to day management of the Service. This responsibility shall include ensuring compliance with these Standards, the Quality Management System (QMS) in place, research and development program, and the financial management of the Service.

1.2.4 There shall be area managers responsible for the main activities of the Service which are among others; Blood Procurement, Laboratory Services, Administration and Quality Management.

1.2.5 A designated individual (Quality Manager) shall be appointed with overall responsibility for quality within the Service or health institution. This person is responsible for the implementation of the quality policy and the maintenance of the quality management system. This person shall report directly to the Service or health institution head, or to another designated person who has no direct managerial or supervisory role in collection, processing or testing of blood.

1.2.6 Job descriptions are required for all staff outlining key responsibilities and duties to be performed. Staff shall have access to their job descriptions. There shall be a process for reviewing job descriptions and organogram(s) at regular intervals and updating them when required.

1.2.7 Top level support shall be given to the development, implementation and maintenance of the quality management system. Top management shall provide evidence of its commitment to quality management by:

a) Communicating to BTS staff and other senior levels of healthcare within the country the importance of providing safe and effective blood and blood products.

b) Meeting statutory and regulatory requirements.

c) Ensuring that quality objectives are realistic and clear to all staff.

1.3 Resources

The Service or health institution shall identify and ensure the provision of adequate resources to perform, verify, and manage all activities in the blood bank. The respective management shall determine and provide the necessary human, material, physical and capital resources required for implementing, maintaining and continually improving the effectiveness of these Standards.

1.3.1 Human Resources

There shall be adequate qualified staff to perform assigned procedures. All staff members are expected to demonstrate high levels of competence in order to ensure an adequate and reliable supply of quality blood, blood products and services. Documentation of qualification, training, continuing professional development and competence shall be maintained.

a. At least two qualified medical laboratory scientists shall work in the blood bank.
b. The Service or health institution shall provide a job description for each position.

c. There shall be a process for identifying training needs and the provision for the training of all personnel performing activities affecting quality.
d. The Service or health institution shall provide the opportunity for staff to gain proficiency and experience in their assigned activities, and establish mechanisms for their retention and professional development.
e. Evaluations of competence shall be performed at specified intervals. Professionals shall be registered with the relevant bodies and shall have a valid practicing certificate at any given time.
f. Training programs shall be developed, implemented and monitored to ensure staff members are competent in the tasks that they perform, and they are aware of the relevance and importance of their activities in achieving the Service's or health institution's objectives.
g. Records of education, training, skills and experience must be maintained.

1.3.2 Infrastructure

a. Management shall provide the necessary facilities, equipment and reagents for collection, processing, testing, storage and issuing of blood and blood products.
b. Management shall ensure that the working environment, whether permanent, temporary or rented, complies with relevant statutory requirements.
c. Premises shall be appropriate for the activities performed, adequate in size, well ventilated, adequately lit and kept tidy.
d. Premises shall allow for an orderly workflow with adequate separation between different functions. Facilities should not invalidate or adversely affect operations or test results.
e. There shall be evidence of compliance with national health and safety regulations.
f. The management shall ensure scheduled maintenance and repairs to buildings, utility installations, fixtures, instruments and equipment.

1.3.3 Equipment

a. All equipment and instruments procured shall meet requirements and technical specifications.
b. All equipment and instruments shall be validated for their intended use. Validation records shall be kept and be easily accessible when required by an authorised officer.
c. Suppliers of new equipment shall train and certify a critical number of staff.
d. All instruments and equipment shall be uniquely identified.
e. The Service or health institutions shall identify, calibrate, maintain, and monitor instruments and equipment defined as critical to the provision of safe blood and blood components and services.
f. The organisation shall have a process for scheduled monitoring of all critical instruments and equipment. This process shall include a review of preventive maintenance records, standard operating procedures, operation manuals, and maintenance logs for all equipment.
g. The continuity of services shall be ensured through the availability of back-up equipment, where applicable.
h. Storage equipment shall have the capacity and design to ensure that the proper temperature is maintained and monitored continuously.
i. There shall be a process to monitor the temperature of refrigerators, freezers and platelet incubators, and water baths continuously.
j. The Service and hospital blood banks shall establish mechanism to allow for inventory management of blood and blood components.
k. The Service and hospital blood banks shall have a policy for "retiring" obsolete and unserviceable equipment.
l. Room temperature shall be maintained at 18 – 25^{o}C
m. There shall be appropriate boxes for transportation of blood to and from hospitals and from the blood bank to the hospital ward.

1.4 Purchasing and sub-contracting

1.3.1 There shall be a process in place for the selection and evaluation of suppliers of critical materials. An up-to-date list of approved suppliers shall be kept.

1.3.2 Management shall implement policies, processes and procedures to ensure that the providers of critical goods and services can consistently meet the defined Standards of quality.

1.3.3 The Service and hospital blood banks shall ensure that agreements to obtain blood, blood products, supplies and services (including equipment) are in place and define each party's expectations.

1.3.4 The Service and hospital blood banks shall receive, inspect and where necessary, qualify incoming critical materials, blood and blood products, and products prior to acceptance or use.

1.5 Quality Policy and Management System

1.5.1 The Service and hospital blood banks shall ensure that there is a defined and documented policy for achieving and maintaining quality. The quality policy shall:

a. be appropriate and cover all activities

b. include the commitment to comply with any statutory or accreditation requirements

c. include the commitment to continually improve the effectiveness of the quality management system

d. be communicated and understood within the Service or health institution Service or health institution so that all staff understand their role in ensuring quality

e. Be reviewed for ongoing suitability.

1.5.2 The Service and hospital blood banks shall develop and implement policies, processes and procedures to ensure that the requirements of these Standards are met. All such policies, processes, and procedures shall be in writing and shall be adhered to.

1.5.3 Top management shall ensure that corporate and departmental quality objectives and strategies are set. These shall be measurable and consistent with the requirements of the Quality Policy.

1.5.4 The integrity of the quality management system shall be maintained when changes to the quality management system are planned and implemented.

1.5.5 Top management shall review the quality management system, at planned intervals, to ensure its continuing suitability adequacy and effectiveness. This review shall include:

a. Outcomes of audits performed.
b. Non-conformances/ errors and corrective and preventive outcomes recorded.
c. Production and product monitoring records
d. Staff training activities
e. Donor and customer feedback
f. Outcomes and actions from previous reviews
g. Changes within the Service or health institution.

1.5.6 The review shall be used to assess opportunities for improvement, and the need for changes to the quality management system, including the quality policy and any quality objectives.

1.5.7 The output from the management review shall be documented and shall include any decisions and actions related to:

a. Improvement of the effectiveness of the quality management system and its processes.
b. Improvement of product related to customer requirements
c. Resource needs.

1.6 Documentation

1.5.1 The Service and hospital blood banks shall have policies, processes, and procedures to ensure that documents are identified, approved, implemented, retained and that records are created, stored and archived in accordance with record retention policies.

1.5.2 Documented procedures must exist for all activities that may impact on the health and safety of donors and recipients of human blood and blood products.

1.5.3 There shall be a process for document control which provides for:

a. Approval of documents for adequacy prior to issue
b. Review and revision of documents as necessary and their re-approval
c. Identification of changes and the revision status of documents
d. The provision of approved, current revisions of documents at points of use.
e. The protection of documents so that they remain legible and readily identifiable
f. The identification and management/control of documents of external origin.
g. Measures to prevent the unintended use of obsolete documents and to mark them suitably should they be retained for any purpose.

1.7 Records

1.7.1 The Service and hospital blood banks shall implement a procedure for the identification, collection, indexing, access, filing, storage and disposition of records.

1.7.2 All records shall be stored in facilities that prevent damage and deterioration in a format that allows easy retrieval.

1.7.3 There must be an audit trail allowing traceability for blood and blood product from the donor to the recipient. The key to traceability is the donation number. From the donation number it must be possible to trace every step in the history of each unit of blood or production history of each product made, including all screening results and the results of any other monitoring performed.

1.8 Information Communication Technology

1.8.1 The Service and hospital blood banks shall have a process to support the introduction of new software, hardware, or databases, or modifications of existing software, hardware or databases relating to the requirements of these Standards.

1.8.2 The responsibility for final validation, or accepting the validation of the supplier of the software and hardware, is that of the Service or hospital blood banks.

1.8.3 A designated person in each Service or hospital blood banks must ensure that the design, validation, documentation and changes to software are controlled in a systematic way.

1.8.4 A designated person should be responsible for auditing the quality aspects of the computer system.

1.8.5 Responsibility for editing and release of test results/ blood products shall be documented.

1.8.6 The Service and hospital blood banks must have an alternative system that ensures continuous operation in the event of computer failure.

1.9 Process Control

1.9.1 The Service or hospital blood bank shall control the processes needed for production and service provision through

a. Availability and use of work instructions
b. Use of suitable equipment in all processes
c. Implementation of monitoring and measuring activities using suitable equipment
d. Clearly defined product and service specifications

1.9.2 The Service or hospital blood bank shall ensure that process steps are accomplished as documented and are performed in a manner consistent with defined procedures.

1.9.3 There shall be a program for the qualification/ validation of equipment, facilities, processes, test methods, reagents and software to ensure that they continually meet defined specifications.

