NBTC
राष्ट्रीय रक्त संचरण परिषद
National Blood Transfusion Council

सत्यमेव जयते
Ministry of Health & Family Welfare
Government of India

NATIONAL STANDARDS FOR BLOOD CENTRES & BLOOD TRANSFUSION SERVICES

(2nd Edition)

Second Edition-2022

Technical Support by

World Health Organization India Country Office

Directorate General of Health Services
National AIDS Control Organization
Ministry of Health & Family Welfare, Government of India

NATIONAL STANDARDS FOR BLOOD CENTRES

&

BLOOD TRANSFUSION SERVICES

(2nd Edition)

डॉ. मनसुख मांडविया
DR. MANSUKH MANDAVIYA

सत्यमेव जयते

स्वास्थ्य एवं परिवार कल्याण
व रसायन एवं उर्वरक मंत्री
भारत सरकार
Minister for Health & Family Welfare
and Chemicals & Fertilizers
Government of India

आज़ादी का अमृत महोत्सव

MESSAGE

Blood Transfusion Services is a vital part of the Health Care delivery system in any Country. Transfusion of blood and components is a lifesaving procedure for patients during emergency and non emergency situations especially for children suffering from Blood disorders like Thallasaemia, Sickle cell anemia etc. There are significant developments in the field of Blood Transfusion in last few decades and now this specialty has been renamed as Transfusion Medicine.

For quality, safety and efficacy of blood and blood products, well equipped Blood Centres with adequate infrastructure and trained manpower is an essential requirement. To achieve these objectives, it is essential to have appropriate updated standards for the Blood Centres.

I am happy to note that the first standards for Blood Transfusion Services were brought out long back in 2007 which are nearly one and a half decade old now. Since the world is changing very fast, there is a need to keep pace with the changing technologies globally.

I would like to appreciate the initiative of National AIDS Control Organization (NACO) to give adequate priority to this issue and constituting a Technical Committee for updating these standards. I also commend the efforts of Directorate General of Health Services for taking forward the initiative shown by NACO and ensuring that these standards see the light of the day.

I also commend the efforts of all the committee members for giving their valuable inputs and efforts for bringing out the Second edition of the standards in a time bound manner. I have been given to understand that all the technical developments in this field as well as changes in regulatory aspects of transfusion medicine have been adequately incorporated in this document.

I wish that this document is made available to all the Blood Centres right up to the remotest corner of the country so as to make safe and adequate blood available for the masses.

(Dr. Mansukh Mandaviya)

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Dr. Bharati Pravin Pawar

सत्यमेव जयते

सर्वेसन्तु निरामया

स्वच्छ भारत
एक कदम स्वच्छता की ओर

स्वास्थ्य एवं परिवार कल्याण राज्य मंत्री
भारत सरकार
MINISTER OF STATE FOR
HEALTH & FAMILY WELFARE
GOVERNMENT OF INDIA

Message

A well organised Blood transfusion service (BTS) with quality systems in all areas is a prerequisite for safe and effective use of Blood and Blood products. This is a vital component of any healthcare delivery system. An integrated strategy of Blood safety is required for elimination of Transfusion Transmitted Infections (TTI) and for provision of safe and adequate blood supply to the community.

There have been a number of initiatives for improving the blood transfusion services in the country including bringing out the first edition of Standards for Blood Centers and Blood Transfusion Services in the year 2007 which have been extensively used as a guiding document to establish uniform practices across various blood banks and improve the availability, accessibility, safety & quality of blood and blood products in the country.

It is pertinent to emphasize that the Government of India, under the able guidance of Hon'ble Prime Minister Shri Narendra Modi, is taking new initiatives to meet all the health needs of the people of India and therefore, with the advent of these new technologies- With emerging and re-emerging pathogens and regulatory changes in blood services, a need was felt to revisit these standards.

I would appreciate the efforts of **National AIDS Control Organization (NACO)** for bestowing due priority to this issue and constitute an expert committee for revising these standards. I also place on record my appreciation to DGHS for taking this initiative forward and bring it to conclusion. I also commend the efforts of all the technical committee members who contributed their valuable inputs and efforts in bringing out the revised standards in a timely manner.

I hope these standards are widely disseminated and made available to all the stakeholders right up to the last corner of the country so that these can be appropriately applied in making available safe and adequate blood for the community

Dr. Bharti Pravin Pawar

"दो गज की दूरी, मास्क है जरूरी"

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सचिव
RAJESH BHUSHAN, IAS
SECRETARY

सत्यमेव जयते

Azadi Ka Amrit Mahotsav

भारत सरकार
स्वास्थ्य एवं परिवार कल्याण विभाग
स्वास्थ्य एवं परिवार कल्याण मंत्रालय
Government of India
Department of Health and Family Welfare
Ministry of Health and Family Welfare

MESSAGE

Blood Transfusion Services is a very important component of Health Care delivery system in any country. Transfusion of blood and its components is a lifesaving panacea for patients during emergency situations e.g. road accidents and for transfusion dependent patients suffering from diseases like Thalassemia, Sickle cell anemia and others. There are significant developments in the field of blood transfusion in last few decades and now this specialty has been renamed as Transfusion Medicine.

In order to make available safe blood for the community, well equipped Blood Centres with proper infrastructure and manpower are extremely crucial and to achieve this, it is important to have appropriate benchmarks/standards to be followed

The National Standard for Blood Centres were first published in the year 2007 by National AIDS control Organization(NACO) which was managing the Blood transfusion services till recently. However, there have been many new technical developments and regulatory changes in this area since the last publication. I commend the efforts of NACO to initiate the process of revising these standards through a technical committee and also congratulate Directorate General of Health services in taking this initiative forward. The second revised edition of National Standards has been skillfully prepared incorporating latest technical and regulatory developments.

I would like to acknowledge the sincere contributions made by Expert Members of the Technical Committee, who have contributed in developing the revised standards in a timely manner. These revised National Standards will act as the main driver for continuous improvement in quality and serve as the bench mark for assessing the functional status of Blood Centres in our country.

It should be the collective endeavor of all to ensure that all Blood Centres in the country get access to these standards in order to upgrade their services for ensuring safe and adequate blood for the general population.

(Rajesh Bhushan)

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स्वास्थ्य सेवा महानिदेशक
DIRECTOR GENERAL OF HEALTH SERVICES

सत्यमेव जयते

भारत सरकार
स्वास्थ्य एवं परिवार कल्याण मंत्रालय
स्वास्थ्य सेवा महानिदेशालय
Government of India
Ministry of Health & Family Welfare
Directorate General of Health Services

MESSAGE

A well organised Blood Transfusion Services (BTS) with quality assurance is an indispensable component of any healthcare delivery system. Blood Safety is integral to elimination of Transfusion Transmitted Infections (TTI) and of safe and optimal blood supply to community, as and when required.In order to ensure the safety of blood supply as discussed, blood centres need to be appropriately equipped and staffed besides ensuring standard operating procedures as per guidelines.

National AIDS Control Organization (NACO) initiated this with the first edition of Standards for Blood Centres in the year 2007, which have been extensively used as a guiding document for uniform practice across various blood banks in the country, thereby improving the availability, accessibility, safety & quality of blood and blood products. Thereafter, an initiative for revision of these practice guidelines was started a few years back through a committee of experts who gave valuable inputs for the 2nd edition of these standards.

This second edition of standards for Blood Centres and Blood Transfusion Services will further the cause of improvement of blood and blood products. The scope of these standards includes all aspects of transfusion medicine with special emphasis on Good Laboratory Practices, Quality Management Systems, Updated Regulatory Requirements and Hemovigilance. Blood centres can adopt and implement them to achieve optimal blood and blood product safety for patients in need.

I would like to express my gratitude to National Blood Transfusion Council (NBTC) under NACO for initiating this process of review and revision of the first edition. A special token of appreciation to all members of the Technical Committee for their invaluable inputs and suggestions during this effort.

I hope that the second edition of NBTC standards would be of immense help in improving and standardizing blood transfusion practices and services across the country and help the personnel in this field abreast of advances in the field of transfusion medicine. I'm sure Blood Transfusion Division under Directorate General of Health Services will ensure timely revision of these guidelines in future as well.

(Atul Goel)

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MESSAGE

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There have been a number of initiatives for improving the Blood Transfusion Services in the Country including bringing out the first edition of Standards for Blood Centers and Blood Transfusion Services in the year 2007, which have been extensively used as a guiding document to establish uniform practices across various Blood Centers and improve the availability, accessibility, safety & quality of blood and blood products in the Country.

It is pertinent to emphasize that the Government of India, under the able guidance of Hon'ble Prime Minister Shri Narendra Modi, is taking new initiatives to meet all the health needs of the people of India and therefore, with the advent of these new technologies, emerging & re-emerging pathogens and regulatory changes in blood services, a need was felt to revisit these standards.

I would appreciate the efforts of National AIDS Control Organization (NACO) for bestowing due priority to this issue and constitute an expert committee for revising these standards. I also place on record my appreciation to DGHS for taking this initiative forward and bring it to conclusion. I also commend the efforts of all the technical committee members who contributed their valuable inputs and efforts in bringing out the revised standards in a timely manner.

I hope these standards are widely disseminated and made available to all the stakeholders right up to the last corner of the Country so that these can be appropriately applied in making available safe and adequate blood for the community.

Anil Kumar

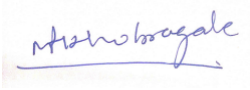
(Dr. Anil Kumar)

Acknowledgements

Blood transfusion services (BTS) in India is one of the major elements in health care delivery system. It is a lifesaving intervention and therefore, blood and blood components must be safe and of consistent quality for clinical effectiveness. The national blood policy and framework aims to ensure the implementation of standards in the quality and safety of blood and blood products. The National Standards for Blood Centres and BTS in India were first published in 2007 and have been the main technical guidance for Indian Blood Centres and BTS. Many changes have taken place since the first edition of Standards was published. Thereupon, the National Blood Transfusion Council (NBTC) entrusted the responsibility to a committee to 'review and revise' the Standards. The Technical Committee put in efforts to include all the recent developments, regulatory changes and existing elements of the quality management systems at the time of publication. We express gratitude to the President and members of NBTC for reposing trust in the Technical Committee for this assignment of National interest. Over the time, BTS has been transferred under the office of the Director General of Health Services.

We are grateful to the Director General of Health Services for his Chairmanship for completion of the project. We thankfully acknowledge contribution of Team NBTC which started the initial process of formation of the Technical Committee (TC), guided the TC for successful completion of the Standards for the last few years and ultimately reached the stage of publication. Guidance and hand holdings during the preparation of these Standards from the President, NBTC; Chairperson, NBTC and other NBTC committee members were of immense value. Special contributions from NBTC team led by Dr. Sunil Gupta with Dr. Shobini Rajan, Dr. Sai Bhavsar, Dr. Srinivas Murthy have been highly acknowledged. We are grateful to all of them without which this document may not have seen the light of the day. After the transition of BTS to the office of the DGHS, there is a great contribution of Dr. Anil Kumar, Additional Deputy Director General and BTS Team in finalization of the final print version. We appreciate the contribution of Dr. Rajiv Garg, Professor of Excellence, DGHS in finalizing the print ready version of the Standards. We would like to express our heartfelt thanks to the members of WHO India Team, Dr Hilde De Graeve, Dr Madhur Gupta, Dr Vimlesh Purohit, Dr Alexandra Vokaty, Dr Sonali Rawal and Dr Smriti Chawla.

Last but not the least, we are highly grateful to the members of the Technical Committee who have worked tirelessly on the Standards. Now, it is the time to implement these National Standards in every Blood Centre and strengthen the Blood Transfusion Services in India to improve quality parameters to make blood transfusion, a safe procedure.



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9. Dr. Sangeeta Pathak, New Delhi
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Contents

Terms and definitions

Accuracy of measurement: Closeness of the agreement between the result of a measurement and a true value of the measure.

Apheresis: The process by which blood is drawn from a donor, after separating desired plasma or cellular component is returned simultaneously to the same donor.

ART: Anti retroviral therapy

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

Blood: Includes whole human blood, drawn from a donor and mixed with an anti-coagulant.

In-Charge Blood Centre / **Blood Centre Director:** Competent person (s) with responsibility for, and authority over, a Blood Centre.

Blood Centre Management: Person (s) manages the activity of a Blood Centre headed by a Blood Centre In-Charge/ Director.

Blood Component: A drug prepared, obtained, derived or separated from a unit of blood drawn from a donor.

Blood Product: A drug manufactured or obtained from pooled plasma of blood drawn from donors by fractionation.

Closed system: A system, the contents of which are not exposed to air or outside elements during preparation and separation of components.

CDSCO: Central Drugs Standard Control Organization

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

Corrective Action: An activity performed to eliminate the cause of an existing non-conformance or other undesirable situation to prevent a recurrence.

COVID–19: Coronavirus disease 2019 (Covid-19) is an illness caused by a novel coronavirus now called severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2). On March 11th 2020, WHO declared Covid - 19 as a global pandemic.

DGHS: Director General of Health Services, Government of India

Disaster: An event (internal, local, or national) can affect the blood supply or the safety of staff, patient/recipients, volunteers, and donors.

Document (noun): Written or electronically generated information and work instructions. Examples of documents include quality manuals, procedures or forms.

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

E-Raktakosh: E-Raktkosh is an initiative to connect, digitize and streamline the workflow of blood banks across the nation/ India for Blood Centres from all sectors.

Erythrocytapheresis: Erythrocytapheresis is a collection of RBCs by automated apheresis. This procedure allows the collection of two units of red cells.

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

Graft - Versus – Host Disease (GvHD): Transfusion-associated GvHD is a complication of blood component therapy or bone marrow transplantation. GvHD disease occurs if donor–functional lymphocytes engraft and multiply in a severely immunodeficient recipient. These engrafted donor cells react against the foreign tissue of the host (recipient).

Haemovigilance: Haemovigilance is a set of surveillance procedures covering the whole transfusion chain from the collection of blood and its components to the follow-up of its recipients intended to collect and assess information on unexpected or undesirable effects resulting from the therapeutic use of labile blood products and to prevent their occurrence and recurrence. It is an important tool for improving safe blood transfusion practices in a country.

Incident: An unplanned deviation from a facility's established policy, process or procedure.

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

Labelling: Information required or selected to accompany a unit of blood, component, tissue, derivative or sample, which may include content, identification, description of the process, storage requirements, expiration date, cautionary statements or indications for use.

Laboratory: Laboratory for the biological, microbiological, immunological, serological, immunohaematological, haematological, or other examination of materials derived from the human body to provide information for the diagnosis, prevention, pre-transfusion check and treatment of disease in, or assessment of the health of, human beings, and which may provide a consultant advisory service covering all aspects of laboratory investigation including the interpretation of results and advice on further appropriate investigation.

Measurement: Set of operation having the object of determining a value or a quantity.

Non-conformance: Failure to meet the requirement.

Nucleic Acid Amplification Testing (NAT): Nucleic acid testing (NAT) is a molecular technique for screening donated blood to reduce the risk of transfusion-transmitted infections in the recipients, thus providing an additional layer of blood safety. NAT is highly sensitive and specific for viral nucleic acids, narrows the window period of HIV, HBV and HCV infections. It is an optional test.

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

Organization: An Institution, or part thereof that has its functions and executive management.

PLHA: Patients living with HIV/ AIDS

Policy: A documented general principle that guides present and future decisions.

Preventive action: An action taken to reduce the potential for non-conformance or other undesirable situations.

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

Process: A set of related tasks and activities that accomplish a work goal by transforming inputs into outputs.

Process control: The efforts to standardize and control processes to produce predictable output, meet standards, and minimise variation.

Product: A tangible result of a process or procedure.

Professional donor: A person who donates blood for a valuable consideration, in cash or kind, from any source, on behalf of the recipient-patient / recipient and includes a 'blood seller' or 'paid donor' or a 'commercial donor'.

Proficiency testing: The structured evaluation of laboratory methods assesses the suitability of processes, procedures, equipment, materials and personnel.

Quality: Characteristics of a unit of blood, component, tissue, derivative, sample, critical material, or service that bear on its ability to meet requirements, including those defined during agreement review.

Quality Management System: The organisational structure, processes, or procedures necessary to ensure that overall outcome and direction of an organisation's quality programme is met and the quality of the product or service is ensured. This includes strategic planning, resource allocation, and other systemic activities such as quality planning, implementation and constant evaluation.

Quality Assurance: Activities involving quality planning, control, assessment, reporting and improvements necessary to monitor progress towards changing quality standards and requirements.

Quality indicators: Measurable aspects of process outcomes that indicate condition or direction of performance over a while and progress towards stated quality goals or objectives.

Qualification: Demonstration that an entity is capable of fulfilling specified requirements and verification of attributes that must be met or complied with so that a person or a thing is considered fit for performing a particular function.

Quality Control: Testing performer routinely on materials and equipment, product and services to ensure their proper function.

Quarantine: To isolate untested / inconclusive or results pending confirmation including blood, components, tissues, derivatives or materials to prevent their distribution or use.

Reference standards: Reference standards define how or within what parameters an activity shall be performed and are most detailed than management system requirements.

Replacement donor: A donor who is a family friend or relative of the patient / recipient.

Sample: One or more parts taken from a system and intended to provide information on the system, often to serve as a basis for a decision on the system or its production.

Traceability: Property of the result of a measurement or the volume of a standard whereby it can be related to stated references, usually national or international standards, through an unbroken chain of comparisons, all having stated uncertainties.

Transfusion Service: A facility that performs one or more of the following activities: compatibility testing, storage, selection and issuing of blood and components to intended recipients. Transfusion services do not necessarily collect blood or process whole blood into components.

True Positive: A positive result on both the initial test and the confirmatory test.

The trueness of measurement: Closeness of agreement between the average values obtained from an extensive series of measurements and a true value.

Uncertainty of measurement: Parameter associated with the result of a measurement that characterised the dispersion of the values that could reasonably be attributed to the measurement.

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

Validation: Establishing recorded evidence that provides a high degree of assurance that a specific process will consistently produce an outcome, meetings its predetermined specifications and quality attributes.

Verification: Confirmation by examination and provision of objective evidence that specified requirements that have been met.

Voluntary (Non-remunerated) blood donor: A person who voluntarily donates blood after he/she has been declared fit after a medical examination, for donating blood, on fulfilling the criteria given hereinafter, without accepting in return any consideration in cash or kind from any source, but does not include a professional or a paid donor.

Chapter-1:
Introduction

1.1 GENERAL:

1.1.1 Blood Centres and Transfusion Services should accept blood from only voluntary non-remunerated safe blood donors and do away with the high-risk donors and professional blood donors. In addition, they should gradually phase out replacement blood donors. Professional blood donors have been banned as per the Honorary Supreme Court of India directive.

1.1.2 The Blood Centre shall provide appropriate preventive clothing to all personnel working in different areas, including clean overall, head gears, foot wears, gloves etc., wherever applicable.

1.1.3 The Blood Centre shall provide adequate regular health check-up and protection for health, including vaccination.

1.1.4 There shall be adequate provision for hand washing/ hand hygiene, protective equipment/ clothing and toilet facility for employees.

1.1.5 The Blood Centre shall have a program of safe and acceptable housekeeping.

1.1.6 The Blood Centre shall practice proper disposal of general waste and biomedical waste as specified by competent authorities from time to time.

1.1.7 All materials for blood collection and transfusion shall be sterile, pyrogen-free and disposable and should be stored in an air-conditioned area.

1.1.8 All containers and anticoagulants used for storage, preservation of blood and blood components, and required reagents used to test blood samples shall meet the Standards of Drugs and Cosmetics Act and Rules and Bureau of Indian Standards (BIS).

1.2 LEGAL IDENTITY:

1.2.1 The Blood Centre or Blood Transfusion Service shall have its own legal identity with a constitution, which defines the responsibility and authority of the management. It should be affiliated with a compliant identity as per the legal system of the country.

1.2.2 The regulations and guidelines approved by the DGHS/National Blood Transfusion Council/CDSCO and subsequently modified by respective State.

1.3 QUALITY PARAMETERS:

1.3.1 All Blood Centres shall have their Quality Policy.

1.3.2 Blood Centres should prepare an organogram presenting reporting structure in the organization.

1.3.3 The Blood Centre is encouraged to define a quality system and to prepare a Quality Manual.

1.3.4. Blood Centres shall enrol in at least one External Quality Assessment Scheme (EQAS) program.

1.3.5 Every section responsible for various services will define its Quality Control (QC) program, including outsourcing services.

1.3.6 Each Blood Centre shall maintain a detailed standard operating procedure manual, as well as records in hard copies (forms, registers, labels) or in electronic format as prescribed by Drug & Cosmetics Rules.

1.3.7 There shall be adequate and competent staff as prescribed in Schedule F Part XII B & C of Drug and Cosmetic rules. The records of their qualifications, training and competency should be maintained.

1.3.8 The Blood Centre shall have a suitable space and environment for the operation as per the requirement of the Drugs and Cosmetics Rules.

1.3.9 All equipment required for the operation of the Blood Centre to deliver quality outcome shall be available on the premises in adequate quantities. Additional or advanced equipment may be added to obtain better safety for better quality on blood and components. All equipment should meet the minimum standard as specified by manufacturers to deliver quality components. The equipment maintainance should be taken up by the state health department for government Blood Centers under equipment maintanance programme, if possible. There shall be a regular program for equipment maintenance in all Blood Centres. The records of calibration, maintenance and validation of equipment shall be maintained as specified in Drugs and Cosmetics Rules.

1.3.10 The Blood Centre should develop a process to identify deviations, reporting and taking corrective actions.

1.3.11 The Blood Centre shall develop a process to control documents by maintaining and archiving all documents/ records as specified by the Drug and Cosmetics Rules.

1.3.12 The Blood Centre should be encouraged to carry out an internal audit at least once a year by its employees or by external personnel in a planned manner.

1.3.13 The Blood Centre personnel should follow all ethical codes prescribed by their respective professions. The management should follow all ethical practices mandated by applicable national and international guidelines.

Chapter-2:

Organization and Management

2.1 GENERAL:

2.1.1 The Blood Centre or Blood Transfusion Service shall have its constitution, which defines the responsibility and authority of the management.

2.1.2 The Blood Centre shall function under the direction of a licensed physician qualified by training and by experience as a Transfusion Medicine Specialist (Medical Officer, Blood Centre) who shall be responsible for all medical, technical and administrative services.

2.1.3 All Blood Centres shall be licensed by State Drugs Control (Licensing Authority) and approved by Drugs Controller General (India) and shall be regulated by Drugs and Cosmetics Act and rules there under. The Blood Centre shall have a valid license from Central Drugs Standard Control Organization (CDSCO) and approved by Drugs Controller General (India), central license approving authority under Drug and Cosmetic Rules-1945 with further amendments.

2.1.4 Blood Centre shall comply with laid-down standards in Drugs and Cosmetic Rules in recruitment and selection of blood donors, collection, processing, storage and distribution.

2.1.5 Applications for grant or renewal of license for operation of Blood Centre or processing of human blood components shall be made by the Blood Centre run by the Government, Indian Red Cross Society, Hospital, Charitable Trust or Voluntary organization. Blood Centre run by Charitable Trust or Voluntary organization needs to be approved by a State or Union territory Blood Transfusion Council as per procedure laid down by the National Blood Transfusion Council.

2.2 ORGANOGRAM:

2.2.1 There should be an authorised organogram showing a clear delineation of reporting structure and inter-relationships between operations, support services and quality functions. This organizational structure should be captured in writing or electronically.

2.2.2 The organogram should be reviewed at establishment defined intervals and updated as required.

2.3 QUALITY MANAGEMENT SYSTEM:

2.3.1 All Blood Centres should have their Quality Policy and Quality Manual that addresses the systems in use.

2.3.2 Every section responsible for various services will define its own Quality Control program, including outsourced services. Blood Centre shall participate in EQAS programmes, properly document it and take corrective action if necessary.

2.3.3 The in-charge of the Blood Centre shall be responsible for the design, implementation, maintenance and improvement of the quality management system.

2.3.4 The in-charge of Blood Centre or designated person from the management shall be authorized to issue, approve, delete and control the Quality Manual of the Blood Centre and related documents. Quality Manual shall include the scope of services, objective of quality management system with management commitment to comply with the standards and local regulations.

Quality Manual will describe all the aspects of the quality management system and the structure of the documentation used in the quality management system. Therefore, all personnel should be familiar with the quality management system with the use and application of the Quality Manual and all referenced documents. The Quality Manual should be kept updated under the authority of In-charge, Blood Centre.

2.3.5 Each Blood Centre shall maintain a Policy Document and a standard operating procedure manual and records (forms, registers, labels) in a prescribed format as mandated by the Drugs & Cosmetics Rules.

2.3.6 There shall be adequate and competent staff as prescribed in Schedule F Part XII B & C of Drugs and Cosmetic rules. The records of their qualifications, training and competency shall be maintained.

2.4 QUALITY ASSURANCE SYSTEM:

The Blood Centres shall establish and maintain a quality assurance system based on any current national or international standard that includes the following essentials.

- Organization and Management
- Resources
- Equipment
- Supply and customer issues
- Process control
- Documents and records
- Deviations, non-conformances and complications
- Assessments
- Process improvements
- Facilities and safety

2.5 FINANCIAL ACTIVITIES:

2.5.1 Accurate costing enables accurate planning and budgeting so that the Blood Centre runs efficiently without shortage of supply in the middle of the year. It also enables planning for future expansion, evaluates cost-effectively and helps in the mobilisation of resources.

2.5.2 There shall be an adequate budget allocated for all essential activities such as staff and all related costs, including training; reagents; kits; blood bags; general laboratory supplies; stationery and printing; equipment maintenance/replacement; capital assets, e.g., vehicles; building maintenance/expansion; utilities; electricity, telephone, water etc.; public relations and IEC materials.

2.5.3 Processing charges of a unit of blood shall be derived by dividing the total cost per year (capital and recurrent) by the number of units collected per year. The price of blood components shall be following the guidelines laid out by National Blood Transfusion Council and respective State Blood Transfusion Council (SBTC) and shall be revised as per the amendments from time to time.

2.5.4 The policy of charging a deposit against a replacement of blood to be made later shall be discontinued. All attempts should be made to collect blood/ components from voluntary non-remunerated donors. However, in the case of family members' donation, they should be motivated to retain as voluntary donor in the future.

2.5.5 The processing charges of the Blood Centre shall be displayed at a prominent place, and NBTC guidelines on processing charges shall be followed.

2.6 PREVENTION OF SEXUAL HARASSMENT (PoSH):

The Blood Centre shall have a policy and procedure to address sexual harassment at workplaces. Existing guidelines from national authorities shall be followed.

2.7 DISASTER MANAGEMENT:

The Blood Centre shall have a policy and procedure to counter manmade and natural disasters affecting the premises and services of the organization.

Chapter-3:
Accommodation

3.1 GENERAL:

3.1.1 The Blood Centre shall have minimum operational areas as recommended by the Drugs and Cosmetics Act and Rules and other statutory bodies. The minimum area mentioned below shall commensurate with the quantum of work in a Blood Centre. The minimum area prescribed by the Drugs and Cosmetic Act is 100 sq meter for whole blood donation and operation. There shall be a room each for:

3.1.1.1 Registration and medical examination with adequate furniture and facilities for registration, selection and waiting of donors

3.1.1.2 Donor counselling and motivation area with adequate privacy

3.1.1.3 Blood collection area (air-conditioned). This area may be used for any apheresis procedures (addition of minimum 10 square meters), including platelets, plasma and cellular components like granulocytes, leucocytes and other mono-nuclear cells.

