Ministry of Health

KENYA NATIONAL STANDARDS FOR BLOOD TRANSFUSION SERVICES

2ND EDITION

Kenya Blood Transfusion and Transplant Service

DamuKE
The Kenya Blood Banking Management System

Citation:
Ministry of Health Kenya, Kenya Blood Transfusion and Transplant Service, 2022. Kenya National Standards for Blood Transfusion Service, 2nd Edition. Nairobi, Kenya

Standards Development by:
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ABBREVIATIONS AND ACRONYMS

AIDS	Acquired Immunodeficiency Syndrome
BTC	Blood Transfusion Centre
CCC	Coombs Control Cells
CMIA	Chemiluminescence Microparticle Immuno Assay
CPDA	Citrate Phosphate Dextrose Adenine
ELISA	Enzyme Linked Immuno-Assay
EQAS	External Quality Assessment Scheme
FFP	Fresh Frozen Plasma GSH:
GSH	Group Screen and Hold
Hb%	Hemoglobin
HBsAg	Hepatitis B Surface Antigen
HBV	Hepatitis B Virus
HCV	Hepatitis C Virus
HIV	Human Immunodeficiency Virus
HR	Human Resource
IAT	Indirect Antiglobulin test
IQC	Internal Quality Control
MLT	Medical laboratory Technologist
MoH	Ministry of Health
NBTC	National Blood Transfusion Committee
NBTS	National Blood Transfusion Service
PRC	Packed Red Cell
PC	Platelet Concentrate
QA	Quality Assurance
QM	Quality Manager
QS	Quality System
RBC	Regional Blood Centre
SOP	Standard Operating Procedure
TPHA	Treponema Pallidum Haemagglutination
TTI	Transfusion Transmissible Infections
VBD	Voluntary Blood Donation
VCT	Voluntary Counseling and Testing
VNRBD	Voluntary Non-remunerated Blood Donors
WHO	World Health Organisation
WB	Whole Blood

GLOSSARY

Autologous blood: The blood drawn from the patient/recipient for re-transfusion
into him /her at later date.

Apheresis: A special kind of blood donation where specific components-platelets, red cells, plasma or white cells are collected and the rest of the blood returned to the body.

Blood: A body fluid in the (human) circulatory system that is composed of cellular components suspended in plasma.

Blood Transfusion Service: An organisation, generally with multiple facilities, that performs one or more of the following activities: donor mobilization, donor screening, blood collection, processing of blood into components, compatibility testing, storage, selection, and distribution of blood and blood components.

Blood storage centre: A centre that is involved in the following functions only; Receiving and storing of screened blood and blood components from another authorized blood establishment, performing compatibility tests, blood issue for transfusion.

Blood component: Any therapeutic constituent of blood that is separated by physical or mechanical means (e.g. red cells, platelets, plasma). It is not intended to capture plasma derived products.

Blood collection: A procedure whereby a single donation of blood is collected in an anticoagulant solution.

Blood product: Any therapeutic substance derived from human blood, including whole blood, blood components and plasma derived products.

Calibrate: To set measurement of equipment against a known standard.

Clinically Significant Antibody: Any allogenic or autologous antibody that is capable of producing a significant adverse reaction to transfused blood or component.

Closed System: A system for collecting and processing blood in containers that have been connected together by the manufacturer and sterilized, so that there is no possibility of bacterial or viral contamination from outside after collection of blood from the donor.

Corrective Action: An activity performed to eliminate the cause of an existing nonconformance, or other undesirable situation in order to prevent recurrence.

Competence: Ability of an individual to perform a specific task according to standard procedure.

Conformance: Fulfillment of requirements as defined by standards.

Critical: Capable of affecting quality.

Document (noun): Written or electronically generated information involved in providing a product or service. Examples are policies, standards, standard operating procedures, work instructions, reports and records.

Document (verb): To capture information for use in documents through writing or electronic media.

Donor: A person who gives whole blood or one of its components.

Donor-Patient: A person whose blood or tissue is collected for possible autologous
transfusion or transplantation.

Expiry: The last day on which blood, component, or tissue is considered suitable for transfusion or transplantation.

Equipment: A durable item, instrument or device used in a process or procedure.

Establishment: A facility that performs all or any of the following functions: recruiting blood donors, screening and selecting blood donors, blood collection, testing, and processing of blood units, transportation, receiving, and storage of blood units, pre-transfusion tests on patients' blood samples, issue of blood or blood components for clinical transfusion (compatibility testing and issue of blood components for clinical use).

Evaluation: It is a specific selection process to determine the suitability of a procedure or material (equipment, blood bags, or reagents).

Guidelines: Documented recommendations.

Good Laboratory Practice: Ensuring that laboratory functions are carried out in accordance with requirements and may include planning, performance, monitoring,recording and reporting of laboratory functions.

Good Manufacturing Practice:
Ensuring that products are consistently produced and controlled in accordance with appropriate standards and regulatory requirements.

Issue: To release for clinical use / transfusion.

Internal Quality Control: Testing that's routinely performed on material and equipment to ensure their proper function.

Label: An inscription affixed to a unit of blood, component or sample for identification.

Labeling: Information that is required or selected to accompany a unit of blood, component or sample, which may include content, identification, and description of process, storage requirements, expiration date, cautionary, or indication for use.

Maintain: To keep in the current state.

Material: A good or supply item used in manufacturing process. Materials are a type of input product. Reagents are a type of material.

Neonate: A young child less than 4 weeks of age.

Non-conforming units: Units that do not meet the set requirements

Organisation: An institution, or part thereof that has its own functions and administration.

Open System: A system, the contents of which are exposed to air and outside elements during preparation and separation of components.

Policy: A written statement which guides present and future decisions. It determines the future course of action to be established.

Process: A set of related task and activities, often performed by one person according to instruction.

Processing of blood: Any procedure that takes place after the blood is collected.

Process Control: The efforts to standardized and control process in order to produce predictable out-put.

Procedure: A series of task usually performed by one person according to instructions.

Pre-donation procedure: It includes mandatory process and activity done before proceeding with bleeding a donor.

Post-donation procedures: All procedures and activities done after bleeding a donor.

Preventive action: An action taken to reduce the potential for an error to occur.

Product: A tangible result of a process.

Quality: Characteristics of a unit of blood, component, sample, or service that bear on its ability to meet requirements. Fit for its purpose.

Quality System: The organisational structure, responsibilities, policies, processes, procedures, and resources established by executive management to achieve quality.

Quarantine: To isolate nonconforming blood, component or materials.

Reaction: In reference to a transfusion, a suspected or proven, unexpected response to a blood transfusion, manifested by signs and/or symptoms.

Reagent: A substance used to perform an analytical procedure. A substance used (as in detecting or measuring a component or preparing a product) because of its biological or chemical activity.

Replacement /family donation: donation given by an individual when it is required by a member of his/her family or community. This may involve a hidden paid donation system in which the donor is paid by the patient's family.

Satellite Centre: a facility that performs the following functions; Recruiting blood donors, donor selection, Pre-donation screening, Blood collection, Processing of blood units, Labelling of blood units, Storage and distribution of blood units.

Service: An intangible result of a process or procedure.

Shall: A term used to indicate a requirement.

Supplier: Individual or organisation that provides an input material or service.

Supplier Qualification: An evaluation method designed to ensure that input materials and services (e.g., materials, blood component, patient blood sample) obtained from a supplier meet specified requirement.

Traceability: The ability to follow all steps of a process or procedure from the beginning to end.

Unit: A container of blood or one of its components in a suitable volume of anticoagulant obtained from a collection of blood from one donor.

Urticarial Reaction: The development of hives, maculopapular rash, or similar allergic manifestation.

Validation: Establishing recorded evidence that proves a high degree of assurance that a specific process will consistently produce an outcome meeting its predetermined specification and quality attributes.

Verification: Evaluating the performance of a system with regard to its effectiveness based on intended use.

Voluntary non-remunerated donation: Donation is considered voluntary and non-remunerated if the person gives blood, plasma or cellular components of his / her own free will and receives no payment for it, either in cash or any other form of payment that could be considered a substitute for money. Small tokens, refreshments are compatible with voluntary, non-remunerated donation.

Whole blood: Blood collected in an anticoagulant solution with or without additives.

FOREWORD

Kenya is a signatory to World Health Assembly (WHA) resolution on availability safety and quality of blood products (WHA 63.12) that urges member states to take the necessary steps to ensure operation of regulatory authorities.

The Article 43 of the Constitution of Kenya, requires that all citizens access the highest attainable standards of healthcare services including emergency and reproductive health care. These emergency services include transfusion services. The Government of Kenya is thus mandated to ensure that there is safe and quality blood and blood products to the citizenry.

The Policy on Donation, Transfusion and Transplant of Human-Derived Medical Products guides on the developing standards and guidelines including on blood transfusion services.

These Kenya National Standards for Blood Transfusion Services stipulates the minimum requirements to be fulfilled so as to deliver quality transfusion services. The Policies will ensure safety of blood and blood products for all Kenyans. Importantly they provide the first regulatory framework, within which the public, private stakeholders and actors in blood ecosystem are required to operate in.

As a Ministry, we urge the players in the blood ecosystem to adhere to the set standards to ensure delivery of safe and quality blood and blood products to all Kenyans.

Dr. Patrick Amoth, EBS
Ag. Director General for Health

ACKNOWLEDGEMENTS

The Ministry of Health (MOH) will continue prioritizing and investing in the transfusion services and ensure the self-sufficiency of blood and blood products. These investments will be aligned to the stipulated standards of blood transfusion services to offer quality transfusion services.

Adherence to the set standard will ensure standardization of transfusion services across all actors in Kenya and enhance coordinated blood ecosystem.

All establishments within the National and County Governments, Faith Based Organisations and Private Sector offering transfusion services shall adhere to the laid down standards as per the guidance of this National Standards for Blood Transfusion Services.

We acknowledge and sincerely appreciate the commitment by the developers, reviewers and validators of the 2nd edition of the National Standards for Blood Transfusion Service in Kenya.

Dr. Julius Ogato
Ag. Head, Directorate of Health Care Services

EXECUTIVE SUMMARY

The Ministry of Health through the Kenya National Blood Transfusion Services (KNBTS) has revised the first edition of the blood transfusion standards. The objectives of the review were to update the standard with the current practices in blood transfusion practices. The standards apply to blood establishments that perform functions such as mobilization, recruitment, selection and screening of blood donors, collection of blood, processing of blood into blood products/components, testing of blood for blood group and transfusion transmissible infectious diseases, pre-transfusion compatibility testing, storage, handling, transportation and distribution of blood and blood products, collection and processing of plasma for fractionation.

These standards are anchored to the Constitution of Kenya 2010 and align to the Policy on Human Derived Medical Product Donation, Transfusion and Transplant, and other international jurisdictions. They cover the general quality system requirements as well as the more specific technical requirements.

Dr. Nduku Kilonzo, PhD, EBS
Head, Kenya Blood Transfusion and Transplant Service

INTRODUCTION TO KENYA NATIONAL STANDARDS FOR BLOOD TRANSFUSION SERVICE

This second edition of the Kenya National Standards for Blood Transfusion Services (KNBTS) was prepared by the Standards Committee of the KNBTS with support from the World Bank through the Covid -19 Health Emergency Response Project (C-HERP).

