

1. Purpose:

To ensure the availability of safe blood unit with facility for compatibility testing, storage and issue of blood in an aseptic environment on 24*7 basis through trained professionals.

2. Scope :

To store and issue collected blood to patient, organizing blood donation camp, counselling for blood donation and testing of blood for HBsAg, HIV, VDRL and MP.

3. Overall Responsibility: Blood Bank In-Charge/Pathologist.

4. Procedure:

Sr. No.	Activity/ Description	Res ponsi bility	Ref. Doc. / Record
4.1	DONOR SELECTION & COLLECTION OF BLOOD FROM DONORS <ul style="list-style-type: none">• Donor should be free from skin disease at the site of phlebotomy, cleaning• Blood shall be accepted only from voluntary, non-remunerated, low risk, safe and healthy donor with informed consent.• No person shall donate blood more than once in three months.• Donor should be in age group of 18 to 65 years, Not less than 45 KG for whole blood and 50 KG for components.• Temperature and Pulse should be normal.• Haemoglobin of donor should not be less than 12.5g/dl.• The systolic and diastolic blood pressures are within normal limits without medication• Donor should be free from Acute Respiratory Diseases.• arms and forearms of the donor shall be	Physi cian	

free from skin punctures or scars indicative of professional blood donors or addiction of self injected narcotics.

Donor should be free from any history of hepatitis.

➤ Any donor having *Cancer, Heart Disease, abnormal bleeding tendencies, unexplained weight loss, IDDM, Chronic Nephritis, Liver diseases, TB, Polycythemia Vera, Asthama, Epilepsy, Leprosy, Schizophrenia, Endocrine disorders* **MUST BE BARREED.**

➤ **Deferment condition:**

- | | |
|---|--------------------------|
| (a) Abortions | 6 months |
| (b) History of Blood transfusion | 6 months |
| (c) Surgery | 12 months |
| (d) Typhoid after recovery | 12 months |
| (e) History of Malaria and (endemic) Duly treated (non endemic area) | 3 months
3 years |
| (f) Tattoo | 6 months |
| (h) Breast feeding FEEDING | UP TO BABY FEEDING |
| (i) Immunization (Cholera, Typhoid, Diphtheria, Tetanus, Plague, Gammaglobulin) | 15 days |
| (j) Rabies vaccination | 1 year after vaccination |
| (k) History of Hepatitis in family or close contact | 12 month |
| (l) Immunoglobulin | 12 months. |

Blood shall be drawn from the donor by a Qualified Technician and/or under supervision of

Pathologist.

- All Donor site must comprises of beds, bed side tables, recovery beds, seperate refrigerators with digital thermometer for untested blood, sphygmomanometer and stethoscope, weighing machine for donor and sample, Hb determination equipments, (CuSo₄ or better technology may be adopted if available.) PVC bag for blood collection, sterile lancet, alcohol swabs, clinical thermometers, watch, oxygen cylinder with mask gauge, pressure regulator, 5% Glucose or NS, disposable Syringes, Sterile IV sets,
- Emergency tray containing Adrenaline, Noradrenaline, Mephentin, Betamet hasone/Dexamethasone, Metoclopropamide injections.
- **COLLECTION OF BLOOD: Blood collection should be done by aseptic methods** using a sterile closed system.
- Items for phlebotomy must be for single use.
- Blood bags must contain sufficient quantity of anticoagulant according to the quantity of blood to be collected.
- Identify donour record, Label bags & tubes with identical records.
- BP cuff should be tied pressure should be 40-60mmHg.
- Once the vein is selected, pressure device should be released before the skin site is prepared.
- Blood collected should not more than 10.5ml/Kg/donation
- Needle disposed off safely.
- Always verify the labeling on unit and samples.

Syncope(fainting/vasovagal syndrome) weakness, sweating, dizziness, pallor, loss of consciousness, convulsions and involuntary passage of urine.

	<p>1:Fainting:apply cold compress to forehead or back of neck. Administer aromatic spirits of ammonia Raise legs above head level Loosen tight clothing Monitor pulse,BP,Respiration periodically</p> <p>2:Nausea&Vomitting:make donor comfortable Breathe slowly and deeply Donor head turned to side. Give water after vomiting.</p> <p>3:Twitching/muscular spasms:d/t hyperventilation so divert the attention by conversation. Do not give oxygen.</p> <p>4:Hematoma during or after phlebotomy:firm pressure with $\frac{3}{4}$ sterile gauze for 7-10 minutes with arm over heart level. Apply ice</p> <p>5:convulsions:call for immediate help Maintain airway</p> <p>6:cardiac difficulties:call for immediate medical aid.</p>		
4.3	<p>TESTING OF DONATED BLOOD The blood units have to be screened for: Infectious diseases tests (<i>HIV,Hepatitis B, Hepatitis C,VDRL,Malarial Parasite</i> etc.)</p> <p>(1) It shall be responsibility of the blood bank to ensure that the whole blood collected, processed and supplied conforms to the standards by the Government.</p> <p>(2) Freedom from HIV antibodies (AIDS) Tests,The results of such testing shall be recorded on the label of the container.</p> <p>(3) Each blood unit shall also be tested for freedom from Hepatitis B surface antigen, and Hepatitis C Virus antibody VDRL and malarial parasite and results of such testing shall be recorded on the label of the</p>	Technician	Blood Bank Record