3.1.1.4 Refreshment-cum-rest room (air conditioned)

3.1.1.5 Blood component preparation (additional 50 square meters area; air-conditioned and to maintain an ambient temperature between 20-25°C)

3.1.1.6 Laboratory for blood group serology (air-conditioned)

3.1.1.7 Laboratory for blood-transmissible diseases like hepatitis, syphilis, malaria, HIV-antibodies (air-conditioned)

3.1.1.8 Identified Quality Control area with component preparation area

3.1.1.9 Sterilization-cum-washing area

3.1.1.10 Store-cum-records area as well as an air-conditioned area for storage of blood bags and apheresis kits.

3.2 BLOOD DONATION DRIVES / CAMPS:

A blood donation camp is one of the key factors for achieving maximum voluntary blood donation in the country. Adequate publicity and IEC material shall be available.

3.2.1 As per the Drugs and Cosmetic Act, it shall be organised by-

a) A licensed designated Regional Blood Transfusion Centre
b) A licensed Government Blood Centre
c) An Indian Red Cross Society Blood Centre
d) A licensed Blood Centre run by registered voluntary or charitable organisations recognised by State or Union Territory Blood Transfusion Council
e) A hospital-based licensed Blood Centre

Note: Designated Regional Blood Transfusion Centre shall be the centre approved and designated by a State Blood Transfusion Council to collect, process and distribute blood and its components to cater for the needs of the region and licensed and approved by the State Licensing Authority and Central Licence Approving Authority for the purpose.

All blood centres approved by respective State Blood Transfusion Councils shall intimate within seven days the venue where blood camp was held and the details of group-wise blood units collected in the said camp to the Licensing Authority and the State Blood Transfusion Council.

3.2.2 For holding a blood donation camp, the following shall be complied with:

3.2.2.1 Premises

Premises for the blood donation camp shall have sufficient area, and the location shall be hygienic so as to allow proper operation, maintenance and cleaning. The area shall be cleaned before and after the blood collection.

3.2.2.2 Personnel

To collect blood from 50 to 70 donors in about 3 hours or from 100 to 120 donors in 5 hours, the following requirements shall be fulfilled:-

(i) One Medical officer and two nurses or phlebotomists for managing 6-8 donor couches

(ii) Two medical social workers or counsellors

(iii) Three Blood Bank technicians

(iv) Two attendants

All information regarding the personnel working at a camp shall be well documented and made available for inspection if required.

3.2.2.3 Equipment and consumables

Minimum equipment/consumables required (not limited to) as follows for blood donation camp should be carried by the team in sufficient numbers.

1. Blood pressure apparatus
2. Stethoscope
3. Thermometers / thermal scanner
4. Blood bags (single, double, triple, quadruple etc.)
5. Donor questionnaire
6. Weighing device for donors
7. Weighing device for blood bags
8. Artery forceps; scissors
9. Stripper for blood tubing
10. Bed sheets
11. Blankets/ mattress
12. Lancets
13. Swab stick/tooth picks & glass slides (optional)
14. Portable Hb meter/copper sulphate (or equivalent approved validated method)
15. Test tube (large) and 12x100mm (small), test tube stand, test tube cap/ films
16. Anti-A, Anti-B and Anti-AB, Antisera and Anti-D (optional)
17. Insulated blood bag containers with provision for storing between 2^{o} C to 10^{o} C.
18. Dielectric sealer or portable tube sealer
19. Miscellaneous items like medicated adhesive tape, plastic waste basket, donor cards, refreshment for donors, emergency medical kit
20. Vehicle having a seating capacity for 8-10 persons, with provision for the carriage of goods at the blood donation camp.

All information regarding the equipment used and facilities available at such a camp shall be well documented and made available for inspection if required.

3.2.2.4 Facilities required (not limited to):

(i) Continuous and uninterrupted electrical supply for the equipment used
(ii) Adequate lighting for all the required activities
(iii) Hand washing facilities for staff
(iv) Reliable communication system
(v) Furniture and equipment arranged within the available place
(vi) Refreshment facilities for donors and staff
(vii) Facilities for medical examination of the donors
(viii) Availability for proper disposal of waste.

Chapter-4:
Personnel

4.1 GENERAL:

The Blood Centre shall have a defined process to ensure the employment of an adequate number of individuals qualified by education, training and/or as per applicable regulations.

4.1.1 Qualification

4.1.1.1 *Medical Director/In-charge/ Medical Officer, Blood Centre*

The operation of Blood Centre and/ or processing or both of whole human blood for components shall be conducted under the active direction and personal supervision of competent medical staff consisting of at least one person who is a whole time employee and who is Medical Officer, and possessing—

(a) Degree in Medicine M.B.B.S. having experience of working in Blood Centre, not less than one year during regular service and also has adequate knowledge and experience in blood group serology, blood group methodology and medical principles involved in the procurement of blood or preparation of its components or both; or

(b) Degree in Medicine M.B.B.S. with Diploma in Clinical Pathology or

Diploma in Pathology and Bacteriology with one year experience in a licensed Blood Centre; or

(c) Degree in Medicine M.B.B.S. with Diploma in Transfusion Medicine or Diploma in Immunohematology or Blood Transfusion with three months experience in a licensed Blood Centre; or

(d) Doctor of Medicine Pathology or Diplomate of National Board Pathology with three months experience in a licensed Blood Centre; or

(e) Postgraduate degree in Transfusion Medicine-Doctor of Medicine Transfusion Medicine or Diplomate of National Board Transfusion Medicine, Doctor of Medicine Immunohematology and Blood Transfusion, the degree or diploma being from a University recognized by the Central Government or State Government.

The degree or diploma is from a University recognized by the Central Government or State Government.

(f) In case of availability of both MD/ DNB in Transfusion Medicine and MD/ DNB Pathology, preference shall be given to MD/ DNB in Transfusion Medicine in Medical Colleges/ teaching institutes after fulfilling eligibility criteria for the post. In case of all blood centres in medical colleages/ teaching institutes, the incharges shall be either MD/ DNB Transfusion Medicine or MD/ DNB Pathology.

Explanation: For this condition, the experience in Blood Centre shall not apply in the case of persons who are approved by the Licensing Authority or Central Licence Approving Authority or both prior to the commencement of the Drugs and Cosmetics (Second Amendment) Rules, 1999

4.1.1.2 *Blood Centre Technicians*

(a) Blood Centre Technician(s) shall be full-time competent staff possessing the following qualification –

(i) Diploma in Medical Laboratory Technology (DMLT) or Transfusion Medicine or Blood Bank Technology after 10+2 with one year experience in the testing of blood and/or its components in licensed Blood Centre; or

(ii) Degree in Medical Laboratory Technology (M.L.T.) or Blood Bank Technology with six month's experience in the testing of blood and/or its components in licensed Blood Centre; or

(iii) B.Sc. in Hematology and Transfusion Medicine with six month's experience in the testing of blood and/or its components in licensed Blood Centre; or

(iv) M.Sc. in Transfusion Medicine with six month's experience in the testing of blood and/or its components in licensed Blood Centre; or

(v) Post-Graduate Diploma in Medical Laboratory Technology (PGDMLT) / Post Graduate Diploma in Medical Laboratory Science (PGDMLS) with six month's experience in the testing of blood and/or its components in licensed Blood Centre.

(b) Technical supervisor (where blood components are manufactured), possessing-–

(i) Diploma in Medical Laboratory Technology or Transfusion Medicine or Blood Bank Technology after 10+2 with one year experience in the testing of blood or its components or both in licensed Blood Centre; or

(ii) Degree in Medical Laboratory Technology or Blood Bank Technology with six month's experience in the testing of blood or its components or both in licensed Blood Centre; or

(iii) B.Sc. in Hematology and Transfusion Medicine with six month's experience in the testing of blood or its components or both in licensed Blood Centre; or

(iv) M.Sc. in Transfusion Medicine with six month's experience in the testing of blood or its components or both in licensed Blood Centre; or

(v) Post-Graduate Diploma in Medical Laboratory Technology or Post Graduate Diploma in Medical Laboratory Science with six month's experience in the testing of blood or its components or both in licensed Blood Centre; or

(vi) Post Graduate Diploma in Transfusion Technology (PGDTT) approved by the Central Government or State Government with experience of 6 months in the testing of blood or its components or both in licensed blood centre.

4.1.1.3 *Registered Nurse(s)*

Registered with state/ central nursing council

4.1.1.4 *Counsellor*

The Blood Centre shall have whole-time or part-time counselling staff (Counsellor or Medical Social Worker) possessing the following qualification. They will also take the required number of counsellor in each blood donation camp

(a) Master's degree in social work, sociology, psychology with six months of experience; or

(b) Degree in Science or Health Science with one year of experience; or

(c) Person with 10+2 education having three years of experience in the field of counselling. Blood Centre collecting blood less than 3000 units per annum can share counsellor or medical social worker within the institution

4.1.2 All Blood Centres shall provide full-time competent staff, ensuring proper cadres for both medical and paramedical personnel.

4.1.3 All medical colleges should be encouraged to develop a Department of Transfusion Medicine where faculty is appointed in accordance with the rules of the Medical Council of India whenever teaching departments are planned.

4.1.4 A Quality Manager may be appointed/deputed (either a medical officer or a senior technician trained in quality management) in all Blood Centres collecting >10,000 units per year.

4.1.5 All Blood Centres should recruit other staff as per recommendations given in Drugs & Cosmetics Rules.

4.1.6 The job descriptions or specifications should be clearly recorded and laid down for all staff members.

4.1.7 The staff members should be given induction training soon after the appointment. The training records should be maintained, updated and reviewed.

4.1.8 It is recommended that proficiency test (written/oral/ practical) of competency of all technical staff may be conducted at least annually to ensure the reliability of their performance.

4.1.9 All staff should be provided training and facilities for implementing universal safety precautions for hospital-acquired infections and Biosafety Guidelines.

4.1.10 All staff members should be encouraged to participate in CME programmes at regular intervals.

4.1.11 Personnel records for all staff shall be maintained centrally in case of a hospital-based Blood Centre or in the Blood Centre as per the decision of the management.

4.2 JOB DESCRIPTION/ RESPONSIBILITIES:

4.2.1 Current job descriptions shall be maintained and shall define appropriate qualifications for each job position.

4.2.2 Personnel shall perform assigned activities on the basis of appropriate qualification, education, training and/ or experience.

4.2.3 Responsibilities of Medical Director/Head/Medical Officer, Technical Manager/ Quality Manager:

4.2.3.1 The responsibilities of the Blood Centre Medical Director/ In-charge/Medical Officer shall include professional, scientific, consultative, advisory organizational, administrative and educational matters. These shall be relevant to the services offered by the Blood Centre. In case of more than one Medical Officer is there in the Blood Centre, the responsibility shall be defined by the Medical Director/ In-charge.

4.2.3.2 Quality Manager shall have the responsibility and authority to oversee compliance with the requirements of the quality management system. The Quality Manager shall report on the performance of the quality management system directly to the top management, which decides on Blood Centre policy and resources.

4.2.3.3 Technical Manager shall have overall responsibility for the Blood Centre operations and the provision of resources needed to ensure the required quality of Blood Centre procedures.

In a Blood Centre collecting less than 5000 units per year, the same person can be designated as Technical and Quality Manager.

4.3 PERSONNEL HEALTH:

A pre-employment medical examination and regular health check-up shall be conducted on all the employees as per institutional policy. Occupational health hazards shall be adequately addressed. All staff members shall be vaccinated for the hepatitis B vaccine.

4.4 PERSONNEL RECORDS:

The Blood Centre management shall maintain records of the personnel information, relevant educational and professional qualification, training and experience and competence of all personnel. This information should be readily available to relevant personnel and may include:

a) Certificate or license
b) Reference from previous employment
c) Job Description
d) Record of continuing education and achievements
e) Provision for untoward incident or accident reports
f) Record of identification of signature and initials
g) Competency evaluation
h) Grievance redressal record
i). Pre-employment health check-up record
j). Yearly health check-up records

Other records available to an authorized person relating to personnel health may include records of exposure to occupational hazards and records of immunization status.

4.5 TRAINING:

4.5.1 Training in the Blood Centre is very important during different stages of operations. All personnel shall have training specific to Blood Centre operations and Quality management system.

4.5.2 The staff members should be given induction training soon after the appointment. It should include training and acclimatization in different areas/ sections of the Blood Centre or organization. The training records should be maintained, updated and reviewed. It shall be the responsibility of the management to ensure that the personnel in Blood Centre activities are adequately trained for the tasks undertaken and receive initial and continual training relevant to their needs.

4.5.3 There shall be a continuing education program for staff at all levels.

4.5.4 All staff should be encouraged to participate in CME programmes at regular intervals

4.5.5 Employees shall be trained to prevent adverse incidents and/or contain the effects of and report adverse incidents.

4.5.6 Blood Centre employees shall be trained in other regulatory and safety issues of Blood Centre like biomedical waste management and fire safety etc.

4.6 COMPETENCE:

Competency test of all technical staff may be conducted annually in term of written/ oral/ practical tests to ensure the reliability of their performance. The Competency of each person to perform the assigned tasks shall be assessed following training and periodically thereafter. Retraining and reassessment shall be undertaken when necessary.

Chapter-5:
Equipment

5.1 GENERAL:

5.1.1 Equipment requirement

The Blood Centre shall be furnished with all equipment required for the provision of services (including collection, component preparation, processing, examination and storage of blood and its components and all other functions). The Blood Centre shall have policies, processes and procedures to ensure that calibration, maintenance, and monitoring of equipment conform to the Blood Centre standards and other specified requirements.

The record of each piece of equipment shall be properly maintained. Whenever equipment is found to be defective, it shall be taken out of service.

5.1.2 Selection, installation and validation of equipment.

Blood Centre shall have a policy for selection, procurement and installation of the equipment. It includes the following qualifications:

a) Installation qualification
b) Operational qualification
c) Performance qualification

5.1.3 Use of equipment

Only authorized personnel shall operate all equipment. Up-to-date instructions on the use and maintenance of the equipment (including relevant manuals and direction for use provided by the manufacturer of the equipment) should be readily available to personnel. Equipment used in the collection, processing, testing storage and distribution of blood and its components are maintained in a clean and proper manner and suitably placed to facilitate cleaning and maintenance.

5.1.4 Equipment detail record, unique identification

The records shall be maintained for each equipment. These records should include at least the following:

a) Unique identification of the equipment.
b) Manufacturer's name, type, identification and serial no. or other unique identification.
c) Manufacturers /service provider's contact person and Contacts details.
d) Date of receiving and date of putting into service,
e) Current location, where appropriate,
f) Condition when received (new, used or reconditioned)
g) Manufacturer's instructions, if available, or reference of their retention
h) Equipment performance record that confirms the equipment suitable for use
i) Maintenance carried out and that planned for the future
j) Damage to or malfunction, modification or repair of the equipment

k) All equipment shall have labels identifying the equipment, calibration status & due date of calibration.

All these records shall be maintained and shall be readily available for the life span of the equipment or for any time period required by law/regulation.

5.1.5 Programme for calibration and maintenance of equipment

5.1.5.1 Blood Centre management shall establish a program that regularly monitors and demonstrates proper calibration and function of instruments, reagents and analytical system. It should also have a documented and recorded program of preventive maintenance, which at a minimum, follows the manufacturer's recommendations.

5.1.5.2 The equipment should be observed, standardized and calibrated regularly on a scheduled basis as described in the Standard Operating Procedure manual and shall operate in the manner for which it was designed so as to ensure compliance with the legal requirement (the equipment) as stated below for the blood and its compocnent.

5.1.5.3 The program for calibration of equipment should be designed and operated so as to ensure that calibrations are traceable to the international system of units (SI). The link to SI units may be achieved by reference to national measurement Standards. In case of any equipment shows out of range values, necessary actions shall be taken before putting equipment back in service.

5.1.5.4 The Blood Centre should have a system for investigating and follow up of equipment malfunction, failure or adverse event while working. This should minimally include assessment of consequences when equipment is found to be out of calibration, such as effect on donor eligibility and quality of blood components.

5.2 EQUIPMENT FOR STORAGE OF BLOOD AND COMPONENTS:

5.2.1 Blood Centre shall have an adequate storage facility corresponding to its workload.

5.2.2 Storage devices shall have been designed to ensure that the proper temperature is maintained.

5.2.3 There shall be a process to monitor and record the temperature of blood storage refrigerator, deep freezer and platelet incubators continuously. The temperature shall be recorded at least every 4 hours. In case the Blood Centre is not monitoring the temperature continuously, the recording shall be at least at 4 hourly intervals. It is advisable to follow two temperature recording systems.

5.2.4 If platelets are stored in an open storage area on an agitator, the ambient temperature shall be maintained at 22 $\pm$ 2 ^{0}C and recorded at least at 4 hourly intervals.

5.3 COMPUTER SYSTEM:

When computers or automated equipment are used for the collection, processing, recording, reporting, storage or retrieval of examination date, the Blood Centre should ensure that:

a) Computer software, built in equipment, is documented and suitably validated as adequate for use in the facility.

b) Procedures should be established and implemented for protecting the integrity of data at all times.

c) Computer and automated equipment should be maintained to ensure the proper functioning and provided with environmental and operating conditions necessary for maintaining the integrity of data.

d) Computer programmes and routines shall be adequately protected to prevent access, alternation and destruction by unauthorized persons.

e) An alternative system that ensures continuous operation shall be available in the event that computerized data and computer functions are unavailable. The alternatives systems should be tested periodically.

5.4 BREAKDOWN OF EQUIPMENT:

5.4.1 Blood Centre shall have a procedure for replacement or repairing of defective equipment.

5.4.2 Whenever equipment is found to be defective, it shall be taken out of service, clearly labelled and appropriately stored until it has been repaired and shown to be calibrated to meet specified acceptance criteria.

5.4.3 The Blood Centre should have a policy and procedure for appropriate alternate storage where the blood/blood components shall be shifted in the event of breakdown of storage equipment.

Annexures:

Chapter-6:

External Services and Supplies

6.1 GENERAL:

6.1.1 Blood Centre management shall define and document its policies and procedures for the selection and use of purchased external services, equipment and consumables. All items should consistently meet the Blood Centre quality requirements.

6.1.2 As per management policy, the organizational purchase may be made centrally (e.g. hospital-based Blood Centres), partially (e.g. NACO supported Blood Centres) or independently (e.g. stand-alone Blood Centres). Purchased equipment and consumable supplies that affect the quality of the service shall not be used until they have been verified as complying with standard specifications or requirements defined for the procedure concerned.

6.1.3 Blood Centre shall ensure that all supplies and reagents requiring cold chain maintenance are received at the appropriate temperature.

6.1.4 Supplies and reagents used in the collection, processing, compatibility testing, storage and distribution of blood and blood components shall be stored at the proper temperature in a safe and hygienic place in a proper manner.

6.1.5 Acceptance criteria for critical incoming materials, i.e. blood bags, labels, reagents and test kits, may be available and records of acceptance kept.

6.1.6 All supplies coming in contact with blood and blood components intended for transfusion shall be sterile, pyrogen-free, and shall not interact with the product in such a manner as to have an adverse effect upon the safety, purity, potency or effectiveness of the product. Sterility testing of blood containers should be made mandatory.

6.1.7 Supplies and reagents that do not bear an expiry date shall be used in a manner that those received first are used first.

6.1.8 Supplies and reagent shall be used in a manner consistent with instructions provided by the manufacturer.

6.1.9 Each blood collecting container and its satellite container(s), if any, shall be examined visually for damage or evidence of contamination prior to its use and immediately after filling; such examination shall include inspection for breakage of seals. When there is such indication the container shall not be used or, if detected after filling, shall be properly discarded.

6.1.10 Reagents and test kits

a. Acceptance testing shall be performed on each batch/delivery of reagents and test kits.

b. Reagents and test kits shall be stored and used according to the manufacturer's instructions.

c. Reagents and test kits without validation and proper instruction should not be accepted.

d. Reagent antisera must be validated and assured for specificity and potency as per quality control requirements

e. A system of inventory control must be in place that records as a minimum reagent or test kit:

- Lot number
- Expiry date
- Supplier
- Stock levels
- Dates of receiving and issue

6.2 INVENTORY CONTROL:

6.2.1 There shall be an inventory control system for supplies.

This system shall include the recording of the lot number of all relevant reagents, control materials and calibrators, the date of receipt in the Blood Centre and the date the material was placed in service. The critical level for all reagents and consumables should be defined.

6.3 EVALUATION OF SUPPLIERS:

6.3.1 The Blood Centre should evaluate suppliers of critical reagents, supplies and services that affect the quality of tests and should maintain records of these evaluations.

6.3.2 A list of approved suppliers for critical items should be maintained and reviewed at defined intervals.

6.3.3 Contracts should be maintained between the establishment and suppliers for critical materials.

6.3.4 Service contracts/ Service Level Agreements (SLA) should be maintained between the establishment and suppliers of critical equipment

Chapter-7:

Records and Document Control

7.1 GENERAL:

7.1.1 Blood Centres shall have a list of documents in various formats, e.g. registers, forms and files or in electronic format etc.

7.1.2 There shall be an SOP on how to manage documents, duration of shelf life and method of archiving and retrieving documents/records.

7.1.3 Blood Centre shall identify documents that are to be controlled and authorized for use by responsible personnel.

7.1.4 All controlled documents shall carry unique numbers as per different versions/ issues.

7.2 ELECTRONIC/COMPUTER RECORDS MAINTENANCE:

7.2.1 All electronic including computer data shall have a regular backup provision for data safety. Hourly, daily, weekly and monthly backup system should be developed by the organization depending upon volume and criticality of data, as per defined need.

7.2.2 Sufficient data security shall be maintained to protect all relevant data in the system.

7.2.3 Proper maintenance and up-gradation of the software shall be taken care of.

7.3 RECORDS:

7.3.1 Hard copies of all records should be preserved for 5 years as required by regulatory requirements. However, records related to plasma fractionation shall be preserved for ten years.

7.3.2 Blood Centre shall develop a SOP for proper record keeping, including a system for identification, archiving and retrieving in dust-free, insect/ rodent-free, water-free conditions so that records are legible till the end of the storage period.

7.3.3 The record system in a Blood Centre should be strong enough to trace any blood and components from collection from a donor to transfusion in a patient with complete traceability.

7.3.4 All Blood Centre records must be preserved in a safe way away from termite, insect and other physical deteriorations. All recent records shall be preserved in the store cum record room or on the premises. However, in case of space constraint, storage may be outsourced to a reliable vendor under contract with terms and conditions of storage and retrieval.

7.3.5 There shall be one procedure to identify current documents in use in the Blood Centre. Obsolete documents shall be clearly identified, marked, taken out of working areas and archived in a suitable place for an identified period.

7.3.6 The records that the Blood Centre must maintain shall include inter alia as mentioned in the annexure mentioned below. However, it is encouraged to develop a proper documentation system and maintain records as per requirements, not limited to said annexure.

7.4 BLOOD UNIT IDENTIFICATION:

A system should be in place to ensure that the final container is labelled only after all mandatory testing is completed as per regulatory requirements. Requirements shall ensure

- Traceability of products
- Appropriate storage and handling of units
- Appropriate selection of units for transfusion

7.4.1 The label shall be attached firmly to the container and shall be clear and readable. Any hand-written information should be legible and in permanent and moisture-proof ink.

7.4.2 A numeric or alphanumeric system should be used that will make it possible to trace any unit of blood or component from source to final destination and to recheck records applying to the specific unit.

7.4.3 The numeric and alphanumeric identification on the label shall be provided by the collecting facility to each unit of blood/its components. This number should be documented for traceability. Traceability of products through bar codes and radio frequency identification for real time visibility of blood products.

7.4.4 A maximum of two numeric or alphanumeric identification should be on a blood or component container, i.e., that of the original collecting facility. This does not preclude the use of patient identification. Donor's name should not be written on the label. In case of transfer of blood unit to another Blood Centre, original label with the same identification should be retained.

7.5 LABELLING FOR WHOLE BLOOD/COMPONENT:

After processing the blood, a final label shall be affixed on the bag with the following information.

7.5.1 Name of the product, i.e., whole blood or component or intended component.

7.5.2 The numeric or alphanumeric identification.

7.5.3 The date of collection and expiry.

7.5.4 The name and amount of anticoagulant and the approximate volume of blood collected. For platelet concentrate, plasma and for component obtained through apheresis, the approximate volume of the components should be indicated.

7.5.5 Colour Scheme: The following colour code is used to differentiate the ABO group label

Blood group O – Blue;

Blood group A - Yellow

Blood group B – Pink;

Blood group AB – White

7.5.5 Special Requirements for Component Label:

a. Rh (D) type is not required to be mentioned for plasma, but it is necessary for platelet and granulocyte concentrates especially in case of red cell contamination of the product. It is not necessary to mention ABO and Rh(D) type on Cryoprecipitate label.
b. Storage temperature should be indicated.
c. Expiry date/time for use should be recorded.
d. If the plasma is intended for the use of fractionation, suitable documentation and labelling should be done.
e. Label should indicate whether the component is prepared by the apheresis method.
f. Label should indicate the addition of any adjuvant or cryoprotective agents used
g. Storage temperature
h. ABO and Rh type.
i. Interpretation of HBsAg/HCV/HIV 1 & 2/Syphilis/malaria test/unexpected antibodies
j. Name, Address and Manufacturing license number of the collecting facility.

7.6 INSTRUCTIONS FOR TRANSFUSION:

The following information should be printed on the label.

7.6.1 Do not use if there is any visible evidence of deterioration.

7.6.2 Keep red cells at 4°C +/- 2°C before use if there is a delay

7.6.3 Shake gently before use.

7.6.4 Do not add any other medication to the blood/blood component.

7.6.5 Check blood group on the label and that of the recipient before administration.

7.6.6 Use a fresh, clean, sterile and pyrogen-free disposable transfusion set with a filter to transfuse blood.

7.6.7 Do not dispense without a prescription.

7.7 SPECIAL REQUIREMENTS FOR COMPONENT LABELS:

7.7.1 The label shall contain information to identify the facilities that carried out any part of the preparation.

7.7.2 Rh (D) type is not required to be mentioned for plasma, but it is necessary for platelet and granulocyte concentrates especially in case of red cell contamination of the product. It is not necessary to mention ABO and Rh (D) type on the Cryoprecipitate label.

7.7.3 Storage temperature shall be indicated.

7.7.4 Expiry date/time for use shall be recorded.

7.7.5 If the plasma is intended for the use of fractionation, suitable documentation and labelling shall be done.

7.7.6 Label should indicate whether the component is prepared by the apheresis method.

7.7.7 Label shall indicate the addition of any adjuvant or cryo-protective agents used.

7.7.8 If Red cell unit is irradiated, the expiry dates shall be modified, keeping in mind 28 days after the irradiation process, whichever is earlier.

