



NATIONAL BLOOD SERVICE COMMISSION (NBSC)

Safe Blood Saves Lives



OPERATIONAL GUIDELINES FOR BLOOD TRANSFUSION PRACTICE IN NIGERIA

AUGUST 2021

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Authorised by: **Director General**

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FOREWORD

Nigeria is a large country whose public health is administered at three levels of government. The private sector is a large player in health issues accounting for about 70% of all health facilities in the country, Blood transfusion services in Nigeria are in the process of evolving from the current limited level of hospital-based, family replacement donor service which is unable to meet the demands of the entire country, to a functional, centralized service which would be based on blood donations from regular, voluntary, low-risk, non-remunerated blood donors, who would be free from transfusion-transmissible infections with a comprehensive Haemovigilance programme. This is an enormous challenge and task.

A National Blood Policy was formally launched in September, 2016 and it is now being implemented with the establishment of blood transfusion centres all over the country. While recognizing that facilities and resources differ appreciably from one part of the country to the other, these operational guidelines represent minimally acceptable performance requirements expected of all blood transfusion centres in Nigeria whether at our National Blood Service Commission (NBSC) outlets or the hospital blood banks. The operationalization of these guidelines would be a major step in achieving the national goal of coordination, regulation and ensuring the provision of quality blood, blood products and services as well as related matters in line with the national health plan for all those who may need it.

This document was originally prepared by the National Technical Committee on Blood Transfusion Services with inputs from other experts in 2006. The 2021 Expert Committee on National Blood Safety Standards for Blood Establishments reviewed this document as a result of dynamic changes in the science. It provides comprehensive guidelines and information to assist clinical, laboratory and other workers involved in the provision of safe blood. It is an excellent text designed as reference material which should be made available to all workers in this field. Although this document presently represents the most up-to-date material on the subject matter in the country, I advise all relevant health workers to continually update themselves in this ever-changing field of blood transfusion practice.



Dr. E. Osagie Ehanire, MD, FWACS
Honourable Minister Of Health.

ACKNOWLEDGEMENTS

It is the general consensus that a nationally coordinated, and properly regulated Blood Transfusion Service, would strengthen any national health system and its management. A Law or Legal framework without operational guidelines could be likened to a bicycle without wheels. This document is a guideline prepared by a body of experts with varying backgrounds and experiences in blood service, to aid the implementation of the National Health Act 2014 and the National Blood Service Commission Act 2021, along with the National blood policy 2006; and are sure to provide the information and procedures required by clinical, laboratory and other workers in the blood service. The 2021 Expert Committee on National Blood Safety Standards for Blood Establishments have reviewed these guidelines within the context of recent emergent and re-emergent discoveries in science.

I anticipate that this document will serve as a valuable companion to all who are involved in the operationalization of the visionary and collaborative plans within the mandate of the National Blood Service Commission (NBSC).

A document of this nature is a sine qua non in any institution or establishment desirous of providing excellent service in blood transfusion. The text has been produced through the painstaking efforts of the National Technical Committee on Blood Transfusion Services in 2006, with contributions from other experts. As a result of the recent events in the legal status of the Blood service in Nigeria, a more recent review by an Expert Committee on National Blood Safety Standards for Blood Establishments was carried out in August 2021.

While we may not be able to list the names of all those who have contributed to the production of this document, I would like to acknowledge the 15 members of the Technical Committee chaired by Prof. J.O. Adewuyi in 2006. We are also indebted to the 2021 Expert Committee on National Blood Safety Standards for Blood Establishments led by Professor Aisha Gwarzo, members of staff of the NBSC and others too numerous to mention here, who have worked committedly at great personal sacrifice to ensure that these guidelines would be ready at the scheduled time. Additionally, we commend the efforts of the team of editors who have put the text in its present form.

We acknowledge the visionary leadership of the Honourable Minister of Health, Dr. Osagie Ehanire, *FWAC*, whose unwavering interest and support for safe, quality blood transfusion services in Nigeria ensured that this document and indeed, the entire re-invigorated National Blood Service Commission have both become a reality. We are grateful to the support of the entire federal ministry of health system, technically led by the Permanent Secretary, Abdula-ziz Abdullahi Mashi.


Dr. Omale Joseph Amedu, PhD, mni
Director General

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SECTION 1: INTRODUCTION

These Guidelines represent accepted performance requirements that may be exceeded in practice and where blood services establishments may be more rigorous in their internal requirements. Attempts have been made to ensure that these Guidelines comply with national and international laws and regulations. The use of these Guidelines should aid in implementing the National Blood Policy and embracing processes and procedures that provide safe and effective blood transfusion services and a safe work environment for personnel.

1. Definitions

- **“Allogeneic”** (allogenic) means genetically dissimilar within the same species.
- **“Apheresis”** means removal of one component of blood and the return of the remaining components to the donor.
- **“BE”** means Blood Establishment. It is any structure or body corporate involved in the collection, testing and use of blood, blood products, tissue and gametes in human as well as the manufacturing of plasma - derived medicinal products; as provided for in Part 6, Section 47-57 of the National Health Act 2014.
- **“Blood”** means blood intended for transfusion purposes including the components thereof but excluding blood specimens intended for pathology testing.
- **“Blood component or components”** mean(s) any constituent of human blood separated from whole blood donations or collected by apheresis which include red cells, white cells, platelets and plasma.
- **“Blood product or products”** mean(s) any therapeutic derivative of human blood through physical and or chemical means.
- **“Blood donation”** means the act of withdrawing blood or plasma from a blood donor and may refer to the unit of blood so collected.
- **“Blood Donor”** means a person who gives blood or blood component freely/voluntarily and receive no compensation.
- **“Compatibility test”** means a procedure whereby a donor blood component is tested to ensure serological non-reactivity with the intended recipient.
- **“Constituent part”** means any regional unit, branch, office or any other unit or premise of the National Blood Service Commission.
- **“Container”** means blood bag containing appropriate volume of anticoagulant for blood collection meant for transfusion
- **“Cross-match”** means a procedure whereby the donor red blood cells/serum is directly mixed with the recipient serum/red blood cells to detect ABO and/or other red cell antigen compatibility.
- **“Cytapheresis”** means the removal of the cellular component(s) of blood and the return of the remaining components to the donor.
- **“Document”** means all written instructions and records involved in providing a product or service.
- **“Document control”** means the control of the issue, use and review of authorized documents within the quality management system.
- **“Fractionation”** means the preparation of blood components from whole blood.

- **“Good Laboratory Practice (GLP)”** means ensuring that a laboratory carries out its activities to ensure safety and quality of results in accordance with regulatory requirements.
- **“Good Manufacturing Practice (GMP)”** means ensuring that products are consistently produced and controlled in accordance with appropriate standards and regulatory requirements.
- **“Guidelines”** mean Operational Guidelines for Blood Transfusion Practice in Nigeria.
- **“Haemoglobin”** means the constituent of the red blood cell responsible for its oxygen carrying capacity.
- **“Haematocrit”** means the proportion of red blood cells in the whole blood
- **“Haemovigilance”** means a set of organized surveillance procedures relating to the outcome of blood donation and transfusion activities in order to identify and follow up adverse or unexpected events.
- **“ISBT”** means International Society of Blood Transfusion.
- **“Licensed”** means authorized and registered by the appropriate government body.
- **“Management”** means senior personnel appointed by the Chief Executive Officer (and other executive directors) to supervise and manage designated departments of the Blood Transfusion Service.
- **“Minister”** means the Minister of Health.
- **“Medical Practitioner”** means a medically qualified officer of a Blood Establishment
- **“National Coordinator”** means the Chief Executive Officer of the NBS appointed by the Honourable Minister of Health.
- **“NBS”** means National Blood Service
- **“NBSC”** means National Blood Service Commission
- **“Phlebotomy”** means the withdrawal of blood from the vein of a blood donor
- **“Plasmapheresis”** means the removal of the plasma component of blood and return of the remaining components to the donor.
- **“Quality assurance”** means a comprehensive system developed by the service incorporating all arrangements and processes that ensure that blood products meet specifications as laid down in the Guidelines.
- **“Quality management system”** means a set of procedures to achieve total quality.
- **“Quality record”** means a document stating results achieved or providing evidence of activities performed which have an effect on quality.
- **“Regulations”** mean the rules, guidelines and policies relating to blood and blood products, as well as to blood donation and transfusion.
- **“Sample”** means a small quantity of blood taken from a blood donor, donation, or a patient for testing purposes.
- **“Services”** mean all facilities involved in Blood Transfusion Services (Blood Establishments)
- **“Service”** means the National Blood Service Commission.
- **“Standard Operating Procedure (SOP)”** means a document that provides step-by-step instructions for the performance of a particular procedure.

- **“Therapeutic phlebotomy”** means the removal of whole blood or components for treatment purposes.

SECTION 2: QUALITY MANAGEMENT SYSTEM

2.1 Quality Policy

- 2.1.1 The Service shall define and document its quality policy and communicate it to all employees.

2.2 Responsibility and Authority

- 2.2.1 The Service shall define its management structure and the relationship between operations, support services and quality functions.
- 2.2.2 If the Head of the Service is not a registered medical practitioner, the responsibility for all medical matters shall be referred to the medical practitioner
- 2.2.3 The Service shall appoint a Quality Manager (QM) who shall be responsible for ensuring that the quality system is implemented and maintained.
- 2.2.4 The Quality Manager shall report directly to the Head of the Service.
- 2.2.5 The Service shall create, and issue written job descriptions for all positions outlining key responsibilities and duties to be performed.
- 2.2.6 The Service shall periodically review and update job descriptions.

2.3 Quality Management System

- 2.3.1 The Service shall develop, document, and maintain a quality system.
- 2.3.2 The Service shall prepare a quality manual covering the requirements of the quality system and the structure of the documentation used in the system.
- 2.3.3 The Service shall have Standard Operating Procedures (SOPs) for all processes and practices.

2.4 Document Control and Quality Records

- 2.4.1 The Service shall establish and maintain a system for handling and controlling all documents.
- 2.4.2 Procedures shall be established and implemented for protecting the integrity of data.
- 2.4.3 Documents and data may be in any type of medium, such as hard copy or electronic media provided that ethical and legal requirements are met. Adequate backup systems shall exist where electronic documents are maintained.
- 2.4.4 Documents relating to the quality of products or services shall be uniquely identified.
- 2.4.5 Documents shall be reviewed and approved by authorized personnel prior to issue.
- 2.4.6 A system shall be established for identifying the current revision status of approved documents to preclude use of invalid or obsolete documents.
- 2.4.7 Approved current editions of appropriate documents shall be available at all relevant locations.
- 2.4.8 Invalid or obsolete documents shall be removed from points of issue or use.
- 2.4.9 Obsolete or superseded master documents shall be retained for legal and/or reference purposes and the nature of the change should be documented.
- 2.4.10 Changes to documents and data shall be reviewed and approved by authorized personnel and the nature of the change should be documented.
- 2.4.11 The record system shall ensure documents are securely stored to prevent illicit copying, deterioration, and damage and to ensure ready access and availability during storage.

- 2.4.12 Documents and records shall be legible, readable, and reproducible and the method of copying, and archiving shall be appropriate for the record system in use.
- 2.4.13 The Service shall define a document disposal policy.