	<p>container.</p> <ul style="list-style-type: none"> • Blood samples of donors in pilot tube and the blood samples of the recipient shall be preserved for 7 days after issue in the separate refrigerator. • The blood intended for transfusion shall not be frozen at any stage. • Blood containers shall not come directly in contact with ice at any stage. <p>Record shall be maintained for the name of the donor along with the results.</p> <p>The blood group & Rh are indicated on the bag along with UID number given in blood bank register at which the details of the donor & blood sample are recorded.</p>		
4.3	<p>PREPARATION OF BLOOD COMPONENTS</p> <p>Preparation of blood components shall be carried out only under closed system using double, triple or quadruple plastic bags or bags with SAGM.</p> <p>The whole time competent technical staff meant for processing of blood components ie MO, Technical Supervisor, BB technician, BB nurse. processing of the blood component preparation should be done in the BB having blood component laboratory using manual/automated technology. separation should be done using manual/automatic differential centrifugation. hand spin and soft spin should be done in refrigerator through modern centrifuge separation using plasma expressor.</p> <p>A: Concentrated RBCs:</p> <p>Storage: Immediately after processing, the Packed Red Blood Cells shall be kept at a temperature maintained between 2 degree centigrade to 6 degree centigrade.</p> <p>(b) Inspection: The component shall be inspected immediately after separation of the plasma, during storage and again at the time of issue. The product shall not be issued if there is any abnormality in</p>		

	<p>color or physical appearance or any indication of microbial contamination.</p> <p>C:Granulocyte Concentrate: it shall be kept between 20-24 degree centigrade for a maximum period of 24 hrs.unit of granulocyte shall not be less than 1×10^{10} when prepared on cell separator. Group specified tests/HLA test wherever required shall be carried out.</p> <p>D:Fresh frozen plasma:plasma frozen within 6 hrs after blood collection and stored at a temperature not warmer than -30 degree centigrade,shall be preserved for a period of not more than 1 year.</p> <p>E:Cryoprecipitate:concentrate of anti hemophiliac factor shall be prepared by thawing of the fresh plasma frozen stored at -30 degree centigrade.cryoprecipitate shall preserved at a temperature not highr than -30 degree centigrade and may be preserved for a period of not more than 1year from date of collection.</p>		
4.4	STORAGE, TRANSPORTATION AND ISSUE OF BLOOD FOR TRANSFUSION		
4.4.1	<p>Storage of Blood and ItsComponents:</p> <p>A designated area shall be used for storage of untested,tested and expired blood. The area shall be properly labelled and the access to such areas shall be controlled.</p> <p>Adequate alternate storage facility with written display of instructions to maintain the blood and components at a particular temperature conditions.</p> <p>In the event of failure of power UPS shall be provided in the area of preservation.</p> <p>The storage equipment are so placed that the temperature alarm (beyond the prescribed limits) is audible to the blood bank personnel to ensure</p>		

	immediate corrective action.		
4.4. 2	Transportation of Blood and Its Components <ul style="list-style-type: none"> • A system must be use to ensure that all blood components shipped in to a blood bank have been maintained within temperature required. • All liquid RBC components kept at 1-10 degree centigrade during transport. • All components routinely stored at 20-24 degree centigrade and should maintain temperature during shipment. • All frozen components should be transport in frozen state at 18 degree or colder. • Periodic temperature check and documented to ensure the transportation adequate to meet the criteria 		
4.4. 3	Issue of Blood After successful testing of blood sample and cross matching, blood is issued to the patient. Issue of blood to be documented by blood bank staff.		Blood Bank Register
4.5	ISSUE OF BLOOD IN CASE OF URGENT REQUIREMENT: Transfusion requests must be fulfilled by..... <ul style="list-style-type: none"> • Identification of patient • Identification of componenet and the quantity • Name of requisitioning physician • Gender/Age/diagnosis,history of transfusion of recieipient • Confirmation of ABO type of Red blood components. • Confirmation of Rh type of Rh negative units. • Selection of components of ABO &Rh types appropriate for the recieipient • Crossmatching ➤ If blood transfusion needed in dire	Nurse I/C	Blood Requisition Form & Blood Bank Register