1.9.4 All qualifications/validations shall be planned and approved prior to the work being undertaken. Post-implementation validation (re-validation) shall be performed where major changes have occurred or results indicate the need.

1.9.5 Results of qualification/validations shall be reviewed and acceptance/ rejection decisions made by designated persons. Validation activities shall demonstrate the ability of processes to achieve planned results.

1.9.6 Full records of qualifications/ validations undertaken shall be kept.

1.10 Corrective and Preventive Actions

1.10.1 There shall be a process in place to detect, document, classify and manage errors and non-conformances (actual and potential non-conformances) in the Service or health institution in order to correct the problem and prevent recurrences.

1.10.2 Root cause analysis shall be performed. Corrective and preventive actions shall be completed within defined time frames.

1.10.3 There shall be formal regular reviews of errors/non-conformances, preventive and corrective actions to detect and address trends. Any areas requiring specific action shall be identified.

1.10.4 Follow up shall be performed to verify and record the appropriate implementation of the corrective and preventive action taken.

1.11 Process Improvement

1.11.1 The Service or hospital blood banks shall have policies, processes and procedures for data collection, analysis, and follow-up of issues requiring corrective and preventive action.

1.11.2 Appropriate, timely, corrective and preventive action shall be taken to reverse any negative trends.

1.11.3 Data captured by the Service and hospital blood bank shall be standardized. Data type, frequency of analysis shall be reviewed periodically.

1.12 Control of non-conforming products

1.12.1 Upon discovery, nonconforming blood, blood components, critical materials and services shall be evaluated and their potential impact determined.

1.12.2 Nonconforming blood and blood components shall be identified and quarantined.

1.12.3 Blood, blood products, or critical materials that do not conform to these Standards shall be prevented from unintended distribution or use.

1.12.4 Blood or blood products determined after release not to conform to these Standards shall be recalled and quarantined to determine the effect of the nonconformity on the quality of the product and the health of the patient. The hospital shall be duly informed.

1.13 Assessments: Internal and External

1.13.1 **The** Service or health institution shall develop and implement appropriate internal quality assessment programmes.

1.13.2 The Service or health institution shall participate in appropriate external quality assessment programmes.

1.13.3 The Service or health institution shall have a proficiency testing programme in place to ensure technical competence of staff.

1.13.4 The results of all quality assessment and proficiency programmes shall be constantly reviewed and the outcomes recorded. Any issues arising should be investigated and the appropriate corrective and preventive actions performed.

1.14 Health and Safety

1.14.1 **The** Service or health institution shall maintain a programme and procedures to ensure the safety of donors, staff, patients and visitors on the premises in accordance with national regulations.

1.14.2 Baseline medical checks shall be done on staff and records shall be kept.

1.14.3 Accidents and incidents in the workplace should be reported and investigated in accordance with national regulations, to determine possible cause so that corrective and preventive action can be taken where applicable.

1.14.4 Appropriate personal protective equipment and clothing shall be provided and appropriately used.

1.14.5 The Service or health institution shall take adequate measures to ensure protection of the environment, for example, with regard to air emissions and disposal of waste particularly sharps and biohazardous waste.

1.14.6 There shall be an annual assessment, internal or external, of the establishment's safety programme.

1.14.7 Procedures for needle stick injuries or other injuries in the course of work should be attended to according to established policy. The Service or health institutions shall have such a policy in place and staff regularly informed of its contents.

1.14.8 The Service or health institutions shall have a designated health and safety officer responsible for occupational health and safety.

1.14.9 There shall be fully stocked first aid boxes at designated points.

1.15 Internal Audits

1.15.1 The Service or blood bank shall develop and implement a comprehensive internal audit programme to verify whether the quality system and operational processes are adequately implemented, comply with requirements of this standard and are effective.

1.15.2 The status and importance of processes as well as results of previous audits shall be taken into account when planning the audit programme.

1.15.3 Trained personnel shall be designated to carry out internal audits. Auditors shall be independent of the area being audited.

1.15.4 Internal auditors shall prepare reports that include deficiencies found and person(s) responsible for corrective actions. Reports shall be reviewed by the relevant department head and head of quality/auditing.

1.15.5 Timelines for the completion of corrective actions shall be defined and met.

1.15.6 There shall be a programme of external audits, by a suitable, independent body, to ensure that quality standards applied to the Service or health institution are achieved and maintained.

1.15.7 The Service or health institution shall maintain procedures for scheduling and conducting, and reviewing the outcomes of all audits.

1.16 Complaints and feedback

1.16.1 The Service or blood bank shall proactively gather information on the perception of their customers as to whether it has met customer requirements to their satisfaction or not.

1.16.2 The Service or health institution shall have a system for obtaining feedback from donors and customers/clinicians. The Service or health institution shall have a procedure for recording, reviewing and investigating relevant complaints.

1.16.3 Information from complaints and feedback shall be reviewed at defined intervals to detect trends and appropriate corrective and preventive action must be taken.

SECTION 2: ELEMENTS OF A BLOOD SERVICE

2.1 Introduction

This part covers activities that shall be carried out by the Service mandated to collect, test and distribute blood and blood products.

2.2 Donor Recruitment

2.2.1 The Service shall have responsibility for encouraging and retaining adequate numbers of volunteer donors. Blood donors shall be persons who voluntarily come and are recruited for non-remunerated blood or blood component donation to be used to save lives.

2.2.2 Donors shall be recruited and retained in a manner that recognizes the unique nature of their contribution and the right of the donor to be treated with dignity and in a fair and cordial manner. Recognition programmes that conform to the spirit of voluntarism shall be established and managed according to local policies.

2.2.3 Appropriate donor comforts shall be availed during the donation process.

2.2.4 The Service shall endeavour to educate the donor population regarding the value of voluntary blood donation, demystification of the donation process and risk to the recipient of blood products from Transfusion Transmissible Infections (TTIs).

2.2.5 The Service shall appoint an individual responsible for donor recruitment. Appropriately qualified donor recruiters shall be employed and accorded the necessary resources for donor mobilisation and recruitment.

2.2.6 The Service shall:

a. Solicit feedback from blood donors and take appropriate action based on the results received.
b. Create and maintain relationships with donors, other donor recruiters and other organisations.
c. Maintain appropriate donor records in order that donor follow-up be implemented.

2.3 Donor Selection and Qualification

2.3.1 Donors shall receive pre-donation counselling prior to donating blood so that they can make an informed decision. Donor selection criteria shall be developed and implemented. The Service shall have a policy to ensure that the donor qualification process is private and confidential.

2.3.2 Before each donation, the prospective donor must be interviewed in order to confirm that he or she is of normal health and has not suffered, or is not suffering from any illness. If the information is obtained verbally it must be suitably documented. Confidentiality shall be maintained.

2.3.3 Medical criteria for acceptance of blood donors in respect of the donor's health should be the same for donors of whole blood and of blood components. Additional criteria pertaining to aphaeresis donors are recommended where appropriate. The physical fitness of a prospective blood donor must be assessed at the time of the intended donation.

2.3.4 The prospective donor must meet the donor qualification requirements. Each establishment must maintain a document (guide) detailing medical and surgical conditions, medications (including immunisations and vaccinations) and exposure to potential transfusion transmissible diseases constituting grounds for deferral of donors, whether temporary or permanent. This document must be readily available at all times to staff whose responsibility it is to assess the suitability of donors.

2.3.5 Any donor who appears to be under the influence of alcohol or drugs or any person who appears not to provide reliable answers to the medical history or other questions must not be accepted as a blood donor.

2.3.6 Before donation, the prospective donor's history shall be evaluated and the donor examined to minimize the risk of harm to the donor and the potential recipient. Donors shall be evaluated by staff certified competent to carry out the task.

2.3.7 A questionnaire that includes national and local accepted criteria shall be prepared in a language which is understood by the donor, and shall be completed prior to each

donation. For donors who are illiterate or handicapped, assistance shall be given by donor registration staff.

NB: A mechanism must be established to permit a donor to request, in confidence and subsequent to a donation, for his/her donation to be discarded.

2.4 Informed Donor Consent

The blood collection staff shall ensure that donors understand the donation process and agree in writing prior to donation. The following issues shall be addressed in the agreement:

a. Tests done on donated blood including HIV, Hepatitis B, Hepatitis C and Syphilis
b. Processes that will be performed on donated blood;
c. The donor deferral, notification, counselling and referral procedure.
d. The possible uses of donated blood including its possible use for anonymous research purposes at the discretion of the Service.
e. Confidentiality i.e. donor specific information shall not be shared with third parties without appropriate consent.
f. Post-donation advice, care, and information about possible donor adverse events.

2.5 Donor Notification of Abnormal Results

2.5.1 Donors shall be informed of any medically significant abnormality identified during pre-collection evaluation which precludes them from donating.

2.5.2 Donors shall be informed and counselled about any clinically or serologically significant abnormality detected during laboratory testing.

2.5.3 All donors shall be notified of their test results as soon as possible where applicable, but not exceeding 30 days after donation.

2.5.4 The Service shall notify results and offer counselling or referral for a donor who has any confirmed reactive infectious disease marker.

