ASBTC
অসম ৰাজ্যিক ৰক্ত সংৰচণ পৰিষদ
Assam State Blood Transfusion Council

Department of Health & Family Welfare
Government of Assam

A HANDBOOK ON BLOOD CENTRE PRACTICES IN ASSAM

PUBLISHED BY
ASSAM STATE BLOOD TRANSFUSION COUNCIL
KHANAPARA, GUWAHATI – 22

A
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1st December 2022
ISBN : Applied for

DEPARTMENT OF HEALTH & FAMILY WELFARE
GOVT. OF ASSAM

ড° হিমন্ত বিশ্ব শর্মা
Dr. Himanta Biswa Sarma

মুখ্যমন্ত্রী, অসম
Chief Minister, Assam

सत्यमेव जयते

Dispur
21 Kārtikaḥ, 1429 Bhaskarabda
8th November, 2022

MESSAGE

I congratulate Assam State Blood Transfusion Council (ASBTC) for having published *A Handbook on Blood Center Practices in Assam*, which will go a long way in providing important information regarding blood centres of Assam as well as serve as a comprehensive clinical manual of blood transfusion practices.

The world needs enough safe blood for everyone. In every few seconds someone, somewhere needs blood. Transfusion of blood and blood products, save millions of lives every year. Regular blood donation is needed all over the world to ensure access of individual and communities to safe and quality assured blood and blood products.

The Handbook on Blood Center Practices in Assam is first of its kind in the entire state, widely covering regulatory and clinical essentials related to blood transfusion practice. The handbook aims to ensure easy access of blood center by a common man as well as to guide the clinicians and health care professionals about the adequate supply of safe and quality blood and blood components across Assam through a comprehensive, efficient and total quality management approach. ensuring the judicious use of blood.

The Handbook will play an important role for providing important information about blood centers in Assam in a comprehensive manner. I am sure the handbook would go a long way to make the transfusion services better in Assam.

I wish this endeavour achieves great success.

(Dr. Himanta Biswa Sarma)

Keshab Mahanta

MINISTER
Health & Family Welfare Dept.
Medical Education & Research Dept.
Science,Technology & Climate Change Dept.
Information Technology Department

सत्यमेव जयते

MESSAGE

Blood transfusion is an essential component of the health care system of every country and patients who require blood transfusion service as part of the clinical management of their condition have the right to expect that sufficient and safe blood will be available to meet their needs. However, this is not always the case, especially in developing countries. To recruit and retain adequate regular voluntary non-remunerated blood donor, the motivators and barriers of donor must be understood. Equally important to this goal is the quality, safety and efficacy of blood and blood products, well equipped blood centres with adequate infrastructure and trained manpower. For effective clinical use of blood, it is necessary to train clinical staff and make them aware of the latest SOPs and other guidelines. To attain good manufacturing practices and quality management is vital for the proper management of blood transfusion services.

I would like to acknowledge the contribution made by Assam State Blood Transfusion Council (ASBTC) in preparing this Handbook on Blood Center Practices, which will provide technical expertise to persons working in a blood center.

The lucidity and easy language will benefit even the common man, who is interested in gaining knowledge about Blood Center Practices in Assam.

I hope that this Handbook which is a first of a kind in our State will improve the standards and thereby provide excellent and high quality services to the citizens of our State.

(Keshab Mahanta)

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The Department of Health & Family Welfare, Govt. of Assam, through the Assam State Blood transfusion Council (ASBTC), has been taking various initiatives to strengthen blood banking and blood transfusion services in the State of Assam. The ASBTC has been working as the primary coordinating agency in standardization of Blood Centre, Blood Component Separation Unit, Blood Storage Unit, Voluntary Blood Donation Camps, Mobile Blood Donation etc. in the State. The ASBTC is taking up concerted effort for building the capacity of the functionaries involved in blood transfusion services.

I congratulate Assam State Blood Transfusion Council and the team of experts for publishing "A Handbook on Blood Centre practices in Assam" which aims to be a compact guide describing the current paradigm in transfusion practice, for enhancing the knowledge of Blood Bank medical officers and staff working in a Blood Centre/ Blood component separation Unit/ Blood storage unit. This structured compact guide presents essential information on blood and blood products and their indication, various aspects of blood administration, essential immune haematology, Voluntary Blood Donation, Blood Bank licensing etc.

I hope this handbook will serve as an important guide for everyone involved in this noble cause by assisting them to make discretionary judgments on the optimum and safe use of blood and blood products in their daily practice.

(AVINASH JOSHI)

PREFACE

Ms. Pomi Baruah, ACS

Director cum Member Secretary ASBTC

Everything begins with a new idea. The idea for "A Hand Book on Blood Centre Practices in Assam" was conceived in my office chamber, one fine morning in the month of July, 2022, after I had joined as Director, Assam State Blood Transfusion Council. This Handbook, which is the first of its kind in Assam, has been prepared keeping in mind the basics of blood transfusion knowledge for achieving the objective of safe blood transfusion. This is a maiden attempt to cover all aspects of blood transfusion practices in blood centres for the benefit of those who are involved in blood donation, transfusion and storage. The expert team involved in the preparation of this Handbook has made every effort to include relevant information in this Handbook, to make it an easy reference for blood centre practices. Transfusion of blood and blood products continues to be an important aspect of modern clinical practice and this handbook is an effort to provide a compact guide for describing the dynamics in current transfusion practice.

I take the opportunity to place on record my humble gratitude to the expert team, who have worked tirelessly to turn an idea into a reality. The expert team, comprising Dr. Dipankar Baruah, MD, Associate Professor of Pathology and In Charge, State of the Art Model Blood Centre, GMCH, Guwahati, Dr. Dharmakanta Kumbhakar, Professor & Head of the Department, Pathology, Dhubri Medical College & Hospital, Md. Fokhrul Alam Choudhury, Asstt. Director, ASBTC, In Charge BTS, Assam and last but not the least, Shri Rikku Dutta, Councellor, Blood Centre, B.P. Civil Hospital, Nagaon, have left no stone unturned in framing this handbook in a very short period of time, despite their busy work schedules.

Our sincere gratitude to Hon'ble Chief Minister, Dr. Himanta Biswa Sarma, for his valuable guidance, to Hon'ble Health Minister, Shri Keshab Mahanta, for being a constant source of encouragement and to Principal Secretary, Health & Family Welfare Department, Shri Avinash Joshi, IAS, for his kind help and support. We are grateful to NBTC, ASACS and all members of ASBTC for their contribution.

It is earnestly hoped that this document will serve its purpose and be a beacon for all future enceavours towards improvement of blood transfusion services in our State. I acknoeledge the support extended by NBTC for providing technical inputs for giving a final shape to this handbook.

Ms. Pomi Baruah, ACS

EDITORIAL BOARD

CONTENT

INTRODUCTION

Blood/blood components transfusion is an important component of the modern health care system and in most of the time, a life saving one. In many cases, people lose their lives because of lack of blood or blood component. In major surgeries, emergency care of trauma patients, women with complications during pregnancy, severely anaemic women and children, cancer patients and persons suffering from sickle-cell anaemia, thalassemia, haemophilia, etc. safe blood/blood components transfusion is indispensable. Safe blood/blood components transfusion improves life expectancy and quality of life of patients suffering from life-threatening diseases. In mass casualties caused by road traffic accidents, natural calamities, etc., safe blood transfusion plays a vital role in the life-saving process. Transfusion of safe blood/blood components helps to save millions of lives every year worldwide.

Blood is considered to be an essential element of human life with no substitute till date. Nothing is comparable to the preciousness of human blood. All we know is that, in spite of rapid and remarkable conquests of medical science today, no one can manufacture blood/blood components. It is only in human beings that human blood/blood components are made and circulated. If someone requires blood or blood components, donations from other fellow humans is the only means.

To maintain a safe and sustainable blood/blood components supply, healthy voluntary non-remunerated blood donors must come forward for voluntary blood donation. Maintenance of sufficient stock of blood and blood components to deliver in the right quantity at the right time cannot be assured without a regular flow of voluntary non-remunerated blood donors. Voluntary non-remunerated blood donors donate blood or its components of their own will and receive no payment, either in the form of cash or kind. Any healthy person aged 18 to 65 years having normal blood pressure, normal body temperature, weighs more than 45kg and has haemoglobin level of more than 12.5 gm/dL, can usually donate whole blood, although other limits apply for donation of plasma and platelets. For safety reasons, users of injectable drugs, carriers of transmissible infections (HIV, HBV, HCV, syphilis, malaria, etc.), recipients of organ transplants or recent blood transfusions can no longer be a blood donor. Any healthy person can donate blood up to four times every year at an interval of three months. Plasma and platelets may be donated frequently.

However, blood/blood components transfusion is not free of its various risks. Out of such risk, one of the risks of blood/blood components transfusion is transfusion-transmitted infections (TTIs). TTIs are infections that transmit pathogens into blood/blood components recipient through improper blood testing and transfusions. Among these HBV, HCV, HIV, malaria and syphilis are common in India. Lack of quality system in blood centre, lack of

proper testing facilities, in-appropriate laboratory services, poor or non-standard laboratory testing procedure, inadequate testing of donated blood, lack of trained hands or out dated reagents and inappropriate use of blood/ blood components may contribute in spreading of TTIs. TTIs are also a cause of health threat for the health-care providers. Therefore, it is mandatory for every blood centre in India to screen every unit of donated blood for HBV, HCV, HIV, malaria and syphilis.

Blood centres collect and process blood, screen mandatory tests and issue blood for transfusion and store it for later use. They need to provide safe blood whenever and wherever required. So, blood centres are responsible to ensure safety, adequacy, accessibility & efficiency of blood supply. Therefore, it is imperative to observe high technological standard by blood centres to provide assurance of safety to both donor and recipient. Proper donor selection, donor counselling, strict screening and use of proper testing to detect the TTIs in the donated blood in blood centres are necessary to reduce the incidences of TTIs among the blood recipients. Voluntary blood donation is associated with reduced prevalence of TTIs. Moreover, judicious use of blood and blood products is also essential for better patient outcome and efficient healthcare delivery.

It is seen that there is no standard hand book to guide the technical persons working in blood centres in our state in this regard. This handbook on blood centre practices in Assam is prepared to guide them for proper donor selection, donor counselling, proper testing and evaluation of transfusion reactions. The handbook attempts to summarise current knowledge on transfusion services. It covers entire range of technical aspects related to blood transfusion services. Wherever possible the handbook draws upon evidence based guidelines. The blood centres will be able to use this handbook as a quick reference in blood transfusion practices.

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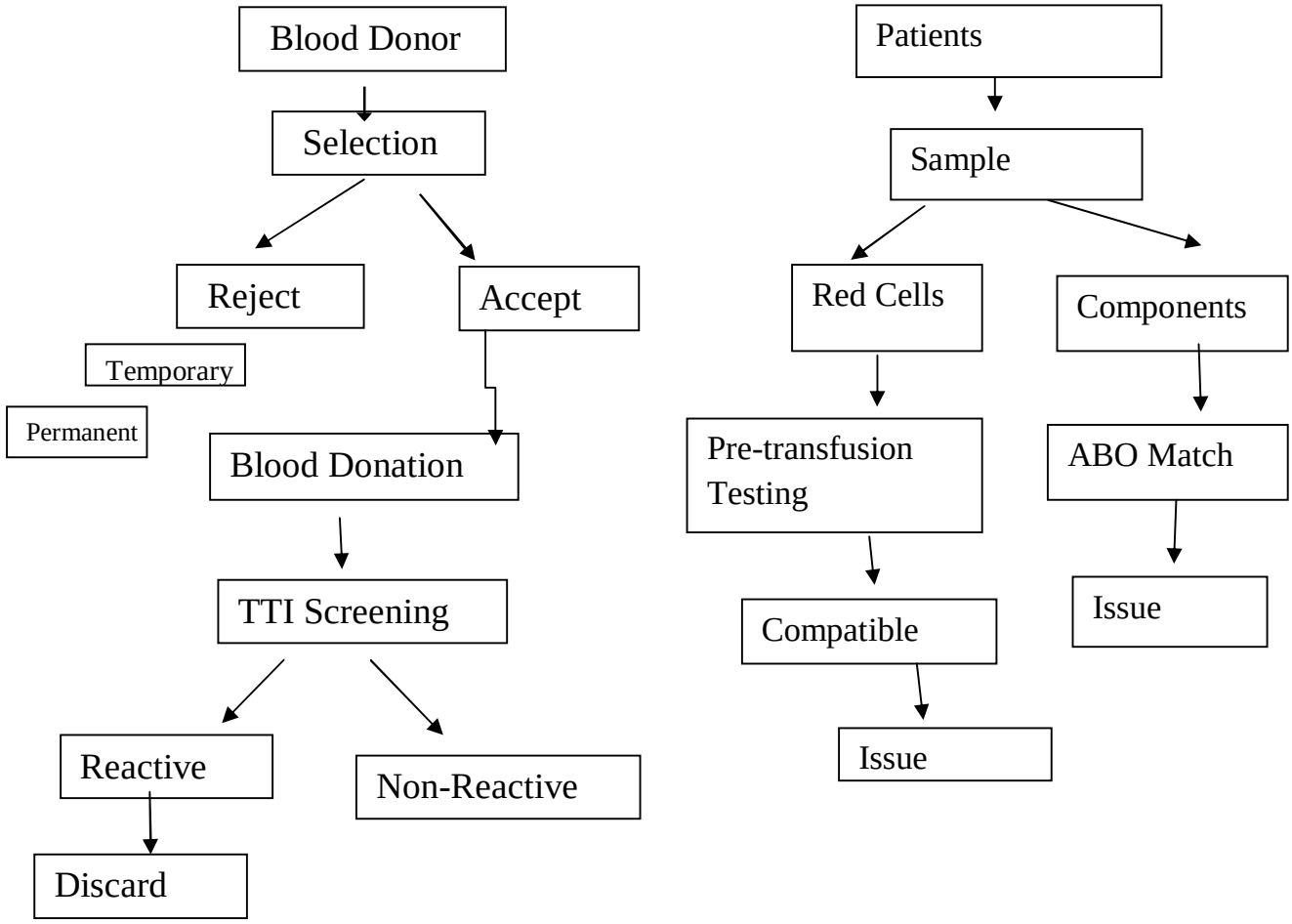
OVERVIEW OF A BLOOD CENTRE

A blood centre previously known as "Blood Bank" is a centre where blood is collected, processed, issued for transfusion and stored for later use. A blood centre should have the following areas –

- **Waiting Area:** This area is accessible to the public who come for blood donation as well as to receive blood for needy patients. This area should have sitting facility as well as amenities like T.V., etc. It should also have lavatory facility for donors.
- **Reception:** The blood requisition form and patient's sample should be received in this area.
- **Blood Donor Registration Area**: In blood donor registration area the blood donor has to fill up a donor consent and questionnaire form.
- **Blood Donor Counselling Room**: In this area the blood donor is counselled by a trained counsellor regarding his/her health condition and accordingly inform him/her about the benefits of blood donation and the eligibility criteria for blood donation.
- **Medical Examination Room**: In this area, blood donors are examined by a medical officer as per standard guidelines and examine him/her for eligibility to donate blood. And, if any donor is found unfit for blood donation then he/she should be deferred accordingly.
- **Blood Collection Area:** The blood is collected in this area by a phlebotomist. The donor is laid down comfortably in the donor couch to collect the blood.
- **Donor Refreshment cum Rest Room:** After collection of blood from the blood donor, he/she is advised to take rest and is asked to take the donor refreshment and post donation advices are given.
- **Serology Room:** Blood grouping and compatibility tests are done in this section.
- **TTI Laboratory:** Transmission-transmitted infections screening are done from the collected blood samples by ELISA method.
- **Blood Issue Section**: Here blood units are issued after verification of all the documents and records that are maintained in the register. Along with blood unit, transfusion reaction form and blood issue form is provided to the patient's attendant.
- **Wash cum Sterilization Room:** The reactive blood units are discarded by autoclaving. Used glassware are washed and sterilized by hot air oven.
- **Blood Unit Storage Area**: Both processed and untested blood units are preserved in separate blood bank refrigerator.
- **Quality Control Room:** Quality control tests for whole blood and components are performed here.
- **Component Preparation Room:** Blood components are prepared in refrigerated centrifuge machine. Random donor platelets prepared from whole blood are stored in platelet incubator cum agitator.
- **Component Storage Area:** Fresh frozen plasma and cryoprecipitate are stored here in deep fridge (minus 40^0 C or minus 80^0 C)
- **Store Room:** All the consumables (reagents/antisera/blood bags etc.) are stored here.

- **Record Room:** All kind of forms, labels and registers are kept in this room.
- **Staff Room:** One room should be designated for blood centre's staff.
- **Office Room:** All the official works related to blood centre are done in this room.
- **In-Charge Room:** Room designated for blood centre in-charge

Flow Chart of Functions of Blood Centre



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BLOOD DONOR ELIGIBILITY AND DONOR SELECTION

Any healthy adult, both male and female can donate blood. Men can donate blood safely once in every three months while women can donate blood safely in every four months.

"Safe Blood Starts with me"

General Criteria		
S.No.	**Criteria**	**Recommendations**
1.	Well being	The donor shall be in good health. mentally alert and physically fit and shall not be inmates of jail or any other confinement. "Differently abled" or donor with communication and sight difficulties can donate blood provided that clear and confidential communication can be established and he/she fully understands the donation process and gives a valid consent.
2.	Age	Minimum age 18 years Maximum age 65 years First time donor shall not be over 60 years of age; for repeat donor upper limit is 65 years. For aphaeresis donors 18-60 years
3.	Whole Blood Volume Collected and weight of the donor	350 ml- 45 kg 450 ml- more than 55 kg Apheresis- 50 kg
4.	Donation Interval	For whole blood donation, once in three months (90 days) for males and four months (120 days) for females. For apheresis, at least 48 hours interval after platelet/ plasma - apheresis shall be kept (not more than 2 times a week, limited to 24 in one year) After whole blood donation, a plateletpheresis donor shall not be accepted before 28 days. Apheresis platelet donor shall not be accepted for whole blood donation before 28 days from the last platelet donation provided reinfusion of the red cell was complete in the last plateletpheresis donation. If the reinfusion of red cells was not complete, then the donor shall not be accepted within 90 days. A donor shall not donate any type of donation within 12 months after a bone marrow harvest, within 6 months after a peripheral stem cell harvest.
5.	Blood Pressure	100-140mm Hg systolic 60-90 mm Hg diastolic with or without medications. There shall be no findings suggestive of end-organ damage or secondary complication (cardiac, renal, eye or vascular) or history of feeling giddiness, fainting made out during history and examination. Neither the drug nor its dosage should have been altered in the last 28 days.
6.	Pulse	60-100 Regular

S.No.	Criteria	Recommendations
7.	Temperature	Afebrile:37^{0}C/98.4^{0}F
8.	Respiration	The donor shall be free from acute respiratory disease.
9.	Haemoglobin	>or =12.5g/dL Thalassemia trait may be accepted, provided haemoglobin is acceptable.
10.	Meal	Meal The donor shall not be fasting before the blood donation or observing fast during the period of blood donation, and the last meal should have been taken at least 4 hours prior to donation. The donor shall not have consumed alcohol and show signs of intoxication before the blood donation. The donor shall not be a person having regular heavy alcohol intake.
11.	Occupation	The donor who works as aircrew member, long-distance vehicle driver, either above sea level or below sea level or in emengency services or where strenuous work is required, shall not donate blood at least 24 hours prior to their next duty shift. The donor shall not be a night shift workers without adequate sleep.
12.	Risk behaviour	The donor shall be free from any disease transmissible by Wood transfusion, as far as can be determined by history and examination. The donor shall not be a person considered "at-risk"- or HIV, Hepatitis B or C infections (Transgender, Men who have sex with men, Female sex workers, injecting drug users, persons with multiple sexual partners or any other high risk as determined by the medical officer deciding fitness to donate blood).
13.	Travel and residence	The donor shall not be a person with history of residence or travel in a geographical area which is endemic for diseases that can be transmitted by blood transfusion and for which screening is not mandated or there is no guidance in India.
14.	Donor Skin	The donor shall be free from any skin diseases at the site of phlebotomy. The arms and forearms of the donor shall be free of skin punctures of scars indicative of professional blood donors or addiction to self-infected narcotics.
Physiological Status for Women		
15.	Pregnancy or recently delivered	Defer for 12 Months after delivery
16.	Abortion	Defer for 6 months after abortion
17.	Breast-Feeding	Defer for a total period of lactation
18.	Menstruation	Defer for the period of menstruation
Non-specific illness		
19.	Minor non-specific symptoms including but not limited to general malaise, pain, headache	Defer until all symptoms subside, and the donor is afebrile
Respiratory (Lung) Diseases		
20	Cold. flu, cough, sore throat or acute sinusitis	Defer until all symptoms subside, and the donor is afebrile
21	Chronic sinusitis	Accept unless on antibiotics
22	Asthmatic attack	Permanently Defer
23	Asthmatics on steroids	Permanently Defer

Surgical Procedures		
S.No.	**Criteria**	**Recommendations**
24.	Major surgery	Defer for 12 months after recovery. (Major surgery being defined as that requiring hospitalisation, anaesthesia (general/Spinal) had Blood Transfusion and/or had significant Blood loss)
25.	Minor surgery	Defer for 6 months after recovery
26.	Received Blood Transfusion	Defer for 12 months
27.	Open heart surgery. Including By-pass surgery	Permanently defer
28.	Cancer surgery	Permanently defer
29.	Tooth extraction	Defer for 6 months after tooth extraction
30.	Dental surgery under anaesthesia	Deler for 6 months after recovery
Cardio-Vescular Diseases (Heart Disease)		
31.	Has any active symptom (Chest Pain, Shortness of breath, swelling of feet)	Permanently defer
32.	Myocardial infarction (Heart Attack)	Permanently defer
33.	Cardiac medication (digitals, nitro-glycerine)	Permanently defer
34.	Hypertensive heart disease	Permanently defer
35.	Coronary artery disease	Permanently defer
36.	Angina pectoris	Permanently defer
37.	Rheumatic heart disease with residual damage	Permanently defer
Central Nervous System/ Psychiatric Diseases		
38.	Migraine	Accept if not severe and occurs at a frequency of less than once a week
40.	Convulsions and Epilepsy	Permanently defer
41.	Schizophrenia	Permanently defer
42.	Anxiety and mood disorders	Accept person having anxiety and mood (affective) disorders like depression or bipolar disorder, but is stable and feeling well on the day regardless of medication
Endocrine Disorders		
43.	Diabetes	Accept person with Diabetes Mellitus well controlled by diet or oral hypoglycaemic medication, with no history of orthostatic hypotension and no evidence of infection, neuropattiy or vascular disease (in particular peri pheral ulceratiorn) - Permanently defer person requiring insulin and/ or complications of Diabetes with multi-organ involvement- Defer if oral hypoglycaemic medication has been altered/dosage adjusted in last 4 weeks