	<p>emergency, and time taken to process the recipient's blood would cause a detrimental delay, O-ve blood should be issued.</p> <ul style="list-style-type: none"> ➤ Clearly label blood sample tube and blood request form, if patient is unidentified use emergency admission no. ➤ If another request has to be sent use same identifiers as on the first request form and blood sample so blood bank knows they are dealing with same patient. ➤ If several staff working on emergency cases, one person should take charge of ordering blood. urgency of blood requirement to be communicated by predecided words. ➤ Blood bank may send group O (possibly O-ve) if there is any risk of patient identification. ➤ Individuals with type O-ve blood are UNIVERSAL DONORS and those with type AB+ve are UNIVERSAL RECIPIENTS. ➤ If patient is conscious ask him detail of name etc. in unconscious patients ask relatives or second member of staff. blood sample is taken in tubes/vials and labeled with patient's name, ward, bed no., date, signature of person taking sample. ensure patient's name is spelt correctly, do not label tubes before taking blood sample. 		
4.5.1	<p>Sample collection:</p> <p>The blood group & Rh of the patient are tested through sample collected by the blood bank technician either in blood bank or in inpatient department based on the patient's condition. Sample collection & cross matching is done in a hygienic environment.</p>	Blood Bank Technician	
4.5.2	<p>Identification of sample:</p> <p>Sample drawn from the patient is identified by putting a label mentioning name, age & registration no. of patient on the sample collection tube.</p>		

4.5. 3	Previous records Previous record of ABO and Rh type of patient shall not be used for cross matching; across matching report must be generated and name of person performing test and generating report must be recorded.		
	Blood Group	Color of the label	
	O	Blue	
	A	Yellow	
	B	Pink	
	AB	White	
4.6. 2	To overcome transfusion reactions the blood bank should have: <ul style="list-style-type: none"> • The patient's original cross match specimen, which is normally preserved for at least 48 hours after dispatching the blood or its products. • The donor's pilot tubing/bottle, this should also be preserved for 48 hours. • The entire laboratory and bloodbank records. • The blood should take immediate steps to establish the cause of the transfusion reaction. • Proper records must be maintained and the results should be communicated to the concerned department. 	Blood bank I/C	
4.7	CALIBRATION AND MAINTENANCE OF EQUIPMENTS For maintenance of Equipments like Refrigerator Deep Freezer, and others is done by checking temperature daily and every three months by engineer for accuracy of speed and time Calibration of equipments is done on annual basis or when required.		
4.8	DISPOSAL OF BLOOD AND BIO MEDICAL WASTE After blood collection, sample remaining in the tubing is collected in test tubes for infectious		Bio-Medical Waste (Management & Handling) Rules

	<p>disease screening and cross match. The needles containing portion of the tube cut down and disposed into sharp disposal containers.</p> <p>Units deemed unsuitable for transfusion, those not transfused and those designated for disposal for any reason, shall be disposed of by an appropriate method in accordance with all applicable regulations and requirements.</p> <p>All such components/bloods shall be disposed-off as per Bio Medical Waste (Management & Handling) rule 2016&2018(Ammendment)</p> <p>:Disposal of filled blood bags returned from facility:All returned units must be first autoclaved with bags and then handed over to BMW collecting Agency.</p> <p>:Disposal of Reactive filled blood bags:First treat with bleaching powder for 30 minutes,then autoclav the unit,then handover the unit to the BMW agency.</p> <p>Documentation of each unit discarded should be maintained.</p> <p>:Disposal of Empty Bags:Empty blood bags must be first cut and disinfected and then disposed in Red container & handed over to the BMW agency.the facilities not covered by the BMW agency should autoclave the bag by a dedicated BMW autoclave & then disposed off in the deep burial pit .</p>		2016
4.9	<p>MAINTENANCE OF RECORDS</p> <p>Following records are maintained in the Blood Bank:</p> <ul style="list-style-type: none"> ➤ Blood Donor Record ➤ Master Record for Blood and its components ➤ Issue Register for Whole Blood ➤ Record of components supplied ➤ Register for Diagnostic Kits and Reagents used 		