2.5 Records

- 2.5.1 **Donor Register:** The Service shall maintain a register of blood donors into which the following details are entered prior to the withdrawal of blood from such blood donor:
 - 2.5.1.1 The surname, first name and initials of the other names, in that order.
 - 2.5.1.2 The gender.
 - 2.5.1.3 The date of birth and age.
 - 2.5.1.4 An identity number referenced to a recognized identity document e.g. identity card, international passport, National Identity Card, Voter's Card or driver's license, where available.
 - 2.5.1.5 The contact or e-mail address.
 - 2.5.1.6 Telephone number(s) where available
 - 2.5.1.7 Blood Group and the Rh (D) type or any blood group antigen (as previously determined by the Blood Service).
 - 2.5.1.8 Other relevant remarks
- 2.5.2 **Donation Register:** The Service shall keep a record of blood donation with the following information in respect of each donation of blood:
 - 2.5.2.1 The unique serial number of the donation on the label of the container (ISBT128).
 - 2.5.2.2 The ABO blood group and the Rh (D) type.
 - 2.5.2.3 The results of tests for transfusion-transmissible infections (TTIs).
 - 2.5.2.4 The date and place where the whole blood or blood component was withdrawn or separated.
 - 2.5.2.5 The name of the phlebotomist.
 - 2.5.2.6 The number or designation of the batch to which the donation belongs, if applicable.
- 2.5.3 **Issue Register:** The Service shall keep a record of blood issues with the following information in respect of each unit:
 - 2.5.3.1 The date and time of the issue of each unit of blood or component.
 - 2.5.3.2 The type of blood component issued, identification number, ABO and Rh group
 - 2.5.3.3 The initials of the persons responsible for the inspection of the unit and the blood therein at the time of issue.
 - 2.5.3.4 The condition of the unit of blood/component at time of issue.
 - 2.5.3.5 The name of the medical practitioner, laboratory, hospital, or medical institution to which the blood was issued and the date of issue.
 - 2.5.3.6 Donor's unit or pool identification number
- 2.5.4 **Discard Register:** If blood was condemned or discarded, the Service shall keep a record of:
 - 2.5.4.1 The date on which it was condemned or discarded.
 - 2.5.4.2 The reason for which it was condemned or discarded.
 - 2.5.4.3 The Service shall have procedures to record, identify and segregate blood products that are found to be unacceptable for further processing or issue at any stage in processing, from collection to issue.

2.5.4.4 The Service shall keep a record of disposal of non-conforming blood products for purpose of completing the audit trail for such products.

2.5.4.5 Disposal methods shall comply with the requirement of the waste disposal authority and/or local environmental regulations.

2.5.5 Incoming Product Register: The Service shall keep a record of every batch of blood received for processing with the following details:

2.5.5.1 The date of receipt of the batch.

2.5.5.2 The batch number or designation.

2.5.5.3 Collection dates of each unit in the batch

2.5.5.4 The expiry dates of the processed products in the batch. In the case of a blood component, the date on which the blood component was separated and the conditions under which it was stored before it was received.

2.5.6 Component Preparation Register: The Service shall keep a record of blood components prepared with the following details:

2.5.6.1 Date of preparation

2.5.6.2 Donor number

2.5.6.3 Component number

2.5.6.4 Expiry date of the component

2.5.7 Haemovigilance Register: The Service shall keep a haemovigilance register with the following information:

2.5.7.1 Date of occurrence of adverse reaction

2.5.7.2 Nature of adverse reaction

2.5.7.3 Identification number of implicated unit

2.5.7.4 Name of attending medical practitioner and institution

2.5.7.5 Patient's biodata including name, age, gender and indication for transfusion

2.5.7.6 Summaries of actions and findings in the ward(s)

2.5.7.7 Report of actions and findings in the laboratory

2.5.7.8 Monthly reports from Hospital's Transfusion Committee

2.5.8 Guiding Principles:

2.5.8.1 The National Haemovigilance Unit shall submit a monthly report of all incidents to the Service.

2.5.8.2 Strict confidentiality shall be observed throughout the system by all employees at all levels of the Service.

2.5.8.3 The Service shall retain records pertaining to donor assessment, laboratory tests and final disposition of each product for a minimum period of 10 years or as required by law.

2.6 Computer Systems

2.6.1 The Service should, where feasible, use electronic information technology (IT) system(s) in donor management, laboratory testing and product issuing systems for the recording, extraction, and analysis of data. The Service shall have systems for preserving the integrity and retrieval of data.

- 2.6.2 The Service shall be responsible for the installation and training of staff on the use of the software provided by the Service.
- 2.6.3 The Service shall have procedures to ensure continuous operation of essential processes in the event of any IT system failure through an effective back up system.
- 2.6.4 The Service may use an IT system to facilitate accurate review of records, and to permit or withhold the issuance of individual blood products.

2.7 Management Review

- 2.7.1 Designated management shall review the quality system of the Service at defined intervals to ensure its continuing suitability and effectiveness.
- 2.7.2 The review shall take into account the outcome of assessments by external bodies and internal audits, conformance of products to specifications and feedback from donors and blood users.
- 2.7.3 Records of the management review shall be maintained.

2.8 Process Control

- 2.8.1 The Service shall have procedures to ensure that purchased items that have an effect on product quality, conform to specified requirements.
- 2.8.2 The Service is responsible for ensuring that external service providers performing services falling within the ambit of these standards comply with the regulations.
- 2.8.3 The Service shall ensure that blood is collected, processed, tested, and issued under specific control conditions.
- 2.8.4 The Service shall monitor the effectiveness of processes and equipment used in the collecting and processing of blood and blood components. Records of cleaning, maintenance and calibration of premises and equipment shall be kept.

2.9 Product Status and Traceability

- 2.9.1 The Service shall have a system to ensure the status of blood products can be identified at all times.
- 2.9.2 The status of a blood product shall be identified by appropriate labelling of the blood product. If the product is not labelled, it shall be stored in a particular physical location that is segregated and labelled indicating the status (**quarantined**).
- 2.9.3 The Service shall maintain records of blood movement (manual or computerized) so that an audit trail can be generated for each blood product showing the history from collection of blood donation to issue of the blood product for recipient use or the issue of plasma for further processing.
- 2.9.4 An IT system record may confirm the identification of result.
- 2.9.5 The audit trail referred to above shall include the following:
 - 2.9.5.1 A record of the donor and donation details
 - 2.9.5.2 The unique donation identification number of each unit of blood.
 - 2.9.5.3 A record of the blood products into which each donation is processed.
 - 2.9.5.4 A record of the final disposition of the product such as the hospital to which, or recipient to whom, the product is issued.

2.10 Control of Non-conforming Products

- 2.10.1 The medical practitioner (or designated medical officer) shall be responsible for reviewing and giving authority for the acceptance of non-conforming blood products where the non-conformance is not anticipated to have an adverse effect on the recipient.
- 2.10.2 Except in dire emergencies and at the discretion of the medical officer, blood products shall not be released for recipient use until all the required tests have been satisfactorily completed.

2.11 Complaints

- 2.11.1 The Service shall have a procedure for recording, reviewing, and investigating relevant complaints.

2.12 Internal Quality Audits

- 2.12.1 The Service shall set up an internal quality audit system
- 2.12.2 Members of the internal audit system shall be trained personnel independent of those having direct responsibility for the activity being audited.
- 2.12.3 Internal auditors shall prepare reports of their findings including deficiencies observed and make recommendations for corrective actions.
- 2.12.4 Internal audit reports shall be reviewed and signed by the head of the relevant department of the Service and by the Quality Manager.
- 2.12.5 Immediate and appropriate corrective actions shall be implemented by the head of the relevant department.
- 2.12.6 Follow-up internal quality audits shall be performed where necessary.

2.13 Training

- 2.13.1 Personnel shall be assigned to perform specific tasks based on appropriate professional registration.
- 2.13.2 The Service shall have a system for identifying the training needs of staff.
- 2.13.3 The Service shall ensure that such needs are met through documented training programmes.
- 2.13.4 The Service shall maintain training records of staff.

2.14 Statistical Analysis

- 2.14.1 The Service shall carry out periodic monitoring and evaluation of all data and draw inferences for evidence-based decision making and improvement of service delivery systems

2.15 Safety, Health and Environment (SHE)

- 2.15.1 The Service shall maintain a programme in keeping with the requirements of Occupational Health and Safety Policies and other relevant legislation.

SECTION 3: BLOOD DONOR CRITERIA

3.1 Blood Donation Centres

3.1.1 Fixed Blood Donation Centre:

- 3.1.1.1 Blood donation centres shall be established solely for the purpose of sensitising, recruiting, testing, bleeding, and caring for voluntary donors
- 3.1.1.2 A fixed blood donation centre, which shall preferably be separate or distinct from the hospital transfusion facilities, shall have the following minimal infrastructure:
 - 3.1.1.2.1 A general waiting room/area which can also serve for donor sensitization and staff seminars
 - 3.1.1.2.2 A counselling room, which guarantees individual prospective donor's privacy
 - 3.1.1.2.3 A pretesting area for haemoglobin check, and other pre-donation check procedures
 - 3.1.1.2.4 A registration room or bay for accepted donors
 - 3.1.1.2.5 A bleeding room with sufficient couches or chairs to match the expected donor turnover at the centre
 - 3.1.1.2.6 A recovery room or post-donation rest room or bay
 - 3.1.1.2.7 A product sorting, storage, and processing room
 - 3.1.1.2.8 Additional provisions shall be made as necessary for personal offices, staff common room, convenience, and other utilities

3.1.2 Mobile Blood Donation Units:

- 3.1.2.1 Mobile blood donor units (MBDU) may be employed in blood donation drives
- 3.1.2.2 Preferably, the MBDU should utilise purpose-built or suitably modified vehicles and have the following minimal facilities:
 - 3.1.2.2.1 Enough room to transport adequate numbers of personnel
 - 3.1.2.2.2 Privacy for interviewing, testing and registration of donors
 - 3.1.2.2.3 Couches, beds, or chairs for bleeding of donors in the vehicle or at the venue
 - 3.1.2.2.4 Suitable temporary blood storage facilities
 - 3.1.2.2.5 Resuscitation equipment
 - 3.1.2.2.6 Dedicated mobile phone lines or other accelerated means of communication with base.

3.2 Criteria for the Selection of Whole-Blood and Apheresis Donors

3.2.1 Nature of Donation

- 3.2.1.1 Blood shall be donated only on a voluntary basis and donors shall not be remunerated for their donation.
- 3.2.1.2 Blood donation for monetary gain shall be a criminal offence.
- 3.2.1.3 During the transition period to 100% Voluntary Non-Remunerated Blood Donation, true family replacement donors shall be assessed by the same criteria and shall be encouraged to become regular voluntary non-remunerated donors.

3.2.2 Informed Consent

- 3.2.2.1 Prospective donors, whether of whole blood or apheresis, shall be given adequate verbal and/or written information about the procedure.
- 3.2.2.2 Every blood donor shall give informed consent prior to each blood donation.

3.2.3 Age

- 3.2.3.1 Blood donors shall be healthy persons between the ages of 18 to 70 years.
- 3.2.3.2 Persons under the age of 18 years shall require parental consent to donate blood.

3.2.4 Weight

- 3.2.4.1 Whole blood donors shall weigh 50 kg or more and apheresis donors 55 kg or more.
- 3.2.4.2 Persons of less than 50kg body weight may donate half the volume of the standard unit (220-275ml).

3.2.5 Identification

- 3.2.5.1 The blood donor shall be positively identified as the particular person who is registered or being registered by the Service at each donation.
- 3.2.5.2 The phlebotomist shall ensure that the donor in question has been positively identified.