S.No.	Criteria	Recommendations
44.	Thyroid disorders	Accept donations from individuals with Benign Thyroid Disorders if euthyroid (Asymptomatic Goitre, History of Viral Thyroiditis, AutoImmune Hypo Thyroidism) Defer if under investigation for Thyroid Disease or thyroid status is not known Permanently defer if: 1) Thyrotoxicosis due to Graves' Disease 2) Hyper/Hypo Thyroid 3) History of malignant thyroid tumours
45.	Other endocrine disorders	Permanently defer
	Liver Diseases and Hepatitis infection	
46.	Hepatitis	Known Hepatitis B, C- Permanently defer Unknown Hepatitis- Permanently defer Known hepatitis A or E; Defer for 12 months
47.	Spouse/ partner/ close contact of individual suffering from hepatitis,	Defer for 12 months
48.	At risk for hepatitis by tattoos, acupuncture or body piercing, scarification and any other invasive cosmetic procedure by self or spouse/ partner	Defer for 12 months
49.	Spouse/ partner of individual receiving transfusion of blood/components	Defer for 12 months
50.	Jaundice	Accept donor with a history of jaundice that was attributed to gall stones, Rh disease, mononucleosis or in the neonatal period.
51.	Chronic Liver disease/ Liver Failure	Permanently defer
	HIV Infection/AIDS	
52.	At risk for HIV infection (Transgender, Men who have Sex with Men, Female Sex Workers, Injecting drug users, persons with multiple sex partners)	Permanently defer
53.	Known HIV positive person or spouse/ partner of PLHA (the person living with HIV AIDS)	Permanently defer
54.	Persons having symptoms suggestive of AIDS	Permanently defer person having lymphadenopathy, prolonged and repeated fever, prolonged & repeated diarrhoea irrespective of HIV risk or status
	Sexually Transmitted Infections	
55.	Syphilis (Genital sore, or generalized skin rashes)	Permanently defer

S.No.	Criteria	Recommendations
56.	Gonorrhoea	Permanently defer
	Other Infectious diseases	
57.	History of Measles, Mumps, Chickenpox	Defer for 2 weeks following full recovery
58.	Malaria	Defer for 3 months following full recovery.
59.	Typhoid	Defer for 12 Months following full recovery
60.	Dengue/Chikungunya	In case of history of Dengue/Chikungunya : Defer for 6 Months following full recovery. Following a visit to Dengue/Chikungunya endemic area: 4 weeks following return from a visit to the dengue-endemic area if no febrile illness is noted.
61.	Zika Vitus/ West Nile Virus	In case of Zika infection: Defer for 4 months following recovery. In case of history of travel to West Nile Virus endemic area or virus outbreak zone: Defer for 4 months.
62.	Tuberculosis	Defer for 2 years following confirmation of cure
63.	Leishmaniasis	Permanently defer
64.	Leprosy	Permanently defer
	Other Infections	
65.	Conjunctivitis	Defer for the perod of illness and continuation of local medication.
66.	Osteomyelitis	Defer for 2 years following completion of treatment and cure.
	Kidney Disease	
67.	Acute infection of kidney (pyelonephritis)	Defer for 6 months after complete recovery and last dose of medication
68.	Acute infection of bladder (cystitis)/ UTI	Defer for 2 weeks after complete recovery and last dose of medication
69.	Chronic infection of kidney/ kidney disease/renal failure	Permanently defer
	Digestive System	
70.	Diarrhoea	Person having history of diarrhoea in preceding week particulaly if associated with fever. Defer fort weeks after complete recovery and last dose of medication
71.	GI endoscopy	Defer for 12 months.
72.	Acid Peptic disease	Accept person with acid reflux, mild gastro-oesophageal reflux, mild hiatus hernia, gastro-oesophageal re flux disorder (GERD), hiatus hernia: Perrnanently defer person with stomach ulcer with symptoms or with recurrent bleeding:
	Other diseases/ disorders	
73.	Autoimmune disorders like Systemic lupus erythematosis. scleroderma, dermatomyositis,, ankylosing spondylitis or severe rheumatoid arthritis '	Permanently defer
74.	Polycythaemia Vera	Permanently defer
75.	Bleeding disorders and unexplained Bleeding tendency	Permanently defer

S.No.	Criteria	Recommendations
76.	Malignancy	Permanently defer
77.	Severe allergic disorders	Permanently defer
78.	Haemoglobinopathies and red cell enzyme deficiencies with a known history of haernolysis	Permanently defer
Vaccination and inoculation		
79.	**Non-live vaccines and Toxoid:** Typhoid, Cholera, Papillomavirus, Influenza, Meningococcal, Pertussis, Pneumococcal, Polio injectable, Diphtheria, Tetanus, Plague	Defer for 14 days
80.	**Live attenuated vaccines:** Polio oral, Measles (rubella) Mumps, Yellow fever, Japanese encephalitis, influenza, Typhoid, Cholera, Hepatitis A	Defer for 28 days
81.	Anti-tetanus serum, anti-venom serum, anti-diphtheria serum, and anti-gas gangrene serum	Defer for 28 days
82.	Anti-rabies vaccination following the animal bite, Hepatitis B Immunoglobulin, Immunoglobulins	Defer for 1 year
83.	Swine Flu	Defer for 15 days
Medications taken by prospective blood donor		
84.	Oral contraceptive	Accept
85.	Analgesics	Accept
86.	Vitamins	Accept
87.	Mild sedative and tranquillizers	Accept
88.	Allopurinol	Accept
89.	Cholesterol lowering medication	Accept
90.	Salicylates (aspirin), other NSAIDs	Defer for 3 days if blood is to be used for Platelet preparation
91.	Ketoconazole, Antihelminthic drugs including mebendazole,	Defer for 7 days after last dose if donor is well
92.	Antibiotics	Defer for 2 Weeks after last dose if donor is well

S.No.	Criteria	Recommendations
93.	Ticlopidine, clopidogrel	Defer for 2 Weeks after last dose
94.	Piroxicam, dipyridamole	Defer for 2 Weeks after last dose
95.	Etretinate, Acitretin or Isotretinoin. (Used for acne)	Defer for 1 month after the last dose
96.	Finasterideused to treat benign prostatic hyperplasia	Defer for 1 month after the last dose
97.	Radioactive contrast material	8 weeks deferral
98.	Dutasteride used to treat benign prostatic hyperplasia	Defer for 6 months after the last dose
99.	Any medication of unknown nature	Defer till details are available
100.	Oral anti-diabetic drugs	Accept if there is no alteration in does within the last 4 weeks.
101.	Insulin	Permanently defer
102.	Anti-arrhythmic. Anti-convulsions. Anticoagulant. Anti-thyroid drugs, Cytotoxic drugs. Cardiac Failure Drugs (Digitalis)	Permanently defer
Other conditions requiring Permanent deferral		
103.	Recipients of organ, stem cell and tissue transplants Donors who have had an unexplained delayed faint or delayed faint with injury or two conseculive faints following a blood donation.	Permanently defer
Residents of other countries		
104.	Residents of other countries	Accept only after staying in India for three continuous years
COVID-19 infections		
105.	History of travel to country/ place with Covid 19 transmission in community and areas as notified by Ministry of Health and Family werfare time to time	Deferred from donating blood for 28 days after departure
106.	Any history of possible close contact exposure to a person who is confirmed/ Suspected case of Covid-19, including those under quarantine.	Deferred from donating blood for 28 days after last possible contact/ exposure
107.	Confirmed cases of COV1D-19	Deferred till complete recovery from disease. Including radiological and virological clearance.

গোপনীয় CONFIDENTIAL *(পৃষ্ঠা-১ Page-1)*

ৰক্তদানৰ বাবে প্ৰশ্নাৱলী আৰু সম্মতি পত্ৰ Blood Donor Questionaire & Consent Form

ব্লাড বেঙ্কৰ নাম আৰু ঠিকনা Name & Address of Blood Bank	ব্লাড বেঙ্ক লাইচেঞ্চ নং Blood Bank Licence No. 13/DR/MFG
Blood Bank B.P. Civil Hospital, Nagaon (Assam)	তেজৰ নং (ৰক্ত দাতাৰ নং) Blood Unit No (Blood Donor No)

অনুগ্ৰহ কৰি প্ৰশ্নসমূহৰ সঠিক উত্তৰ দিয়ক। এয়া আপোনাৰ আৰু আপোনাৰ তেজ লোৱা ৰোগী দুয়োৰে সুৰক্ষাৰ বাবে প্ৰয়োজনীয়। প্ৰয়োজন সাপেক্ষে সঠিক উত্তৰত শুদ্ধ চিন (✓) দিয়ক। Please answer the following questions correctly. This will help to protect you and the patient who receive your blood.

ৰক্তদাতাৰ নাম Name of donor | পুৰুষ Male | মহিলা Female | বয়স Age

পিতৃ/মাতৃ/স্বামীৰ নাম Father/Mother/Husband's Name | জন্মৰ তাৰিখ Date of Birth | যোগাযোগৰ ঠিকনা Address for Communication

গাঁও/চহৰ Vill/Town

বৃত্তি/পেশা Occupation | সংস্থাৰ নাম Organization

ডাকঘৰ PO

জিলা District

মোবাইল ফোন নং Mobile No | ফেক্স Fax | ই মেইল E-mail

লেণ্ডলাইন ফোন নং Land line No

? আপোনাক আমি মোবাইল ফোনত যোগাযোগ কৰাটো বিছাৰেনে? Would you like us to call on your mobile?	হয় Yes	নহয় No
? আগতে কেতিয়াবা ৰক্তদান কৰিছেনে? Have you donated blood previously?	হয় Yes	নহয় No
? যদি কৰিছে- কিমান বাৰ কৰিছে? If yes, on how may occasions? ? শেষৰ বাৰ কেতিয়া কৰিছিল? When did you donate last?	তেজৰ গ্ৰুপ Blood Group	
	ABO	
	Rh	
? ৰক্তদানৰ সময়ত আৰু পিছত কষ্ট/অসুবিধা পাইছিল নেকি? Did you have any discomfort during/after blood donation?	হয় Yes	নহয় No
? আজি আপুনি সুস্থ নে? Do you fell well today?	হয় Yes	নহয় No
? যোৱা চাৰি ঘণ্টাৰ ভিতৰত আপুনি কিবা আহাৰ খাইছেনে? Did you have something to eat in last four hours?	হয় Yes	নহয় No
? যদি খাইছে কিমান সময়ত খাইছে? At what time did you have your last meal today?		
? যোৱা নিশা আপুনি ভালকৈ টোপনি গৈছিলনে? Did you sleep well last night?	হয় Yes	নহয় No
? আপুনি নিজকে হেপাটাইটিছ, মেলেৰিয়া, এইচ আই ভি/এইড্‌ছ নাইবা যৌন ৰোগত আক্ৰান্ত হৈ আছে বুলি সন্দেহ কৰে নেকি? Have you any reason to believe that you may be infected by either Hepatitis, Malaria, HIV/AIDS and/or venereal diseases?	হয় Yes	নহয় No

? যোৱা ছয় মাহৰ ভিতৰত তলত দিয়া লক্ষণ/উপসৰ্গ আপোনাৰ শৰীৰত দেখা দিছিল নেকি?
In last six months, did you have any history of the following :

♦	অস্বাভাবিক ভাৱে ওজন কমা Unexplained weight loss	হয় Yes / নহয় No	♦	সঘনাই পেট চলা বা ডায়ে�ৰিয়া হোৱা Repeated diarrhoea	হয় Yes / নহয় No
♦	অনবৰতে জ্বৰ Continous low grade fever	হয় Yes / নহয় No	♦	গ্ৰন্থি উখহা/গাঙঠি Swollen glands	হয় Yes / নহয় No

? যোৱা ছয় মাহৰ ভিতৰত তলত দিয়াবোৰ কৰিছিল নেকি? In last six months, have you had any of the following :

♦	টাটু কৰিছিল নেকি? Tattoo	হয় Yes / নহয় No	♦	কাণ ফুটাইছিল নেকি? Ear piercing	হয় Yes / নহয় No
♦	দাঁত সৰাইছিল নেকি? Dental extraction	হয় Yes / নহয় No	♦	লঘু অস্ত্ৰোপচাৰ হৈছিল? Minor surgery	হয় Yes / নহয় No
♦	তেজ লৈছিল নৈকি? Blood transfusion	হয় Yes / নহয় No			

? এই ৰোগসমূহৰ যিকোনো এবিধৰদ্বাৰা আপুনি আক্ৰান্ত হৈ আছে নাইবা হৈছিল নেকি?
Do you suffer or have been suffering from any of the following diseases?

♦	হৃদ ৰোগ Heart Disease	হয় Yes / নহয় No	♦	শ্বাসৰোগ Lung Disease	হয় Yes / নহয় No
♦	কৰ্কট ৰোগ Malignant Diseases/Cancer	হয় Yes / নহয় No	♦	বৃক্কৰোগ Kidney Disease	হয় Yes / নহয় No

♦ মৃগী ৰোগ Epilepsy	হয় Yes	নহয় No	♦ মধুমেহ Diabetes	হয় Yes	নহয় No
♦ যক্ষ্মা Tuberculosis	হয় Yes	নহয় No	♦ হেপাটাইটিছ বি.চি. Hepatities B/C	হয় Yes	নহয় No
♦ এলার্জি Allergy	হয় Yes	নহয় No	♦ যৌনৰোগ VD/STD	হয় Yes	নহয় No
♦ মেলেৰিয়া Malaria	হয় Yes	নহয় No	♦ টাইফয়েড Typhoid	হয় Yes	নহয় No
♦ অস্বাভাৱিক ৰক্তক্ষৰণ প্ৰৱণতা Abnormal bleeding tendency	হয় Yes	নহয় No	♦ মূৰ্চ্ছা যোৱা Fainting spells	হয় Yes	নহয় No
♦ জণ্ডিছ Jaundice	হয় Yes	নহয় No			

? যোৱা ৭২ ঘণ্টাৰ ভিতৰত এনে দ্ৰব্য সেৱন/গ্ৰহণ কৰিছে নেকি?
Are you taking or have taken any of these in last 72 hours?

♦ এণ্টিবায়টিক Antibiotics	হয় Yes	নহয় No	♦ এছ্‌পিৰিন Aspirin	হয় Yes	নহয় No
♦ মাদক দ্ৰব্য Alcohol	হয় Yes	নহয় No	♦ ষ্টেৰয়ড Steroid	হয় Yes	নহয় No
♦ ছিটা/টিকা Vaccine	হয় Yes	নহয় No			

? যোৱা এবছৰৰ ভিতৰত In last one year?

♦ কুকুৰে কামোৰা বেজী লৈছিল নেকি? Did you take Anti Rabies Vaccine?	হয় Yes	নহয় No	♦ গুৰু অস্ত্ৰোপচাৰ হৈছিল নেকি? Did you have Major surgery?	হয় Yes	নহয় No

? *কেৱল মহিলাৰ বাবে FOR WOMEN DONORS ONLY :*

♦ আপুনি গৰ্ভৱতী নেকি? Are you pregnant?	হয় Yes	নহয় No	♦ আপোনাৰ সন্তানৰ বয়স এবছৰতকৈ কম নেকি? Your child is 1 year of ago?	হয় Yes	নহয় No
♦ গৰ্ভপাত কৰিছিল নেকি? (যোৱা ৩মাহৰ ভিতৰত) You had abortion in last 3 months?	হয় Yes	নহয় No	♦ স্তন পান কৰি থকা শিশু আছে নেকি? You have breast-feeding child?	হয় Yes	নহয় No
♦ আজি মাহেকীয়া স্ৰাৱ হৈ আছে নেকি? You are having period today?	হয় Yes	নহয় No			

? আপোনাৰ তেজ পৰীক্ষাৰ অস্বাভাৱিক ফলাফল জনাবলগীয়া হ'লে আপুনি দিয়া ঠিকনাত জনাম নে? Would you like to be informed about any abnormal test result at the address furnished by you? হয় Yes | নহয় No

? ওপৰত দিয়া প্ৰশ্নবোৰ পঢ়ি আৰু বুজিলৈ সেইবোৰৰ সঠিক আৰু বিশ্বাসযোগ্য উত্তৰ/তথ্য দিছেনে, যিহেতুকে ব্যক্তিগত তথ্য ইয়াত প্ৰকাশ নকৰিলে আপোনাৰ নিজৰ আৰু আপোনাৰ তেজ লোৱা ৰোগীৰ অপকাৰ হ'ব পাৰে?
Have you read and understood all the information presented and answered all the truthfully, as any incorrect statement or consealment may affect your health or may harm the patient? হয় Yes | নহয় No

মই বুজিছো যে, I understand that,

ক) ৰক্তদান সম্পূৰ্ণৰূপে স্বেচ্ছামূলক প্ৰক্ৰিয়া, ইয়াক ধনৰ বিনিময়ত অথবা হেঁচা প্ৰয়োগৰদ্বাৰা কৰোৱা নহয়
Blood donation is a totally voluntary act and no inducement or remuneration has been offered

খ) তেজ/তেজৰ উপাদান দান কৰাটো এক চিকিৎসা প্ৰক্ৰিয়া আৰু ইয়াৰ বাবে দায়বদ্ধ হৈ স্বেচ্ছাই ৰক্তদান কৰিলোঁ
Donation of blood/components is a medical procedure and that by donating voluntary, I accept the risk associated with this procedure.

গ) হেপাটাইটিছ বি/চি, মেলেৰীয়া, এইচ আই ভি/এইড্‌ছ আৰু যৌন ৰোগৰ উপৰিও প্ৰয়োজনীয় সকলো পৰীক্ষা কৰি মোৰ তেজ ৰোগীৰ বাবে নিৰাপদ বুলি নিশ্চিত কৰা হ'ব My blood will be tested for Hepatitis B, Hepatitis C, Malarial parasite, HIV/AIDS and venereal diseases in addition to any other screening tests required to ensure blood safety

মোৰ বিনা অনুমতিত মোৰ তথ্য আৰু ৰক্তদানৰ বিষয়ে কোনো ব্যক্তি, ব্যক্তিগত অথবা চৰকাৰী অনুষ্ঠানৰ ওচৰত প্ৰকাশ কৰিব নোৱাৰিব।
I prohibit any information provided by me or about my donation to be disclosed to any individual or government agency without my prior permission.

তাৰিখ Date | সময় Time | ৰক্তদাতাৰ চহী Donor's Signature

সাধাৰণ স্বাস্থ্য পৰীক্ষণ General physical examination

ওজন Weight | নাড়ী Pulse | হিম'গ্লবিন % Heamoglobin%

শৰীৰৰ তাপমাত্ৰা Temperature | ৰক্তচাপ Blood pressure

গৃহীত Accept | বাতিল Defer | বাতিল কৰাৰ কাৰণ Cause of deferral

পৰামৰ্শ দাতাৰ চহী Counsellors sign | চিকিৎসা বিষয়াৰ চহী M O's signature

*****

HOW TO APPLY FOR LICENSING OF A NEW BLOOD CENTRE AND RENEWAL

Licensing process of new blood centre and provision of DGHS support

Step 1: The authority / Institute who proposes to establish a blood centre shall ensure the following as per drugs and cosmetic act 1940 and rules 1945.

a. Infrastructure
b. Equipment
c. Competent technical staff

The concern institute shall liaise with the state and district level office of the drug control authority for specifications of infrastructure, equipment and technical manpower. These are to be obtained before applying for blood centre license.

Infrastructure: The concerned authority / institute shall ensure the development of infrastructure.

The area for processing whole blood I.P. should be not less than 100 square meters having not less than seven rooms. These are –

1. Registration and Medical examination room
2. Bleeding room (Air conditioned)
3. Donor refreshment room (Air conditioned)
4. TTI laboratory (Air conditioned)
5. Serology room (Air conditioned)
6. Store cum record room
7. Wash and sterilization room

Drawing / layout of the venue has to be prepared by the local executive engineer (PWD) and it has to be incorporated with the application form of license.

Equipment: The required equipments are as follows –

i. Equipment for medical examination of the donor– Stethoscope, BP instrument, Weighing machine, and Hemoglobin estimation items, etc.
ii. Equipment at the bleeding room – Electrically operated donor couch, Blood collection monitor, Tube sealer, etc.
iii. Blood storage –Refrigerators (vibration free) for storing untested blood and blood storage Refrigerator (vibration free) for storing tested blood, etc.
iv. Equipment for TTI testing of viral markers, i.e. ELISA reader, Washer, Incubator, VDRL shaker, Centrifuge machine and Reagent refrigerator.
v. Equipment for serology laboratory, e.g. Binocular microscope

Technical Manpower: The concerned authority/institute shall ensure the recruitment of competent technical staff.

i. Medical Officer: MD Pathology/ DCP with blood centre experience/ training or MBBS with experience in blood centre.
ii. Laboratory Technician: Diploma in medical laboratory technology with experience/training in blood centre.
iii. Staff Nurse: Diploma in Nursing with experience/training in blood centre.
iv. Counsellor/ social worker: Having experience in counselling services and from social sciences/psychology/ anthropology, etc.

Step II: The format of application for blood centre license, form 27C may be obtained from the state/district drug authority. Registration fee is to be deposited at the time of submission of the application form as per existing govt. norms indicated by drugs control department.

Step III: The state team and regional team of the drug control authority will have to inspect, approve and forward the report to CLAA (Central License Approving Authority), New Delhi. CLAA will approve the license subject to compliance by the incumbent blood bank with the norms of D&C Act and Rules.

The licensed blood centre may apply for affiliation with DGHS through the State Blood Transfusion Council.

Renewal of Blood Bank License: The renewal of a blood centre license is to be done in duration of three years and notification of expiry of the license should be report to State Drug Licensing Authority before two months of the expiry.

Govt. of Assam

Assam State Blood Transfusion Council

(A Registered Society under Society Registration Act XXI of 1860)

Khanapara, Guwahati-22

FORM –B
APPLICATION FOR NO OBJECTION CERTIFICATE FOR RENEWAL OF BLOOD BANK LICENSE

(As per National Blood Transfusion Council Norms)

The name of the blood bank, _____Address_____

_____

Telephone:_____FAX:_____E-Mail:_____

Mobile No_____ has applied for **Renewal of No Objection Certificate** of Blood Bank's License. In this connection the _____blood bank has to furnish the following documents which appear to be in order.