The standards are based on input from a variety of sources, including comments from recognized experts in blood banking and transfusion medicine and KNBTS staff.

The process of developing the standards started in December 2020. A Technical Working Group (TWG) was constituted and developed several drafts which were informed by the ministry's intent to address shortages, safety of blood and blood products and gaps in management of blood services.

Several meetings were held by the TWG and the first final draft subsequently shared with both internal and external stakeholders for inputs and comments. This was followed by several consensus meetings with key stakeholders during which validation and adoption of the draft was undertaken. The draft documents were then reviewed by the Ministry of Health heads of directorates to further contextualize the desired blood transfusion services standards.

Some terms or phrases are specifically defined for the purposes of these standards. The term "shall" is used to indicate a mandatory statement and describe the single acceptable activity or method; failure to meet the specified requirement would constitute nonconformity. The phrase "The blood establishment shall have a policy" or "have a process" indicates that an institution must have a specific policy or process to achieve the goal required by the standards. The word, "should" is advisory but is not required, it indicates a commonly accepted activity for which there may be effective alternatives

A glossary is included for the purposes of defining terms to define their usage in the context of this standard, not general usage. Therefore, it is recommended that users of these standards review the glossary before reviewing the standards.

These standards represent accepted performance requirements that may be exceeded in practice. Many organisations working in special situations can, and should, be more rigorous in their internal requirements. These standards have been developed on the basis of good medical practice and, when available, scientific data.

The guiding principle of this document is to be consistent with available scientific information while focusing on patient advocacy and optimal care for donors who provide blood and blood components. The requirements are intended to be simple, clear, and practical. The use of these standards should aid in developing and maintaining policies, processes, and procedures that will provide safe and effective transfusion, as well as a safe work environment for the personnel within the blood establishment.

The structure of this edition of Standards has been adapted from the Africa Society for Blood Transfusion (AfSBT) standards.

There are 11 Chapters in the standards. The first chapter provides a background on the blood needs versus the achieved collections. The second chapter focuses on Quality management and covers the most general quality requirements. These general requirements require that each level of the blood establishment have policies, processes and procedures to meet the intent of the chapter.

The subsequent chapters are technical, more specific and require the existence of policies, processes and procedures that guide their implementation while addressing the elements of blood establishment in day-to-day operations. The detailed and specific requirements are contained in the referenced standards, guidelines, and manuals which are listed in the annexes.

It is important to note, however, that all requirements are of equal importance, whether contained in a chart, a specific technical requirement, or a general quality standard.

01.

BACKGROUND

1.1 Global Situation on Blood Safety and Availability

According to the WHO Blood Safety and availability report of 10th June 2020, 118.5 million donations were collected globally. 60% of those collections were from low-income countries while the high-income countries accounted for 40%. The high-income countries represented 16% of the global population. In low-income countries, blood utilization was predominantly higher in the under-5-year age group whereas in the high-income countries those above 60 years of age accounted for 75% of blood transfusions utilization.

The blood donation rate was reported to be higher in the high-income countries with 31.5 donations per 1000 people. In the lower-middle and lower-income countries, the rate was 6.8 and 5.0 respectively. There was a reported increase of 7.8 million blood donations from voluntary unpaid donors from 2013 to 2018. In total, 79 countries collected over 90% of their blood supply from voluntary unpaid blood donors. 56 countries collected more than 50% of their blood supply from family/ replacement or paid donors.

With regards to plasma-derived medicinal products (PDMP), 55 countries produced these from plasma collected within the country, ninety countries imported all PDMP, while sixteen did not use PDMP at all.

1.2 Kenyan Situation

1.2.1 Blood need and supply

The WHO guidelines recommend minimum blood needs as 1% of a country's population. The Kenyan population has increased since 2000 when the US Government supported the establishment of the KNBTS following the 1998 terror attack. Since then, 35 blood centre, including 6 regional blood transfusion centre and 29 satellite centre have been set up to respond to the increasing blood needs.

With a population of approximately 47 million people (2019 Kenya Population and Housing Census, KPHC), this, therefore, means that the minimum blood needs in Kenya stand at approximately 470,000 units per year.

In the year 2019, 136,305 blood units were collected, while 100,108 were collected in the year 2020. These collections met only 29% and 21.2%, respectively, of the country's annual blood needs. Most of the donations were from volunteer donors, followed by those from family replacement donations. 77% of those donations were from first time donors. The onset of the COVID-19 pandemic worsened the situation further and there was a remarkable decrease in the number of blood units collected between January and December 2020.

1.3 Goals

The goal of the Standards is to provide a benchmark to maintain and enhance the quality and safety of blood transfusion in Kenya and to an extent, provide the minimum requirements to be fulfilled while facilities prepare for accreditation.

1.4 Purpose

These standards aim to ensure the provision of safe and quality services to all citizens by guiding, monitoring, and mitigating risks through the establishment and implementation of required systems and supportive structures within different categories of health facilities.

1.5 Objectives

1.5.1 Broad objective

Harmonize provision of quality blood transfusion services in the country per the aspirations of Universal Health Care.

1.5.2 Specific objectives

1. Guide KNBTS managers and staff at all levels of establishment in continuous assessment of performance and identification of strengths and gaps; for meaningful appraisal.
2. Improve equity and access to quality blood transfusion services.
3. Ensure efficiency and safety of blood transfusion.
4. Strengthen the national coordination structure for effectiveness and efficiency in blood transfusion services.
5. Strengthen partnerships collaboration for improved financing of KNBTS activities.

1.6 Scope

These Standards apply to blood establishment in public, private, faith-based, or non-governmental organisations providing the following services

i. Mobilization, recruitment, selection, and screening of blood donors.

ii. Collection of blood.

iii. Processing of blood into blood components.

iv. Testing of blood for blood group and transfusion transmissible infectious diseases.

v. Pre-transfusion/ compatibility testing.

vi. Storage, handling, transportation, and distribution of blood and blood components.

The specific requirements will, however, not apply if an establishment is not responsible for some activities.

1.7 Target Audience

These standards are designed for use by the personnel in transfusing facilities, blood establishments, managers involved in blood transfusion services.

1.8 Mission Statement

To coordinate and regulate the provision of blood tissue and human organ transplant services in Kenya.

1.9 Vision Statement

World class producer of blood transfusion, human organs and transplant services.

02.

QUALITY SYSTEMS

2.1 Organisation and Structure

2.1.1 Policy

The blood establishment shall be guided by the Kenya National Transfusion policy and shall conduct its activities in accordance with the policy's principles and code of ethics.

2.1.2 Organisational structure

The Blood Establishment shall have a clearly defined organisational structure that clearly defines and documents the parties responsible for licensed activities performed by the Blood Establishment. This structure shall be captured in writing or electronically and form part of the Quality Management Systems documentation.

The responsibilities of governance, organisational management, financial management and quality performance including any delegated responsibilities shall be clearly defined.

There shall be an organogram showing the clear delineation of these responsibilities, accountability and inter-relationships that will be reviewed every two years and updated as required.

2.2 Top Management

The blood establishment shall have clearly defined top or executive management under the direction of a qualified, trained designated person(s).

The top or executive management of the blood establishment will be responsible and accountable for operations, compliance with applicable legislation, policies- including quality-, regulations and conformance with these standards.

The defined roles of positions that constitute top or executive management of the establishment shall correlate with documented job descriptions.

2.3 Medical Director

The blood establishment shall have a locally licensed medical director qualified by education, training or experience.

The medical director shall be responsible for all medical matters, consultative and support care relating to the care and safety of donors and/or patients.

The medical director may delegate responsibilities to another qualified and licensed individual but will ultimately retain accountability for designated duties.

Exceptions to procedures warranted by clinical situations require case-by-case pre-approval by the Medical Director or designated medical officer.

2.4 Quality System Requirements

The blood establishment shall have a defined quality system that is documented and implemented, addressing the quality requirements in this standard.

All personnel shall be trained in the application of this system/or this shall be communicated to all personnel at the blood establishment so that they may know their role in ensuring quality.

The top/executive management of the blood establishment/establishment shall review and evaluate the quality system annually and use these reviews as opportunities for continuous quality improvement.

The annual quality system review should include a review of organisational management, governance, services with donor and client feedback, audit outcomes, identified non-conformances with their corrective and preventive actions, training activities, quality control results of produced blood components.

2.5 Quality Manual

The blood establishment shall maintain a quality manual that covers both the quality system and technical requirements and shall apply to all activities of an establishment:

2.6 Resources

The blood establishment shall have adequate human and financial resources allocated to perform their activities and meet the requirements of these standards.

2.6.1 Human resources

The blood establishment shall have a staffing plan to meet the establishment's needs ensuring that the blood establishment has an adequate number of trained and competent personnel to perform its activities.

The blood establishment shall have and keep job descriptions for all personnel with clearly delineated duties and responsibilities, job titles and reporting lines in correlation to the establishment's organogram.

Job descriptions of blood establishment personnel shall be updated and reviewed as needed; at least every two years.

The blood establishment shall have a training policy and plan that includes continuous education, training and assessment for all establishment staff to ensure acquisition and maintenance of the necessary competence to perform their assigned activities.

The blood establishment shall have a system for assessment of staff competence after initial training and at least once a year.

The personnel records for each employee shall be maintained and shall include at minimum:

i. Job description.

ii. Curriculum Vitae with both education and professional qualifications.

iii. Copy of certification or license where applicable.

iv. Training in current job tasks and records of continuing education.

v. Competency assessments.

vi. Immunization status where relevant.

vii. Accident and occupational hazard exposure reports.

viii. Record of signature and initials.

2.6.2 Financial resources

The blood establishment shall identify adequate financial resource requirements to perform the establishment's activities.

A budget to ensure ongoing operations shall be developed by the establishment.

2.7 Documents and Records

Only recognized or defined abbreviations or acronyms shall be used in the blood establishment/facility's documents and records.

2.7.1 Documents

The blood establishment will have and maintain a document control system with processes and procedures to address document creation, identification, review, revision, change control, approval, retention, and final disposition.

The blood establishment shall have written standard operating procedures that are maintained and followed for all procedures and activities affecting:

i. Donor safety.

ii. Recipient safety.

iii. Facility staff and visitors' safety.

iv. Quality and safety of blood and blood components.

Establishment documents shall be:

i. Maintained in a document control system Master List (s) with a unique identifier.

ii. In a standardized format.

iii. Legible and accessible to personnel who require them for their activities.

iv. Dated to ensure only current documents are used and obsolete documents are archived.

v. Reviewed and revised as needed, at least every two years as per the blood establishment's procedures for change control.

The blood establishment shall have a system for staff to record and sign that they have read and understood the facility's Standard Operating Procedures.

2.7.2 Records

The blood establishment shall ensure identification, collection, indexing, access, filing, storage and disposition of records as required by the Records Reference Standard 5.2A.

The blood establishment records, including electronic, shall be complete, legible, retrievable in a period of time appropriate to the circumstances, and protected from accidental or unauthorized disclosure, destruction or modification.