2.6 Information about Donors

2.6.1 The Service shall have a process for managing post-donation information received from the donor or a third party about a donor's suitability.

2.6.2 Donor test results shall be maintained in a confidential manner and in conformance with the laws of the country.

2.6.3 The record of Donor counselling performed shall be kept in a counselling register which shall be kept as a confidential document

2.7 Criteria for Protection of the Donor

2.7.1 Donor Identification

The blood donor must be positively identified as the particular person who is registered or is being registered by the Service. Establishment of donor identity must be carried out at each time of registration, determination of physical fitness and during blood collection respectively. The person performing the act of withdrawal of the blood is responsible for ensuring that the donor in question has been positively identified and that he or she meets the necessary health and other recommendations. Donor identification shall be done by verifying name, date of birth and residential address. National Identification numbers shall be used where appropriate.

2.7.2 Donor Age

Blood donors must be healthy persons aged 16 years and above. The maximum age of donation is 65 years which can be extended to 70 years on the recommendation of a medical director.

2.7.3 Donation Interval

The interval between consecutive blood donations must not be less than 56 days unless authorised by a medical director. The donation interval for Apheresis platelet donors should be at least 28 days.

2.7.4 Volume of Donation

No donor should have more than10.5mL/kg donor weight of blood taken at any one donation. There shall be a mechanism to indicate that this volume has been reached so that collection is stopped forthwith.

2.7.5 Drug Therapy

A registered nurse or medical practitioner must evaluate prospective donors who are taking medications to determine their suitability to donate blood. A list of drugs requiring deferral from donation must be available in the Medical Guide available to staff during blood collection.

2.7.6 Blood Pressure

The systolic blood pressure should be minimum 90mmHg, maximum 180 mmHg and the diastolic minimum 60mmHg, maximum 100 mm Hg.

2.7.7 Pregnancy

Known existing pregnancy shall preclude routine donation until six months following normal conclusion of pregnancy.

2.7.8 Donor weight

Donors must have a minimum weight of 50 kg. Unexplained weight loss of a significant degree (at least 4,5 kg) shall be a reason for exclusion.

2.7.9 Haemoglobin estimation

The haemoglobin concentration shall not be less than 12,5 g/dl(125g/l) for females and not less than 13,5g/dl(135g/l) for males.

2.8 Criteria for the Protection of the Recipient

2.8.1 Risk of disease transmission

No blood shall be released for transfusion purposes if there is any reason to suspect from the donor's medical history, lifestyle, past donation record or physical condition that his or her blood may transmit disease, irrespective of the serological test results.

2.8.2 Venepuncture Site

The skin at the venepuncture site must be free of lesions. The site for venesection shall be thoroughly cleaned using surgically clean or sterile swabs and an approved swabbing solution

2.8.3 Receipt of Blood or Blood Components

Prospective donors who have received blood components or other human tissues known to be possible sources of blood-borne pathogens shall be deferred for a period of twelve months following such receipt.

2.8.4 Infectious Diseases

All prospective donors must give consent in writing for the donation to be screened for the following TTIs:

a. **HIV:** Prior to enrolment by an establishment, all prospective donors must be given and/or be shown educational materials informing them of the high-risk behaviour activities for contracting HIV and that a person who indulges in these high-risk activities must refrain from donating blood. Persons unable to understand such written information must be informed orally of the contents thereof, but due regard must be taken of the level of understanding of such donors. In addition, donor screening must include verbal or written questions relating to signs and symptoms associated with HIV-infection.

b. **Hepatitis**: Individuals with a history of jaundice or hepatitis shall only be considered as blood donors twelve months after recovery from the illness. At this stage, approved tests for HBsAg and HCV antibodies must be negative. Prospective donors who have been in close contact with an individual with hepatitis must also be deferred for a twelve month period.

c. **Syphilis and other Sexually Transmitted Diseases:** A prospective donor with a history of sexually transmitted disease must be deferred for twelve months following completion of therapy. In general, however, these infections are often associated with high-risk behaviour for other transmissible diseases and it is recommended that the Service should defer such donors permanently.

2.8.5 Potential Exposure to Blood or Body Fluids

Prospective donors shall be deferred from donating for 6 months following tattoo, scarification or skin penetration with instruments, weapons, or equipment contaminated with blood or body fluids.

2.9 Blood Collection

This section applies to the blood collection at fixed or mobile sites. The ultimate responsibility for the blood collection procedure lies with the medical director of the Service.

The responsibility at the blood collection site may be delegated to a medical practitioner or a registered nurse in attendance at the clinic.

The Service must have standard operating procedures (SOPs) for all phases or activities of the blood collection procedure covering but not limited to:

a. Donor Selection and identification
b. Preparation of the venepuncture site
c. Preparation of the blood pack
d. Performance of the venepuncture
e. Blood donation procedure and donor care
f. Taking of specimens.
g. Labelling of blood packs
h. Handling of donor adverse reactions.
i. Transportation of blood from mobile teams

2.10 The withdrawal of blood

2.10.1 The venepuncture site must be prepared by a method that provides reasonable assurance that the blood collected will be sterile. The collection shall be by an aseptic technique using a sterile closed system and a single venepuncture.

2.10.2 Continuous blood flow shall be maintained throughout the collection process. Blood must be mixed with anticoagulant at several intervals during donation process through gentle agitation.

2.10.3 Only approved sterile, pyrogen-free blood packs must be used to draw blood and for subsequent separation into blood components.

2.10.4 With the exception of certain modified red-cell concentrates the original pack (or closed system of blood packs) with a pilot-tube attached as an integral part thereof should be the final container for blood or red-cell concentrates.

2.10.5 Immediately prior to collection of blood, the pack to be filled must be inspected by the phlebotomist in a manner recommended by the manufacturers to ensure that the hermetic seal is intact, that there has been no leakage of the anticoagulant or

preservative solution from the pack and that the pack is in all other respects suitable for use. If there is reason to suspect that the seal is not intact or that leakage has occurred, the pack must not be used for the collection of blood.

2.11 Labelling

2.11.1 The Service must develop procedures to avoid possibility of errors in the labelling of blood containers and blood samples.

2.11.2 Blood collection staff must ensure that the unique number assigned to the donation appears on the donor session record, the primary pack, secondary packs and all the samples tubes used. If additional numbers are required for other purposes, they must be affixed to the primary pack. The unique number assigned must enable traceability of the donation back to the donor as well as to the recipient.

2.11.3 The donation record, blood container, and corresponding sample tubes must be labelled at the time of donation. Filling of the sample tubes must directly follow the cessation of donation. The location where each donation is bled should have its own separate facilities for handling of samples during donation and labelling.

2.12 Volume of Blood

2.12.1 The amount of blood collected shall be as specified by the manufacturer of the blood pack, with an allowance of ± 10%.

2.13 Inspection

Prior to release from the blood collection site, the pack and its associated tubing must be re-inspected for defects and its integrity must be checked by applying pressure to the pack to detect any leaks. Any defective packs must be marked for disposal and held separately from intact packs.

2.14 Storage and transportation of blood from donor clinics to Laboratory

After collection, blood shall be stored under conditions appropriate to the products to be made from it. The service shall put in place a procedure to be followed for storage of blood at mobile sessions and static clinics. The procedure shall guarantee safety of blood from point of collection up to the time of delivery to laboratory.

2.15 Care of Donors

2.15.1 The donor shall be observed closely during the donation and for 15 minutes thereafter.

2.15.2 Refreshments shall be offered to all donors after giving blood.

2.15.3 The Service shall have a process for treating donor adverse events and providing for medical care as necessary. Immediate assistance and the necessary equipment and supplies shall be available at all times.

2.16 Apheresis Procedures

2.16.1 Criteria for acceptance of donors

Other than in exceptional circumstances (to be decided by a medical director) donors for apheresis shall meet the usual selection criteria for ordinary whole blood donors. Prospective platelet cytapheresis donors with platelet count of less than $200x10^9/1$ should not undergo plateletapheresis. The full blood count should be determined before every donation. The donor's fitness to continue on an apheresis programme should be assessed by a designated medical officer, in the light of these results.

2.16.2 Frequency of aphaeresis and volume collected

Except at the discretion of a medical officer the following shall apply:

a. Donors shall not normally undergo
    i. plasmapheresis more than once every two weeks, or
    ii. a total of more that twenty-four plateletapheresis per annum

Apheresis donors must not donate blood for 48 hours after apheresis procedure.

b. During the aphaeresis procedure, the peak extracorporeal volume during any one cycle (excluding the volume collected but including the plasma collected during that cycle) should not exceed 15% of the estimated total blood volume.

c. The final collection volume (exclusive of anticoagulant) should not exceed 15% of total blood volume and should not exceed 600ml (reference), (excluding anticoagulant) unless intravenous replacement is given.

d. Not more than 390mls of platelets and 210mls of plasma shall be donated by one donor during a single apheresis procedure.

e. Red cell loss during an apheresis procedure should be kept below 25ml

2.16.3 Staffing and training in apheresis

The medical officer in charge of the apheresis programme must be responsible for establishing adequate staffing levels and for ensuring that the staff is properly trained. Responsibility for the day–to-day running of apheresis may be delegated to appropriately trained staff. A suitably trained doctor or registered nurse must be available on the premises at all times when donors are undergoing apheresis.

