Standards for Blood Banks & Blood Transfusion Services

National AIDS Control Organisation
Ministry of Health and Family Welfare
Government of India
New Delhi

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FOREWORD

Blood Transfusion Service is a vital part of the health care service. Increasing advancement in the field of Transfusion Medicine and Technology has necessitated enforcing measures to ensure quality of Blood and its products. The blood transfusion system has made significant advancement in areas of donor management, storage of blood, grouping and cross matching, testing for transmissible diseases, rationale use of blood and distribution etc.

In order to improve the standards of Blood Banks and the Blood Transfusion services in our country, National AIDS Control Organization through Technical Resource Group on Blood Safety, has formulated comprehensive standards to ensure better quality control system on collection, storage, testing and distribution of blood and its components.

For quality, safety and efficacy of blood and blood products, well-equipped blood centres with adequate infrastructure and trained manpower is an essential requirement. For effective clinical use of blood, it is necessary to train clinical staff. To attain maximum safety, the requirements of good laboratory practices (GLP), good manufacturing practices (GMP) and moving towards total quality management is vital for organization and management of Blood Transfusion Services.

I would like to acknowledge the contribution made by the experts in Transfusion Medicine as members of "Technical Resource Group on Blood Safety" for providing their technical expertise in framing the Standards for Blood Banks and Blood Transfusion Services.

I hope that these standards will help Blood banks in the country for improving their standards and thereby provide excellent and high quality services to the citizens of our country.

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PREFACE

A well-organised Blood Transfusion Service (BTS), with quality systems in all areas, is a pre-requisite for the safe and effective use of blood and blood products. This is a vital component of any health care delivery system. An integrated strategy for Blood Safety is required for elimination of transfusion transmitted infections (TTI) and for provision of safe and adequate blood supply to the people.

The BTS in India is highly decentralized and lack many vital resources like manpower, adequate infrastructure and financial base. The main issue, which plagues blood banking system in the country, is fragmented management. The standards vary from State to State, cities to cities and centre to centre in the same city. The blood component production/availability and utilization is extremely limited. There is shortage of trained health-care professionals in the field of Transfusion Medicine.

A well defined standard for Blood Banks was a long-felt demand for improving the blood transfusion services in the country. National Blood Transfusion Council has entrusted this responsibility to the Technical Resource Group on Blood Safety to develop a comprehensive standards which will help to bring a paradigm change in the functional status of blood banks in India. This document will help the State Health Authorities, Licensing Authorities, administration of the hospital-based blood banks and blood banks run by charitable organization to understand the basic standards required to operate a blood bank in the most efficient way and thereby provide quality service delivery.

I acknowledge the initiative taken by National Blood Transfusion Council for providing support to Technical Resource Group for developing these standards. The technical inputs provided by all the members of TRG are highly praiseworthy. Their contribution for giving a final shape to this document is extremely commendable.

Dr. Zarine S. Bharucha
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A. General Guidelines

The Blood Bank or Blood Transfusion Service should have its own constitution, which defines the responsibility and authority of the management.

A. General Guidelines

A-1.0 The Blood Bank or Blood Transfusion Service should have its own constitution, which defines the responsibility and authority of the management.

A-1.1 The blood bank should function under the direction of a licensed physician qualified by training and by experience as Transfusion Medicine Specialist (Medical Officer, Blood Bank) who should be responsible for all medical, technical and administrative services.

A-1.2 All blood banks should be licensed by State Drug Controller and approved by Drugs Controller General-(India) and should be regulated by Drugs and Cosmetics Act and rules there under.

A-1.3 Blood bank should comply with laid-down standards in Drugs and Cosmetic Rules in recruitment and selection of blood donors, collection, processing, storage and distribution.

A-2.0 All blood banks should have their own quality policy and prepare a quality manual that addresses the systems in use.

A-2.0.1 Every section responsible for various services will define its own QC program including outsource services. It is also recommended that centers participate in various EQAS programs.

A-2.1 Each blood bank should maintain a detailed standard operating procedure manual, as well as records (forms, registers, labels) in a prescribed format prescribed by Drug & Cosmetics Rules.

A-3.0 There should 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. (*Refer A-7.0*)

A-4.0 Suitable space, environment and equipment should be available to maintain safe and acceptable standards of house keeping. The records

of calibration, maintenance and validation of equipment should be maintained.

A-5.0 All materials for blood collection and transfusion should be sterile, pyrogen free and disposable and should be stored in an air conditioned area.

A-5.1 All containers and anticoagulants used for storage, preservation of blood and blood components and required reagents used for testing of blood samples should meet the standards of Drugs and Cosmetics Act and Rules and Bureau of Indian Standards (BIS).

A-6.0 The blood banks and transfusion services should aim to accept blood from only voluntary non-remunerated safe blood donors and to do away with the high risk donors and blood sellers. They should gradually phase out replacement donors. (N.B.: Blood sellers have been banned as per Supreme Court directive).

A-7.0 QUALITY ASSURANCE SYSTEM

The blood banks should establish and maintain a quality assurance system based on any current international standard that includes the following essentials.

- Organisation and Management
- Resources
- Equipment
- Supply and customer issues
- Process control
- Documents and records (Refer Section O - Documentation in Transfusion Services)
- Deviations nonconformances and complications
- Assessments
- Process improvements
- Facilities and safety

A-8.0 MANPOWER

A-8.1 All blood banks should provide full time competent staff ensuring proper cadres for both medical and paramedical personnel.

A-8.2 In all medical colleges effort should be made to develop a Department of Transfusion Medicine where faculty as required by Medical Council of India rules is appointed.

A-8.3 All blood banks collecting more than 10,000 units of blood and/or having blood component license should employ a Diploma or M.D (TM) or M.D. (Pathology) with minimum one year experience in blood bank to head the services.

A-8.3.1 Blood banks collecting < 10,000 units should at least have an MBBS doctor with minimum one year experience in blood bank to manage the services

A-8.4 A quality manager should be appointed / deputed (either a medical officer or a senior MLT trained in quality management in all blood banks collecting >10,000 units per year.

A-8.5 All blood banks should recruit other staff as per recommendations given in Drugs & Cosmetics Rules.

A-8.6 The job specifications should be clearly laid down for all staff members.

A-8.7 The staff members, should be given induction training, soon after appointment. The training records should be maintained, updated and reviewed.

A-8.7.1 All staff should be encouraged to participate in CME programmes at regular intervals

A-8.7.2 Proficiency test of all technical staff should be conducted annually to ensure reliability of their performance.

A-8.8 All staff should be provided training and facilities for implementing universal precautions for hospital acquired infections and Biosafety Guidelines. (Ref Q)

A-8.9 Blood Transfusion Service should provide safe handling facilities for disposal of wastes.

A-9 FINANCIAL ACTIVITIES

A-9.1 Accurate costing enables accurate planning and budgeting so that the department runs efficiently without shortage of supply in the middle of the year. It also enables planning for future expansion, evaluates cost effectivity and helps in mobilisation of resources.

A-9.2 There should 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.

A-9.3 Service charges of a unit of blood should be derived by dividing the total cost per year (capital + recurrent) by the number of units collected / year

A-9.4 The policy of charging a deposit against a replacement of blood to be made later should be discontinued.

B. Donor Selection

DONOR RECRUITMENT & RETENTION

Blood should be accepted only from voluntary, non-remunerated, low risk, safe and healthy donors.

B. Donor Selection

B-1.0 DONOR RECRUITMENT & RETENTION

B-1.1 Blood should be accepted only from voluntary, non-remunerated, low risk, safe and healthy donors.

B-1.2 Efforts should be directed towards encouraging and retaining adequate numbers of repeat donors. Donors should be appropriately recognised and felicitated for their contribution.

B-1.3 The blood bank should educate donors prior to collection of blood regarding the risk of transfusion transmissible infections.

B-2 **DONOR SELECTION**

B-2.1 Pre-donation counselling by trained staff should be made available maintaining privacy and confidentiality. Pre-donation information should include:

- Modes of transmission leading to risk behaviour and self exclusion for patient's safety.
- Alternative testing site
- Tests carried out on donated blood
- Confidentiality of test results
- Need for honest answers in view of window perioid.

B-2.2 A questionnaire should be prepared in English and local languages which is simple and easy to understand to be answered by the donor.

B-2.3 For donors who are illiterate, assistance should be given by donor registration staff.

B-2.4 Medical officer with MBBS qualification should be responsible for reviewing the donor's health conditions and performing physical examination of the donor.

B-2.5 Demographic details such as name and address of donor, date and time of donor selection and donation should be registered.

B-2.6 Consent should be obtained in writing from the donors after explaining the procedure, potential adverse reactions as well as the tests carried out on the donated blood.

B-3 CRITERIA FOR SELECTION OF DONORS

Following guidelines should be observed in order to determine that the blood donation will not be detrimental to the donors/recipients.

B-3.1 Physical Examination

A medical officer should certify the donor fit for blood donation.

B-3.1.1 General Appearance

The prospective donor should appear to be in good health.

B-3.1.2 Age

Donors should be between the age of 18 and 65 years.

B-3.1.3 Haemoglobin or packed Cell Volume (Haematocrit):

The haemoglobin should be not less than 12.0 gm/dl or the packed cell volume (haematocrit) should be not less than 36%. The screening should be carried out by using any appropriate and validated methodology. A more sensitive method of hemoglobin testing should be available as a reference or control.

B-3.1.4 Weight

Blood collection from donors weighing 45-55 Kg should be 350 ml blood and from those weighing 55 Kg and above should be 450 ml.