1. The Blood Bank Operated By (√ Tick Appropriate as)

i). Government	☐	iv) Trust	☐
ii). Semi-Government	☐	v) IRCS	☐
iii). Private BB	☐	vi) Hospital based	☐

2. The registered voluntary or charitable organisations, which are registered in the Union Territory of India, as the case may be under any such law which is at the time of enforcement of this rule in force vide page_____/c.

3. The organisation must be at least 2 (Two) years old and it should not be a family society or trust vide Page _____ /c.

4. In the Objective of Memorandum of Association the organisations must include the activities related to health care delivery system or blood transfusion services vide page _____/c.

5. The activities undertaken must showcase social accountability and reflected in the annual audit statements of last two years vide page_____/c.

6. Photocopy of Blood Bank License vides page _____/c.

7. Annual blood collection report (Total collection, Voluntary collection, Total voluntary blood donation camp conducted, Total camp collection & Replacement donation)- the annual blood collection should be more than 2000 units per year and

nearing 100 per cent voluntary blood donation collection but may relaxed for rural, tribal, hilly area, desert island and armed forces) vide page____/c.

8. Details of appointment of Medical Social Worker (MSW) and Counsellor in the blood bank for organising Voluntary Blood Donation camps, Pre & Post-test counselling respectively and training status of Medical Social Worker & Counsellor vide page _____/c

9. Annual report indicating blood component separation facility vide page _____/c

10. Detail of processing charges collected by the blood banks after the 12th February 2014 vides page ____/c..

11. The blood bank should be undertaking to abide with the guidelines of SBTC / NBTC issued time to time, including the guideline of processing charges for blood and blood component vide page _____/c

Declaration

I hereby declare that all the details submitted are true & correct to the best of knowledge and belief. If any information is found false, incorrect or incomplete, the application is liable to be rejected or cancelled at any stage.

Yours Faithfully

Signature

(Name ……)

For Renewal of blood bank license, the activities undertaken by the organisation must showcase social accountability and reflected in the annual Audited Statement of last two years. The organisation should submit photocopy of license and application two months before the expiry period of validity.

Form 27-C
[See Rule 122-F]

Application for grant/renewal of licence for the operation of a Blood Bank for processing of whole blood and / or preparation of blood components.

1. I/We.....of M/S..... hereby apply for the grant of licence / renewal of licence number .... dated .....to operate a Blood Bank, for processing of whole blood and / or* for preparation of its components on the premises situated at ....

2. Name(s) of the item(s):

(1).....
.....

(2).....
.....

(3).....
.....

3. The name(s), qualification and experience of competent Technical Staff are as under:

(a) Name(s) of Medical Officer.

.....
.....
.....

(b) Name(s) of Technical Supervisor.

.....
.....
.....

(c) Name(s) of Registered Nurse.

.....
.....
.....

(d) Name(s) of Blood Bank Technician.

.....
.....
.....

4. The premises and plant are ready for inspection/will be ready for inspection on .....

5. A licence fee of rupees .....
and an inspection fee of rupees .....
has been credited to the Government under the head of account .....
..... (receipt enclosed).

Date:.....
Signature.....

Name and Designation .....

* Delete whichever is not applicable.

Note: 1. The application shall be accompanied by a plan of the premises, list of machinery and equipment for collection, processing, storage and testing of whole blood and its components, memorandum of association/ constitution of the firm, copies of certificate relating to educational qualifications and experience of the competent technical staff and documents relating to ownership or tenancy of the premises.

2. copy of the application together with the relevant enclosures shall also be sent to the Central Licence Approving Authority and to the concerned Zonal / Sub-Zonal Officers of the Central Drugs Standard Control Organization.

*****

VOLUNTARY BLOOD DONATION DRIVE BY BLOOD CENTRES

Voluntary non-remunerated blood donors are the corner stone of a safe blood transfusion practice. Time to time blood centre organises voluntary blood donation camps with the help of NGOs and institutions. For smooth conduction of the blood donation camps the blood centres must provide all the amenities to the blood donors who have come for blood donation. Medical examination is done in the voluntary blood donation camp site for each and every donor. Donor appreciation certificates are provided to all voluntary blood donors.

Categories of Voluntary Blood Donor

i. **New Voluntary Donor:** A voluntary non-remunerated blood donor who has donated blood for the first time.
ii. **Lapsed Voluntary Donor:** A voluntary non-remunerated blood donor who has donated blood previously but does not fulfil the criteria for a regular blood donation.
iii. **Regular Voluntary Donor:** A voluntary non-remunerated blood donor who is to donate blood on a regular basis in every three months and without any break for a longer duration.

Other Categories of Blood Donor

i. **Family/replacement blood donor:** A donor who donate blood when it is required for family members or friends. These donors are under pressure to donate blood and may conceal potentially important information about their health status, particularly the risk of TTI disease, which compromises the safety of the blood.
ii. **Autologous Blood Donor:** These are the donors who donate blood for themselves to be used at a later date. Recipients who serve as their own donors receive the safest possible blood since the risk of TTI and alloimmunizaton are completely eliminated. For autologous donation, minimum hemoglobin level should be 11 gm/dl or heamatocrit > 34 %. There is no upper or lower age limit and no weight restriction. Volume should not exceed 9 ml/kg body weight.
iii. **Apheresis Donor:** These are special category of donors who willingly donate only the specific blood component through the process of cell separation.

Voluntary Blood Donation Programme

The programme is to be implemented by Blood Centre, State Blood Transfusion Council and recognized Voluntary Blood Donor Organisations, IRCS, CBOs, NGOs as per the following broad parameters.

Need Assessment

In India, the gap between the demand and supply of blood and blood components can be reduced by carrying out a proper assessment so that the demand can be fulfilled through planned donor recruitment and retention, and thereby planned production of blood components. A group of NGOs and agencies engaged in the field will need to be prepared and made available to Blood Transfusion Council and State/UT Government.

Education

a) There should be a planed programme to create awareness amongst the general public so as to ensure a regular supply of safe blood without having the experience of seasonal shortage. The educational programme, therefore, should be so designed that the community understand in depth the advantage of regular blood donation.
b) The donor education and information material, donor questionnaire and donor consent forms should be prepared in simple language and translated for use in local areas.

Awareness campaigns for the people

a) Education programmes in schools where a community of future blood donors can be created.
b) Short-term training courses for donor motivators, social activists, trainers, blood bank personnel and volunteers who have an aptitude to serve the cause.

Donor Motivation

The underlying principle of donor motivation is to make the voluntary blood donors feel the importance and need of voluntary blood donation. It should aim to create general awareness and to imbibe essence of firm determination in the minds of the potential donors. Any hesitance on the part of the donor will have to be tackled skilfully. The motivation of donors should be carried out as follows:

a) By holding symposia, seminars, talks, discussions, get-togethers and street corner meetings at regular interval.
b) By displaying posters and hoardings at prominent places. These hoardings and posters should be appropriate and attractive and should be replaced at regular interval.
c) By holding competitive contests and public exhibitions. Following groups may be considered for motivation: Educational institutions, industrial and commercial houses, social and cultural organisations, religious and spiritual groups, political organisations, uniformed services, medical institutions, women's organisations, fan groups (film artist or sportsperson) and government organisations.

Donor Recruitment & Retention

Recruitment and retention of voluntary donors is the key to safe and sufficient blood supply. The goal to be achieved is a panel/registry of repeat donors who are well informed, committed and regularly screened for markers of transfusion - transmissible diseases. The universal principle is careful planning, organisation, knowledge about the communities and their motivating factors, effective communication and campaign. Good service and support for donors as well as good public reputation goes a long way in increasing voluntary safe donors.

The task of bringing in 100 per cent voluntary donation will take time but we have the greatest resource – PEOPLE. Success lies in harnessing "People Power". One key secret of the success of blood donor recruitment is to go to the donor, rather than expecting the donor to come to the blood centre. The policy for blood donations aims at:

a) Organising and holding blood donation camps in centres of public assembly, viz. educational institutions, youth groups, offices, factories, etc.

b) By identifying and popularising specific ways of motivation of different communities and social groups. Blood donation drives should be evenly spread out throughout the year.

c) Voluntary donations at the blood centre will continue to be encouraged.

Recognition

Blood donors should be treated as a valuable resource and deserve courtesy and recognition. The policy therefore, should aim at rewarding and honouring donors and donor organisations through awards, certificates, badges and trophies. A list of honoured donors and panel donors should be compiled and maintained. Preference may be provided to blood donors identified by the blood centre for queues in hospitals, banks, railway booking centres, etc.

Media

Mass media approach for raising the awareness of the people and sensitizing them towards their participation is the most effective way to mobilize voluntary blood donation. All channels of media therefore, have to be utilised fully through a regular and sustained publicity campaign with a professional approach. To mobilise the media there should be a three pronged approach:

a) Mass approach: Newspaper advertisements, articles, supplementary/articles in periodicals, journals, house magazines, stickers, posters, hoardings, radio programmes and TV spots should be used extensively.

b) Group approach: Use of audio visual aids like posters, stickers, folders and hoardings are useful.
c) Personal approach: Letters, face-to-face discussion, distribution of campaign material, newsletters, bulletins, telephone requests for repeat donation or on-call donations and emergency donations give good results.

Database of Donors

a) To maintain a detailed database of names, addresses and contact numbers of blood donor organisations and also data base of blood donors for ready and easy access at the time of need.
b) To network between the states so as to make data on blood donors available to the State Governments and donor organisations.

Interaction and sharing of experiences

All efforts should be made to facilitate blood donor organisations and blood donors to interact and share experiences by holding conferences, workshops, seminars, consultative meetings, colloquiums etc. These would help in bringing the organisations together and sharing information and experience on related areas.

Publications

a) The State Blood Transfusion Council should bring out a quarterly News Bulletin (bulletins in different regional languages) for wide circulation.
b) Regular publication of annual, six monthly and quarterly reports should be brought out and distributed for extensive publicity purposes by NBTC/SBTC.
c) Publication of working manuals for voluntary workers, guide books for blood centre, associates and for teaching personnel in adequate quantities for circulation.

Policy regarding legislation and regulations

Regulations governing blood transfusion services should encompass the infrastructure facilities including manpower, equipment, space, and testing as well as donor selection procedures. The regulations must be in line with the National Blood Policy.

Donor Organisers

Individuals involved in organising blood donation campaigns should be provided adequate training in communication skills and motivation. Office infra-structure, telephone, vehicle, staff are essential to make them effective. All blood bank staff should be properly and smartly dressed, polite, sympathetic and trained in public relations.

Blood donation camps can be organised by

- A licensed designated regional blood transfusion centre.
- A licensed government blood centre.
- The Indian Red Cross Society.
- A licensed registered voluntary or charitable trust organization recognized by State Blood Transfusion Council.

Retention and recruitment are about people and community, about understanding them, capturing their interest and influencing their behaviour. Once a blood donor motivator raises awareness, they must motivate and persuade people to donate blood. One key secret of successful blood donor recruitment is to bring blood collection procedure close to blood donor on their convenient date and time rather than expecting donor to come to the blood centre. The closer the blood collection site to potential donor, the stronger is likelihood of success. This is possible only through outdoor blood donation camps.

Role of Stake Holders in Voluntary Blood Donation Programme

a) **State Blood Transfusion Council (SBTC)-** To provide permission to blood centre to hold the V.B.D. camp. Beside regular camps, each SBTC should fix a particular date every month in their state to organize blood donation camps throughout all the districts of the state. This date should be widely published to make people aware about the sites of camps on that particular date so that they can visit the camps according to their convenience.
b) **Blood Centre-** Collect blood in the premises, offer refreshments to the donors, process the collected blood for transfusion and display relevant information.
c) **Blood Donor Organization / NGOs/ Red Ribbon Clubs**-To co-ordinate a planned schedule of V.B.D. camps.
d) **Organizers**- To provide infrastructure to hold the V.B.D. camp and list of committed healthy blood donors
e) **Donor Motivators / Social Workers-** For motivating the community and providing supervisory support during the V.B.D. camp.
f) **Media-** Publicity of the camps, preferably with photos.

Phases of outdoor voluntary blood donation camps

A) Pre-camp phases
B) Camp phases
C) Post-camp phase

A) Pre-camp phase

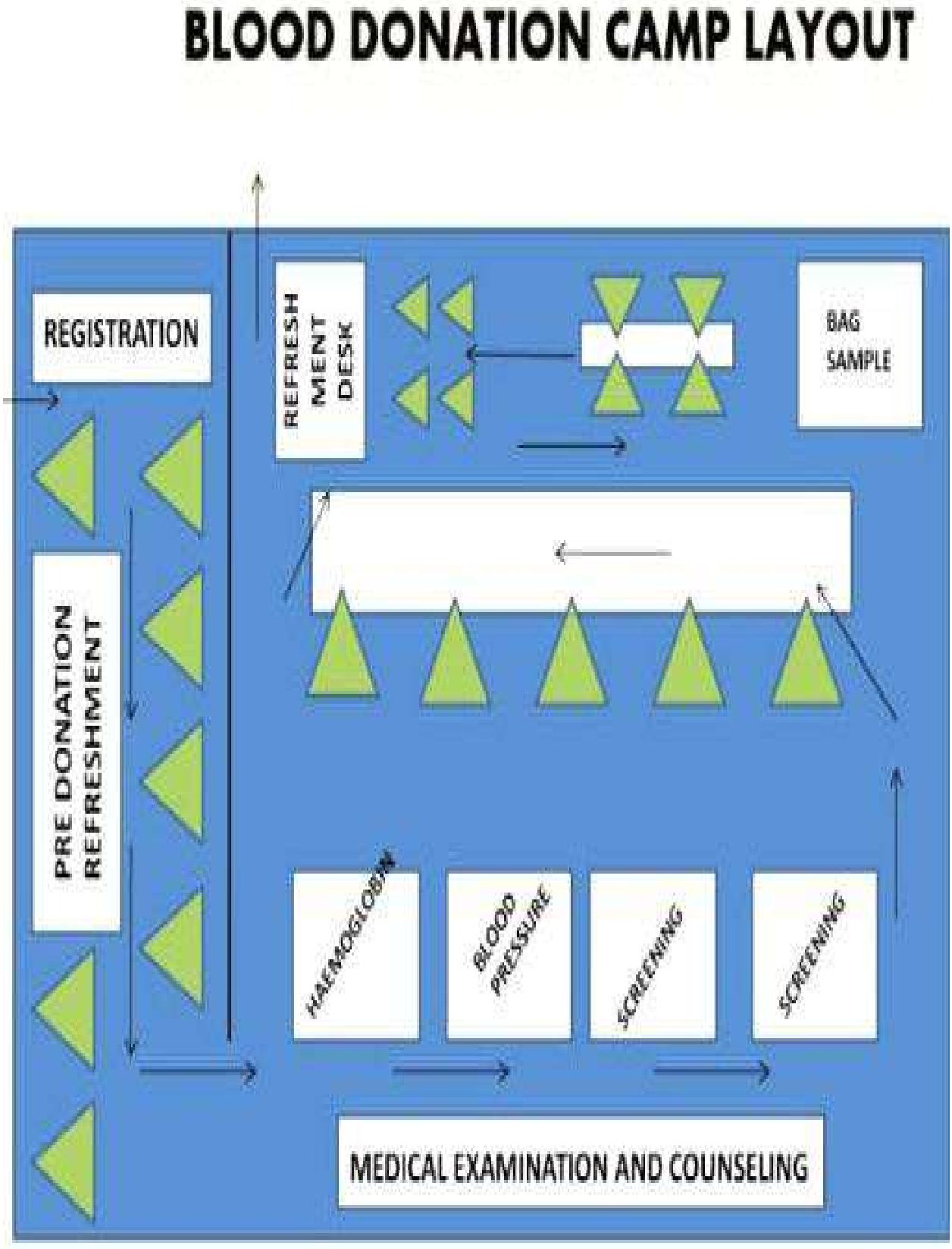
1. The blood centre estimates its requirement of blood units for a particular period.
2. Based on the availability of blood units in their stock, they determine the number of blood units required by them through camps.

3. Blood centre provide their requirement to the blood donor organization and request to arrange camps for them.
4. Blood donor organization coordinates with various schools / colleges /universities, industries, religious bodies, etc for organising camps.
5. Date, time and venue are fixed with the organisers.
6. The number of donations required is discussed with the organisers.
7. Organizers provide a list of committed healthy blood donors
8. Blood donor organisation liaises with blood centre and the camp givers about a mutually convenient date.
9. Blood centre takes a prior permission from SBTC.
10. Medical Director or representative of the blood centre visits the site of the venue to inspect its suitability for the space criteria - A checklist may be provided to the organiser.
11. Few days before the camp, NGO/ Social Worker/ Donor Motivator can arrange a talk on the importance of voluntary blood donation to the potential donors.
12. IEC materials on the subject should be provided to the organisers to be displayed in their working premises.
13. Media may be approached to give adequate coverage to the camp.
14. The registration of the camps should be enrolled in E-Raktkosh registration.

B) **Camp phase**

1. The blood centre team arrives at the venue of the camp well before the time given to donors.
2. Supervise the venue for adequate facilities like space, furniture, heaters/coolers, etc.
3. Inspect pre-donation, donation and post-donation areas as per standard.
4. Liaise with the Organiser and voluntary donor organisation.
5. IEC materials and banners should be displayed everywhere.
6. Arrangement for inauguration of the camp by a celebrity.
7. The camp should be started on time.
8. Screening and medical examination of blood donors by medical personnel.
9. Over-crowding of the area should be prohibited.
10. Comfortable and adequate seating arrangement for blood donors.
11. Bleeding area should have adequate lighting and proper ventilation.
12. Bleeding procedures should be as per standard.
13. Provision for donor refreshment.
14. Provision for cold chain maintenance.
15. Provision for management of donor reactions.
16. Area should be cordoned off from other persons.
17. Camp should be completed at the stipulated time.

18. All the discarded blood bag tubing and needles have to be segregated separately for disposal as per bio-safety protocols and waste management.



Pre-Donation Counselling- It shall focus on the donor and preferably be done one-to-one. The objectives include:

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

On Donation Chair

1. To prevent adverse reactions like giddiness, the donor should be asked not to get up from the chair for 8-10 minutes even if he/she feels perfectly all right.
2. Observe for another 10 minutes in refreshment area while donor has refreshment (a juice and a packet of biscuit).
3. Inspect the venipuncture site before the donor leaves the donor room. Apply an adhesive tape only after oozing stops. If there is persistent oozing at the site of venipuncture, apply pressure with a dry, sterile cotton swab.
4. Issue donor appreciation certificate and ensure that the donor puts his/her signature on the donor record register.
5. Thank the donor and encourage him/her to become a regular voluntary donor .
6. Ask the donor to write his/her comments/suggestions in the donor refreshment register.

Post Donation Care & Counselling- Instruct the donors regarding the following

1. Please wait for 15 minutes after donation.
2. Take more fluids than usual in next 4 hours.
3. Do not smoke or drive for next 30 minutes.
4. Do not drink alcohol for next 24 hours.
5. Do not remain hungry.
6. If bleeding occurs from phlebotomy site, raise the arm and apply pressure on the venipuncture site.
7. If the donor is feeling dizzy, make him/her lie down with legs slightly raised above the head level and if symptoms still persist consult nearest doctor, blood bank doctor or clinician.
8. Remove the adhesive band after 5-6 hours.
9. Do not apply any medication on venipuncture site on your own.

10. Avoid lifting heavy weight or strenuous exercise to prevent bruising or bleeding from venipuncture site.
11. No extra/special diet is needed. However, iron rich foods may be advised like green leafy vegetables, jaggery, dates, meat (for non-vegetarian) etc.
12. Rest and refreshment should be given to all. Thank the donor for their valuable contribution and ask them to repeat the same for this noble cause. An appreciation card goes a long way for the donor to come back as a repeat donor.

Never Be Left Unattended

1. Needles, lancet and syringes should be destroyed with the needle cutter.
2. The entire area should be cleaned with a disinfectant (sodium hypochlorite - working area and phenyl or bleaching powder- floor) after the camp is over.
3. The collected units should be kept under cold chain maintenance.
4. Before leaving the camp premise, blood donors and organizers should be appreciated for their gesture. They should be encouraged to donate again and organize similar camps in future.
5. The blood bank team should reach their destination in time.

C) Post-camp phase

(a) Medical Director/Blood centre in-charge must send letters of appreciation to the organiser for arranging the V.B.D. camp.
(b) They should be encouraged to organize similar camps on a regular basis.
(c) Blood donors of the camp should receive thank-you letter and blood group cards either individually or through their particular organization.
(d) Constant touch with blood donors should be maintained through birthday cards, anniversary cards, etc.

Infrastructure Requirement for a Blood Donation Camp

Required number of beds according to the expected number of donor

Number of Donors	Number of Beds
50-100 donors	6-8 beds
100-200 donors	8-10 beds
200-300 donors	10-14 beds
>300 donors	14-16 beds

Furniture Requirement

- Big tables as per number of donor loads.
- Folding donor couches for mobile camps.
- Chair with arm or Sofa Sets for donors in the refreshment area.

Blood Mobile Van

The blood mobile van is one of the modern methods of mobile blood collection facility funded through the third phase of National AIDS Control Programme (NACO) by National Blood Transfusion Council (NBTC) of India. The concept was to reach the blood donor with the blood collection facility in order to minimize the time spent on travel to the nearest blood donation centre or outdoor blood donation camp/drive. The blood mobile van was introduced with the concept of stationing it for blood collection at prominent public place and rotate the schedule in a manner that repeat voluntary blood donors know that the blood mobile van will be stationed for collection near his/her workplace /housing and could thus plan his/her blood donation in advance.

SUMMARY

- Blood transfusion services need to ensure that donors are retained and they become regular donor.
- To do this donor need must be recognised and satisfied.
- Satisfaction and retention are directly influenced by the quality of donor care.
- Donor complaints must be formally investigated to satisfy the donor addressed properly.
- Pre & Post donation information and counselling is an important aspect of donor care.

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BASIC RED CELL SEROLOGY

There are several blood group systems. Some of them are clinically significant

Blood Group System

Clinically significant	Clinically insignificant
ABO	Lewis
Rh	M,N
Kell	P1
Duffy	Lutheran
Kidd	A1
Ss	

Development of Antigen at Birth

- All the ABH antigens develop as early as day 37 of fetal life but do not increase very much in strength during gestational period
- Red cell of newborn carries 25-50 % of number of antigenic sites found on adult RBC.
- A or B antigen expression fully developed at 2-4 yrs. of age and remain constant throughout life.
- Presence or absence of the ABH antigens on the red cell membrane is controlled by the H gene
- The H antigen is the foundation upon which A and B antigens are built.