7.7.9 For leukodepleted products, proper labels shall be used, mentioning the amount of (log) of leukocytes removed.

7.7.10 If the hermetic seal of the component is breached, the shelf life shall be modified accordingly.

Annexures:

Annexure-3. List of documents (page no-76)

Chapter-8:
Process Control

8.1 BLOOD DONATION

8.1.1 GENERAL

The primary responsibility of a Blood Transfusion Service is to provide safe, sufficient and timely supply of blood and blood components. In fulfilling this responsibility, the BTS should ensure that the act of blood donation is safe and causes no harm to the donor. It should build and maintain a pool of safe, voluntary non-remunerated blood donors and take all necessary steps to ensure that the products derived from donated blood are efficacious for the recipient, with minimal risk of any infection that could be transmitted through transfusion.

8.1.2 OBJECTIVES

8.1.2.1 The donor selection criteria recommended in the Standards apply to donors of whole blood, red cells, platelets, plasma and other blood components, donated as whole blood or through apheresis, including plasma for fractionation.

8.1.2.2 Clauses in this Standards are designed to promote best practice in Blood Transfusion Services to ensure the collection of donations from the lowest risk donors possible.

8.2 DONOR RECRUITMENT AND RETENTION

- Blood should be accepted only from voluntary, non-remunerated, low risk, safe and healthy donors. Blood collections from family replacement donors should be avoided, and these donors should be converted to voluntary non-remunerated blood donors (VNRBD).
- Efforts shall be directed towards encouraging and retaining adequate numbers of repeat donors.
- Donors shall be appropriately recognized and thanked for their contribution.
- The Blood Centre should educate donors before collecting blood regarding the risk of blood donation and transfusion transmissible infections.

8.3 DONOR SELECTION

The steps for donor selection include:

8.3.1 Pre-donation information

8.3.2 Pre-donation counselling

8.3.3 Donor Questionnaire and Health check-up

8.3.4 Counselling during blood donation

8.3.5 Post-donation counselling

8.3.1 PRE-DONATION INFORMATION SHOULD INCLUDE:

- Nature and use of blood and its components.
- Eligibility for blood donation

- The rationale for donor questionnaire and pre-donation health assessment
- Options for the donor to withdraw or self-defer at any time before, during or after donation
- Blood donation process and potential adverse donor reactions
- Common TTI, modes of transmission and window period
- Basic information on tests performed on the donated blood
- Possible consequences for donors and donated blood in the case of abnormal TTI test results

It can be done as a one-on-one or as a group and shall be integrated with the activities undertaken for donor recruitment and retention.

8.3.2 PRE-DONATION COUNSELLING shall focus on the donor and preferably be done one-to-one.

The objectives include:

- Understanding of Donor Questionnaire to enable correct responses
- Reiterate understanding of TTI testing and the disclosure of results
- Clarify any misunderstanding about donor selection, blood donation and blood screening
- Explain self-deferral
- Explain temporary and permanent deferral
- Familiarize donor to the process of blood donation
- Obtain donor's Informed consent

8.3.2.1 The World Health Organization defines blood donor counselling as "a confidential dialogue between a blood donor and a trained counsellor about issues related to the donor's health and the donation process."

8.3.2.2 Counselling of blood donors should be provided by trained blood donor counsellors, maintaining privacy and confidentiality. All Blood Centres may also train their donor motivator/medical officers to undertake to counsel, in case dedicated manpower is not available.

8.3.3 DONOR QUESTIONNAIRE AND HEALTH CHECK-UP is administered to every prospective donor to enable a quick history taking, limited physical examination and haemoglobin test.

8.3.3.1 A bilingual questionnaire shall be prepared (e.g. English and local language), which is simple and easy to understand, to be answered by the donor.

8.3.3.2 For donors who are illiterate, assistance should be given by counsellor/ donor registration staff.

8.3.3.3 Medical officer with minimum MBBS qualification shall be responsible for reviewing the donor's health condition and performing a physical examination of the donor.

8.3.3.4 Demographic details of the donor, date and time of donor selection and donation shall be registered. Informed consent shall be obtained in writing from the donor on the questionnaire. All care shall be taken as per regulation so that the blood seller does not donate blood in disguise.

8.3.3.5 Prior to blood donation, the consent of the donor shall be obtained in writing with the donor's signature or thumb impression after the procedure is explained, and the donor is informed regarding testing of blood for all mandatory tests for the safety of recipients. The donor shall be provided with an opportunity to ask questions and refuse consent.

Donor consent shall be taken for the following :

i. Blood donation is a totally voluntary act, and no inducement or remuneration has been offered.
ii. Donation of blood/ components is a medical procedure, and that by donating voluntarily, I accept the risk associated with this procedure.
iii. I confirm that I have answered all questions truthfully and accurately without hiding any facts willfully. I also understand that any willful misinterpretation of the facts could endanger the life of the patient who receives my blood/ components.
iv. My donated blood and plasma recovered from my donated blood may be sent for plasma fractionation for the preparation of plasma-derived medicines, which may be used for the larger patient population and not just this Blood Centre.
v. My blood will be tested for Hepatitis B, Hepatitis C, Malaria parasite, HIV/AIDS and Syphilis, in addition to any other screening tests required to ensure blood safety.
vi. I would like to be informed about any abnormal test results done on my donated blood- Yes/No
vii. I understand that screening tests are not diagnostic and may yield false-positive results, which may need further confirmatory tests.
viii. I confirm that my age is more than 18 years and not beyond 65 years.
ix. My donated blood/ components may be utilized in this Blood Centre or beyond this Blood Centre for any patient in need.
x. My donated blood/components may be used for the purpose of preparation of panels, indigenous manufacture and scientific research.

8.3.3.6 Criteria for Selection of Donors is given in annexure as mentioned at the end of the chapter.

8.3.3.7 In case a donor reports back to the Blood Centre or camp organizer about any communicable or transfusion transmissible diseases, including COVID-19, the Blood Center will have a look back phenomenon in the interest of patient safety.

8.3.4 BLOOD/ COMPONENT DONOR COUNSELLING: Counseling during blood donation shall ensure that the donor feels comfortable. History of previous allergies, phobias and fainting attacks during previous injections or blood donation should be asked. The phlebotomist shall provide gentle reassurance to relax the donor, reduce his anxiety and minimize the risk of any adverse reactions.

8.3.5 POST DONATION COUNSELLING: Post donation counselling shall include 'Do's and Don'ts immediately after blood donation in order to ensure donor safety and the details shall be displayed in post donation/ refreshment area.

8.4 RECALL AND REFERRAL MECHANISM FOR SERO-REACTIVE BLOOD DONORS

8.4.1 INFORMATION OF TEST RESULTS: To inform them about the sero-reactive result of transfusion-transmitted infection (TTI).

- Donors who have consented to be contacted by the Blood Centre in case of an abnormal test result shall be recalled to the Blood Centre so as to inform them about the sero-reactive result of transfusion-transmitted infection (TTI).
- Donors shall be provided post-donation counselling prior to referring to appropriate medical services for confirmation of diagnosis, follow up and treatment whenever necessary.

- In some donors, NAT tests may be reactive, whereas routine serology may be non-reactive. NAT yield donors should be recalled and advised to go for clinical consultation.
- Adequate efforts must be made by the Blood Centre staff to contact the initial sero-reactive blood donors for recall-referral, and the process should be documented on record as mentioned in the annexure.
- Result seeking blood donors, even if non sero-reactive, should also be informed of their TTI status with reiterated counselling to remain negative and continue to donate blood.
- State AIDS Control Societies shall make an available updated list of ICTC along with contact details of counsellors to all licensed Blood Centres.

8.4.2 DUTIES OF A BLOOD CENTRE:

- All initial sero-reactive donors shall be recalled, offered post donation counselling and referred to an appropriate facility for further counselling, confirmation and management.
- All initial sero-reactive blood units shall continue to be discarded as per the standard operating protocol of Blood Centre and in compliance with Biomedical Waste Management Rules 2018. If at all Donor is contacted telephonically, ensure that communication is done with the donor only. He/ she should be convinced to come to the Blood Centre and test results shall not be revealed telephonically.
- Consent of the Blood Donor shall be obtained for performing the screening tests and to be informed of the results thereof at the time of blood donation.
- Blood Centre shall repeat the test using the same technique using the pilot tube/ sample from the blood bag prior to labelling the donor as sero-reactive and recalling for a referral.
- All initial sero-reactive donors shall be recalled, offered post donation counselling and referred to an appropriate facility for further counselling, confirmation and management.
- A standard referral format for the same shall be used, and the Blood Centre shall maintain all records of recall and referral.
- Signatures of the blood donor shall be obtained on the consent form attached to the referral format so as to avoid litigation due to discordant results of screening at Blood Centres and confirmatory tests of the reference centre.
- In case the initial sero-reactive donor does not return to Blood Centre despite three consecutive weekly attempts, the list of HIV sero-reactive blood donors shall be shared with the linked ICTC under shared confidentiality under guidance from State AIDS Control Society.

8.4.3 REFERRAL MECHANISM OF HIV SERO-REACTIVE BLOOD DONORS TO ICTC:

- The testing Strategy used in the Blood Centres for HIV is “Strategy I”, and the test done in the Blood Centre is considered to be a test of triage.
- The blood unit is subjected to one test of high sensitivity for HIV reactivity. If non-reactive, the specimen shall be considered free of HIV (negative), and if reactive, the blood unit is considered as HIV positive and discarded. This strategy is focused on ensuring recipient safety and is also used in the setting of screening of organs, tissues, sperm and other donations.

8.4.4 ALGORITHM FOR BLOOD DONORS REFERRED TO ICTC

- The donor shall be offered HIV pre-test counselling at the ICTC, and consent shall be taken to perform the HIV test.

- ICTC shall perform the first test. If the first test is positive, ICTC shall perform the remaining two tests and give a positive result after three sequential reactive tests.
- In case the first test is negative, ICTC shall report the result as HIV inconclusive and recall the donor for re-testing after two weeks.
- All blood donors found to be positive for HIV shall be counselled to permanently defer them from the donor pool, in addition to referral for Pre-ART during post-test counselling.
- In addition, the message for all PLHA (people living with HIV/ AIDS) to permanently defer themselves/ spouses/ partners from donating blood shall be incorporated into the information for all PLHA during post-test counselling.

8.4.5 REFERRAL MECHANISM OF OTHER TTI SERO-REACTIVE BLOOD DONORS TO CLINICIANS:

- The blood unit is subjected to one test of high sensitivity for HBV, HCV, Malaria and syphilis reactivity. If non-reactive, the specimen is to be considered free of infection (negative), and if reactive, the blood unit is considered as positive and discarded.
- Prior consent shall be taken from the donor for both conduction of screening tests and to be informed of the result of testing at the time of donation by the Blood Centre along with complete contact details and telephone number.

  (Instruction to printer: please remove this line, above)
- All blood donors found to be sero-reactive at Blood Centre for HBV, HCV, Syphilis, and Malaria shall be referred to clinicians in the Out-Patient Department of associated hospitals or others for assessment and re-testing.
- Blood Centre shall fill out the referral form as per the standard format (in annexure at the end of chapter) and send it along with referred donor.
- Confidentiality shall be maintained at all levels.

8.4.6 ALGORITHM FOR BLOOD DONORS REFERRED TO CLINICIANS:

- The donor shall be assessed by the clinician with history taking and clinical examination.
- The donor shall be referred to the laboratory for re-testing and confirmation of the test results.
- The donor shall be offered appropriate treatment by the assessing clinician or referred to a higher centre for the same.
- All blood donors found to be positive for HBV, HCV, Malaria, and Syphilis should be counselled to defer themselves and their spouses/partners from the donor pool, in addition to appropriate management.

8.5 COLLECTION OF BLOOD

8.5.1 Blood shall be collected only by a licensed Blood Centre. The blood shall be drawn from the donor by a qualified physician or under his/her supervision by phlebotomist (nurse or technician) trained in the procedure. A physician should be present on the premises when the blood is being collected. Blood should be collected by single venepuncture, and the flow of blood should be continuous.

8.5.2 The blood donor area shall be clean, congenial, comfortable and conveniently approachable. As the temperatures vary widely in different seasons, it is mandatory to have air-conditioned rooms to make the donor comfortable and to minimise chances of contamination.

8.5.3 Method: A strict, standardised procedure shall be in use to achieve surgical cleanliness for preparing venepuncture site to provide maximum possible assurance of the sterile product.

8.5.4 Equipment: The blood bags for collection of blood shall be sterile, pyrogen-free and disposable, with a closed system of the collection. Multiple interconnected plastic bags shall be used for blood component preparation (closed system). Venting of any container (if needed) shall be done under a laminar airflow bench, and such a container shall be used within 24 hours. To avoid venting in case of paediatric use, multiple inter-connected closed containers shall be used.

8.5.5 Anticoagulant Solutions: The anticoagulant shall be sterile and pyrogen-free. One of the following solutions shall be used in the indicated volumes.

a. Citrate-Phosphate-Dextrose (CPD) Solution 14 ml solution is required for 100 ml of blood

b. Citrate-Phosphate-Dextrose-Adenine (CPDA-1) solution. 14 ml solution is required for 100 ml of blood

8.5.6 Additive Solutions: SAG-M/ADSOL or any approved additive solution containing saline adenine and glucose (or with mannitol) is added to packed cells after separation of plasma for storage.

8.5.7 Volume of Blood: The volume of blood collected shall be proportionate to the volume of anti-coagulant, with ±10% variation and shall not exceed 10 ml/kg body weight limited to a volume of 450 ml. Units of blood where volume collected is out of the permitted limits should not be used for transfusion.

8.5.8 Samples for Laboratory Tests: The blood samples in the pilot tubes (clotted and anticoagulated) shall be collected at the time of blood collection by the same person who collects blood. They should be marked before collection to be identified with the unit of blood. The integral donor tubing of the plastic bag shall be filled with anticoagulated blood and sealed in such a manner that it will be available with segment numbers for traceability for subsequent compatibility tests.

8.5.9 Identification: Each container of blood/blood components /pilot tubes shall be identified by a numeric or alpha numeric number at the time of collection of blood so that it can be traced back to the donor and also to the recipient. The segment number printed on the integral donor tubing should be recorded.

8.5.10 Temperature: Immediately after collection, the blood shall be placed at 4^0C +/- 2^0C, except if it is used for component preparation, it will be stored at 22^0C +/- 2^0C until the platelets are separated.

8.5.11 Donor Reaction: Necessary drugs and equipment shall be available to treat donor reaction if any. Blood collection staff shall be trained in the identification and management of donor reactions. The Blood Centre shall document the same under Donor Hemovigilance of Hemovigilance Program of India.

8.5.12 Therapeutic Phlebotomy: Therapeutic phlebotomy shall be done only at the request of the patient's physician. The Blood Centre physician must decide whether to accept the responsibility of the patient. The blood collected in such circumstances shall not be used for transfusion.

8.6 OUTDOOR BLOOD DONATION DRIVES/ CAMPS

GENERAL:

Blood donation camps shall be organised only by Blood Centres (RBTCs) authorised by State Blood Transfusion Council (SBTC) in accordance with the procedure laid down by the National Blood Transfusion Council in this regard to

augment blood stocks. Hospital based blood banks are allowed for outdoor blood donation camps as per approval of competent authority.

8.6.1 Donor organiser/ medical social worker of the Blood Centre should contact offices, institutions, industries, social and religious organisations, colleges and schools to collect need-based volume of blood from a targeted group of donors located at a particular venue at regular intervals.The blood centre shall ensure that adequate effort is made to encourage voluntary blood donations.

8.6.2 Adequate publicity and IEC material should be made available to the organisations.

8.6.3 The number of blood units collected shall be commensurate with the actual requirement of blood units rather than by social or emotional pressures.

8.6.4 The donation site should be inspected before the day of blood collection to ensure the availability of all facilities as prescribed by Drugs and Cosmetics Rules.

8.6.5 The outdoor camp should be organised in an environment that is conducive and comfortable. The area should be cleaned before and after the blood collection.

8.6.6 Blood Centre should maintain quality at each step from donor recruitment, selection and collection to the final product. The method of blood collection and management of donors should be the same as in the blood centre.

8.6.7 Universal precautions should be followed during outdoor blood donation camps.

LARGE CAMPS:

8.6.8 The large camps organised on a day shall be planned as per criteria laid down by the Drugs & Cosmetics Act. Quality measures and pre-donation counselling procedures shall not be compromised. Large blood camps shall be discouraged.

8.7 APHERESIS

8.7.1 GENERAL

Apheresis is a procedure carried out to harvest a particular component and returning the rest of the blood to the donor by an automated machine. This procedure shall be carried out only in a Blood Centre licensed for this purpose.

8.7.1.1 A medical officer trained in apheresis technique shall be responsible for the procedure.

8.7.1.2 There shall be provision for emergency medical care in the event of any adverse reaction to the donor.

8.7.1.3 The staff working on the equipment shall be trained in apheresis procedure and shall work directly under the supervision of the medical officer.

8.7.1.4 The donor shall be asked to sign an informed consent for apheresis in the language, which he understands after being explained the procedure and the risks involved.

8.7.1.5 At least 48 hours must elapse between successive apheresis and not more than twice in a week. For haematopoietic stem cells, the procedure can be done daily.

8.7.1.6 Types of Apheresis:

1) Plasmapheresis
2) Cytapheresis

8.7.2 PLASMAPHERESIS:

It is a procedure to harvest plasma from whole blood and returning the cellular components to the donor. Plasma is harvested by an automated machine.

8.7.2.1 Selection of donors

For selection of plasmapheresis donor, the donor shall fulfill all the crieteria as per regulatory guidelines.

The total serum protein shall be more than 6 gm/dl before the first plasmapheresis procedure. It should be tested before the third procedure if done within four weeks, and it shall be ≥ 6 gm/dl

8.7.2.2 In occasional plasmapheresis in which donors undergo the process once every 12 weeks, the standards for whole blood donation should apply.

8.7.2.3 In repeated plasmapheresis in which plasma is donated more frequently than once every 12 weeks, the donor should be tested before every pheresis procedure. Haemoglobin should be ≥ 12.5 g/dl and/or Hct ≥ 38%

8.7.2.4 In repeated plasmapheresis programme with the return of the cellular components a minimum interval shall be of 48 hours between two procedures (not more than 2 times a week, limited to 24 in one year)

8.7.2.5 **Volume of plasma:** Volume of plasma obtained excluding anticoagulants from a donor weighing at least 55 kg shall not exceed 500 ml with serum protein within normal limit during one procedure or not more than 1000 ml per month with a maximum of 12 L / year. Extra corporeal blood volume should not exceed 15% of the donor's estimated blood volume.

8.7.2.6 **Records:** Records of donor's periodic examination, laboratory tests, consent of donor/patient, date of last apheresis procedure, certificate of the attending physician, procedure details, volume of product separated, drugs used, adverse reaction if any and their treatment shall be maintained.

8.7.3 CYTAPHERESIS

Cytapheresis is the procedure for the separation of individual cellular components of blood. It can be achieved by the cell separator machine, using a continuous or intermittent cell separator. It includes

1) Plateletpheresis
2) Leucapheresis for harvesting
   a. Granulocyte concentrate
   b. Lymphocytes
   c. Mononuclear cells
3) Erythrocytapheresis
4) Haematopoietic stem cells (peripheral blood stem cells): Attempt should be made for harvesting a minimum of $2x10^6$ CD34 cells and/or minimum of $2x10^8$ MNCS/Kg of the recipient.

8.7.3.1 Selection of donors: With the exception of donation interval, the donation criteria applied to allogeneic donor qualification shall apply for the selection of apheresis donors. Donors who do not meet allogeneic donor requirements shall undergo apheresis only when the components are expected to be of particular value to an intended recipient and only when approved by the medical director. The interval between procedures for platelet, erythrocyte and leucocyte donors shall be as per regulatory requirements.A donor (except for erythrocytes) shall undergo the procedure a maximum of two times in 7 days period or not more than 24 times in a year.

8.7.3.2 In case of blood donors who undergo cytapheresis no more than once every 4 weeks should be treated as ordinary blood donors and routine donor screening with laboratory tests should be done.

8.7.3.3 Donors who undergo repeated cytapheresis, more than once every 12 weeks, should be tested as under:

- Haemoglobin should be ≥12.5 g/dl and/ or Hct of ≥38%.
- Total serum protein should not be below 6.0 gm/dl. It should be tested in case of repeated collection if done within 4 weeks.

8.7.3.4 After whole blood donation a platelet/plasma pheresis donor shall not be accepted before 28 days. Platelet/plasma pheresis donor shall not be accepted for whole blood donation before 28 days from the last platelet/plasma donation provided reinfusion of red cell was complete in the last platelet/plasma pheresis donation. If the reinfusion of red cells was not complete, then the donor shall not be accepted within 90 days.

8.7.3.5 Care of donors

a. Extracorporeal blood volume should not exceed 15% of the donor's estimated blood volume.
b. Interval between two cytapheresis (except erythrocytaphersis) should be 48 hours and not more than twice a week.
c. The donors should be tested appropriately to detect developing cytopenia.
d. Red blood cell loss incidental to the procedure should be no more than 25 ml per week.
e. Donors should be observed closely during cytapheresis as regards the untoward reactions like headache, fainting attack, tachycardia, twitching, dyspnea etc.
f. Written standard criteria used to determine donor suitability, the procedure of hemapheresis, precautions to ensure reinfusion of donor's own red cells, and time frame shall be maintained.

8.7.4 PLATELETPHERESIS

The term plateletpheresis includes platelets collected by apheresis using a cell separator, and the product is called single donor platelets and includes washed single donor platelets, modified single donor platelets (with replacement of compatible plasma), leuko-reduced single donor platelets and double (single donor) platelets collected from single donor.

8.7.4.1 Donor selection

Platelet-pheresis shall not be carried out on donors who have taken medication containing aspirin or similar medicines within 3 days prior to donation.

Donors with a personal and family history of bleeding tendency are not suitable for plateletpheresis. Platelet count should be determined before plateletpheresis and should not be below 150,000 / ul. Plateletpheresis donors with a platelet count of less than 1,50,000/ul shall be deferred from platelet donation until a subsequent platelet count is at least 1,50,000/ul. WBC counts and differential counts may be carried out and should be normal.

8.7.4.2 Storage

Shall be kept up to 5 days between 20° C to 24° C with continuous agitation.

8.7.4.3 Quality Control

i) Apheresis platelet concentrate should contain a minimum of 3 X 10^{11} platelets/ unit in 75% of the units tested amongst 1% of monthly production or 4 platelet concentrates per month, whichever is higher.
ii) pH must be 6 or higher at the end of the permissible storage period.
iii) To be considered leucocyte reduced, platelet must contain less than $5x10^6$ leucocytes per unit.

iv) Minimum SDP volume shall be 200 ml in order to maintain optimum pH of platelets.

v) If a blood centre uses PAS as additive solution volumes may change, however, the shelf-life shall still be limited to 5 days or in accordance with regulatory requirement.

8.7.5 LEUCAPHERESIS

This procedure includes a collection of granulocytes (granulocytapheresis), lymphocytes or peripheral blood stem cells or haematopoietic stem cells for the treatment of traditional conditions followed by their preservation.

8.7.5.1 Before leucapheresis total white blood cells counts should be ≥ 4000 /ul with the normal differential count.

8.7.5.2 Donors may receive drugs to facilitate leucapheresis. Such drugs should not be used for donors whose medical history is suggestive of some disease.

8.7.5.3 Leucocyte concentrate should contain at least 1 x 10^{10} leucocytes.

8.7.5.4 Granulocyte concentrates shall be stored at 20^0 to 24^0 C for 24 hours without agitation.

8.7.5.5 The red cells in the concentrates should be ABO compatible with the recipient's plasma. The component should be cross-matched if >2ml of red cells are present.

8.7.5.6 These should be transfused as soon as possible, preferably within 6 hrs.

8.7.5.7 Transfusion should not be given through micro aggregate filters because it will remove the collected granulocytes.

8.7.5.8 Irradiation is required to prevent GvHD.

8.7.6 ERYTHROPHERESIS

This is the collection of two units of red cells from a single donor meeting specified requirements.

8.7.6.1 The donor should have haemoglobin ≥ 13.5g /dl and weigh more than 65 Kgs.

8.7.7 RECORDS OF APHERESIS

Records of the donor's periodic examinations, laboratory tests, consent of the donor/patient, with the date of last apheresis, certificate of the attending physician, details of the procedure, the volume of product separated, drugs used, adverse reactions if any and their treatment should be maintained. Facilities must have policies to ensure that donor red cell loss during each procedure shall not exceed acceptable limits.

8.7.8 THERAPEUTIC PLASMAPHERESIS AND CYTAPHERESIS

8.7.8.1 Therapeutic Apheresis activity is allowed in the Blood Centre attached to the hospital having Apheresis facilities under the responsibility of Registered Medical Practitioner (RMP) who has obtained the consent of the patient and record of which shall be maintained and signed by the Blood Centre Medical Officer.

8.7.8.2 This shall be done only at the written request of the patient's physician, either in the Blood Centre or preferably in the ward depending on the patient's clinical condition.

8.7.8.3 Patient's informed consent shall be taken in the language he/she understands.

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

8.7.8.5 The patient's physician will be responsible for providing emergency care to the patient.

8.8 TESTS FOR BLOOD GROUPING AND ANTIBODY SCREENING

8.8.1 DETERMINATION OF ABO GROUP

ABO group should be determined by testing red cells with Anti-A, Anti-B, Anti-AB reagents by tube or microplate method or column agglutination technology or any other validated technology (manual or automated method) and by testing serum or plasma for expected and unexpected antibodies with known type A, B and O pool cells/panel cells if available. For each group, a pool of 3 different cells should be used. The blood should not be released until any discrepancy, if found, is resolved.

8.8.2 DETERMINATION OF Rh (D) TYPE

The Rh (D) type should be determined for each collection with anti-D reagent from two different sources using a validated method. It is preferable to use one IgM and another a blend, i.e., IgM and IgG. If blood is typed as D negative, it should be tested to detect D^u / weak D using the IAT method. When the test for weak D is positive, the label should read 'Rh (D) Positive'. When the test for weak D is negative, the label should read 'Rh (D) negative'.

8.8.3 PREVIOUS RECORDS

ABO and Rh typing of the donor shall be comparable to historical type, if available. However, the donor's previous record of ABO and Rh (D) type should not serve as identification of units of blood subsequently given by the same donor. A new determination should be made for each collection. The discrepancy with the previous record should be investigated and resolved.

8.8.4 TESTS FOR DETECTING UNEXPECTED ANTIBODIES IN SERUM

8.8.4.1 Serum or plasma from donors should be tested for unexpected antibody/ies with pooled O Rh (D) positive cells or preferably screening cell panel which shall include indirect AHG (anti-human globulin) test which can identify clinically significant antibodies. Appropriate controls shall be used.

8.8.4.2 Blood in which such antibody/ies are found should be used as packed cells only, provided that they are DAT negative.

8.9 TESTS FOR INFECTIOUS DISEASES

All mandatory tests shall be carried out on blood samples in pilot tubes taken at the time of collection. The whole blood or components from any unit that tests positive/ reactive/ initial reactive shall be discarded. Test methods for screening TTI shall be those approved by regulatory authorities.

8.9.1 TESTS FOR SYPHILIS: Each donation of whole blood shall be subjected to a serological test for syphilis by VDRL/ RPR Method / TPHA/ ELISA / CLIA or any other validated, sensitive method.