The establishment's records shall be maintained for a minimum period of 7 years or more where the regulations give such requirements .

A system designed to ensure confidentiality of records and prevent unauthorized access shall be established and followed by the facility.

The blood establishment shall have a system to ensure that copies of records are identified as such and verified to contain the original content; and shall be legible, accessible, and complete.

The blood establishment's record system shall ensure that donors are uniquely identified.

The record system shall make it possible to trace blood or blood components from source to final disposition, including all screening, testing and, if performed, monitoring results; and to investigate any adverse events in the recipient.

The records system shall ensure that all donors are uniquely identified.

Records shall be created, concurrently with activity performance, and maintained to include:

i. Critical activities performed.

ii. The individual who performed the activity.

iii. When the activity was performed.

iv. The outcome or result and final interpretation on activity completion.

Any changes or corrections made shall be dated and signed or initialed.

2.7.3 Electronic records

There shall be procedures to support the management of the blood establishment's computer systems/ information systems

The blood establishment shall have a system in place for routine back-up of critical data, with back-up data stored in an off-site location.

The blood establishment shall have procedures to ensure that the back-up data are retrievable and usable.

2.8 Suppliers, Purchasing, Inventory and Service Providers

2.8.1 Suppliers

The blood establishment shall have policies, processes and procedures to evaluate the ability of suppliers and critical materials, equipment and services to consistently meet required specifications; and shall participate as far as possible in the selection of these suppliers.

For facilities that do not participate in procurement activities, the blood establishment shall define its requirements to the procurement authority and report any failure of a supplier to meet those specifications.

The blood establishment shall maintain records of suppliers' performance which shall be reviewed and updated at least every two years.

2.8.2 Inventory

The blood establishment shall develop, implement and maintain an inventory management system for all supplies.

All relevant records shall be maintained.

2.8.3 Agreements

The establishment shall specify by agreement any activities covered in and defined by these standards that are performed by a subcontractor.

Agreements shall define supplier and customer expectations and reflect agreements between the two parties.

When more than one facility is involved in the activities covered by these standards, the responsibility of each facility shall be specified by an agreement.

Agreements shall be reviewed at least every two years, and prior to any renewals or extensions.

2.9 Incoming Receipt, Inspection and Testing

The blood establishment shall have a procedure for the receipt, inspection and if required, testing of incoming blood and blood components, and critical materials before acceptance or use.

All critical materials used by the blood establishment shall meet required specifications as given by the applicable authority's criteria. This includes (but is not limited to):

i. All reagents used for required tests on blood samples.

ii. All containers used for collection and storage of blood and blood components, and blood samples.

iii. All solutions used for preservation of blood and blood components and blood samples.

The blood establishment shall ensure by inspection that each container used for the collection, preservation, and storage of blood and blood components is intact.

The label on each container shall be complete, securely affixed, and legible.

2.10 Equipment

2.10.1 Requirements

The establishment shall have a have a documented procedure for the selection, purchasing and management of equipment.

The blood establishment shall identify equipment that is critical to the provision of blood, blood components and/or services.

The blood establishment shall have adequate equipment to carry out procedures in the required time-frame.

The establishment shall maintain an equipment inventory.

The blood establishment shall have processes and procedures to ensure proper functioning of this equipment to meet its required specifications. This shall include, but is not limited to calibration, monitoring and maintenance.

Equipment Calibration

i. Calibration shall be performed using materials and equipment with adequate accuracy and precision.

ii. Calibrated settings should be protected from invalidation by adjustments using adequate measures or safeguards.

iii. Calibration shall be performed before use, at manufacturer prescribed intervals and after any activities that may invalidate calibrated settings.

2.10.2 Equipment monitoring and evaluation

The blood establishment shall have a programme for scheduled monitoring and preventive maintenance that is in accordance with the manufacturer's instructions. The programme shall define/include:

a. frequency of checks.

b. methods of checks.

c. acceptance criteria.

d. actions to be taken for unsatisfactory results.

2.10.3 Equipment malfunction

Incidents of equipment malfunction or damage shall be investigated with follow-up to include:

i. Investigation of the malfunction or damage.

ii. Removal from use or isolation of the damaged or malfunctioning equipment with identification of said equipment as not suitable for use.

2.10.4 Equipment records

The establishment shall maintain records of all equipment within its custody.

Such records will include but not limited to the following

i. Identity of the equipment;

ii. manufacturer's name, model and serial number or other unique identification;

iii. contact information for the supplier or the manufacturer;

iv. date of receiving and date of entering into service;

v. location;

vi. condition when received (e.g. new, used, or reconditioned);

vii. manufacturer's instructions;

viii. Records that confirmed the equipment's initial acceptability for use when equipment is incorporated in the laboratory;

ix. Maintenance carried out and the schedule for preventive maintenance;

x. Equipment performance records that confirm the equipment's ongoing acceptability for use;

xi. Damage to, or malfunction, modification, or repair of the equipment.

2.11 Safety and Risk Management

2.11.1 Risk management

The establishment shall have a procedure to Identify and address potential functions safety risks.

The establishment shall evaluate the impact of work processes and potential failures on all its process as they affect patient safety, and shall modify processes to reduce or eliminate the identified risks and document decisions and actions taken.

Annual risk assessments shall be conducted to identify potential hazards in the workplace, to the environment, to staff and to clients.

2.11.2 Work environment

The work environment shall be suitable for the activities performed.

Premises shall be adequate in size, well ventilated, adequately lit and shall not invalidate or adversely affect operations. Special conditions for mobile collections shall apply.

Premises shall allow for an orderly workflow with adequate separation between different functions.

2.11.3 Safety programme

A safety programme shall be designed to mitigate or prevent occupational hazards.

The programme to protect the health and safety of the staff should include:

i. A disaster preparedness plan.

ii. The provision of protective clothing and appropriate safety equipment.

iii. Regular workplace safety audits.

iv. Staff vaccination as appropriate.

v. Prevention of needle stick accidents.

vi. Prevention of exposure to radiation or dangerous chemicals.

The establishment shall take adequate measures to ensure protection of the environment, and disposal of waste, including biohazardous waste.

2.11.4 Working conditions

The establishment shall have procedures to ensure the provision of safe working conditions that meet national laws and regulations.

Accidents, incidents and near misses in the workplace shall be reported, recorded and investigated.

Necessary personal protective equipment and clothing shall be defined, provided and used by all persons entering areas with a potential biohazard.

No unauthorized entry shall be permitted for visitors or unauthorized staff.

The establishment shall maintain procedures to ensure the safety of donors, patients and visitors on the premises.

The establishment shall maintain a procedure for post exposure prophylaxis for workplace exposure to HIV and hepatitis.

The establishment shall maintain a safety programme for infection prevention and control.

2.12 Internal and External Audits

2.12.1 Audit system requirements

The establishment shall have procedures to ensure that audits of operations and quality systems are scheduled and conducted at least once in each calendar year.

The establishment shall have procedures for reviewing the outcomes of all audits.

2.12.3 Internal audits

Personnel performing audits shall be independent of the area being audited

The internal audit reports shall be reviewed by personnel having responsibility for the area audited and the quality/auditing manager

When non-conformances are identified, corrective action shall be taken.

2.12.3 External audits

The establishment shall participate in external audit programme(s) performed by a qualified independent body.

2.13 Non-conformances

2.13.1 Identification of non-conformances

The establishment shall have procedures to detect, capture, assess,

investigate and monitor non-conformances, including those found as the result of internal and external audits.

The responsibility for review and authority for the disposition of non-conforming blood, blood components, critical materials, and services shall be defined.

2.13.2 Corrective action

The establishment shall have procedures for corrective action of non-conformances, complaints, workplace accidents and incidents, to include the following elements:

i. Description of the event.

ii. Immediate remedial action.

iii. Investigation of the root cause.

iv. Determination of corrective action required.

v. Follow up to ensure that corrective action is taken in a defined time frame and its effectiveness.

2.13.3 Preventive action

The establishment shall have procedures for preventive action that include the following elements:

i. Review of information including audit results, proficiency testing results, quality control records, and complaints to detect and analyse potential causes of non-conformances.

ii. Determination of steps needed to respond to potential problems requiring preventive action.

iii. Initiation of preventive action and application of controls to monitor effectiveness.

2.13.4 Non-conformance review

There shall be scheduled reviews of non-conformances to detect trends and address areas requiring specific action.

2.14 Non-conforming Units

The establishment shall have policies in place in the event of issue of non-conforming units.

The establishment shall be legally liable when non-conforming units are issued.

2.14.1 Discard of non-conforming units

The establishment shall have a procedure for the discard of non-conforming blood or blood components. Such units shall be labelled as not suitable for therapeutic use and shall be disposed of as biohazardous waste.

2.14.2 Recall of non-conforming units

The establishment shall have procedures for the recall of non-conforming blood or blood components that are determined after release for failure to meet specified requirements.

2.15 Continual Improvement

2.15.1 Requirements for continual improvement

A quality improvement plan that includes all parts of the establishment shall be developed and implemented.

The plan shall promote continual quality improvement, shall allocate responsibilities for effective implementation and shall be subject to regular evaluation.

2.15.2 Feedback from donors and customers/clinicians

The establishment shall have procedures to collect and evaluate quality indicator data on a quarterly basis.

Monitoring and evaluation data shall be used to improve operations of the establishment.

2.16 Process Control

The establishment shall ensure that activities that affect the quality of blood, blood components, and services are carried out under controlled conditions.

2.16.1 Validation activities

The establishment shall develop and implement procedures for the validation of new or changed procedures, and test methods prior to implementation.

Validation plans shall be approved prior to the work being undertaken.

Results shall be reviewed and acceptance/rejection decisions made by authorized individuals.

Re-validation shall be performed where changes have occurred or results indicate the need.

2.17 Change Control

The establishment shall have procedures for the management of changes to the establishment's operations and quality system so that the quality of the components and services is maintained.

2.17.1 Internal and External Quality Assessment (IQA/EQA)

The establishment shall develop and implement a system of IQA/EQA for determining the accuracy and reliability of tests.

As a minimum, the establishment shall participate in a formal EQA programme for all TTI tests.

If the establishment does not participate in EQA programmes for some of the other tests that it conducts, there shall be an IQA programme to ensure the accuracy of those tests.

Results of IQA and EQA shall be reviewed and corrective action taken, where appropriate, when expected results are not achieved.

If the establishment is not participating in an EQA system, then an inter-laboratory testing programme to compare results of laboratory testing shall be defined and documented.

2.18 Quality Control

A programme of quality control that is sufficiently comprehensive shall be established to ensure that personnel, reagents, equipment and methods function as expected.

The establishment shall randomly sample and perform quality control testing on blood and 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 75% of components tested should comply with the specifications set.

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

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

Results of quality control testing shall be reviewed to ensure that specifications are met and expected outcomes obtained.

Reagents shall not be used if quality control tests fail.

2.19 Use of Materials

All materials (including containers and solutions used for collection, preservation and storage of blood, blood components and reagents used for required tests on blood specimens) shall be stored and used in accordance with the manufacturer's written instructions and shall meet specified requirements.

Reagents that are prepared by the establishment shall be standardized to meet or exceed performance specifications of commercial reagents.