2.16.4 Specifications and inspection of apheresis sets

a. Blood components must be collected by apheresis using sterile single use disposable items from a licensed manufacturer.

b. A record must be kept of all lot numbers and / or batch numbers of all apheresis harness components and injectable materials to be used.

c. The complete harness / plasmapheresis set and individual packaging must be thoroughly inspected for faults prior to use and during the setting–up procedure.

d. If an occlusive kink or a leak becomes apparent during a machine procedure, then that procedure must be abandoned and any remaining blood constituents must not be returned to the donor.

2.16.5 Specification for automated donor apheresis machines

Machines must be correctly installed, commissioned and maintained according to manufacturer's instructions.

2.16.6 Anticoagulant

A licensed anticoagulant must be used at a ratio which achieves a final concentration of 15-25mmol/l citrate.

2.17 Autologous donations

2.17.1 The Service must comply with all the relevant sections of these Standards. There shall be written procedures and guidelines to cover the process of autologous donations and to prevent the possibility of the donations being used for unintended recipients.

2.17.2 Pre-operative blood donation procedures require the consent of the donor/patient's physician and the Service's medical director. Informed consent for the procedure must be obtained from the donor/patient.

2.17.3 It is recommended that the unit be kept separately from units for allogeneic transfusion and used solely for the purpose of autologous transfusion. However, the NBSZ may cross the unit over to the allogeneic supply if not required by the patient who donated the blood.

2.17.4 Autologous donors shall comply with all the donor selection and deferral criteria for allogeneic whole blood donations except where specifically indicated. In addition, certain minimum standards shall be met as follows: .

a. The volume of blood collected at any one procedure must comply with that outlined in these Standards.
b. The haemoglobin concentration of the donor-patient blood shall be not less than 130g/L (13g/dl) for males and 125g/L (12.5g/dl) for females, equivalent to a haematocrit of 0.39 unless specifically authorised by a medical doctor.
c. Blood should not be drawn from the donor-patient within 72hours of the time of anticipated surgery or transfusion.

2.17.5 Pre-operative donation must not be undertaken when the donor patient has, or is being treated for bacteria, viraemia or has a significant viral infection, malignant cancer or who has any local skin lesions.

2.17.6 ABO group, Rh-type and TTI testing must be performed according to these Standards prior to collecting the first unit of autologous blood. Where test results are abnormal, the patient's physician shall be informed and blood shall not be collected from the donor-patient.

2.17.7 In addition to the labelling requirements outlined for allogenic blood, the following information shall appear on a label attached to the blood containers: **AUTOLOGOUS DONOR; NAME, DOB, REFERRING PHYSICIAN**

2.17.8 Pre-transfusion testing shall be performed as for allogenic transfusions. Pre-transfusion compatibility testing, prior to the issue of autologous units, shall include obtaining a blood sample from the autologous donor and shall confirm that the ABO group and Rh D type match the donated units.

2.17.9 Peri-operative collection

Blood may be collected from the patient immediately pre-operatively, or collected intra-operatively from the operative site or from an extra-corporeal circuit. Although licensed hospitals do not usually perform such procedures, certain guidelines should be followed:

a. Blood collected peri-operatively shall not be transfused to another patient.
b. Methods for peri-operative blood collection and re-infusion shall be safe, aseptic and ensure accurate identification of all blood and blood components. The equipment used shall be pyrogen-free, shall include a filter capable of retaining particles potentially harmful to the recipient and must preclude air-embolism.
c. Units collected for isovolaemic haemodilution shall be stored under one of the following conditions prior to transfusion:
    i. At room temperature for up to 8 hours or
    ii. At 2-6^{0}C for up to 24 hours
d. The same storage criteria apply for units collected and processed under sterile conditions by other means that involve washing with 0.9% saline solution.
e. Infusion of blood collected intra-operatively by other means shall begin within 6 hours of initiating the collection.

2.18 Directed Donations

2.18.1 Directed donations are not considered good practice hence the Service shall discourage directed donations. However if there is shortage of a particular blood group, the Medical Director can use his discretion provided the donor meets the required criteria for blood donation.

2.18.2 Where there is no other blood available, the Service can consider allowing

a. A parent to donate to a child.
b. A donation from a regular donor to an immediate family member (not a female of child bearing age)
c. A donation to a family member necessitated by the presence of unusual blood group allo-antibodies that family member may have a better chance of providing compatible blood.

2.18.3 The unit of blood shall be clearly labelled with the pack number and name of intended recipient, provided it has passed all essential laboratory tests.

2.18.4 In the event that the unit of blood is not used for the intended patient the donor should agree that the unit is disposed of in a manner deemed fit or transferred for allogeneic transfusion if all criteria are met.

2.19 Therapeutic Venepuncture

2.19.1 Individuals for therapeutic venepuncture should be referred by their doctors. The doctor making a request should make a special written request to the medical director, specifying reasons for the request.

2.19.2 No request for therapeutic donation should be accepted without prior ratification by the medical director.

2.19.3 Individuals with haemochromatosis/ secondary polycythaemia may be enrolled as allogeneic blood donors with the consent of the Medical Director.

2.19.4 Units classified as therapeutic phlebotomies for primary erythrocytosis (polycythaemia vera) shall not be used for allogeneic transfusion.

2.19.5 Records shall be maintained including the patient's identification, diagnosis, therapeutic procedures, haemapheresis method, volume of blood removed and returned, time taken, nature and volume of replacement fluids, adverse reaction, if any, and medication administered.

2.19.6 Provisions for emergency care shall be available.

2.20 Blood Processing

2.20.1 Processing methods that ensure the quality and safety of all components including pooled platelets shall be employed. If the blood bag seal is broken during processing, components shall be considered to have been prepared in an open system and shall be discarded.

2.20.2 The sterility of all components must be maintained during processing by using aseptic techniques and pyrogen-free equipment.

2.20.3 The final container for plasma-reduced blood or a red-cell concentrate (other than a modified red-cell concentrate) must be the container in which the blood was originally collected, or satellite container attached as an integral part thereof. Alternatively, a sterile container which has been attached to the original container using a validated sterile connecting device may be used.

2.20.4 The final container for all other components must have been designed by the manufacturer for the purpose for which they are being used. When the final container is filled, it must be given a number or other symbol to enable identification of the donor(s) of the source of blood.

2.20.5 Wherever appropriate each secondary container must be similarly labelled according to the requirements for labelling stated in these Standards.

2.20.6 The timing and the method of separation and the storage temperature prior to separation will depend upon the components being prepared from the donation concerned.

2.20.7 When platelets and coagulation factors are being prepared from the same donation, separation of the components should be performed within six hours from the time of donation.

2.20.8 If platelet concentrates are to be prepared from whole blood unit, the blood should be kept at a temperature within +20°C to +24°C and the process completed within six hours from the time of donation.

2.20.9 Separation of blood cells by means of centrifugation must be done in a manner that will not raise the temperature of the blood. Provided that sterility is maintained, the type of separation used does not influence the expiry date of red-cell concentrates. However, if an open system which may not maintain sterility is used, (e.g. washed red cells) the expiry date must be 24 hours after separation.

Whole blood

Storage	At +4 °C ±2 °C.
Expiry date	35 days after collection if CPDA-1 anticoagulant solution used. 21 days if ACD-A, CPD or CP2D anticoagulant solution used.
Specifications	Volume to be set in accordance with national specifications.

ACD-A is acid citrate dextrose solution.
CPD is citrate phosphate dextrose solution.
CP2D is citrate phosphate dextrose-dextrose solution
CPDA-1 is citrate phosphate dextrose solution with adenine.

Plasma Reduced Red-cell concentrates

Preparation	Plasma-reduced red cells shall be prepared from whole blood collected in plastic bags, preferably in double or multiple bag systems. Red cells should be re-suspended in additive solution, or other suitable solution, to decrease the haematocrit and extend the shelf-life.
Separation time	Should be prepared within 72 hours preferably but not more than 7 days after collection.
Storage	At +4 °C ±2 °C.
Expiry date	If a closed system is used for separation, the expiry date shall be the same as whole blood. If additive solution is used, the expiry date may be extended in accordance with the blood container manufacturer's recommendations. If an open system is used with aseptic technique, the expiry date shall be 24 hours after separation. If aseptic technique is not used, the expiry time shall be 6 hours after separation.
Specifications	Volume shall be in accordance with national specifications. Haematocrit shall be 0.6 l/l ± 0.1. Leucocyte count shall be $\leq 2.4 \times 10^9$/unit for red cells in additive solution, buffy coat removed.

Red-cell concentrate, leucocyte-poor (filtered)

Preparation	Prepared by a method known to reduce leucocytes in the final component to specified levels. For achieving a level less than $5x10^6$ white cells, use of a leucocyte filter is necessary.
Separation time	Not more than 5 days after collection.
Storage	At +4 °C ±2 °C.
Expiry date/ time	If a closed system is used, each product shall have the same expiry date as the original donation from which it was prepared. If an open system is used, the expiry time shall be 24 hours.
Specifications	Volume shall be in accordance with national specifications. Haematocrit shall be 0.6 l/l ± 0.1. Leucocyte count shall be $\leq 5 \times 10^8$/unit when intended to prevent febrile reactions. Leucocyte count shall be $\leq 5 \times 10^6$/unit when required to prevent allo-immunisation or minimize the risk of CMV infection.