3.2.6 Donation interval

- 3.2.6.1 The interval between consecutive whole blood donations (except autologous pre-deposit donation) shall not be less than 90 days for male and 120 days for a female unless otherwise authorised by a medical practitioner.

3.2.7 General Health

- 3.2.7.1 Before each donation, the appropriate donor clinic staff shall establish and document that the prospective donor is in good health using a standard questionnaire.
- 3.2.7.2 A comprehensive list of medical conditions, medications (including immunization and vaccinations) and transfusion transmissible infections, which may constitute grounds for deferral of donors, whether temporary or permanent, shall be displayed in the donor waiting area.
- 3.2.7.3 The list referred to above shall be updated periodically by the Service.
- 3.2.7.4 Any person who appears to be clearly under the influence of alcohol or any drug with a narcotic or other adverse effect or who appears not to be providing reliable answers to the medical history or other question shall not be accepted as a blood donor.

3.2.8 Medication

- 3.2.8.1 A registered practitioner or registered nurse under his supervision shall evaluate a prospective donor who is taking medication to determine suitability to donate blood.

3.2.9 Haemoglobin or Haematocrit

- 3.2.9.1 Each prospective donor shall be screened for haemoglobin concentration or haematocrit prior to donation.
- 3.2.9.2 The haemoglobin concentration shall not be less than 12.5 g/dL; alternatively, the *haematocrit value shall not be less than 38%*.

3.2.10 Pulse and Blood Pressure

- 3.2.10.1 The pulse and blood pressure shall be determined for each prospective donor prior to donation.
- 3.2.10.2 The donor's pulse rate shall not exhibit any irregularity and shall be between 50 to 100 beats per minute, except in highly trained athletes where a lower pulse rate may be accepted.
- 3.2.10.3 The systolic blood pressure shall not be higher than 140 mmHg and the diastolic not higher than 90 mmHg.

3.2.11 Pregnancy

- 3.2.11.1 Known existing pregnancy shall preclude routine donation until 3 months following conclusion of pregnancy.
- 3.2.11.2 *Autologous donation from a pregnant or post-partum woman is acceptable if her Hb is over 11.0g/dL and if the procedure is approved by her physician or a medical practitioner.*

3.2.12 Full Blood Count (for apheresis donors only)

- 3.2.12.1 Prospective apheresis donors require a full blood count prior to enrolment in the programme and the results shall be within normal limits.
- 3.2.12.2 At each follow up visit, the full blood count shall be determined to ascertain the donor's suitability for subsequent apheresis.

3.3 Therapeutic Phlebotomy

- 3.3.1 Therapeutic phlebotomy shall be performed only when prescribed by the patient's physician and with the concurrence of the medical practitioner.
- 3.3.2 Units of blood derived from therapeutic phlebotomies such as primary erythrocytosis (polycythaemia rubra vera) shall not be used for allogeneic transfusion.

3.4 Notifying Donor of Test Results

- 3.4.1 The Service shall notify the donor verbally or in writing of the result of pre-donation evaluation unless the donor had otherwise directed.
- 3.4.2 Donors found reactive for any transfusion transmissible infection or other relevant medical condition(s) shall be referred for appropriate evaluation, counselling, management and follow-up as the case may require.

3.5 Criteria for the Protection of a Recipient

- 3.5.1 Donor assessment: No blood shall be released for transfusion purposes if there is reason to suspect from the donor's medical history, lifestyle, past donation record or physical condition that his blood may transmit disease.
- 3.5.2 Receipt of blood or blood components: Prospective blood donors who have received blood components or other human tissues shall be deferred for a period of 52 weeks following such receipt.
- 3.5.3 **HIV or AIDS (Acquired Immunodeficiency Syndrome)**
 - 3.5.3.1 Prior to enrolment by the Service, all prospective blood donors shall be given information on high-risk behaviour for HIV/AIDS.
 - 3.5.3.2 Prospective donors with history of high-risk behaviour shall be given the opportunity for self-deferral.

- 3.5.3.3 Persons unable to demonstrate understanding of the information in 3.5.3.1 above shall be deferred.
- 3.5.3.4 A prospective donor shall give consent in writing for his donation to be tested for HIV infection.
- 3.5.3.5 Where a donor makes a request in confidence, a donated unit of blood shall be discarded, on account of high-risk behaviour.
- 3.5.3.6 Donation from a donor assessed to be high-risk by donor clinic staff, but who refuses to self-defer, should be permanently deferred.
- 3.5.3.7 Donation from a donor whose sole aim for donation appears to be to get tested for HIV shall be treated as in 3.5.3.6 above.

3.5.4 Hepatitis

- 3.5.4.1 Individuals with a history of jaundice or hepatitis shall be treated as 3.5.3.6 above
- 3.5.4.2 Prospective blood donors who have been in close contact with an individual with hepatitis shall also be deferred for a 12-month period.

3.5.5 All forms of Creutzfeldt-Jakob Disease

- 3.5.5.1 Individuals who have received pituitary growth hormone or dura mater grafts or therapy, unless of synthetic origin, shall not donate blood and shall be deferred permanently

3.5.6 Potential Exposure to Blood and Body Fluids

- 3.5.6.1 Prospective donors with history of actual or potential exposure to blood and body fluids or who have recently undergone the following procedures shall be deferred for 12 months:
 - 3.5.6.2 A tattoo
 - 3.5.6.3 Scarification
 - 3.5.6.4 Mucous membrane exposure, including blood splashes to the eyes.
 - 3.5.6.5 Skin penetration with instruments, weapons, or equipment suspected to be contaminated with blood or body fluids, including assaults where they have been bitten. However, ear piercing or acupuncture using sterile disposable equipment is acceptable.

3.5.7 Acute febrile illnesses

- 3.5.7.1 A prospective donor who has suffered from an acute febrile illness e.g. malaria and other febrile illnesses and has not had a relapse for more than 4 weeks may donate blood.

3.5.8 Prophylactic immunizations

- 3.5.8.1 Donors who have been vaccinated with attenuated bacteria and viruses shall be deferred for four weeks e.g. BCG, yellow fever, rubella, measles, poliomyelitis (oral), mumps, and live attenuated cholera vaccine.
- 3.5.8.2 Donors who have been vaccinated with killed bacteria may be accepted if well at time of donation e.g. cholera, typhoid, capsular polysaccharide typhoid fever vaccine.
- 3.5.8.3 Donors who have been vaccinated with inactivated viruses may be accepted if well at time of donation e.g. poliomyelitis (injection), influenza vaccine.
- 3.5.8.4 Donors who have been vaccinated with toxoids may be accepted if well at time of donation e.g. diphtheria, tetanus vaccine.
- 3.5.8.5 Donors who have been vaccinated with hepatitis A or hepatitis B vaccines may be accepted if they are well and have had no exposure to the disease.

- 3.5.8.6 Donors who have had vaccinations such as rabies and tick-borne encephalitis vaccine shall be deferred for 12 months.
- 3.5.8.7 Donors who have had emergency approved vaccines of any brand, shall be deferred for 12 months.

SECTION 4: BLOOD COLLECTION

4.1 General blood collection

4.1.1 Materials at blood collection centres:

- 4.1.1.1 A first aid box, a resuscitation kit and a telephone shall be provided at the blood collection centres and in mobile clinics to manage emergencies.

4.1.2 Responsibility

- 4.1.2.1 The head of the BE is ultimately responsible for the correct and safe procedure for the collection of blood.

4.1.3 Documentation

- 4.1.3.1 The Service shall have its own standard documented procedures for all phases of activity of the blood collection procedure including:

- 4.1.3.1.1 Donor identification.
- 4.1.3.1.2 Pre-donation counselling
- 4.1.3.1.3 Haemoglobin or haematocrit screening
- 4.1.3.1.4 Preparation of the venepuncture site
- 4.1.3.1.5 Preparation of the blood pack
- 4.1.3.1.6 Performance of the venepuncture
- 4.1.3.1.7 Blood donation procedure
- 4.1.3.1.8 Sample collection
- 4.1.3.1.9 Donor care

4.1.4 Withdrawal of Blood/ Phlebotomy

- 4.1.4.1 Phlebotomy can only be done under the supervision of a qualified medical practitioner, donor care manager or phlebotomist.
- 4.1.4.2 The collection shall be by an aseptic technique using a sterile closed system and a single venepuncture.
- 4.1.4.3 The skin at the venepuncture site shall be free of lesions.

4.1.5 Containers

- 4.1.5.1 Only sterile, pyrogen-free containers containing blood preservatives and approved by the National Agency for Food and Drug Administration and Control (NAFDAC) where necessary shall be used for blood collection.
- 4.1.5.2 A closed system must be maintained throughout the subsequent processing of blood.
- 4.1.5.3 If there is reason to suspect that the container is not suitable for the collection of blood, it shall be discarded.

4.1.6 Volume of Blood

- 4.1.6.1 The amount of blood allowed to flow into the container shall be as described by the manufacturer in the insert.

4.1.7 Labelling

- 4.1.7.1 Donor session staff shall ensure that the unique number assigned to the donation appears on the donor session record, the primary packs and all the blood sample tubes used.
- 4.1.7.2 Where additional numbers are required for secondary packs or for other purposes, they shall also be affixed to the primary pack.
- 4.1.7.3 The donation record, blood container, and corresponding blood sample tubes shall be labelled or checked at the chair-side.
- 4.1.7.4 Filling and labelling of the sample tubes shall be done as part of the donation procedure. Blood sample tubes shall be filled after the collection bag has been clamped and detached.
- 4.1.7.5 The arrangement of the donor clinic shall ensure that there is no possibility of crossover of donor samples and labels.

4.1.8 Mixing

- 4.1.8.1 The container/blood bag shall be placed on automatic blood unit mixer or regularly mixed at intervals during the donation process to ensure adequate mixing of the blood and preservative.

4.1.9 Inspection

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

4.2 Apheresis

4.2.1 Facilities for Apheresis

- 4.2.1.1 A procedure shall be in place for emergency services.
- 4.2.1.2 A medical practitioner or registered nurse shall be immediately available on the premises at all times when donors are undergoing apheresis.
- 4.2.1.3 A current copy of the Standard Operating Procedure (SOP) and relevant manufacturer's manual for each type of machine in use shall be available on site.

4.2.2 Frequency of Apheresis and Volume Collected

4.2.2.1 Cytapheresis

- 4.2.2.1.1 The interval between procedures for cytapheresis donors shall be at least 48 hours.
- 4.2.2.1.2 A cytapheresis donor shall not undergo the procedure more than 2 times in a 7-day period or 24 times in a year except in unusual circumstances as determined by a medical practitioner.
- 4.2.2.1.3 A cytapheresis donor shall be tested appropriately to detect developing cytopenia. Abnormal results shall be reviewed by the medical practitioner to consider continued suitability for donation.
- 4.2.2.1.4 Donors with a family or personal history of bleeding shall not be accepted for plateletpheresis.
- 4.2.2.1.5 Donors who have ingested aspirin and other non-steroidal anti-inflammatory drugs within 72 hours shall not be accepted for plateletpheresis.