B-3.1.5 Blood Pressure

The systolic blood pressure should be between 100 and 160 mm of mercury and the diastolic pressure should be between 60-90 mm of mercury.

B-3.1.6 Temperature

Temperature should not exceed 37.5^{0}C/ 99.5^{o}F

B-3.1.7 Pulse

Pulse should be between 60 to 100 beats per minute and regular.

B-3.1.8 Donor Skin

The skin at the venepuncture site should be free of any skin lesion or

scar indicative of addiction to narcotics or infection as well as marks of repeat venepuncture.

B-3.1.9 Examination of respiratory system, cardiovascular system and abdomen should be carried out if necessary.

B-3.2 MEDICAL HISTORY

B-3.2.1 Conditions that affect safety of donors:

Before each donation questions should be asked to determine that the donor is in normal health and has not suffered or is not suffering from any serious illness e.g. malignant disease, epilepsy, bronchial asthma, diabetes, excessive menstrual bleeding, cardio-vascular conditions, renal disease, allergic diseases, abnormal bleeding tendency.

B-3.2.2 Pregnancy:

Prospective donor should not be accepted during period of pregnancy and till 12 months after full term delivery and also during lactation. Donors who have abortions should be deferred till 6 months after 2nd and 3rd trimester abortion. Menstruation in itself should not be a cause for deferral.

B-3.2.3 Any donor who appears to be under the influence of alcohol or any drug abuse and who does not appear to be providing reliable answers to questions on their medical history should not be accepted.

B-3.3 Conditions that affect safety of recipients.

B-3.3.1 Any donor on antibiotic therapy or other medications should be deferred after evaluating his/her suitability as donor.

B-3.3.2 Infectious disease

B-3.3.2.1 Donors having history of malaria should be accepted after 3 months..

B-3.3.2.2 Donors having history of jaundice should be deferred up to 1 year.

B-3.3.2.3 Donors having history of being HIV, HBsAg / HCV antibody positive should be permanently deferred.

B-3.3.2.4 Donors having intimate contact with HIV, HBsAg / HCV antibody positive individual should be deferred for 1 year.

B-3.3.2.5 Donors having history of measles/mumps/chickenpox should be deferred for 8 weeks.

B-3.3.2.6 Donors having history of influenza and URTI (Upper Respiratory Tract Infections) should be deferred till 1 week after treatment. Donors

having history of diarrhoea in preceding week particularly if associated with fever should be deferred.

B.3.3.2.7 For emerging potential transfusion transmissible infections, the guidelines published from central health authorities should be followed.

B.3.3.2.8 Private interview of each donor is essential to assess the risk of HIV infection due to high risk sexual behaviour and unsafe sexual practice.

B.3.3.2.9 Donors who give history suggestive of HIV infection such as;

- swollen glands
- persistent cough
- unexplained weight loss
- night sweats/fever
- skin rashes and skin infections and
- prolonged diarrhoea Should be deferred permanently.

B-3.3.3 Vaccinations

B-3.3.3.1 Individuals who have taken vaccination against TAB/TT/CHOLERA/ HEPATITIS-A - should be accepted if free of symptoms. Those who have received Hepatitis B vaccination should be accepted after 7 days of vaccination.

B-3.3.3.2 Yellow fever/measles/polio - should be deferred for 2 weeks

B-3.3.3.3 Rabies vaccination - should be deferred for 1 year. Those bitten by any animal should be deferred for one year.

B-3.3.3.4 Hepatitis B Immunoglobulin - should be deferred for 1 year

B.3.4 Aspirin Ingestion

B.3.4.1 Ingestion of Aspirin or any related medicine within three days prior to donation should preclude use of donor as a source of platelet preparation.

B.3.5 Surgical Procedures

B.3.5.1 Donors should be accepted one year after the recovery from major operations and six months after recovery from minor operations including acupuncture, tattooing and scarification.

B-3.5.2 Donors having history of receiving transfusion of blood or blood products should be deferred for 12 months

B-4.0 DONATION INTERVAL

- The interval between two blood donations should be at least 12 weeks.
- At least 48 hours must elapse after plasma pheresis or Cytapheresis before whole blood is collected from a donor.
- Apheresis should be done only after 90 days of whole blood collection or in an event when red cells are not returned at the end of pheresis.

B-5.0 INFORMATION PROVIDED TO THE DONORS

B-5.1 Requirement of consent

Prior to blood donation, the consent of the donor should be obtained in writing with 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 safety of recipients. The donor should be provided an opportunity to ask questions and refuse consent.

B-5.2 Post-phlebotomy advice

Donors should be given advice regarding post-phlebotomy care and cautioned as to possible adverse reactions. This should also be displayed in the blood collection/observation room

B-5.3 Information of test results

- The medical officer of blood bank should inform the donor about any sero-reactive result of transfusion transmitted infection (TTI).
- Donors who are HIV sero-reactive should be referred to a Integrated Counselling and Testing Centre (ICTC) for post donation confirmation and counselling.

B-5.4 Counselling and Referral

B-5.4.1 For ensuring blood safety, the blood banks should provide pre and post donation counselling services.

B-5.4.2 All blood banks should train their donor organisers / medical officers to undertake counselling, besides appointing a donor counsellor.

B-5.4.3 Donors should be referred to appropriate medical services for follow up and treatment whenever necessary.

B-5.4.4 For post-donation counselling on HIV, blood banks should have facilities of counselling in Major Blood banks, while other District level Blood banks will avail the service of ICTC in their area. All blood banks should procure a list of ICTC from their respective State AIDS Control Societies.

C. Collection of Blood from Donors

Blood should be collected only by a licensed blood bank. Blood should be drawn from the donor by a qualified physician or under his/her supervision by assistants trained in the procedure.

C. Collection of Blood From Donors

C-1.0 Blood should be collected only by a licensed blood bank. Blood should be drawn from the donor by a qualified physician or under his/her supervision by assistants 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 flow of blood should be continuous.

C-1.1 The blood donor area should 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.

C-2.0 METHOD

A strict standardised procedure should be in use to achieve surgical cleanliness for preparing venepuncture site to provide maximum possible assurance of sterile product.

C-3.0 EQUIPMENT

The blood bags for collection of blood should be sterile, pyrogen free and disposable, with a closed system of collection as per standards provided by ISO / ISI. Multiple interconnected plastic bags should be used for blood component preparation (closed system). Venting of any container should be done under laminar airflow bench and such container should be used within 24 hours. To avoid venting in case of paediatric use, multiple inter-connected closed containers should be used.

C-4.0 ANTICOAGULANT SOLUTIONS

The anticoagulant solution should be sterile and pyrogen free.

One of the following solutions should be used in the indicated volumes.

C-4.1 Citrate-Phosphate-Dextrose (CPD) Solution. 14 ml solution is required for 100 ml of blood.

C-4.2 Citrate-Phosphate-Dextrose-Adenine (CPDA-1) solution. 14 ml solution is required for 100 ml of blood.

C-4.3 100 ml 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.

C-5.0 VOLUME OF BLOOD

Volume of blood collected should be proportionate to the volume of anti-coagulant, with ±10% variation and should not exceed 10 ml/kg body weight limited to a volume of 500 ml. Units of blood where volume collected is out of the permitted limits should not be used for transfusion. No attempt should be made to collect blood from such donor during the same session.

C-6.0 SAMPLES FOR LABORATORY TESTS

The blood samples in the pilot tubes (clotted and anticoagulated) should be collected at the time of collection of blood 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 plastic bag should 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.

C-7.0 IDENTIFICATION

Each container of blood/blood components /pilot tubes should be identified by a numeric or alpha numeric 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.

C-8.0 TEMPERATURE

Immediately after collection, the blood should be placed at 4^0C to 6^0C $\pm$ 2^0C except if it is used for component preparation it will be stored at 22^0C $\pm$ 2^0C until the platelets are separated.

C-9.0 DONOR REACTION

Necessary drugs and equipment should be available for treatment of donor reaction if any. Donor collection staff should be trained in identification and management of donor reactions.

C-10.0 THERAPEUTIC PHLEBOTOMY

Therapeutic phlebotomy should be done only on the request of the patient's physician. The blood bank physician must decide whether to accept the responsibility of the patient. The blood collected in such circumstance should not be used for transfusion.

C-11.0 OUTDOOR BLOOD DONATION CAMPS

C-11.1 Blood donation camps should be organised to augment blood stocks. Donor organiser / medical social worker of the blood bank should contact offices, institutions, industries, social and religious organisations, colleges and schools to collect need based volume of blood from targeted group of donors located at a particular venue at regular intervals.

C-11.2 Adequate publicity and IEC material should be made available to the organisations.

C-11.3 The number of blood units collected should commensurate with the actual requirement of blood units rather than by social or emotional pressures.

C-11.4 The donation site should be inspected prior to the day of blood collection to ensure availability of all facilities as prescribed by Drugs and Cosmetics Rules.

C-11.5 The outdoor camp should be organised in an environment which is conducive and comfortable. The area should be cleaned before and after the blood collection.

C-11.6 Blood bank 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 at fixed sites.

C-11.7 Blood and its components could contain infectious agents and hence these should be handled with precautions.

C-11.8 Large CampsThe large camps organised on a day should be planned as per criteria laid down by the Drugs & Cosmetics Act. All quality measures and predonation counselling procedures should not be compromised.