	<ul style="list-style-type: none"> ➤ Transfusion Adverse Reaction Records ➤ Elisa Test Records ➤ Component daily Preparation Record Quality Control Register ❖ The records which required to maintain shall include inter alia the following particulars, namely:- <p>(1) Blood donor record: It shall indicate serial number, date of bleeding, name, address and signature of donor with other particulars of age, weight, hemoglobin, blood grouping, blood pressure, medical examination, bag number and patient's detail for whom donated in case of replacement donation, category of donation (voluntary/replacement) and deferral records and signature of Medical Officer In-charge.</p> <p>(2) Master records for blood and its components: It shall indicate bag serial number, date of collection, date of expiry, quantity in ml. ABO/Rh Group, results for testing of HIV I and HIV II antibodies, Malaria, V.D.R.L., Hepatitis B surface antigen and Hepatitis C virus antibody and irregular antibodies (if any), name and address of the donor with particulars, utilisation issue number, components prepared or discarded and signature of the Medical Officer Incharge.</p> <p>(3) Issue register : It shall indicate serial number, date and time of issue, bag serial number, ABO/Rh Group, total quantity in ml, name and address of the recipient, group of recipient, unit/institution, details of cross-matching report, indication for transfusion.</p> <p>(4) Records of components supplied: quantity supplied; compatibility report, details of</p>		
--	--	--	--

	<p>recipient and signature of issuing person.</p> <p>(5) Records of A.C.D./C.P.D/CPD-A/SAGM bags giving details of manufacturer, batch number, date of supply, and results of testing.</p> <p>(6) Register for diagnostic kits and reagents used: name of the kits/reagents, details of batch number, date of expiry and date of use.</p> <p>(7) Blood bank must issue the cross matching report of the blood to the patient together with the blood unit.</p> <p>(8) Transfusion adverse reaction records.</p> <p>(9) Records of purchase, use and stock in hand of disposable needles, syringes, blood bags, shall be maintained.</p> <p>➤ NOTE: The above said records shall be kept by the blood bank for a period of five years</p>		
--	--	--	--

4.10	QAULITY CONTROL OF EQUIPMENTS :			
	EQUIPMENT	PERFORM ANCE	FREQUENCY	FREQUENCY OF CALIBRATION
	Temperature recorder	Compare against thermometer	Daily	As often as necessary
	Refrigerated centrifuge	Observe speed and temperature	Each day of use	As often as necessary
	Hematocrit centrifuge	--	--	Standardise before initial use, after repair or adjustments, and annually.
	General	--	--	Tachometer. every

	lab. centrifuge			6 months,
	Automated Blood typing	Observe controls for correct results	Each day of use	---
	Haemoglobinometer	Standardize against cyanmethemoglobin standard	Each day of use	---
	Refractometer or Urinometer	Standardize against distilled water .	---ditto ---	---
	Blood container weighing device	standardize against container of known weight	---ditto --	As often as necessary,
	Water Bath	Observe Temperature	---ditto --	----ditto----
	Rh view box(wherever necessary)	--ditto --	--ditto--	----ditto----
	Autoclave	--ditto --	Each time of use	-- ditto --
	serologic rotators	Observe controls for correct results	Each day of use	speed as often as necessary
	Laboratory thermometers	--	--	Before initial use
	Electronic thermometers	--	Monthly	--
	Blood agitator	Observe weight of the first container of blood filled for correct results	Each day of use	standardize with container of known mass or volume before initial use, and after repairs or adjustments.

QAULITY CONTROL OF REAGENTS:

All supplies and reagents used in the collection, processing, compatibility, testing, storage and distribution of blood and blood components shall be stored at proper temperature in a safe and hygienic place, in a proper manner and in particular –

- (a) all supplies coming and contact with blood and blood components intended for transfusion shall be sterile, pyrogen-free, and shall not interact with the product in such a manner as to have an adverse effect upon the safety, purity, potency or effectiveness of the product.
- (b) supplies and reagents that do not bear an expiry date shall be stored in a manner that the oldest is used first.
- (c) supplies and reagents shall be used in a manner consistent with instructions provided by the manufacturer .
- (d) all final containers and closures for blood and blood components not intended for transfusion shall be clean and free of surface solids and other contaminants.
- (e) each blood collecting container and its satellite container(s), if any, shall be examined visually for damage or evidence of contamination prior to its use and immediately after filling. Such examination shall include inspection for breakage of seals, when indicated, and abnormal discoloration. Where any defect is observed, the container shall not be used or, if detected after filling, shall be properly discarded.
- (f) representative samples of each lot of the following reagents and/or solution shall be tested regularly on a scheduled basis by methods described in the Standard Operating Procedures Manual to determine their capacity to perform as required :

Reagents and solutions	Frequency of testing alongwith controls
Anti-human serum	Each day of use
Blood grouping serums	Each day of use
Lectin	Each day of use
Antibody screening and reverse grouping cells	Each day of use
Hepatitis test reagents	Each run
Syphilis serology reagents	Each run
Enzymes	Each day of use
HIV I and II reagents	Each run
Normal saline (LISS and PBS)	Each day of use
Bovine Albumin	Each day of use