2.20 Identification and Traceability

For each critical step in collection, processing, blood grouping, transfusion transmissible infection screening, compatibility testing and transportation of blood and blood components, there shall be a mechanism to identify the individual who performed the step and when it was performed, and the equipment that was used, where practical.

The establishment shall ensure that blood, blood components and critical materials used in their processing, as well as laboratory specimens and donor and patient records, are identified and traceable from source to final issue or disposition.

Where pooled products are prepared traceability to individual donations shall be maintained.

03.

BLOOD DONOR MANAGEMENT

The availability of safe blood for donation is dependent on voluntary donors who give blood for the benefit of others without expecting any benefits for themselves. Blood transfusion service and hospital transfusion practice established by the Ministry of Health shall function in compliance with the ISBT code of ethics guided by the principles of autonomy, non-maleficence, beneficence, and justice. (Reference International Society for Blood Transfusion (ISBT) Code of Ethics 2017.

3.1 Mobilization and Recruitment of Blood Donors

The facility shall have SOPs for Donor Management (including mobilization and recruitment) that are inclusive and non-discriminatory.

Prior to collection, relevant pre-donation information shall be provided to educate potential donors through the medium of written materials in the appropriate languages, regarding:

i. the voluntary blood donation,

ii. informed consent,

iii. confidentiality,

iv. the donation process,

v. the risk of transmitting infectious diseases through blood transfusions,

vi. donor notification,

vii. the option to self-exclusion,

viii. possible adverse outcomes.

Blood shall be collected from healthy, voluntary non-remunerated donors identified by the facility to be at low-risk for transfusion transmissible infections and who meet the specified donor selection criteria

The establishment shall liaise with the public health authorities to monitor emerging infectious diseases that may be transmissible by blood.

Blood donors shall donate voluntarily without expectation of any incentives (monetary or in-kind).

Donors shall be appropriately recognized for their contributions. This recognition shall not unduly influence donor behavior or contradict the nature of voluntary non-remunerated blood donation.

The facility shall maintain appropriate donor records and mechanisms for donor follow-up.

3.2 Donor Selection Criteria

The facility shall develop donor selection criteria that are based on these standards, national laws, and regulations, for whole blood and/or apheresis donors (see guidelines on selection of apheresis donors).

The facility shall have procedures to ensure that medical consultation is offered when necessary. Records of such medical consultations and outcomes shall be kept.

Assistance shall be given by donor registration personnel to donors with special needs, including illiterate donors according to facility defined criteria

3.3 Donor Screening

The Blood establishment shall have a blood donor questionnaire that shall be in all the National languages and understood by the donor which shall be completed to determine eligibility for donation

The blood donor questionnaire shall have the bare minimum questions as provided by the standard KNBTS questionnaire. The questionnaire shall be evaluated, periodically updated, and used in a confidential manner and shall be completed prior to all collections.

Donors shall be interviewed to determine their suitability for donation. This interview shall be conducted in a manner that preserves the privacy and confidentiality of the donor.

Any medical queries shall be referred to suitably qualified medical personnel such as a registered nurse or medical officer.

3.4 Donor Consent

Donors shall be informed about the blood donation procedure, potential adverse reactions and post-donation care, the tests carried out on the donated blood, the process for notification of abnormal results, and information that may be released to a third party.

Written informed consent for donation, testing, and notification of normal and abnormal test results shall be obtained from all donors prior to donation.

The donor shall have the opportunity to ask questions and refuse consent. In the event that a potential donor refuses to provide consent, the blood donation shall not be drawn.

The blood establishment shall ensure that a mechanism exists to allow the donor to request withdrawal of the donated unit from the facility's inventory.

Written assent shall be obtained from donors below the age of 18 years.

Permission shall be sought in institutions when blood activities involve minors.

3.5 Donor Follow-up and Retention

The facility shall request feedback from blood donors and take appropriate action based on responses received.

The facility shall create and maintain professional relationships with donors, other donor recruiters, and facilities.

3.6 Donor Notification and Counseling

Donors shall be notified in a confidential manner of any medically significant finding(s) identified during the pre-donation evaluation.

Donors found to be reactive during screening for one or more TTI shall be notified and provided with counseling services.

When counseling services are not available, the facility shall identify and refer donors to appropriate external medical services.

The outcome of the donation process including infectious disease testing results, and blood type shall be accessible to the blood donor within 14 days of donation.

3.7 Information about Donors

The blood establishment shall have a system to manage donor information.

The information shall be accessible only to the authorized personnel.

3.8 Care of Donors

The collection facility shall have SOPs to ensure that the donor qualification process is private and confidential.

The donor shall be observed closely during the donation and not less than 20 minutes thereafter.

The collection facility shall have a process for management of donor adverse events and provision for availing first aid and referral for emergency medical care as necessary.

On the day of collection and before collection, the prospective donor history shall be evaluated and the donor examined to minimize the risk of harm to the donor and potential recipient.

3.9 Iron Deficiency Due to Donation

The purpose of this section is to prevent iron depletion caused by blood donation and minimize post-donation anemia while maintaining the adequacy of the blood supply. Long-term care- regular donors to be supplemented with iron with reference to the AABB donor iron deficiency risk-based decision-making assessment report.

Blood establishments should have a policy for each of the category of donors;

a. Frequent adult donors.

b. Adolescent donors (ages 16-18).

c. Premenopausal women.

d. Donors near Hb cutoff.

e. Deferral due to low Hb.

f. Donor return after Hb deferral.

Appropriate donor comforts shall be availed e.g. audio-visual privacy, physical comfort, and refreshments during the donation process.

04.

BLOOD COLLECTION

This chapter covers the processes involved in blood collection.

4.1 Sterility

Blood shall be collected into a sterile, pyrogen-free container that is a closed system for single-use.

4.2 Protection Against Contamination

Prior to collection of blood, the container to be filled shall be inspected in a manner recommended by the manufacturer to ensure that the hermetic seal is intact, that there has been no leakage of the anticoagulant or preservative solution from the container and that the container is in all other respects suitable for use.

The venepuncture site shall be free from lesions and signs of infection that might create a risk of contaminating the donation.

The venepuncture site shall be disinfected so as to minimize the risk of microbial contamination by following a validated method and using a qualified material that will not adversely affect the blood collected.

Blood shall be collected by single venepuncture and the flow of blood shall be continuous.

Maximum collection time for whole blood intended for production of labile components shall be no longer than 12 minutes for platelets and 15 minutes for cryoprecipitate and FFP.

4.3 Samples for laboratory tests

The blood samples for laboratory tests shall be collected at the same time as the collection of blood, as part of the collection process.

Donor identity shall be verified prior to venepuncture.

Samples shall be labeled before the collection begins and shall be re-identified with the blood container immediately before the collection of the samples.

Each sample shall be identified by a numeric or alpha-numeric system at the time of collection of blood, so that donations can be traced back to the donor.

The pilot tubing of the plastic blood bag shall be filled with anticoagulated blood and sealed in such a manner that it will be available for subsequent compatibility testing.

Donated blood sample aliquots should be stored in a stable and retrievable manner for at least two years to facilitate look-back.

4.4 Ratio of Blood to Anticoagulant

The volume of blood collected shall be proportionate to the volume of anticoagulant according to the manufacturer's instructions.

Blood shall be gently agitated to mix the blood and anticoagulant in a manner that prevents the formation of micro clots and thus the consumption of clotting factors, either by automatic or manual mixing.

4.5 Temperature During Transportation

After collection, blood shall be stored under conditions appropriate for the components to be made from it.

4.6 Apheresis

This section relates only to apheresis donations by healthy, voluntary donors and not to any therapeutic procedure.

Apheresis donors shall comply with all the donor selection and deferral criteria for allogeneic whole blood donations except where specifically indicated.

Donors who have ingested aspirin or anticoagulants within 72 hours prior to donation shall not be suitable for platelet-pheresis.

The apheresis procedure shall be carried out using only equipment that automatically returns blood to the donor.

Apheresis components shall be collected using sterile, single-use disposable kits.

Anticoagulant shall be used at a ratio that meets, while not exceeding, the manufacturer's instructions.

Extracorporeal blood volume, including final collection volume, shall not exceed 15% of the donor's estimated blood volume.

In addition to the usual information recorded for whole blood donors, Apheresis donor records shall include:

a. Results of laboratory tests including platelet count and serum protein levels.

b. These should include results of tests conducted prior to the enrolment of the donor, as well as pre-donation, post-donation and product test results.

c. Date of last apheresis procedure or whole blood donation.

d. Frequency of donation.

e. Volume of component separated.

f. Drugs administered.

g. Duration of procedure.

h. Lot number of disposables.

i. Replacement fluids.

j. Adverse reactions and their management.

The minimum interval between two apheresis collections shall be 48 hours and, at most, 24 procedures shall be performed on any individual donor within a 12-month period.

If plasma is donated more frequently than once every 4 weeks, the donor shall be checked before every procedure to ensure that their haemoglobin and/or haematocrit and total serum protein and immunoglobulin levels meet the minimum levels required by facility defined criteria.

Donors who undergo apheresis for cellular components no more than once every 12 weeks, shall be tested in accordance with facility defined criteria, but at least once every 6 months, for haemoglobin /haematocrit, total serum protein, and platelet count.

A maximum of 750 ml of plasma shall be collected per donation.

Resources shall be available and personnel shall be trained in the management of adverse reactions in apheresis donors.

If it becomes impossible to return the donor's red cells during plasma- or platelet-pheresis, at least 8 weeks shall elapse before a subsequent apheresis procedure.

05.

HANDLING, TRANSPORTATION, AND STORAGE

This chapter is guided by the Cold Chain Management of Blood and Blood components Manual. It outlines the transportation and storage requirements of various components, storage equipment, and their maintenance.

5.1 Transportation Following Collection

The facility shall have procedures to ensure that blood and blood components are handled, stored, and transported in a manner that prevents damage, limits deterioration and meets specified requirements.

5.2 Transportation Temperatures

Following collection, blood shall be placed in a qualified container for a maximum of 24 hours.

The transportation container shall have sufficient refrigeration capacity to cool the blood continuously towards the required temperature range.

Donations for platelet components shall be cooled towards +20ºC to +24ºC until arrival at the processing laboratory.

Donations for production into components other than platelets shall be cooled towards +1°C to +10°C until arrival at the processing laboratory.

5.3 Pre-Processing Storage

Blood collected for processing into components other than platelets shall be placed in an environment with a temperature range of +1°C to +6°C within 24 hours of collection.

Blood collected for processing into buffy coat-derived platelet components shall be placed in an environment with a temperature range of +20ºC to +24ºC within 24 hours of collection.

Blood collected for processing into platelet-rich plasmas shall be placed in an environment with a temperature range of +20ºC to +24ºC within 8 hours of collection.

5.4 Storage Devices for Blood and Blood Components

Storage devices shall have the capacity and design to ensure that the correct temperature is maintained.

Refrigerators, freezers and platelet incubators shall have their temperature either continuously monitored or shall be monitored at least 3 times at regular time intervals over 24 hours.