8.9.2 TESTS FOR VIRAL HEPATITIS: Test for hepatitis B (HBsAg) and hepatitis C (anti-HCV) by Enzyme-Linked Immunosorbent Assay (ELISA)/ Chemiluminescence Immunoassay (CLIA)/ or an alternative approved method with similar or higher sensitivity, which is a validated method should be done on each unit of blood. Any technology with similar or higher sensitivity, like nucleic acid test (NAT) may be used additionally to improve blood safety.

Small centres which do not have provisions to do ELISA/ CLIA may release blood after rapid tests. However, rapid testing is not recommended, and every effort should be made to shift to ELISA/CLIA.

8.9.3 TEST FOR HIV: All blood units collected shall be tested for HIV 1 & 2 antibodies using Enzyme-Linked Immunosorbent Assay (ELISA) / Chemiluminescence,

Immunoassay/ or an alternative approved validated method with similar or higher sensitivity, which is a validated method. Any alternative technology like nucleic acid test (NAT) with similar or higher sensitivity may be used.

8.9.4 Universal NAT testing in Blood Centre is recommended. It may be implemented in phased manner

8.9.5 TEST FOR MALARIA: All blood units should be tested for malarial parasites using a validated, approved and sensitive antigen test.

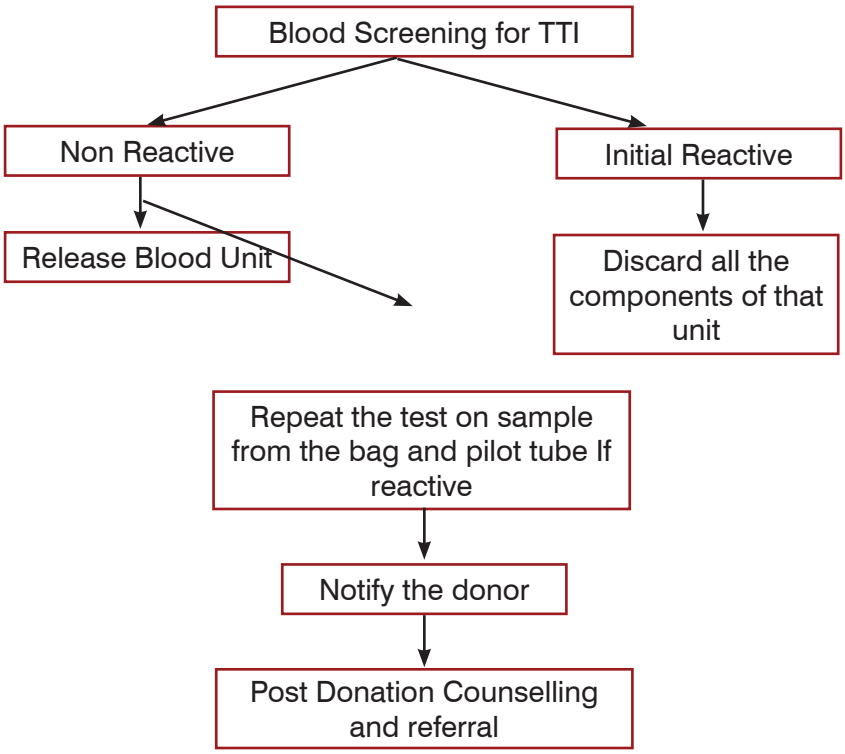
Any technology with similar or higher sensitivity may be used to improve blood safety. Use of 4th Generation kits for ELISA/ CLIA is recommended.

All initial sero-reactive blood units shall continue to be discarded as per the standard operating protocol of Blood Centre and in compliance with Biomedical Waste Management Rules 2018.

Blood Centre shall repeat the test using the same technique using the pilot tube/ sample from the blood bag prior to recalling the donor for counselling and referral as per guidelines issued by competent authorities from time to time.

8.9.6 **ALGORITHIM FOR RELEASING BLOOD/ COMPONENTS AFTER TTI TESTING**

FLOW CHART FOR RELEASE OF BLOOD



(Follow the guidelines of NBTC for blood donor notification, counselling and referral)

8.10 BLOOD COMPONENTS

8.10.1 GENERAL:

8.10.1.1 Sterility: The sterility of all components shall be maintained during processing by the use of aseptic methods and sterile pyrogen-free disposable bags and solutions.

8.10.1.2 Seal: Blood bags that allow transfer of component without breakage of the seal (closed system) shall be recommended. If the seal is not broken, the viability and

stability of the component are assured. The seal shall not be considered broken if a sterile connection device or sterile tube welder is used, resulting in a closed system.

Weld: A sterile connecting device is used to produce sterile welds between two pieces of compatible tubing; the weld should be inspected for completeness.

8.10.1.3 If the seal is broken during processing, components stored between $4^0C \pm 2^0C$ must be transfused within 24 hours and component stored between $22^0C \pm 2^0C$ should be transfused as early as possible and not beyond 6 hours.

8.10.1.4 Once the frozen components are thawed, these shall be transfused at the earliest and positively within 6 hours.

8.10.1.5 At the time of preparation of the final components, the integrally connected tubing shall be filled with an aliquot of the components and sealed in such a manner that it shall be available for subsequent compatibility and assay testing if needed.

8.10.1.6 A process of feedback should be in place with the clinician in order to periodically assess the efficacy of all blood components.

8.10.2 RED BLOOD CELL COMPONENTS

8.10.2.1 Packed Red Blood Cells

Red blood cell concentrate shall be prepared from the whole blood collected in plastic bags, preferably in double or multiple plastic bags systems. Plasma is separated from red blood cells following either centrifugation or undisturbed sedimentation at any time before the expiry date of blood. If the closed system is in use, the expiry date of red cells should be the same as whole blood. The RBC units of packed cells should be adjusted so that it is between 65%- 75% when stored in CPDA1 solution and 55%- 65% when stored in SAGM solution. Packed red cell aliquot if prepared for transfusion to paediatric patients, sterility shall be maintained during preparation and preservations.

8.10.2.2 Saline Washed Red Cells

Red blood cells should be washed with normal isotonic saline by an automatic cell washer or manually by centrifugation that will remove almost all the plasma. The cells should be washed 2-3 times with normal saline by centrifuging at $2^0C \pm 8^0CA$ closed system of washing is recommended. If washing is done in an open system, the expiry of the components shall be within 24 hours, if preserved at 4-6° C. . A laminar bench that is validated from time to time should be used.

8.10.2.3 Leucodepleted red blood cells

Red blood cells shall be labeled as Leucoreduced or Leucodepleted provided the unit contains less 5 millon ($5x10^6$) white blood cells. The method used for leucoreduction and its QC shall be specified by the blood centre. The loss of red cells during leucodepletion shall not exceed 15%. Buffy coat reduced red blood cells shall contain white blood cells less than $5x10^8$ per unit.

8.10.2.4 Red blood cell low volume

Acceptable variation in whole blood volumn is +/- 10%. This means for a 450 ml collection, acceptable range is 405 to 495 ml. The acceptable variation for 350 ml or other collections shall be proportationally calculated by the blood cenre.

When 300 to 404 ml of whole blood is collected into an anticoagulant volume calculated for 450+ 63 ml, red blood cells prepared from the resulting unit shall be labelled Red Blood Cell low volume. No other components shall be made from a low volume collection.

8.10.2.5 Frozen and deglycerolised red blood cell concentrate

Red cells should be stored frozen continuously at a low temperature of-80^0 to -196^{0}C in the presence of cryoprotective agent. The red cells should be washed to remove the cryoprotective agent prior to transfusion. The method of preparation, storage, thawing and washing should ensure recovery of at least 80% of original red cells or larger depending on the procedure in use.

Red blood cells should be ordinarily frozen within 6 days of collection of blood and can be kept frozen for up to 10 years. The cryoprotective agent in most common use is glycerol. The concentration of glycerol used should depend on the storage temperature.

8.10.2.6 Irradiated red cells

They are prepared by gamma irradiations or x- radiation at 25Gy to prevent graft versus host disease due to the proliferation of lymphocytes. The unit will be transfused within 28 days from the date of irradiation or as per regular shelf life whichever is lower

8.10.2.7 Apheresis red blood cells

Blood Centre shall have policy and procedure for apheresis red cells collection by validated method. Donor selection criteria for Apheresis red cell collection shall be appropriately modified as per regulatory requirement.

8.10.3 PLATELET CONCENTRATE:

Platelet concentrate should be prepared by centrifugation of a single unit of whole blood collected with a smooth venepuncture and a continuous flow of blood.

8.10.3.1 Platelet concentrate should be separated from whole blood within 6 hours of collection by centrifugation at 22^{0}C +/- 2^{0}C using either platelet-rich plasma (PRP) or buffy coat (BC) method, which is validated.

8.10.3.2 Platelet concentrate prepared from 450 ml whole blood should contain a minimum 5.5x10^{10} platelets and from 350 ml whole blood minimum of 3.5x10^{10} platelets in at least 75% of units tested from 1% total prepared or 4 units every month, whichever is higher. It is recommended that only 450 ml bags are used for platelet separation.

8.10.3.3 Platelets should be suspended in approximately 50 ml of plasma and stored at 22^{0}C +/- 2^{0}C. The pH at storage temperature should not be lower than 6.0 at the end of the storage period.

8.10.3.4 Continuous gentle agitation (60-70 oscillations / per min) using a horizontal agitator or a rotor with 5–10 cycles/minute should be maintained throughout the storage period varying from 3-5 days depending on the nature of the plastic of the bag in use considering the day of blood collection as day zero.

8.10.3.5 There should be no grossly visible platelet aggregates during the storage. The swirling phenomenon should be checked daily and before issue.

8.10.3.6 The concentrate prepared should not be contaminated with red cells. The degree of a reddish tinge of the concentrate indicates red cell contamination. The units contaminated with red cells should be used as group-specific.

8.10.3.7 A total of 1% of all platelet concentrates prepared should undergo tests for bacterial detection by a validated method as part of routine quality control.

8.10.3.8 Preparation of pooled platelet concentrate: One single unit of random donor platelets is not enough to provide an adequate haemostatic dose in an adult patient. Therefore, up to 6 units of random donor platelets, preferably ABO or Rh type matched, are pooled into one bag of “Pooled Platelet Concentrate”.

8.10.3.9 The preparing facility shall maintain records of the ABO/Rh, donation identification number, and collecting facility for each unit in the pool.

8.10.3.10 The pooled platelets may be prepared by pooling buffy coats and then processed into one unit of buffy coats pooled platelet concentrate. Alternatively, pooling can be done after the preparation of random donor platelets by platelet-rich plasma method or buffy coat method.

8.10.3.11 If the pooling is done in an open system (using spikes for pooling), the shelf life of the pooled platelets will be 6 hours, while for a closed system (using the sterile connecting device) the expiry date will be that of the platelet unit having the shortest expiry date.

8.10.3.12 The labelling requirements for the final pooled product shall remain the same as any other platelet product except that the final pack should have a unique pool number or donation numbers of all contributing units.

8.10.3.13 The platelet content in the pooled product should be $\geq 2 \times 10^{11}$/unit. Modified platelet components include leucodepleted, irradiated, washed platelets or platelets suspended in additive solution.

8.10.3.14 To label the platelets as leukoreduced platelets, it should have a white cell count of less than 5 million (5×10^6) per unit.

8.10.3.15 Platelet-rich plasma: plasma which is rich in platelets and separated from whole blood.

8.10.4 GRANULOCYTE CONCENTRATE

8.10.4.1 Granulocyte concentrate is prepared by pooling multiple units of buffy coat or by apheresis. Pooled granulocytes and apheresis granulocytes should have $1x10^{10}$ leucocytes and should be kept at $22^oC+/- 2^0C$ for a maximum period of 24 hours.

8.10.4.2 Granulocytes, pooled, are made by pooling up to 12 ABO identical buffy coats suspended in either ABO matched plasma or additive solution, as per need.

8.10.4.3 Individual Granulocytes shall have $0.5\text{-}1 \times 10^9$ and pooled granulocyte concentrates shall have 1×10^{10} granulocytes per unit.

The recommended dose for an adult is 1-2 units daily and for a child 0.3×10^9 granulocytes/kg.

8.10.4.3 Granulocytes, pooled have a significant content of red blood cells, lymphocytes and platelets and must be irradiated.

8.10.4.4 Granulocytes, pooled are not suitable for storage and must be transfused to ABO compatible recipient as soon as possible after collection. At the very latest, transfusion should commence by midnight on the day following donation (day 1).

8.10.5 PLASMA

8.10.5.1 Plasma: Plasma should be separated from whole blood at any time up to 5 days after the expiry of the whole blood. The plasma separated after 5 days of expiry date should be used only for fractionation.

8.10.5.2 Fresh Frozen Plasma: Fresh plasma frozen within 6 hours after blood collection and stored at a temperature not warmer than minus 30 degree centrigrade, shall be preserved for a period of not more than one year. Prior to infusion the frozen plasma should be thawed rapidly at $30\text{-}37^0C$ either in a water bath with a shaker/ or in a similar validated equipment. Once thawed it should be used within 6 hours at room temperature or till 24 hours if kept in refigerator, at 4^o C.

Fresh frozen plasma should contain a minimum of 70 IU of F VIII per bag in at least 75% of units tested i.e. 1% of total manufactured or 4 units/ month, whichever is higher.

8.10.5.3 Plasma frozen within 24 hours after phlebotomy: Plasma frozen within 24 hours after phlebotomy shall be prepared from whole blood or apheresis collection. The product prepared from a whole blood collection must be separated and placed at -18^{0}C or below within 24 hours from whole blood collection. When prepared from an apheresis collection, the product is stored at 1 to 6^{0}C within 8 hours of collection and frozen at -18^{0}C or colder within 24 hours of collection. This type of component is recommended for fractionation.

8.10.5.4 Plasma frozen within 24 hours after phlebotomy held at room temperature up to 24 hours after phlebotomy: Plasma frozen within 24 hours after phlebotomy held at room temperature upto 24 hours after phlebotomy shall be prepared from an apheresis plasma collection. The product can be held at room temperature for upto 24 hours after collection and then frozen at <-18^{0}C. This type of component is recommended only for fractionation.

8.10.5.5 Liquid plasma: Plasma in a unit of whole blood, if separated at any time during storage upto 5 days of expiration and if not frozen, it is called liquid plasma. It is stored at 2 to 6^{0}C . This type of component is recommended for fractionation.

8.10.5.6 Thawed Plasma: Thawed plasma shall be prepared from fresh frozen plasma, plasma frozen within 24 hours after phlebotomy or plasma frozen within 24 hours after phlebotomy held at room temperature up to 24 hours after phlebotomy that has been collected in a closed system. This type of component is recommended for fractionation.

8.10.5.7 Pathogen inactivated plasma: Plasma can be treated to inactivate microbial agents for pathogen reduction by a validated method.

8.10.5.8 Cryo poor plasma or Factor VIII Deficient Plasma: This is plasma from which cryoprecipitate has been removed. It should be stored at -30^{0}C or lower and, once thawed, should be used within 6 hours.

8.10.6 CRYOPRECIPITATE (Concentrate of anti-hemophiliiac factor)

Concentrate of anti-haemophiliac factor shall be prepared by thawing FFP at 4^{o}C in a cold room or blood centre refrigerator or 4-10^{0}C in a cryobath. Minus 80^{o}C deep freezer should be used for faster freezing of plasma for preparation of cryoprecipitate.

8.10.6.1 Thawed plasma should be immediately centrifuged and separated from the cold insoluble material under sterile conditions.

8.10.6.2 The cryoprecipitate is the cold insoluble material and should be frozen within 1 hour and should be kept at -30^{0}C or lower up to 1 year. Once thawed, it should be used within 6 hours.

8.10.6.3 The component should have a volume of 15-20 ml, should contain a minimum of 80 IU of factor VIII and 150 mg of fibrinogen per bag in at least 75% of units tested out of 1% of total manufactured or 4 units/month whichever is higher.

8.10.6.4 Preparation of pooled cryoprecipitate: One single unit of cryoprecipitate is not enough to provide an adequate haemostatic dose in an adult patient. Therefore, multiple units of cryoprecipitate may be pooled in one bag. Cryoprecipitate units can also be pooled immediately before transfusion. If the pooling is done in an open system (using spikes for pooling), the shelf life of the pooled cryoprecipitate will be 6 hours at room temperature. The number of units for pooling can range from 4-10 units

8.10.6.5 The labelling requirements for the final pooled product shall remain the same as any other cryoprecipitate product except that the final pack should have a unique pool number or donation numbers of all contributing units.

8.10.6.6 Quality parameters of the pooled unit are calculated by multiplying the number of units with 80 IU for factor VIII and 150 mg for fibrinogen.

8.10.7 QUARANTINE STORAGE

The whole blood or components shall not be issued for transfusion till the mandatory tests are completed and reported as non-reactive. In order to ensure this procedure, the untested blood shall be kept in quarantine storage. The units which test reactive in any test shall be segregated immediately and kept in a separate quarantine area till sent for disposal. It is preferable to use biohazard labels.

8.10.8 STERILITY

Each donation of whole blood or its component intended for transfusion constitutes a single batch. The sterility of the blood should be checked on 1% of the blood units collected or 4 per month, whichever is higher. The sterility test should not be done by a method that entails breaching the final container before the blood is transfused. The blood sample from the tubing attached to the container should be used for sterility testing, i.e. culture at 4°C, 22°C & 37°C.

8.10.8.1 The Blood Centre should establish a procedure to identify a recipient of a transfusion of blood from a donor who is subsequently found to have been infected with transfusion transmissible infection. In case, this happens the Blood centre should inform the patient's physician. An appropriate record of such events should be kept. The unused components from this unit should be discarded.

8.11 COMPATIBILITY TEST

8.11.1 A sample taken from a segment attached to the bag shall be used for compatibility tests. It is desirable that the cross-matching sample is different from the orignal blood grouping sample. Wherever possible historical records of blood grouping shall be verified before compatibility testing. The method used should demonstrate ABO incompatibility and clinically significant unexpected complete and/or incomplete antibodies.

The compatibility test for red cells shall include antiglobulin test or similar sensitive validated techniques to detect incomplete/ unexpected antibodies.

8.11.2 If clinically significant antibody/ies are detected in the recipient, blood lacking corresponding antigens on cells should be crossmatched. If the facility for same is not available, cross-match compatible blood (by trial method) may be issued. In certain clinical conditions, where auto antibodies are present, the least incompatible unit shall be issued, depending on the clinical requirement and with specific instructions to the clinicians.

8.11.3 Minor cross matching using donor's serum or plasma and recipient's cells shall not be necessary as tests for complete and incomplete unexpected antibodies in donor samples are mandatory.

8.11.4 Retaining and storing of blood samples: The recipient's and donor's blood samples should be retained for 7 days at 4°C to 6°C+/- 2°C after each transfusion. In case of a need for transfusion after 48 hours of earlier transfusion, a fresh sample should be asked for to perform a cross match.

8.12 SELECTION OF BLOOD AND COMPONENTS FOR TRANSFUSION

8.12.1 Whole blood, red cell components: The recipient should receive ABO group-specific whole blood or ABO group-specific/ compatible red blood cell components. Rh(D) negative recipient should receive Rh(D)negative whole blood or red blood cell components except for reasonable qualifying circumstances when Rh-positive may be issued only when Rh antibodies are absent and with due consent of treating physician. Rh(D) positive recipient can receive either Rh(D) positive or negative whole blood or red blood cell components.

8.12.2 If clinically significant unexpected antibodies are detected in the recipient, whole blood or red blood cells component which do not have corresponding antigens and are compatible should be transfused. Transfusion services should have a policy concerning transfusion of components containing significant amounts of incompatible ABO/ unexpected red blood cell antibodies.

8.12.3 Single donor plasma and fresh frozen plasma: Single donor plasma or fresh frozen plasma should be ABO group-specific/compatible with the recipient's red blood cells. In neonates, ABO group specific plasma should be preferred. Cryoprecipitate should not require ABO/ Rh grouping.

8.12.4 Platelet concentrate: Platelet concentrate should be ABO and Rh(D) type-specific with the recipient blood as far as possible. In case of shortage, random donor platelets of any ABO/Rh group shall be used provided there is no visual red cell contamination of the platelet concentrate. In such cases, red blood cells should be ABO compatible with the recipient's plasma. In the case of single donor platelets prepared by apheresis, plasma should be reduced when incompatible plasma is in use (e.g. use of 'O' group SDP to B patient).

8.12.5 Granulocyte concentrate: Leucocyte concentrate should be ABO and Rh(D) type-specific or compatible with the recipient blood and same should be irradiated.

8.13 MASSIVE TRANSFUSION

When an amount of blood approaching or exceeding the recipient's total blood volume is transfused within 24 hours, a fresh blood sample should be used for the cross match at the time of subsequent transfusion of blood. Component therapy should be actively considered, as per massive transfusion protocols, in these cases.

8.14 NEONATES

8.14.1 For ABO grouping, only cell grouping with anti-A, anti-B and anti-AB sera should be required. DAT shall be done as a part of neonatal blood grouping.

8.14.2 Serum of the mother should be tested for unexpected antibody / ies.

8.14.3 In the management of haemolytic disease of the new born, it is preferable to use the mother's serum for cross-matching. In the absence of a mother's serum, the child's serum should be used for compatibility testing. If a non- group O neonate is to receive non-group O red blood cells that are not compatible with the maternal ABO group, the neonate's serum or plasma shall be tested for anti A or anti B.

8.14.4 Neonatal recipient shall not be transfused with whole blood/plasma/ component containing clinically significant antibodies. Red cells with additive solutions are generally avoided for neonatal transfusions.

8.14.5. For exchange transfusion or in hypoxic condition, it is recommended that the donors are screened for Haemoglobin S in geographic regions where Hb S is prevalent.

8.14.6 Paediatric blood collection bags are available and should be preferred. Normal blood collection bags should not be used for collecting lesser volume after removing the proportionate amount of anti-coagulant solution.

8.14.7 Red blood cells less than 5-7 days old shall be used for exchange transfusion.

8.15 RECIPIENTS

8.15.1 Blood Request Form: The request form for whole blood or components accompanied by the recipient's blood samples shall be legible and shall have the following information:

- Recipient's name
- Age, sex, ward and bed number
- The blood group of the recipient if done earlier
- Name of the head of treating unit
- Amount of blood/component needed
- Date and time of blood component requirement
- Routine/emergency/ life saving
- Diagnosis
- Indication for transfusion- Hemoglobin / platelet count
- History of the previous transfusion
- Obstetric history in the case of a female patient
- Name of the hospital/ Hospital Registration number
- Signature of the medical officer
- Name and signature of the phlebotomist collecting patient's sample

The request form should indicate that the patient's consent for transfusion has been taken. BTS should accept only complete, accurate and legible requests.

8.15.2 BLOOD SAMPLES

8.15.2.1 Blood samples of the recipient should be obtained in a (1) stoppered plain vial/tube (2) vial/tube containing anticoagulant/ EDTA, with labels having:

- Patient's full name
- Identification number
- Name of hospital
- Ward/bed number
- Date and time
- Phlebotomist's signature/ initials (identification number if available)

BTS should have the policy to minimize the risk of misidentification of the patient's pre-transfusion sample.

8.15.2.2 When the recipient's blood sample is received in the laboratory, a qualified member of the staff should confirm that the information on the label and on the transfusion request form are identical. In case of any discrepancy or doubt, a new sample should be obtained.

8.15.2.3 Retaining and storing of blood samples: The recipient's and donor's blood samples should be retained for 7 days at 4^0C +/- 2^0C after each transfusion. In case of a need for transfusion after 72 hours of earlier transfusion, a fresh sample should be asked to perform a cross match.

8.15.3 BLOOD UNIT IDENTIFICATION

8.15.3.1 A unique numeric or alphanumeric system should be used that will make it possible to trace any unit of blood or component from source to final destination and to recheck records applying to the specific unit.

8.15.3.2 The numeric and alphanumeric identification on the label shall be provided by the collecting facility to each unit of blood/ components. This number shall be documented for traceability. Any advanced technology for identification, such as a barcode system, is preferable.

8.15.3.3 A maximum of two numeric or alphanumeric identification should be on a blood or component container, i.e., that of the original collecting facility. This does not preclude the use of patient identification. Donor's name should not be written on the label. In case of transfer of blood to another Blood centre, the original label with the same identification should be retained.

8.15.4 LABELLING FOR WHOLE BLOOD/ COMPONENT

8.15.4.1 A system shall be in place to ensure that the final container is labelled only after all mandatory testing is completed as per regulatory requirements.

The Requirements should ensure

- Traceability of products
- Appropriate storage and handling of units
- Appropriate selection of units for transfusion

8.15.4.2 The label shall be attached firmly to the container and should be clear and readable. Any hand-written information shall be legible and in permanent and moisture-proof ink.

8.15.4.3 After processing of blood/ components, a final label shall be affixed on the bag with detailed information as mentioned in clause 8.5

8.15.4.4 Label for Instructions for transfusion. Transfusion instructions in labels shall include as per regulatory requirements.

8.16 STORAGE, TRANSPORTATION AND SHELF LIFE OF BLOOD AND COMPONENTS

8.16.1 A designated area shall be used for storage to limit deterioration and prevent damage to materials in-process and final products. The access to such areas shall be controlled.

8.16.2 Refrigerators or freezers in which blood and blood components are stored should be used to store blood, blood components and blood samples only and not for any other items. All reagents should be stored in separate refrigerators in specific laboratories.

8.16.3 Blood Centre refrigerator/walk-in-cooler should have an inside temperature of $4^0C \pm 2^0C$ and should have a system to monitor temperature continuously, or at least the temperature should be recorded every 4 hours. An alarm system and a provision for an alternate power supply should be available.

8.16.4 Deep freezer should have an inside temperature of -30^0C or -80^0C having a temperature indicator/recording facility with an alarm system and provision for an alternate power supply.

8.16.5 Platelet incubator with agitator should have an inside temperature of 22^0C +/- 2^0C having temperature indicator/recording facility with alarm system and provision for

alternate power supply. The equipment should keep the platelet units in continuous gentle agitation.

8.16.6 Adequate alternate storage facility and written display of instructions to maintain the blood and components in the event of failure of power or equipment should be provided in the area of preservation. The alarm of all storage equipment should signal in an area that has adequate personnel coverage round the clock to ensure immediate corrective action.

8.17 TRANSPORTATION

Whole blood, red cell concentrate, should be transported in a manner that will maintain a maximum temperature of 10^0C. Platelet/ granulocyte concentrate are stored and transported at 22^0C ± 2^0C. Components stored frozen should be transported in a manner to maintain them frozen. When these are issued for transfusion, these should be thawed at 37^0C prior to issue. The temperature during transport should be monitored. Appropriate transportation boxes shall be used in order to ensure that the cold chain is maintained. In case of temperature controlled transportation, the temperature of blood unit should not go beyond 10^oC .

8.18 STORAGE AND EXPIRATION

8.18.1 WHOLE BLOOD

8.18.1.1 Whole Blood should be stored at 4^0C ±2^0C.

8.18.1.2 Whole blood collected in anticoagulant citrate-phosphate-dextrose solution (CPD) should have an expiry date, not exceeding 21 days after phlebotomy. Whole blood collected in anticoagulant citrate-phosphate-dextrose with adenine (CPDA-1) should have an expiry date not exceeding 35 days after phlebotomy.