Red-cell concentrate, washed

Preparation	Units of red blood cells may be washed aseptically with sterile normal saline to remove contaminating white blood cells as necessary. This may be done by an automatic cell washer or manually by centrifugation. Units are to be washed 2-3 times with normal saline by interrupted or continuous-flow centrifugation at +4 °C ±2 °C. Recommendations for pilot-samples, labels and temperature for storage and transport are the same as those for red-cell concentrates
Storage	At +4 °C ±2 °C.
Expiry date/ time	When prepared in an open system, washed red cells shall be used within 24 hours.
Specifications	Volume shall be in accordance with national specifications. Haematocrit shall be 0.6 l/l ± 0.1.

Red-cell concentrate, frozen

Preparation	Red cells may be frozen at any time during the normal shelf life of the donation but should preferably be undertaken within 6 days of collection in the presence of a cryo-protective agent. Prior to transfusion, the cells must be washed to remove the cryo-protective agent. The method of preparation, storage, thawing and washing shall ensure a recovery of at least 70 % of original red cells. Requirements for pilot-samples, labels and temperatures for storage and transport are the same as those of red-cell concentrates.
Storage	At minus 65 °C to minus 196 °C.
Expiry date/ time	10 years from date of freezing. Once thawed and washed, the product shall be used within 24 hours.
Specifications	Volume shall be in accordance with national specifications. Haematocrit shall be 0.6 l/l ± 0.1.

Red-cell concentrates, paediatric

Preparation	Paediatric red-cell concentrate is prepared by separating into equal portions of a single donation of blood bled into a closed system. The separation is performed after the removal of the plasma and buffy-coat from the blood and after the addition of an approved red-cell preservative solution.
Storage	At +4 °C ±2 °C.
Expiry date/ time	Same as for the original donation of blood from which it is prepared.
Specifications	Volume shall be in accordance with national specifications. Haematocrit shall be 0.6 l/l ± 0.1.

Red Cell Concentrate, Paediatric, Filtered

Preparation	Paediatric red-cell concentrate is prepared by separating into equal portions of a single donation of blood bled into a closed system. The separation is performed after the removal of the plasma and buffy-coat from the blood and after the addition of an approved red-cell preservative solution. The buffy coat depleted red-cell concentrate in additive solution is passed through a leucocyte depletion filter before it is dispensed into satellite packs in appropriate volumes. Each unit of red-cell concentrate, paediatric, (filtered) must be individually labelled in accordance with the recommendations of these Standards for labelling.
Storage	At +4 °C ±2 °C.
Expiry date/ time	Same as for the original donation of blood from which it is prepared.
Specifications	Volume shall be in accordance with national specifications. Haematocrit shall be 0.6 l/l ± 0.1.

Plasma and plasma components from single donations

a. Fresh Frozen Plasma (FFP)

Preparation	Fresh plasma shall be separated from the whole blood within 6 hours of collection and frozen solid at minus 18 °C or, preferably, at minus 25 °C or lower as early as possible. FFP may be used for preparing cryoprecipitated Factor VIII before its expiry. It may be used for preparation of recovered plasma for fractionation even after its expiry date.
Storage	At minus 18 °C or below OR At minus 25 °C or below.
Expiry date/ time	12 months if stored at minus 18 °C or below. 24 months if stored at minus 25 °C or below. FFP must be reconstituted by thawing at a temperature not exceeding 37^{o}C. The use of a purpose-made plasma-thawing device is recommended. After thawing, the product shall be transfused as soon as possible or stored at +1 ^{o}C to +6^{o}C for up to 24 hours.
Specifications	Volume shall be in accordance with national specifications. FVIII:C should be $\geq$ 0,7 IU/ml. Test to be done where possible.

b. Paediatric FFP

Preparation	Prepared by making two separate units with a final volume of approximately 150ml from a fresh single blood donation from a group AB donor blood within 6 hours of collection and frozen solid at minus 18 °C or, preferably, at minus 25 °C or lower as early as possible. FFP may be used for preparing cryoprecipitated Factor VIII before its expiry. It may be used for preparation of recovered plasma for fractionation even after its expiry date.
Storage	At minus 18 °C or below OR At minus 25 °C or below.
Expiry date/ time	12 months if stored at minus 18 °C or below. 24 months if stored at minus 25 °C or below. FFP must be reconstituted by thawing at a temperature not exceeding 37^{o}C. The use of a purpose-made plasma-thawing device is recommended. After thawing, the product shall be transfused as soon as possible or stored at +1 ^{o}C to +6^{o}C for up to 24 hours.
Specifications	Volume shall be in accordance with national specifications. FVIII:C should be $\geq$ 0,7 IU/ml. Test to be done where possible.

c. Cryoprecipitate

Preparation	Single unit of cryoprecipitated Factor VIII plasma is obtained from a donated blood unit or by plasmapheresis. The product may also be prepared as a pool from a small number of donations, which must not exceed 12 in number. Fresh plasma for preparation of cryoprecipitate shall be frozen at minus 60 °C to minus 70 °C and thawed in a +4 °C circulating water bath or in a +4 °C cold room/blood bank refrigerator. The supernatant is drained and the remaining cryoprecipitate shall be frozen within 1 hour.
Storage	At minus 25 °C or below is ideal – at temperatures between minus 18 and minus 23 °C FVIII slowly deteriorates – although the product may be stored as such, shelf life is reduced.
Expiry date/ time	3 months if stored between minus 18 °C and minus 25 °C OR 24 months if stored at minus 25 °C or below. Cryoprecipitate must be thawed before infusion at a temperature between 30^{o}C and 37^{o}C. After thawing, the product shall be transfused as soon as possible or within 6 hours if it is a closed single unit or has been pooled prior to freezing. It should be transfused within 4 hours if it is an open

	system or units have been pooled after thawing.
Specifications	Volume shall be in accordance with national specifications. FVIII:C should be $\geq$ 80 IU/ml in at least 75% of tested cryoprecipitates. Test to be done where possible. Fibrinogen should be > 12 mg/ml or > 300 mg/ml if cryoprecipitate is made for fibrinogen. Test to be done where possible.

NB: Storage temperature and expiry dates of FFP and cryoprecipitate shall be as outlined in Table 2, Appendix II

d. Platelet concentrates, single random

Preparation	The donor shall not have taken aspirin-containing medication in the 72 hours preceding donation. The blood from which platelet concentrates or platelet–rich plasma is derived should be maintained within a temperature range of 20°C to 24°C until the platelets are separated. Platelet concentrates shall be separated from whole blood by centrifugation at +22 °C ±2 °C from either platelet rich plasma or buffy coats using validated methods. Platelet production methods adopted shall ensure that less than $5x10^6$ leucocytes remain in the final platelet concentrate. Platelets shall be suspended in at least 50 ml of plasma.
Storage	At +22 °C ±2 °C with continuous gentle agitation using horizontal agitator or rotor.
Expiry date/ time	3-5 days after blood collection, depending on the nature of the plastic bag used, except if an open system has been used then the unit shall be used within 6 hours. Filtration of concentrate may be effected at the time the product is infused by passing it through a bedside filter designed to remove leucocytes from platelet concentrates.
Specifications	Platelet count shall be $\geq 2.4 \times 10^{11}$. Leucocyte count, if leucocyte-reduced, shall be $\leq 5 \times 10^6$/unit. pH at +22 °C ±2 °C, at not more than 24 hours after expiry, shall be $\geq$ 6.0. The volume of original plasma or platelet additive solution to be used for resuspension must be such that a pH of 6.4 to 7.4 is maintained for the duration of storage.

e. Platelet concentrate, apheresis

Preparation	Platelet concentrates shall be collected by continuous/ intermittent flow apheresis.
Storage	At +22 °C ±2 °C with continuous gentle agitation using horizontal agitator or rotor.
Expiry date/ time	5 days after blood collection - except if an open system has been used, then the unit shall be infused within 6 hours.
Specifications	Platelet count shall be $\geq 3 \times 10^{11}$ in at least 75% of the units tested.. Leucocyte count, if leucocyte-reduced, shall be $\leq 5 \times 10^{6}$/unit. pH at +22 °C ±2 °C, at not more than 24 hours after expiry, shall be ≥ 6.0.

2.21 Testing of Blood

2.21.1 No blood or blood components shall be issued for transfusion unless at least two independent determinations of the ABO and Rh group have been performed.

2.21.2 The ABO blood group for each collection shall be determined by testing the red cells with anti-A and anti-B reagents and by testing the serum for expected antibodies with A and B reagent red cells.

2.21.3 The Rh D type shall be determined for each collection with anti-D reagent. If positive the label shall read "Rh D positive." If the initial test with anti-D is negative, the blood shall be tested using a method designed to detect weak D and when the test is positive, the label shall read "Rh D POSITIVE." When the tests for both D and weak D are negative, the label shall read "Rh D NEGATIVE."