If storage utilizes liquid nitrogen, liquid nitrogen levels or temperature shall be either continuously monitored or monitored every eight hours.

The facility shall use designated storage areas to limit deterioration and prevent damage to materials, in-process and final products. The facility shall control access to such areas.

Refrigerators or freezers used for blood storage shall contain only donor blood, blood samples, reagents or blood components and no other items, such as foodstuffs.

The facility shall have procedures to maintain blood and blood components at the required temperature, in the event of failure of power or equipment.

5.5 Alarm Systems

Storage devices for blood and blood components shall have alarms that conform to the following standards.

i. The alarm shall be set to activate under conditions that will allow timely action to be taken before blood or blood components reach an unacceptable temperature.

ii. The alarm system shall be tested at least every 6 months, or in accordance with manufacturer's instructions if this is more frequent.

iii. The alarm system in liquid nitrogen freezers shall be activated before the contained liquid nitrogen reaches a level that could result in the thawing of the contained blood component or other material.

iv. Activation of the alarm shall initiate a process for immediate investigation and appropriate corrective action.

5.6 Transportation of Screening samples, Blood and Blood Components

Containers used for the transportation of blood and blood components shall be validated to ensure they are suitable for maintaining required temperatures.

The facility shall verify that the establishment receiving the containers of blood and blood components maintains a system for checking that such containers arrive at their destination within the stipulated temperature ranges.

Screening samples shall be handled as biohazardous materials as per IATA Standards for packaging and shipment of samples.

Corrective action shall be taken by the receiving facility if the container did not arrive at the required temperature.

06.

TESTING OF DONATED BLOOD

6.1 General Testing Requirements

Blood group serology and testing for infectious diseases shall be carried out on a sample collected at the time of donation, on every unit of whole blood or apheresis unit collected.

The facility shall have procedures for the appropriate segregation and quarantine of untested units or those waiting further testing.

Test methods shall be validated prior to implementation.

Any discrepancies in test results shall be resolved before the unit is released from quarantine and made available for transfusion.

6.2 Blood Group Serology

Records of testing for blood groups shall be maintained.

ABO and RhD groups shall be tested at each donation.

In new donors, the ABO and RhD groups shall be confirmed by performing two independent determinations, one on the sample and one from a segment on the blood bag, prior to issue.

In repeat donors, the ABO and RhD groups obtained shall be compared with previous records from the same donor and shall concur.

When ABO and/or RhD groups on record do not concur with current test results an investigation to resolve the anomaly shall be undertaken. Units in which an anomaly remains unresolved shall not be transfused.

The ABO group shall be determined for each collection by testing the red cells with anti-A and anti-B reagents and by testing the serum or plasma with A and B cells for the detection of expected antibodies.

The RhD type shall be determined with anti-D reagent. If blood is initially typed as RhD negative it shall be further tested to detect weak D unless a monoclonal IgM anti-D reagent stated by the manufacturer as able to detect weak D has been used. When the test for weak D is positive, the unit shall be labelled as Rh positive. When the tests for RhD and weak D are negative, the unit shall be labelled as RhD negative.

Group O donations shall be tested for high titre allo-agglutinins.

Whole blood and plasma containing high titre allo-agglutinins shall be labelled 'High Titre'.

Red cell concentrates need not be labelled high titre if much of the plasma is removed.

Whole blood or plasma labelled as "High Titre" shall be transfused into patients of the same ABO group only.

Serum or plasma from donors shall be tested for unexpected red cell antibodies using a method known to detect clinically significant antibodies. When these are detected, plasma from these units shall not be used for transfusion.

6.3 Tests for Infectious Diseases

The following tests shall be performed on blood samples taken at the time of collection:

i. Human Immunodeficiency Virus (HIV). Minimum - antibodies to HIV-1 and HIV-2.

ii. Hepatitis B virus (HBV). Minimum - Hepatitis B surface antigen i.e. HBsAg.

iii. Hepatitis C virus (HCV). Minimum - antibodies to HCV.

iv. Syphilis (Treponema pallidum). Minimum - antibodies to T. pallidum or VDRL test or RPR test.

Only tests kits approved by relevant regulatory bodies should be used and the test system in which such a test kit is used shall be verified by the establishment.

Only donations that are non-reactive for the markers listed above shall be transfused.

Initially reactive donations should be re-tested in duplicate by the same assay. A repeatedly reactive donation should not be used for therapeutic use and should be destroyed unless used for non-therapeutic purposes.

Further confirmatory testing should be performed using a different platform on all reactive samples according to the facility-defined algorithm that shall not compromise the safety of recipients.

Additional infectious disease testing shall be performed based on national health guidelines and local epidemiological conditions.

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

07.

PREPARATION OF BLOOD COMPONENTS

7.1 Separation Procedures

Methods that ensure the quality and safety of components, including aliquots and pooled components, shall be employed. [Reference: Table 3].

Blood components shall be separated from whole blood no more than 8 hours after collection.

If a facility plans to use the red cells only and to discard the plasma, the separation step can be performed at any point up to the expiry date unless an additive solution is being used, in which case the separation must occur within a maximum of 7 days of collection, in conformance with the manufacturer's instructions.

The expiry date of blood or blood components shall be calculated by considering the day of donation as day zero and in accordance with the anticoagulant used.

The sterility of components shall be maintained during processing by the use of closed systems, aseptic methods, and sterile pyrogen-free disposable bags and solutions.

If the closed system is compromised, the expiry of the component shall be 6 hours from the time of opening, unless indicated otherwise in Table 3.

The facility shall implement procedures for using a sterile connecting device that does not compromise the closed system.

7.2 Visual Inspection and Release

The component shall be physically inspected for container integrity and normality of appearance prior to release. Action shall be taken if anomalies or errors are detected.

7.3 Labeling and Issue

All blood and blood components shall be accurately labeled using clear and legible labels that adhere firmly to pack surfaces at the range of temperatures experienced.

Label(s) shall not interfere with inspection of the contents or normal function of the container.

Additional labels affixed shall not obscure/cover primary donor identification numbers and other information that will subsequently be relied upon to identify the unit and its important characteristics.

The facility shall use a numeric or alphanumeric system that will make it possible to:

Uniquely identify every unit and blood component and its status at any stage during process.

Trace any unit of blood or blood component from source to final disposition and to recheck records applying to the specific unit.

Identify the blood establishment that carried out any part of the preparation.

The numeric or alphanumeric identification on the label shall be applied by the collecting facility to each unit of blood and/or its components.

After processing the blood, a final label shall contain the following information, as a minimum:

i. Name of the component.

ii. The unique numeric or alphanumeric identification.

iii. The date of collection of the blood or component from the donor.

iv. The name and volume of anticoagulant solution and additive solution, where applicable, and the approximate volume of blood collected.

v For platelet concentrates, plasma, and components obtained through apheresis donation, the approximate volume of the component is required, but not the volume of the anticoagulant.

vi. Storage and transportation temperatures.

vii. Expiry date, and time where appropriate.

viii. The ABO blood group and RhD type of the donor (except for fresh frozen plasma and cryoprecipitate where RhD type is not required).

ix. Titre (if applicable).

x. Name of the blood collection facility.

7.4 Information on Handling of blood and blood components

The blood collection facility shall provide the transfusing facility with information on the handling and administration of blood and blood components.

Such information will include the following:

i. Components shall not be used if there is any visible evidence of deterioration.

ii. Gentle agitation before use.

iii. That medications shall not be added to the blood components.

iv. Match of blood group on label and blood group of the recipient (if known) to check for suitability before administration.

v. Use of a sterile and pyrogen-free disposable transfusion set with filter to transfuse blood.

vi. Checking of patient identity against that of the blood or blood component.

vii. What to do in the event of transfusion reaction.

7.5 Standard requirements for Quality Control of Blood and Blood Components

Blood components shall be subjected to Internal quality control as indicated in subsection 2.16.6.

08.

RECEIPT, ORDERING, SELECTION AND ISSUING OF BLOOD AND BLOOD COMPONENTS

This chapter applies to the transfusing facilities while requesting for blood from a blood collection or storage establishment. It also covers requests made to the blood bank for specific patients. The request, issuance, and use of blood and blood components shall be as per the Guidelines on the Appropriate Use of Blood and blood components.

8.1 Receipt of Blood Components

The facility shall have procedures to check all incoming blood and blood components from another establishment or other organisation against the delivery document for number and group of components.

There shall be procedures to check for component integrity, expiry date, and temperature on receipt.

Discrepancies shall be reported to the collecting facility and shall be resolved before use.

8.2 Orders for Blood and Blood Components for a Specific Patient

A request for blood shall be completed by a qualified medical practitioner or other authorized healthcare professional.

The request form (Guidelines for the Appropriate use of Blood) for blood or blood components, shall accompany the recipient's blood samples, be legible and shall include the following information:

i. Recipient's given name and surname.

ii. Hospital number (or second identifier, if hospital number is not available).

iii. Date of birth, sex, hospital and ward.

iv. Name of the individual ordering the blood.

v. Quantity and specific blood or blood components needed.

vi. Routine or emergency.

vii. Date and time the blood is required.

viii. Clinical diagnosis and/or reason for transfusion.

ix. Name and signature of the individual completing the request form.

x. Date and time the request form was completed.

The individual taking the recipient's sample shall label the sample with at least the following information:

i. Recipient's given name and surname.

ii. Hospital number if available.

iii. A second identifier, such as the date of birth, shall be used if the hospital number is not available.

If the following information is not recorded on the label, it shall be traceable:

i. Name of hospital and ward.

ii. Date and time taken.

iii. Name and signature of individual drawing the blood sample.

The request form and blood samples which are received in the compatibility testing laboratory shall be reviewed. In case of discrepancy, incomplete forms, unsuitable samples, or doubt, the sample shall not be used; a new sample and request form shall be requested and used.

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

8.3 Selection of Blood and Blood Components for Transfusion

Red Blood Cell-Containing Components:

a. Recipients shall receive whole blood and red blood cell-containing components which are ABO compatible.

b. RhD negative recipients should receive RhD negative whole blood or red blood cell-containing components.

The facility shall have a procedure determining the circumstances for the transfusion of RhD positive red blood cell-containing components to RhD negative recipients.

If clinically significant unexpected antibodies are detected in the recipient or the recipient has a history of such antibodies, whole blood or red blood cell components which do not have corresponding antigens and are compatible shall be prepared for transfusion. If antigen typing of donor blood is not possible, cross-match compatible blood shall be issued.

Where clinically significant unexpected antibodies are detected in the recipient, negative results should be confirmed.

Plasma and Platelet Components:

- Plasma and platelet components should be ABO compatible for transfusion.

- If group O units are transfused into a patient of another ABO group, then low titre units shall be used.

09.

COMPATIBILITY TESTING

This chapter is applicable to the establishments performing compatibility testing.

Each blood sample submitted from a potential transfusion recipient shall be tested for ABO group, RhD type (it is not necessary to test for weak D variants) and for clinically significant unexpected antibodies.

9.1 Serologic Compatibility Testing

A sample of the recipient's serum or plasma shall be tested for compatibility with a sample of the donor's red cells from an originally attached whole blood or red blood cell segment before being issued for transfusion.