8.18.1.3 Whole blood in heparin solution should have an expiry period not exceeding 24 hours after collection.

8.18.2 RED CELL COMPONENTS

8.18.2.1 Packed Red Blood Cells: Red blood cells which are separated in a closed system shall have the same expiry date as the whole blood from which it is prepared. The time of removal of plasma is not relevant to the expiry date of red cell concentrates. However, if an open system is used, the expiry date shall be 24 hours after separation. Red cell concentrate should be stored at 4^0C +/- 2^0C. Red cells containing additive solutions such as SAGM, ADSOL, and NUTRICEL should be stored up to 42 days, with the day of collection considered as day zero. At midnight (12 'O' clock) the day is completed, e.g., if platelets are separated on the first of the month, the expiry date should be 6th midnight.

8.18.2.2 Frozen Packed Red Cells: The expiry date for glycerolized (low or high) frozen red cells is 10 years and shall be stored between -80^0 and -196^0C.

8.18.2.3 Washed and Deglycerolised Red Blood Cells: Washed red blood cells and deglycerolized red blood cells shall be stored at 4^0C +/- 2^0C and should be transfused as soon as possible and within 24 hours after processing.

8.18.2.4 Leucodepleted Red Csells: Leucocyte-poor red blood cells shall be stored at 4^0C +/- 2^0C. It shall have the same expiry date as whole blood from which it has been prepared if a closed system is used. In the case of an open system, the expiry shall be within 24 hours.

8.18.3 PLATELET CONCENTRATE

The platelet concentrate shall be stored between 22^{0}C +/- 2^{0}C with continuous gentle flatbed agitation (60-70/min), or a rotor (5–10 cycles/min.) maintained throughout the storage period. The expiry date of platelet concentrate prepared in a closed system shall be 3 or 5 days (as per manufacturer's instructions) after the collection or as specified by the regulator from time to time.

8.18.4 GRANULOCYTE CONCENTRATE

The storage temperature for leucocyte concentrate is 22^{0}C +/- 2^{0}C. It should be transfused as soon as possible and not later than 24 hours of phlebotomy.

8.18.5 PLASMA

8.18.5.1 Plasma: Plasma should be separated from whole blood at any time up to 5 days after the expiry of the whole blood. The plasma separated after the expiry date shall be used for fractionation. If separated during shelf life, it should be stored for 1 year at -30^{0}C or lower and used as plasma for transfusion.

8.18.5.2 Fresh Frozen Plasma and Cryoprecipitate: These components shall be stored at -30^{0}C or below and should be stored no longer than 12 months. If Fresh Frozen Plasma remains unused at the end of 1 year at -30^{0}C, it may be labelled as "plasma" AND used up to 5 years (i.e. 4 more years).

8.18.6 Source plasma for fractionation: In case of excess plasma, the Blood Centre should send plasma for fractionation to an indigenous plasma fractionator in India. Proper documentations, intimations/ permissions to concerned authorities etc., shall be followed as per NBTC guidelines.

8.18.7 EXPIRY DATE

The expiry date of any component shall be calculated by considering the day of collection as day zero.

8.19 ISSUE OF BLOOD/ COMPONENT FOR TRANSFUSION

8.19.1 Blood shall be issued from the Blood centre along with the blood cross-matching report form/ compatibility report. A portion of the integral tube with at least one numbered segment should remain attached with the blood bag being issued.

8.19.2 The cross-matching report form shall have the patient's first name with surname, age, sex, identification number, ward, bed number, ABO and Rh(D) type.

8.19.3 The form shall have donor unit identification number, segment number, ABO and Rh(D) type and expiry date of the blood.

8.19.4 Interpretation of cross-matching/ compatibility report and the name of the person performing the test and issuing the blood should be recorded.

8.19.5 A label or a tag with the patient's name, hospital, identification number, blood unit number assigned by the collecting/intermediary facility, interpretation of the cross-matching test should also be attached to the blood bag container before it is released from the Blood centre.

8.19.6 Each unit of blood should be visually inspected before issue. It should not be issued if there is any evidence of leakage, hemolysis or suspicion of microbial contamination such as unusual turbidity or change of colour.

8.19.7 Reissue of Blood: It is recommended that blood, once issued, should not be taken back by the Blood centre, especially if the cold chain is broken and the blood is returned to the Blood Centre after 30 minutes.

The Blood centre shall have a policy for acceptance and reissue of blood unit returned within 30 minutes or after 30 minutes when the cold chain has not been broken.

8.19.8 Urgent Requirement of Blood

8.19.8.1 Blood Centre shall have written guidance for routine, urgent and life saving situations

Blood or blood components shall be issued before completion of routine cross-matching tests in cases where delay in providing blood may jeopardize the patient's life. On receipt of a signed written request of the treating physician stating that the clinical condition of the patient requires urgent blood may be released before completing ABO, and Rh(D) tests and compatibility testing. Records of such requests should be retained for 5 years as per the relevant standards.

8.19.8.2 Under such circumstances, recipients whose ABO and Rh(D) type is not known shall receive red cells of group O Rh(D) negative if available; otherwise, O Rh(D) positive blood shall be used as a lifesaving measure. Such events shall be documented.

8.19.8.3 Recipient whose ABO, Rh(D) type has been determined shall preferably receive ABO and Rh(D) specific blood group whole blood or ABO and Rh(D) compatible packed red cells before the tests for compatibility have been completed. Acceptable scientific practices shall be allowed by standards.

8.19.8.4 However, a standard compatibility test should be completed promptly. If a discrepancy in the result is noted, the concerned clinician should be informed immediately to discontinue the transfusion.

8.20 BULK TRANSFER OF BLOOD AND COMPONENTS

8.20.1 In case of low inventory and to maintain adequate supply to patients by a licensed Blood Centre, blood and components from another licensed Blood Centre may be taken into the inventory of the first Blood centre.

8.20.2 Proper documentations, intimations to concerned authorities, maintenance of cold chain etc., shall be followed as per guidelines laid down by the NBTC.

Annexures:

Annexure-4. Criteria for selection of blood donors (page no: 79)

Annexure-5. Infectious makers testing and referral strategy (page no: 86)

Annexure-6. Stages of blood donor counselling (page no: 88)

Chapter-9:
Quality Assurance

9.1 GENERAL

9.1.1 Blood Centres shall maintain quality assurance to ensure that the products produced are fit for their purpose, free from infection risk and containing required bioactive substances to provide clinical benefit.

9.1.2 Quality assurance of blood components should be periodically assessed to ensure that their safety and consistency are appropriately controlled for their intended use.

9.1.3 From the total collection, 1% or a minimum of 4 units of each component produced per month, whichever is higher, shall be tested for quality control, out of which 75% should match the acceptable ranges.

9.1.4 Quality control of all reagents shall be carried out to ensure that the test is working accurately to produce valid and acceptable results.

9.1.5 Internal and external quality control shall be carried out to ensure that the tests performed are as per the protocol and the results obtained are reliable and reproducible.

9.1.6 Blood Centres shall participate in a proficiency testing program conducted by NBTC.

9.1.7 The records of all quality control shall be maintained.

9.2 ABO AND ANTI-D REAGENTS

9.2.1 A vial of every new batch shall be checked for its potency (titre) besides specificity and avidity on receipt.

9.2.2 All the antisera and other reagents used for serological work in the Blood Centre shall be checked daily for their specificity and avidity, using known positive and negative controls

9.2.3 All reagents showing turbidity and discolouration suggesting contamination shall be discarded.

9.2.4 Manufacturer's insert shall specify titre, avidity and all other relevant information.

9.2.5 Methods followed shall be as per manufacturer's instructions. No reagents after the date of expiry shall be used.

9.2.6 At any given time, there shall be two different batches of anti-D reagents available- either from two different manufacturers or two different batches from the same manufacturer.

9.3 REAGENT CELLS

9.3.1 Cells shall be prepared daily and shall be free of haemolysis. There shall be a minimum pool of 3 individual cells for each group.

9.3.2 Each batch of reagent cells (A, B and O) for serum grouping prepared shall be tested to confirm specificity.

9.4 RED CELL PANEL

9.4.1 Either commercially available or prepared in house panels shall be in use.

9.4.2 The red cells shall be stored frozen or at 4^0C.

9.4.3 Commercially available red cell panel shall not be used beyond the expiry date of red cells. However, expired red cell panel can be used for solving complicated immunohematology cases as select cells using controls provided the facility shall have a proper Standard Operating Procedure (SOP) in place.

9.5 ANTI-HUMAN GLOBULIN REAGENT

9.5.1 One vial from every new batch shall be checked for its specificity and reactivity using (incomplete anti-Rh) IgG coated cells.

9.5.2 Each test shall include positive and negative controls.

9.5.3 Non-sensitised A, B and O cells shall be checked to rule out non-specific reactions.

9.5.4 All negative AHG tests shall be confirmed by the addition of IgG coated cells in the test. IgG coated cells shall give positive agglutination.

9.6 BOVINE SERUM ALBUMIN

9.6.1 The reagent shall be free of the non-specific agglutinins and shall not react with the saline suspension of A, B and O cells.

9.6.2 Reagent shall give a positive reaction with Rh(D) positive cells coated with incomplete anti-Rh(D).

9.7 ENZYME REAGENTS

9.7.1 Enzymes such as papain, ficin, trypsin or bromelin shall be used for the detection of incomplete antibodies depending upon types of antibodies.

9.7.2 Using the standard technique employed by the individual laboratory, the reagent shall give specific results using incomplete anti-Rh(D) with positive and negative controls.

9.7.3 Preparation of working reagent shall be by standard method.

9.7.4 Enzymes shall be aliquoted and stored in a frozen state. The only required amount for the the day shall be thawed.

9.7.5 The unused enzyme remaining at the end of each day shall be discarded.

9.8 HEPATITIS B ANTIGEN, ANTI-HCV AND ANTI-HIV 1 & 2 TEST

9.8.1 Use of enzyme-linked immunosorbent assay (ELISA)/ Rapid test is recommended, using kits approved by CDSCO. Any other recently approved technology with the same or increased sensitivity may be used.

9.8.2 Test shall be performed as per the instructions of the manufacturers.

9.8.3 Positive and negative controls (kit and in-house) shall be run with every batch and shall be interpreted with Levy-Jennings Chart (L-J Chart) and as per Westgard Rules.

9.8.4 Rapid tests approved by CDSCO shall be used for screening in an emergency; in rural areas or any centre collecting small volumes or where power and equipment maintenance is a problem.

9.8 TEST FOR SYPHILIS

9.8.1 VDRL or TPHA or RPR or ELISA or CLIA or any other validated approved method can be used.

9.8.2 Test shall be performed as per manufacturer's instructions. Positive and negative controls (kit and in-house) must be included with every test.

9.9 NORMAL SALINE AND BUFFERED SOLUTIONS

9.9.1 These solutions shall be checked daily for pH (6.7-7.2). The absence of haemolysis with random A, B and O cells provide a useful indication for its suitability.

9. 10 QUALITY CONTROL OF COMPONENTS

9.10.1 WHOLE BLOOD: Volume shall be 350/450 ml$\pm$10% (in 350 ml or 450 ml bag), PCV shall be greater than 30 %, and the units shall be sterile on culture. All units shall be TTI negative, including HBsAg, Anti HCV, Anti HIV 1 & 2, Syphilis and Malaria

9.10.2 RED CELL CONCENTRATE (Prepared from 450 ml blood in CPDA1 solution): The volume of PRC units from 450 ml blood in CPDA1 solution shall be 250 ml +/-10%, Hct shall be 65-70 %, and the units shall be sterile on culture.

9.10.3 RED CELL CONCENTRATE (Prepared from 350 ml blood in CPDA1 solution): Red cell units prepared from 350 ml blood in CPDA1 solution volume shall be150 ml +/-10%, Hct shall be 65-70 %, and the units shall be sterile on culture.

9.10.4 RED CELL in preservative solution prepared from 450 ml whole blood (ADSOL/SAGM): Red cell units prepared from 450 ml blood and in preservative solution (ADSOL/SAGM) volume shall be 300-400 ml +/-10% , Hct shall be 50-60 %, and the units shall be sterile on culture.

9.10.5 RED CELL in preservative solution prepared from 350 ml whole blood (ADSOL/SAGM): In PRC units from 450 ml blood in CPDA1 solution volume shall be 245 ml-325 ml, Hct shall be 50-60% and the units shall be sterile on culture.

9.10.6 LEUCODEPLETED RED CELLS

Residual white cells post filtration shall be less than 5X 10^{6}. In cases of apheresis, residual white cells in the units post apheresis shall be less than 5X 10^{6}.

9.10.7 PLATELET CONCENTRATE prepared from 350/450 ml of whole blood: Volume of platelet concentrate units prepared from 350/450 ml whole blood shall be 50-70 ml, the pH shall be>6.0 ,RBC contamination shall be <0.5 ml, and platelet count shall be 3.5- 4.5x10^{10}.

9.10.8 PLATELET CONCENTRATE prepared from buffy coat: The volume of platelet concentrate units prepared from buffy coat of 350/450 ml whole blood shall be 50-90 ml, the pH shall be>6.0, RBC contamination shall be <0.5 ml, and platelet count shall be 5.5x10^{10}. Four units of platelets should undergo quality control or 1% of all units (whichever is more)

9.10.9 PLATELET CONCENTRATE by apheresis: In platelet concentrate units by apheresis the volume shall be >200 ml in all units, the pH shall be>6.0, RBC contamination shall be <0.5 ml, and platelet count at the end of the permissible storage period shall be $\geq$3.0 x 10^{11}.

9.10.10 QUALITY CRITERIA for labelling platelet concentrates for labelling platelet concentrate (RDP) or apheresis platelets (SDP) as Leukoreduced/ Leucodepleted.

Basic criteria: Same as in 10.16, 10.17, 10.18. Additional criteria include residual leukocyte count in RDP <8.3X10^{5} and SDP <5X10^{6}

9.10.11 FRESH FROZEN PLASMA (FFP): The units shall have volume of 180-220 ml from 350 ml bag and 220-300 ml from 450 ml bag. The stable coagulation factors shall be checked by PT and APTT, the Factor VIII values shall be least70 iu/bag, and Fibrinogen value shall be more than 200 mg /bag.

9.10.12 CRYOPRECIPITATE (Factor-VIII): The volume in tested units shall be 15-20 ml, Factor VIII shall be at least 80 i.u. / bag and Fibrinogen values shall be at least 150mg/bag.

9.10.13 PLASMA (Frozen): The units shall have volume of 180-220 ml from 350 ml bag and 220-300 ml from450 ml bag. The stable coagulation factors shall be checked by PT and APTT.

9.10.14 GRANULOCYTES

Granulocytes from hemapheresis shall have granulocyte count of $1X10^{10}$ other leucocytes count 0.1X $0.7X10^{9}$, platelet count $2\text{-}10X10^{11}$, red cells 5–50 ml, plasma 200–400 ml and HES if used 6–12 % of volume. Granulocytes prepared from a single unit of blood shall have a volume of 200-250 ml and Granulocyte count of $0.5–1x10^{9}$.

Annexures:

Annexure-7. Specifications, acceptance criteria and quality control for reagents and blood/ components (page no: 89)

Chapter-10:

Biosafety and Waste Management

10.1 GENERAL:

Biosafety and waste disposal in the blood transfusion services need special attention because of:

10.1.1 Large volume of blood is collected and handled from apparently healthy asymptomatic donors

10.1.2 A significant amount of blood is discarded due to various reasons like seropositivity, contamination, out-dating or unsuitable units.

10.1.3 A greater degree of potential hazard among healthcare workers

10.1.4 Use of wide-bore needles for blood collection and a large amount of biological waste generated during the process (e.g. blood samples of blood donors/ patients, reagents, controls etc.)

10.2 MANDATORY BASIC RULES

10.2.1 Every BTS shall follow all applicable rules under Bio-Medical Waste (BMW) Management, and Handling Rules (2018) amended from time to time.

10.2.2 There shall be a proper agreement with an outsourced agency in case waste is disposed of by outside agency or any other modalities as approved by BMW Rules.

10.2.3 Every BTS shall have an SOP for waste handling, including generation, segregation, transportation, storage and disposal as per BMW Rules.

10.3 PROTECTION OF BLOOD CENTRE PERSONNEL AGAINST LABORATORY INFECTION

10.3.1 All laboratory personnel shall be informed of the hazards, including transmission of viral infection involved while working in a Blood Centre laboratory. Possible routes of infection may be skin abrasion or puncture or through body orifices.

10.3.2 Incidental exposure to infected samples like bag breakage, splash, needle stick injury shall immediately be reported to the concerned authorities.

10.3.3 Preventive inoculation of the Blood Centre staff against Hepatitis-B infection after appropriate tests shall be necessary. Immunization against hepatitis B infection shall be mandatory before joining service, after which their immune status will be determined.

10.3.4 All protective apparel for universal precaution shall be provided.

10.3.5 Access to areas such as Blood Centre laboratories, components preparations and storage should have restricted entry. The Blood centre must be restricted to authorized personnel only.

10.3.6 The staff shall be made aware of universal precautions. While centrifugation of test tubes, the lid of the centrifuge shall always be closed to prevent aerosol formation.

10.3.7 Wash hands before leaving the laboratory and before eating or drinking.

10.3.8 Wash hands immediately after they have been in contact with blood or blood products.

10.3.9 Wear disposable gloves when handling all materials suspected of being infective or when opening samples of blood.

10.3.10 Keep open wounds and cuts covered with an adhesive dressing or disposable gloves during working.

10.3.11 Never invert a tube containing blood or a blood derivative by covering the mouth of the tube with a finger. Cover the mouth of the tube with parafilm or with a similar product, if necessary.

10.3.12 Laboratory protective garments/ disposables: Always use a clean lab coat with buttons closed while working. If a laboratory coat becomes soiled with blood or serum, change to a clean one. The soiled coat shall be soaked in hypochlorite or autoclaved before it is laundered. Do not wear a lab coat when you proceed for lunch. Provide a lab coat to visitors also.

10.3.13 Do not put fingers or other objects such as pens in the mouth.

- Do not use mouth pipetting
- Eating, drinking, smoking is not permitted in any working area of the laboratory.
- No food or beverage be stored in any laboratory refrigerator, freezer, hot air oven or incubator.
- Always avoid needle stick injuries
- Never recap or bend needles
- Dispose of all sharps in puncture-proof containers
- In case of a needle stick injury, clean the area, wash the hand with the anti-septic and prepare an incident report.
- Post-exposure prophylaxis as per guidelines under State AIDS Control Programme.
- All work surfaces must be decontaminated before and after the routine work is begun and after any spillage.
- All contaminated waste or reusable materials must be appropriately decontaminated before disposal or reuse.
- All the waste produced at the mobile blood donation camps is also to be segregated at source and then transported back to the BTS for proper treatment and disposal.

10.4 DISPOSAL OF BLOOD AND LABORATORY MATERIAL

10.4.1 Method of Disposal of Blood Bags shall comply with requirements of Biomedical Wastes Rules of Ministry of Environment and Forests and local pollution control board.

10.4.2 Needles shall not be burnt in a needle cutter. Needles shall be disposed of in a puncture a proof container as per BMW Rules.

10.4.3 Disinfection of glassware**:** All reusable glassware shall be disinfected by treating with hypochlorite and detergent before cleaning. Subsequently, glassware shall be disinfected by keeping in a hot air oven at 160^{0}C for 1 hour.

10.4.4 Spills on the table tops/sinks: The spill shall be covered with filter papers or plain cloth and soaked with 1% hypochlorite solution for at least 30minutes and later swabbed. Soaked paper or cloth shall be treated as biohazardous waste material and discarded appropriately.

10.4.5 Hypochlorite – detergent solution 0.5-1.0% solution of hypochlorite may be used as general-purpose disinfectant if contact is maintained for at least 30 minutes. (Except for metallic equipment, which could be autoclaved or put in an appropriate medium).

10.4.6 Disposal by Sterilisation – Autoclaving for 30 minutes at 121^{0}C and 15 p.s.i. (68.5 cm Hg) is the method of choice. Validation with use of biological indicator (*B. stereothermophilus*) shall be done at least once a month. All modifications introduced by the Ministry of Environment and Forest, from time to time, shall be implemented.

10.5 BIOMEDICAL WASTE MANAGEMENT

10.5.1 GENERATION OF WASTE:

10.5.1.1 Non-risk waste: Kits or bags, packages, boxes and wrappings

10.5.1.2 Infectious waste:

- Gloves, gauze, swabs, used haemoglobin cuvettes contaminated with blood.
- Blood and blood component units discarded due to TTIs, expired and unsuitability.
- Used blood bags, transfer bags and accessories for component preparations.
- Segments from blood bag tubing. IV sets, used test tubes, micro-capillary tubes, and glassware, used syringes.
- Apheresis kits.
- Blood and serum samples.
- Red cell suspension for blood group serology testing.

10.5.1.3 Sharps

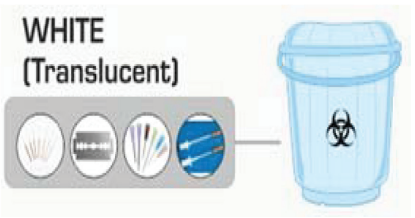
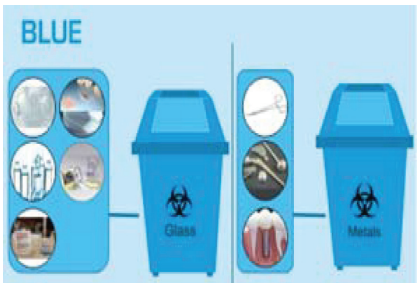
- Needles from blood collection bags, blood administration sets and other disposable needles.
- Broken test tubes, glass slides. Broken glassware and ampoules, lancets, scissors, wafers for sterile connecting devices

10.5.1.4 Chemical waste

- Anticoagulant solutions, Copper Sulfate, disinfectants, reagents, anti-sera, buffer solutions

Biomedical wastes categories and their segregation, collection, treatment, processing and disposal options

Category	Type of Waste	Type of Bag or Container to be used	Treatment and Disposal options
 Yellow	Soiled Waste: Items contaminated with blood, body fluids like cotton swabs and bags containing residual or discarded blood and blood components. Discarded linen, mattresses, beddings contaminated with blood or body fluid.	Yellow coloured non-chlorinated plastic bags	Incineration or Plasma Pyrolysis or deep burial*

Category	Type of Waste	Type of Bag or Container to be used	Treatment and Disposal options
	Blood bags	Autoclave safe plastic bags or containers	Pre-treat to sterilize with nonchlorinated chemicals on-site as per National AIDS Control Organisation or World Health Organisation guidelines thereafter for Incineration.
 Red	Contaminated Waste (Recyclable) (a) Wastes generated from disposable items such as tubing, bottles, intravenous tubes and sets, urine bags, syringes (without needles and fixed needle syringes) and vaccutainers with their needles cut) and gloves.	Red coloured non-chlorinated plastic bags or con tainers	Autoclaving or micro-waving/ hydroclaving followed by shredding or mutilation or a combination of sterilization and shredding. Treated waste to be sent to registered or authorized recyclers or for energy recovery or plastics to diesel or fuel oil or for road making, whichever is possible. Plastic waste shall not be sent to landfill sites.
 White (Translucent)	Waste sharps including Metals: Needles, syringes with fixed needles, needles from needle tip cutter or burner, scalpels, blades, or any other contaminated sharp object that may cause puncture and cuts. This includes both used, discarded and contaminated metal sharps	Puncture proof, Leak proof, tamper proof containers	Autoclaving or Dry Heat Sterilization followed by shredding or mutilation or encapsulation in a metal container or cement concrete; a combination of shredding cum autoclaving; and sent for final disposal to iron foundries (having consent to operate from the State Pollution Control Boards or Pollution Control Committees) or sanitary landfill or designated concrete waste sharp pit.
 Blue	(a) Glassware: Broken or discarded and contaminated glass including medicine vials	Cardboard boxes with blue colored marking	Disinfection (by soaking the washed glass waste after cleaning with detergent and Sodium Hypochlorite treatment) or through autoclaving or microwaving or hydroclaving and then sent for recycling.

Chapter-11:
Bed-Side Transfusion Practices

11.1 TRANSFUSION OF BLOOD AND COMPONENTS

GENERAL:

The final step in the transfusion of blood occurs at the bedside in the clinical setting. No matter how well the blood centre has observed quality norms, unless the clinical team also follows the procedures to ensure safe transfusion rigorously, the patient can be subjected to unnecessary and sometimes hazardous unintended results of transfusion. The Hospital Transfusion committee shall coordinate the dissemination of these best practices and ensure that all staff authorised to transfuse blood or any of its components are trained and deemed competent to do so.

11.1.1 INFORMED CONSENT

The patient shall be informed about his/her need for blood, alternatives available, as well as risks involved in transfusion and non-transfusion and document the same in the medical record that it has been done. His / her written consent shall be taken in the language he/she understands best only after providing information. For minors and unconscious patients, the parents or legal guardians or next of kin should sign the informed consent.

11.1.2 One-time consent for repeated transfusion may be permitted for a single admission

11.1.3 The patient shall be provided with the opportunity to ask questions and has the right to accept or refuse transfusion.

11.2 IDENTIFICATION OF RECIPIENT AND DONOR UNIT

11.2.1 Immediately before transfusion, the doctor / transfusionist shall verify the identification of the patient, the blood unit, blood group and cross-matching report and associated records.

11.2.2 Immediately before transfusion, the doctor/transfusionist shall verify the following information matching the blood or blood component with the intended recipient:

11.2.3 The intended recipient's two independent identifiers are verified by two individuals in the presence of the recipient. This involves asking the patient to state his/her name and date of birth and/or by checking the identification details on the patient's wrist-band against the information provided on the compatibility label

11.2.4 The recipient's ABO and Rh type as well as a patient identification number

11.2.5 The donor's ABO and Rh type as well as a donation identification number

11.2.6 The interpretation of crossmatch tests

11.2.7 Special transfusion requirement

11.2.8 The expiration date (or time) of the unit.

11.2.9 All identifications attached to the container should remain attached at least until the transfusion is over.

11.2.10 The blood compatibility report should be attached to the patient's file.

11.3 SUPERVISION OF BLOOD/ COMPONENT TRANSFUSIONS

Transfusion should be prescribed and administered under medical direction. The doctor/ transfusionist should observe the patient for an appropriate time at the initial stage and during the transfusion to observe any evidence of untoward reaction and to regulate the speed of transfusion.

11.3.1 To ensure good clinical practice (GCP) the user hospital shall formulate a hospital transfusion committee.

11.3.2 Transfusion should be prescribed and administered under medical direction.

11.3.3 A doctor or a qualified and trained nurse shall administer blood/blood components and observe the patient during and after transfusion. Observation during the first 15 minutes of the transfusion is especially important to allow early detection of signs of serious acute reactions.

11.3.4 Specific instructions regarding possible adverse events should be provided to the patient or a responsible caregiver when direct observation is not available following transfusion

11.3.5 Vital signs should be measured and recorded before starting the transfusion, at 15 minutes after the start of the transfusion and at the end of the transfusion of every blood component transfused.

11.3.6 The time when transfusion is started, interrupted and stopped shall be clearly reported in patient records, as well as vital signs or any other symptoms that could indicate a transfusion reaction.

11.3.7 Confirmation of transfusion of the blood component should be sent back to the hospital Blood Centre.

11.3.8 An assessment of the effe ctiveness of the transfusion should be performed (by post-transfusion increment rates or improvements in patient symptoms and clinical signs) and documented in a clinical record, identifying whether the desired effect was obtained and the likely need for further transfusion.