D. Testing of Donated Blood

DETERMINATION OF ABO GROUPABO group should be determined by testing red cells with Anti-A, Anti-B, Anti-AB reagents (by tube or microplate method or gel technology by any validated manual or automated methods) and by testing serum or plasma for expected & unexpected antibodies with known type A, B and O pool cells / panel cells if available.

D. Testing of Donated Blood

D-1.0 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 gel technology by any validated manual or automated methods) and by testing serum or plasma for expected & 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.

D-2.0 DETERMINATION OF Rh(D) TYPE

The Rh(D) type should be determined with Anti-D reagent from two different sources using a validated method. It is preferable to use one IgM and other a blend i.e., IgM + IgG. If blood is typed as D-Negative it should be tested to detect 'D^{u}'/ weak D using IAT method. When the test for D or 'D^{u}' is positive, the label should read 'Rh(D) Positive. When the test for D and 'D^{u}' is negative, the label should read 'Rh(D) Negative'. Testing with anti-CDE should not be routinely required.

D-3.0 PREVIOUS RECORDS

A 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. New determination should be made for each collection. Discrepancy with previous record should be investigated and resolved.

D-4.0 TESTS FOR DETECTING UNEXPECTED ANTIBODIES IN SERUM

Serum or plasma from donors should be tested for unexpected antibody/ies with pooled O Rh (D) positive cells or preferably screening cell panel using albumin/enzyme/indirect AHG test which can identify clinically significant antibodies.

D-4.1 Blood in which such antibody/ies are found, should be used as packed cells only.

D-4.1.1 Any component with cold antibody should be transfused only with special instructions to warm before transfusion.

D-4.1.2 If warm allo antibody is present only packed cells should be used for transfusion under observation.

D-4.1.3 In case when warm auto-antibody is present least incompatible blood should be used, depending on patient's clinical condition, necessitating transfusion.

D-5.0 LABORATORY TESTS FOR INFECTIOUS DISEASES

All mandatory tests should 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 should be discarded.

D-5.1 Test for Syphilis Each donation of whole blood should be subjected to a serological test for syphilis by VDRL / RPR Method / TPHA.

D-5.2 Test for Viral HepatitisA test for hepatitis B (HBsAg) and hepatitis C (anti-HCV) by ELISA/Rapid test which is a validated method should be done on each unit of blood. Any technology with similar or higher sensitivity may be used additionally to improve blood safety.

D-5.3 Screening for HIV AntibodiesAll blood units collected should be tested for HIV 1&2 antibodies using ELISA/Rapid which is a validated method. Any alternative technology with similar or higher sensitivity may be used.

D-5.4 Test for Malaria All blood units should be tested for malarial parasites using a validated and sensitive antigen test.

D-6.0 QUARANTINE STORAGE

The whole blood or components should 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 should be kept in quarantine storage. The units which test reactive in any test should be segregated immediately and kept in a separate quarantine area till sent for disposal. It is preferable to use biohazard labels.

D-7.0 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 4oC, 22oC & 37oC.

D- 8.0 The blood bank 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 bank should inform the patient's physician. Appropriate record of such events should be kept. The unused components from this unit should be discarded.

E. Preparation of Blood Components

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

E. Preparation of Blood Components

E-1.0 GENERAL PRINCIPLES

E-1.1 Sterility

The sterility of all components should be maintained during processing by the use of aseptic methods and sterile pyrogen free disposable bags and solutions.

E-1.2 Seal

Blood bags that allow transfer of component without breakage of the seal (closed system) should be recommended. If the seal is not broken, the viability and stability of the component is assured. The seal will not be considered broken if a sterile connection device is used resulting in a closed system.

E-1.2.1 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.

E-1.2.2 Once the frozen components are thawed, these should be transfused at the earliest and positively within 6 hours.

E-1.2.3 At the time of preparation of the final components the integrally connected tubing should be filled with aliquot of the components and sealed in such a manner that it should be available for subsequent compatibility and assay testing if needed.

E-1.3 A process of feedback should be in place with the clinician in order to periodically assess the efficacy of all blood components.

E-2.0 RED BLOOD CELL COMPONENTS

E-2.1 Red Blood Cells

Red blood cell concentrate should be prepared from the whole blood collected in plastic bags, preferably in double or multiple plastic bags system. Plasma is separated from red blood cells following either

centrifugation or undisturbed sedimentation at any time before the expiry date of blood. If closed system is in use, the expiry date of red cells should be the same as whole blood. The hematocrit of packed cells should be adjusted so that it is not more than 70%.

E-2.2 Washed Red Cells

Red blood cells should be washed with normal saline by automatic cell washer or manually by centrifugation. The cells should be washed 2-3 times with normal saline by centrifuging at $4^0C \pm 2^0C$. A laminar bench that is validated from time to time should be used. Closed system of washing is recommended.

E-2.3 Leucocyte depleted red blood cells

Leucocyte depleted red blood cells concentrate should be prepared by a method known to reduce leucocytes in the final component to less than $5x10^8$ when intended to prevent febrile reactions and to less than $5x10^6$ when it is required to prevent alloimmunisation or CMV infection. For achieving a level $<5x10^6$, use of leucocytes filter is necessary.

E-2.4 Frozen and deglycerolised red blood cell concentrate

Red cells should be stored frozen continuously at low temperature of -80^0 to -196^0C in the presence of cryoprotective agent. The red cells should be washed to remove the cryoprotective agent prior to transfusion.

E-2.4.1 The method of preparation, storage, thawing and washing should ensure a recovery of at least 80% of original red cells or larger depending on the procedure in use.

E-2.4.2 Red blood cells should be ordinarily frozen within 6 days of collection of blood and can be kept frozen upto 10 years.

E-2.4.3 The cryoprotective agent in most common use is glycerol. The concentration of glycerol used should depend on the storage temperature.

E-3.0 PLATELET CONCENTRATE: (Random Donor Platelets)

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.

E-3.1 Platelet concentrate should be separated from whole blood within 8 hours of collection by centrifugation at $22^0C \pm 2^0C$ using either platelet rich plasma (PRP) or buffy coat (BC) method, which is validated.

E-3.2 Platelet concentrate prepared from whole blood (450 ml) should contain a minimum $4.5x10^{10}$ platelets and from 350 ml whole blood minimum of $3.5x10^{10}$ platelets in at least 75% of units tested on storage from 1%

of total prepared or 10 units every month whichever is higher. It is recommended that only 450 ml bags are used for platelet separation.

E-3.3 Platelets should be suspended in approximately 50 ml of plasma and stored at $22^0C \pm 2^0C$. The pH at storage temperature should not be lower than 6.0 at the end of storage period.

E-3.4 Continuous gentle agitation (60-70 oscillations / per min) using 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 plastic of the bag in use considering day of blood collection as day zero.

E-3.5 There should be no grossly visible platelet aggregates during the storage. Swirling phenomenon should be checked before issue.

E-3.6 The concentrate prepared should not be contaminated with red cells. The degree of reddish tinge of the concentrate indicates red cell contamination. The units contaminated with red cells should be used as group specific.

E-3.7 1% of all platelet concentrates prepared should undergo tests for bacterial detection by a validated method as part of routine quality control.

E-3.8 Leucocytes reduced platelets

Platelets prepared by buffy coat method should contain 5×10^8 leucocytes. To achieve a level of d" 5×10^6 leucocytes, platelets should be filtered using leucocyte filters.

E-4.0 GRANULOCYTE CONCENTRATE

E-4.1 Use of unit of granulocytes prepared by use of cell separator should have $1x10^{10}$ leucocytes and should be kept at $22^oC \pm 2^0C$ for a maximum period of 24 hours.

E-5.0 PLASMA

E-5.1 Single donor 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 will be used only for fractionation.

E-5.2 Fresh Frozen Plasma

Fresh plasma should be separated from the whole blood not later than 6 - 8 hours of collection and frozen solid at -30^0C or lower as early as possible. Prior to infusion the frozen plasma should be thawed rapidly at $30\text{-}37^0C$ in a water bath with shaker. Once thawed it should be used within 6 hours.

E-5.2.1 Fresh plasma should contain a minimum of 0.7 IU of F VIII per ml in at least 90% of units tested (1% of total manufactured) or 10 units/ month whichever is higher.

E-5.3 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 and once thawed should be used within 6 hours.

E-6.0 SINGLE DONOR CRYOPRECIPITATE (Cryoprecipitated Anti-hemophilic factor)

E-6.1 For preparation of cryoprecipitate the fresh frozen plasma should be frozen within 6 hours of collection at –80^{0}C or lower and thawed at 4^{0}C circulating water bath or in 4^{0}C cold room/Blood Bank Refrigerator.

E-6.2 Thawed plasma should be immediately centrifuged and separated from the cold insoluble material under sterile conditions.

E-6.3 The cryoprecipitate - cold insoluble material - should be frozen within 1 hour and should be kept at -30^{0}Cor lower up to 1 year. Once thawed, it should be used within 6 hours.

E-6.5 The component should contain a minimum of 0.8 IU. of factor VIII and 1.5 mg of fibrinogen per ml in at least 75% of units tested out of 1% of total manufactured or 10 units / month whichever is higher.

F. Labelling

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

F. Labelling

F-1.0 A system should be in place to ensure that final container is labelled only after all mandatory testing is completed as per pharmacopoeal requirements.

F-1.1 Requirements should ensure

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

F-1.2 The label should be attached firmly to the container and should be clear and readable. Any hand-written information should be legible and in permanent and moisture proof ink.

F-2.0 BLOOD UNIT IDENTIFICATION

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.

F-2.1 The numeric and alphanumeric identification on label should be provided by the collecting facility to each unit of blood/its components. This number should be documented for traceability. Any advanced technology for identification such as barcode system is preferable.