The compatibility testing procedure shall include a method that will demonstrate ABO incompatibility.

If the recipient's serum was not screened for abnormal antibodies using standardized antibody screening cells, the compatibility test using the recipient's serum and the donor's red cells shall include an anti-human globulin procedure.

There shall be a process to ensure that the patient's historical record(s) of ABO group, RhD type and clinically significant antibodies have been reviewed and compared to current records and that discrepancies have been investigated and appropriate action taken before a unit is issued for transfusion.

If clinically significant red blood cell antibodies are detected in the recipient, red cell-containing components lacking the corresponding antigens shall be compatibility tested by a method that includes an anti-globulin phase.

If antigen typing of donor blood is not possible, cross-match compatible blood shall be issued.

A compatibility testing record shall be completed for each recipient and shall include all units of blood or blood components issued, indicating the following:

a. Recipient's name.

b. Hospital identification number if available. A second identifier (such as date of birth) shall be used if the hospital number is not available.

c. Recipient ABO group and RhD type, if applicable.

d. Donor unit or pool identification number.

e. Donor ABO group and RhD type.

f. Interpretation of compatibility tests if performed.

g. Name/signature of the individual who performed the compatibility testing.

h. Date of issue for transfusion.

A label shall be attached securely to each unit intended for transfusion. The following information shall appear on the label:

a. Recipient's given name and surname.

b. Hospital name and number if available, A second identifier (such as date of birth) shall be used if the hospital number is not available.

c. ABO and RhD type of recipient.

d. Date of compatibility test.

e. Name and signature of individual who performed the compatibility testing.

If it is not possible to include the name and signature of the individual who performed the compatibility testing on the label of the unit, there shall be a method to associate that individual with the unit.

The recipient's samples shall be kept at +1 to +6°C for a minimum of 5 days after the transfusion.

9.2 Issue of Blood Components for Transfusion

At the time a unit is issued for transfusion, there shall be a final check of facility records against each unit of blood or blood component. Verification shall include:

a. Visual inspection of blood and blood component.

b. Comparison with current records of the patient.

c. The intended recipient's two independent identifiers (i.e. recipient's full name and hospital number or date of birth), as well as ABO group, and RhD type.

d. The donation identification number, the donor ABO group, and, if required, the RhD type.

e. The interpretation of compatibility testing, if performed.

f. The date and time of issue.

g. Name/signature of individual who releases the blood component.

h. Name/signature of individual who takes delivery of the blood component, if applicable.

In case of an anomaly or error detected during the time of issue, the unit shall be withheld for further investigation and appropriate corrective and preventive action taken.

9.3 Return and Reissue of Blood and Blood Components

Blood and blood components that have been returned in the blood bank or transfusion unit shall be re issued only if the following conditions have been observed

a. The blood bag is intact.

b. All components have been maintained at appropriate temperature.

c. At least one sealed segment of integral donor tubing has remained attached to the container.

d. The records indicate that the blood or component has been inspected and that is acceptable for reissue.

e. The blood has been returned to the transfusion unit within 30 minutes of issue.

f. The blood has been maintained in a cold chain system.

9.4 Special Instances

Massive Transfusion:

The facility shall have a procedure regarding compatibility testing when, within 24 hours, a patient has received an amount of blood or blood components approximating or exceeding the patient's total blood volume.

Transfusion of infants aged 4 months or less:

- Only anti-A and anti-B reagents are required to determine the infant's ABO group.
- The RhD type shall be determined as previously prescribed (See 7.1).
- ABO group compatible red blood cell components shall be issued.
- RhD compatible red blood cell components shall be issue.

The serum or plasma of the mother shall be used to perform the test for clinically significant antibodies and if unavailable, then the infant's sample shall be used, where possible. If the screening test for red cell antibodies is negative, and the infant is to be transfused with group O blood, it is unnecessary to perform compatibility testing for the initial or subsequent transfusions.

If the initial antibody screen demonstrates clinically significant unexpected red cell antibodies, units shall be prepared for transfusion that either do not contain the corresponding antigen or are compatible during cross-matching which includes by indirect anti-globulin compatibility testing.

In the management of haemolytic disease of the new-born, the mother's sample shall be used for compatibility testing. In the absence of maternal serum or plasma, infant's serum or plasma shall be used.

Blood units selected for compatibility testing shall be ABO and RhD compatible with both infant and mother.

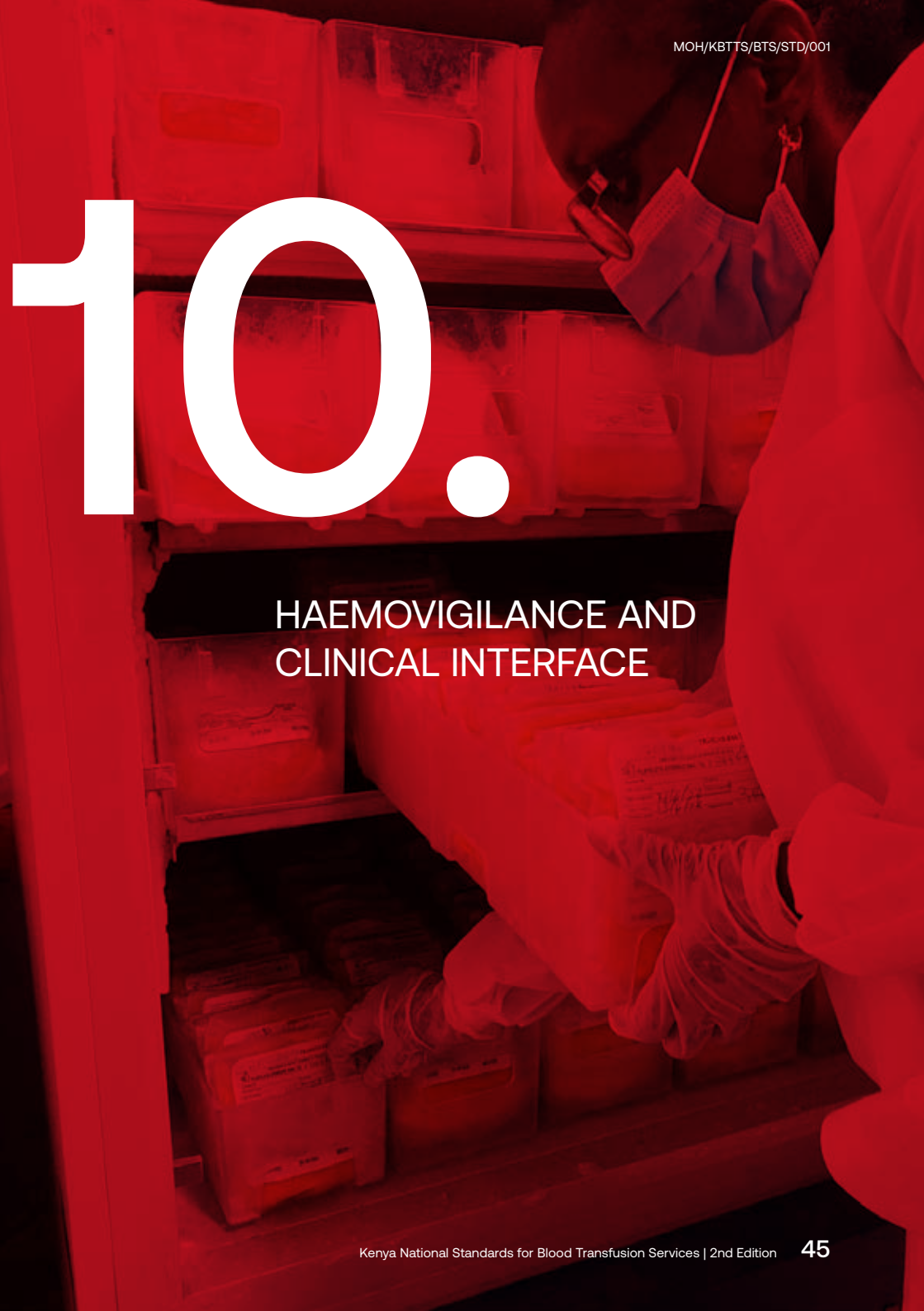
If a non- group O infant is to receive group specific red cells that are not compatible with the maternal ABO group, the infant's sample shall be used for compatibility testing.

Test methods shall include an antiglobulin phase.

9.5 Blood Transfused in Cases of Dire Emergency

There shall be a process for handling emergency requests and the facility issuing blood shall be legally liable.

When a sample from the patient is submitted for compatibility testing, but the blood is required prior to testing being completed due to the urgency of the situation, then segments from the units provided for transfusion shall be retained and the compatibility testing shall be completed after the blood is issued.



10.

HAEMOVIGILANCE AND CLINICAL INTERFACE

In exceptional circumstances, at the discretion of the medical director, blood and blood products may need to be issued when not conforming to all mandatory test requirements [SU1].

The facility shall notify the recipient's physician that all requirements have not been met.

The recipient's physician shall acknowledge in writing that the clinical situation is sufficiently urgent to require the release of the blood product before completion of the compatibility and/or infectious disease testing.

A label on the container shall indicate that the required tests have not yet been performed or completed.

The required testing shall continue after the release of the units, and if any of the blood units are found to be unsuitable, it shall be reported immediately to the attending physician who shall be instructed to stop the transfusion immediately.

The non-conforming unit(s) shall be recalled, if possible.

The request, issuance and use of blood and blood components is as per the Hemovigilance manual for Blood Transfusion Facilities.

10.1 Donor Adverse Events

Adverse events related to the blood donation process shall be assessed, investigated and monitored.

10.2 Adverse Transfusion Events

A facility that collects blood and/or performs compatibility testing or administers blood shall educate its health care workers on the identification, recording, management and reporting of adverse events in transfusion recipients.

When a suspected transfusion reaction is reported and samples are provided, the facility that performed the compatibility testing or administered the blood shall investigate the adverse event.

At a minimum, the investigation shall include:

a. Records of all previous relevant blood transfusion records.

b. Visual inspection of blood or blood components transfused (if available), and of post-transfusion sample for haemolysis.

c. Determination of ABO group and RhD type of both pre- and post-transfusion samples and transfused units, if available.

d. Compatibility testing using both pre- and post-transfusion samples.

e. Direct anti-globulin test on both pre- and post-transfusion samples.

When an adverse event occurs, the results of the evaluation shall be recorded in the transfusion record of the patient and shall be reported to the patient's doctor.

10.3 Transfusion Transmissible Infections

10.3.1 Look-back: Patient initiated

When transmission of an infectious disease is suspected to be the result of transfusion, the facility that transfused the blood shall report that information to the collecting facility.

The collecting facility shall have procedures for investigating and deferring donors when such reports are received.

10.3.2 Look-Back: Donor initiated

The collecting facility shall have procedures to notify the hospital or doctor of recipient(s) of units from a blood donor who is subsequently found to be infected with HIV, HBV or HCV.

The facility shall provide guidance to the administering facility (hospital or doctor) which shall act on the information in the best interests of the patient.

10.4 Clinical Interface

A facility that transfuses blood shall develop or adopt clinical guidelines on the appropriate use of blood and blood components and to advocate for best transfusion practices, and promote continuing education in transfusion practice for clinical personnel. The guidelines shall include information on the products and services offered by the facility.