Anti-A and Anti-B Antibodies

Not present in the newborn, appear in the first years of life (4- 6 months usually), reach adult level at 5-10 years of age and decreases in elderly. These antibodies are present without any specific red cell antigenic stimulus but due to cross reactivity of ABO antigen with naturally occurring bacteria, viruses and pollen grains present in the environment. They are usually IgM in nature.

**'*Landsteiner's law*': ** The plasma contains natural antibodies to A or B, if corresponding antigens are absent from the red cells of that person.

Characteristics of Bombay Phenotype

- First reported by Bhende et al in Bombay in 1952.
- Absence of H, A & B antigens. No agglutination with anti-A, anti-B or anti-H.
- Presence of anti-H, anti-A and anti-B in the serum.
- No A, B or H substances present in saliva.
- Incompatible with any ABO blood groups, compatible with Bombay phenotype only.

ABO Subgroups

ABO subgroups differ in the amount of antigen present on the red blood cell membrane. Subgroups of A are more common than subgroups of B.

Subgroups of A: Two principle subgroups of A are: A_1 and A_2

- Both react strongly with reagent anti-A
- To distinguish A_1 from A_2 red cells, the lectin dolichos biflorus is used (anti-A_1)
- 80% of group A or AB individuals are A_1 and A_1B, 20% are A_2 and A_2B

Rh (D) Antigen

- Common Rh antigen are D, C, E,c and e.
- Rh refers to the presence or absence of the D antigen on the red blood cell membrane.
- A very potent antigen (50% may form antibody to exposure)
- Unlike the ABO system, individuals who lack the D antigen do not naturally produce anti-D.
- Production of antibody to D requires exposure to the D antigen.
- The D antigen is very immunogenic, i.e., individuals exposed to it will very likely make an antibody to it. Unlike ABO antigens, Rh antigens are present only on red blood cells. These antigens are not found on other blood cells including platelets and leukocytes.

Rh Antibodies

- All Rh antibodies are immune in nature, developed after immunizing event
- React at 37^0C and require anti- globulin test to demonstrate the reaction
- Generally do not react at room temperature in saline
- Most are IgG in nature and therefore can cross the placenta
  All are important in haemolytic disease of new born and delayed haemolytic transfusion reaction

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BLOOD GROUPING

Principle of Blood Grouping

1. Test unknown red blood cells with known antibodies.
2. Test unknown serum/plasma with known red blood cells
3. The patterns are compared and the blood group is determined.

Blood Sample for Blood Grouping

- Clearly labelled blood samples in sterile tubes (plain & EDTA).
- Test should be performed on the fresh sample for best results. In case the test cannot be performed immediately, sample can be stored at 4^0C and should be tested within 48 hours.
- No signs of haemolysis should be there.
- If serum is not completely separated, centrifuge tube at 3000 rpm for 3 min
- Preferably use saline washed red cells and make 2-5% suspension

Red cell suspensions for Blood Grouping

- 2-5%: Test Tube Method
- 0.8-1%: Gel technology
- 1%: Micro plate

General Precaution

- Freshly collected (3-5ml) sample should be accepted in a vial bearing a gum pasted, temper proof paper, label marked with the patients identification details and they should tally with the same on the requisition form .In case of any discrepancy, we have to ask for a fresh sample.
- We should check the specificity of the reagent antisera daily before use with known positive and negative RBCs apart from other Q.C tests done for every lot.
- We should use clean test tube.
- Serum should always be added before adding cells.
- We have to keep the ratio between cells and serum 1:2 to avoid discrepant results.

Test Tube Method of ABO Grouping

It is the recommended method for ABO Grouping-

- Allows longer incubation of antigen and antibody mixture without drying.
- Tubes can be centrifuged to enhance reaction.
- Can detect weaker antigen / antibody.

Two steps in ABO grouping

1. Cell grouping (Forward grouping) – Tests the patient's red cells with known Anti-A & Anti-B to determine the antigen expressed.
2. Serum grouping (Reverse grouping) – Test the patient's serum with known A & B red cells to determine the presence of antibody.

Practical aspects of ABO grouping

- Routine ABO grouping must include both cell & serum testing as each test serves as a check on the other.
- Test should be done at room temperature or lower; testing at 37^0C weakens the reactions.
- Tubes, slides should be dry and labelled properly.
- Serum should always be added before adding cells.
- Results should be recorded immediately after observation.
- Haemolysis is interpreted as positive result.

Micro plate Method

- It is ideal for testing large number of blood samples.
- More sensitive to detect weaker antigen-antibody reactions.
- Results can be photographed for archival storage.
- There is significant saving in time and in the cost of disposables and reagents.
- Micro plates can be adapted for automation.

Column Agglutination Technology

- One card is basically a set of 6 micro tubes.
- Micro tubes contain either Sephadex Gel or glass micro beads impregnated with antisera.
- Antigen-antibody reaction takes place in the reaction chamber of micro tube.
- Gel matrix or glass beads act as sieve and allow free cells (un-agglutinated) to pass through and settle at the bottom of micro tube while agglutinated cells are trapped in the matrix.

Rh typing

- Normal typing for Rh antigens only includes typing for Rh (D).The result of this typing determines the Rh status of the cells (Rh - positive or Rh - negative).
- It is recommended to use two monoclonal anti-D sera from two different manufacturers labelled as D1and D2, especially to confirm all Rh negatives

Monoclonal Anti-D

Three types-

- IgM anti-D monoclonal reagent
- Blend of IgM and IgG monoclonal antibodies
- Monoclonal IgG anti-D.

IgM antibodies are highly specific and saline reacting equally at RT and 37^0C but unreliable for detection of weak. Blended antibodies are now routinely used and can be used for detecting weak D.

Weak D (Du)

Inheritance of D genes which result in lowered densities of D Antigens on RBC membranes, gene codes for less D.

Partial D

- Absence of a portion of the total material that comprises the D antigen (qualitative defect)
- If the partial D patient is transfused with D positive red cells, they may develop an anti-D alloantibody to the part of the antigen (epitope) that is missing.

Significance of Weak D

Donors

- Weak D testing on donor is required.
- Labelled as D positive
- But as recipient D negative

Patients

- Weak D testing on patient is not required.
- Standard practice to transfuse with D negative

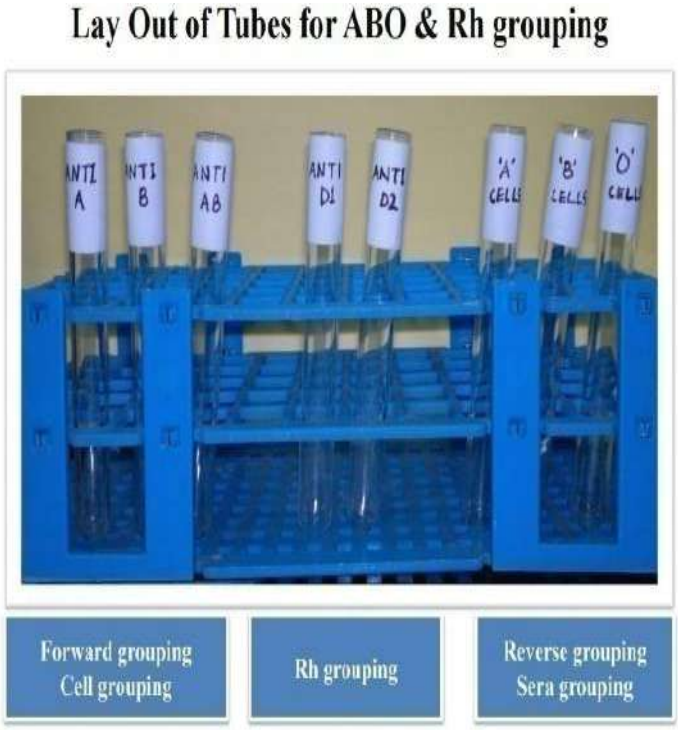
Weak D is much less antigenic in comparison to D; however, such red cells may be destroyed if

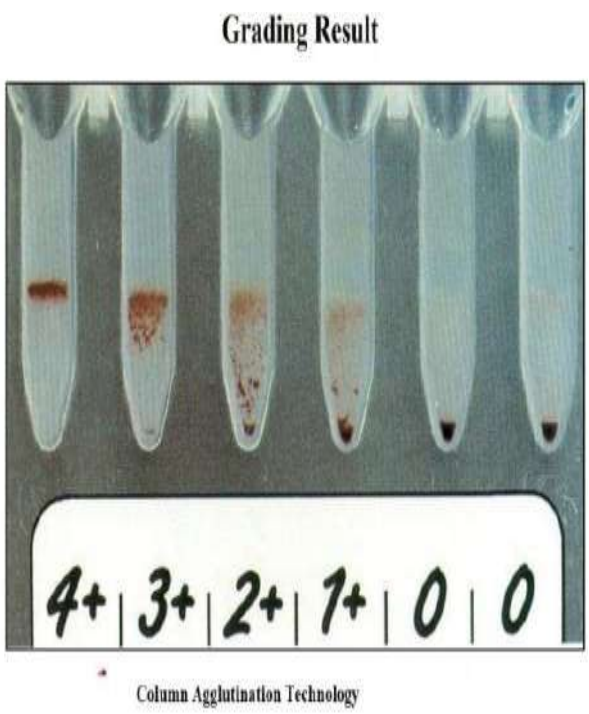
- Transfused to a patient already having anti-D. Hence, weak D donor units are labelled as Rh positive.
- The weak D positive recipients are classified as Rh negative and safely transfused with Rh negative blood.
- Du positive infant can suffer from haemolytic disease of newborn if the mother possess anti-D antibodies

- Rh immunoprophylaxis is recommended for the Rh negative mother if the newborn is Du positive.

Detection of weak – D

Weak variant of D – antigen is detected only by indirect antiglobulin test.





Labelling for whole blood/component

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

- Name of the product, i.e., whole blood or component or intended component.
- The numeric or alphanumeric identification.
- The date of collection and expiry.
- The name and amount of anticoagulant and the approximate volume of blood collected. For platelet concentrate, plasma and for component obtained through apheresis, the approximate volume of the components should be indicated.
- Colour Scheme: The following colour code is used to differentiate the ABO group label-

Blood group	Colour code for label
O	Blue
A	Yellow
B	Pink
AB	White

Special Requirements for Component Label

- 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.
- Storage temperature should be indicated.
- Expiry date/time for use should be recorded.
- Label should indicate whether the component is prepared by the apheresis method.
- Label should indicate the addition of any adjuvant or cryoprotective agents used
- Interpretation of HBsAg/HCV/HIV 1 & 2/Syphilis/malaria test/unexpected antibodies.
- Name, Address and Manufacturing license number of the collecting facility.

Requisition for Blood and Components

1. All blood requisition must have following information, without which requisition will not be accepted.
    - Name of the patient & Father's or Husband's Name
    - Hospital Number
    - Location of patient(ward/bed/OPD Unit)
    - Gender
    - Age
    - Haemoglobin, other haematological parameters as required for different blood components.
    - Name of the Consultant & Signature of Resident In-Charge with date.
    - Mobile number of Resident and PABX number of ward.**(IMPORTANT)**
    - In case of previous transfusions feedback form with Blood group & Rh type is mandatory.
2. Check the appropriate box to indicate what type of component and number of units to be cross-matched.
3. MSBOS given below may be referred for number of blood units required.
4. Provide relevant clinical details, such as diagnosis, indication for transfusion, history of transfusion or reactions, any medications, history of haemolytic disease etc.
5. Check the appropriate box to indicate the priority of the transfusion requirement.

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COMPATIBILITY TESTING

Compatibility tests are done to ensure that particular unit of blood may be safely transfused to a recipient. It includes-

- Acceptable donor's red cell survival in the recipients.
- No destruction of recipient's red cells.
- Confirms ABO compatibility of transfused blood and recipient's blood.
- Detects clinically significant unexpected antibodies.

Importance of cross matching

Routine blood grouping involves only ABO and Rh typing. Other clinically significant blood group systems are not routinely matched. Though, antibodies to minor antigens are of rare occurrence, they may sometimes be able to cause transfusion reactions.Cross matching between patient's serum and donor's cells will detect antibodies to other blood groups, if present.

Pre-transfusion testing procedure

Donor Unit Testing

- ABO grouping: Forward and Reverse.
- Rh typing: Rh (D) including weak D (Du).
- TTD testing for mandatory markers.

Recipient Testing

- ABO grouping: Forward and Reverse.
- Rh typing, Weak D (Du) not required.
- IAT testing: Antibody screen.
- Cross match: Major & Minor.

Serological cross match

Major cross match: Test donor's red cells with recipient's serum to detect antibodies in patient's plasma.
Minor cross match: Test donor serum with recipient's red cells to detect antibodies in donor's plasma.
Inclusion of auto control helps to rule out

- Auto antibodies
- Allo antibodies
- Rouleaux formation

Cross matching procedure

- Cross matching should be performed at following phases
    - Saline phase at room temperature: To detect compatibility of IgM antibody in patient's serum against antigen on donor's red cells.
    - AHG phase: Indirect anti human globulin test is the most important and widely used serological procedure to test IgG compatibility between recipient's serum and donor's cell.
- Cross matching can be performed using conventional test tubes or by using newer technologies such as
    - Column Agglutination Technology
    - Solid Phase Technology
    - Electro Magnetic (EM) Technology

Immediate Spin Technique (IST)

- Detects only IgM antibody, reactive at 22^0C.
- Clinically significant IgG antibody reactive at 37^0C not detected.

Cross Matching for Platelets & Plasma

- No compatibility testing required for platelets and plasma components
- Only ABO matching is required for fresh frozen plasma
- No need for compatibility, ABO and Rh matching for platelet concentrates and cryoprecipitate

Exceptions

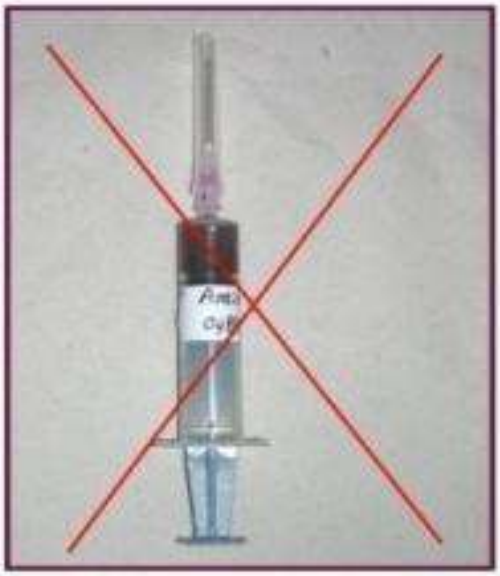
- Neonates, alloimmunized patients – Preferably ABO & Rh matched platelets
- If RBC contamination is > 2 ml, compatibility testing is required

Cross Matching: Special Circumstances

Neonatal (< 4 months) Transfusions

- Only ABO and Rh grouping should be determined by cell grouping, no serum grouping needed.
- Maternal serum should be screened for any irregular antibody.
- Direct AHG test on baby's cell should be performed.
- In the management of haemolytic disease of newborn, it is preferable to use mother's serum for cross matching.
- Transfuse ABO and Rh compatible blood to baby i.e.- which must be compatible with both baby and mother.

- Red blood cells less than 5 to 7 days old shall be used for exchange transfusion.
- Irradiated unit should be transfused for infant weight < 1500 gm



Normal sample Hemolyzed

Selecting Blood (PRBCs)For Exchange Transfusion In Neonates

Baby's Blood Group	Mother's Blood Group	1st choice	2nd choice
O	O	O	-
O	A	O	-
O	B	O	-
O	AB	O	-
A	O	O	-
A	A	A	O
A	B	O	-
A	AB	A	O
B	O	O	-
B	A	O	-
B	B	B	O
B	AB	B	O
AB	O	O	-
AB	A	A	O
AB	B	B	O
AB	AB	AB	A,B,O
Rh positive	Rh Negative	Rh Negative	-
Rh Negative	Rh positive	Rh Negative	-

•If mother's blood is not available, or group is not known, give O Rh negative
•Blood used should not be more than 5 to 7 days old.'
• A compatible plasma or AB plasma should be issued for reconstitution.

Transfusion in Auto Immune Haemolytic Anaemia (AIHA)

- We should avoid transfusion as far as possible in warm AIHA.
- There could be problems in blood grouping
    - Spontaneous agglutination of red cells on addition of antisera in WAIHA.
    - Nonspecific agglutination of reagent cells during serum grouping in cold AIHA.
    - Difficult to find absolutely compatible blood for such patients.
    - In emergency, consider the least incompatible blood.
    - Blood unit showing minimum strength of reaction in terms of titre designated as the 'least incompatible'.
    - Blood unit must be compatible with the patient's autoabsorbed-serum.
    - Transfusion should be done under strict medical supervision.

Documentation

All records to be initialled by the technician performing the test and also by the medical officers. Result to be entered in blood grouping register, cross matching register, donor register and master register.

Anti Globulin Test (AGT)

- Introduction by Coombs in 1945
- Detects incomplete antibodies
- **Principle of AGT**
    - Antibodies and complement components are globulins.
    - Animals injected with human globulins produce anti-human globulin (AHG).
    - AHG forms bridges between antibody coated red cells.

Anti human Globulin Reagents

- **Polyspecific**
    - Contains both, anti-IgG and anti-C3d (complement)
- **Monospecific**
    - Contains only one specificity, either anti-IgG or anti C3D

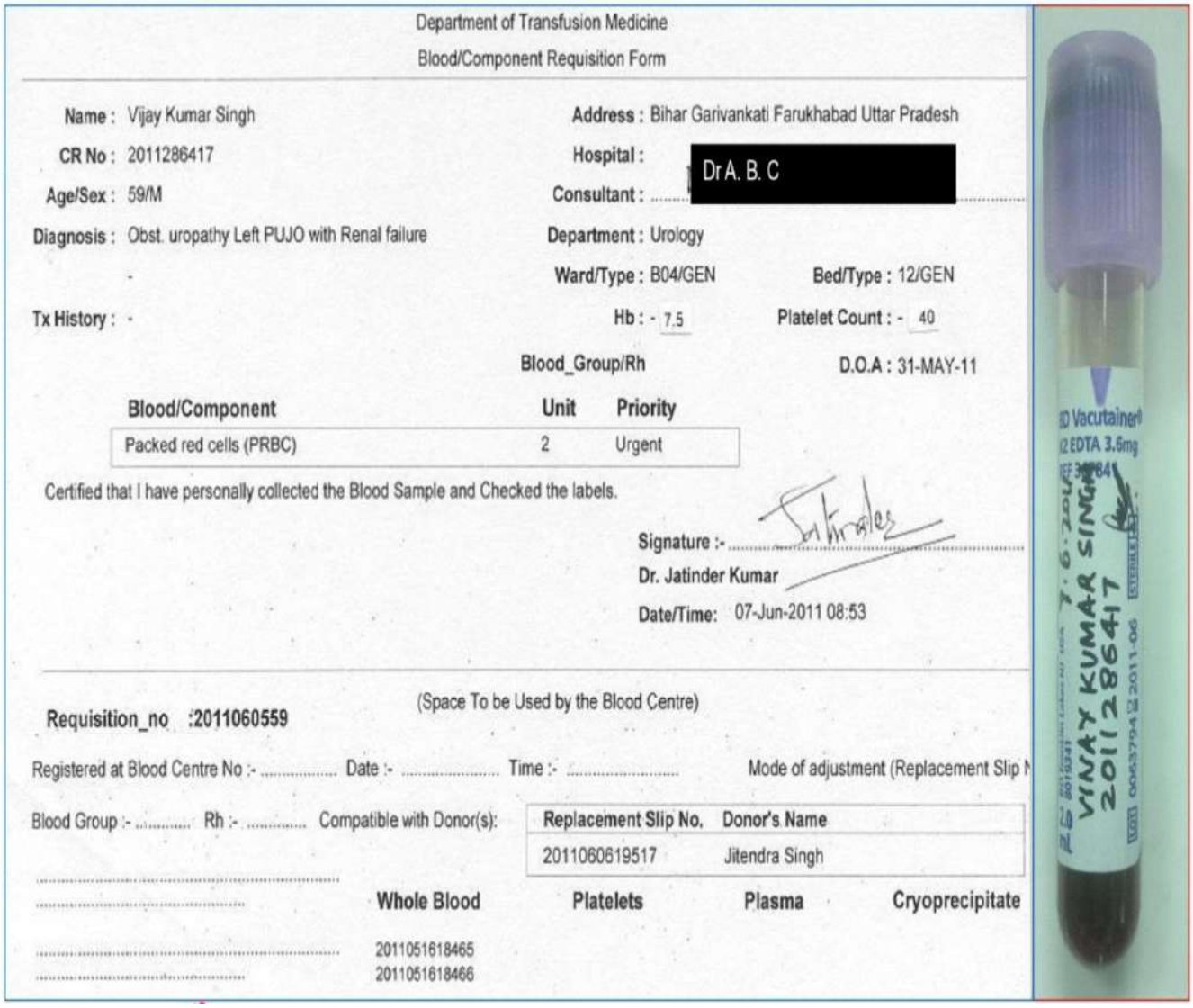
Applications of Direct Anti globulin Test

- Diagnosis of HDN in newborn
- Diagnosis of autoimmune haemolytic anemia
- Diagnosis of drug induced immune haemolytic anemia
- Investigation of haemolytic transfusion reaction

Applications of Indirect Anti globulin Test

- Detection and identification of unexpected antibodies in the serum
- Cross matching
- Typing of minor red cell antigens such as Duffy, Kell, Kidd
- Detection of weak D (earlier Du test)
- Titration of antibodies
- Anti-D in maternal serum in HDN.

Ideal Requisition Form & Sample



Department of Transfusion Medicine

Blood/Component Requisition Form

Name : Vijay Kumar Singh
Address : Bihar Garivankati Farukhabad Uttar Pradesh
CR No : 2011286417
Hospital :
Age/Sex : 59/M
Consultant : Dr A. B. C
Diagnosis : Obst. uropathy Left PUJO with Renal failure
Department : Urology
Ward/Type : B04/GEN
Bed/Type : 12/GEN
Tx History : -
Hb : - 7.5
Platelet Count : - 40
Blood_Group/Rh
D.O.A : 31-MAY-11

Blood/Component	Unit	Priority
Packed red cells (PRBC)	2	Urgent

Certified that I have personally collected the Blood Sample and Checked the labels.