4.2.2.2 Plasmapheresis

- 4.2.2.2.1 A donor shall not normally undergo plasmapheresis more than once in 14 days or more than 24 times in a year.
- 4.2.2.2.2 Except at the discretion of a medical practitioner, not more than 15L of plasma shall be donated by one donor a year or more than 2.4L plasma in any 4-week period and not more than 1L of plasma shall be donated by one donor in any 1-week period.
- 4.2.2.2.3 Total serum protein levels shall be monitored at least quarterly and shall be greater than 50g/L.
- 4.2.2.2.4 Apheresis donors shall not donate whole blood for 48 hours after an apheresis procedure.
- 4.2.2.2.5 The final collection volume (exclusive of anticoagulant) shall not exceed 600mL unless intravenous replacement is given.
- 4.2.2.2.6 After a blood donation, or the loss of an equivalent volume of red cells during a failed apheresis procedure, a donor shall not normally donate plasma, platelets, or leucocytes for a period of 90 days, except at the discretion of the medical practitioner.

4.2.3 Apheresis procedure

- 4.2.3.1 Blood components shall be collected by apheresis using sterile, single use disposable items from an approved manufacturer.
- 4.2.3.2 An appropriate anticoagulant (citrate) shall be used at a ratio that achieves a final concentration of 15-25mmol/l.
- 4.2.3.3 A record shall be kept of all lot numbers and/or batch numbers of all apheresis components and injectable material used, in accordance with the Service's quality system.
- 4.2.3.4 Equipment shall be correctly installed, calibrated, and commissioned according to the manufacturers' instructions.
- 4.2.3.5 The collection procedure shall be detailed in SOPs and/or the equipment manual.
- 4.2.3.6 The SOP for manual apheresis shall include stringent controls for the return of red blood cells to the donor. The greatest danger is confusion between packs of concentrated red cells during their centrifugation and return to individual donors. A proper identification system to avoid this is essential.
- 4.2.3.7 Apheresis platelet components shall be stored at 20°C to 24°C with continuous agitation.
- 4.2.3.8 Apheresis platelet component are tested in accordance with prescribed guidelines

4.3 Collection of Immune Plasma

4.3.1 Immunization of Donors

- 4.3.1.1 If the need for certain specific immunoglobulin is such that an adequate supply is unlikely to be obtained from the general population, deliberate immunization of suitable donors may be undertaken by the blood transfusion service and the donor shall be fully informed of the procedure and the risks involved.
- 4.3.1.2 These procedures shall be carried out at the National Reference Centre.

4.3.2 Immune Plasma Donors

- 4.3.2.1 The Service may identify suitable donors by random screening of routine donors or selected screening of those with an appropriate history.
- 4.3.2.2 Immunity to the specific antigen for which immunoglobulin is being sought may be acquired through natural infection or through active immunization.
- 4.3.2.3 Immunization may be for the donor's own protection or may be purposely employed for the production of immune plasma in a suitable and willing donor.
- 4.3.2.4 Donation of plasma following natural infection should take place within a period of 1-12 months following disappearance of symptoms (depending on the nature and/or cause of illness).
- 4.3.2.5 Whenever a donor with a suitable level of an immune antibody is identified, further donations shall preferably be by plasmapheresis in order to obtain maximum yield of the antibody.
- 4.3.2.6 Plasma obtained by therapeutic plasmapheresis shall not be used for the preparation of blood products, except in the case of anti-D plasma. In the latter situation, the donor shall be screened, tested, and shall conform to the requirements for acceptance by the fractionation unit.

4.3.3 Immunization of Donors

- 4.3.3.1 Immunization of donors shall be carried out only when sufficient supplies of materials of suitable quality cannot be obtained by the selection of suitable donors from the donor pool
- 4.3.3.2 Before any planned immunization of a willing donor, the suitability of that individual to donate by plasmapheresis shall be assessed by the medical practitioner.
- 4.3.3.3 When immunization is intended, the donor shall be informed of the procedure and associated risks. Informed consent shall be obtained.
- 4.3.3.4 Donors may undergo investigations to test for hypersensitivity to a proposed antigen at the discretion of the medical practitioner.
- 4.3.3.5 New vaccines used for immunization shall be registered by NAFDAC.
- 4.3.3.6 Ethical approval for a new immunization programme shall be obtained from the appropriate National Ethics Committee.

4.3.4 Red Cell Immunization of Donors

- 4.3.4.1 Any procedure involving red cell immunization of donors shall be in accordance with a protocol approved by an appropriately constituted ethics committee.

4.4 Collection of Blood for Laboratory Use

- 4.4.1 It may be justified from time to time to collect blood for use in the Service laboratories. The guidelines in use for the protection of blood donors shall apply.
- 4.4.2 The Service may collect donations for laboratory use into appropriate packs without donor blood preservatives.

SECTION 5: PROCESSING OF BLOOD PRODUCTS

5.1 Starting Materials for Processing

- 5.1.1** The starting materials for components preparation shall be donated whole blood or products of apheresis collected from donors who satisfy selection criteria in Section 3.
- 5.1.2** Platelet concentrates may be obtained either from blood donation or by plateletpheresis.
- 5.1.3** The NBSC/BE shall prepare components only from individual donations of blood.
- 5.1.4** Certain components may be pooled provided that the size of a pool never exceeds six individual donations.

5.2 Containers for Components

- 5.2.1** The final container for red cell concentrate (other than a modified red blood cell concentrate) shall be the container in which the blood was originally collected, or satellite container attached as an integral part thereof.

5.3 Storage of Blood Donation Prior to Processing

- 5.3.1** Blood collected shall be placed in a 2°C to 6°C storage environment within 8 hours of collection
- 5.3.2** Where refrigeration is likely to be delayed beyond 8 hours, a eutectic shall be placed in direct contact with each unit of blood, within 30 minutes of donation, and then may be placed in an insulated container to maintain the temperature between 20°C and 22°C for a maximum of 24 hours before being processed or placed in a 2°C to 6°C environment.
- 5.3.3** The eutectic shall preferably be of the butane-1, 4-diol type and should be at a temperature of between 2°C and 8°C before being placed in contact with unit of blood.
- 5.3.4** The system shall be validated to ensure that the temperature is maintained within the specified limits.

5.4 Components Separation Procedures

- 5.4.1** An SOP describing the procedures involved in components preparation shall be available for each product.
- 5.4.2** The Service shall evaluate the methods employed for components separation before implementation of such methods.
- 5.4.3** At regular intervals the quality of the final products shall be monitored.
- 5.4.4** The timing of separation of components shall conform to the following:
 - 5.4.4.1** Blood components shall be separated from whole blood preferably within 6 to 18 hours after collection (unless a eutectic is used as in 5.3.2 above to maintain for 24 hours.)
 - 5.4.4.2** Red cell products in additive solution shall be prepared preferably within 72 hours but not more than 7 days after collection.
 - 5.4.4.3** Filtered or leukocyte-reduced red cell products shall preferably be prepared within 48 hours of collection.
 - 5.4.4.4** Frozen red cell products shall preferably be frozen within 6 days of collection
 - 5.4.4.5** Recovered plasma, for fractionation may be separated at any time after collection but not more than 5 days after the expiry date of the whole blood and shall be frozen

immediately after separation. The method of separation which minimizes the risk of bacterial contamination shall be employed.

- 5.4.5 Separation of blood components by means of centrifugation shall be done in such a manner that the temperature will be maintained within the limits specified in the SOP.
- 5.4.6 The Service shall maintain the sterility of all components during processing by using aseptic techniques and pyrogen-free containers.
- 5.4.7 Where there are special clinical circumstances which require components to be modified for specific recipient needs, such products may be made under the direction and approval of the top management of the Blood Establishment/NBSC and if this entails using an open system then the appropriate requirements shall apply.
- 5.4.8 Arrangement for external contract fractionalization of plasma shall be entered into by the Blood Establishment with approval from NBSC.

5.5 Storage of Blood Components after Processing

5.5.1 After processing, blood components shall be stored at the following temperatures:

- 5.5.1.1 Whole blood and red blood products at 2°C to 6°C.
 - 5.5.1.2 Frozen red cell product at less than (minus) - 65°C (in the presence of a cryopreservation agent).
 - 5.5.1.3 Platelet products at 20°C to 25°C in suitable containers using equipment with constant agitation for maximum of 5 days.
 - 5.5.1.4 All frozen plasma products at lower than (minus) -20°C for 1 year and at lower than (minus) -25°C for 2 years.
 - 5.5.1.5 Plasma, fresh, freeze-dried below 25°C.
 - 5.5.1.6 Freeze-dried anti-haemophilic factor at 2°C to 10°C for the period stipulated by the manufacturer.
- 5.5.2 Whole blood and red cell components shall be continuously kept at 2°C to 6°C (except when being transported in cold chain within 2-8°C) until immediately prior to infusion and may only be placed at room temperature for any single period not exceeding 60 minutes as may be necessary for testing, labelling, transfer, or processing.
- 5.5.3 Blood donations and red cell components shall not be frozen at any time (except as recommended with reference to frozen red blood cells).

5.6 Storage Facilities

5.6.1 The NBSC/BEs Shall:

- 5.6.1.1 Have storage areas for blood components that provide adequate space, suitable lighting and which are arranged and equipped to allow dry, clean, and orderly storage.
- 5.6.1.2 Secure bio-hazardous materials awaiting disposal in exclusive labelled storage areas.
- 5.6.1.3 Maintain security and status labelling of component storage areas.
- 5.6.1.4 Maintain an inventory of components in each storage category.
- 5.6.1.5 Have mechanisms in place to ensure that blood is maintained within the appropriate temperature range.

- 5.6.1.6 Install and maintain storage alarm system(s) so that prompt action can be taken in the event of equipment failure to ensure that quality of components is not compromised.
- 5.6.1.7 Keep a record of storage temperatures.
- 5.6.1.8 Categorize or separate components in line with GMP, according to their status e.g. components awaiting testing, non-conforming components, available stock, or expired components.

5.7 Transport of Blood Components

- 5.7.1 Blood or red cell components shall be transported at a temperature between 2°C to 8°C in qualified containers. Transportation time shall preferably not exceed 24 hours.
- 5.7.2 The NBSC/ BEs responsible for the transport of containers of blood and red cell components shall maintain a system for checking that such containers arrive at their destination within this temperature range.
- 5.7.3 Platelets shall be transported within a temperature range of 20°C to 25°C. Transportation time should preferably not exceed 24 hours.
- 5.7.4 Frozen plasma products shall be transported at a temperature range of lower than -18°C.
- 5.7.5 Freeze-dried anti-haemophilic factor and freeze-dried plasma may be transported at temperatures not higher than 25°C.

5.8 Components Identification

- 5.8.1 The NBSC/ BEs shall use a unique coded and/or eye-readable donation number to link the donation to its donor.
- 5.8.2 When component production requires the use of packs that are not an integral part of the pack assembly, a secure system shall be used to ensure that the correct eye-readable and bar-coded donation number is placed on each additional pack or aliquot used.
- 5.8.3 To ensure that all constituents of a component pool can be traced, a unique batch number shall be assigned to the pool that shall be placed on the pack or aliquot used.
- 5.8.4 When a component is divided for neonatal use, a secure system shall be used to ensure that all satellite units can be traced, and this also applies to components prepared by apheresis.

5.9 Expiry Dates and Time

5.9.1 Whole Blood and Red Cell Products:

- 5.9.1.1 The expiry date for the whole blood and red cell products, in additive solution, is in accordance with the container manufacturer's specifications e.g. 35days in Citrate phosphate dextrose adenine (CPDA) or 42 days Saline Adenine Glucose Manitor (SAG-M)
- 5.9.1.2 Red cell products without additive solution shall have an expiry date of 21 days.
- 5.9.1.3 Frozen red cell products shall have an expiry date of 10 years from date of freezing.
- 5.9.1.4 If an open system which may not maintain sterility is used, (e.g. filtered or washed red cells) the expiry time shall be a maximum of 24 hours after filtration or washing is commenced, but the product should be infused as soon as possible.