A facility that transfuses blood shall have procedures to communicate with clinical personnel to inform and educate on the availability of blood and blood components and their appropriate use.

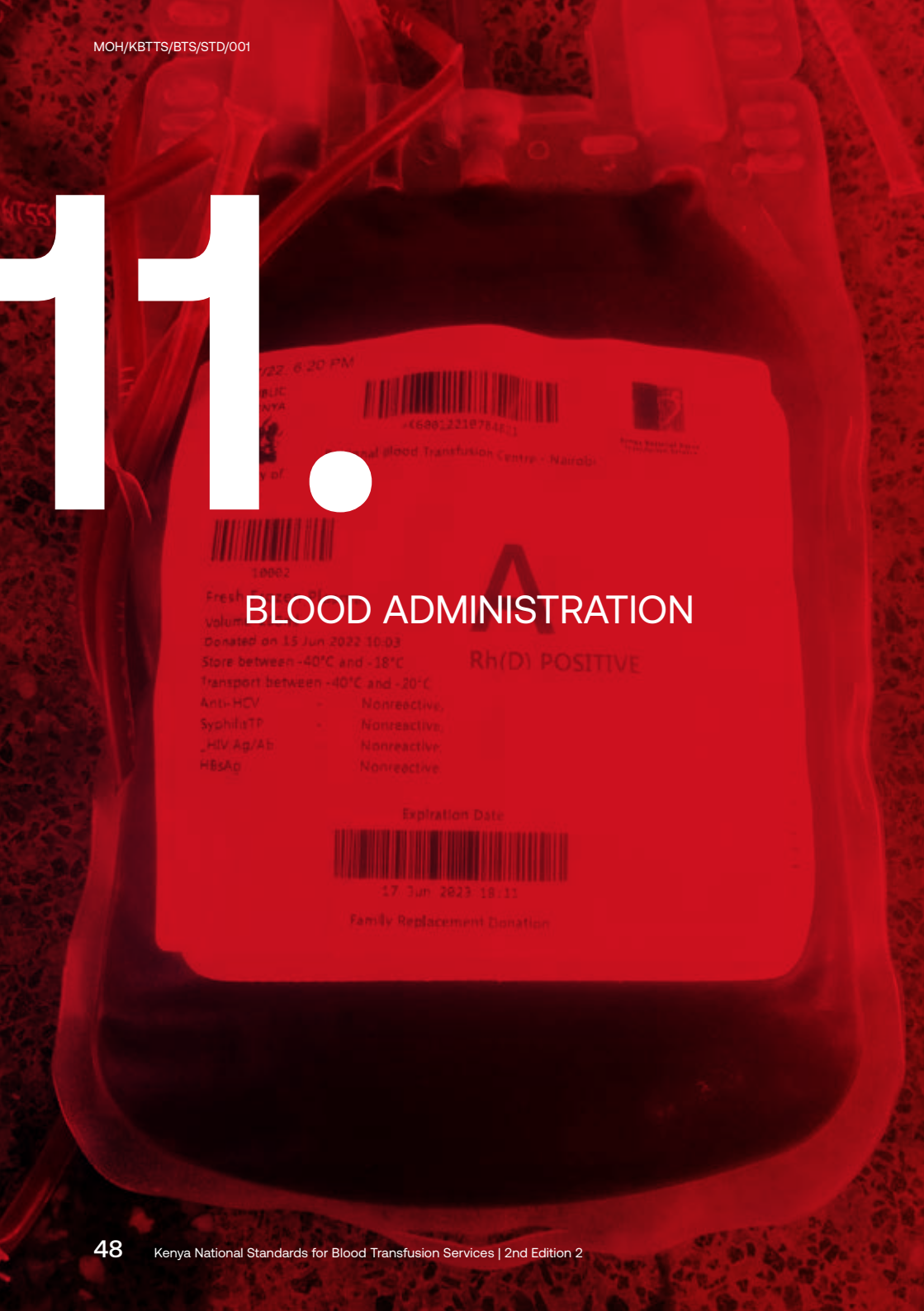
A facility that transfuses blood shall have procedures in place to provide timely clinical consultation to clinical personnel, 24 hours a day and seven days a week.

10.5 Monitoring of Blood Usage

A facility that collects or issues blood for transfusion shall perform at least annual evaluations of blood need, blood supply and blood usage and shall use the information gained for continuous improvement and planning.

11.

BLOOD ADMINISTRATION



This chapter outlines the required guidelines and procedures that are required when administering blood to a recipient.

11.1 Administration of Blood and Blood Components

The facility shall have guidelines available for the administration of blood and blood components including the use of infusion devices and ancillary equipment and the identification, evaluation and reporting of adverse events related to transfusion. The guidelines shall cover all the issues following hereafter in section 9.

The clinician/ medical practitioner/ transfusionist shall advise the patient, in a language that he/she understands, of the risks and benefits of transfusion and obtain written informed consent for the transfusion from the patient.

At a minimum, elements of consent shall include:

a. A description of the risks, benefits and treatment alternatives (including non-treatment)

b. The opportunity to ask questions.

c. The right to accept or refuse transfusion.

Before transfusion the blood or blood component shall be visually inspected and the expiry date on the label confirmed.

The blood or blood component shall be used only if its appearance is normal and the expiry date has not been exceeded.

Immediately before transfusion, two individuals shall independently verify the identity of the patient at the bedside, the blood component, blood group, and compatibility testing report and associated records.

The recipient's vital signs shall be assessed and recorded prior to transfusion.

The transfusion shall be given with a sterile, pyrogen-free and disposable transfusion set with filter.

Medication shall not be added to the blood components being transfused. Similarly, no other intravenous fluid shall be administered with blood components, except solutions that do not contain calcium or dextrose.

Transfusion of one unit of blood or a component shall not take longer than 4 hours. For patients requiring long-term transfusion the intravenous (IV) line shall be changed at least every 24 hours.

All identifications attached to the blood or blood component container shall remain attached during and after transfusion. The transfusion record shall be included in the patient's file.

The individual administering the blood or blood component shall regulate the speed of the transfusion and observe the patient for the first 15 minutes at the start of the transfusion, approximately every hour during the transfusion and periodically for 24 hours after the transfusion to observe any evidence of untoward reaction.

In the event of an adverse reaction the transfusion shall be stopped immediately and reported promptly to the attending clinician /doctor and the compatibility testing laboratory.

11.2 Blood Warmers

Warming of blood to body temperature should be done in cases of rapid transfusion, massive transfusion, for patients with cold agglutinins and for exchange transfusion in infants.

The blood shall not be warmed above +37°C.

Where applicable warming of blood should be accomplished using a blood warming device attached to the transfusion set.

The warming device shall be equipped with an alarm system.

Blood that has been warmed shall be transfused within 4 hours and if not transfused, shall be clearly labeled as condemned, discarded and not be used for another patient.

If blood warmer is under control of blood facility, Equipment Qualification and Process Control shall apply.

11.3 Administration of Platelet Concentrate

Platelets shall be administered through a standard platelet filter. Micro aggregate filters shall not be used for the administration of platelet components.

11.4 Thawing of Fresh Frozen Plasma

Plasma shall be thawed at a temperature not exceeding +37°C.

Plasma that has been thawed shall not be refrozen and shall be clearly labeled as condemned and discarded if not transfused. The transfusion shall be completed within 4 hours of completion of thawing or 24 hours if the plasma is kept at +1°C to +6°C.

ANNEXES

Annex I. Record Retention

Item	Record to be retained	Minimum Retention Time (Years)
1.	The facility's organogram	5
2.	Approved exceptions	5
	Top Management review of quality system	5
4.	Quality manual, policies, processes 7& SOPs	5
5.	Job descriptions	1 year after termination of service
6.	Training policy	5
7.	Evaluation of competence	1 year after termination of service
8.	Personnel records	1 year after termination of service
9.	Approved suppliers	5
10.	Agreement review	5
11.	Agreement concerning sub contractors	5
12.	Inspection of incoming materials and products	5
13.	Selection criteria for equipment	5
14.	Monitoring and maintenance of equipment	5 years or life of equipment
15.	Accident and incidence reporting	10
16.	Internal audit review	10
17.	Corrective action	5
18.	Review of external audit results	5
19.	Detection, capture, assessment, investigations and monitoring of nonconformances	5
20.	Medical director approval of issue of blood and blood products that may not conform to all mandatory test requirements	10
21.	Discard of non-conforming units	10
22.	Review of feedback from donors and customers/ clinicians	10

Item	Record to be retained	Minimum Retention Time (Years)
23.	Validation of new or changed procedures, test methods or software implementation	10
24.	Quality control programme	10
25.	Traceability of blood, blood products and critical materials	10
26.	Donor selection criteria	10
27.	Donor deferral criteria	10
28.	Donor history questionnaire	10
29.	Donor consent	10
30.	Donor adverse events	10
31.	Apheresis donor records	10
32.	Temperature monitoring of refrigerators, freezers and platelet incubators	10
33	Monitoring of liquid nitrogen level or temperatures	10
34	Blood group serology	10
35	Infectious disease testing of blood specimens	10
36	Unique identification of blood or blood products	10
37	Receipt of blood or blood products	10
38	Requests for blood or blood products	5
39	Test results of ABO group and RhD type	10
40	Blood transfusion record	10
41	Management of adverse reactions in recipients	5
42	Investigation of the transmission of transfusion transmitted infections	5
43	Look back to identify recipient(s) of units from a blood donor who is subsequently found to have been infected with HIV, HBV or HCV	10
44	Inspection of blood and blood products prior to release for transfusion	5
45	Verification of patient identity at the bedside, prior to transfusion	5
46	Transfusion record in hospital file	5
47	Observation record during transfusion episode	5

Annex II . Requirements for Allogenic Donor Qualification

Category	Criteria/Description/ Examples	Deferral Period
Age	• Donors shall be 16 years of age or more	Defer until 16 years
Whole blood volume Collected	• Volume collected shall not exceed 10,5 mL/kg of donor weight,including specimens	N/A
	Volume collected shall be proportional to the anticoagulant	
	Whole blood collected into an anticoagulant volume calculated for 450ml should be between 405mL and 495mL	
	• When 300 to 404 mL of whole blood is collected into an anticoagulant volume calculated for 450 ± 45 mL, or when 333 to 449 mL of whole blood is collected into an anticoagulant volume calculated for 500 mL ± 50, red cells prepared from them shall be labelled as 'red cells, low-volume' and may be made available for transfusion. No other blood products blood shall be made from low volume collection	
Donor body mass (weight)	• The lower limit of body weight shall be 50 kg for a blood pack holding 450 mL ±10%. • The lower limit of body weight shall be 50 kg for a blood pack holding 300 mL ±10%.	N/A
	• Unexplained recent weight loss of more than 10% of body weight shall be a reason for reason	6 months