F-2.2 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 use of a patient identification. Donor's name should not be written on the label. In case of transfer of blood unit to another blood bank, original label with the same identification should be retained.

F-3.0 LABELLING FOR WHOLE BLOOD/COMPONENT

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

F-3.1 Name of the product i.e., whole blood or component or intended component.

F-3.2 The numeric or alphanumeric identification.

F-3.3 The date of collection and expiry.

F-3.4 The name and amount of anticoagulant and the approximate volume of blood collected.

F-3.5 For platelet concentrate, plasma and for component obtained through apheresis, the approximate volume of the components should be indicated.

F-3.6 Colour Scheme:

F-3.6.1 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

F-3.7 Storage temperature, expiry date.

F-3.8 ABO and Rh type.

F-3.9 Interpretation of HBsAg/HCV/HIV 1 & 2/VDRL/malaria test/unexpected antibodies

F-3.10 Name, Address and Manufacturing license number of the collecting facility.

F-4.0 INSTRUCTIONS FOR TRANSFUSION

Following information should be printed on the label.

F-4.1 Do not use if there is any visible evidence of deterioration.

F-4.2 Keep at 4^0C $\pm 2^0$C before use.

F-4.3 Shake gently before use.

F-4.4 Do not add any other medication to the blood/blood component.

F-4.5 Check blood group on label and that of the recipient before administration.

F-4.6 Use a fresh, clean, sterile and pyrogen free disposable transfusion set with filter to transfuse blood.

F-4.7 Do not dispense without a prescription.

F-5.0 SPECIAL REQUIREMENTS FOR COMPONENT LABEL

The label should contain information to identify the facility that carry out any part of the preparation.

F-5.1 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.

F-5.3 Storage temperature should be indicated.

F-5.4 Expiry date/time for use should be recorded.

F-5.5 If the plasma is intended for use of fractionation, suitable documentation and labelling should be done.

F-5.6 Label should indicate whether the component is prepared by apheresis method.

F-5.7 Label should indicate the addition of any adjuvant or cryoprotective agents used.

G. Apheresis

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 should be carried out only in a blood bank licensed for this purpose.

G. Apheresis

G-1.0 INTRODUCTION

G-1.1 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 should be carried out only in a blood bank licensed for this purpose.

G-1.2 The guidelines relate only to apheresis of healthy voluntary donors and not to any therapeutic procedure

G-1.3 A medical officer trained in apheresis technique should be responsible for the procedure.

G-1.4 There should be provision for emergency medical care, in the event of any adverse reaction to the donor.

G-1.5 The staff working on the machine should be trained in apheresis procedure and should work directly under the supervision of the medical officer.

G-1.6 The donor should be asked to sign a consent form in the language, which he understands after being explained the procedure and the risks involved.

G-2.0 PLASMAPHERESIS

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

G-2.1 Selection of donors

G-2.1.1 In an occasional plasmapheresis in which donors undergo the process once every 12 weeks the standards for whole blood donation should apply.

G-2.1.2 In a 'serial' plasmapheresis in which plasma is donated more frequently than once every 12 weeks, the donor should be tested before every pheresis procedure - Haemoglobin and/or haemotocrit should be $\geq$ 12 g/dl and/or Hct 36% - Total serum protein - should not be below 6.0 gm/dl

G-2.1.3 In serial plasmapheresis programme with return of the cellular components a minimum interval should be of 48 hours between two procedures and not more than two procedures in a week should be allowed.

G-2.1.4 If a participant of such programme donates a unit of blood or if it is not possible to return red cells, the donor should not undergo platelet / plasmapheresis for 12 weeks.

G-2.2 Records

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

G-2.3 Volume of plasma

Volume of plasma obtained excluding anticoagulants from a donor weighing at least 55 kg. should 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 donor's estimated blood volume.

G-3 CYTAPHERESIS

Cytapheresis is the procedure for separation of individual cellular component of blood. It can be achieved by the cell separator machine.

G-3.1 Plateletpheresis is the harvesting of platelets from whole blood using continuous or intermittent flow cell separator.

G-3.2 Leukapheresis is the harvesting of granulocytes from whole blood using continuous or intermittent cell separator.

G-3.2.1 Peripheral blood stem cells are harvested using continuous or intermittent cell separator. Attempt should be made for harvesting minimum of $2x10^6$ CD34 cells and / or minimum of $2x10^8$ MNCS/Kg of the recipient.

G-3.4 Selection of donors

G-3.4.1 Donors who undergo cytapheresis no more than once every 4 weeks should be treated as ordinary blood donors with regards to laboratory studies.

G-3.4.2 Donors who undergo serial cytapheresis, more than once every 12 weeks, should be tested as under :

- Haemoglobin and/or haematocrit should be > 12 g/dl and or Hct of 36%.
- Total serum protein should not be below 6.0 gm/dl. It should be tested before the 3rd collection if done within 4 weeks.

- Platelet count should be determined before plateletpheresis and should not be below 150,000 / ul.
- Total and differential white cell count should be normal.

G-3.4.3 Persons who have ingested aspirin or similar anti-platelet drugs in the last 72 hours should not be suitable for plateletpheresis.

G-3.4.4 Donors with personal and family history of bleeding tendency should not be suitable for plateletpheresis.

G-3.4.5 Before leukapheresis total white blood cells counts should be 4000 /ul with normal differential count.

G-3.4.6 In serial pheresis a minimum interval should be of 48 hours and not more than two procedures in a week should be allowed.

G-3.4.7 A participant of such a programme donates a unit of blood or if it has not been possible to reinfuse the red cells during a pheresis procedure should not be accepted for cytapheresis for 12 weeks.

G-3.5 Care of donors

G-3.5.1 Extracorporeal blood volume should not exceed 15% of the donor's estimated blood volume.

G-3.5.2 Interval between two cytapheresis should be 48 hours and not more than twice a week.

G-3.5.3 The donors should be tested appropriately to detect a developing cytopenia.

G-3.5.4 Red blood cell loss incidental to the procedure should be no more than 25 ml per week.

G-3.5.5 Donors may receive drugs to facilitate leukapheresis. Such drugs should not be used for donors whose medical history is suggestive of some disease.

G-3.5.6 Donors should be observed closely during cytapheresis as regards the untoward reactions like headache, fainting attack, tachycardia, twitching, dyspnea etc.

G-3.5.7 Written standard criteria used to determine donor suitability, procedure of haemapheresis, precautions to ensure reinfusion of donor's own red cells, and time frame should be maintained.

G-3.6 Records

Records of the donor's periodic examinations, laboratory tests, consent of the donor/patient, with date of last apheresis, certificate of the attending physician, details of the procedure, volume of product

separated, drugs used, adverse reactions if any and their treatment should be maintained.

G-3.7 Platelet concentrates (Single Donor Platelets)

G-3.7.1 Platelet concentrates should contain minimum 3 x 10^{11} platelets in 75% of the units tested amongst 1% of monthly production or 4 platelet concentrates per month, whichever is higher. They can be stored for 3/ 5 days at 22^{0}C $\pm$2^{0}C with continuous agitation depending on the blood bag used.

G-3.7.2 The pH must be 6 or higher at the end of permissible storage period (3-5 days)in all the PC units.

G-3.8 Granulocyte concentrates

G-3.8.1 Leucocyte concentrates should contain at least 1 x 10^{10} leucocytes. They should be transfused as soon as possible, preferably within 6 hrs.

G-3.8.2 Transfusion should not be given through microaggregate filters.

G-3.9 Double Red Cell Collection

G-3.9.1 The donor should have hemoglobin 13.5g/dl and weigh >65 Kgs. The interval between the 2 procedures should be six months.

G.4.0 THERAPEUTIC PLASMAPHERESIS AND CYTAPHERESIS

G-4.1 Therapeutic plasmapheresis / cytapheresis should be done only at the written request of the patient's physician either in the blood bank or preferably in the ward depending on patient's clinical condition.

G-4.2 Records of patient's identification, diagnosis, therapeutic procedures, haemapheresis method, volume of blood removed and returned, time taken, nature and volume of replacement fluids, adverse reaction if any and medication administered, should be maintained.

G-4.3 Informed consent of the patient should be taken in the language he / she understands.

G-4.4 Provisions for emergency care should be available.

H. Storage, Transportation and Expiration of Blood and its Components

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

H. Storage, Transportation and Expiration of Blood and Its Components

H-1.0 REFRIGERATORS AND FREEZERS FOR STORAGE

H-1.1 A designated area should be used for storage to limit deterioration and prevent damage to materials in process and final products. The access to such areas should be controlled.

H-1.2 Refrigerators or freezers in which blood and blood components are stored should be used for storage of blood, blood components and blood samples only and not for any other items. All reagents should be stored in separate refrigerators in the specific laboratories.

H-1.3 Blood bank refrigerator/walk-in-cooler should have 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 alternate power supply should be available.

H-1.4 Deep freezer should have inside temperature of -30^0C or -80^0C having temperature indicator/recording facility with alarm system and provision for alternate power supply.

H-1.5 Platelet incubator with agitator should have inside temperature of $22^0C \pm 2^0C$ 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.

H-1.6 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.

H-2.0 TRANSPORTATION

Whole blood, red cell concentrate, should be transported in a manner that will maintain a maximum temperature of $10^0C \pm 2^0C$. Platelet/ granulocyte concentrate stored and transported at $22^0C \pm 2^0C$. 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.