5.9.2 Platelets:

- 5.9.2.1 The expiry date for platelet concentrates is 5 days after collection.
- 5.9.2.2 After pooling, the expiry time shall be a maximum of 5 hours under aseptic conditions.

5.9.3 Plasma products:

- 5.9.3.1 The expiry date for all plasma products (including Cryoprecipitate and Cryofibrinogen) is 2 years if kept frozen at below (minus) -25°C, and 1 year if kept frozen at (minus) -20°C
- 5.9.3.2 The expiry date for freeze-dried plasma is 2 years from date of freezing or 5 years if not used for clotting factors and if stored at temperatures not higher than 25°C.
- 5.9.3.3 The expiry date for freeze-dried anti-haemophilic factors is 2 years if stored at temperatures not higher than 25°C.
- 5.9.3.4 Frozen plasma products (including Cryoprecipitate and Cryofibrinogen) shall be thawed at 30°C to 37°C and after thawing the expiry time shall be a maximum of 6 hours. It is recommended that the product be transported/stored at a temperature no higher than 24°C after thawing.
- 5.9.3.5 Expired Fresh Frozen Plasma may be used for preparation of recovered plasma for fractionation provided the expiry date has not exceeded 2 years and provided it meets the requirements for plasma fractionation.

5.10 Labelling of Containers

- 5.10.1 A container of blood or component shall have a label securely affixed to it and the label shall not obstruct ready inspection of the contents of the container.
- 5.10.2 The NBSC/ BEs shall ensure that at the minimum, the following information is printed on a label referred to in 5.10.1 above in easily legible and indelible letters.
 - 5.10.2.1 The proper name of the content.
 - 5.10.2.2 The type and volume of anticoagulant solution and/or additive solution used in the container, where applicable.
 - 5.10.2.3 The name and address of the NBSC/BEs responsible for collecting the blood donation or components.
 - 5.10.2.4 The unique number of the blood donation or components whereby the donor(s) may be identified.
 - 5.10.2.5 The date of withdrawal of the blood or components from the donor, where applicable
 - 5.10.2.6 The expiry date, and the component in the container.
 - 5.10.2.7 The ABO blood group of the donor (except Cryoprecipitate, freeze-dried anti-haemophilic factor and Cryofibrinogen)
 - 5.10.2.8 The Rh D type of the donor (except for Fresh Frozen Plasma, Cryo-poor Plasma, Cryoprecipitate, freeze- dried anti-haemophilic factor and Cryofibrinogen)
 - 5.10.2.9 The minimum volume or mass of the contents of the container expressed in millilitres or gram.
 - 5.10.2.10 Temperature conditions for storage and transport (e.g. store at 2°C to 8°C and transport at 2°C to 8°C) for whole blood and red cell concentrates

5.11 Labelling of platelet concentrates

- 5.11.1 A platelet concentrate label shall carry the following in addition to the data referred to in Section 5.9
 - 5.11.1.1 The storage temperature of 20°C to 24°C.
 - 5.11.1.2 Instructions that the infusion of the contents shall be completed within 30-60mins through a standard platelet filter.

SECTION 6: TESTING AND DISPOSITION OF BLOOD PRODUCTS

6.1 Types of Testing

- 6.1.1 The BE shall perform the following tests:
 - 6.1.1.1 Mandatory red cell serology
 - 6.1.1.2 Transfusion Transmissible Infections (TTIs) screening tests on each donated blood
 - 6.1.1.3 Quality control tests on random units of blood components
 - 6.1.1.4 Visual inspection of blood components during processing and immediately prior to issue.
- 6.1.2 The BE shall ensure that blood and blood components cannot be released for transfusion until all mandatory laboratory tests have been completed, documented, and approved, except at the discretion of the Medical Practitioner.
- 6.1.3 The BE shall periodically evaluate the suitability of test kits used for screening transfusion transmissible infections in the Nigerian population.

6.2 Mandatory Tests

- 6.2.1 The BE shall perform the following tests on each donation:
 - 6.2.1.1 Tests for transfusion transmissible infections (TTIs)
 - 6.2.1.2 Red cell serology including ABO grouping and Rh typing
 - 6.2.1.3 Alpha and Beta haemolysin and high titre allo-agglutinin screening on groups O, A and B blood intended for non-homologous recipients
- 6.2.2 The BE shall perform laboratory tests only on a sample taken from a blood donor at the time of collection of blood or components, or, if suitable, such laboratory tests may be done from pre-sealed segments of the pilot tubing that is an integral part of the final container. In case of apheresis, the sample will be collected for initial assessment before donation.
- 6.2.3 The results of the ABO and Rh tests shall be used for the correct labelling of all units of blood or blood components intended for transfusion and for the compatibility testing.

6.3 Tests for Transfusion Transmissible Infections (TTIs)

- 6.3.1 The BE shall perform the following tests on each donation:
 - 6.3.1.1 Serological tests for syphilis (ELISA or higher technology)
 - 6.3.1.2 Test for hepatitis B surface antigen (HBsAg) (ELISA or higher technology)
 - 6.3.1.3 Test for antibodies to the hepatitis C virus (anti-HCV) (ELISA or higher technology)
 - 6.3.1.4 Test for antibodies to human immunodeficiency virus Type 1 and 2 (anti-HIV 1&2) and p24 antigen using Fourth Generation ELISA or higher technology.
 - 6.3.1.5 Any other mandatory test specified by NBSC from time to time.
- 6.3.2 No blood products giving reactive or repeat reactive results for any of the tests shall be released for transfusion.
- 6.3.3 Only test kits designed for blood screening that are approved by NAFDAC and validated by MLSCN shall be used where applicable.

6.4 Red Cell Grouping

- 6.4.1 ABO grouping

6.4.1.1 A donation of blood or blood components collected from a first-time blood donor shall be classified by the BE according to its ABO cell and serum grouping, which shall be done in duplicate independently.

6.4.1.2 For repeat blood donors the ABO blood grouping result shall agree with that obtained at previous donations from the same donor.

6.4.2 Rh Grouping

6.4.2.1 The BE shall classify a donor as Rh D positive or confirmed to have weak D. The BE shall classify a donation as Rh D negative if there is no observable reaction during confirmatory test.

6.4.2.2 The Rh D blood group of all first-time donors shall be established by testing in duplicates by Two (2) independent persons.

6.4.2.3 For repeat donors, Rh D blood group testing shall be established by testing and the results should be in agreement with previous records of Rh D blood group from the same donor.

6.5 Quality Control Tests

6.5.1 The BE shall draw random samples from blood components production line for quality control tests periodically on monthly basis.

6.5.2 The target for quality testing is 1% of the annual production.

6.5.3 The BE shall analyze the quality control results, and if the results of analysis show a consistent deviation away from the specification detailed in the relevant SOPs, the cause thereof shall be investigated

6.5.4 The investigation process as in 6.5.3 above shall include the following steps:

6.5.4.1 A review of the testing and production procedures

6.5.4.2 Checking that SOPs are up to date and followed

6.5.4.3 Checking the operation of equipment and storage conditions

6.5.4.4 Introduction of additional investigations as may be determined by the quality assurance officer

6.6 Visual Inspection

6.6.1 A donation of blood, or blood component derived therefrom, shall be inspected by the laboratory manager or the issuing officer during processing and immediately before issue and shall not be issued if there is any evidence of leakage, air bubble, or suspicion of microbial contamination.

6.6.2 In addition to the above, plasma products with significant red cell contamination and aggregates or clots shall not be issued.

6.7 Release of Components, Not Conforming to Mandatory Requirements

6.7.1 In exceptional circumstances, and with the approval of the medical practitioner (or designated medical officer), blood or components that do not conform to all mandatory requirements may be issued on request.

6.7.2 The BE shall have an SOP on the procedure that details the circumstances under which blood or components referred to in 6.7.1 above can be issued and these instructions shall, as a minimum, include the following:

6.7.2.1 Blood products that have not been subjected to all mandatory requirements referred to in this Section shall have a warning attached to the container indicating an increased level of risk.

- 6.7.2.2 The BE shall notify the registered medical practitioner of the issue of blood products referred to in 6.7.2.1 and such notification shall be documented
- 6.7.2.3 The reason for the issue of blood products referred to in this 6.7.2.1 shall be fully documented.
- 6.7.2.4 The name of the recipient shall be entered on the issue documentation and on the blood product.

6.8 Discard of Non-conforming Blood Components

- 6.8.1 The BE shall have a procedure for the discard of non-conforming blood products arising at any stage during the processing or testing and ensure that an appropriate record is maintained
- 6.8.2 Donations that are repeatedly positive for mandatory screening tests, or donations from donors whose records indicate that their blood products should be destroyed because of previous mandatory test results, shall be classified, and discarded as biohazardous.
- 6.8.3 The BE shall ensure that all non-conforming blood products and samples are disposed of, and these include:
 - 6.8.3.1 Labelling of the blood products to indicate that they are not suitable for therapeutic use.
 - 6.8.3.2 Using a system to trace all blood products prepared from the donation.
 - 6.8.3.3 Maintaining a record of the blood donor and the laboratory discarding each non-conforming blood product.
- 6.8.4 When non-conforming material, e.g. plasma, is retained for laboratory use, the BE shall store such material in a secure and appropriately labelled area, separate from any products which might be used for therapeutic purpose and in a manner which will prevent it from ever being used for transfusion.

SECTION 7: BLOOD PRODUCTION SPECIFICATIONS

7.1. Compliance with specifications

7.1.1. The NBSC/ BEs shall ensure that the components it produces comply with the specifications in this section.

7.2. Whole blood and cell products

PRODUCT		SPECIFICATIONS
Whole blood	Volume Haematocrit	525 ml $\pm$ 50 ml (incl. anticoagulant)
Red cells without additive solution	Volume Haematocrit	230 ml $\pm$ 50 ml 0.8 N $\pm$ 0.1 N
Red cells in additive solution	Volume Haematocrit	320 ml $\pm$ 50 ml 0.6 N $\pm$ 50 ml 0.6 N $\pm$ 0.1 N
Red cells in additive solution, buffy coat removed	Volume Haematocrit Leucocytes	300 ml $\pm$ 50 ml 0.6 N $\pm$ 0.1 N <2.4x10 ¹⁰ /unit
Red cells, leucocyte-depleted	Volume Haematocrit Leucocyte count	260 ml $\pm$ 50 ml 0.6N $\pm$ 0.1N <5 x10 ⁸ unit
Red cells, leucocyte-depleted.	Volume Haematocrit Leucocyte	130+ $\pm$ 25 ml 0.6 N $\pm$ 0.1N <5x10 ⁸ /primary unit
Red cells, leucocyte-depleted, infant	Volume Haematocrit Leucocyte count	75+20 ml 0.6 N $\pm$ 0.1N <5x10 ⁸ /primary unit
Red cells, washed	Volume Haematocrit Protein content of supernatant	> 185 ml 0.6 N $\pm$ 0.1 N < 5 mg/ unit
Red cells, cryopreserved	Volume Haematocrit Sterility	>185 ml 0.6 N $\pm$ 0.1 N Negative

7.3. Platelet products (tested at expiry)

PRODUCT		SPECIFICATIONS
Single random donor platelets	Volume Platelet count Leucocyte count, if leuco-depleted pH (within 24 hours of expiry)	> 40 ml > 5.5 x 10 ¹⁰ < 1 x 10 ⁸ / unit 6.9 $\pm$ 0.5 at 22°C