Signature :-
Dr. Jatinder Kumar
Date/Time: 07-Jun-2011 08:53

(Space To be Used by the Blood Centre)

Requisition_no :2011060559

Registered at Blood Centre No :- ..... Date :- ..... Time :- ..... Mode of adjustment (Replacement Slip

Blood Group :- ..... Rh :- ..... Compatible with Donor(s):

Replacement Slip No.	Donor's Name
2011060619517	Jitendra Singh

Whole Blood Platelets Plasma Cryoprecipitate

2011051618465
2011051618466

*****

ABO BLOOD GROUPING DISCREPANCIES

It can be due to

- **Technical Discrepancy**
- **Clinical Discrepancy**

A) Technical Discrepancy

1. Clerical errors
2. Missed identification of blood specimen
3. Mixing of blood samples
4. Contaminated reagents or not following manufacturer instruction
5. Non-calibrated centrifuge
6. Cell suspension either too light or too heavy.
7. Contaminated or dirty glass wares.

B) Clinical Discrepancy

To solve this type of discrepancy essential information regarding patient's age, diagnosis, transfusion history, history of medication and pregnancy must be taken into account.

1. Group 1 Discrepancy: It is mainly seen in reverse grouping due to weak / missing antibodies

(1)Newborns,
(2)Elderly patients,
(3)Patients with leukaemia or lymphoma
(4) Immunosuppressive drugs
(5)Patients with immunodeficiency diseases
(6) Patients with bone marrow transplant

These discrepancies can be solved by enhancing the serum grouping reaction by either incubating the cell serum mixture at low temperature or by prolonging incubation at room temperature.

2. Group 2 Discrepancy: This is due to missing or weak antigens

(1) Subgroups of A or B,
(2) Leukaemia and lymphoma
(3) Excess antigen of blood group soluble substances,
(4) Acquired A or B antigen.

Those discrepancies can be solved by

(1) Repeating blood grouping by using washed cells
(2) Use of anti AB antisera and anti A1lactin
(3) Adsorption and Elution technique.

3. Group 3 Discrepancy

(1) Elevated level of plasma globulin i.e. Multiple Myeloma, Hodgskin lymphoma
(2) Elevated level of fibrinogen
(3) Use of plasma expander
(4) Wharton's jelly in cord blood sample.

These discrepancies can be resolved by

(a) Washing the cells with normal saline 6-8 times
(b)Reagent cell and patient serum centrifuged to allow antigen and antibody to react.
(c) Serum is removed and replaced by an equal volume of saline
(d) Tube is mixed, centrifuged and re-examined for agglutination

4. Group 4 Discrepancy

(1) Polyagglutination.
(2) Patient with cold auto antibodies
(3) A2 or A2B individual with A1 – antibodies.
(4) Naturally occurring or irregular antibodies reacting at room temperature.

These discrepancies can be resolved by-In Polyagglutination

(a) Symptoms suggestive of infection
(b) Auto control negative
(c) DAT negative
(d) Use of various lectins

In cold auto agglutination

(a) Warm saline washes auto agglutinated cells.
(b) Pre-warming of sera and reagent cells.
(c) Performing the test at 37^0C.

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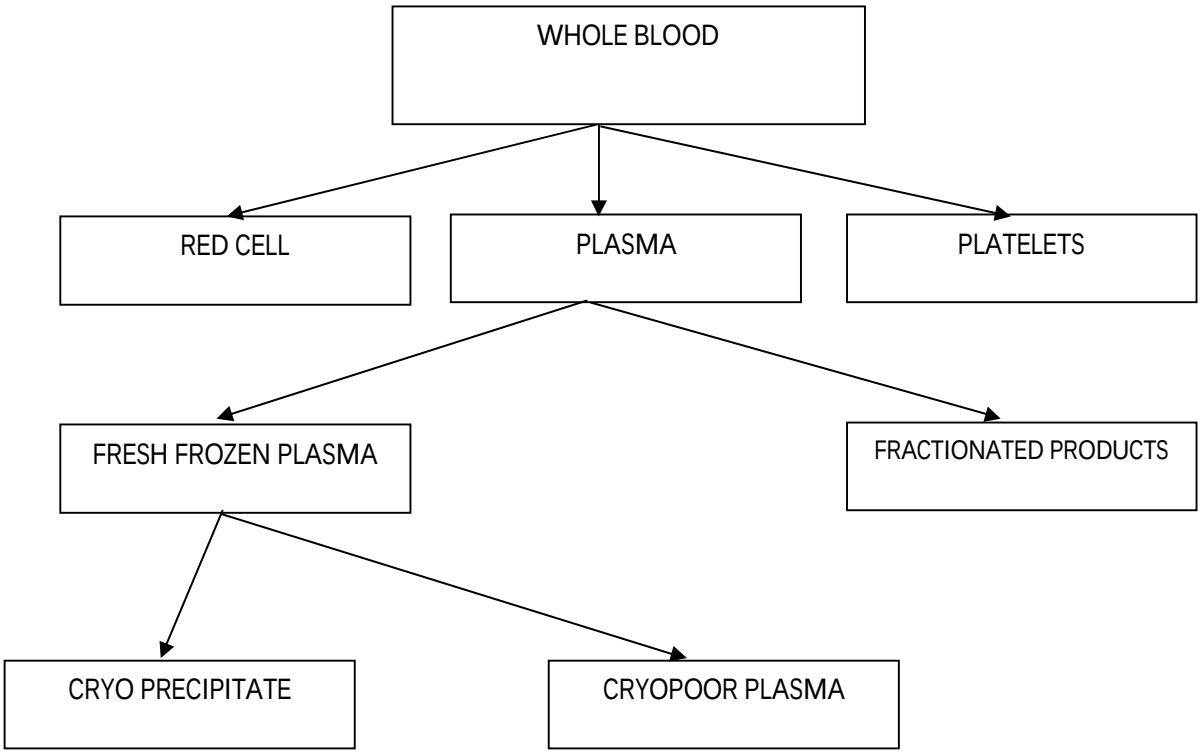
BLOOD COMPONENTS

Blood component overview



From the whole blood collected in multiple blood bags various blood components can be separated by centrifugation and separation technique because of the differences in the specific gravities of different components of blood. Blood components such as red blood cells, platelets concentrate; plasma (fresh frozen plasma, cryoprecipitate, cryopoor plasma) can be separated from whole blood by centrifuging at different centrifugal force (g) for different time in a refrigerated centrifuge machine. Moreover, blood components can be collected from donors by apheresis technique also (plasmapheresis, Plateletpheresis, etc).

Standard Blood Components

1. Packed red blood cell
2. Platelet concentrate
3. Fresh Frozen Plasma
4. Cryoprecipitate
5. Cryo poor plasma

Specialised Blood Components

1. Saline Washed RBC
2. Frozen RBCs
3. Leucodepleted RBCs
4. Irradiated RBCs
5. Plasma derivatives such as human albumin concentrate, fibrinogen, immunoglobulin, and other coagulation factors.

The different components that can be separated

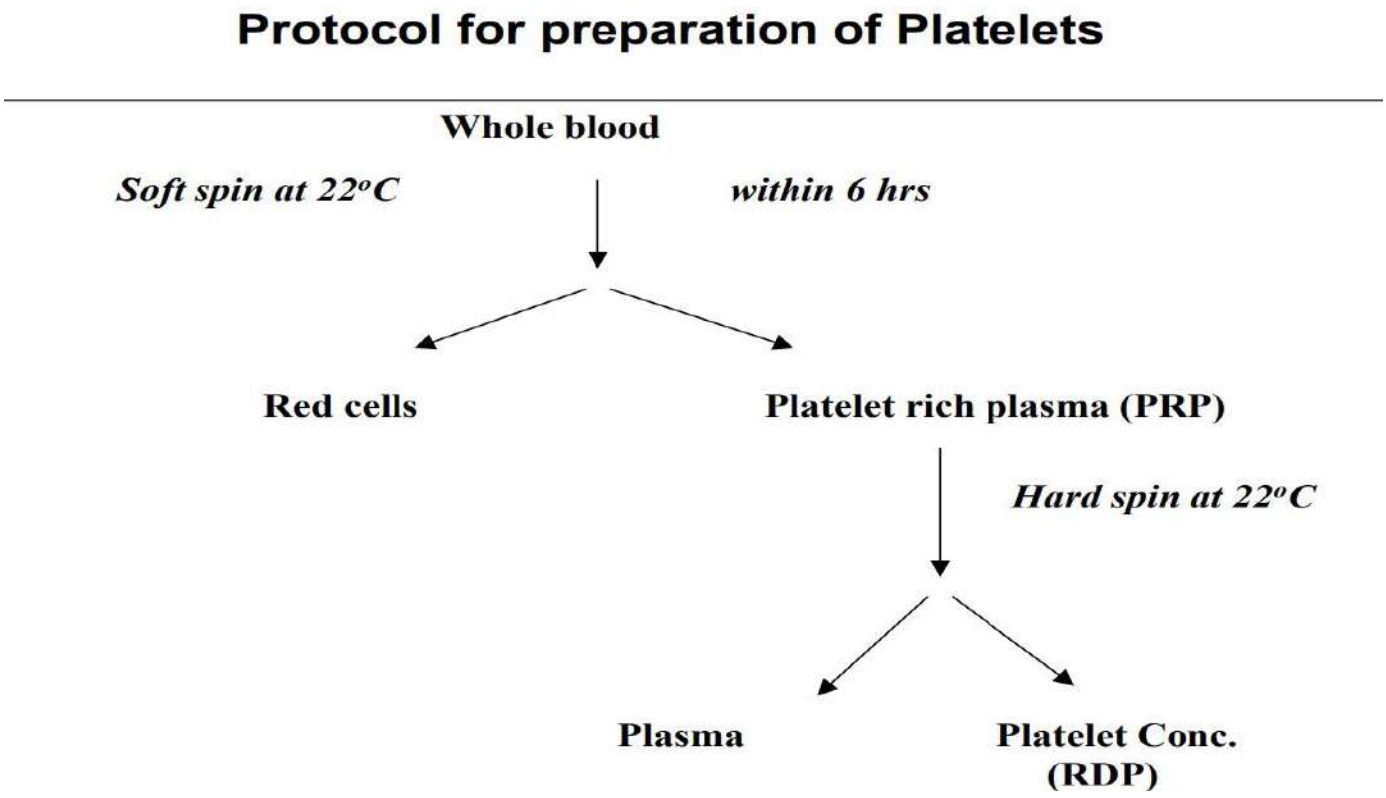
Component	Common Abbreviation
Packed Red Cells	PRBC
Platelet concentrate	PC
Fresh Frozen Plasma	FFP
Cryoprecipitate	C
Cryopoor Plasma/Cryodeficient Plasma	CPP/CDP

Standard Blood Components

Packed Red Blood Cells

Packed red blood cells can be prepared from whole blood collected in a closed double or triple blood bags by centrifugation and separation techniques using a refrigerated centrifuge. It must always be stored at a temperature between 2^0 to 6^0 degree Celsius; they must never be allowed to freeze. The upper limit of 6^0 C is essential to prevent the growth of any bacterial contamination in the unit of blood. Below 2^0 C the red blood cells are haemolysed. Once issued red blood cells should be transfused within half an hour of release from the blood centres and if not required it should be sent back to blood centre immediately.

Platelet concentrate



Platelet concentrate is stored at 22^0 to 24^0Celsius in a platelet agitator. Volume of platelet concentrate is 30 to 50ml. Platelet concentrate are to be transported in a blood transport box that keeps the temperature at about 22^0 to 24^0Celsius. Platelet products must not be refrigerated at any state. Platelet should be transfused as soon as possible. Platelet concentrates should not be transfused through the set used for transfusing other blood components. Platelets will adhere to fibrin captured in the filter.

Fresh Frozen Plasma (FFP)

FFP is plasma prepared from a unit of blood after a blood donation by centrifugation within 6-8 hours and rapidly frozen there after immediately. It contains all coagulation factors and the most labile coagulation factors (V and VIII) and preserved for one year if FFP is kept at minus 30^0 degree Celsius or below. Thawing of FFP is done at 37^0C in water bath and takes about 30 to 45 minutes. Approximate volume of FFP is 150-175ml/bag. It can be transported in blood transport box in which temperature is maintained between 2 to 6 degree Celsius. Once thawed the FFP cannot be refrozen and if not transfused then it has to be discarded. A standard blood administration set is satisfactory for transfusion of plasma components and platelets. FFP should be transfused within 30- 60 minutes.

Approximate content of coagulation factors in 100ml FFP

Fibrinogen	280 mg/100 ml
Factor II	110 U/100 ml
Factor V	114 U/100 ml
Factor VI	116 U/100 ml
Factor VIII	115 U/100 ml
VWF	130 U/100 ml
Factor IX	100 U/ 100 ml
Factor X	130 U/100 ml

Cryoprecipitate

Cryoprecipitate contains precipitated proteins of plasma, rich in factor VIII and fibrinogen, obtained from FFP prepared within 6-8 hours of collection with subsequent thawing. It is stored at minus 30^0 Celsius or lower and thawed at 30^0 to 37^0 Celsius in a water bath and takes about 15-30 minutes. Once thawed it should be transfused within 30 minutes. If not immediately transfused it is kept at 2^0 to 4^0Celsius and can be transfused within 4 hours of thawing. It cannot be refrozen, so if not transfused it has to be discarded.

Approximate content of coagulation factor in 100 ml of cryoprecipitate

Factor VIII	62 U/100 ml
Fibrinogen	240 mg/100 ml
VWF	129 U/100 ml
Fibronectin	21 mg/100 ml
Factor XIII	113 U/100 ml

Cryopoor Plasma

Cryopoor plasma contains all the coagulation factors except Von Willebrands factors and factor VIII.

Specialised Blood Components

Saline washed red blood cells

Red blood cells washed with normal isotonic saline by an automatic cell washer or manually by centrifugation remove almost all the plasma of a blood unit, which reduces the chances of transfusion reaction due to plasma protein. It is obtained from secondary processing of red cell components, which involves sequential washing and re-suspension of red cells in an additive solution. When an open system is used for washing, the storage time should be as short as possible after washing and must never exceed 24 hrs. They should be stored at 2-6^{0}C. If a closed system and a suitable additive solution are used, storage times may be prolonged, subject to validation. Indications for washed red cells include, recurrent attacks of FNHTR and urticarial reactions,

Frozen Red Blood Cell

Red cells should be cryopreserved within 6 days of collection and Glycerol is the most common cryopreservative agent. Frozen red cells shall be stored at temperature less than minus 65^{0}C and have a shelf life of 10 years. Frozen units should be thawed at 37^{0}C followed by removal of glycerol. If the open system is used, the shelf life of the final unit is 24hrs.at 1-6^{0}C, while it is 14 days at 4^{0}C in case of closed system. Cryopreserved red cells are required for storage of autologous units of patients with rare blood groups with antibody to high frequency antigens.

Leucocyte Reduction of Blood Components (Leucodepleted RBC)

Leucoreduction is the removal of white blood cells from the blood or blood components, used for transfusion after the removal of leucocytes the red blood cell concentrate is called leucoreduced red blood cells.

Methods

- Washing (saline washed red cells)

- Freezing and Thawing
- Buffy coat removal
- Microaggregate filtration
- Specific leucodepletion filters
- Low leucocyte apheresis devices (cell separators)

Of the various methods used, leucocyte filter is the most efficient; it removes 99.99% of leucocytes. Leucofiltration can be done-

- At the bedside
- In the laboratory before issue
- Leucocyte depletion using inline filters

Irradiated Red Blood Cell

Packed red blood cells are irradiated by exposing the bags to gamma radiation from Cobalt-60 or Cesium-137 using an instrument called irradiator. The minimum radiation dose to kill the T lymphocytes is 25 Gy. Irradiated red blood cells prevents TA-GVHD (Transmission associated graft versus host disease)

INDICATION

- Bone Marrow Transplant
- Congenital immunodeficiency
- Premature infants
- Intrauterine transfusions
- First degree relatives

Fractionated Plasma (Plasma Derivatives)

Plasma derivatives are manufactured by fractionation of large volume of pooled human plasma in fractionation centre.

1. Human albumin concentrate
2. Factor VIII concentrates
3. Fibrinogen
4. Immunoglobulin
5. Other coagulation Factors

Human albumin concentrate is prepared by cold ethanol fractionate of pooled human plasma. It is used as a replacement fluid in therapeutic plasma exchange and in hypoproteinemia. Factor VIII concentrate is the treatment of choice for hemophilia A and severe Von Willebrands disease. Fibrinogen, immunoglobulin and coagulation factors are also prepared by fractionation of pooled human plasma.

Components – Storage Temperature and Shelf Life

Component	Storage Temperature	Shelf Life	Compatibility
Platelet concentrate	22 ± 2^0C	5 days	Preferably ABO match
Red cells	2^0 to 06^0C	35 days	ABO/Rh
Red cells with additive solution	2^0 to 06^0C	42 days	ABO/Rh
Fresh Frozen Plasma	-30^0 or below	1 years	ABO
Cryoprecipitate	-30^0 or below	1 year	Any group
Cryopoor Plasma	-30^0 or below	5 years	ABO

Planning a Component Lab

To establish a blood component separation unit, planning should be done based on the following requirements:

- Type of hospital and bed strength.
- Adequate AC space (+ 50 sqm).
- Availability of equipment.
- Availability of double, triple or quadruple bags.
- Trained manpower.
- License from regulatory authorities.

Blood Donors

Donor has to fulfil the following criteria for preparation of blood components from the donated blood

- Donor must have - Hb $\geq$ 12.5 gm/dl.
- Weight of the donor should be more than 45 kg (350 ml) or 50 kg (450 ml).
- Blood must be collected in single bold venipuncture.
- Donor should not have taken Aspirin for past3 days before blood donation.
- Free flow of blood during the blood collection.
- Blood unit collection time should be less than 10 minutes with frequent mixing.

Equipment required in a blood component lab

- Weighing balance
- Two pan balance
- Refrigerated centrifuge
- Laminar air flow bench
- Platelet shaker/ incubator
- Refrigerated water bath

- Plasma expresser
- Tube sealer Additional
- Sterile tubing welder
- Gamma irradiator
- Cell separator (aphaeresis)

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ADMINISTRATION OF RED BLOOD CELL COMPONENTS

We have to determine the correct intravenous access required for blood transfusion. Transfusing rapidly and under pressure through too small an intravenous access can cause haemolysis of red blood cells. Blood products must not come in contact with medications or incompatible solutions (e.g. D5W, HES, Ringer Lactate).

Rate of infusion	IV Access
Rapid Transfusion in adults	16 to 18 G (Gauge)
Routine Transfusion in adults	20 to 22 G
Paediatrics	22 to 25 G

- A doctor or a qualified nurse should administer blood/ blood component to the patient.
- The patient should be informed all about the blood transfusion process in his/her language and written consent to be taken. For minors, permission should be taken from legal guardian.
- All blood components must be transfused through BT set containing a 170-micron filter to capture any fibrin debris.
- BT set must be changed at least every 2-4 units and at least 12- hourly during blood component transfusion
- Patient must be under direct observation upto the first half an hour of blood transfusion
- Blood warming is not necessary.

Time Limit for Administration of Blood

- It should be less than 4 hours and blood filter should be changed in every 4 hours.

Rate of Transfusion:

- It varies with blood volume /urgency of volume replacement, hemodynamic condition and cardiac status.

Patient Monitoring

- Monitoring of the patient should be done for each and every unit of blood or blood components transfused.

Frequency of observation

- Before the start of the transfusion
- 15 minutes after starting the transfusion
- At least every hour during transfusion
- On completion of the transfusion.

Documentation

- Record of the patient's vital signs in the patient's case notes/files and reporting of any adverse effects is essential.
- The record you make in the patient's case-notes is your best protection if there is any medico-legal challenge occurs later on.

Safe transfusion depends on

- Correct storage conditions
- Usage within correct time limits
- Inspection before infusion

Few Undesirable Practice

Blood centre, physician and hospital authority should monitor these undesirable practice to avoid any adverse effects during transfusion.

- Blood warming by hot water.
- Delay in transfusing after issue from blood centre.
- Use of unmonitored refrigerator for storage in nursing station.
- No monitoring of rate and duration of transfusion.
- Routine pre transfusion medication.
- Use of transfusion set for more than one unit.
- Addition of drugs to blood bag.

Transfusion reaction must be reported immediately to the blood centre for proper investigation so that similar reactions can be avoided in future if possible. In case of any untoward reaction immediately stop the transfusion, maintain intra venous access and check vital signs, take necessary resuscitative measures to stabilize the patient.

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ADVERSE REACTIONS

Any unfavourable transfusion related events occurring in a patient during or after transfusion of blood or blood components.

Types of Transfusion Reactions

- Immune reactions
- Non immune reactions
- Immediate
  - During or within few hours of transfusion
- Delayed
  - Days or weeks after the transfusion

Immune Transfusion Reactions

- Patient antibodies against antigens or vice versa
  - Red cells
  - White cells
  - Platelets
- Reaction to plasma proteins

Immune Reactions

- Haemolytic Transfusion Reactions
  - Acute
  - Delayed
  - Febrile Non Haemolytic Transfusion Reactions
  - Allergic / Anaphylactic reactions
  - Allo-immunization
  - TRALI (Transfusion Related Acute Lung Injury)
  - TA-GvHD
  - PTP (Post Transfusion Purpura)
  - Immunomodulation

Haemolytic Transfusion Reactions

- Increased destruction of donor red cells
  - Acute - Intravascular haemolysis
  - ABO incompatibility – due to activation of Complement cascade
  - Delayed - Extravascular haemolysis
  - Rh / minor group incompatibility- IgG/C3d coated cells removed in RES

Causes for acute haemolysis

- Red cell incompatibility – ABO incompatibility.
  Commonest causes of ABO incompatibility are clerical error followed by technical error (grouping & cross matching).
- Accidental heating or freezing of RBC
- Red cells in contact with water or 5% Dextrose
- Bacterial contamination
- Administering red cells through small gauge needle

Non Haemolytic Febrile Transfusion Reactions

- Antibodies in recipient against antigens of donor platelets or WBC
  - HLA Antigens
  - Granulocyte specific Antigens
  - Platelet specific Antigens
- Presence of cytokines in blood components
- More common in multi-transfused patients

Allergic/Anaphylactic reactions

It mainly occurs due to plasma protein.

Transfusion Related Acute Lung Injury - TRALI

- Not rare but under diagnosed.
- Presents as pulmonary oedema.
- Occurs 1-4 hrs of starting transfusion.
- Due to reaction between donor leucoaglutinins with recipient leucocytes.
- Aggregates of recipient leucocytes trapped in pulmonary circulation.
- Vascular damage & change in vascular permeability causes oedema.

Transfusion Associate -Graft vs. Host Disease (TA-GVHD)

- Rare & potentially fatal complication-Mortality rate - > 90% .
- Occurs in severely immunocompromised patients.
- Patients with immature immunological system (premature infants).
- In immunocompetent patients, when donor is homozygous for one of the patients' HLA haplotypes (certain communities'/ blood relatives).
- Due to successful engraftment of allogeneic T lymphocytes& their precursors.
- Donor lymphocytes engrafted in recipient & multiply.
- Engrafted lymphocytes react with host tissues.
- Occurs 4-30 days after transfusion.