H-3.0 STORAGE AND EXPIRATION

H-3.1 Whole blood

H-3.1.1 Whole Blood should be stored at $4^0C \pm 2^0C$ in plastic blood bags.

H-3.1.2 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.

H-3.1.3 Whole blood in heparin solution should have expiry period not exceeding 24 hours after collection.

H-3.2 Red Blood Cell Components

H-3.2.1 Red blood cells

Red blood cells which are separated in a closed system should 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 should be 24 hours after separation. Red cell concentrate should be stored at $4^0C \pm 2^0C$Red cells containing additive solutions such as SAGM, ADSOL, NUTRICEL should be stored up to 42 days with day of collection considered

as day zero. At midnight (12 'O' clock) the day is completed, e.g., if platelets are separated on first of the month, expiry date should be 6th midnight.

H-3.2.2 Frozen red cells

The expiry date for glycerolized (low or high) frozen red cells is 10 years and should be stored between -80^0 and -196^{0}C.

H-3.2.3 Washed and deglycerolised red blood cells

Washed red blood cells and deglycerolized red blood cells should be stored at 4^{0}C $\pm$ 2^{0}C and should be transfused as soon as possible and within 24 hours after processing.

H-3.2.4 Leucocytes depleted red blood cells

Leucocyte-poor red blood cells should be stored at 4 ^{0}C $\pm$ 2^{0}C. It should have the same expiry date as whole blood from which it has been prepared, if closed system is used. In case of open system, the expiry will be within 24 hours.

H-3.3 Platelet concentrate

The platelet concentrate should be stored between 22^{0}C $\pm$ 2^{0}C with continuous gentle flat bed 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 should be 3 days after the collection of original blood. The expiry date may be extended to 5 days or longer when special plastic bags or anticoagulants are in use.

H-3.4 Granulocyte concentrate

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

H.-3.5 PLASMA

H-3.5.1 Single donor plasma

Single donor plasma should be separated from whole blood at any time upto 5 days after the expiry of the whole blood. The plasma separated after expiry date should be used for fractionation. If separated during

shelf life, should be stored for 1 year at -30^{0}C or lower and used as plasma for transfusion.

H-3.5.2 Fresh frozen plasma and cryoprecipitate

These components should 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 & used up to 5 years (i.e. 4 more years). If FFP is stored at -60^o C or below with continuous monitoring it should be used up to 5 years.

H.4 Expiry date of any component should be calculated by considering the day of collection as day zero.

I. Compatibility Testing

The blood bank performing cross matching should confirm ABO and Rh(D) group of all blood units using a sample obtained from an attached segment.

I. Compatibility Testing

I-1.0 REPEAT TESTING OF DONOR BLOOD

The blood bank performing cross matching should confirm ABO and Rh(D) group of all blood units using a sample obtained from an attached segment.

I-2.0 TESTING OF RECIPIENT BLOOD

I-2.1 Determination of ABO type

ABO type should be determined by testing red cells with anti-A, anti-B, anti-AB sera and testing serum or plasma for expected antibodies with fresh pooled A, B and O Cells (pool of 3 for each group) using tube/ microplate method/gel technology (manual or automated). Either monoclonal or polyclonal antisera may be used.

I-2.2 Determination of Rh(D) type

The Rh(D) type should be determined with anti-D reagent from 2 different sources (Ref.D.2.0) by tube/microplate method/gel technology. If negative it should be labelled as 'Rh(D) negative'.

I-2.3 Test for detection of unexpected antibodies

Serum of the recipient should be tested for unexpected antibodies with pooled O Rh(D) positive cells or screening red cell panel at room temperature by saline technique and at 37^0C by albumin/enzyme as well as indirect antiglobulin test with proper controls (positive, negative and end point). If on screening, antibody/ies are detected, the antibody/ies should be identified by red cell panel, if possible.

I-2.4 A control system using red blood cells sensitised by IgG, Anti-D must be used with antiglobulin tests to detect false negatives.

I-3.0 CROSS-MATCH

I-3.1 A sample of donor cells from a segment attached to the bag and recipient serum or plasma should be crossmatched. The method used should

demonstrate ABO incompatibility and clinically significant unexpected complete and/or incomplete antibodies and should include an antiglobulin test. If there is no previous record of presence of antibodies and if clinically significant antibodies are not detected during antibody screening test, the antiglobulin crossmatch should not be required.

I-3.2 If clinically significant antibody/ies are detected in recipient, blood lacking corresponding antigens on cells should be crossmatched or by trial method the blood which is compatible should be issued. In certain clinical conditions, where auto antibodies are present, the least incompatible unit should be issued.

I-3.3 Minor cross matching using donor's serum or plasma and recipient's cells should not be necessary as tests for complete and incomplete unexpected antibodies in donor samples are mandatory.

I-4.0 SELECTION OF BLOOD AND COMPONENTS FOR TRANSFUSION

I-4.1 Whole blood, red cell components

Recipient should receive ABO type specific compatible whole blood or red blood cell components. In the absence of ABO type specific blood, group O packed red cells should be transfused. 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.

I-4.2 If clinically significant unexpected antibodies are detected in recipient, whole blood or red blood cells component which do not have corresponding antigens and are compatible should be transfused. On reasonable qualifying circumstances indicated by the clinician, a least incompatible unit should be issued, and the clinician should be instructed to transfuse under constant observation.

I-4.3 Single donor plasma and fresh frozen plasma

Single donor plasma or fresh frozen plasma should be ABO type specific / compatible with recipient's red blood cells. In neonates ABO specific

plasma should be preferred. Cryoprecipitate should not require ABO/ Rh grouping.

I-4.4 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 should be used provided there is no visual red cell contamination of the platelet concentrate. In case of single donor platelets prepared by apheresis, plasma should be reduced when plasma in compatible concentrate is in use (e.g. use of 'O' group SDP to B patient).

I-4.5 Granulocyte concentrate

Leucocyte concentrate should be ABO and Rh(D) type specific or compatible with the recipient blood.

I-5.0 MASSIVE TRANSFUSION

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

I-6.0 NEONATES

I-6.1 For ABO grouping only cell grouping with anti-A, anti-B and anti-AB sera should be required.

I-6.2 Serum of the mother should be tested for unexpected antibody / ies.

I-6.3 In the management of haemolytic disease of the newborn it is preferable to use mother's serum for the cross matching. In absence of mother's serum, child's serum should be used for compatibility testing.

I-6.4 Neonatal recipient should not be transfused with whole blood/plasma/ component containing clinically significant antibodies.

I-6.5 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.

I-6.6 Paediatric blood collection bags are available and are preferable for use. Normal blood collection bags should not be used for collecting lesser volume after removing proportionate amount of anti-coagulant solution. Multiple blood bags should be used to make one aliquot for adult and one for paediatric transfusion.

I-6.8 Blood preferably within 72 hours of collection, but not exceeding 5 days should be used for exchange transfusion.

J. Recipient

When recipient's blood sample is received in the laboratory, a qualified member of the staff should confirm, if 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.

J. Recipient

J-1.0 BLOOD REQUEST FORM

Request form for whole blood or components accompanied by the recipient's blood samples should be legible and should have the following information:

- Recipient's name
- Age, Sex, ward and bed number
- Blood group of recipient if done earlier
- For error prevention it is preferable to get blood grouping done before the request for cross match is received
- Name of the head of treating unit
- Amount of blood/component needed
- Date and time of blood component requirement
- Routine/emergency
- Diagnosis
- Reason for transfusion- Hemoglobin / platelet count
- History of previous transfusion
- Obstetric history in the case of female patient
- Name of the hospital/ Hospital Registration number
- Signature of the medical officer
- Name and signature of the phlebotomist collecting patient's sample

J-2.0 BLOOD SAMPLES

J-2.1 Blood samples of recipient should be obtained (1) in a stoppered plain vial/tube (2) in a vial/tube containing anticoagulant, with labels having:

- Patient's full name
- Identification number

- Name of hospital
- Ward/bed number
- Date and time
- Phlebotomist's signature/ initials

J-2.2 When recipient's blood sample is received in the laboratory, a qualified member of the staff should confirm, if 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.

J-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 to 6^0C$\pm$ 2^0C 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.

K. Issue of Blood for Transfusion

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

K. Issue of Blood for Transfusion

K-1.0 Blood should be issued from the blood bank along with the blood cross matching report form.A portion of the integral tube with at least one numbered segment should remain attached with the blood bag being issued.

K-1.1 The cross matching report form should have patient's first name with surname, age, sex, identification number, ward, bed number, ABO and Rh(D) type.

K-1.2 The form should have donor unit identification number, segment number, ABO and Rh(D) type and expiry date of the blood.

K-1.3 Interpretation of cross matching report and the name of the person performing the test and issuing the blood should be recorded.

K-2.0 A label or a tag with 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 bank.

K-3.0 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.

K-4.0 REISSUE OF BLOOD

K-4.1 It is recommended that blood once issued should not be taken back by the Blood Bank, especially if the cold chain is broken.

K-5.0 URGENT REQUIREMENT OF BLOOD

K-5.1 Blood or blood components should 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 release of blood 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.

K-5.2 Under such circumstances, recipients whose ABO and Rh(D) type is not known should receive red cells of group O Rh(D) negative if available, otherwise O Rh(D) positive blood should be used.

K-5.3 Recipient whose ABO, Rh(D) type has been determined should receive ABO and Rh(D) specific blood group whole blood or red cells before the tests for compatibility have been completed.

K-5.4 The donor tag or label on the blood container and the cross match report form should indicate that compatibility testing has not been completed at the time of issue.