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Pooled platelets	Volume (x no. units in pool) Platelet count (for pool > 5) Leucocyte count, if leuco-depleted pH (within 24 hours of expiry)	> 40 ml > 2.4×10^{10} < 5×10^8 / unit 6.9 ± 0.5 at 22°C
Apheresis	Volume Platelet count Leucocyte count, if leuco-depleted pH (within 24 hours of expiry)	>200 ml > 2.4×10^{10} < 5×10^8 / unit 6.9 ± 0.5 at 22°C

7.4. Plasma products

PRODUCT		SPECIFICATIONS
Fresh frozen plasma (FFP)		280 ml $\pm$ 70 ml > 0.7 IU ml
Cryo-poor plasma		250 ml $\pm$ 60 ml
Fresh frozen plasma, pediatric (Group AB)* no antibodies		130 ml $\pm$ 30 ml > 0.7 IU ml
Plasma, fresh, freeze-dried (on Random batch samples)		< 2% Negative
Cryoprecipitate		15 ml $\pm$ 10 ml > 80 IU/ unit > 12 mg/ ml
Cryoprecipitate for fibrinogen use		30 $\pm$ 10 ml > 300 mg/ unit
Heat treated, freeze-dried anti-Haemophilic factor (on random batch Samples)		< 80% stated activity < 2% Negative

SECTION 8: COMPATIBILITY TESTING AND TRANSFUSION OF BLOOD PRODUCTS

8.1. Requests for Blood and Blood Components

- 8.1.1. Requests for blood or components for transfusion must be made and signed by registered medical practitioner or authorized personnel
- 8.1.2. Request forms for blood or components and the blood sample(s) from recipient shall contain sufficient information to uniquely identify the recipient and shall include 2 independent identifiers (e.g. name, hospital identification number, age and gender).
- 8.1.3. The requesting medical practitioner shall give information on the request form on the clinical diagnosis and indication for transfusion, type and quantity of product requested, and when, and other relevant transfusion and/or clinical history.
- 8.1.4. The BE shall accept only complete, accurate and legible requests except when not feasible.
- 8.1.5. Requests received for emergency patients shall have at least one unique identifier (e.g. emergency unit number and gender).
- 8.1.6. If there is no unique identifier in a life- threatening situation, request should be attended to and the relevant record populated later when provided.
- 8.1.7. Under an extreme emergency situation where a sample of the patient may not be provided at the point of request, the most suitable unit should be issued to rescue the patient and cross matching procedures may continue after the sample has been received.
- 8.1.8. All details on the request form and sample must be entered in a Receiving Register which should be signed by both the person delivering and receiving the samples.

8.2. Testing of Donor's Blood

- 8.2.1. The laboratory performing a compatibility test shall confirm the ABO group of all units of the blood or blood components.
- 8.2.2. Discrepancies shall be reported to the collecting facility and shall be resolved before issue of the blood for transfusion.

8.3. Testing of Recipient's Blood

- 8.3.1. Each blood sample submitted to the BE with a request for transfusion of blood or red cell components shall be tested by such Service for ABO group, Rh D type and for clinically significant antibodies.
- 8.3.2. If a recipient has been transfused within the preceding 3 months with a red cell component, or has been pregnant within the preceding 3 months, or if the history is uncertain or unavailable, such recipient's sample shall be obtained within 3 days of the scheduled transfusion.

8.4. Compatibility Test

- 8.4.1. A major compatibility test using donor red cells from pilot tube or segment of the component to be transfused and the recipient's serum shall be performed before administration of blood and red cell components.

- 8.4.2. The compatibility test shall use methods that demonstrate ABO incompatibility and other clinically significant antibodies and shall include at least saline reaction at room temperature, at 37°C and indirect antiglobulin techniques.
- 8.4.3. A compatibility test register and form shall be completed for each unit of blood or component (or pooled component) indicating the:
 - 8.4.3.1. Intended recipient's names
 - 8.4.3.2. Hospital patient's identification number
 - 8.4.3.3. Recipient's ABO group and Rh D type
 - 8.4.3.4. Donor unit or pool identification number
 - 8.4.3.5. Donor's ABO group and Rh D type
 - 8.4.3.6. Interpretation of compatibility tests
 - 8.4.3.7. Date of cross-match
 - 8.4.3.8. Result of compatibility test
 - 8.4.3.9. Signatures of personnel certifying compatibility in both the register and the form
- 8.4.4. If a computer system has been validated to prevent the release of ABO incompatible blood and component, then it may be used prior to transfusion to detect ABO incompatibility instead of a serological cross-match, provided that:
 - 8.4.4.1. 2 (two) separate determinations (not duplicate testing) of the recipient's ABO group have been made;
 - 8.4.4.2. The system contains the donor unit number, the component name, ABO group and Rh type of the component, the interpretation of the ABO confirmatory test of the product and recipient information of the ABO group and Rh D type.
 - 8.4.4.3. A method to verify correct entry of data should be instituted
 - 8.4.4.4. The system contains logic to alert the user to discrepancies between donor unit labelling and blood group confirmatory test interpretation, and ABO incompatibilities between the recipient and the donor unit.
 - 8.4.4.5. A sample of serum from recipient that was used for compatibility testing shall be stored at 2°C to 6°C for a minimum of seven (7) days post transfusion.
 - 8.4.4.6. In case of dire emergency, blood may be administered without a compatibility test, in which case the attending medical practitioner shall take documented responsibility.

8.5. Transfusion Responsibilities

- 8.5.1. Transfusion of blood, red cell components and other components shall be prescribed in the medical records of the recipient by the attending doctor and administered under medical direction.
- 8.5.2. If national regulations so direct, fees may be charged to recover part of the processing costs of blood transfusion, provided that blood is not denied any patient seriously in need on account of inability to pay.
- 8.5.3. The transfusion shall be administered by a medical practitioner, or a registered nurse delegated by the attending doctor.
- 8.5.4. The recipient shall be observed during the transfusion and for an appropriate time thereafter for possible adverse reaction.

8.6. Selection of Blood Products for Transfusion

- 8.6.1. The BE shall ensure that recipients receive preferably ABO group identical, but in all cases ABO group-compatible red blood cell or other components.
- 8.6.2. For Rh D negative recipients, Rh D negative blood shall be given except in times of emergency where males and post-menopausal females may be transfused with Rh D positive blood provided it is serologically compatible.
- 8.6.3. All Rh D positive recipients may receive either Rh D positive or Rh D negative whole blood or red cell components.
- 8.6.4. Plasma and platelet products should preferably be ABO compatible, especially in the case of infants. However, low titre and haemolysin free ABO incompatible plasma and platelet products may be infused provided they are not contaminated with red cells.
- 8.6.5. Platelets prepared by apheresis shall have a red cell compatibility test performed.
- 8.6.6. The following special considerations are applicable to a recipient under the age of 6 months:
 - 8.6.6.1. An initial pre-transfusion sample from the neonate shall be tested in order to determine ABO group and Rh D type.
 - 8.6.6.2. A test for unexpected antibodies shall be performed using serum from the infant and the mother.
 - 8.6.6.3. Donors red cells that are group compatible with both mother and infant shall preferably be cross matched using both infant and mother's serum
 - 8.6.6.4. If the initial antibody screen demonstrates clinically significant red cell antibodies, unit shall be prepared for transfusion that either do not contain the corresponding antigen or are compatible by a full antiglobulin compatibility test.
 - 8.6.6.5. If non-Group O red cells whose compatibility with the maternal ABO group is not established are to be issued the neonate's serum shall be tested for anti-A and anti-B. If anti-A or anti-B antibodies are detected, red cells lacking the corresponding antigen shall be transfused.

8.7. Issue of Blood Products for Transfusion

- 8.7.1. Before blood is released for transfusion, interpretations of recipient's current tests shall be compared with the records (if any) to detect possible error or potentially dangerous clinical situations.
- 8.7.2. A label with the recipient's name and hospital identification number and interpretation of compatibility tests (if performed), shall be attached securely by the blood bank staff to the blood bag, provided emergency situations do not warrant non-inclusion of full identifiers, *ab initio*.
- 8.7.3. A container of blood intended for infusion shall not be opened or entered by piercing the hermetic closure unless for the purpose of preparing for a transfusion.

8.8. Condition of Blood for Transfusion

- 8.8.1. Blood and its components shall be maintained in a controlled environment at the recommended temperature until released for transfusion.
- 8.8.2. Blood or blood components shall be transfused through a sterile, pyrogen-free transfusion set that has a filter designed to retain particles potentially harmful to the recipient. A filter with a pore size of 150 to 240 micrometer is recommended.
- 8.8.3. When warming of blood is indicated this shall be accomplished by a blood warming apparatus specifically designed for that purpose.

- 8.8.4. During warming of blood, the temperature shall never exceed 25°C.
- 8.8.5. Once the blood is warmed, the unit shall be labelled by the practitioner responsible for the transfusion to indicate this and shall be transfused within 6 hours of warming to minimize the risk of bacterial growth.
- 8.8.6. Drugs or medications shall not be added to blood or its components.

8.8.7. Irradiation

- 8.8.7.1. Cellular components shall be irradiated in order to reduce the risk of graft versus host diseases and elimination of some TTIs not screened for in the following recipient categories:
 - 8.8.7.1.1. Foetuses receiving intrauterine transfusions.
 - 8.8.7.1.2. Immuno-compromised recipients.
 - 8.8.7.1.3. Recipients who have undergone bone marrow or peripheral blood progenitor cell transplantation.
- 8.8.7.2. The dose delivered shall be between 25 and 50 Grays and targeted to the central portion of the blood bag. Once irradiated, the component shall be labelled by the BE performing the irradiation, to indicate this.
- 8.8.7.3. Red cell components may be irradiated up to 14 days after collection and thereafter the expiry date is 28 days after collection.

8.9. Re-issue of Whole Blood and Red Cell Concentrates

- 8.9.1. Whole blood and cell components issued by the BE shall not be re-issued, unless:
 - 8.9.1.1. The components container closure has not been tampered with.
 - 8.9.1.2. Segments containing an adequate amount of blood for pre-transfusion testing purposes are still attached to the blood bag, unless re-issued to the same recipient.
 - 8.9.1.3. There is satisfactory evidence that the blood has been maintained at a temperature of 2°C to 8°C and is returned within 24 hours of issue.
 - 8.9.1.4. It is recorded that the component is being re-issued.
 - 8.9.1.5. The label of compatibility attached to the components is cancelled and replaced with a new one, unless re-issued to the same recipient within 48 hours.
- 8.9.2. If a returned donation is deemed as not safe for re-issue, it shall immediately have a label conspicuously and securely affixed to it indicating that the unit shall not be used for transfusion and put away in a designated storage compartment.
- 8.9.3. The plasma from a component deemed unsafe for re-issue following its return, may nevertheless, be sent to a blood fractionation Service for fractionation, provided that it conforms to the minimum specification of that fractionation unit.

8.10. Urgent Requirement for Blood

- 8.10.1. When a delay in transfusion may be detrimental to the recipient, blood may be issued as follows:
 - 8.10.1.1. Recipients whose ABO group is not known shall receive group O red cells.
 - 8.10.1.2. Recipients, whose ABO group has been determined without reliance on previous records, may receive ABO group-compatible blood or red cell components before other test for compatibility have been completed.
 - 8.10.1.3. Where the Rh D type is unknown, urgent blood issued should be Rh (D) negative, if issued to a female prior to or during childbearing years.