2.21.4 ABO and Rh group shall be tested at each donation. Results shall be compared with previous records from the same donor and any discrepancies shall be investigated and resolved. If discrepancies cannot be resolved the unit may not be issued.

2.21.5 A donor's previous record of ABO and Rh D type shall not serve as identification of units of blood subsequently given by the same donor and each donation shall be identified and tested.

2.21.6 All donations shall be tested for immune ABO antibodies and units with high titres shall be labelled as such and issued to same group patients.

2.21.7 Serum or plasma from donors shall be tested for unexpected antibodies with pooled O Rh D positive cells or preferably a screening cell panel using a validated method known to identify clinically significant antibodies.

2.21.8 If a clinically significant allo or auto antibody is detected in the donor, the components prepared from this collection shall be released only after careful consideration as to the impact on the recipient. The outcome shall be documented.

2.21.9 A sample of blood from each donation shall be tested for HBsAg, HCV, HIV-1/2 antigen and antibody, and syphilis. The following minimum testing requirements shall be met:

a. Human Immunodeficiency Virus (HIV) Type 1 and 2 antibodies and antigen.
b. Hepatitis B virus (HBV). Minimum – Hepatitis B surface antigen i.e. HBsAg.
c. Hepatitis C virus (HCV). Minimum – antibodies to HCV.

d. Syphilis (Treponema pallidum). Minimum – antibodies to Treponema pallidum.

2.21.10 Whole blood and components shall not be distributed or issued for transfusion unless the results of all of these tests are non-reactive. Donors testing reactive for any of the above shall be added to a deferral registry.

2.21.11 The Service shall maintain algorithms for testing procedures and the rejection or re-entry of reactive donors.

2.21.12 Where no system exists that assures a positive match of sample and donated unit match, the testing strategy shall include testing of the unit itself.

2.22 Release and disposition

2.22.1 The Service shall have a process to ensure that all specified requirements have been met.

2.22.2 Testing and acceptability criteria shall be defined and there shall be evidence that all records relating to testing and acceptability criteria for the current donation, and the facility's deferral registry, have been reviewed.

2.22.3 The component shall be physically inspected for container integrity and normality of appearance.

2.22.4 ABO/Rh D grouping shall be compared to an historical group of the donor, if available. Discrepancies shall be resolved before release.

2.22.5 The Service shall ensure that blood and blood components found to be unsuitable are quarantined and are not issued for transfusion.

2.22.6 There shall be a method to confirm that the ABO/Rh D label is correct. Confirmation shall be performed after the ABO and Rh D label has been affixed to the units.

2.22.7 When a computer system is used, it shall be validated to prevent the release of ABO- and Rh D- mislabelled components.

2.22.8 The confirmation process shall be completed before release of blood and blood components.

2.22.9 The Service shall have a process to ensure that fully processed blood, blood components, and services are acceptable before distribution or issue. Whole blood or

components shall not be issued for transfusion until the mandatory TTI tests are completed and reported as non-reactive.

2.22.10 If due to urgent need, blood or components are distributed or issued before completion of these tests, a notation that testing has not been completed shall appear conspicuously on an attached label or tie tag. Required tests shall be completed and results reported to the health institution as soon as possible. The tag shall indicate that the clinician takes responsibility for using such blood or blood component. **Rapid tests for the markers should be carried out before issue**. Records shall be kept.

2.22.11 All blood and blood products that are unsuitable for transfusion purposes shall be discarded (incinerated) or used for reagents preparation and research purposes. Incineration shall be carried out as per environmental management guidelines and by-laws.

2.23 Transportation of blood

If blood is to be transported from the collection site to the component processing laboratory, it shall be placed in a container having sufficient refrigeration capacity to cool the blood and blood products continuously towards a temperature range as indicated in **Table 1**(**Appendix II)**. The same conditions shall apply for transportation of blood from the blood bank to the hospital. The 30-minute rule shall be observed.

2.24 Quality control

2.24.1 The Service or health institution shall have written procedures for the random sampling and quality control testing of blood components. A minimum of 1 % of the total number of each component routinely prepared or 4 units per month, whichever is higher, should be tested and at least 80 % of components tested should comply with specifications set.

2.24.2 A test for sterility should be done on 1 % of the blood units collected or 10 per month whichever is higher. The microbiological test shall not be done by a method that entails breaching the final container before the blood is transfused. The blood sample

from the tubing attached to the container should be used for sterility testing using appropriate techniques.

2.24.3 The Service or health institution shall analyse quality control results. If the analysis shows a consistent deviation away from specifications, the cause thereof` shall be investigated and corrective measures shall be taken.

SECTION 3: BLOOD TRANSFUSION ACTIVITIES

3.1 Introduction

This section covers all hospital-related issues from the organisational structure of the blood bank, expected blood bank activities, transfusion and post-transfusion activities, reporting and resolution of issues emanating from blood transfusion.

3.2 Structure of the Hospital Blood Bank

Each hospital blood bank shall have a defined structure that clearly identifies the parties responsible for ordering of blood and blood components, blood products, compatibility testing, storage and issue of blood products and related services. The head of the institution shall be the overall head of the blood bank.

3.3 Samples and Requests

3.3.1 The patient and the blood samples shall be positively identified and counter-checked at the bed side. The patient's doctor shall be identifiable.

3.3.2 Requests for blood and blood components, and the associated blood samples from the patient shall contain sufficient information to uniquely identify the patient. . This information shall include; patient's full names, hospital number, hospital name, ward and doctor. The Service and hospital blood bank shall accept only complete, accurate, and legible requests.

3.3.3 Blood samples shall be identified with an affixed label bearing sufficient information for unique identification of the patient and the date of the sample collection. The completed label shall be attached to the specimen tube before leaving the side of the patient.

3.3.4 The Service and hospital blood bank shall confirm that all identifying information on the request form is in agreement with that on the sample label. In case of discrepancy or doubt, another sample shall be requested.

3.4 Pre-transfusion testing

3.4.1 Patient samples shall be stored at +2^{o}C to +6^{o}C for up to seven days after date of receipt.

3.4.2 Prior to transfusion, the ABO group and the Rh D type of each Whole Blood and Red Blood Cell component shall be confirmed by a serologic test on a sample drawn from a segment of the pilot tube. Discrepancies shall be reported to the nearest Service branch and shall be resolved before issue of the blood for transfusion purposes.

3.4.3 If additional transfusions are required and the time period since the last transfusion is more than 72 hours, a new sample shall be submitted to perform compatibility testing.

3.4.4 Patient's blood submitted for compatibility testing shall be tested for ABO group, Rh D type and unexpected antibodies to red cell antigens. If ABO discrepancy is detected and transfusion is necessary before resolution, only group O Rh-negative red blood cells shall be issued. For unexpected antibodies:

a. When clinically significant antibodies are detected, additional testing shall be performed to identify the antibody and determine the titre.
b. In patients with previously identified clinically significant antibodies, methods of testing shall be those that identify additional clinically significant antibodies.
c. A control system using Coomb's Control cells (IgG-coated O red blood cells) shall be applied to each antiglobulin test interpreted as negative.

3.5 Selection of Compatible Blood and Components for Transfusion

3.5.1 Recipients shall receive ABO/Rh group-compatible Red Blood Cell components or ABO group-specific whole blood.

3.5.2 Rh negative recipients must receive Rh negative blood or red cell components except that in times of shortage of Rh-negative blood, males and post-menopausal females may be issued with Rh positive blood provided it is ABO-compatible and cross match compatible.

3.5.3 Plasma should be ABO-compatible with the recipient's red cells, especially when the component is to be transfused to infants. Exception can be made for group AB plasma (which should preferably be reserved for neonates)

3.5.4 The donor plasma in platelet concentrates should be ABO-compatible with the recipient's red cells, especially in the case of infants.

3.5.5 When clinically significant red cell antibodies are detected or the recipient has a history of such antibodies, serologically compatible Red Blood Cell components or Whole Blood shall be prepared for transfusion. In reasonable qualifying circumstances and in agreement with the clinician, the least incompatible unit shall be issued. In these situations the patient must be transfused under constant observation. The reasons for that decision shall be recorded in the patient records.

3.6 Serological Cross-match

3.6.1 Prior to issue, a sample of the recipient's serum shall be cross matched against a sample of donor cells. The cross match shall use methods that demonstrate ABO incompatibility and clinically significant antibodies to red cell antigens and shall include an antiglobulin test.

3.6.2 If clinically significant antibodies are detected in the recipient, blood lacking corresponding antigens on cells shall be crossmatched by a method including an antiglobulin phase, and the blood that is compatible, shall be issued. If antisera are available, units must also be confirmed negative for the corresponding antigen.

3.6.3 In certain clinical conditions, where auto-antibodies are present, the least incompatible unit may be issued as long as the reaction is no stronger than that given by the auto-antibody.

3.7 Special Considerations for Neonates

3.7.1 An initial pre-transfusion specimen must be tested in order to determine ABO group and Rh. Type. The serum of either the infant or the mother may be used to perform tests for unexpected clinically-significant antibodies.