11.4 ADMINISTRATION OF BLOOD & BLOOD COMPONENTS

11.4.1 Blood and blood components shall be maintained at the optimum temperature before transfusion.

11.4.2 Red cells should not be administered with IV solution containing calcium, dextrose or Ringer's solution.12.4.3 Inspect the blood bag before transfusion for any sign of damage/contamination/leakage like hemolysis, change in colour, any clot.

11.4.3 The transfusion shall be given with sterile, pyrogen-free and disposable transfusion set with integral mesh filter (usually 170- 260 microns) to filter out large clots and macroaggregates. The transfusion should be started immediately on receipt of blood. Manufacturer's instructions should be followed, and no transfusion set should be used for more than 6 hours.

11.4.4 Transfusion should be completed within 4 hours of removal from controlled storage

11.4.5 Warming of blood to body temperature should be done in case of rapid transfusion, massive transfusion, exchange transfusion in infants and patients with cold agglutinins. The rates of transfusion should be >50 ml/kg/hr in adults, (350 ml in 7 minutes for 60kg adult) and >15 ml/kg/hr in children. Warming of blood should be accomplished using an approved blood warming device or technique attached to the transfusion set. The warming system should be equipped with a visible thermometer and ideally with an audible alarm system. Blood warmers should be validated before use to ensure that temperature regulators are operating properly. Blood should not be warmed above 37^0C.

11.4.6 Medication shall never be added to the whole blood or components. Similarly, no other intravenous fluid except 0.9% Sodium Chloride Injection I.P. should be administered with blood components, if at all necessary. ABO-compatible plasma, 5% albumin, or plasma protein fraction may be added with proper documentation and with sufficient clinical indications.

11.4.7 Medical Record Documentation

The patient's medical record shall include transfusion orders, documentation of patient consent, the name of the component, the donation identification number, the date and time of transfusion, pre- and post-transfusion vital signs, the amount transfused, the identification of the transfusionist and, if applicable, transfusion-related adverse events. It is advisable if blood/ component unit(s) are identified at the bedside by two persons.

11.5 TRANSFUSION PRACTICES AT BEDSIDE

11.5.1 There shall be a written protocol for the administration of blood and blood components and the use of infusion devices and auxiliary equipment.

11.5.2 For appropriate use of blood, guidelines available should be used.

11.6 SPECIAL CONSIDERATIONS FOR USE OF COMPONENTS

11.6.1 Red Cell Transfusion

11.6.1.1 Red cell transfusion should be ABO & Rh (D) compatible.

11.6.1.2 Transfusion of one unit of red cells should not take longer than 4 hours.

11.6.1.3 The viscosity of red cell concentrate should be reduced by the addition of a small volume (50 ml) of sterile normal saline through one limb of a Y infusion set.

11.6.1.4 Red cells should be transfused at 1-2 ml/min for the first 15 minutes and as tolerated thereafter.

11.7 FRESH FROZEN PLASMA

11.7.1 Plasma transfusion should be ABO compatible. Cross-matching tests are usually not performed on plasma products.

11.7.2 Products that have been thawed should be infused without delay to avoid bacterial proliferation. While thawing, water should not touch transfusion ports of the plasma bag.

11.7.3 Thawing is done at a temperature of 37^0C. If it is used as a source of labile coagulation factors, it should be used immediately and in any case within 6 hours of thawing. If used for a purpose other than coagulation factor replacement, it should be transfused within 24 hours after it is thawed and stored at 1-6^0C. Thawed plasma held longer than 24 hours must be relabelled as Thawed Plasma, and it can be stored for an additional 4 days at 1 to 6^0 C

11.7.4 FFP should be transfused at 2-5 ml/min for the first 15 minutes and as tolerated thereafter

11.8 CRYOPRECIPITATE

11.8.1 The component should be thawed at a temperature of 37^0C and should be used immediately. ABO compatibility and cross-matching tests should not be a must. It should be transfused as rapid as to be tolerated.

11.9 SINGLE DONOR PLASMA

It should be transfused within 24 hours after it is thawed and stored at 1-6°C.

11.10 PLATELETS/ LEUKOCYTES/ GRANULOCYTES

11.10.1 Platelets should be ABO-identical, but in the absence of availability of ABO compatible platelets, ABO-incompatible platelets can be used. If there is visible red cell contamination in platelet and leucocytes concentrate, group-specific and crossmatched product should be used.

11.10.2 Platelets and leucocytes shall be administered through a standard filter. Micro aggregate filters should not be used for these products.

11.10.3 RhD-negative female recipients of child-bearing age or younger should preferably not be transfused with platelets from RhD-positive donors. If unavoidable, administration of anti-D immunoglobulin should be considered

11.10.4 Platelets and leucocytes should be infused at 1-2 ml/minute for the first 15 minutes or and as tolerated thereafter by the patient, while granulocytes should be transfused at 1-2 ml/min for the first 15 minutes and as tolerated thereafter.

11.10.5 Granulocyte concentrates should be irradiated before transfusion.

11.11 LEUKOCYTE DEPLETED REDUCED COMPONENTS

11.11.1 Storage should depend on whether a closed or open system is in use.

11.11.2 The verification of leucocyte reduction should be done in 1% of products prepared, of which 75% should contain less than $5x10^6$ leukocytes in the blood bag.

11.11.3 Leukocyte reduction by filtration of RBCs should result in a component that contains at least 85% of the original red cell content.

11.11.4 For WB-derived platelets, the leukocyte reduction process should ensure that 95% of the platelet units sampled contain $<8.3 \times 10^5$ leukocytes per unit, at least 75% of the units sampled contain 5.5×10^{10} platelets, and at least 90% of the units samples have a pH of 6.2 at the of the allowable storage time. 12.12 Pooling of platelets:

11.12 VOLUME OF REDUCED PLATELETS

11.12.1 They are required in patients who cannot tolerate an increased amount of plasma-like cardiac overload, to minimize ABO antibody infusion or for intrauterine transfusion.

11.12.2 Platelet concentrate volume can be reduced to 10-15 ml/unit via centrifugation, and in-vitro properties are maintained for 5 days.

11.12.3 The addition of 10% ACD-A to platelets to lower the pH before centrifugation will allow resuspension of high-concentration platelets and avoid aggregation.

11.12.4 The shelf life is 4 hours in case of open system.

11.13 CRYOPRESERVATION

11.13.1 Red cells should be cryopreserved within 6 days of collection and glycerol is the most common cryopreservative agent.

11.13.2 Frozen red cells shall be stored at temperature $<-65^0$C and have a shelf life of 10 years.

11.13.3 Frozen units should be thawed at 37^0C followed by removal of glycerol. If the open system is used, the shelf life of the final unit is 24 hours at 1-6^0C, while it is 14 days at 4^0C in case of a closed system.

11.13.4 For QC, determining the volume of red cells in the unit after deglycerolization and examining the last wash for hemolysis are recommended. Post wash units should have a haematocrit of 51-53%, with a mean count of 9.0×10^6 leukocytes per unit

11.13.5 Cryopreserved red cells are required for storage of autologous units of patients with rare blood group with antibody to high-frequency antigens or patients with multiple red cell antibodies for future use.

11.13.6 Platelets are cryopreserved, usually with 5%/6% DMSO in case of platelet refractoriness, and shelf life is usually 2 years with 75% platelet recovery rate in-vitro post thawing.

11.14 WASHED RED CELLS

11.14.1 Washed red cells are obtained from secondary processing of a red cell component which involves sequential washing and re-suspension of red cells in an additive solution.

11.14.2 When an open system is used for washing, the storage time should be as short as possible after washing and must never exceed 24 hours. They should be stored 2-6°C

11.14.3 If a closed system and a suitable additive solution are used, storage times may be prolonged, subject to validation.

11.14.4 Washed red cells should have a minimum haematocrit of 50-70%, residual leukocyte count of $< 5 \text{ X } 10^6$/unit and protein content of final supernatant < 0.5 g/unit

11.14.5 Indications for Washed red cells include Recurrent attacks of FNHTR and urticarial reactions, Antibodies to plasma proteins, IgA deficient patients with anti-IgA antibodies, PNH patients sensitive to complement.

11.15 AUTOLOGOUS BLOOD

11.15.1 PREDEPOSIT

11.15.2 Pre-deposit autologous donation refers to removal and storage of blood or blood components of donor-patient's own blood for intended transfusion to that person when required at a later date.

11.15.3 Autologous pre-deposit procedure requires the consent of the donor-patient and a request from the treating physician.

11.15.4 The records of all units collected for autologous use should be maintained.

11.15.5 Pre-deposit unit should be labelled "For Autologous Use Only" segregated and used solely for this purpose. The donor - patients' signature should be on the label.

11.15.6 Precaution shall be taken to identify the donated unit and donor patient before the transfusion procedure.

11.15.7 If the blood collected for autologous transfusion is not used for the Donor - patient, it should be discarded.

11.15.8 Criteria for donation: For autologous transfusion, rigid criteria required for donor selection are not applicable. Whenever requirements for donor selection or collection cannot be applied, suitable guidelines applicable for the individual donor-patient should be established in consultation with the donor patient's physician and medical officer of the Blood Centre. The individual guidelines should be recorded in the procedure manual of the Blood Centre and clinical records of the donor-patient. Suitable guidelines include:

11.15.9 The volume of blood collected should be proportionate to the donor patient's weight and volume of preservative used.

11.15.10 There should not be any age limits for autologous transfusion procedure.

11.15.11 The haemoglobin concentration of donor-patient should not be less than 11 g / dl and haematocrit not less than 33% and must not fall below 10 gms per dl, at the end of this autologous program. However, this level should be adjusted to higher or lower values by the medical officer depending on the clinical circumstances of the donor. Iron supplementation should be started much in advance of this program and must continue sufficiently to replenish iron stores.

11.15.12 Donation of pre-deposit autologous transfusion should not be undertaken when the donor-patient has or is being treated for bacteraemia or has any local skin lesions.

11.15.13 Phlebotomy for autologous units should not be undertaken more frequently than every three days and at least 72 hours prior to surgery.

11.15.14 The frequency of phlebotomy for a number of autologous transfusion units should be determined by the Blood Centre medical officer and donor-patient's physician.

11.15.15 Transfusion of the autologous units should be under medical supervision.

11.15.16 Testing of autologous units

11.15.16.1 ABO-Rh(D) type should be determined.

11.15.16.2 The tests for irregular antibodies and infectious disease tests should be done at least on the first unit collected from the patient-donor.

11.15.16.3 Any abnormal test results should be reported to the patient's physician. Blood should be discarded if the test result is positive for any mandatory test.

11.15.17 Labelling requirements

11.15.17.1 Following information should be provided on a label or tag attached to the blood container:

- Name of the Blood Centre (collecting facility) and its manufacturing license number.
- Name of the patient and the hospital where he is hospitalised;
- Patient's hospital registration number and other details (Ward-
- Bed or any other identifying information;
- ABO and Rh(D) type;
- Date of collection and expiry;
- HIV/HCV/HBsAg status;
- VDRL test;
- Malaria Parasite
- Notice that the unit is 'For Autologous Use Only'.

11.15.18 Pre transfusion testing

11.15.18.1 The patient's blood sample should be accompanied by a pre-transfusion requisition form for autologous transfusion as per the requirements to confirm the ABO and Rh blood group.

11.16 PERIOPERATIVE HAEMODILUTION

11.16.1 The treating physician shall be responsible for the peri-operative autologous program. The policies and procedures should be developed jointly with the medical officer in Blood Centre.

11.16.2 Units collected by hemodilution method or intraoperatively should be stored at room temperature (22^0C) up to 8 hours or 4^0 C + 2^0C up to 24 hours.

11.16.3 Intraoperative autologous transfusion using blood salvaged intraoperatively from the operative site or extracorporeal circuit should preferably be avoided unless the need to perform such transfusion can be justified under only lifesaving emergency and having proper facility for the safety of the patient.

11.16.4 Intra-operative salvage methods should be safe if aseptically carried out using equipment that should be pyrogen-free and should include a filter capable of retaining potentially harmful particles and preclude air embolism.

11.16.5 Complete written protocol of all transfusion procedure should be maintained, including criteria for selection, dosage, ancillary agents used, prevention and treatment of adverse reactions.

11.16.6 Blood collected intra-operatively and not used during or immediately following the operation should not be transfused to other patients.

11.17 POSTOPERATIVE AND POST-TRAUMATIC AUTOTRANSFUSION

11.17.1 Blood from mediastinal drainage following cardiac surgery or from chest following blunt trauma can be salvaged for autologous transfusion blood only. It should not be used for any other patient other than the donor patient.

11.17.2 Such blood should be transfused within 6 hours of the collection after appropriate manipulation.

11.18 RECORDS

11.18.1 Records of all autologous procedures should be maintained in Blood Centre as per existing regulations.

Chapter-12:

Special Procedures

12.1 HISTOCOMPATIBILITY TESTING

12.1.1 GENERAL

12.1.1.1 The Human Leukocyte Antigen (HLA) system is a part of the major histocompatibility complex (MHC), which plays a critical role in regulating the immune response. Therefore it plays a major role in transplantation as well as disease association. Histocompatibility testing refers to the determination of tissue antigens (serologically or by DNA based methods) and detection of anti HLA antibodies which are produced by any previous sensitization event like blood transfusion, pregnancy & transplant. HLA typing and the crossmatch by serological methods are based on complement-dependent micro lymphocytotoxicity.

12.1.1.2 Today HLA typing at most centres is conducted by various DNA based techniques like a sequence-specific primer (SSP), sequence-specific oligonucleotide probe (SSOP), sequence-based typing(SBT) & most recent is Next-generation sequencing (NGS).

12.1.1.3 Antibody detection includes antibody screening, identification of antibodies with Single Antigen Bead Assay, Panel Reactive antibody tests, as well as methods of cross-match like Complement Dependent Cytotoxicity (CDC), Flow crossmatch or Lysate cross match.

12.1.1.4 Terminology of HLA antigens should conform to the nomenclature adopted by the World Health Organisation committee for HLA system.

12.1.2. REAGENTS

12.1.2.1 HLA typing reagents

12.1.2.1.1 Well characterised HLA typing antisera of confirmed specificity procured from commercial firms and reference laboratories should be used for HLA typing. When HLA typing is performed by DNA based methods: Reagents includes primers/probes & master mix provided by manufacture or developed in house.

12.1.2.1.2 HLA typing reagents should be stored at -30^{0}C or at the temperature recommended by the kit manufacturer.

12.1.2.2 Control sera

12.1.2.2.1 Each typing or crossmatching should be carried out with appropriate controls, which include complement-dependent positive controls and negative controls (neutral AB serum).

12.1.2.2.2 Cell viability in negative control well at the end of incubation should permit accurate interpretation of results. The positive and negative control should give cytotoxicity results of 80% and less than 15%, respectively.

12.1.2.3 Complement

12.1.2.3.1 Complement should be stored in small aliquots either in lyophilised state or in liquid form at below -30^{0}C.

12.1.2.3.2 Each new batch of complement should be tested for its potency to induce cytotoxicity in the presence of a specific antibody but is not cytotoxic to the test cells in the absence of a specific antibody.

12.1.3 HLA TYPING

12.1.3.1 Typing for each of the antigens for HLA Class I- A, B, C and Class II-DR, DQ & DP loci should be defined by at least two antisera, one of which is mono-specific.

12.1.3.2 HLA typing should be performed by complement-dependent micro lymphocytotoxicity method or by other equally sensitive tests.

12.1.3.3 When DNA-amplification-based methods are used following apply:

12.1.3.3.1 The laboratory should use physical and/or biochemical barriers to prevent DNA contamination.

12.1.3.3.2 The specificity of each primer and each oligonucleotide probe should be defined and documented.

12.1.3.3.3 All reagents, equipment, and work areas should be monitored periodically for the absence of contamination.

12.1.3.3.4 Negative control should be included in each amplification.

12.1.3.3.5 Reports should designate the type of assay used.

12.1.4. **HLA MATCHING FOR ORGAN TRANSPLANTATION OR BLOOD TRANSFUSION**

12.1.4.1 HLA matched blood components are required in case of Platelet refractoriness or any specific clinical reason. When HLA matched blood components are required for transfusion, donor and recipient HLA-A and -B antigens should be determined to obtain compatible donor.

12.1.4.2 For living related stem cell transplantation donors, all available family members (preferably siblings & parents) should be typed to determine compatibility by High resolution HLA typing method

12.1.4.3 For organ transplantation, donor and recipient should be typed for ABO, HLA-A, -B – C; –DR/DQ and DP antigens are required.

12.1.4.4 HLA antibody detection

12.1.4.4.1 Comprehensive panel to ensure all WHO accepted antigens, including working antigens, should be used for antibody detection in sera from multiparous women and multi-transfused patients. In addition, because of higher sensitivity, bead-based solid phase assays are performed for antibody detections.

12.1.4.4.1 When solid-phase assays are used for antibody screening, Panel Reactive Antibody Assay (PRA) or Single Antigen Bead Assay (SAB), proper validation is required as well as appropriate controls to be used. Panel Reactive antibody testing provides information about the sensitization in the patients and Single Antigen Bead assay identifies the anti HLA antibody/ies.

12.1.5 LYMPHOCYTOTOXICITY CROSSMATCH

12.1.5.1 Crossmatch should be done using enhancing test methods available such as prolonged incubation, washing, and augmentation with anti-globulin reagents or flow-cytometry on recently collected blood samples of the recipient.

12.1.5.2 If serum shows the presence of antibodies, it is preferable to preserve the serum sample for the further cross match.

12.1.5.3 All serum samples should preferably be preserved, in a frozen state for at least 3 months following transplantation.

12.1.5.4 Every crossmatch test, whether complement-dependent cytotoxicity, flow crossmatch or solid-phase lysate cross-match appropriate positive & negative controls have to use. Interpretation of crossmatch should be made based on national or international guidelines.

12.1.6 PRETRANSPLANTATION TESTS

12.1.6.1 A sample of blood from prospective transplant donor should be tested for ABO blood group VDRL, anti-HCV, HBs Ag, anti-HIV-1, and anti-HIV-2.

12.1.7 RECORDS

Records of all HLA typing, antibody detection, lymphocyte crossmatch and pre-transplantation tests, along with the results of necessary and external controls tests, should be maintained for a period of at least 5 years.

12.2 IRRADIATION OF BLOOD COMPONENTS

12.2.1 GENERAL

Irradiation of blood and components is a lifesaving procedure to prevent graft versus host disease (GvHD). It is to be performed with validated equipment that delivers gamma rays on these units so that the DNA of a cellular component is destroyed, including T lymphocytes. It will prevent graft versus host disease (GvHD).

12.2.2 TECHNICAL DETAILS

12.2.2.1 License shall be obtained from regulatory agencies for irradiation of blood and components.

12.2.2.2 For the protection of employees from irradiations, instructions from regulatory agencies shall be followed. Radio sensitive badges shall be issued, monitored and documented on a regular basis.

12.2.2.3 Quality assurance of irradiated components shall be carried out

12.2.2.4 Cellular components should be irradiated in order to reduce the risk of post-transfusion graft versus host disease when a patient is identified as being at risk for GVHD e.g.

- For all immunosuppressed patients, including bone marrow transplant (BMT) patients.
- When blood from a blood relative is used
- In case of exchange transfusion following intrauterine transfusions

12.2.2.5 Irradiated blood and blood components shall be prepared by a method known to ensure that irradiation has occurred with each batch.

12.2.2.6 The intended dose of irradiation shall be a minimum of 25 Gy (2500 cGy) delivered to the central portion of the container. The minimum dose at any point in the components shall be 15 Gy (1500 cGy). Alternate methods shall be demonstrated to be equivalent.

12.2.2.7 Verification of dose delivery shall be performed using a fully loaded canister as follows:

- Annually for cesium-137 as a radiation source.
- Semiannually for cobalt-60 as a radiation source.
- Periodically, as recommended by the manufacturer for alternate sources of radiation.
- Upon installation, major repairs, or relocation of the irradiator.

12.2.2.8 The component should be labelled accordingly.

12.2.2.9 The expiry date should be the original date. However, in the case of red cell concentrate, it will be 28 days from the date of irradiation or the original, whichever is earlier. In the case of a neonate, the component should be transfused immediately after irradiation.

12.3 PATHOGEN REDUCTION TECHNOLOGY FOR BLOOD COMPONENTS

12.3.1 GENERAL

Pathogen inactivation is a relatively recent medical process introduced in Transfusion Medicine to kill/ inactivate pathogens. This technology carries good prospect to make blood and component safer however, this technology cannot be applied on all available components.

12.3.1.1 Pathogen Reduction Technology (PRT) of blood components reduce the infectivity of residual pathogens in blood components. The benefit of PRT is primarily mitigation of emerging pathogens and platelet associated bacterial infection.

12.3.2 TECHNICAL DETAILS

PRT processes that are available or in development are summarized as below:

Component	Technology
Plasma: Individual units	• Amotosalen +UV light • Riboflavin + UV light • Solvent detergent • Methylene blue + UV light
Platelets	• Amotosalen +UV light • Riboflavin + UV light • UV light
Red Blood Cells	• Frangible nucleic acid crosslink • Riboflavin + UV light

12.3.2.1 The method used for PRT should be approved by the national regulatory authority.

12.3.2.2 Manufacturer instructions should be followed for the PRT process of blood components.

12.3.2.3 There should be written policies and procedures for maintaining different inventories, i.e. Pathogen Reduced Blood components and Non-pathogen reduced Blood Components

12.3.2.4 The PRT of the component should be done soon after the blood collection.

12.3.2.5 If the UV light has been used as a part of PRT, such blood component should not be used for neonates undergoing phototherapy.

12.3.2.6 All documentation related to the PRT process of blood component should be maintained.

12.4 NUCLEIC ACID TESTS (NAT)

12.4.1 GENERAL

Despite stringent donor screening and testing for TTIs, blood and its components still carry an inherent risk of TTI transmission. Immunoassays detect antibodies

to viruses or viral antigens. Even though serology tests may have a high degree of sensitivity, there is a window period during which infection is not detectable by serological tests. It is during this period that the risk of infection in donated blood can be missed.

This constitutes a residual risk of infection, which may be significant, particularly, in areas with high prevalence rates of infection in the general population.

12.4.2 CAUSES OF RESIDUAL RISK INCLUDE

1. Early stage of infection, the so-called diagnostic window period
2. A low-level chronic carrier state may exist in which the donor is asymptomatic and persistently testing negative in screening
3. Non seroconverts
4. Laboratory, human, mechanical or technical errors

12.4.3 TECHNICAL DETAILS

It detects the presence of viral infection by directly testing for viral nucleic acids. Nucleic acid sequences specific to the pathogen in question is amplified and detected.

12.4.3.1 Commonly used NAT assays detect HIV-1/2 RNA, HCV RNA, HBV DNA.

12.4.3.2 PRESENTLY AVAILABLE NAT TECHNIQUES include Polymerase Chain reaction with Real-Time Fluorescence detection or Transcription Mediated Amplification with endpoint chemiluminescence detection

12.4.3.3 NAT shortens the window period; thereby, blood centres attain a much higher sensitivity for detecting viral infections.

12.4.3.4 NAT is an optional but recommended test (for reducing the residual risk of infection) for screening of TTIs because of higher sensitivity and for reducing window period to make transfusion safer.

12.4.3.5 Blood Centres should not replace serology screening of TTIs but use an additional test to improve sensitivity.

12.4.3.6 Blood Centres doing NAT testing shall have a policy for release of blood following completion of ELISA/ CLIA but pending NAT results, especially in urgent cases.

12.4.3.7 In case of testing donor samples by methods involving pooling of samples, every positive pool should be retested individually and the pool shall be quarantined till testing is completed

Chapter-13:
Hemovigilance

13.1 GENERAL

The primary aim of the centralized hemovigilance program is to improve transfusion safety and quality by collecting, collating, analysing and disseminating information on a common set of serious adverse reactions due to the transfusion of blood and blood products.

13.1.1 The blood centre shall aim to participate in the Hemovigilance Programme of India (HvPI).

13.1.2 The blood centre shall have registration for Haemo-Vigil software for reporting of Adverse Transfusion Reactions (www.nib.gov.in).

13.1.3 The blood centre shall develop a procedure to obtain all the details of adverse transfusion reactions to be able to report to HvPI.

13.1.4 The blood centre shall ensure the training of clinical and paramedical staff for appropriate reporting of adverse transfusion reactions to transfusion services.

13.1.5 The blood centre shall assign the responsibility to ensure regular reporting of adverse transfusion reaction HvPI after adequate training. Regular monitoring and analysis shall be done by the Medical Officer of the blood centre for all reported adverse transfusion reactions.

13.2 DOCUMENTING AND REPORTING OF ADVERSE REACTIONS/ EVENTS ASSOCIATED WITH TRANSFUSION OF BLOOD AND COMPONENTS:

13.2.1 Documenting and reporting transfusion reactions in blood transfusion service to involve many aspects and interrelationships involving medical and nursing staff, hospital management, the blood centre and the hospital transfusion committee.

13.3 RESPONSIBILITIES OF MEDICAL AND NURSING STAFF

13.3.1 Physicians and nurses attending to patients having suspected transfusion complications shall perform the following documentation and reporting functions:

13.3.2 Attending nursing staff shall report suspected transfusion reaction immediately to the attending physician.

13.3.3 Document the details of the patient as well as the implicated units/ products and retain them in the patient's file.

13.3.4 Send the details of the transfusion reaction to the Department of Transfusion Medicine/ Blood Centre inappropriate documents accompanied by the patient samples and unit transfused, required for investigation.

13.3.5 Protocol for the investigation of an acute transfusion reaction is given at annexure-9

13.3.6 Assess the imputability levels of the adverse reactions in coordination with the Department of Transfusion Medicine/ Blood Centre.

13.3.7 Maintain records of the complication in the patient's medical record, including the report of the investigation completed by the Department of Transfusion Medicine/ Blood Centre.

13.4 RESPONSIBILITIES OF THE DEPARTMENT OF TRANSFUSION MEDICINE/ BLOOD CENTRE

13.4.1 The transfusion service shall be responsible for documenting and reporting transfusion reactions and complications to the national haemovigilance program.

13.4.2 Reports in details of the clinical and laboratory investigation shall be provided to the respective clinical ward and to the Hospital Transfusion Committee.

13.4.3 To do the investigations as per the workup form and documenting the results in the workup form.

13.4.4 To enter the necessary details as per the documentation required in the Transfusion Reaction-Traceability document (TR-TD)

13.4.5 Determine the imputability levels of the adverse reactions.

13.4.6 Custodian of the Transfusion Reaction-Traceability document (TR-TD)

13.4.7 To assure the completeness of the Transfusion Reaction-Traceability document (TR-TD)

13.4.8 Report the details as per the transfusion reaction reporting form to the technical associate Pharmaco Vigilance Program of India (PvPI).

13.4.9 The hospital transfusion committee shall periodically review the adverse reactions reported and provide guidance and support for improvement.

Annexures

Annexure-8. Adverse blood donor reaction form (Page no: 97)

Annexure-9. Transfusion reaction reporting form (Page no: 98)

Chapter-14:
Blood Storage Facility

14.1 GENERAL

14.1.1 First referral Units, Community Health Centres, Primary Health Centres or any other hospitals are required to obtain approval for setting up of Blood storage facility from the State/Union Territory licensing authority.