- 8.10.1.4. There shall be a record signed by the requesting medical practitioner indicating that the urgency of the clinical situation was significant to require release of red cells before completion of compatibility testing.
- 8.10.1.5. The blood bag label shall indicate, in a conspicuous fashion, that compatibility testing has not been completed at the time of issue.
- 8.10.1.6. Standard compatibility tests shall be completed promptly.
- 8.10.1.7. The result of the compatibility test which will be carried out on units released during emergency shall be communicated with appropriate recommendation to the attending medical practitioner. In case the unit released was incompatible, the potential replacement which would have been cross matched concurrently will be issued immediately.

8.11. Monitoring of Blood Transfusion

- 8.11.1. Blood transfusion shall be undertaken where the full complement of clinical staff is on duty and around, except in emergencies. Such emergency transfusion shall be duly documented.
- 8.11.2. A nurse or other qualified staff shall be specifically assigned and held responsible for monitoring each blood transfusion exercise.
- 8.11.3. A medical practitioner (or an appropriately trained officer) shall be assigned and be available physically or on call to cover the staff monitoring the transfusion.
- 8.11.4. A Blood Transfusion Monitoring Form shall be duly completed for every blood unit or component transfused.
- 8.11.5. The monitoring officer shall observe and record the following in the Blood Transfusion Monitoring Form from the commencement till completion of transfusion:
 - 8.11.5.1. The blood group, type, date of collection and expiry and the condition of the blood or component about to be transfused.
 - 8.11.5.2. The positive identification of the recipient by agreement of all identification information in the clinical case file, the compatibility test form and data on the blood or component container or label.
 - 8.11.5.3. Name of the prescribing medical practitioner, specific type of product and the quantity prescribed.
- 8.11.6. The following clinical observations shall be made and recorded before the commencement, at the commencement, hourly during and two hours post transfusion exercise:
 - 8.11.6.1. Vital signs including temperature, pulse rate, blood pressure and respiratory rate.
 - 8.11.6.2. Physical and general condition of the client (including complaints, if any).
 - 8.11.6.3. Condition of any urine voided during and until two hours post transfusion
 - 8.11.6.4. Signs and symptoms such as fever, rigor, itching, vomiting, tightness of the chest, sweating and convulsions or unconsciousness
- 8.11.7. The designated transfusion monitoring officer shall set the rate of flow in accordance with the prescribed period of completion of the transfusion and periodically check to confirm that the set rate is maintained.
- 8.11.8. A full unit of blood or red cell concentrate shall not take less than one hour or more than six hours to flow through, unless in emergencies or otherwise directed by the attending medical practitioner.

8.12. Haemovigilance

- 8.12.1. The BE shall have a system for reporting and evaluating suspected complications of transfusion.
- 8.12.2. In the event of a suspected transfusion reaction, the person attending to the recipient shall notify the responsible medical practitioner immediately.
- 8.12.3. The medical practitioner shall report the incident as soon as possible in writing to the designated authority including the head of the transfusion laboratory and the chairman of the hospital's Transfusion Committee.
- 8.12.4. In the event of severe morbidity or mortality, the report may be initially verbal, and then subsequently in writing.
- 8.12.5. All suspected transfusion reactions shall be promptly investigated and documented.
- 8.12.6. It is the responsibility of the National Blood Service Commission to maintain a Haemovigilance Register of all reported reactions.
- 8.12.7. The Haemovigilance Register shall document all relevant data as enumerated in 2.5.7.
- 8.12.8. The BE shall conform to all requirements of the national haemovigilance programme and submit a monthly report to the National Haemovigilance Unit of the NBSC.

8.13. Transfusion Reactions

- 8.13.1. Any adverse reaction experienced by a recipient that is reasonably attributable to the transfusion is to be regarded as transfusion reaction.
- 8.13.2. The BE shall maintain a documented procedure for the investigation of transfusion reactions.
- 8.13.3. If there are symptoms or findings suggestive of a transfusion reaction the following shall be done immediately:
 - 8.13.3.1. The transfusion shall be stopped forthwith, and the attending physician notified immediately.
 - 8.13.3.2. The label on the blood bags and all other records examined to determine if an error has occurred in identifying the recipient or the blood.
 - 8.13.3.3. A labelled blood sample and urine sample from the recipient shall be obtained and sent, with the blood bag and any attached transfusion set and intravenous solutions, promptly to the hospital blood bank laboratory.
 - 8.13.3.4. Immediately on receipt of the blood sample and blood bag(s) referred to in 8.13.3.3 above, the hospital blood bank laboratory shall do at least the following:
 - 8.13.3.4.1. Ascertain that no clerical error has occurred.
 - 8.13.3.4.2. Inspect the returned blood bag(s) for any abnormalities.
 - 8.13.3.4.3. Inspect the recipient's post-transfusion serum or plasma for evidence of haemolysis.
 - 8.13.3.4.4. Perform an ABO and Rh D group on the recipient's pre- and post- transfusion samples as well as on the donor pack(s).
 - 8.13.3.4.5. Repeat the cross-match using both pre- and post-transfusion recipient serum versus donor cells. Both the actual unit and the original pilot sample collected at the time of donation should be used.
 - 8.13.3.4.6. Perform a direct antiglobulin test on the pre- and post-transfusion samples from the recipient.
 - 8.13.3.4.7. Screen recipient pre- and post-transfusion serum for atypical antibodies
 - 8.13.3.4.8. Culture remnant of donor blood to exclude infection as a cause of haemolysis.
 - 8.13.3.4.9. Assess the post transfusion urine from the recipient for Haemoglobin, Urobilinogen and bilirubin.

- 8.13.3.4.10. A report of investigations and significant findings shall be forwarded to the attending physician for recording in the recipient's file and to the blood transfusion committee.

8.13.4. Recipient Notification

- 8.13.4.1. The BE shall implement procedures to identify recipients of blood products from donors who at subsequent donations are found to have transfusion transmissible infections and, as far as possible, to have the recipients informed of the risk of infection.
- 8.13.4.2. If such a blood component has been supplied to the fractionation unit, the fractionation unit shall be informed accordingly.

8.14. Blood Transfusion Committee

- 8.14.1. A forum shall be established at different levels of the Service, other than at the national, to bring together providers, users of blood and management.
- 8.14.2. Such bodies shall be called Zonal, State, Local and/or Hospital Transfusion Committees
- 8.14.3. The functions of the Transfusion Committee in their particular areas of jurisdiction shall include, but not be limited to the following:
- 8.14.3.1. Advising on strategies to promote availability and adequacy of blood supply.
- 8.14.3.2. Advocacy and monitoring on appropriate use of blood and blood products.
- 8.14.3.3. Developing local maximum blood ordering schedules for planned surgery.
- 8.14.3.4. Receiving reports of adverse blood transfusion events and steps taken to minimize effects and advising on future prevention.
- 8.14.3.5. Promoting continuing education in transfusion practice for hospital staff
- 8.14.3.6. Working with local communities in advocating, mobilizing, and recruiting for voluntary non-remunerated blood donation.

SECTION 9: AUTOLOGOUS AND DESIGNATED BLOOD DONATIONS

9.1. Autologous Blood Donation Service

- 9.1.1. The BE may set up an autologous blood donation service for the purpose of re-infusion of blood and blood components back to the donor, during or after surgery.
- 9.1.2. An autologous blood donation service referred to above shall comply with these guidelines and adhere to Good Laboratory Practices and Good Manufacturing Practices.

9.2. Pre-operative Autologous Blood Donation

- 9.2.1. Pre-operative autologous blood donation requires the written consent of the patient's physician and the BE's medical practitioner
- 9.2.2. Informed written consent for the autologous donation shall be obtained from the patient.
- 9.2.3. Blood collected shall be used solely for the purpose of autologous transfusion except at the discretion of the medical practitioner.

9.3. Criteria for Donation of Autologous Blood

- 9.3.1. Because of the special circumstances regarding autologous blood transfusion, rigid criteria for donor selection are not required.
- 9.3.2. Suitable guidelines for autologous donation of blood shall be documented by the BE.
- 9.3.3. The following minimum standards regarding the donation of blood shall be met by the BE:
 - 9.3.3.1. The volume of blood collected at any one procedure shall not be more than 495ml
 - 9.3.3.2. The haemoglobin concentration of the patient's blood shall not be less than 11 g/dL , or a haematocrit value of 33% unless specifically prescribed by the medical practitioner
 - 9.3.3.3. Pre-operative donation shall not be undertaken when the patient has, or is being treated for bacteraemia, viraemia.

9.4. Testing of Autologous Donations

- 9.4.1. Autologous donations undergo the same mandatory testing as for blood donors as laid out in these guidelines.
- 9.4.2. The recipient's physician shall be informed of any abnormal test results with informed consent from the donor.

9.5. Autologous Labelling Requirements

- 9.5.1. In addition to the labelling requirements outlined in 5.10 and 5.11 for allogeneic blood units, the following information shall appear on a label attached, by the BE to the blood bag: **AUTOLOGOUS DONOR.**
- 9.5.2. In addition to the labelling requirement outlined in 5.10.and 5.11 for allogeneic blood units, if it is unsuitable for allogeneic use (on other conditions aside TTIs), the following information shall appear on a label attached, by the BE, to the blood bag: **FOR AUTOLOGOUS USE ONLY.**
- 9.5.3. A biohazard label shall be applied to each unit by the BE if any of the tests are reactive for any Transfusion Transmissible Infection.

9.6. Pre-transfusion Testing

- 9.6.1. Pre-transfusion testing shall include obtaining a blood sample from the recipient and confirming that the ABO group and Rh D type match the donated units before issue in accordance with the provisions of 8.7 of these Guidelines.

9.7. Peri-operative Blood Donation

- 9.7.1. Blood may be collected from the recipient immediately pre-operatively or collected intra-operatively. The following standards shall be adhered to:
- 9.7.1.1. Blood collected peri-operatively shall not be transfused to another recipient.
 - 9.7.1.2. Methods for peri-operative blood donation and re-infusion shall be safe, aseptic and ensure accurate identification of all blood and blood components collected.
 - 9.7.1.3. Equipment used for peri-operative blood collection and re-infusion shall be pyrogen-free, shall include a filter capable of retaining particles potentially harmful to the recipient and shall preclude air-embolism.
 - 9.7.1.4. A comprehensive SOP of all peri-operative collection procedures shall be maintained.
 - 9.7.1.5. Units collected as above may be stored at room temperature for up to 8 hours or at 2-8°C for up to 24 hours prior to transfusion.
 - 9.7.1.6. The storage criteria referred to in 9.7.1.5 also apply to units collected and processed under sterile conditions with a device for intra-operative blood collection that washes with 0.9% saline solution.
 - 9.7.1.7. Transfusion of blood collected intra-operatively by other means shall be given within eight hours of initiating the collection.