3.7.2 Repeat ABO grouping and Rh typing may be omitted for the remainder of the infant's hospital admission.

3.7.3 If the initial antibody screen is negative, group O, Rh compatible blood may be issued. It is then unnecessary to crossmatch donor red cells for the initial or subsequent transfusions.

3.7.4 If the initial antibody screen is negative and non group O red-cell components have been issued, compatibility testing should then be performed for subsequent transfusion of all red-cell components.

3.7.5 In the management of haemolytic disease of the newborn, it is preferable to use the mother's serum for cross matching and issue red blood cells which are compatible with the mother. In the absence of maternal serum, neonatal serum shall be used.

3.7.6 If a non-group-O neonate is to receive group specific blood cells that are not compatible with the maternal ABO group, the neonate's serum or plasma shall be tested for anti-A or anti-B. Test methods shall include an antiglobulin phase using either donor or commercial A_1 or B cells.

3.7.7 If anti-A or anti-B is detected, red blood cells lacking the corresponding antigen shall be transfused.

Note: In relevant geographic regions where haemoglobin S is prevalent, it may be necessary to screen donors for haemoglobin S. Refer to a specialist immunohaematologist if required.

3.7.8 To perform exchange transfusions, the freshest (less than 5 days old), usually group O Rh D negative blood, available shall be used.

3.8 Massive Transfusion

The Service and hospital blood bank shall have a policy regarding compatibility testing when, within 24 hours; a patient has received an amount of blood approximating the total blood volume.

3.9 Final Inspection

3.9.1 The blood bank shall have a process to confirm agreement of the identifying information, the patient records, blood or blood component and the request. Discrepancies shall be resolved before issue.

3.9.2 Blood and blood components shall be inspected and verified by the blood bank and the clinician prior to transfusion.

3.9.3 Each blood bag or blood component shall have an attached label or tie tag indicating:

a. The intended recipient's name, hospital and laboratory numbers.
b. Pack number or pool number.
c. Special transfusion requirements.
d. The date and time of issue.
e. Signatures of the person issuing and receiving.

3.10 Special considerations for components

Fresh frozen plasma shall be thawed at 37oC in the in the blood bank. Upon completion of thawing it must be transfused immediately and the transfusion completed within 6 hours.

Cryoprecipitate shall be thawed at room temperature in the ward were transfusion is taking place. Upon completion of thawing it must be transfused immediately and the transfusion completed within 6 hours.

3.11 Reissue of Blood and Blood Components

Blood and blood components that have been returned to the Service or hospital blood bank shall be reissued only if the following conditions have been observed:

a. The blood has been returned to the blood bank within 30 minutes of issue.
b. The container closure has not been tampered with.
c. All components have been maintained at the appropriate temperature.
d. The records indicate that the blood or component has been inspected and that it is acceptable for reissue.

3.12 Urgent Requirements for Blood

3.12.1 The Service and hospital blood bank shall have a process for the provision of blood and blood components before completion of compatibility tests. Recipients whose ABO group is not known shall receive group O Rh D negative red blood cells.

3.12.2 If blood is issued before completion of compatibility testing, recipients whose ABO group has been determined shall receive only ABO group-compatible red blood cell components or ABO group-specific whole blood. The blood bag tie tag or label shall indicate in a conspicuous fashion that compatibility testing was not completed at the time of issue.

3.12.3 Compatibility testing shall be completed as per procedure after release of units. If any incompatibility is noted, the attending physician shall be notified immediately and the transfusion stopped. The units shall be recalled where possible.

NB: The records shall contain a signed statement from the requesting physician indicating that the clinical situation is sufficiently urgent to require release of blood before completion of compatibility testing.

3.13 Administration of Blood and Blood Components

3.13.1 There shall be a procedure for the administration of blood and blood components, including the use of infusion equipment and ancillary equipment.

3.13.2 The Service and hospital blood bank shall participate in the development of policies, processes and procedures regarding recipient consent for transfusion. At a minimum, elements of consent shall include:

a. A description of the risks, benefits and treatment alternatives;
b. The opportunity to ask questions; and
c. The right to accept or refuse transfusion

NB: In emergency cases the medical officer may transfuse blood on behalf of the head of health institution in order to save life.

3.13.3 Transfusions shall be prescribed by a medical doctor and administered by a qualified nurse.

3.13.4 Immediately before transfusion, the clinician shall verify that all information matching the blood or blood component with the intended recipient has been verified in the presence of the recipient.

3.13.5 All identification attached to the pack shall remain attached until the transfusion has been terminated or completed.

3.13.6 The patient's medical record shall include transfusion order and requisition, the name of the component, the donor unit or pool identification number, the date and time of transfusion, pre- and post-transfusion vital signs, the amount transfused, the identification of the clinician and, if applicable, transfusion adverse events.

3.13.7 The patient shall be observed for potential adverse events during the transfusion.

3.13.8 Specific instructions concerning possible adverse events shall be provided to the patient or a responsible caregiver when direct medical observation or monitoring of the patient will not be available after transfusion.

3.13.9 Blood and blood components shall be transfused through a sterile, pyrogen-free blood transfusion set that has a filter designed to retain particles potentially harmful to the recipient.

3.14 Transfusion complications

3.14.1 Each hospital shall have a system for reporting and evaluating suspected adverse transfusion reactions. In the event of a suspected transfusion reaction, the person attending the patient shall immediately stop the transfusion and notify the responsible clinician immediately.

3.14.2 The clinician must report the incident verbally as soon as possible and subsequently in writing to the Service or hospital blood bank using forms designed for this purpose.

3.14.3 All suspected transfusion reactions must be evaluated promptly and to the extent considered appropriate by the medical officer of the health institution. It is the responsibility of the health institution to maintain a register of all reported transfusion reactions. It is recommended that where there has been a severe reaction or death

following the transfusion of blood or a component, the clinician responsible for the transfusion must report it to the relevant hospital authorities.

3.14.4 Immediate Complications

Any adverse reaction experienced by a recipient in association with a transfusion is to be regarded as a suspected transfusion reaction. If there are symptoms or findings suggestive of a transfusion reaction the following must be done immediately;

b. The transfusion must be stopped forthwith,
c. The label on the blood packs and all other records must be examined to determine if an error has occurred in identifying the patient or the blood.
d. Obtain a labelled blood specimen from the recipient and send it promptly to the blood bank. In addition, the blood pack must be sent with the attached blood transfusion set and intravenous solutions to the blood bank.

3.14.5 A documented procedure detailing a protocol for the investigation of transfusion reactions must be maintained by the blood bank. Immediately on receipt of the blood specimen and container(s), the blood bank must do the following;

a. Inspect the recipient's post transfusion serum or plasma for evidence of haemolysis;
b. Perform a direct antiglobulin test on the post transfusion sample
c. Inspect the returned container for any abnormalities
d. Ascertain that no clerical error has occurred
e. Carry out ABO and Rh testing on pre- and post transfusion samples.
f. The blood bank must evaluate the results of the investigation and any clinically significant findings must be immediately reported to the clinician. A written report of all investigations must also be forwarded for recording in the patient's file.

NB: A separate laboratory unit should investigate all reported cases of transfusion reactions.

3.14.6 Delayed complications

If a delayed transfusion reaction is detected or suspected, tests must be done to determine and confirm the cause of the reaction.

3.15 Recipient notification (Look-Back)

Procedures must be established to identify recipients of blood components from donors who are subsequently found to have infection of HIV or other transfusion-transmissible diseases and, as far as possible, to have these recipients, doctors and health institution informed of the risk of infection; this must include fractionated products. The health institution must ensure that the necessary counselling services are available to the recipient.

3.16 Emergency Preparedness

The Service and hospital blood bank shall have emergency operation policies, processes and procedures to respond to the effects of internal and external disasters.

3.17 Hospital Transfusion Committees

Each health institution with at least fifty beds shall establish a hospital transfusion committee (HTC).

3.17.1 Goals

The HTC's goals shall be:

a. To provide an objective and accurate assessment of the use of blood and blood products in hospitals, and
b. To make recommendations on all aspects of transfusion medicine in order to promote the highest standards for patient care.

3.17.2 Responsibilities and Basic Functions of the Transfusion Committees

The responsibility of HTCs shall be to oversee the development of, and to monitor hospital-wide processes and procedures in the following areas:

a. Ordering practices for blood and blood products
b. Patient identification
c. Blood sample collection and labelling
d. Infectious and non-infectious post-transfusion adverse events
e. Errors and near-miss events
f. Usage and discard of blood and blood products
g. Appropriate use of blood and blood products.
h. Blood administration policies
i. The ability of the blood supply and related services to meet patient needs
j. Effective alternatives to transfusion
k. Compliance of practitioners (e.g., transfusing physicians) with peer-reviewed recommendations.
l. Any other activities that may be deemed necessary

3.17.3 Administration of Committee Matters

The following issues concerning committee administration should be agreed upon:

a. Committee Authorization: The source of the committee authority shall be from the MoHCW.
b. Committee purpose and Terms of Reference
c. Reporting structure
d. Chairmanship should at least have some background in transfusion management.
e. Composition of Membership should represent all areas that interact substantially with transfusion medicine issues. Suggested members include Senior representatives of:
    i. Hospital blood bank / Service.
    ii. clinical specialties that prescribe blood in the hospital such as Paediatrician, Obstetrician-gynaecologist, Surgeon, Anaesthesiologist, internist
    iii. Hospital Administration
    iv. Ward Sisters

v. Medical Records Administrator

vi. Junior doctors

NB: In the event that it is not possible to have representation from all of these areas, it is recommended that at a minimum the Service's medical director and senior representatives of clinical specialties that prescribe blood be on the committee.