K-5.5 However, standard compatibility test should be completed promptly. If discrepancy in the result is noted, the concerned clinician should be informed immediately to discontinue the transfusion.

N.B. *It is the responsibility of the blood bank to train the clinical staff and provide necessary forms to be used.*

L. Transfusion of Blood and Components

The patient should be informed about his/her need for blood, alternatives available, as well as risks involved in transfusion and non transfusion.

L. Transfusion of Blood and Components

L-1.0 INFORMED CONSENT

The patient should be informed about his/her need for blood, alternatives available, as well as risks involved in transfusion and non transfusion. His / her written consent should be taken in the language he / she understands best only after providing information. For minors and unconscious patients the next of kin should sign the informed consent.

L-2.0 IDENTIFICATION OF RECIPIENT AND DONOR UNIT

L-2.1 Immediately before transfusion, the doctor / transfusionist should verify the identification of the patient, the blood unit, blood group and cross matching report and associated records.

L-2.2 All identifications attached to the container should remain attached at least until the transfusion is over.

L-2.3 The blood compatibility report should be attached in the patient's file.

L-3.0 SUPERVISION

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.

L-3.1 To ensure good clinical practice (GCP) the user hospital should formulate a hospital transfusion committee.

L-4.0 ADMINISTRATION OF BOOD & BLOOD COMPONENS

L-4.1 Blood and blood components should be maintained at the optimum temperature before transfusion.

L-4.2 The transfusion should be given with sterile, pyrogen free and disposable transfusion set with filter. The transfusion should be started immediately on receipt of blood.

L-4.3 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. Warming of blood should be accomplished using a blood warming device attached to the transfusion set. The warming system should be equipped with a visible thermometer and ideally with an audible alarm system. Blood should not be warmed above 37^0C.

L-4.4 Medication should 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.

L-4.5 Red cells should not be administered with I / V solution containing calcium, dextrose or Ringer's solution.

L-5.0 GUIDELINES FOR TRANSFUSION PRACTICES

L-5.1 There should be a written protocol for administration of blood and blood components and the use of infusion devices and auxiliary equipment.

L-5.2 For appropriate use of blood, guidelines available should be used.

L-6.0 SPECIAL CONSIDERATIONS FOR USE OF COMPONENTS

L-6.1 Red Cell Transfusion

L-6.1.1 Red cell transfusion should be ABO & Rh (D) compatible.

L-6.1.2 Transfusion of one unit of red cells should not take longer than 4 hours.

L-6.1.3 The viscosity of red cell concentrate should be reduced by the addition of small volume (50 ml) of sterile normal saline through one limb of a Y-infusion set.

L-6.2 Fresh Frozen Plasma

Plasma transfusion should be ABO compatible. Cross matching tests are usually not performed on plasma products. Products that have been thawed should be infused without delay to avoid bacterial proliferation. This is thawed at 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.

L-6.3 Cryoprecipitate

The component should be thawed at temperature of 37^{0}C and should be used immediately. ABO compatibility should not be a must.

L-6.4 Single donor plasma

It should be transfused within 24 hours after it is thawed and stored at 1-6^{0}C.

L-6.5 Platelets and Leucocytes

L-6.5.1 Platelets should be ABO-identical but in 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.

L-6.5.2 Platelets and leucocytes should be administered through a standard filter. Micro aggregate filters should not be used for these products.

L-6.5.3 Platelets and leucocytes should be infused at 1-2 ml/minute or as tolerated by the patient.

L-6.5.4 Granulocyte concentrates should be irradiated before transfusion.

L-7.0 Irradiation

L-7.1 Cellular components should be irradiated in order to reduce the risk of post transfusion GVHD when a patient is identified as being at risk for GVHD eg.

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

L-7.2 The minimum dose delivered to the blood bag should be 25 Gy $\pm$ 2.

L-7.3 Verification of dose delivery system of the irradiator should be performed and documented annually.

L-7.4 The component irradiated should be labelled accordingly.

L-7.5 Irradiated components should be issued to immunologically normal patients provided there is compliance with required storage conditions and protocols of issue.

L-7.6 The expiry date should be the original date. However, in case of red cell concentrate it will be 28 days from the date of irradiation or the original

whichever is earlier. In case of neonate, the component should be transfused immediately after irradiation.

L-8.0 Leucocyte Depleted Component

L-8.1 Storage should depend on whether a closed or open system is in use.

L-8.2 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.

M. Transfusion Complications

As the most common cause of hemolytic transfusion reaction is a clerical error, a system of preventing such errors should be in place.

M. Transfusion Complications

M-1.0 ERROR PREVENTION

As the most common cause of hemolytic transfusion reaction is a clerical error, a system of preventing such errors should be in place.

M-1.1 The request form and the sample label should have the phlebotomist's name and initials.

M-1.2 The blood group of the bag being issued should be re-confirmed by testing the sample from the donor tubing attached to the bag.

M-1.3 Instructions should be given to transfusionists to check the identity of patient and ensure correctness of unit number on the bag as well as segment and the crossmatch report.

M-1.4 Barcoding should be introduced and used whenever feasible.

M-2.0 DETECTION, REPORTING & EVALUATION

M-2.1 Each blood bank should have a system for detection, reporting and evaluation of suspected adverse reaction to transfusion (Hemovigilance). In the event of suspected transfusion reaction, the personnel attending the patient should notify immediately the responsible physician and transfusion service with necessary documentation and appropriate samples.

M-2.2 All suspected transfusion reactions should be evaluated promptly. The evaluation should not delay proper clinical management of the patient.

M-2.3 The details of all cases along with the interpretation of evaluation should be recorded and reported to the transfusion committee.

M-2.4 There should be a written protocol for the investigations of transfusion reactions.

M-2.5 Reported cases of serious reactions should be evaluated.

M-3.0 IMMEDIATE COMPLICATION

M-3.1 If there are symptoms or findings suggestive of a haemolytic transfusion reaction, transfusion should be discontinued and the following must be done immediately and records maintained.

M-3.1.1 The label on the blood container and all other records should be checked to detect if there has been an error in identifying the patient or the blood unit.

M-3.1.2 A post transfusion properly labelled blood sample, (avoiding haemolysis) should be obtained from the patient and sent to transfusion service along with blood container and attached transfusion set.

M-3.1.3 The patient's post-reaction serum or plasma should be inspected for evidence of haemolysis, comparing with pre-transfusion sample.

M-3.1.4 A direct antiglobulin test should be done on the post transfusion specimen and on pre reaction sample for comparison.

M-3.2 Based on evaluation of clinical findings, review of accuracy of records and results of laboratory tests, additional tests should be done such as:

M-.3.2.1 Determination of ABO and Rh(D) types on pre and post reaction blood sample from the patient and from the blood bag.

M-3.2.2 Repeat tests for unexpected antibodies in donor and recipients' blood and repeat cross-match using pre and post reaction blood samples of the patient and donor blood from the bag.

M-3.2.3 Examination of post transfusion urine should be carried out for haemoglobin and its metabolites.

M-3.2.4 Determination of bilirubin concentration in serum should be obtained preferably 5 to 7 hours after the transfusion.

M-3.2.5M-3.2.6 Supernatant plasma and remaining blood in the blood container as well as the post-reaction sample of the patient should be tested for smear and culture.Expiry dated blood units should be tested periodically for bacteriological smear and culture.

M-3.3 If investigations are suggestive of a haemolytic reaction or bacterial contamination, patient's physician should be informed immediately.

M-4.0 DELAYED COMPLICATIONS

M-4.1 Weak antibodies in recipient's serum directed against antigen on the donors red blood cells undetectable at the time of pre transfusion tests, may appear after a week and result in delayed haemolysis or unexplained fall in haemoglobin. Appropriate tests should be done to detect the cause of reaction. A record should be maintained in patient's medical file.

M-4.2 Reported cases of suspected transfusion transmitted disease should be evaluated. If confirmed, the involved blood unit must be identified in the report. Attempt should be made to recall the donor for retesting and counselling. Other recipients who received components from the suspected blood unit should also be investigated.

M-4.3 All reported cases of unexplained acute liver dysfunction occurring between two weeks to 6 months after the transfusion of blood or components should be investigated as possible post transfusion hepatitis. The donor of the implicated unit should be informed, counselled and permanently deferred.

N. Autologous Blood

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 later date.

N. Autologous Blood

N-1.0 PREDEPOSIT

N-1.1 General principles

N-1.1.1 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 later date.

N-1.1.2 Autologous pre-deposit procedure requires consent of the donor-patient and a request from treating physician.

N-1.1.3 The records of all units collected for autologous use should be maintained.

N-1.1.4 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.

N-1.1.5 Precaution should be taken to identify the donated unit and donor-patient before the transfusion procedure.

N-1.1.6 If the blood collected for autologous transfusion is not used for the donor-patient, it should be discarded.

N-1.2 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 donor-patient's physician and medical officer of blood bank. The individual guidelines should be recorded in the procedure manual of the blood bank and clinical records of the donor-patient. Suitable guidelines include:

N-1.2.1 The volume of blood collected should be proportionate to the donor-patient's weight and volume of preservative used.

N-1.2.2 There should not be any age limits for autologous transfusion procedure.

N-1.2.3 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 programme. 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 programme and must continue sufficiently to replenish iron stores.

N-1.2.4 Donation of predeposit autologous transfusion should not be undertaken when donor-patient has, or is being treated for bacteraemia or has any local skin lesions.

N-1.2.5 Pre-deposit donation for autologous transfusion should not be drawn from donor-patient within 72 hours of the anticipated operation or transfusion.