SECTION 10: HAEMOPOIETIC PROGENITOR STEM CELLS

10.1. Procedures

- 10.1.1. Before processing there should be a written request from the transplant physician. This is not required for unrelated cord blood collections.
- 10.1.2. Processing should be performed according to written procedures and policies. All procedures must be validated prior to implementation. Aseptic techniques must be employed. Any deviation from such written procedures shall be documented and reviewed.
- 10.1.3. Documented process simulation must be routinely undertaken to demonstrate that all processes and facilities are fit for purpose and staff are competent to perform the procedure.
- 10.1.4. Before material is accepted from a third party, including receipt from abroad, the laboratory accepting the donation should, wherever possible, ensure that standards equivalent to those in National/ International guidelines have been met. Material should be inspected upon receipt and the condition of the product recorded.
- 10.1.5. Where appropriate the HPC donation should be passed through a sterile non-reactive aggregate filter to remove fat, clots or bone spicules that may be present. A closed system must be used.
- 10.1.6. Processing and transplant facilities must agree and validate the adequacy of dose (total nucleated cells, mononuclear cells, CD34 positive cells and/or CFU-GM (colony-forming unit – granulocyte /macrophage) as appropriate for each source of HPC) required to achieve reliable and sustainable engraftment. Tests for cell dose and viability should be performed.

10.2. Testing of haemopoietic progenitor cell donors and components including therapeutic cells

- 10.2.1. Infectious disease marker testing: This must be done in accordance with International and National Directives on Tissues and Cells. The minimum current requirements include testing for HIV, HTLV I/II, HBV, HCV and syphilis. Additional testing may be required in some cases, e.g. for malaria and toxoplasmosis. The table below indicates the requirements for the timing of testing for each type of HPC

Requirements for the timing of testing

Test	Allo HPC- A/ HPC-M/TC	Auto HPC-A/ HPC-M	HPC-C donor mother	HPC-C
ABO + RhD	Test at each donation	Test at first donation		Day 0 to Day +7
Anti- HIV ½ antibody	Day -30 to Day 0	Day -30- to Day 0	Day -7 to Day +7	Prior to release
Anti-HCV antibody	Day -30 to Day 0	Day -30 to Day 0	Day -7 to Day +7	Prior to release
Anti-HTLV I/II/(pooled) antibody	Day -30 to Day 0	Day -30 to Day 0	Day -7 to Day +7	Prior to release
HCV RNA (pooled)	Day -30 to Day 0	Day -30 to Day 0	Day -7 to Day +7	Prior to release
HBsAg	Day -30 to Day 0	Day -30 to Day 0	Day -7 to Day +7	Prior to release
Anti-HBc antibody	Day -30 to Day 0	Day -30 to Day 0	Day -7 to Day +7	Prior to release
CMV	Day -30 to Day 0	Day -30 to Day 0	Day -7 to Day +7	Prior to release
Pregnancy test	-7 Days preconditioning			
Malaria	Where clinical	Where clinical	Were clinical	

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	indication	indication	indication. All mothers were at risk	
Haemoglobinopathy, i.e sickle cell	Where clinical indication	Where clinical indication		Prior to release
Syphilis screen*	Day -30 to Day 0	Day -30 to Day 0	Day -7 to Day +7	On final product
Bacteriology testing	If manipulation	If manipulation		
FBC	Before each apheresis procedure	Before each apheresis procedure		Pre and post process
*Confirmatory tests should be performed if screen positive				

10.2.2. Additional tests must be undertaken for quarantined HPC-C products where a Day 180 repeat test has not been performed on the mother. The following tests should be performed on the mother's initial sample to permit release:

- 10.2.2.1. HIV PCR pooled/single
- 10.2.2.2. HCV PCR pooled/single
- 10.2.2.3. HBV PCR single

10.2.3. Mechanisms should be in place to ensure that archived material/samples can be re-tested at the time of issue of donation for all current markers of infection including the latest generation of assays.

10.2.4. Testing of haemopoietic progenitor cell donors and components including therapeutic cells

10.2.5. HLA typing. At initial registration: HLA-A, -B, -DR type by a Clinical Pathology Accreditation (CPA) and National and Internationally accredited laboratory. As a minimum these antigens should be defined at low/medium resolution level using DNA techniques.

10.2.6. Confirmatory typing: Must be performed on a sample drawn independently of that used for initial registration. HLA-A, -B, -C, -DRB3, -DRB4, -DRB5 and -DQB1 types should be defined, at a minimum, to medium resolution using DNA techniques. HLA-DRB1 should be defined to the allele level by DNA techniques. High/allele resolution typing for HLA-A, -B, -C, -DRB3, -DRB4, -DRB5, -DQB1 and -DPB1 can also be performed as required by the transplant protocol.

10.2.7. For cord blood donations it is recommended that a maternal sample is HLA typed to confirm identity. High resolution typing of cord blood units shall take place when requested by a transplant centre. In cord blood banking, prior to the release of a cord blood unit for transplantation a sample obtained from a contiguous segment of the cryopreserved cord blood unit must be tested to verify HLA type or short tandem repeat (STR) can be performed according to applicable Standards.

10.2.8. ABO and RhD typing: For allogeneic donors of HPC-A and HPC-M, ABO and RhD typing must be performed on samples taken from the donor or cell therapy component at the time of each collection. For autologous donors of HPC-A and HPC-M, ABO and RhD typing must be performed on samples taken from the donor or cell therapy component at the time of first collection. For HPC-C the ABO and RhD type of each donation shall be determined.

10.2.9. Clonogenic assays: Clonogenic assays (e.g. CFU-GM) may be undertaken as part of a quality programme or when specifically indicated or requested by the transplant physician. Consideration should be given to performing surrogate tests for viability prior to conditioning on a representative archive sample of any cryopreserved HPC components. For cord blood

units CD34+ cells should be enumerated according to applicable National and International Standards and progenitor cell assays should be assessed on a thawed sample before release of the unit for transplant.

- 10.2.10. Sterility: Bacteriological and fungal screening employing aerobic and anaerobic conditions must be performed on the final HPC component after processing and before cryopreservation, unless validation studies demonstrate that bacteriological screening of waste processing material, such as plasma or erythrocytes, are equivalent to screening of the final product. All positive cultures should be subsequently identified, and antibiotic sensitivities performed if the material is to be put to clinical use.
- 10.2.11. Test samples: Archival samples must be stored for reference and any future testing that may be required as described in the National and International Directives on Tissues and Cells, Applicable Standards. Documentation must be kept to ensure security and accurate retrieval of the stored samples when required. Storage conditions must: maintain cell viability (below -150°C) be suitable to obtain material for the preparation of 50 mg DNA.

10.3. Storage of cellular therapy products

- 10.3.1. Policies must be put in place by the facility for the storage of all materials whether or not destined for cryopreservation, e.g. HPC-M undergoing red cell depletion and for other HPCs prior to cryopreservation. Details should be specified for all types of storage conditions. These should cover: labelling, primary and secondary containers, storage temperature and duration, and cell concentration. It is recommended that donations with a nucleated cell concentration above $200 \times 10^9 /\text{L}$ are diluted to less than $200 \times 10^9 /\text{L}$, preferably with autologous plasma. HPC-A donations must be placed at $4 \pm 2^{\circ}\text{C}$ if they are for liquid storage and/or are not being processed immediately. It is recommended that the final concentration after addition of the cryoprotectant is less than $100 \times 10^9 /\text{L}$ transport if appropriate. Where donations of known virology or bacteriology positive materials are stored, appropriate risk Assessments and mitigation ensuring adequate controls must be in place.

10.4. Duration

- 10.4.1. Facilities storing HPC components shall establish policies for the duration and conditions of storage and indications for discard. Patients, donors, and associated transplant centres should be informed about these policies and consent obtained where appropriate.

10.5. Alarm systems

- 10.5.1. Storage devices shall have alarm systems that are continuously active.
- 10.5.2. Alarm systems shall have audible signals.
- 10.5.3. If laboratory personnel are not always present in the immediate area of the storage device, a remote alarm device shall be required at a location staffed 24 hours a day. Alternatively, an auto-dial facility connecting to an on-call member of staff may be satisfactory.
- 10.5.4. Alarms shall be set to activate at temperatures, or an unsafe level of liquid nitrogen, to allow time to salvage components.
- 10.5.5. There shall be a written procedure to be followed if the storage device fails. A procedure for notifying laboratory personnel shall be in place.
- 10.5.6. Alarm systems shall be checked periodically for function.
- 10.5.7. Additional storage devices of appropriate temperature shall be available for component storage if the primary storage device fails.

10.6. Inventory control:

- 10.6.1. There shall be an inventory control system to enable component and quality control vials to be located.
- 10.6.2. It should include the donor's name or unique identifier, date of collection, type of storage device and location within it, and state the number of containers and vials and number issued, dates of issue and numbers of containers and vials remaining.

10.7. Cryopreservation:

- 10.7.1. Archive samples Aliquots of the HPC component, processed and stored under the same conditions as the HPC component, must be available for additional testing as necessary.
- 10.7.2. Methods should be validated, taking into account critical pre-freeze variables such as temperature, duration of storage, cell density and type of cryoprotectant.
- 10.7.3. A secondary container, 'double bagging', must always be used to prevent cross-contamination between donations and to effectively quarantine the unit.
- 10.7.4. The containers must be clearly and unambiguously labelled using labels that have been validated for use under the required storage conditions.
- 10.7.5. The data on the labels must be in accordance with applicable Standards.
- 10.7.6. Cryopreservation of the HPC product must be with an established cryoprotectant (e.g. 10% DMSO), used in a validated procedure with defined times and temperatures of exposure to specified concentrations.
- 10.7.7. Established conditions of time and temperature of exposure of the HPC component to the cryoprotectant must be observed. These must be specific to the cryoprotectant system used.
- 10.7.8. Validated storage conditions for the cryoprotectant must be observed.
- 10.7.9. Frozen HPCs should be stored at a sufficiently low temperature to ensure recovery of living cells after the intended preservation period.
- 10.7.10. HPC donations are generally stored for named patients in low volumes using containers with a high surface area. To minimise the risk of transient warming events that may reduce viability and to maximise the time available to salvage donations should a storage device fail a temperature below -150°C should be used.
- 10.7.11. It is recommended that the vapour phase of liquid nitrogen is used to reduce the risk of cross contamination. It is recognised, however, that this is associated with a greater temperature fluctuation and measures should be taken to ensure that the paragraph above applies.

11.1. Storage of cellular therapy products

- 11.1.1. Partial immersion in liquid phase to store HPC donations. Whatever method of storage is used it must always be assumed that liquid nitrogen is microbially contaminated and secondary enclosure must be employed.
- 11.1.2. For vapour phase the storage vessels should be fitted with a minimum of two temperature probes that are linked to a remote central monitoring system manned continuously. For liquid phase storage the vessel should be fitted with a minimum of a single probe. Records must be kept of these temperatures.
- 11.1.3. If liquid nitrogen refrigeration is used an automatic filling mechanism or a standardised manual procedure must be provided to ensure and document that adequate levels of liquid nitrogen are maintained

- 11.1.4. The NBSC/BEs shall maintain detailed SOPs for the selection of donors and the collection, processing, cryopreservation, and quality control systems used in the preparation of haemopoietic progenitor cells. The SOPs shall be in line with accepted international/National standards and practices.

11.2. Complaints

- 11.2.1. The NBSC/BEs shall have a procedure for recording, reviewing and investigating relevant complaints.

11.3. Non-Compliance with the Guidelines

- 11.3.1. All established/known cases of non-compliance with the provisions of these Guidelines and all violators thereof in any respect whatsoever shall be reported /referred to the appropriate authorities by relevant officers for necessary action and be dealt with by relevant professional bodies under existing rules and regulations, laws, and statutes.
- 11.3.2. The victim (or victim's family) may report such violators or non-compliant operators to the appropriate authorities to be considered, investigated, and dealt with as stated in paragraph 11.3 above.



SAFE BLOOD SAVES LIVES!!!

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