14.1.2 The main aim of setting up blood storage facilities is to make abundant availability of whole human blood or its components to the said hospitals without starting a new Blood Centre.

14.1.3 The blood storage facility is feasible without opening a Blood Centre to manage life-threatening situations in case of maternal mortality and other situations like roadside accidents etc.

14.2 APPROVAL OF BLOOD STORAGE FACILITY

14.2.1 An application has to be made as per the guidelines in a prescribed format. The State Licensing Authority shall approve the blood storage unit after satisfying the conditions and facilities through inspection.

14.2.2 The approval shall be valid up to a period of two years from the date of issue unless suspended or cancelled. An application for renewal will have to be made three months prior to the date of expiry of the approval.

14.2.3 Before applying for approval, the storage centre will have to identify and obtain consent from the Blood Centre from where they will get the supply of blood/blood components. These could be licensed Blood Centres run by Government Hospitals,/ Indian Red Cross/Regional Blood Transfusion Centres or any other licensed Blood Centre with a good inventory of blood/ components. In case the license of the parent Blood Centre/centre is cancelled, the license of the storage centre will also be automatically cancelled.

14.2.4 The storage centres can, however, get affiliated to more than one Blood Centre/ centre to ensure uninterrupted supplies, but a separate approval will be required in each case.

14.3 REQUIREMENTS:

14.3.1 Space: The area required for setting up the facility is 10 square metres, well lighted, clean and preferably air-conditioned.

14.3.2 Manpower: In the present phase, no additional staff is required. One of the existing Medical Officer and laboratory technicians should be designated for this purpose. They should be trained in the operation of blood storage centres and other basic procedures like storage, blood grouping, cross- matching and release of blood.

The Medical Officer designated for this purpose will be responsible for the overall working of the storage centre.

14.3.3 Electricity: Regular 24 hours supply is essential. Provision of backup Generator is required.

14.4 TRANSPORTATION AND STORAGE

14.4.1 It is necessary to maintain the cold chain at all levels, i.e. from the mother centre to the blood storage centre to the issue of blood. This can be achieved by using insulated carrier boxes. During transportation, the blood should be properly packed into cold boxes.

14.4.2 The storage centre should check the condition of blood on receipt from the mother centre and also during the period of storage.

14.4.3 Fresh frozen plasma and platelets concentrate are required to be stored, the storage procedures of the mother blood bank should be followed.

14.5 ISSUE OF BLOOD

14.5.1 Patients' blood grouping and cross-matching shall be carried out before the issue of blood. A proper record of this should be kept. First In and First Out (FIFO) policy, whereby blood closer to expiry date is used first, should be followed

14.5.2 The Centre shall maintain proper records for procurement, cross-matching and issue of blood and blood components. These records shall be kept for at least for 5 years

Annexures:

Annexure-10. List of Requirements in the Storage Centre (page no: 99)

NB: Refer Guidelines for Blood Storage Center, National AIDS Control Organisation, Ministry of Health and Family Welfare, Government of India, New Delhi, 2007.

Annexure-1:
List of Equipment

1. Donor couches
2. Donor weighing balance
3. Hemoglobinometer/ calorimeter or any other approved point of care haemoglobin estimation device.
4. Clinical thermometer or donor temperature checking device
5. Sphygmomanometer
6. Stethoscope
7. Blood mixer and shaker
8. Tube stripper
9. Di-electric tube sealer
10. Needle destroyer/ sharp container
11. Oxygen cylinder
12. Refrigerated centrifuge
13. Double pan balance with standard weights
14. Plasma expresser
15. Blood Bank Refrigerator
16. – 35°C Deep Freezers
17. – 80°C Deep Freezers
18. Platelet Agitator and Incubator
19. Fixed or variable pipettes
20. pH Meter
21. Laminar Air-flow bench
22. Leuco-reduction device (when required)
23. Cell Separators (apheresis machine)
24. Table top centrifuge
25. Serological water bath
26. Binocular microscope
27. Dry incubator
28. Room temperature and humidity checking thermometers
29. Digital analytical balance
30. Elisa washer
31. Elisa reader (Plate reader/strip reader)

32. VDRL shaker
33. Autoclave
34. Distilled water
35. Air- conditioner (1/1.5/ 2 tonnes)
36. Generator (5 KVA/ 30 KVA)
37. Dry rubber balance material
38. Weighing device for blood bags
39. Insulated blood bag containers with storage temperature from 2oC-10oC
40. Plasma thawing water bath (if components are dispensed)
41. Cryo bath
42. Emergency resuscitation kit with required drugs
43. Domestic refrigerator
44. Lab incubator

List of Equipment Optional in the Blood Bank / Blood Centre

1. Cell Counter (optional)
2. Coagulometer (optional)
3. Walk in Cooler/ Cold Room (optional)
4. Blood Irradiator (optional)
5. Automated Cell Grouping system (optional)
6. Equipment for column Agglutination technology (optional)
7. Sterile Connecting devices (optional)
8. Automatic Cell washer (optional)
9. Microplate centrifuge (optional)
10. Automated ELISA system (optional)
11. Automated Chemiluminscence based immunoassay system (optional)
12. Transportation vans (optional)
13. Blood mobile vans (optional)
14. Outdoor camp collection couches / chairs (optional)
15. Central temperature monitoring system (optional)

Annexure-2:

Calibration schedule for equipment

S.No.	Equipment	Performance	Frequency for performance checking	Minimum frequency of calibration (outsource or in house)
1	Temperature recorder (Display)	Compare against calibrated thermometer	Daily	Once in 6 months/ year
2	Refrigerator/Deep freezer for storage of blood / components	Compare against thermometer	Daily	Once in 6 months
3	Refrigerated blood bag centrifuge	Observe speed temperature and time	Each day of use	Once in 6 months
4	Hematrocrit centrifuge	Observe temperature and time	–	Once a year
5	General lab centrifuge	Observe temperature and time	–	Once in 6 months
6	Automated Blood typing	Observe control of correct result (QC sample)	Each day of use	Once a year
7	Haemoglobinometer	Standardize against cyanmethemoglobin standard	Each day of use	Once a year
8	Refractiometer	Standardized against distilled water	Once a year	Once a year
9	Blood container weighing device	Container of known calibrated weight	Once a year	Once a year
10	Water bath	Observe temperature	Once a year	Once a year
11	Autoclave	Observe temperature and pressure	Once a year	Once a year
12	Serologic rotators	Observe temperature and pressure	Once a year	Once a year
13	Laboratory thermometer	–	–	Before initial use and every 6 months
14	Electronic/ digital thermometer	–	–	Before initial use and every 6 months
15	Blood agitator	Observe the weight of the first blood-filled container for correct results	Once in 15 day	Once a year
16	Platelet shaker cum incubator	Temperature oscillation rate	Each day of use Each day of use once a month	Every 6 months

S.No.	Equipment	Performance	Frequency for performance checking	Minimum frequency of calibration (outsource or in house)
17	Automated blood cell counter	Known controls	Daily	Once a year
18	Pipettes	Volume	Once in a month	Once in 6 months
19	Incubator	Temperature	Once in a month	Once a year
20	Stop watch	–	–	Once a year
21	Tachometer	–	–	Once a year
22	Weight box	–	–	Once a year

Annexure-3:

List of records and documents required in the Blood Centre

(1) **Blood donor record**: It shall indicate serial number, date of donation, name, address of donor with other particulars of age, weight, haemoglobin, blood grouping, blood pressure, medical examination, bag number and patient's detail for whom donated in case of replacement donation, category of donation (voluntary / replacement) and deferral records and signature of Medical Officer(s).

(2) **Master records for blood and its components:** It shall indicate bag serial number, date of collection, date of expiry, quantity in ml. ABO/Rh Group results for testing of HIV I and HIV II antibodies, Malaria, V.D.R.L., Hepatitis B surface antigen and Hepatitis C Virus antibody) and irregular antibodies (if any), name and address of the donor with particulars, utilization issue number, components prepared or discarded and signature of the Medical Officer(s).

(3) **Issue Register**: It shall indicate serial number, date and time of issue bag serial number, ABO/RH Group, total quantity in ml, name and address of the recipient, group of recipient, unit/institution, details of cross-matching report, indication for transfusion.

(4) **Records of components supplied**: Quantity supplied; compatibility report, details of recipient and signature of issuing person.

(5) **Records of ACD/CPD/CPD-A/SAGM/ any other approved anticoagulant** and preservative bags giving details of manufacturer, batch number, date of supply, and results of testing.

(6) **Register for diagnostic kits and reagents used**: name of the kits/reagents, details of batch number, date of expiry and date of use.

(7) **Cross-matching/ Compatibility report:** The blood Centre should issue the cross-matching report of the blood/ components to the patient together with the blood/ component unit.

(8) **Transfusion adverse reaction records**.

(9) **Records of purchase, use and stock in hand** of disposable needles, syringes, blood bags shall be maintained.

Other Records:

1. Daily stock register/ record (group-wise) showing collection, processing, issue and balance
2. Component preparation records (if applicable)
3. Discard and/ or autoclaving register
4. Records of communication with the State Blood Transfusion Council
5. Records of communication (applications/ intimations) to State Drug Controller cum Licensing Authority
6. Hemovigilance reporting records

7. Daily temperature of equipment and ambient temperature records
8. Equipment maintenance records
9. Quality assurance (internal and external) records
10. Staff attendance register/ records or any other system.
11. Staff specimen signature register
12. Blood (Hospital) Transfusion Committee records
13. Grievance redressal record/ feedback register, Record of incident reports
14. Referral records of reactive blood donors to ICTC/ STD clinic/ clinicians
15. Any other records/ registers made mandatory by National/ State Blood Transfusion Council or by the Regulatory Agencies.
16. E-Raktakosh reporting records

DETAILS OF RECORDS:

Records of the donor for blood/ components:

- Demographic details of the donor
- Identification number
- Donor selection record
- Medical history
- Physical examination.
- Donor deferral records
- Donor's blood collection record
- Date of collection
- Batch No. and bag manufacturer's name
- Segment number on the donor tubing
- Particulars of donor
- Identification number
- Amount of blood collected
- Time and duration of the collection
- Signature of phlebotomist and medical officer
- Donor Reactions

Blood components records

- Identification number
- Name and volume of components prepared
- Date, time and mode of preparation
- Disposition record with traceability

Records of blood and components from outside Blood Centre

- Identification number
- Name of the component
- Name of collecting facility
- Date of collection, expiry & all testing records

- Disposition record with traceability

Record of processing of donors' blood

- ABO (cell & serum grouping) and Rh(D) type
- Antibody screening and identification
- Anti-HIV 1 & 2, Anti-HCV, HBsAg, Syphilis, malaria tests and its interpretation
- Details of grouping indicating reaction results, batch number and manufacturer's name of reagents in use, details of reagent red cells in use.
- Details of all infectious disease tests, including ELISA /CLIA printouts showing results and interpretation as well as batch number, expiry date and manufacturer's name of the kit in use. All rapid tests/spot tests should be interpreted preferably by 2 competent individuals and recorded.

Quality control records indicating testing of components, reagents

Records of apheresis procedures

Records of Recipient

- Blood requisition form with full particulars of the recipient and identification number.
- Results of ABO and Rh(D) tests and their interpretation.
- Interpretation of compatibility tests.
- Compatibility record.
- Report of adverse reaction and record of their investigation.

Annexure-4:

Criteria for Selection of Blood Donor

General Criteria		
S.No.	**Criteria**	**Recommendations**
1.	Well being	The donor shall be in good health, mentally alert and physically fit and shall not be inmates of jail or any other confinement. "Differently abled" or donor with communication and sight difficulties can donate blood provided that clear and confidential communication can be established and he/she fully understands the donation process and gives a valid consent.
2.	Age	Minimum age 18 years Maximum age 65 years First time donor shall not be over 60 years of age; for repeat donor upper limit is 65 years. For aphaeresis donors 18-60 years
3.	Whole Blood Volume Collected and weight of the donor	350 ml- 45 kg 450 ml– more than 55 kg Apheresis– 50 kg
4.	Donation Interval	For whole blood donation, once in three months (90 days) for males and four months (120 days) for females. For apheresis, at least 48 hours interval after platelet/ plasma – apheresis shall be kept (not more than 2 times a week, limited to 24 in one year) After whole blood donation, a plateletpheresis donor shall not be accepted before 28 days. Apheresis platelet donor shall not be accepted for whole blood donation before 28 days from the last platelet donation provided reinfusion of the red cell was complete in the last plateletpheresis donation. If the reinfusion of red cells was not complete, then the donor shall not be accepted within 90 days. A donor shall not donate any type of donation within 12 months after a bone marrow harvest, within 6 months after a peripheral stem cell harvest.
5.	Blood Pressure	100-140mm Hg systolic 60-90 mm Hg diastolic with or without medications. There shall be no findings suggestive of end-organ damage or secondary complication (cardiac, renal, eye or vascular) or history of feeling giddiness, fainting made out during history and examination. Neither the drug nor its dosage should have been altered in the last 28 days.
6.	Pulse	60-100 Regular

S.No.	Criteria	Recommendations
7.	Temperature	Afebrile;37°C/98.4°F
8.	Respiration	The donor shall be free from acute respiratory disease.
9.	Haemoglobin	>or =12.5g/dL Thalassemia trait may be accepted, provided haemoglobin is acceptable.
10.	Meal	The donor shall not be fasting before the blood donation or observing fast during the period of blood donation, and the last meal should have been taken at least 4 hours prior to donation. The donor shall not have consumed alcohol and show signs of intoxication before the blood donation. The donor shall not be a person having regular heavy alcohol intake.
11.	Occupation	The donor who works as aircrew member, long-distance vehicle driver, either above sea level or below sea level or in emergency services or where strenuous work is required, shall not donate blood at least 24 hours prior to their next duty shift. The donor shall not be a night shift workers without adequate sleep.
12.	Risk behaviour	The donor shall be free from any disease transmissible by blood transfusion, as far as can be determined by history and examination. The donor shall not be a person considered “at-risk” for HIV, Hepatitis B or C infections (Transgender, Men who have sex with men, Female sex workers, injecting drug users, persons with multiple sexual partners or any other high risk as determined by the medical officer deciding fitness to donate blood).
13.	Travel and residence	The donor shall not be a person with history of residence or travel in a geographical area which is endemic for diseases that can be transmitted by blood transfusion and for which screening is not mandated or there is no guidance in India.
14.	Donor Skin	The donor shall be free from any skin diseases at the site of phlebotomy. The arms and forearms of the donor shall be free of skin punctures of scars indicative of professional blood donors or addiction to self-injected narcotics.
Physiological Status for Women		
15.	Pregnancy or recently delivered	Defer for 12 Months after delivery
16.	Abortion	Defer for 6 months after abortion
17.	Breastfeeding	Defer for a total period of lactation
18.	Menstruation	Defer for the period of menstruation
Non-specific illness		
19.	Minor non-specific symptoms including but not limited to general malaise, pain, headache	Defer until all symptoms subside, and the donor is afebrile
Respiratory (Lung) Diseases		
20.	Cold, flu, cough, sore throat or acute sinusitis	Defer until all symptoms subside, and the donor is afebrile
21.	Chronic sinusitis	Accept unless on antibiotics
22.	Asthmatic attack	Permanently Defer
23.	Asthmatics on steroids	Permanently Defer

Surgical Procedures		
S.No.	**Criteria**	**Recommendations**
24.	Major surgery	Defer for 12 months after recovery. (Major surgery being defined as that requiring hospitalisation, anaesthesia (general/spinal) had Blood Transfusion and/or had significant Blood loss)
25.	Minor surgery	Defer for 6 months after recovery
26.	Received Blood Transfusion	Defer for 12 months
27.	Open heart surgery, Including By-pass surgery	Permanently defer
28.	Cancer surgery	Permanently defer
29.	Tooth extraction	Defer for 6 months after tooth extraction
30.	Dental surgery under anaesthesia	Defer for 6 months after recovery
Cardio-Vascular Diseases (Heart Disease)		
31.	Has any active symptom (Chest Pain, Shortness of breath, swelling of feet)	Permanently defer
32.	Myocardial infarction (Heart Attack)	Permanently defer
33.	Cardiac medication (digitalis, nitro-glycerine)	Permanently defer
34.	Hypertensive heart disease	Permanently defer
35.	Coronary artery disease	Permanently defer
36.	Angina pectoris	Permanently defer
37.	Rheumatic heart disease with residual damage	Permanently defer
Central Nervous System/ Psychiatric Diseases		
38.	Migraine	Accept if not severe and occurs at a frequency of less than once a week
40.	Convulsions and Epilepsy	Permanently defer
41.	Schizophrenia	Permanently defer
42.	Anxiety and mood disorders	Accept person having anxiety and mood (affective) disorders like depression or bipolar disorder, but is stable and feeling well on the day regardless of medication-
Endocrine Disorders		
43.	Diabetes	Accept person with Diabetes Mellitus well controlled by diet or oral hypoglycaemic medication, with no history of orthostatic hypotension and no evidence of infection, neuropathy or vascular disease (in particular peripheral ulceration) - Permanently defer person requiring insulin and/or complications of Diabetes with multi-organ involvement- Defer if oral hypoglycaemic medication has been altered/dosage adjusted in last 4 weeks

S.No.	Criteria	Recommendations
44.	Thyroid disorders	Accept donations from individuals with Benign Thyroid Disorders if euthyroid (Asymptomatic Goitre, History of Viral Thyroiditis, AutoImmune Hypo Thyroidism) Defer if under investigation for Thyroid Disease or thyroid status is not known Permanently defer if: 1) Thyrotoxicosis due to Graves' Disease 2) Hyper/Hypo Thyroid 3) History of malignant thyroid tumours
45.	Other endocrine disorders	Permanently defer
Liver Diseases and Hepatitis infection		
46.	Hepatitis	Known Hepatitis B, C- Permanently defer Unknown Hepatitis- Permanently defer Known hepatitis A or E; Defer for 12 months
47.	Spouse/ partner/ close contact of individual suffering from hepatitis,	Defer for 12 months
48.	At risk for hepatitis by tattoos, acupuncture or body piercing, scarification and any other invasive cosmetic procedure by self or spouse/ partner	Defer for 12 months
49.	Spouse/ partner of individual receiving transfusion of blood/ components	Defer for 12 months
50.	Jaundice	Accept donor with a history of jaundice that was attributed to gall stones, Rh disease, mononucleosis or in the neonatal period.
51.	Chronic Liver disease/ Liver Failure	Permanently defer
HIV Infection/AIDS		
52.	At risk for HIV infection (Transgender, Men who have Sex with Men, Female Sex Workers, Injecting drug users, persons with multiple sex partners)	Permanently defer
53.	Known HIV positive person or spouse/ partner of PLHA (the person living with HIV AIDS)	Permanently defer
54.	Persons having symptoms suggestive of AIDS	Permanently defer person having lymphadenopathy, prolonged and repeated fever, prolonged & repeated diarrhoea irrespective of HIV risk or status
Sexually Transmitted Infections		
55	Syphilis (Genital sore, or generalized skin rashes)	Permanently defer

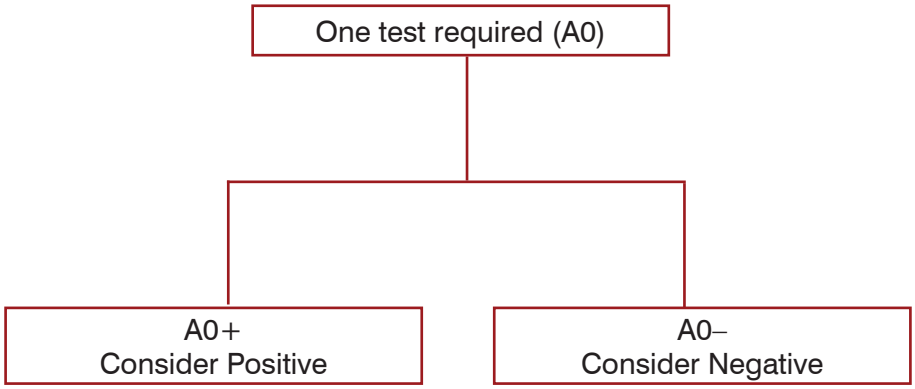
S.No.	Criteria	Recommendations
56.	Gonorrhoea	Permanently defer
Other Infectious diseases		
57.	History of Measles, Mumps, Chickenpox	Defer for 2 weeks following full recovery
58.	Malaria	Defer for 3 months following full recovery.
59.	Typhoid	Defer for 12 Months following full recovery
60.	Dengue/ Chikungunya	In case of history of Dengue/Chikungunya: Defer for 6 Months following full recovery. Following a visit to Dengue/Chikungunya endemic area: 4 weeks following return from a visit to the dengue-endemic area if no febrile illness is noted.
61.	Zika Virus/ West Nile Virus	In case of Zika infection: Defer for 4 months following recovery. In case of history of travel to West Nile Virus endemic area orZika virus outbreak zone: Defer for 4 months.
62.	Tuberculosis	Defer for 2 years following confirmation of cure
63.	Leishmaniasis	Permanently defer
64.	Leprosy	Permanently defer
Other infections		
65.	Conjunctivitis	Defer for the period of illness and continuation of local medication.
66.	Osteomyelitis	Defer for 2 years following completion of treatment and cure.
Kidney Disease		
67.	Acute infection of kidney (pyelonephritis)	Defer for 6 months after complete recovery and last dose of medication
68.	Acute infection of bladder (cystitis) / UTI	Defer for 2 weeks after complete recovery and last dose of medication
69.	Chronic infection of kidney/ kidney disease/ renal failure	Permanently defer
Digestive System		
70.	Diarrhoea	Person having history of diarrhoea in preceding week particularly if associated with fever: Defer for2 weeks after complete recovery and last dose of medication
71.	GI endoscopy	Defer for 12 months.
72.	Acid Peptic disease	Accept person with acid reflux, mild gastro-oesophageal reflux, mild hiatus hernia, gastro-oesophageal reflux disorder (GERD), hiatus hernia: Permanently defer person with stomach ulcer with symptoms or with recurrent bleeding:
Other diseases/ disorders		
73.	Autoimmune disorders like Systemic lupus erythematosis, scleroderma, dermatomyositis, ankylosing spondylitis or severe rheumatoid arthritis	Permanently defer
74.	Polycythaemia Vera	Permanently defer
75.	Bleeding disorders and unexplained bleeding tendency	Permanently defer

S.No.	Criteria	Recommendations
76.	Malignancy	Permanently defer
77.	Severe allergic disorders	Permanently defer
78.	Haemoglobinopathies and red cell enzyme deficiencies with a known history of haemolysis	Permanently defer
Vaccination and inoculation		
79.	**Non-live vaccines and Toxoid:** Typhoid, Cholera, Papillomavirus, Influenza, Meningococcal, Pertussis, Pneumococcal, Polio injectable, Diphtheria, Tetanus, Plague	Defer for 14 days
80.	**Live attenuated vaccines**: Polio oral, Measles(rubella) Mumps, Yellow fever, Japanese encephalitis, influenza, Typhoid, Cholera, Hepatitis A	Defer for 28 days
81.	Anti-tetanus serum, anti-venom serum, anti-diphtheria serum, and anti-gas gangrene serum	Defer for 28 days
82.	Anti-rabies vaccination following the animal bite, Hepatitis B Immunoglobulin, Immunoglobulins	Defer for 1 year
83	Swine Flu	Defer for 15 days
Medications taken by prospective blood donor		
84.	Oral contraceptive	Accept
85.	Analgesics	Accept
86.	Vitamins	Accept
87.	Mild sedative and tranquillizers	Accept
88.	Allopurinol	Accept
89.	Cholesterol lowering medication	Accept
90.	Salicylates (aspirin), other NSAIDs	Defer for 3 days if blood is to be used for Platelet preparation
91.	Ketoconazole, Antihelminthic drugs including mebendazole,	Defer for 7 days after last dose if donor is well
92.	Antibiotics	Defer for 2 Weeks after last dose if donor is well

S.No.	Criteria	Recommendations
93.	Ticlopidine, clopidogrel	Defer for 2 Weeks after last dose
94.	Piroxicam, dipyridamole	Defer for 2 Weeks after last dose
95.	Etretinate, Acitretin or Isotretinoin. (Used for acne)	Defer for 1 month after the last dose
96.	Finasteride used to treat benign prostatatic hyperplasia	Defer for 1 month after the last dose
97.	Radioactive contrast material	8 weeks deferral
98.	Dutasteride used to treat benign prostatatic hyperplasia	Defer for 6 months after the last dose
99.	Any medication of unknown nature	Defer till details are available
100.	Oral anti-diabetic drugs	Accept if there is no alteration in dose within the last 4 weeks.
101.	Insulin	Permanently defer
102.	Anti-arrhythmic, Anti-convulsions, Anticoagulant, Anti-thyroid drugs, Cytotoxic drugs, Cardiac Failure Drugs(Digitalis)	Permanently defer
Other conditions requiring Permanent deferral		
103.	Recipients of organ, stem cell and tissue transplants Donors who have had an unexplained delayed faint or delayed faint with injury or two consecutive faints following a blood donation.	Permanently defer
Residents of other countries		
104	Residents of other countries	Accept only after staying in India for three continuous years
COVID-19 infections		
105	History of travel to country/ place with Covid 19 transmission in community and areas as notified by Ministry of Health and Family welfare time to time	Deferred from donating blood for 28 days after departure
106	Any history of possible close contact exposure to a person who is confirmed/Suspected case of Covid-19, including those under quarantine.	Deferred from donating blood for 28 days after last possible contact/ exposure
107	Confirmed cases of COVID-19	Deferred till complete recovery from disease, including radiological and virological clearance.

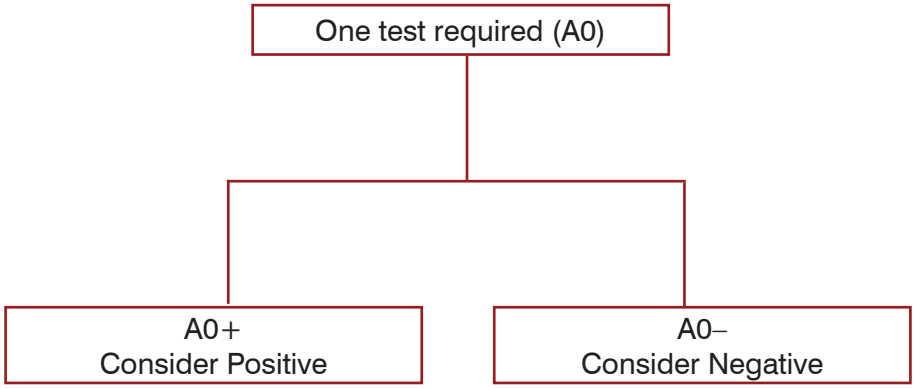
Annexure-5:

Infectious makers testing and referral strategy



Flow chart of Strategy I

1. Prior consent shall be taken from the donor for both conductions of screening tests and to be informed of the result of testing at the time of the donation by the Blood Centre along with complete contact details and telephone number.
2. All blood donors found to be HIV sero-reactive at the Blood Centre shall be referred to Integrated Counselling and Testing Centres (ICTC) for counselling and confirmation.
3. Blood Centre shall fill out the referral form as per the standard format in annexure 2 and send it along with referred donor.
4. Confidentiality shall be maintained at all levels.