N-1.2.6 The frequency of phlebotomy for number of autologous transfusion units should be determined by the blood bank medical officer and donor-patient's physician.

N-1.2.7 Phlebotomy for autologous units should not be undertaken more frequently than every three days and at least 72 hours prior to surgery.

N-1.2.8 Transfusion of the autologous units should be under medical supervision.

N-1.3 Testing of units

N-1.3.1 ABO-Rh(D) type should be determined.

N-1.3.2 The tests for irregular antibodies and infectious disease tests should be done atleast on the first unit collected from the patient-donor.

N-1.3.3 Any abnormal test results should be reported to the patient's physician. Blood should be discarded if test result is positive for any mandatory test.

N-1.4 Labelling requirements

N-1.4.1 Following information should be provided on a label or tag attached to the blood container.

- Name of the blood bank (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 unit is 'For Autologous Use Only'.

N-1.5 Pre transfusion testing

N-1.5.1 The patient's blood sample should be accompanied with pre transfusion requisition form for autologous transfusion as per the requirements to confirm the ABO and Rh blood group.

N-2.0 PERI OPERATIVE

N-2 Hemodilution

N-.2.1 The treating physician should be responsible for peri-operative autologous programme. The policies and procedures should be developed jointly with the medical officer in blood bank.

N-2.2 Units collected by hemodilution method or intra operatively should be stored at room temperature (22^0C) up to 8 hours or 4 ^{0}C + 2^0 C up to 24 hours.

N-2.3 Intra operative autologous transfusion using blood salvaged intra operatively from the operative site or extra corporeal circuit should preferably be avoided unless, the need to perform such transfusion can be justified under only life saving emergency and having proper facility for safety of the patient.

N-2.4 Intraoperative salvage methods should be safe if aseptically carried out using equipment which should be pyrogen free and should include a filter capable of retaining potentially harmful particles and preclude air embolism.

N–2.5 Complete written protocol of all transfusion procedure should be maintained including criteria for selection, dosage, ancillary agents used, prevention and treatment of adverse reactions.

N-2.6 Blood collected intraoperatively and not used during or immediately following the operation should not be transfused to other patients.

N-3.0 POST OPERATIVE AND POST TRAUMATIC

N-3.1 Blood from mediastinal drainage following cardiac surgery or from chest following blunt trauma can be salvaged for autologous transfusion

only. It should not be used for any other patient other than donor-patient.

N-3.2 Such blood should be transfused within 6 hours of the collection after appropriate manipulation.

N-4.0 RECORDS

N-4.1 Records of all autologous procedures should be maintained in blood bank.

O. Documentation in Transfusion Service

For all processes and procedures current version of SOPs should be written by the technologist who performs it, verified by supervisor of the area, Quality Assurance Manager and authorised by medical officer-in-charge.

O. Documentation in Transfusion Service

O-1.0 GENERAL REQUIREMENTS

The quality management system documentation should include

a) documented statements of quality policy and quality objectives

b) a quality manual

c) documents required to ensure the effective planning, operation and control of its processes

d) records required by international/national standards as appropriate

O-2.0 STANDARD OPERATING PROCEDURES

O-2.1 For all processes and procedures current version of SOPs should be written by the technologist who performs it, varified by supervisor of the area, Quality Assurance Manager and authorised by medical officer-in-charge.

O-2.2 All SOPs should be validated.

O-2.3 SOPs should be available on work bench and used by all.

O-2.4 One copy of all SOP should be maintained in a master file.

O-2.5 The obsolete versions of all SOPs should be archived.

O-3.0 RECORDS

O-3.1 Each blood bank and transfusion service should develop a practical record keeping system, which serves its needs.

O-3.2 The record system should make it possible to trace a unit of blood/ component from source (donor and collecting facility) to final destinations.

O-3.3 The system should ensure confidentiality of donor and patient records.

O-3.4 Records should be legible and corrections should be initialled.

O-3.5 Date of performance of procedures, tests and interpretation should be recorded.

O-3.6 All records should be retained for a minimum of 5 years. For donor retention programme, it is preferable to maintain donor records for a longer term.

O-4.0 RECORDS OF DONOR AND DONOR'S BLOOD/COMPONENTS

O-4.1 Following Donor Records should be maintained:

- Demographic details of donor
- Identification number
- Donor selection record
  - Medical history
  - Physical examination.

O-4.1.1 Donor deferral records

O-4.2 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 collection
- Signature of phlebotomist and medical officer

O- 4.3 Donor Reactions - state of donation reaction when occurred needs to be mentioned along with the description, management details and action taken for prevention in future.

O-4.4 Blood components records

- Identification number
- Name and volume of component prepared
- Date, time and mode of preparation
- Disposition record.

O-4.5 Records of blood and components from outside source

- Identification number
- Name of component
- Name of collecting facility
- Date of collection and expiry
- Disposition record.

O-4.6 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, VDRL tests and its interpretation
- Test for absence for Malaria parasites.

O-4.6.1 Documentation of details of grouping indicating reaction results, batch number and manufacturer's name of reagents in use, details of reagent red cells in use.

O-4.6.2 Documentation of all infectious disease tests including ELISA 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.

O-4.7 Quality control records indicating testing of components, reagents and equipment.

O-4.8 Records of apheresis procedures

O-4.9 Records of all blood discarded.

O-5.0 RECORD OF RECIPIENT

O-5.1 Blood requisition form with full particulars of recipient and identification number.

O-5.2 Results of ABO and Rh(D) tests and their interpretation.

O-5.3 Interpretation of compatibility tests.

O-5.3.1 Compatibility record.

O-5.4 Report of adverse reaction and record of their investigation.

O-5.5 Issue Register should have;

- Date and time of issue
- Particulars of patient and his/her ABO and Rh(D) type
- Identification number and segment number of red cell units issued,

ABO and Rh (D) type, blood component issued

- Signature of person issuing and receiving

O-6.0 OTHER RECORDS

O-6.1 Daily group wise blood stock register (Inventory) showing its receipt, issue and balance, units discarded with reason of discarding.

O-6.2 Record showing the daily temperature recordings of the temperature dependent equipment.

O-6.3 Stock register of non-consumable articles.

O-6.4 Stock register of consumable articles

O-6.5 Documentation of staff qualifications and training

O-6.6 Documentation of staff competency and proficiency tests

O-6.7 Staff signature register

O-6.8 Record of quality assurance (Internal and external audits)

O-6.9 Record of incident reports

O-6.10 Record of equipment maintenance

O-6.11 Record of document control

O-7.0 COMPUTER SYSTEM

O-7.1 A SOP should be made available for use.

O-7.2 An alternative method to be used during system breakdowns must be known. Hard copies should be available even when documentation is electronically maintained.

O-7.3 Maintenance and continuous operations must be ensured.

O-7.4 Personnel must be trained.

O-7.5 Validation of system and integrity and security of data entry should be ensured.

O-7.6 Back up should be available.

O-7.7 The records required by Drugs & Cosmetics Act should also be maintained as hard copies.

P. Histocompatibility Testing

Histocompatibility testing refers to the determination of tissue antigens and their immunologic reactions.

P. Histocompatibility Testing

P-1.0 Histocompatibility testing refers to the determination of tissue antigens and their immunologic reactions. Testing includes isolation of cells such as lymphocytes, platelets, granulocytes and other tissue cells, HLA typing for A, B, C, DR and DQ locus antigens, antibody detection, crossmatching and mixed lymphocyte culture.

P-1.1 Terminology of HLA antigens should conform to the nomenclature adopted by the World Health Organisation.

P- 2.0 REAGENTS

P-2.1 HLA typing reagents

P-2.1.1 Well characterised HLA typing antisera of confirmed specificity procured from commercial firms and reference laboratories should be used for HLA typing.

P-2.1.2 HLA typing reagents should be stored at -30^{0}C or below either in bulk or loaded in typing trays.

P-2.2 Control sera

P-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).

P-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.

P-2.3 Complement

P-2.3.1 Complement should be stored in small aliquotes either in lyophilised state or in liquid form at below -30^{0}C.

P-2.3.2 Each new batch of complement should be tested for its potency to induce cytotoxicity in the presence of specific antibody, but is not cytotoxic to the test cells in the absence of specific antibody.

P-3.0 HLA TYPING

P-3.1 Typing for each of the antigens for HLA - A, B, C and DR & DQ loci should be defined by atleast two antisera, one of which is monospecific.

P-3.2 HLA typing should be performed by complement dependent micro lymphocytotoxicity method or by other equally sensitive tests.

P-3.3 When DNA-amplification-based methods are used following apply:

P-3.3.1 The laboratory should use physical and / or biochemical barriers to prevent DNA contamination.

P-3.3.2 The specificity of each primer and each oligonucleotide probe should be defined and documented.

P-3.3.3 All reagents, equipment, and work areas should be monitored periodically for absence of contamination.

P-3.3.4 Negative control should be included in each amplification.

P-3.3.5 Reports should designate the type of assay used.

P-4.0 COMPATIBILITY TESTING

P-4.1 Sample identification

Each specimen should be labelled to ensure proper identification of donor and recipient specimen.

P-4.2 HLA type

P-4.2.1 When HLA type compatible blood components are required for transfusion, donor and recipient HLA-A and -B antigens should be determined to obtain compatible donor.

P-4.2.2 For living related stem cell transplantation donors, all available family members (preferably siblings & parents) should be typed to determine compatibility.