Non Immune Transfusion Reactions

- Circulatory overload
  - Heart failure, pulmonary oedema
- Iron overload
  - Iron deposit in tissues
- Hyperkalaemia
  - Haemolysed blood
- TTI (Transfusion Transmissible Infections)
- Septicemia

Laboratory Investigations to be done for Blood Transfusion Reaction

- Recheck for clerical error / identification error.
- Visual check of post transfusion sample for haemolysis.
- Blood samples from the blood bags should be checked for haemolysis.
- In the post transfusion sample from patient, direct antiglobulin test should be performed.
- Re-grouping of patient's pre transfused and post transfused sample and also from blood bag should be done.
- Re-cross matching of patient's pre transfused and post transfused sample with sample from blood bag should be carried out.
- Fresh post transfused urine sample should be collected for detection of haemoglobinuria.
- In suspected sepsis blood culture from the implicated unit and recipient's blood is to be sent for bacteriological examination.\
- In suspected case of coagulation disorder due to transfusion reaction, coagulation profile of the patient should be done.

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TRANSFUSION TRANSMITTED INFECTION

Transfusion transmitted infection transmits pathogen into blood of recipients through transfused blood / blood components.

Sl. No.	Microbial Agent Type	Name
1	Virus (Enveloped)	HIV-1,HIV-2,HTLV-1,HTLV-2, CMV, HHV-6,HHV-8, EBV,HBV,HCV,HEV,GBV-C, CMV, West Nile virus
2	Virus (Non-Enveloped)	HAV, Parvovirus B 19, TTV, Enteroviruses
3	Bacteria (Endogenous)	Treponema pallidum(Syphilis), Borrelia burgdorferi (Lyme disease), Brucella melitensis (Brucellosis), Yersinia enterocolitica
4	Bacteria (Exogenous – environmental/skin commensals)	Staphylococcus sp., Pseudomonas fluorescens, Salmonella enteritidis, Citrobacter freundii, Serratia marcescens, Enterobacter cloacae, Flavobacterium sp.,Serratia sp., Coxiella burnetti, Rickettsia rickettsii.
5	Protozoa	Plasmodium sp., Babesia microti, B.divergens, Trypansoma cruzi, Leishmania sp., Toxoplasma gondii
6	Prions	Variant creutzfeldt – Jakob disease (vCJD)

Screening of donated blood for TTIs represents an important strategy for blood safety. Among these TTIs, test for HBV, HCV, HIV, malaria and syphilis are common mandatory screening test done in blood centres in India.

MANDATORY TEST

Under Drugs and Cosmetic Act 1940 Rules 1945, (SCH. F, Part XII B)

- ELISA for HIV I /II since 1989
- ELISA for Hepatitis B surface antigen since 1985
- ELISA for Antibody to Hepatitis C since 2001
- VDRL/RPR for Syphilis
- Screening for Malaria Parasite

Mandatory Screening of Blood Units

Infectious Agent	Tests Available
HBV	Rapid tests, ELISA and NAT
HCV	Rapid tests, ELISA and NAT
HIV	Rapid tests, ELISA and NAT
Malaria	PBS, Rapid tests, ELISA
Syphilis	VDRL, RPR, TPHA, ELISA

ELISA Testing

Definition: Detection of antigen and/or antibody in plasma/serum using an enzyme-linked chromogenic end point detection system.

Types of ELISA:

- Indirect
- Competitive
- Sandwich
- Capture

ELISA – Enzyme linked Immunosorbent Assay - Evolution

- **1st generation**: Infected cell lysate is used as an antigen.
- **2nd generation**: Glycopeptides (Recombinant antigens) are used.
- **3rd generation**: Synthetic peptides.
- **4th generation**: Synthetic peptides and antibodies.

Principle of ELISA

It is the most commonly used assay and is based on the use of immobilized viral antigen which captures anti-virus antibodies present in the test sample.

Basis of ELISA

- Depending on the particular assay either antigen or antibody is immobilized onto a solid phase
- The solid phase is normally polystyrene and either a micro well or bead
- Micro wells are generally presented in a 96 removable well plate format (12x8 wells)
- The sample and assay reagents are added sequentially into these wells & the final reaction read.

Method

- Sample is added to the well after dilution
- Incubated at a specified temperature for a specified period of time
- Immobilized antigen or antibody react with any complementary antibody or antigen in the sample resulting in a specific Ag-Ab complex
- At the end of the incubation period the excess sample & diluents is washed away

Detection of the reaction

- Detection systems used are many & varied. Generally, use a further antibody, broad range anti human globulin, an antibody specific to the infectious agent being screened for specific antigen which is chemically labelled with an enzyme. This labelled antibody or antigen is called the conjugate. The conjugate is added to the well after washing and incubated at a specified temperature for a specified time. During the incubation period the conjugate only binds to any specific Ag-Ab complex present & after binding it also becomes immobilized. At the end of the incubation period excess conjugate is washed away, the enzyme part of the conjugate use a synthetic dye known as a chromogen (substrate) which is added to the well after the conjugate has been washed away. It is further incubated at a specified temperature for a specified time. This changes colour in the presence of enzyme. At the end of the incubation period the colour reaction is stopped usually by adding acid & OD values of the individual wells read
- All ELISA have a set of controls that have to be run with each micro plate or set of tests
- The result of these control samples are used to ensure that the test run has performed satisfactorily & to calculate the assay cut off value
- The cut off value is the OD value which is used to decide whether the result is positive or negative.

Interpretation of absorbance values

i. The samples below the cut off are considered non-reactive.
ii. Equal to cut off are considered initially reactive.
iii. Above cut off are considered Reactive.
iv. Sample close to cut off value 10% below cut off (grey zone).
v. Samples with grey zone results are repeated in one well.

Validation of the test

- Check the validity of the Blank (if used) as well as negative and positive control absorbance value as per pack insert of the kit.
- Examine absorbance values of the controls before the sample results can be interpreted. If the run fails to meet the criteria as per package insert, consider the test as invalid and repeat the whole test again.

Indirect Elisa

- Antigens are attached on the solid phase support allowing antibodies in the specimen to bind and these bound antibodies are subsequently detected by enzyme labelled AHG and specific substrate.

- If test specimen contains antibodies, colour reaction takes place.
- It is most commonly used system.

Competitive Elisa

- Test antibodies compete with the enzyme conjugated antibodies in the reagent for binding to the antigen on the solid phase so that less or no labelled antibodies can get attached to the solid phase
- Hence no colour is produced on addition of substrate indicating presence of antibodies.
- Unlike indirect ELISA, absence of colour indicates the presence of antibodies in the test specimen.

4th Generation Elisa

- Simultaneous detection of both antigen and antibody
- HIV
  - HIV P24 antigen
  - Anti-HIV1 and HIV2 antibody
- HCV
  - Capsid core antigen
  - Anti-HCV capsid antibody

Nucleic Acid Test (NAAT)

Nucleic Acid test is highly sensitive and advanced molecular technique that can detect the presence of viral nucleic acid in blood in the initial phase of infection.

- Amplification of viral nucleic acid is done.
- Detects infectious agents before the body produces antibodies.
- Reduces the 'Window period' i.e. the time between the potential infectious period and the probability of detection by laboratory procedures.
- Two types:
  a) Individual Donor NAT: ID-NAT.
  b) Minipool NAT: Pooling of 6 – 16 donor samples before testing.

Documentation

Documentation of the following should be done-

- The date on which the test is run.
- The name of the kit used
- The lot number and expiry date of the kit.
- Standard values for the validity of the test.
- Signature of the Laboratory technologist

- Signature of Medical Officer.
- Reactive samples/units are marked red in the printout and working chart

Syphilis

- A sexually transmitted disease caused by Treponema pallidum
- A spirochete that cannot be easily visualized or isolated.
- Possesses a cardiolipin antigen which is used in tests to detect antibodies. E.g. VDRL test, RPR card test etc.
- Quality of specimen, technical skill and use of calibrated equipment's are essential for obtaining correct results in these tests.
- Sensitivity of these tests are very high

Serological Tests for Syphilis and Their Limitations

- **Methods using cardiolipin (non-treponemal) antigens**
  - VDRL, RPR card test.
  - Limitations - false positivity requires skill and is laborious. Sensitivity is high but specificity is poor
- Treponema Pallidum Heamagglutination assay (TPHA) :
  - Uses treponemal antigens – sensitivity & specificity is high.
  - Does not distinguish past from current infection.

Detection of Malaria

- **Macroscopic methods**
  - Test for malaria antibody
  - Test for malaria antigens
  - Parasitic metabolic products

Detection of malaria antigen remains the method of choice for detection of malaria in blood donors. It is based on the chromatographic immunoassay principle. The malaria antigen test contains a membrane strip, which is pre-coated with two monoclonal antibodies as two separate lines across a test strip. The sample is added into the sample well after which assay buffer is added. The test results are read after 20 minutes. Presence of only the control band indicates negative results. Presence of the both control and test band indicates negative results Absence of control band indicates invalid test. Interpretation of the strip for identification of different species of Plasmodium must be done as per the manufacturer's instructions. No blood or blood products should be released for transfusion until all required test are shown to be non-reactive or negative.

Recall and Referral Mechanism for Sero-Reactive Blood Donors

- **Information of Test Results**: To inform them about the sero-reactive result of transfusion-transmitted infection (TTI).
  - Donors who have consented to be contacted by the Blood Centre in case of an abnormal test result shall be recalled to the Blood Centre so as to inform them about the sero-reactive result of transfusion-transmitted infection (TTI).
  - Donors shall be provided post-donation counselling prior to referring to appropriate medical services for confirmation of diagnosis, follow up and treatment whenever necessary.
  - Adequate efforts must be made by the Blood Centre staff to contact the initial sero-reactive blood donors for recall-referral, and the process should be documented on record.
  - Result seeking blood donors, even if non sero-reactive, should also be informed of their TTI status with reiterated counselling to remain negative and continue to donate blood.

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

- **Referral Mechanism of HIV Sero-Reactive Blood Donors to ICTC**
    - The testing strategy used in the Blood Centres for HIV is "Strategy I", and the test done in the Blood Centre is considered to be a test of triage.
    - The blood unit is subjected to one test of high sensitivity for HIV reactivity. If nonreactive, the specimen shall be considered free of HIV (negative), and if reactive, the blood unit is considered as HIV positive and discarded.

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

- **Referral Mechanism of other TTI Sero-Reactive Blood Donors to Clinicians:**
    - The blood unit is subjected to one test of high sensitivity for HBV, HCV, Malaria and syphilis reactivity. If non-reactive, the specimen is to be considered free of infection (negative), and if reactive, the blood unit is considered as positive and discarded.
    - All blood donors found to be sero-reactive at Blood Centre for HBV, HCV, Syphilis, and Malaria shall be referred to clinicians in the Out-Patient Department of associated hospitals or others for assessment and re-testing.
    - Blood Centre shall fill out the referral form as per the standard format and send it along with referred donor.
    - Confidentiality shall be maintained at all levels.

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EQUIPMENT & PERSONNEL

Equipment

The Blood Centre shall be furnished with all equipment required for the provision of services i.e. collection, component preparation, processing, examination and storage of blood and its components and all other functions. The Blood Centre shall have policies, processes and procedures to ensure that calibration, maintenance, and monitoring of equipment conform to the Blood Centre standards and other specified requirements. The record of each piece of equipment shall be properly maintained. Whenever equipment is found to be defective, it shall be taken out of service.

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

a. Installation qualification
b. Operational qualification
c. Performance qualification

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

Equipment detail record: Unique identification of the records shall be maintained for each equipment. These records should include at least the following:

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

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

***Programme for calibration and maintenance of equipment*:** Blood Centre management shall establish a program that regularly monitors and demonstrates proper calibration and function of instruments, reagents and analytical system. It should also have a documented and recorded program of preventive maintenance. The equipment should be observed, standardized and calibrated regularly on a scheduled basis as described in the Standard Operating Procedure manual. The Blood Centre should have a system for investigating and follow up of equipment malfunction, failure or adverse event while working.

List of Equipments at Blood Centers

1. Donor couches
2. Donor weighing balance
3. Hemoglobinometer/ calorimeter or any other any other approved point of care haemoglobin estimation device.
4. Clinical thermometer or donor temperature checking device
5. Sphygmomanometer
6. Stethoscope
7. Blood mixer and shaker
8. Tube stripper Di-electric tube sealer
9. Needle destroyer/ sharp container
10. Oxygen cylinder
11. Refrigerated centrifuge
12. Double pan balance with standard weights
13. Plasma expresser
14. Blood Bank Refrigerator
15. Minus 35°C Deep Freezers
16. Minus 80°C Deep Freezers
17. Platelet Agitator and Incubator
18. Fixed or variable pipettes
19. pH Meter
20. Laminar Air-flow bench
21. Leuco-reduction device (when required)
22. Cell Separators (apheresis machine)
23. Table top centrifuge
24. Serological water bath
25. Binocular microscope
26. Dry incubator

27. Room temperature and humidity checking thermometers
28. Digital analytical balance
29. Elisa washer
30. Elisa reader (Plate reader/strip reader)
31. VDRL shaker
32. Autoclave
33. Distilled water
34. Air-condition (2 tonnes)
35. Generator (5 Dry rubber b)
36. Dry number
37. Weighing device for blood bags
38. Insulated blood bag containers with storage temperature from 20 C -100 C
39. Plasma thawing water bath (if components are dispensed)
40. Cryo bath
41. Emergency resuscitation kit with required drugs
42. Domestic refrigerator.
43. Lab incubator.

List of Equipment Optional in the Blood Bank / Blood Centre

a. Cell Counter (optional)
b. Coagulometer (optional)
c. Walk in Cooler/ Cold Room (optional)
d. Blood Irradiator (optional)
e. Automated Cell Grouping system (optional)
f. Equipment for column
g. Agglutination technology (optional)
h. Sterile Connecting devices (optional)
i. Automatic Cell washer (optional)
j. Micro plate centrifuge (optional)
k. Automated ELISA system (optional)
l. Automated Chemiluminscence based immunoassay system (optional)
m. Transportation vans (optional)
n. Blood mobile vans (optional)
o. Outdoor camp collection couches / chairs (optional)
p. Central temperature monitoring system (optional)

Calibration schedule for equipment

Sl No	Equipment	Performance	Frequency for performance checking	Minimum frequency of calibration (outsource or in house) Once a year
1	Temperature recorder (Display)	Compare against Thermometer	Daily	Once in 6 months
2	Refrigerator/Deep freezer for storage of blood / components	Compare against thermometer	Daily	Once in 6 months
3	Refrigerated blood bag centrifuge	Observe speed temperature and time	Each day of use	Once in 6 months
4	Hematrocrit centrifuge	Observe temperature and time	-	Once a year
5	General lab centrifuge	Observe temperature and time	-	Once in 6 months
6	Automated Blood typing	Observe control of correct result (QC sample)	Each day of use	Once a year
7	Haemoglobinometer	Standardize against cyanmethemoglobin standard	Each day of use	Once a year
8	Refractometer	Standardized against distilled water	Once a year	Once a year
9	Blood container weighing device	Container of known calibrated weight	Once a year	Once a year
10	Water bath	Observe temperature	Once a year	Once a year
11	Autoclave	Observe temperature and pressure	Once a year	Once a year
12	Serologic rotators	Observe temperature and pressure	Once a year	Once a year
13	Laboratory thermometer	--	-	Before initial use and every 6 months
14	Electronic/ digital thermometer	-	-	Before initial use and every 6 months

15	Blood agitator	Observe the weight of the first blood-filled container for correct results	Once in 15 day	Once a year
16	Platelet shaker cum incubator	Temperature oscillation rate	Each day of use once a month	every 6 months
17	Automated blood cell counter	Known control	Daily	Once a year
18	Pipettes	Volume	Once in a month	Once in 6 months
19	Incubator	Temperature	Once in a month	Once a year
20	Stop watch	-	-	Once a year
21	Tachometer	-	-	Once a year
22	Weight box	-	-	Once a year

Personnel

- **Medical Director/In-charge/ Medical Officer, Blood Centre** : The operation of Blood Centre and/ or processing or both of whole human blood for components shall be conducted under the active direction and personal supervision of competent medical staff consisting of at least one person who is a whole time employee and who is Medical Officer, and possessing—
  - Degree in Medicine M.B.B.S. having experience of working in Blood Centre, not less than one year during regular service and also has adequate knowledge and experience in blood group serology, blood group methodology and medical principles involved in the procurement of blood or preparation of its components or both; or
  - Degree in Medicine M.B.B.S. with Diploma in Clinical Pathology or Diploma in Pathology and Bacteriology with one-year experience in a licensed Blood Centre; or
  - Degree in Medicine M.B.B.S. with Diploma in Transfusion Medicine or Diploma in Immunohematology or Blood Transfusion with three months experience in a licensed Blood Centre; or
  - Doctor of Medicine Pathology or Diplomate of National Board Pathology with three months experience in a licensed Blood Centre; or
  - Postgraduate degree in Transfusion Medicine or Diplomate of National Board Transfusion Medicine, Doctor of Medicine Immunohematology and Blood Transfusion. The degree or diploma should be from a University recognized by the Central Government or State Government.

- **Blood Centre Technicians**: Full-time competent staff possessing the following qualification—
  - Diploma in Medical Laboratory Technology (DMLT) or Transfusion Medicine or Blood Bank Technology after 10+2 with one year experience in the testing of blood and/or its components in licensed Blood Centre; or
  - Degree in Medical Laboratory Technology (M.L.T.) or Blood Bank Technology with six month‘s experience in the testing of blood and/or its components in licensed Blood Centre; or
  - B.Sc. in Haematology and Transfusion Medicine with six month‘s experience in the testing of blood and/or its components in licensed Blood Centre; or
  - M.Sc. in Transfusion Medicine with six month‘s experience in the testing of blood and/or its components in licensed Blood Centre; or
  - Post-Graduate Diploma in Medical Laboratory Technology (PGDMLT) / Post Graduate Diploma in Medical Laboratory Science (PGDMLS) with six months experience in the testing of blood and/or its components in licensed Blood Centre.

- **Technical supervisor** (where blood components are manufactured), possessing-
  - Diploma in Medical Laboratory Technology or Transfusion Medicine or Blood Bank Technology after 10+2 with one year experience in the testing of blood or its components or both in licensed Blood Centre; or
  - Degree in Medical Laboratory Technology or Blood Bank Technology with six month‘s experience in the testing of blood or its components or both in licensed Blood Centre; or
  - B.Sc. in Haematology and Transfusion Medicine with six month‘s experience in the testing of blood or its components or both in licensed Blood Centre; or
  - M.Sc. in Transfusion Medicine with six months experience in the testing of blood or its components or both in licensed Blood Centre; or
  - Post-Graduate Diploma in Medical Laboratory Technology or Post Graduate Diploma in Medical Laboratory Science with six months experience in the testing of blood or its components or both in licensed Blood Centre; or
  - Post Graduate Diploma in Transfusion Technology (PGDTT) approved by the Central Government or State Government with experience of 6 months in the testing of blood or its components or both in licensed blood centre.

- **Registered Nurse(s):** Registered with state/ central nursing council.

- **Counsellor**: The Blood Centre shall have whole-time or part-time counselling staff (Counsellor or Medical Social Worker) possessing the following qualification. They will also take the required number of counsellor in each blood donation camp
  - Master degree in social work, sociology, psychology with six months of experience; or
  - Degree in Science or Health Science with one year of experience; or

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

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

Job Description/ Responsibilities

- Current job descriptions shall be maintained and shall define appropriate qualifications for each job position.
- Personnel shall perform assigned activities on the basis of appropriate qualification, education, training and/ or experience.
- The responsibilities of the Blood Centre Medical Director/ In-charge/Medical Officer shall include professional, scientific, consultative, advisory organizational, administrative and educational matters.
- Quality Manager shall have the responsibility and authority to oversee compliance with the requirements of the quality management system.
- Technical Manager shall have overall responsibility for the Blood Centre operations and the provision of resources needed to ensure the required quality of Blood Centre procedures. In a Blood Centre collecting less than 5000 units per year, the same person can be designated as Technical and Quality Manager.

Personnel Health

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

Personnel Records

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

- Certificate or license
- Reference from previous employment
- Job Description
- Record of continuing education and achievements
- Provision for untoward incident or accident reports
- Record of identification of signature and initials
- Competency evaluation
- Grievance redressal record
- Pre-employment health check-up record.

- Yearly health check-up records

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

Training

All personnel shall have training specific to Blood Centre operations and Quality management system. The staff members should be given induction training soon after the appointment. It should include training and acclimatization in different areas/ sections of the Blood Centre or organization. The training records should be maintained, updated and reviewed. There shall be a continuing education program for staff at all levels. All staff should be encouraged to participate in CME programmes at regular intervals. Employees shall be trained to prevent adverse incidents and/or contain the effects of and report adverse incidents. Blood Centre employees shall be trained in other regulatory and safety issues of Blood Centre like biomedical waste management and fire safety etc.

Competence

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

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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 shall be carried out only in a Blood Centre licensed for this purpose.

A medical officer trained in apheresis technique shall be responsible for the procedure. There shall be provision for emergency medical care in the event of any adverse reaction to the donor. The staff working on the equipment shall be trained in apheresis procedure and shall work directly under the supervision of the medical officer. The donor shall be asked to sign an informed consent for apheresis in the language, which he understands after being explained the procedure and the risks involved. At least 48 hours must elapse between successive apheresis and not more than twice in a week. For haematopoietic stem cells, the procedure can be done daily.

Types of Apheresis

1) Plasmapheresis 2) Cytapheresis

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

***Selection of donors*:** For selection of plasmapheresis donor, the donor shall fulfil all the criteria as per regulatory guidelines. The total serum protein shall be more than 6 gm/dl before the first plasmapheresis procedure. It should be tested before the third procedure if done within four weeks, and it shall be ≥ 6 gm/dl.

In occasional plasmapheresis in which donors undergo the process once every 12 weeks, the standards for whole blood donation should apply. In repeated plasmapheresis in which plasma is donated more frequently than once every 12 weeks, the donor should be tested before every apheresis procedure. Haemoglobin should be ≥ 12.5 g/dl and/or Hct ≥ 38%. In repeated plasmapheresis programme with the return of the cellular components a minimum interval shall be of 48 hours between two procedures (not more than 2 times a week, limited to 24 in one year).