Category	Criteria/Description/ Examples	Deferral Period
Donation interval	• A minimum of 56 days after whole blood donation.	Defer until due
	• The minimum interval between two apheresis collections shall be 48, hours and at most, 24 procedures shall be performed on any individual donor within a 12-month period.	
Blood pressure	• Systolic BP upper limit ≤180 mm Hg • Diastolic BP upper limit ≤100 mm Hg Blood pressure readings should be within the normal range for adults.	Dependent on actual value
Pulse	• Regular and not <50 or >100 beats/ minute	Dependent on value
Haemoglobin OR Haematocrit	• Haemoglobin must be more than or equal to 125 g/L.	Dependent on actual value
	• Haematocrit must be more than or equal to 0.38 L/L	
Drug Therapy	• Aspirin	3 days (>72 hours) before platelet production
Medical history and general health	• The prospective donor shall appear to be in good health, and not under the influence of alcohol	Defer until sober
	• The prospective donor shall be free of major organ disease (e.g. Heart, liver, lungs) cancer, or abnormal bleeding tendency, unless determined eligible by the medical director	Defer at discretion of the medical director
	The venepuncture site shall be evaluated for lesions on the skin.	Defer the venepuncture until site is free of lesions
	The venepuncture site shall be free from infectious skin disease and any disease that might create a risk of contaminating the blood	

Category	Criteria/Description/ Examples	Deferral Period
Dental Extraction/ Surgery	• Simple dental extraction	3 days
	• Root canal work	7 days
	• Dental surgery	1 month
Pregnancy	• Defer for pregnancy and during lactation	As required
	• Termination of pregnancy	3 months
Receipt of blood/ blood components	Defer for receipt of blood, blood products, or plasma-derived clotting factor concentrates	12 months
Immunizations and vaccinations	Receipt of live attenuated viral and bacterial vaccines. Measles (rubella), Mumps, Polio (Sabin/oral), Typhoid (oral), Yellow fever	2 weeks
	Receipt of live attenuated viral and bacterial vaccines. German measles (rubella), Chicken pox (varicella zoster), BCG	4 weeks
	Hepatitis B Vaccination	14 days if given prophylactically
		12 months if given as post exposure prophylaxis
	Receipt of other vaccines, including unlicensed vaccines.	12 months unless otherwise indicated by medical director

Category	Criteria/Description/ Examples	Deferral Period
Transfusion transmissible infections	Present or past clinical or laboratory evidence of infection with HIV, HBV, and HCV	Indefinite
	Malaria: The facility shall develop and follow a policy on the collection and use of blood from donors who have had malaria or who have been exposed to malaria.	Defer in accordance with local policy
	Travel history: Evaluate the potential risks of travel to areas where transmissible infections are endemic and defer accordingly	Defer in accordance with local policy
	Following the diagnosis of a sexually transmitted infection such as syphilis and gonorrhea	Indefinite
	Mucous membrane exposure to blood.	12 months
	Non-sterile skin penetration with instruments, equipment, or weapons contaminated with blood or body fluids other than the donor's own. Included tattoos, body piercing, and scarification	12 months
	Sexual contact or lived with an individual who: Has acute or Chronic hepatitis B (positive HBsAg test, HBV NAT); Has symptomatic hepatitis C; Is symptomatic for any other viral hepatitis	12 months after last contact
	Sexual contact with an individual with HIV infection or at high risk of HIV infection	Indefinite

Annex III. Requirements for Separation, Preparation, Storage and Expiry (of Blood and Blood Products)

	Component	Preparation	Temperature		Expiry date/Time	QC specifications Test 1% or minimum of 4 per month
			Storage	Transport		
1.	Whole blood	N/A	2-6°C	2-10 °C	• 35 days after collection if CPDA-1 (citrate phosphate dextrose with adenine) is used as anti-coagulant • 21 days OR according to blood bag manufacturer's recommendation if ACD-A (acid citrate dextrose solution A) or CPD (citrate phosphate dextrose) or CPG (citrate-phosphate-glucose) is used	Volume: 450 ml ±10% Haemoglobin: ≥45g/unit Haemolysis < 0.8% of red cell mass (test at the end of storage)

	Component	Preparation	Temperature		Expiry date/Time	QC specifications Test 1% or minimum of 4 per month
			Storage	Transport		
2.	Red blood cells, No additive solution	• Prepare from whole blood collected preferably in double or multiple bag systems • Separate red cells and plasma within 6 to 18 hours after collection if platelets are not being produced OR within 24h	2-6°C	2-10 °C	• Same as whole blood if closed system is used for separation • 24 hours after separation if open system is used with aseptic technique • 6 hours after separation If aseptic technique is not used in open system	Volume: 280 ± 50 ml Haematocrit: 65% - 75% Haemoglobin: > 45 g/unit Haemolysis:< 0.8% of red cell mass

	Component	Preparation	Temperature		Expiry date/Time	QC specifications Test 1% or minimum of 4 per month
			Storage	Transport		
3.	Red Blood Cells, With Additive Solution	• Prepare as above • Then suspend red cells in additive solution, or other suitable solution, preferably within 72 hours but not more than 7 days after collection - or as defined by blood bag manufacturer	2-6°C	2-10 °C	• Same as whole blood if closed system is used for separation • Expiry date may be extended per blood bag manufacturer's recommendation • 24 hours after separation if open system is used with aseptic technique • 4 hours after separation if aseptic technique is not used in open system	Volume: 280 ± 50 ml Haematocrit: 65% - 75% Haemoglobin: > 45 g/unit Haemolysis:< 0.8% of red cell mass

	Component	Preparation	Temperature		Expiry date/Time	QC specifications Test 1% or minimum of 4 per month
			Storage	Transport		
4.	Red Blood Cells, Buffy Coat Removed	Separate red cells from plasma and buffy coat within 72 hours preferably. But not more than 7 days after collection	2-6°C	2-10 °C	• Same as whole blood if closed system is used for separation • Expiry date may be extended if additive solution is added - per blood bag manufacturer's recommendation • 24 hours after separation if open system is used with aseptic technique • 6 hours after separation if aseptic technique is not used	Volume: 280 ± 50 ml Haematocrit: 65% - 75% Haemoglobin: > 43 g/unit Haemolysis:< 0.8% of red cell mass; Leukocytes/ unit: < 1.2×10^9

	Component	Preparation	Temperature		Expiry date/Time	QC specifications Test 1% or minimum of 4 per month
			Storage	Transport		
5.	Red cell concentrates, Leucocyte Reduced	Prepare within 5 days of collection. Prepare by a method known to reduce leukocytes in the final products to specified levels. Use a leucocyte filter for achieving a level less than 1.2 x $10^{6/}$ unit.	2-6°C	2-10 °C	• Same as original donation if closed system is used • 24 hours if open system is used	Haematocrit: 50% - 70% Haemolysis: < 0.8% Haemoglobin: > 40 g/unit Leukocytes: < 1 × 106 / unit
6.	Red Cells, Washed	• Prepare by washing red blood cells with normal saline at 2 - 6°C, either manually or with automated cell washer • Repeat washing 2 to 3 times • Re-suspend red cells in saline to meet required specifications	2 - 6 °C	2-10°C	• Unit to be infused as soon as possible but within 24 hours after washing	Volume: > 185 ml Haematocrit: 50% - 70% Haemoglobin: > 40 g/unit Haemolysis: < 0.8 % at process end Leukocytes: < 1.0 × 106 /unit Sterility: Negative

	Component	Preparation	Temperature		Expiry date/Time	QC specifications Test 1% or minimum of 4 per month
			Storage	Transport		
7.	Red Cells, Frozen	• Suspend red cells in cryo-protective agent • Freeze suspended red cells within 6 days of collection • Prior to transfusion, thaw cells then wash to remove cryo-protective agent • Method of preparation, storage, thawing and washing shall ensure a recovery of at least 80 % of original red cell	≤ -65 °C 1 - 6 °C after thawing	Maintain frozen state 1-10°C once thawed	• 10 years from date of freezing • Unit to be used within 24 hours, once thawed and washed	Volume: > 185 ml Haematocrit: 50% - 70% Haemoglobin: > 36 g/unit Haemoglobin: < 0.2 g/unit (supernatant) Leukocytes: < 0.1 × 109 /unit Sterility: Negative

	Component	Preparation	Temperature		Expiry date/Time	QC specifications Test 1% or minimum of 4 per month
			Storage	Transport		
8.	Single Donor Platelets (Whole Blood Derived)	• Separate platelets from whole blood by centrifugation at 20°C to 24°C from either platelet rich plasma or buffy coats, using validated methods • Suspend platelets in at least 40 ml of plasma	20-24°C with continuous gentle agitation using agitator or rotator	20-24°C	• 3 - 5 days after blood collection if closed system is used, depending on nature of the plastic blood bag used • Unit to be used within 6 hours if open system is used	Volume: ≥ 40 ml Leukocytes: < 5.0 × 106 / unit Platelet count: ≥ 5.5 × 1010 /unit pH (at expiry): ≥ 6.0
9.	Apheresis Platelets	Platelet concentrates shall be collected by continuous/ intermittent flow apheresis	20 to 24°C with continuous gentle agitation using agitator or rotator	20-24°C	• 5 days after blood collection • Unit to be infused within 6 hours if open system is used	Volume: 200 - 300 ml Leukocytes: < 1.0 × 106 / unit Platelet count: > 200 × 109 /unit pH (at expiry): 6.4 to 7.4

	Component	Preparation	Temperature		Expiry date/Time	QC specifications Test 1% or minimum of 4 per month
			Storage	Transport		
10.	Fresh Frozen Plasma (FFP)	• Separate fresh plasma from whole blood within 6 to 18 hours of collection • Freeze to minus 30°C within 1 hour • Store at minus 18°C or, preferably, at minus 25°C or lower	≤ -18°C Ambient after thawing	Maintain frozen state 1-10°C once thawed	• 12 months if stored at minus 18°C or below OR • 24 months if stored at minus 25°C or below • After thawing, transfuse as soon as possible but within 6 hours	Volume: ± 10% of stated vol. Factor VIII:C: ≥ 0,7 IU/ml
11.	Frozen Plasma (other than FFP)	• Separate plasma from whole blood following either centrifugation or undisturbed sedimentation at any time up to 5 days after expiry of whole blood • Freeze immediately after separation • This includes plasma recovered for fractionation	≤ -18°C	Maintain frozen state	• 12 months if stored at minus 18°C or below OR • 24 months if stored at minus 25°C or below • After thawing, suitable component to be transfused as soon as possible but within 6 hours	N/A

	Component	Preparation	Temperature		Expiry date/Time	QC specifications Test 1% or minimum of 4 per month
			Storage	Transport		
12.	Cryoprecipitate	• Freeze fresh plasma for preparation of cryoprecipitate at minus 18°C to minus 70°C • Thaw in +4°C circulating water bath or in +4°C cold room/ refrigerator until frozen cryoprecipitate pellet remains • Drain supernatant plasma until ± 40 ml remains, then freeze remaining cryoprecipitate within 1 hour	≤ -18°C	Maintain frozen state	• 12 months if stored between minus 18°C and minus 25°C OR • 24 months if stored at minus 25°C or below • After thawing, components to be transfused as soon as possible but within 6 hours	Fibrinogen: > 150 mg / unit Factor VIII:C: > 80 IU /unit For pooled products, the pool shall contain the above minimum levels times the number of components in the pool

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