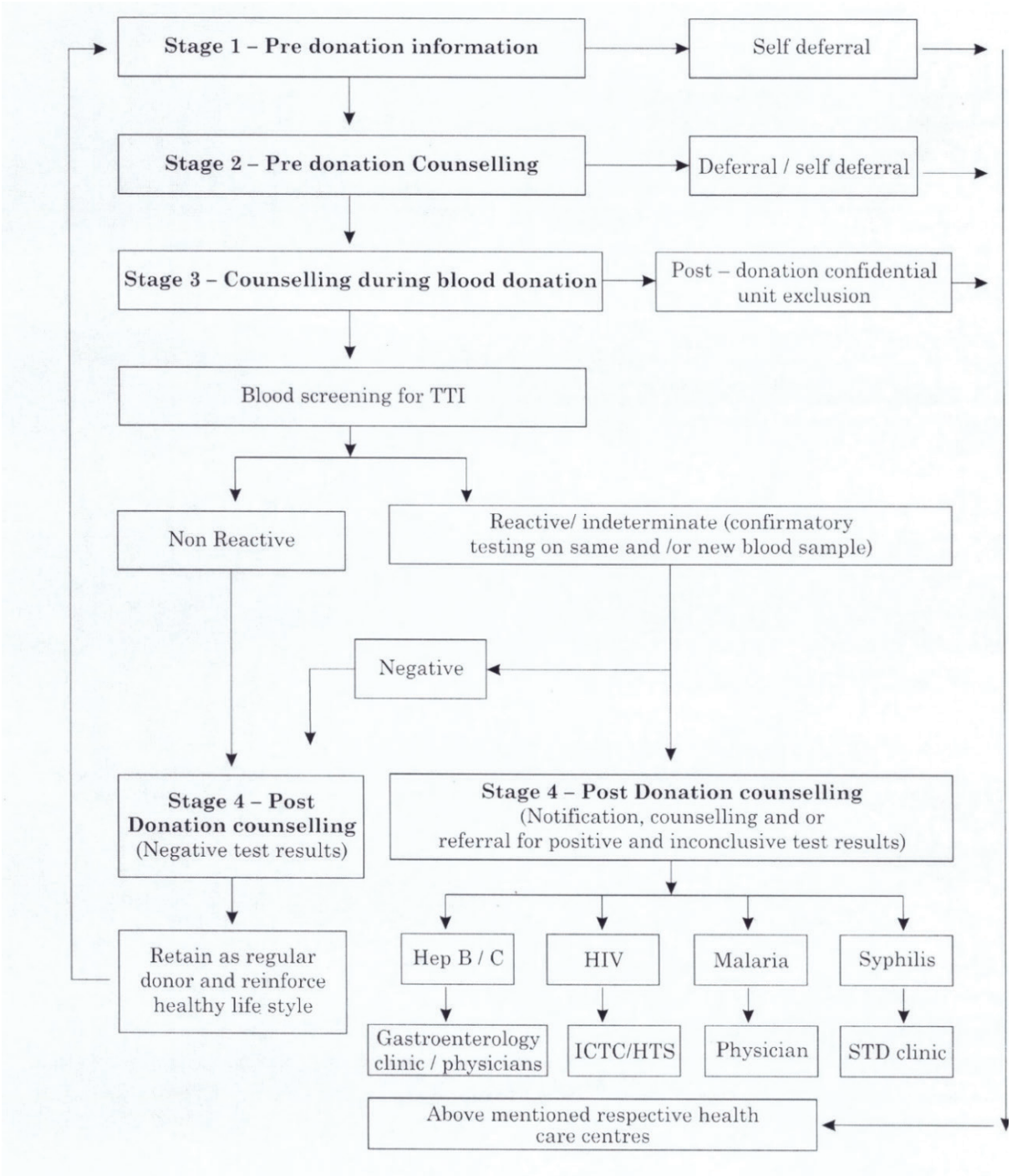
Flow chart of Strategy II

1. Prior consent shall be taken from the donor for both conduction of screening tests and to be informed of the result of testing at the time of the donation by the Blood Centre along with complete contact details and telephone number.

2. All blood donors found to be HIV sero-reactive at the Blood Centre shall be referred to Integrated Counselling and Testing Centres (ICTC) for counselling and confirmation.
3. Blood Centre shall fill out the referral form as per the standard format in annexure 2 and send it along with referred donor.
4. Confidentiality shall be maintained at all levels.

Annexure-6:

Stages of Blood Donor Counselling



Annexure-7:

Specifications, Acceptance Criteria and Quality Control for Reagents and Components

1. Frequency of testing for reagent and solution

Reagents and solutions	Frequency of testing along with Controls
Anti human globulin serum	Each day of use
Blood grouping anti sera	Each day of use
Lectins	Each day of use
Red cells for serum grouping	Each day of use
Reagent red cells for antibody screening	Each day of use
Hepatitis reagents	Each run
Syphilis serology reagents	Each run
Enzymes	Each run
HIV –1/ 2 reagent	Each run
Normal saline (LISS and PBS)	Each day of use
Bovine albumin	Each day of use
MP by ELISA	Each run
Column agglutination cards	Each day of use

NB: All reagents shall be checked for expiry date and used only when within that date.

2. Quality control of reagent red blood cells

Parameters	Quality Requirement	Frequency of Control
Appearance	No haemolysis or turbidity in the supernatant by visual inspections	Each day
Reactivity and specificity	Positive reactions with known sera against red blood cells antigens	Each day

3. Acceptance Criteria for Titre, Specificity and Avidity for Anti-A (Monoclonal) Reagent

Name of the Reagent	Type of the Reagent	Physical Appearance and Color	Type of Red Cells	Titre	Avidity (time in Seconds)	Intensity	Specificity	Reactivity (Rouleaux Haemolysis Prozone)
Anti-A	Monoclonal	Clear, No turbidity, precipitate, particles or gel formation by visual inspection and blue colored liquid	A_1 A_2 A_2B B 0	≥1:256 ≥1:128 ≥1:64 – –	3-4 sec 5-6 sec 5-6 sec – –	3+ 2+ to 3+ 3+ to 4+ – –	Positive Positive Positive Negative Negative	↑ Absent ↓

4. Acceptance Criteria for Titre, Specificity and Avidity for Anti-B (Monoclonal) Reagent

Name of the Reagent	Type of the Reagent	Physical Appearance and Color	Type of Red Cells	Titre	Avidity (time in Seconds)	Intensity	Specificity	Reactivity (Rouleaux Haemolysis Prozone)
Anti-B	Monoclonal	Clear, No turbidity, precipitate, particles or gel formation by visual inspection and blue colored liquid	B A_1B A_1 0	≥1:256 ≥1:128 – –	3-4 5-6 – –	4+ 2+ to 3+ – –	Positive Positive Negative Negative	Absent

5. Acceptance Criteria for Titre, Specificity and Avidity for Anti-AB (Monoclonal) Reagent

Name of the Reagent	Type of the Reagent	Physical Appearance and Color	Type of Red Cells	Titre	Avidity (time in Seconds)	Intensity	Specificity	Reactivity (Rouleaux Haemolysis Prozone)
Anti-A,B	Monoclonal	Clear, No turbidity, precipitate, particles or gel formation by visual inspection and blue colored liquid	A_1 B A_2 A_x 0	≥1:256 ≥1:256 ≥1:128 – –	3-4 sec 3-4 sec 5-6 sec – –	4+ 4+ 3+ – –	Positive Positive Positive Negative Negative	Absent

6. Acceptance Criteria for Titre, Specificity and Avidity for Anti- D (IgM) Monoclonal Reagent

Name of the Reagent and Type of the Reagent	Physical Appearance and Color	Type of Red Cells	Titre	Avidity (Seconds)	Intensity	Specificity	Reactivity (Rouleaux Haemolysis Prozone)
Anti-D (IgM) Blend Monoclonal	Clear, No turbidity, precipitate, particles or gel formation by visual inspection and colorless liquid	O+ve R_1r (or) R_1R_2	IS - 1:64 – 1:128 37°C x 30" 1:128 – 1:256	5-10 sec	3+	Positive	Absent
		Rh-negative (IAT)	–	–	–	Negative	

7. Acceptance Criteria for Titre, Specificity and Avidity for Reagent Anti- D (IgM+IgG) (Blend)

Name of the Reagent and Type of the Reagent	Physical Appearance and Color	Type of Red Cells	Titre	Avidity (Seconds)	Intensity	Specificity	Reactivity (Rouleaux Haemolysis Prozone)
Anti-D (IgG +IgM) Blend Monoclonal	Clear, No turbidity, precipitate, particles or gel formation by visual inspection and colorless liquid	O+ve R_1r (or) R_1R_2	IS - 1:32 – 1:64	10-20 sec	3+	Positive	Absent
			37°C x 30" 1:128 – 1:256				
		Rh-negative (IAT)	–	–	–	Negative	

8. Acceptable quality of anti-globulin reagent

Parameter	Quality requirement	Frequency of control
Appearance	No precipitate, particles or gel formation by visual in inspection.	Each day
Reactivity and Specificity	No prozone phenomenon	Each lot
	No haemolysis or agglutination of unsensitized red cells	Each day
	Agglutination of red cells sensitised with anti-D serum.	Each day and each new lot/ batch.

9. Quality control of proteases (Enzymes)

Parameter	Quality requirements	Frequency of control
Reactivity	No agglutination or haemolysis using inert AB serum. Agglutination (+++/ C) of cells sensitised with a weak IgM (Anti-D).	Each day
Potency	An IgG antibody, preferably anti-D standardized to give a titre about 32-64 by the protease technique, should show the same titre on repeated testing with different batches.	Each batch
	The 2-stage enzyme titre should at least be equal to the titre obtained with IgG (anti-D) by AHG test	Each batch

10. Quality Control of 22% Bovine Serum Albumin (BSA)

Parameter	Quality requirement	Frequency of control
Appearance	No precipitate, particles or gel formation by visual inspection	Each day
Purity	>98% albumin,	Each new lot
Reactivity	No agglutination of unsensitized red cells; no haemolytic activity; no prozone phenomenon	Each new lot
Potency	IgG anti-D should give a titre of 32-64 with 'O' pooled red cells/ R1R1 cells	Each month

11. Quality control of normal saline

Parameter	Quality requirement	Frequency of control
Appearance	No turbidity or particles by visual inspection	Each day
pH	6.0-8.0	Each new batch
Haemolysis	A mixture of 0.1 ml saline and 0.1 ml of 5% red cells suspension centrifuged after 10 min, no haemolysis	Each new batch

12. Quality control of distilled water

Parameter	Quality requirement	Frequency of control
Appearance	Clear, no particles on visual inspections	Each day
PH	6.0-7.0	Each new batch

Detailed specifications, acceptance criteria and quality control for Blood components

Whole Blood

Parameter	Specifications	Frequency of Control
Volume	350/ 450 ml + 10%	1% of all units
PCV (HCT)	>30%	1% of all units or at least 4 units per month (whichever is more)
Sterility	By culture	Periodically (1% of all units)

Whole blood, leucocyte depleted

Parameter	Specifications	Frequency of Control
Volume	350/ 450 ml + 10%	1% of all units
PCV (HCT)	>30%	1% of all units or at least 4 units per month (whichever is more)
Sterility	By culture	Periodically (1% of all units)
Leucocyte count	<5 x10^6/unit	4 units a month

Red cells in CPDA (Prepared from 450 ml Whole blood)

Parameter	Quantity Requirement	Frequency of Control
*Volume	250 ml ± 10% (+1OO ML ADDITIVE SOLUTION)	1% of all units
HCT	65-70%	1% of all units

Red cells in additive solution, Buffy Coat removed (prepared from 450 ml whole blood)

Parameter	Quantity Requirement	Frequency of Control
Volume	250 ml ± 10%	1% of all units
HCT	50-60%	Periodically (1% of all units)

Red cells in additive solution, Buffy Coat removed (Prepared from 350 ml whole blood)

Parameter	Quantity Requirement	Frequency of Control
Volume	150 ml ± 10% (+1OO ML ADDITIVE SOLUTION)	1% of all units
HCT	50-60%	Periodically (1% of all units)

Red Cells in Additive Solution, Leucocyte Depleted (Prepared from 450 ml Whole blood)

Parameter	Specifications	Frequency of Control
Volume	250 ml ± 10% (+1OO ML ADDITIVE SOLUTION)	1% of all units
PCV (HCT)	50-60%	1% of all units
Leucocyte count	<5 $x10^6$/unit	4 units a month

Red Cells, Washed, Leucocyte Depleted

Parameter	Specifications	Frequency of Control
Volume	Within locally specified volume range	1% of all units or if made less frequently, every component
PCV (HCT)	50-60%	1% of all units
Leucocyte count	<5 $x10^6$/unit	4 units a month
Total protein content	< 5 mg/ unit	1% of all units

Red cells, pediatric

Parameter	Specifications	Frequency of Control
Volume	120 ml ± 30 ml	1% of all units or if made less frequently, every component
PCV (HCT)	50-60%	1% of all units

Red cells, infant or neonate

Parameter	Specifications	Frequency of Control
Volume	55 ml ± 20 ml	1% of all units or if made less frequently, every component
PCV (HCT)	50-60%	1% of all units

Red cells, cryopreserved

Parameter	Specifications	Frequency of Control
Volume	Within locally specified volume range	1% of all units or if made less frequently, every component
PCV (HCT)	50-60%	1% of all units
Sterility	Negative	Every unit

Platelet concentrate- Random donor (PRP method)

Parameter Quality	Specifications	Frequency
Volume	50-70 ml	All units
Platelets count	≥3.5/4.5 x 10^{10} platelets per unit from a unit of 350 ml and 450 ml blood, respectively	4 units per month/ 1% of all units (whichever is more)
pH	>6.0	4 units per month/ 1% of all units (whichever is more)
RBC contamination	<0.5 ml	4 units per month/ 1% of all units (whichever is more)

Platelet concentrate- Random donor (Buffy coat method- BC-PC)

Parameter	Quality Requirements	Frequency of control
Volume	50-90 ml	4 units per month/ 1% of all units (whichever is more)
Platelets count	>6X10^{10}	4 units per month/ 1% of all units (whichever is more)
pH	>6.0	4 units per month/ 1% of all units (whichever is more)
RBC contamination	Traces to 0.5 ml	4 units per month/ 1% of all units (whichever is more)

Apheresis platelets

Parameter	Quality requirement	Frequency of control
Volume	>200 ml	4 units per month/ 1% of all units (whichever is more)
Platelets count	> 3.0 x 10^{11}	4 units per month/ 1% of all units (whichever is more)
pH	>6.0 (at the end of permissible storage period)	4 units per month/ 1% of all units (whichever is more)
Red cells	Traces to 5 ml	4 units per month/ 1% of all units (whichever is more)
Leucocyte count	<5 x 10^{6} /unit	4 units per month/ 1% of all units (whichever is more)

Apheresis platelets- Pediatric

Parameter	Quality requirement	Frequency of control
Volume	150 ml ± 50 ml	4 units per month/ 1% of all units (whichever is more)
Platelets count	1.0 x 10^{11} – 3.0 x 10^{11}	4 units per month/ 1% of all units (whichever is more)
pH	>6.0 (at the end of permissible storage period)	4 units per month/ 1% of all units (whichever is more)
Red cells	Traces to 5 ml	4 units per month/ 1% of all units (whichever is more)
Leucocyte count	<5 x 10^{6} /unit	4 units per month/ 1% of all units (whichever is more)

Platelets, Pooled

Parameter	Quality requirement	Frequency of control
Volume	>200 ml	4 units per month/ 1% of all units (whichever is more)
Platelets count	> 2.0 x 10^{11}/ unit	4 units per month/ 1% of all units (whichever is more)
pH	>6.0 (at the end of permissible storage period)	4 units per month/ 1% of all units (whichever is more)
Red cells	Traces to 5 ml	4 units per month/ 1% of all units (whichever is more)

Platelets, suspended in platelet additive solution, leucocyte depleted

Parameter	Quality requirement	Frequency of control
Volume	>200 ml	4 units per month/ 1% of all units (whichever is more)
Platelets count	> 3 x 10^{11}	4 units per month/ 1% of all units (whichever is more)
pH	>6.0 (at the end of permissible storage period)	4 units per month/ 1% of all units (whichever is more)
Red cells	Traces to 5 ml	4 units per month/ 1% of all units (whichever is more)
Leucocyte count	<5 x 10^{6} /unit	4 units per month/ 1% of all units (whichever is more)

Note: Visual inspection of platelet components for the swirling phenomenon, clumping, excessive red cell contamination and abnormal volume is a useful pre-issue check.

Fresh Frozen Plasma (FFP)

Parameter	Quality control	Frequency of control
Volume	180-220 ml from 350 ml bag 220-300 ml from 450 ml bag	4 units per month/ 1% of all units (whichever is more)
Stable coagulation factors	Check by PT & APTT	4 units per month
Factor VIII	at least 70 iu / bag	4 units per month
Fibrinogen	200–400 mg	4 units per month

Cryoprecipitate

Parameter	Quality control	Frequency of control
Volume	15 – 20 ml	1% of all units
Factor VIII	at least 80 iu/bag	1% of all units
Fibrinogen	at least 150 mg/bag	1% of all units

Single Donor Plasma (Frozen)

Parameter	Quality control	Frequency of control
Volume	200–220 ml	1% of all units
Stable coagulation factors	Check by PT & APTT	1% of all units

Red Cells for Intrauterine Transfusion (IUT), Leucocyte Depleted

Parameter	Specifications	Frequency of Control
Volume	Within locally specified volume range	1% of all units or if made less frequently, every component
PCV (HCT)	Within locally specified volume range but not less than 0.70	1% of all units
Leucocyte count	$<5 \times 10^6$ /unit	4 units a month

Red cells for exchange transfusion, leucocyte depleted

Parameter	Specifications	Frequency of Control
Volume	Within locally specified volume range	1% of all units or if made less frequently, every component
PCV (HCT)	0.50–0.60	1% of all units
Leucocyte count	$<5 \times 10^6$ /unit	1% or 4 units a month

Granulocyte Concentrate

Parameter	Specifications	Frequency of Control
Volume	200–250 ml	1% of all units or if made less frequently, every component
Granulocyte count	$0.5–1 \times 10^9$	1% of all units

Granulocytes, Apheresis

Parameter	Specifications	Frequency of Control
Granulocytes	$1X10^{10}$	1% of all units or if made less frequently, every component
Other leucocytes	$0.1\text{-}0.7\ X10^9$	
Platelets	$2\text{-}10X10^{11}$	
Red cells	5–50 ml	
Plasma	200–400 ml	
HES if used	6–12 % of volume	

Note: For mandatory microbiology screening and blood grouping tests, all components must be serologically non-reactive(Culture: Sterile)

Annexure-8:

Adverse Blood Donor Reaction form from Hemovigilance Program by National Institute of Biologicals

National Institute of Biologicals
Ministry of Health & Family Welfare, Govt. of India
NATIONAL BLOOD DONOR VIGILANCE PROGRAMME
(Haemovigilance Programme of India)
Adverse Blood Donor Reaction Reporting Form

Version-2

A) Donor Information

Donor Id *: _____

Type of Donation* **(a)** Whole Blood **(b)** Apheresis__ (Platelets/Plasma/ Plasma + Platelets/RBC/Granulocyte/ Peripheral Blood Stem Cells/ COVID-19 Convalescent Plasma)

Sex * _____ (Male/Female/Other)

Weight of Donor (kg) * _____ Height of Donor (cm)* _____

Donor Type* **(a)** Voluntary **(b)** Replacement **(c)** Family Donor **(d)** Autologous (First Time/Repeat)

Age/ Date of Birth * Yrs: ____ Month: ____ Days: ____ OR _____

Site of Donation* _____ (Blood Centre/Camp)

Pre-Donation Vitals* Pulse: ____ per min BP (Systolic): ____ mmHg BP (Diastolic): ____ mmHg

Date of Donation * _____

Time of Donation Hr ____ Min ____

B) Whole blood Details of Blood Collected/Apheresis Details of Blood Collected

(a) Whole Blood

Lot No. of Blood Bag* _____

Volume Collected (ml)* _____

Manufacturer of Blood Bag* _____ (Terumo Penpol Limited/Mitra Industries Pvt. Ltd/ HLL Lifecare Ltd/Fresenius Kabi AG/Fenwal Inc/Polymed/Other)

Expiry Date of Blood Bag* _____

(b) Apheresis

Lot No. Kit* _____

Volume Collected (ml)* _____

Expiry Date of Kit* _____

C) Adverse Reaction Details

Date and Time of reaction* _____ Hr____Min____

Type of Reaction* _____ (Localised/Generalized/Both/ Other Reactions)

Vitals at the time of Reaction Pulse: _____ per min BP (Systolic): ____ mmHg BP (Diastolic): ____ mmHg

Data Captured* _____ (Onsite/Call back by donor/ Call back by Blood Centre)

Reaction Time* _____ (Pre-Donation/During Donation/After Donation)

Venipuncture Site* _____ (Left/Right/Both)

Injury* _____ (Yes/No)

Venipuncture* _____ (1/2/>2)

Site of Reaction* _____ (At Donation Site/ Outside Donation Site)

Donation Completed* _____ (Yes/No)

D) Type of Complications:*

Localised Complications

☐ **A1-Complications mainly characterized by the occurrence of blood outside the vessels**
- (a) ☐ Haematoma (bruise)
- (b) ☐ Arterial puncture
- (c) ☐ Delayed(bleeding/Re-bleeding) ☐ (Within 30 minutes of Donation/After 30 minutes of Donation)

☐ **A2-Complications mainly characterized by pain**
- (a) ☐ Nerve injury/irritation
- (b) ☐ Other Painful arm

☐ **A3-Localised infection/inflammation along the course of a vein**
- (a) ☐ Thrombophlebitis
- (b) ☐ Cellulitis

☐ **A4- Allergy (local): Itching and redness at the** ☐ (Venipuncture Site/Medical Adhesive Medicated Tape/Skin Disinfection Area)

☐ **A5-Other major blood vessel injury -Serious conditions needing specialist medical diagnosis and attention**
- (a) ☐ Deep venous thrombosis (DVT)
- (b) ☐ Arteriovenous fistula
- (c) ☐ Compartment syndrome
- (d) ☐ Brachial artery pseudoaneurysm

Annexure-9:

Transfusion Reaction Reporting form from Hemovigilance Program by National Institute of Biologicals

National Institute of Biologicals
Ministry of Health & Family Welfare, Govt. of India
(National Coordinating Center)
HAEMOVIGILANCE PROGRAMME OF INDIA

Transfusion Reaction Reporting Form (TRRF) For Blood & Blood Components & Plasma Products (Version-2)

* Mandatory Field

(A) Patient Information

Hospital Code No.:

Patient Initials*: | Gender*: | Blood Group*:

Hospital Admission No.*: | Age/Date of Birth*: | .....Yrs | .....Month | .....Days | .....Hrs | .....Mins

Primary Diagnosis*:

Medical History:

(B) Transfusion Reaction Details*

Was the patient under anaesthesia during transfusion: Yes/No if Yes type : GA/Spinal/LA

Pre-transfusion Vitals:	Temp:	Pulse:	BP:	RR:	SPO2:
Vitals at the time of reaction:	Temp:	Pulse:	BP:	RR:	SPO2:

Please tick mark the relevant signs and symptoms listed below

Generalised		Pain	Respiratory	Renal	Circulatory
☐ Fever	☐ Anxiety	☐ Chest Pain	☐ Dyspnoea	☐ Haematuria	☐ Tachycardia
☐ Chills	☐ Itching (Pruritus)	☐ Abdominal	☐ Wheeze	☐ Haemoglobinuria	☐ Hypertension
☐ Rigors	☐ Edema (Site)____	☐ Back/Flank Pain	☐ Cough	☐ Oliguria	☐ Hypotension
☐ Nausea	☐ Juandice	☐ Infusion Site Pain	☐ Hypoxemia	☐ Other_____	☐ Raised JVP
☐ Urticaria	☐ Other_____	☐ Other_____	☐ Bilateral Infiltrates on Chest X-ray		☐ Arrhythmias
☐ Flushing					☐ Other_____
☐ Restlessness					
☐ Vomiting			☐ Other_____		

Any Other(Specify) : .....

(C) Transfusion Product(s) Details*

Select*	Select Component	Select Indication	Date & Time of Issue of Blood Component	Date & Time of onset Transfusion	Unit Id (Transfused)	Blood Group	Volume Transfused (ml)	Expiry date of Blood Component	Manufacturer of Blood Bag	Batch / Lot No. of the Blood Bag	1st time/ repeat Transfusion
☐	Saline Washed Red Cells										☐ 1st Time
☐	COVID-19 Convalescent Plasma										
☐	Whole blood										
☐	Packed Red blood cells (PRBC)										
☐	Buffy coat depleted PRBC										
☐	Leucofiltered PRBC										
☐	Random Donor platelets/ pooled										☐ Repeat 1 to 10
☐	Apheresis Platelets										
☐	Fresh Frozen Plasma										☐ Repeat > 10
☐	Cryoprecipitate										
☐	Any Other _____										

Add New Plasma Product

Select	Plasma Product	Indication	Date of Administration	Manufacturer	Expiry Date of the Plasma Product	Batch No. / Lot No.	1st Time / Repeat
							☐ 1st Time ☐ Repeat 1 to 10 ☐ Repeat > 10

Annexure-10:

Requirements to Start a Blood / Component Storage Centre

Equipment:

1. Blood Centre Refrigerators having a storage capacity of 50 units of Blood.
2. Deep Freezers for freezing ice packs required for transportation. The deep freezers available in the FRUs under the Immunisation Programme can be utilised for this purpose.
3. Insulated Carrier boxes with ice packs for maintaining the cold chain during transportation of blood bags.
4. Microscope and centrifuge: Since these are an integral part of any existing laboratory, these would already be available at the FRUs. These should be supplied only if they are not already available.

Consumables:

There should be adequate provision for consumables and blood grouping reagents. The following quantities would suffice the annual requirement of an FRU with up to 50 beds.

Consumables	Quantity
Pasteur Pipette	12 dozens/year
Glass tubes	7.5 to 10 mm -100 dozens/year
Glass Slides	1”x2” boxes of 20 or 25 each/year
Test Tube Racks	6 racks, each for 24 tubes
Rubber Teats	6 dozens / year
Gloves	Disposable rubber gloves 500 pairs per year
Blotting/tissue paper	As required
Marker Pen	As required
Tooth Picks	As required

Reagents:

All the reagents should come from the Mother Blood Centre.

Anti-A 2-vials each per month

Anti-B 2-vials each per month

Anti-AB 2-vials each per month

Anti-D 2 vials each per month (Blend of IgM & IgG)

Antihuman Globulin 1 vial per month (Polyclonal – IgG & Complement)

Since the quality of the reagents is an important issue, the supplies of these should be made from the same Blood Centre/centre from where blood is obtained. For this purpose, State Governments / Union Territories should provide the additional budgetary requirements to the mother Blood Centre/centre.

Disinfectants: Bleach and hypochlorite Solution, as required and to follow Bio-Medical Waste management rules

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Technical Support by
World Health Organization India Country Office

Directorate General of Health Services
National AIDS Control Organization
Ministry of Health & Family Welfare, Government of India