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

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

Cytapheresis

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

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

Selection of donors: With the exception of donation interval, the donation criteria applied to allogeneic donor qualification shall apply for the selection of apheresis donors. The interval between procedures for platelet, erythrocyte and leucocyte donors shall be as per regulatory requirements. A donor (except for erythrocytes) shall undergo the procedure a maximum of two times in 7 days period or not more than 24 times in a year. In case of blood donors who undergo Cytapheresis no more than once every 4 weeks should be treated as ordinary blood donors and routine donor screening with laboratory tests should be done.
Donors, who undergo repeated cytapheresis, more than once every 12 weeks, should be tested as under:

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

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

Care of donors

- Extracorporeal blood volume should not exceed 15% of the donor's estimated blood volume.
- Interval between two Cytapheresis (except erythrocytaphersis) should be 48 hours and not more than twice a week.
- The donors should be tested appropriately to detect developing cytopenia.
- Red blood cell loss incidental to the procedure should be no more than 25 ml per week.
- Donors should be observed closely during cytapheresis as regards the untoward reactions like headache, fainting attack, tachycardia, twitching, dyspnoea etc.

- Written standard criteria used to determine donor suitability, the procedure of hemapheresis, precautions to ensure reinfusion of donor's own red cells, and time frame shall be maintained.

Plateletpheresis

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

Donor selection: Plateletpheresis shall not be carried out on donors who have taken medication containing aspirin or similar medicines within 3 days prior to donation. Donors with a personal and family history of bleeding tendency are not suitable for plateletpheresis. Platelet count should be determined before plateletpheresis and should not be below 150,000 / μL. Plateletpheresis donors with a platelet count of less than 1,50,000/ μL shall be deferred from platelet donation until a subsequent platelet count is at least 1,50,000/ μL . WBC counts and differential counts may be carried out and should be normal.

Storage: Shall be kept up to 5 days between 20^{o} C to 24^{o} C with continuous agitation.

Quality Control:

- Apheresis platelet concentrate should contain a minimum of 3 X 10^{11} platelets/ unit in 75% of the units tested amongst 1% of monthly production or 4 platelet concentrates per month, whichever is higher.
- pH must be 6 or higher at the end of the permissible storage period.
- To be considered leucocyte reduced, platelet must contain less than $5x10^{6}$ leucocytes per unit.
- Minimum SDP volume shall be 200 ml in order to maintain optimum pH of platelets.
- If a blood centre uses PAS as additive solution volumes may change, however, the shelf-life shall still be limited to 5 days or in accordance with regulatory requirement.

Leucapheresis

This procedure includes a collection of granulocytes (granulocytapheresis), lymphocytes or peripheral blood stem cells or haematopoietic stem cells for the treatment of traditional conditions followed by their preservation. Before leucapheresis total white blood cells counts should be ≥ 4000/ μL with the normal differential count. Donors may receive drugs to facilitate leucapheresis. Such drugs should not be used for donors whose medical history is suggestive of some disease. Leucocyte concentrate should contain at least 1 x 10^{10} leucocytes. Granulocyte concentrates shall be stored at 20^{0} to 24^{0} C for 24 hours without agitation. The red cells in the concentrates should be ABO compatible with the recipient's plasma. The component should be cross-matched if >2ml of

red cells are present. These should be transfused as soon as possible, preferably within 6 hrs. Transfusion should not be given through micro aggregate filters because it will remove the collected granulocytes. Irradiation is required to prevent GvHD.

Erythropheresis

This is the collection of two units of red cells from a single donor meeting specified requirements. The donor should have haemoglobin ≥ 13.5g /dl and weigh more than 65 Kgs.

Haematopoietic Progenitor Cells

In the field of transfusion medicine there has been significant advancement in the method of the collection of haematopoietic progenitor and their use.

Autologous or allogeneic marrow, which includes the progenitor cells, is collected from the patient's or donor's bone marrow. Once collected marrow undergoes extensive processing before storage. The processing can require cell separation, RBCs removal, buffy coat and mononuclear cell purification. Techniques have been developed using the apheresis equipment to perform these tasks. Following marrow ablation by chemotherapy or radiation therapy or both, the progenitor cells are infused to repopulate the marrow, which begins to redevelop cells.

The progenitor cells are also available in peripheral blood and are termed as peripheral blood stem cells (PBSC). These cells are collected by apheresis techniques. Multiple collections by apheresis are usually needed to collect adequate number of PBSC. Hematopoietic growth factors granulocyte - colony stimulating factor (G-CSF) or granulocyte macro phase-colony stimulating factor (GM-CSF) are used to increase the number of circulating CD34-positive cells in the peripheral blood which can be harvested by apheresis. Daily administration of G-CSF or GM-CSF (5-16 μg/kg) has been shown to increase the blood progenitor concentration by 40 to 100 folds and 2 to 20 folds respectively. The effect of hematopoietic growth factors is more if they are given after chemotherapy. Mobilization of progenitor cells may be accomplished by growth factors alone, collection commonly can be started on the fourth or fifth day of administration and continued for 2-4 days. In the near future the apheresis collection of allogeneic PBSC to repopulate the bone marrow of patients will be used in place of classic bone marrow transplant.

Once mobilization has reached an optimal level, a donor is scheduled for stem cell harvest. Donors are connected to the apheresis machine by their venous catheter. One lumen is used to draw blood out of the donor and into the machine. Here the blood is spun at high speeds in a centrifugation chamber housed within the cell separator machine. The desired stem cells are collected during the entire procedure, either in cycles or continuously, and the remaining blood components are returned to the donor through the second lumen of their catheter. This second lumen additionally can be used to administer intravenous fluids, electrolyte supplements, and medications to the patient. Each apheresis session lasts approximately 2-5 hours during which upwards to 30 litres of blood, or 6 times the average total human blood volume, is processed.

Collections can occur on a daily basis until the target CD34+ levels are achieved. The apheresis process can last for up to 4 days depending on donor characteristics and the mobilisation regimen utilized.

Records of Apheresis

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

Therapeutic Plasmapheresis and Cytapheresis:

Therapeutic Apheresis activity is allowed in the Blood Centre attached to the hospital having Apheresis facilities under the responsibility of Registered Medical Practitioner (RMP) who has obtained the consent of the patient and record of which shall be maintained and signed by the Blood Centre Medical Officer. This shall be done only at the written request of the patient's physician. Patient's informed consent shall be taken in the language he/she understands. The patient's physician will be responsible for providing emergency care to the patient.

Therapeutic Plasmapheresis is not a cure for the underlying disease but rather a way to provide short term relief. The process of therapeutic plasmapheresis is actually a plasma exchange rather than apheresis. During therapeutic plasma exchange, the pathological substances in plasma are removed and replaced with a fluid. The replacement fluid may be plasma, albumin, saline or combination of albumin and saline. The plasma is constantly replaced with the fluid so that patient's blood volume does not change. Plasmapheresis is indicated in the conditions mediated by plasma factors such as auto antibodies, immune complex, drugs or toxins bound to proteins, high cholesterol or triglycerides.

Therapeutic plateletpheresis can be used to treat patients who have abnormally elevated platelet count with related symptoms. i.e. myeloproliferative disorders like polycythemia vera. Therapeutic leucapheresis has been used to treat patients of leukaemia particularly with impending leucocytosis.

Therapeutic Phlebotomy

It is controlled removal of a large volume of blood. It is used mainly to reduce blood volume, red cell mass and iron stores. It is indicated for hemochromatosis, polycythemia vera, porphyria cutanea tarda, cyanotic congenital heart disease etc.

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BIO-MEDICAL WASTE MANAGEMENT

Biomedical Waste means any waste, which is generated during diagnosis, treatment or immunization of human beings or animals or in research activities pertaining there to or in the production or testing of biological and including categories mentioned in Schedule I

- Improper disposal / treatment of un-segregated and segregated medical waste are a potential hazard affecting the health of the patients, health care workers, the community as well as the environment.
- A notification regarding Biomedical Waste (Management & Handling) Rules, 1998 has been published by the Ministry of Environment & Forests.

Categories of bio-medical waste

Category 1	Human Anatomical Waste	Incineration/deep burial
Category 2	Animal waste	Incineration/deep burial
Category 3	Microbiology and biotechnology waste	Local autoclaving/microwaving
Category 4	Waste Sharps	Disinfection(autoclaving/ microwave/ shredding) Final disposal through authorized common BMW Treatment facility or secure landfill or concrete waste sharp pit
Category 5	Discarded Medicines and Cytoxic drugs	Incineration/ destruction and drug disposal in secured and fills
Category 6	Soiled waste (items contaminated with blood and body fluids)	Incineration/autoclaving/ microwaving
Category 7	Infectious Solid waste (tubing, caterers, intravenous sets etc)	Disinfection by chemical treatment autoclaving/microwaving and mutilation/ shredding
Category 8	Chemical waste	Disinfect chemically and discharge into drains

Colour Codes and Types of Containers for Disposal of Bio-Medical Waste

Colour Codes	Types of Container	Waste Category	Treatment Option
Yellow	Plastic Bag	Categories 1,2,5 &6	Incineration
Red	Plastic Bag/Puncture proof container	Categories 3,4,7	Autoclaving/microwaving/ chemical treatment, shredding then secure landfill
Blue	Plastic Bag	Category 8	As per Schedule
Black	Plastic Bag	Municipal Waste	Disposal as per MSW rules

Blood bank Bio-medical waste management

Sl. No.	Area	Type of Waste generated	Segregation	Treatement of waste Disposal
1.	Donor Screening area	Swabs	Yellow Bags	Incineration
		Lancets	Puncture proof Container with Hypochlorite	Landfill/Safe pit
		Micro pipette tip	Red Bag	Shredder
		Gloves	Red Bag	Shredder
2.	Blood collection room	Swabs	Yellow Bag	Incineration
		Bag Needle	Needle destroyer (Puncture proof container)	Landfill/Safe pit
		Blood Bag tubing	Red Bag	Shredder
		Gloves	Red Bag	Shredder
		Wrappers(All Labs)	Black Bag	Municipal garbage
3.	Component lab	Blood bag tubing	Red Bag	Shredder
		Apheresis Kits	Red Bag	Shredder
		Gloves	Red Bag	Shredder

Disinfection

Disinfection is the reduction in the number of pathogenic microbes so that the material/object/surface becomes safe for handling. Sodium hypochlorite is the most frequently used general lab disinfectant. Its advantages are that it is affordable, easily available and has virucidal and bacterial action. Its limitations are that the solution gradually loses its strength, hence requires daily preparation of fresh 1% solution from stock solution (generally available as 4%) and secondly it corrodes metals. Sodium hypochlorite should be poured in plastic jars or bins for use in labs.

Disinfection of glassware and plastic ware is achieved by immersing in 1% sodium hypochlorite for at least 30 minutes.

Autoclave

- Saturated steam under pressure is used to decontaminate infectious material.
- It consists of an insulated pressure chamber in which saturated steam is used to elevate the temperature
- A pressure of 15 psi at 121^0C for 45 to 60 minutes is required for adequate microbial destruction.
- Adequacy of disinfection to be checked with strips of B. Stearothermophilus at least once a month.
- Records of autoclaved blood unit must be monitored.

Discarding TTI Reactive Blood Unit

All the blood units which are reactive or are in the gray zone reactivity in the first run are discarded along with their components. The units which are found to be reactive are kept in the quarantine box. The details of these units are checked by the technical supervisors. Record is made in the discard register. It is confirmed and signed by staff nurse, technical supervisor and the medical officer. The unit is autoclaved and is allowed to cool. After that, it is put in red bag and sent for disposal following the Biomedical Waste Management Rules.

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BIOSAFETY

Biosafety is the use of laboratory practices, procedures and equipment for safety when working with potentially infectious microorganisms.

- **Good Laboratory Practices**
  - All samples should be treated as if they are potentially infectious
  - A biohazard sign must be displayed on the doors of the rooms where infectious agents are handled.
  - Entry to laboratory working area should only be allowed for laboratory personnel.
  - Doors to laboratory should always be kept closed.
  - Eating, Drinking or Smoking must be prohibited in the laboratory area.

- **Universal Precautions**

Universal (standard) precautions should be used consistently by all health care workers; these include barrier protection/ personal protective equipment like gloves, lab coats, occlusive bandages on skin abrasions or cuts, plastic aprons for staff, clean reusable items and disposing waste. Gloves should be of good quality, well-fitting and disposable. One should avoid touching exposed body parts like face with gloved hands and take precautions not to touch the door handles and computers with gloved hands. If gloves get torn while working, they should be removed immediately and hands washed with soap and running water. The protective lab coats and aprons should be removed while leaving the laboratory.

- **Safe Handling of Specimens and Sharps**

All samples should be collected in screw capped containers and capped securely to prevent spills and leaks. Disposable syringes and needles must be used for sample collection. Used needles should be disposed into a “puncture proof blue container”. Used needles should not be recapped. A hub cutter is to be used to cut the needle hub from the syringe. Used syringes to be discarded into red colored disposable bins. Sample (pilot tubes) from donors should be placed in racks in upright position and transported to labs in leak-proof plastic or rigid thermocol containers.

- **Management of Blood Spills**

Blood spills should immediately be covered with absorbent paper or gauze sponges to contain the spread of blood. Gloves must be worn while handling blood spills. It should then be covered with 1% sodium hypochlorite for at least 30 minutes. The paper

towels/gauze should be disposed as biohazard waste. Any broken glass piece should be swept with dustpan and brush and disposed as sharps.

- **Hepatitis B Vaccination for all laboratory staff**

All blood centre staffs should be vaccinated for Hepatitis B with three doses (0, 1 &6 months). Revaccinations should be considered for health care providers working in high risk environment once in 10 years. Previously vaccinated health care workers need to check the Hepatitis B antibody titre and revaccinate if the titres are less than 10IU.

- **Post Exposure Prophylaxis(PEP)**

An exposure that may place a health care worker at risk of contracting blood borne infections is defined as a percutaneous injury which may be through mucous membrane contact, prolonged contact with intact skin or immediate contact with breached skin. The exposure must be reported to the laboratory supervisor immediately and the staff health services and treated as an emergency. The exposed site should be washed immediately. Blood should be collected for testing after written informed consent.

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QUALITY MANAGEMENT IN BLOOD TRANSFUSION SERVICES

Quality is defined as the degree to which product or services satisfy a specified set of attributes or requirements.

Quality control: It is the monitoring system that checks the effectiveness of quality assurance by testing the quality of final products by checking the quality fulfilment of a product, process or a service.

Quality assurance: It is ensuring of quality by taking measures to maintain the standards of all the critical factors at a specified optimum level i.e. to ensure all work is done according to standards.

Quality management: Co-ordinated activities to direct and control an organisation in regard to quality and includes- quality control and quality assurance to be achieved by Good Manufacturing Practices/ Good Laboratory Practices/ Good Clinical Practices, planning and improving.

Total Quality Management: Management approach of an organisation centered upon quality based on participation of all the staff and aiming at long term success through customer satisfaction and benefits to all staff and society.

Need for quality in Blood Transfusion Services

- Appropriate and effective use of blood
- Prevention of errors and risks
- Protection of donors, recipients and staff
- Safe and adequate blood supply
- Self sufficiency
- Confidence in the system of all concerned
    - Public-potential donors/recipients.
    - Regulatory authorities.
    - Management and staff.

As per "*Standards on Blood Banks/Blood centers and Transfusion services*" Quality Management System is divided into ten quality essentials:

1. Organisation and management
2. Accommodation and environment
3. Personnel, Equipment
4. External services and supplies
5. Process control
6. Identification of deviation and adverse events
7. Performance improvement
8. Documentation and document control
9. Records and test reports
10. Internal audit and management review

Quality Control for Reagents

Reagent requirements: It should be stored at prescribed temperature and hygienic place and should also be sterile, pyrogen free, pure and potent, containing a preservative. It must be used according to manufacturer's instructions and tested regularly for appearance, specificity, avidity, reactivity and potency.

Quality Control of ABO Reagent

Parameters	Quality Requirement	Frequency
Appearance	No turbidity, precipitate, particles or gel formation by visual inspection	Daily
Specificity	Positive reaction with red cells having corresponding antigen(s); and no reaction with negative control	Daily and with each new lot
Avidity	Macroscopic agglutination with 10% red cells suspension using the slide test;	Daily and with each new lot
Reactivity	No immune haemolysis, rouleaux formation or Prozone phenomenon.	Each new lot
Potency	Serum should give +++reactions in saline tube test using a 3% red cells suspensions at room temperature.	Each new lot

QUALITY CONTROL-ANTISERA

ANTISERA	TITRE	AVIDITY
Anti-A A1 cells A2 cells A2B cells	 >256 >128 >64	 3-6 sec 5-6 sec 5-6 sec
Anti-B B cells A2B cells	 >256 >128	 3-4 sec 5-6 sec
Anti – AB A1 cells B cells A2 cells	 >256 >256 >128	 3-4 sec 3-4 sec 5-6 sec

Quality Control of Anti-D Antisera

Parameter	Quality Requirements	Frequency
Appearance	No turbidity, precipitates, particles or gel formation by visual inspection.	Each day
Specificity	Clear reaction with O positive red cells and no reaction with O negative cells.	Daily and each new lot
Avidity	Macroscopic agglutination with 40% red cells suspension using slide test .	Daily and each new lot
Reactivity	No immune haemolysis , Rouleaux formation or prozone.	Each new lot
Potency	Sera should give 3+ reaction in saline tube test using a 3% red cell suspension at R.T.	Each new lot

ACCEPTABLE TITER AND AVIDITY

Type of Reagent	Type of red cells	Titer immediate spin	Titer 30 min incubation	Avidity time(s)
IgM monoclonal	O positive	1:64-1:128	1:64-1:128	5-10
Blend of IgM+IgG monoclonal	O positive	1:32-1:64	1:128-1:256	10-20

Quality Control of AHG Antisera

Parameter	Quality Requirements	Frequency
Appearance	No turbidity, precipitates, particles or gel formation by visual inspection.	Each day
Reactivity & Specificity	No Prozone phenomenon.	Each new lot
	No haemolysis or agglutination of unsensitized red cells	Each new lot
	Agglutination of red cells sensitized with anti-D sera	Daily
	Agglutination of red cells sensitized with complement binding antibody	Each new lot
	Agglutination of red cells sensitized with C3b and C3d	Each new lot.

Reagent Red Cells

The red cells used are A cells, B cells and O cells. The cells needs to be washed 3 times in saline to remove serum, plasma, haemolysed cells, small clots which may lead to false positive reactions. The supernatant of last wash should be clear. 2-5% cell suspension should be used for conventional tube techniques. Reagent red cells can be used for reverse ABO grouping, antibody screening, antibody identification and antibody titration.

- **Quality control of Reagent Red cells**

Known red cells	Anti-A	Anti-B
A	4+	Negative
B	Negative	4+
O Positive	Negative	Negative
O Negative	Negative	Negative

Parameter	Quality Requirements	Frequency of Testing
Appearance	No Haemolysis in supernatant	Daily
Reactivity	Clear cut reactions with known antisera	Daily

Quality Control of Blood Components

Indian standards for quality control of blood components:

- Drugs and cosmetics act 1940, Rules 1945(Schedule F, Part XII-b), Govt of India.
- Blood bank standards of NACO, ministry of health and Family Welfare, Govt of India.
- NABH Accreditation Standards for Blood Banks.

➢ Should be performed on at least 1% of all components produced per month for all parameters to be measured.
➢ If fewer than 100 per month, then at least 4.
➢ 75% or more of components monitored must meet specifications.

Quality control of whole blood

Parameter	**Quantity Requirement**	**Frequency of Control**
Volume	350/450 ml + 10%	1% of all units
Anticoagulants	49/63 ml	1% of all units
PCV (Hct)	30 to 40%	4 units per month
Serology HIV1+2, HBsAg, CV,MP, Syphilis)	Negative by ELISA	All units
Sterility	By culture	4 units/month (whichever is higher)

*If 100 units per month then 1% of all units to be checked.

➢ Visual examination of bag for any leakage, precipitate, colour change or evidence of haemolysis.
➢ Volume measurement :-

$$\text{Volume(ml)} = \frac{\text{Total weight of bag(gm) - Weight of empty bag(gm)}}{\text{Specific gravity of component}}$$

➢ Collection of sample and sending for culture
  - Samples should be collected from the blood bags
  - It should be sent to the Department of Microbiology for culture.

Quality Control of red cell concentrates (Prepared from 450 ml Blood)

Parameter	**Quantity Requirement**	**Frequency of Control**
Volume	280 + 40 ml	1% of all units
PCV (Hct)	70%+ 5%	Periodically
Sterility	By culture	Periodically (1% of all units)

Quality Control of red cell in preservative sol. (ADSOL/SAGM)

Parameter	**Quantity Requirement**	**Frequency of Control**
Volume	350 + 20 ml	1% of all units
PCV (Hct)	55-65%	Periodically (1% of all units)
Sterility	By culture	Periodically (1% of all units)

Quality Control of Platelet concentrates prepared from Whole Blood.

Parameter	**Quality Requirements**	**Frequency of control**
Volume	50-70 ml	All units
Platelets count	$\geq$ 5.5 x 1010	4 units per month/ 1% of all units (whichever is more)
pH	>6.0	4 units per month/ 1% of all units (whichever is more)
RBC contamination	<0.5ml	4 units per month/ 1% of all units (whichever is more)
WBC contamination	$<5.5x10^7$-$5x10^8$	4 units per month/ 1% of all units (whichever is more)

Quality Control of Platelet concentrate by Apheresis

Parameter	**Quality requirement**
Volume	>200 ml
Platelets count	$\geq 3.0 – 7.0 \times 10^{11}$
pH	> 6.0 (at the end of permissible storage period)
Residual leucocytes	$< 5.0 \times 10^6$
Red cells	Traces to 0.5 ml

- Swirling test indicates viability of platelets during storage.
- Swirling movement indicates maintain of discoid shape.