3.18 Haemovigilance

The Service and health institutions shall establish a haemovigilance program.

The overall objectives of haemovigilance are:

a. To provide surveillance on blood donation and clinical transfusion activities.
b. To ensure that all adverse events are identified, investigated, reported and corrective measures taken, where possible.
c. To identify opportunities for improvement in areas of blood collection and clinical transfusion.
d. To ensure safe and efficient use of blood and blood products.
e. To promote blood safety and the prevention of adverse events.
f. To maintain awareness and monitor transfusion adverse events.
g. To provide a method for documenting and investigating transfusion reactions.
h. Transfusion consent for patients.

SECTION 4: MONITORING AND EVALUATION

4.1 Introduction

This section provides guidelines for monitoring and evaluation (M&E) of activities that are covered by these Standards.

4.2 M&E Requirements

4.2.1 The Service and hospital blood bank shall develop mechanisms to monitor and evaluate the implementation of these Standards.

4.2.2 The Service and hospital blood bank shall have designated M&E staff responsible for collating and reporting of the M&E indicators.

4.2.3 The Service and hospital blood banks shall identify M&E indicators to be used to monitor and evaluate implementation of these Standards.

4.3 M&E Indicators

Potential Indicators for M&E are shown **Table 4.1**.

Table 4.1 M&E indicators

Assessment Question	Indicators
A. Blood Collection	
Is there a designated national blood donor programme officer/manager? Are competent personnel available to carry out blood collection?	Designated staff
Are information and education materials available for blood donors?	Number of IEC material
Are there national criteria for assessing the suitability of donors for blood donation?	Available criteria
Are there procedures for pre and post donation counselling	Available procedures
Is there a donor care programme (list material under glossary)	Donor care programme

Blood Collections	Units collected by donor categories
B. Blood Testing and Component Preparation	
1. Are methods that ensure quality and safe preparation of blood components in place?	SOPs for component preparation available in the blood bank and adhered to.
2. Are blood and blood products stored and transported properly.	Cold chain records showing compliance of storage temperature requirements for each component.
3. Is competent personnel available to run blood banks nationally?	Qualification records showing training in blood banking principles.
4. Are TTIs and ABO/Rhblood grouping done for every donation?	Results of TTI testing and donor grouping
5. Are there mechanisms to cross check recipient identifiers against blood and blood components issued?	Check list forms showing compliance of information for each recipient in the ward.
C. Blood Distribution	
1. Are adequate and reliable supplies of safe blood and blood products available to meet demand?	Percentage of unfulfilled requests categorised by blood and blood product
D. **Clinical Transfusion**	
1. Is adequate, reliable equipment and supplies available to transfuse blood safely (e.g., transfusion administration sets, sterile saline, etc.)?	Percentage of unfilled transfusion requests by type of equipment and supplies
2. What proportion of blood and blood products is used in each clinical specialty?	Units requested/units transfused by patient category (e.g., obstetrics, paediatrics)
3. Are national guidelines on clinical use of blood utilized by clinicians?	Percentage of clinicians trained and are using the guidelines
4. Is a system to support the guidelines in place?	Monitoring the patient before, during, and after transfusion
5. Do clinicians comply with the guidelines?	Percentage of transfusions prescribed in accordance with the guidelines
6. Is there an HTC/Haemovigilance program?	HTCs in place and Haemovigilance reports

E. **Quality Management System**	
1. Do the policies, quality manuals and SOPs address issues raised in these Standards?	Policies, quality manuals, SOPs should comply with guidelines set in these Standards
2. Do the products meet set criteria for testing?	Testing algorithms for TTIs, SOPs and test results for respective donors
3. Do the products meet specifications set out in these Standards?	QC results as prescribed by these Standards
4. Are there procedures for qualifying equipment and reagents before use?	Validation, and QC results, SOPs
5. Is there a system for reviewing effectiveness of implementation of these Standards?	Audit reports, PT scheme reports, management review reports.
6. Is there a system for obtaining and acting on feedback from hospitals / clinics	HTC reports, transfusion reaction reports.

NB: The Service and health institutions shall design a feedback form for products distribution and usage. These forms shall be submitted to the Service monthly.

APPENDIX I:

SPECIFICATIONS OF BLOOD COMPONENTS MADE FROM DONATED BLOOD.

Product Description	Technical Information	Quality Measurements Required	Acceptable Results / Limits	Storage Temp	Max Storage Period
1. Whole Blood (WB)	A unit of blood collected into a pack with anticoagulant and contains 450mL of blood and 63mL of anticoagulant.	Volume Haemoglobin Haemolysis Haematocrit	420 -520mL approximately 12g/100mL < 0.8% of red cell mass at end of shelf life. 35 – 45%	4 ±2^{o}C	35 days
2. Packed Red Blood Cells with additive solution. (PC)	Red cell components prepared by removing a portion of plasma from whole blood and re-suspending the red cells in an approved additive solution (e.g. SAG-M).	Volume Haemoglobin Haemolysis Haematocrit	150 – 200mL approximately 20g/mL < 0.8% of red cell mass at end of shelf life. 55 – 75%	4 ±2^{o}C	42 days
3. Fresh Frozen Plasma (FFP)	Plasma obtained from whole blood or by aphaeresis and frozen within 6 hours of collection.	Volume: Random FFP Aphaeresis Factor VIII:C Platelets Total Protein Residual Cellular contents: RBC WBC Platelets	 200 – 300mL 200 – 210mL >0.70 IU/mL 30 x 10^{9}/L >50g/L <6.0 x 10^{9}/L <0.1 x 10^{9}/L <50 x 10^{9}/L	< -25^{o}C	1 year
4. Platelets (PLT)	Could either be obtained from single donor preparation or collected by aphaeresis	Volume: Random Aphaeresis Count: Random	 50 - 60mL 150 – 300mL ≥55 x 10^{9}/L	22 ±2^{o}C with agitation	5 days

		Aphaeresis pH Residual Cell Content: RBC WBC	150 – 500 x 10^9/L 6.4 – 7.4 <1.2 x 10^9/L <0.12 x 10^9/L		
5. Cryoprecipitate (CRP)	The component represents a source of concentrated Factor VIII:C, von Willebrand factor, fibrinogen, Factor XIII and fibronectin prepared from a unit of freshly collected plasma.	Volume Factor VIII:C Fibrinogen Residual cellular content: RBC WBC PLT	10 - 20mL 80 – 120IU/ unit 150 – 300mg / unit <0.3 x 10^9/L <0.1 x 10^9/L <50 x 10^9/L	< -25^{o}C	1 year
6. Washed Red Blood Cells	A red cell component washed with 0.9% w/v NaCl for injection and should be used as soon as possible.	Volume Haemoglobin Protein WBC Haemolysis Haematocrit	220 -320mL ≥ 40g/unit <0.5g/L <1 x 10^9/L < 0.8% of red cell mass at end of shelf life. 55 – 65%	4 ±2^{o}C	< 6 hours

Adopted from *The Clinical Use of Blood*, pages21 – 35.

APPENDIX II:

Table 1: Storage and Transportation Conditions for Whole Blood and Cells

Condition	Temperature Range	Storage Time
Transport of pre-processed blood	+20°C to +24°C	Less than 6 hours
Storage of pre-processed blood	+2°C to +6°C	Approximately 35 days
Transport of pre-processed blood	+2°C to +10°C	Less than 24 hours

Table 2: Permitted storage time according to temperature used to store FFP and cryoprecipitate.

Product	Storage Temperature	Maximum storage time
FFP	-65°C or below	7 years
FFP or Cryoprecipitate	-40°C to -64°C	24 months
FFP or Cryoprecipitate	-30°C to -39°C	12 months
FFP or Cryoprecipitate	-25°C to -29°C	6 months
FFP or Cryoprecipitate	-20°C to -24°C	3 months

Table 3: Product Specifications for QC

Parameters	**Product**				
	Platelets		**FFP**	**Whole Blood**	**Packed Cells**
	Random	**Aphaeresis**			
Volume (mL)	50 – 60	120 - 250	200 - 300	420 - 520	220 – 320
pH	6.4 - 7.4	6.4 - 7.4	N/A	N/A	N/A
Platelet	> 55 x 10^9/L	165 x 10^9/L	N/A	N/A	N/A
RBC	<0.3 x 10^9/L	<0.3 x 10^9/L	N/A	N/A	N/A
WBC	<0.1 x 10^9/L	<0.1 x 10^9/L	N/A	N/A	N/A
Haematocrit	N/A	N/A	N/A	N/A	
Culture	No growth	No growth	N/A	N/A	N/A
Storage Period	5 days	5 days	See Table 2	35 days	42 days

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