P-4.2.3 For organ transplantation, donor and recipient should be typed for ABO, HLA-A, -B - C and –DR/DQ antigens.

P-4.3 HLA antibody detection

P-4.3.1 Comprehensive cell panel to ensure all WHO accepted antigens including working antigens should be used for antibody detection in sera from multiparous women and multitransfused patients.

P-5.0 LYMPHOCYTOTOXICITY CROSSMATCH

P-5.1 Crossmatch should be done using enhancing test methods available such as prolonged incubation, washing, and augmentation with antiglobulin reagents or flowcytometry on recently collected blood samples of the recipient.

P-5.2 If serum shows presence of antibodies, it is preferable to preserve serum sample for further cross match.

P-5.3 All serum samples should preferably be preserved, in frozen state for at least 3 months, following transplantation.

P-6.0 PRETRANSPLANTATION TESTS

P-6.1 A sample of blood from prospective transplant donor should be tested for ABO blood group VDRL, anti-HCV, HBsAg, anti-HIV-1, and anti-HIV-2.

P-7.0 RECORDS

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

Q. Biosafety and Waste Disposal

All laboratory personnel should be informed of the hazards including transmission of viral infection involved in working in a blood bank laboratory. Possible routes of infection may be skin abrasion or puncture or through body orifices.

Q. Biosafety and Waste Disposal

Q-1.0 PROTECTION OF BLOOD BANK PERSONNEL AGAINST LABORATORY INFECTION

Q-1.1 All laboratory personnel should be informed of the hazards including transmission of viral infection involved in working in a blood bank laboratory. Possible routes of infection may be skin abrasion or puncture or through body orifices.

Q-1.2 Incidental exposure to infected samples like bag breakage, splash, needle stick injury should immediately be reported to the concerned authorities.

Q-1.3 Preventive inoculation of the blood bank staff against Hepatitis-B infection after appropriate tests should be necessary.

Q-2.0 PERSONNEL PROTECTION

Q-2.1 All protective apparel for universal precaution should be provided.

Q-2.2 The staff should be made aware of universal precautions as under

Q-2.2.1 Hands

Q-2.2.1.1 Wash hands before leaving the laboratory, and before eating or drinking.

Q-2.2.1.2 Wash hands immediately after they have been in contact with blood or blood products.

Q-2.2.1.3 Wear disposable gloves when handling all materials suspected of being infective or when opening samples of blood.

Q-2.2.1.4 Keep open wounds and cuts covered with an adhesive dressing or disposable gloves during working.

Q-2.2.1.5 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.

Q-2.2.2 Coats

- 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 should be soaked in hypochlorite or autoclaved before it is laundered.

- Do not wear lab coat when you proceed for lunch.
- Provide a lab coat to visitors also.

Q-2.2.3 Mouth

Q-2.2.3.1 Do not put fingers or other objects such as pens, in the mouth.

Q-2.2.3.2 Do not use mouth pipetting

Q-2.2.3.3 Eating, drinking, smoking is not permitted in any working area of the laboratory.

Q-2.2.3.4 No food or beverage be stored in any laboratory refrigerator, freezer, hot air oven or incubator.

Q-2.2.4 Avoiding needle stick injuries

Q-2.2.4.1 Never recap or bend needles

Q-2.2.4.2 Dispose all sharps in puncture proof containers

Q-2.2.4.3 In case of a needle stick injury, squeeze out the blood, wash the hand with the anti-septic and make out an incident report.

Q-2.2.4.4 Post exposure prophylaxis as per guidelines under State AIDS Control Programme.

Q-3.0 DISPOSAL OF BLOOD AND LABORATORY MATERIAL

Q-3.1 Method of Disposal of Blood BagsShould comply with requirements of Biomedical Wastes Rules of Ministry of Environment and Forests and local pollution control board.

Q-3.2 Needles should be burnt using electric needle destroyers or soaked in hypochlorite solution or discarded in a puncture proof container of a non-chlorinated plastic. These should then be sent for deep burial or incineration.

Q-3.3 Disinfection of glassware: All reusable glassware should be disinfected by treating with hypochlorite and detergent before cleaning. Subsequently glassware can go to hot air oven at 160^{0}C for 1 hour.

Q-3.4 Spills on the table tops/sinksThe spill should be covered with filter papers or plain cloth and soak with 1% hypochlorite solution for at least 30 minutes and later swabbed.

Q-3.5 Hypochlorite – detergent solution0.5-1.0 per cent solution of hypochlorite is the best general purpose disinfectant if contact is maintained for at least 30 minutes. (Except for metallic equipment which could be autoclaved or put in cidex).

Q-3.6 Disposal by SterilisationAutoclaving 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) should be done at least once a month.

R. Quality Control of Reagents

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

R. Quality Control of Reagents

R-1.0 ABO AND ANTI-D REAGENTS

R-1.1 A vial of every new batch should be checked for its potency (titre) besides specificity and avidity on receipt.

R-1.2 All the antisera and other reagents used for serological work in blood bank should be checked daily for their specificity and avidity, using known positive and negative controls

R-1.3 All reagents showing turbidity and discoloration suggesting contamination should be discarded.

R-1.4 Manufacturer's insert should specify titre, avidity and all other relevant information.

R-1.5 Methods followed should be as per manufacturer's instructions.

R-1.6 At any given time, there should be two different batches of each reagent available - either from two different manufacturers or two different batches from the same manufacturer.

R-1.7 Every new batch of anti-Rh(D) should preferably be checked with R_1r(CcDee), rr (ccdee) and rare cells like R or (ccDee), r'r (Ccdee) and r''r (ccdEe) to confirm anti-Rh(D) specificity.

R-1.8 The use of bovine albumin, enzymes and neutral AB serum for Rh(D) typing, should be checked with their positive and negative controls.

R-2.0 Reagent cells

R-2.1 Cells should be prepared daily and should be free of haemolysis. There should be a pool of 3 individual cells for each group.

R-2.2 Each batch of reagent cells (A, B and O) for serum grouping prepared should be tested to confirm specificity.

R-3.0 RED CELL PANEL

R-3.1 Either commercially available or prepared in house panels should be in use.

R-3.2 The red cells should be stored frozen, or at 4^0C.

R-3.3 Red cells stored for more than 48 hours at 4^0C, should be checked for

reactivity, of at least one weak reactive antigen by saline and indirect anti-globulin test.

R-4.00 ANTI-HUMAN GLOBULIN REAGENT

R-4.1 One vial from every new batch should be checked for its specificity and reactivity using (incomplete anti-Rh) IgG coated cells.

R-4.2 Each test should include positive and negative controls.

R-4.3 Non-sensitised A, B and O cells should be checked to rule out non-specific reactions.

R-4.4 All negative AHG tests should be confirmed by addition of IgG coated cells in the test. IgG coated cells should give positive agglutination.

R-5.0 BOVINE SERUM ALBUMIN

R-5.1 The reagent should be free of the non-specific agglutinins and should not react with saline suspension of A, B and O cells.

R-5.2 Reagent should give positive reaction with Rh(D) positive cells coated with incomplete anti-Rh(D).

R-6.0 ENZYME REAGENTS

R-6.1 Any enzymes, papain, ficin, trypsin or bromelin should be used for detection of incomplete antibodies.

R-6.1.1 Using the standard technique employed by individual laboratory, the reagent should give specific results using incomplete anti-Rh(D) with positive and negative controls.

R-6.1.2 Preparation of working reagent should be by standard method.

R-6.1.3 Enzymes should be aliquoted and stored in frozen state. Only required amount for the day should be thawed.

R-6.1.4 The unused enzyme remaining at the end of each day should be discarded.

R-7.0 HEPATITIS B ANTIGEN, ANTI-HCV AND ANTI-HIV 1 & 2 TEST

R-7.1 Use of Enzyme Linked Immunosorbent-Assay (ELISA) is recommended using kits approved by Drug Controller.

R-7.2 Test should be performed as per the instructions of the manufacturers.

R-7.3 Positive and negative controls (kit and in-house) should be run with every test.

R-7.4 Rapid Tests {approved by Drug Controller General (India)or WHO} should be used for screening in emergency; in rural areas or any centres collecting small volumes or where power and equipment maintenance is a problem.

R-8.0 Test for Syphilis

R-8.1 VDRL/TPHA/ RPR - methods should be used.

R-8.2 Test should be performed as per manufacturer's instructions.Positive and negative controls (kit and in-house) must be included with every test.

R-9.0 NORMAL SALINE AND BUFFERED SOLUTIONS

R-9.1 These solutions should be checked daily for pH (6.7-7.2). Absence of haemolysis with random A, B and O cells provide a useful indication for its suitability.

S. Equipment Maintenance

All equipment should be maintained to ensure efficient and accurate working at all times.

S. Equipment Maintenance

S-1 All equipment should be maintained to ensure efficient and accurate working at all times.

S-2 Staff should be trained to use and maintain equipment.

S-3 An equipment register should be kept to maintain comprehensive records of all equipment including a system to uniquely identify all equipment.

S-4 Specifications of acceptable performance should be established for each equipment. Validation of equipment should be done at the time of installation and at regular intervals thereafter.

S-5 An annual maintenance contract should be undertaken preferably for all equipment with the suppliers, including preventive maintenance and calibration.

S-6 Records of all maintenance should be kept as under:

- Equipment Identification
- Who performed servicing / calibration
- When performed servicing / calibration
- What was the result / conclusion / outcome
- When is the next schedule

S-7 Equipment should be used as per manufacturer's instructions.

S-8 SOP and datasheets regarding records of when and who used the equipment should be available.

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