Quality Control of Fresh Frozen Plasma

Parameter	Quality Requirements	Frequency of control
Volume	200–220 Plasma	4 units per month/ 1% of all units (whichever is more)
Stable coagulation factors	200 units of each factor	4 units per month
Factor VIII	0.7 units/ml	4 units per month
Fibrinogen	200–400 mg	4 units per month

Quality Control of Cryoprecipitate

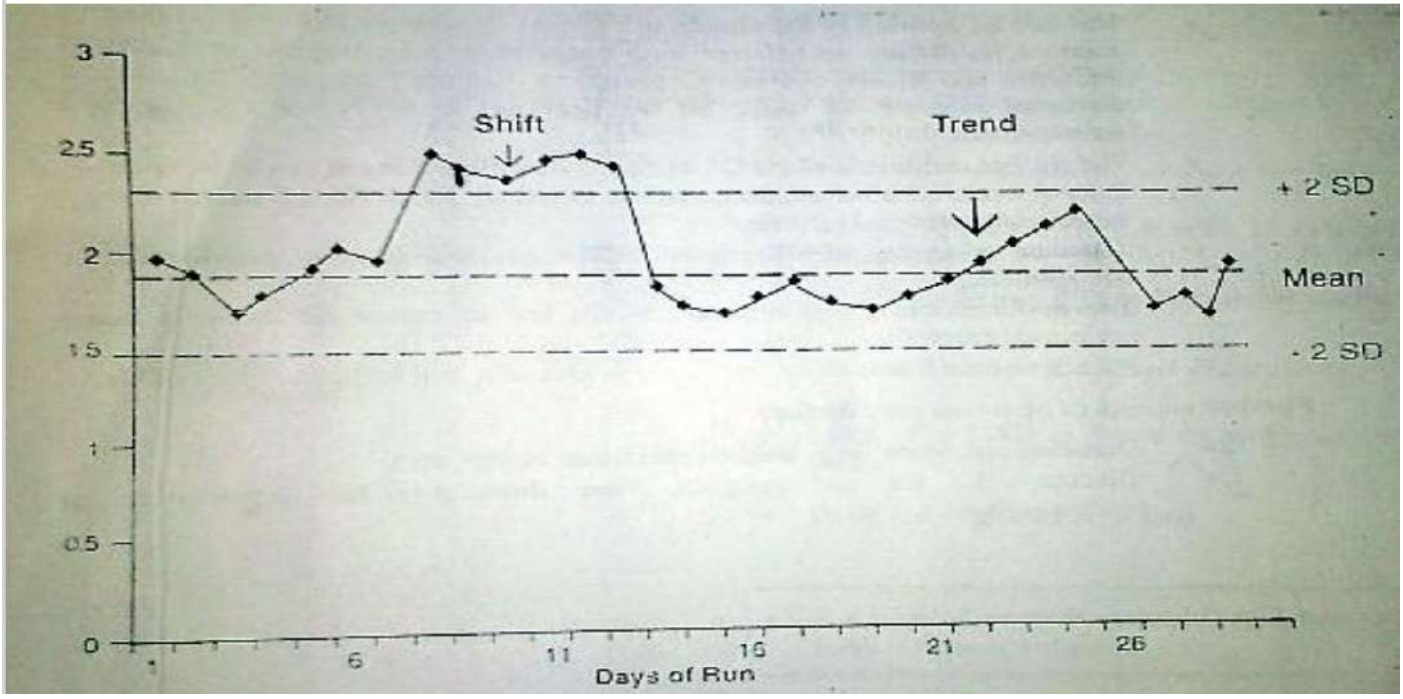
Parameter	Quality Requirements	Frequency of control
Volume	10–20 ml	1% of all units
Factor VIII	80–120 units	1% of all units
Fibrinogen	150–250 mg	1% of all units

Essential Elements Governing Quality in TTI

- Quality of specimen used for testing
  - Should be properly labelled, sterile and clear
  - Lipemic, haemolysed and contaminated specimens do not yield reliable results.
- Quality of kits
  - Should show high sensitivity and specificity
  - Should be approved by certifying authority (DGCI, NACO)
- Quality and calibration of Equipments
  - Standard equipments should be used along with periodic calibration and servicing.
  - Proper documentation should be maintained.
- Validation
  - Assuring that a system, process or equipment is performing the way it is supposed to do
  - Validation tools:
    - Positive and negative control in every test run
    - Additional measures like mechanical readers.

- Interpretation of test results
  - Readings and calculations should be checked by two individuals.
  - Validation should be done for every run.
  - Record should be maintained.
- Controls used in the assay for testing
  - Internal controls
    - It is provided along with kit.
    - Should be used in batches of kit from which they originate
    - Do not detect minor deterioration
  - External controls
    - Controls from outside.
    - It can detect minor errors.
- Levey – Jennings Charts
  - The Levey-Jennings chart usually has the days of the month plotted on the X-axis and the control observations plotted on the Y-axis.
  - By observing the data plotted in the L-J chart, we can determine if test results are in control and accurate, or if test results are not in control and consequently unacceptable.
  - Include at least 30 runs on the same graph.
  - Change of operator and batch of assay should be recorded.

Chart showing shift and trend



L J chart

Scope and application: Detection of the following:

- Systematic variation
    - Trend-Results change gradually in either direction indicating slowly changing parameters-deteriorating reagents, equipment failing. Six consecutive points should be distributed in one general direction.
      Causes are:
        - Deterioration of reagents.
        - Slowly faltering equipment.
    - Shift-Results fall sharply on one side of the mean indicating a major change has occurred. Control values of six consecutive runs should fall on one side of the mean.
      Causes are:

        - Switching to new lot of kits
        - New reagents
        - Changes in incubation temperature
        - New technical hand
- Random variation

    - Observance of one result, significantly different from other results without any pattern

  Causes are:

    - Transcription errors
    - Sample mix-up
    - Poor pipette precision
    - Poor mixing of samples
    - Reader not calibrated
    - Washing inconsistent

- Lot to lot variation
- Day to day variation

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E-RAKTKOSH REGISTRATION

In 2016, the government launched an initiative called E-Raktkosh (Rakt-Blood, Kosh : Repository) a web based mechanism that integrates all blood banks in the state into a single network, providing information about blood camps and availability of blood in hospital throughout the country.

Objective

i. Safe and adequate blood supplies.
ii. Reduced turnaround time.
iii. Preventing wastage of blood.
iv. Restrict professional donor.
v. Networking of blood banks.
vi. Donor repository.

Salient Features

i. Web based application
ii. Adhaar linkage
iii. Decision support
iv. Enforce guidelines
v. Dashboard

E-raktkosh has six major components for management of the blood donation life cycle.

i. The biometric donor management system for identifying traking and blocking donor based on donor health donation history.
ii. It provide features such as blood grouping. TTI screening, antibody screening, component preparation etc. as per the defined process and rules.
iii. A centralised blood inventory management system for keeping track of the blood stock across numorous blood banks.
iv. Biomedical waste management system for disposal of discard blood and other waste generate during the process.
v. Generation of rare blood group donor register and the generation of regular repeat donor.
vi. Alert notification system.

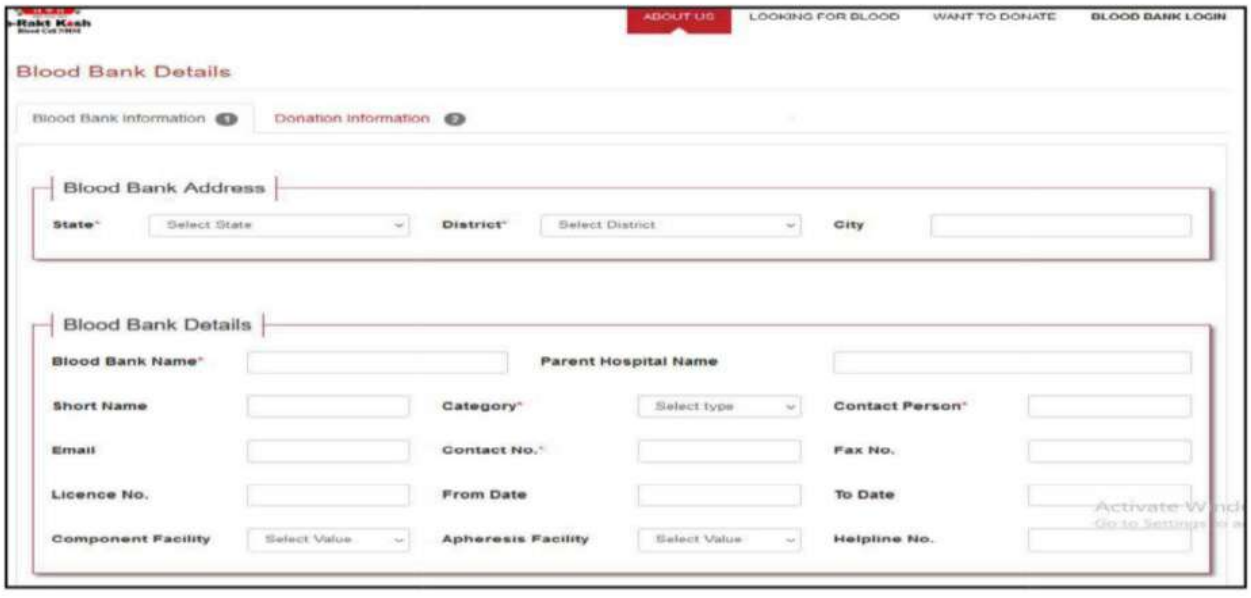
PROCESS OF REGISTRATION

Steps for registration of Blood Banks on e-RaktKosh

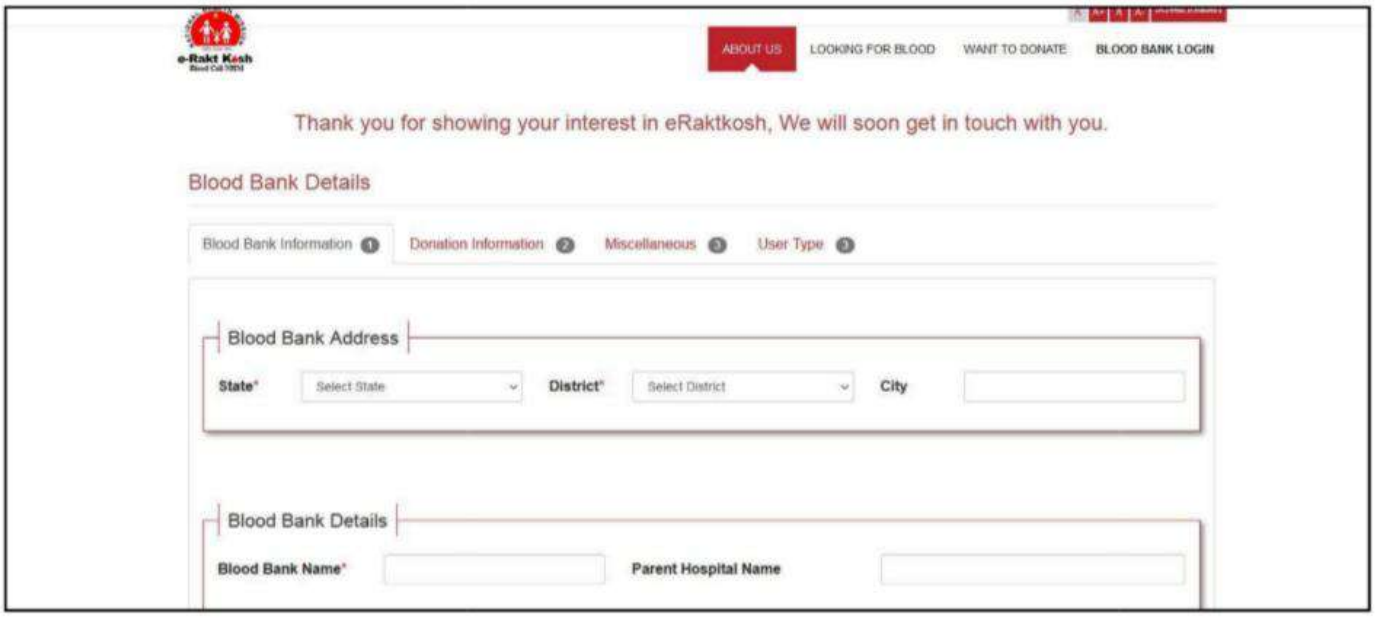
As per the directions of MoHFW Blood Banks needs to register on e-RaktKosh to provide the Blood Stock Availability, Monthly Report and Donor Details. Steps to register on e-RaktKosh are as follows

1. Go to www.eraktkosh.in
2. Click on Blood Bank Login and then click on Add Your Blood Bank

3. Fill the Blood Bank Details and submit it.



4. After successfully submission of form Message will appear as



5. After adding the blood bank valid license copy should be submitted at eraktkosh@cdac.in . The portal login will be provided only after the verification of the license copy.

6. For any query please drop a mail at **eraktkosh@cdac.in**

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HOSPITAL TRANSFUSION COMMITTEE

Roles, Responsibility and Conduct of Hospital Transfusion Committee

Members

i. Chairman : Institutional head or clinical division head.
ii. Member Secretary: In-Charge Blood Centre.
iii. Members : Head of Department, Surgery
Head of Department, Gynaecology
Head of Department, Medicine
Head of Department, Paediatrics
Administrative officials of the hospital
Matron / Nursing Superintendent

Responsibilities

i. Formulating policies for use of blood and blood products.
ii. Developing guidelines for use of blood (Plasma substitutes)
iii. Establishing maximum surgical blood ordering schedules (MSBOS)
iv. Monitoring source and supply of blood.
v. Monitoring adverse effect of blood transfusion.
vi. Auditing blood transfusion practices.

Rules and Regulations

i. The committee shall convene the meeting, preferably in the first week once in three months or as early as possible when required. Number of meetings varies as per institutional requirements. With minimum of two meeting per annum.
ii. The blood bank in-charge shall fix the meeting date and time in consensus with the head of the institutional/ hospital and shall inform the other members accordingly.
iii. A separate register has to be maintained for attendance and minutes of the meeting.
iv. Quorum for the meeting shall be 60% of the number of members.

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HAEMOVIGILANCE

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

Aims and Objectives

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

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

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

iv. The blood centre shall develop a procedure to obtain all the details of adverse transfusion reactions to be able to report to HvPl. The blood centre shall ensure the training of clinical and paramedical staff for appropriate reporting of adverse transfusion reactions to transfusion services.

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

Documenting and Reporting of Adverse Reactions/ Events Associated with Transfusion of Blood and Components:

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

Responsibilities of Medical and Nursing Staff

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

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

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

iv. Protocol for the investigation of an acute transfusion reaction is given at annexure-9 Assess the incompatibility levels of the adverse reactions in coordination with the Department of Transfusion Medicine/ Blood Centre.

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

Responsibilities of the Department of Transfusion Medicine/ Blood Centre

i. The transfusion service shall be responsible for documenting and reporting transfusion reactions and complications to the national haemovigilance program.
ii. Reports in details of the clinical and laboratory investigation shall be provided to the respective clinical ward and to the Hospital Transfusion Committee.
iii. To do the investigations as per the workup form and documenting the results in the workup form.
iv. To enter the necessary details as per the documentation required in the Transfusion Reaction-Traceability document (TR-TD)
v. Determine the incompatibility levels of the adverse reactions.
vi. Custodian of the Transfusion Reaction-Traceability document (TR-TD)
vii. To assure the completeness of the Transfusion Reaction-Traceability document (TRTD)
viii. Report the details as per the transfusion reaction reporting form to the technical associate Pharmaco Vigilance Program of India (PvPl).
ix. The hospital transfusion committee shall periodically review the adverse reactions reported and provide guidance and support for improvement.

Details of Records

Records of the donor for Blood/ components:

- Demographic details of the donor
- Identification number
- Donor selection record
- Medical history
- Physical examination.
- Donor deferral records
- Donor's blood collection record
- Date of collection
- Batch No. and bag manufacturer's name

- Segment number on the donor tubing
- Particulars of donor.
- Identification number
- Amount of blood collected
- Time and duration of the collection
- Signature of phlebotomist and medical officer
- Donor Reactions

Blood Components Records

- Identification number
- Name and volume of components prepared
- Date, time and mode of preparation
- Disposition record with traceability
- Records of blood and components from outside Blood Centre
- Identification number
- Name of the component
- Name of collecting facility
- Date of collection, expiry & all testing records
- Daily temperature of equipment and ambient temperature records.
- Equipment maintenance records
- Quality assurance (internal and external) records
- Staff attendance register records or any other system
- Staff specimen signature register
- Blood (Hospital) Transfusion Committee records
- Grievance redress feedback registers Record of incident reports.
- Referral records of blood donors to ICTCI/STD clinic/ clinicians
- Any other records made mandatory by National/ State blood transfusion Council or by the regulatory Agencies.
- E-Raktakosh reporting records

List of Records and Documents Required in the Blood Centre

(1) Blood donor record: It shall indicate serial number, date of donation, name, address of donor with other particulars of age, weight, hemoglobin, blood grouping, blood pressure, medical examination, bag number and patient's detail for whom the donor is donating in

case of replacement donation, category of donation (voluntary / replacement) and deferral records and signature of Medical Officer.

(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 test of antibodies, HIV I and HIV II antibodies, malaria, V.D.R.L., Hepatitis B surface antigen and Hepatitis C Virus antibody and regular antibodies (if any), name and address of the donor with particulars, utilization issue number, components prepared or discarded and signature of the medical officer(s)

(3) Issue register: It shall indicate serial number date and time of issue bag serial number ABO/Rh Group, total quantity in ml, name and address of the recipient, group of recipient, unit/institution, details of cross-matching report, and indication for transfusion.

(4) Records of components supplied: Quantity supplied, compatibility report, details of recipient and signature of issuing person.

(5) Records of ACD/CPD/CPD-A/SAGM/ any other approved anticoagulant and preservative bags giving details of manufacturer, batch number, date of supply, and results of testing.

(6) Register for diagnostic kits and reagents used: name of the kits/reagents, details of batch number, date of expiry and date of use.

(7) Cross-matching/ Compatibility report: The blood Centre should issue the cross matching report of the blood/ components to the patient together with the blood/component unit.

(8) Transfusion adverse reaction records.

(9) **Records of purchase, use and stock in hand** of disposable needles, syringes, blood bags shall be maintained.

Other Records:

i. Daily stock register/ record (group-wise) showing collection, processing, issue and balance.

ii. Component preparation records (if applicable)

iii. Discard and/or autoclaving register

iv. Records of communication with the State Blood Transfusion Council

v. Records of communication (applications/ intimations) to State Drug Controller cum licensing authority.

vi. Haemovigilance records.

Record of processing of donors' blood

- ABO (cell & serum grouping) and Rh (D) type.
- Antibody screening and identification
- Anti-HIV 1 & 2, Anti-HCV, HBsAg, Syphilis malaria tests and interpreted.
- Details of grouping indicating reaction results, batch number and manufacturer's name of reagents in use, details of reagent red cells in use.
- Details of all infectious disease tests, including ELISA/CLIA printouts showing results and interpretation as well as batch number, expiry date and manufacturer's name of the kit in use. All rapid tests/spot tests should be interpreted preferably by two competent individuals and recorded.

Quality control records indicating testing of components, reagents Records of apheresis procedures and Records of Recipient

- Blood requisition form with full particulars of the recipient and identification number.
- Results of ABO and Rh (D) tests and their interpretation.
- Interpretation of compatibility tests.
- Compatibility record.
- Report of adverse reaction and record of their investigation.

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BLOOD STORAGE CENTER AND LINKAGES

As blood centre is fully equipped to collect blood at its premises and also has mobile teams which go out frequently to hold blood donation camps and accordingly it has stored in the blood centre. The blood centre acts as a mother blood centre to its storage centres for smooth conduction of blood transfusion.

The blood centres who intend to supply the blood units / components shall test the following mandatory test before supply to blood storage centres.

a) Blood grouping
b) Anti body testing
c) Haemoglobin content
d) Hepatitis B surface antigen
e) Hepatitis C Anti body
f) Malaria Parasite
g) Syphilis or VDRL

Technical requirement of Blood storage centre which receives blood from mother blood centre:

a. Blood centre refrigerator having capacity of 50-60 standard blood bags.
b. Binocular microscope
c. Bench top centrifuge
d. Slide/tube etc.
e. Antisera kits

For opening of blood storage centre the NOC to be issued from SBTC and for license it is to be issued from CDSCO/Drug Licensing Authority.

i. First referral Units, Community Health Centres, Primary Centres or any other hospitals are required to obtain approval for setting up of blood storage facility from the State/Union Territory licensing authority.

ii. The main aim of setting up blood storage facilities is to make abundant availability of whole human blood or its components to the said hospitals without starting a new blood centre.

iii. The blood storage facility is feasible without opening a blood centre to manage life-threatening situations in case of maternal mortality and accidents etc.

Approval of Blood Storage Facility

- An application has to be made as per the guidelines in a prescribed format. The State Licensing Authority shall approve the blood storage unit after satisfying the conditions and facilities through inspection.

- The approval shall be valid up to a period of two years from the date of issue unless suspended or cancelled. An application for renewal will have to be made three months prior to the date of expiry of the approval.
- Before applying for approval, the storage centre will have to identify and obtain consent from the Blood Centre from where they will get the supply of blood/blood components. These could be licensed Blood Centres run by Government Hospitals / Indian Red Cross/Regional Blood Transfusion Centres or any other licensed Blood Centre with a good inventory of blood/ components. In case the license of the parent Blood Centre/centre is cancelled, the license of the storage centre will also be automatically cancelled.
- The storage centers can, however, get affiliated to more than one Blood Centre to ensure uninterrupted supplies, but a separate approval will be required each case.

Requirements

- **Space:** The area required for setting up the facility is 10 square meters, well lighted clean and preferably air-conditioned.
- **Manpower**: In the present phase, no additional staff is required. One of the existing Medical Officer and laboratory technicians should be designated for this purpose. They could be trained in the operation of blood storage centres and other basic procedures like storage, blood grouping, cross-matching and release of blood. The Medical Officer designated for this purpose will be responsible for the overall working of the storage centre.
- **Electricity**: Regular 24 hrs. supply is essential. Provision of backup required. It is necessary to maintain the cold chain at all levels, i.e. from the mother centre to the blood storage centre to the issue of blood. This can be achieved by using insulated carrier boxes. During transportation, the blood should be properly packed into cold boxes.

The storage centre should check the condition of blood on receipt from the mother centre and also during the period of storage.

Fresh frozen plasma and platelets concentrate are required to be stored; the storage procedures of the mother blood centre should be followed.

Patients' blood grouping and cross-matching shall be carried out before of blood is issued. A proper record of this should be kept. First in and First out (FIFO) policy, whereby blood closer to expiry date is used first, should be followed.

The Centre shall maintain proper records of all the documents for 5 years.

*****

REFERENCES

1. NBTC, National Standards for Blood Centres and Blood Transfusion Services.
2. Training Module for Blood Banks Medical Officer and Lab Technicians, Ministry of Health and Family Welfare, Government of India.
3. Transfusion Medicine, Technical Manual. Directorate General of Health Services, Ministry of Health and Family Welfare, Government of India.
4. Drug & Cosmetic Act 1940 and Rules 1945, The Medical Device Rules 2017.
5. National Blood Policy, India.
6. NABH standards 3rd edition

Key Website:

1. http://naco.gov.in
2. http://cdsco.gov.in/opencms/opencms/en/nonel.
3. http://nib.gov.in
4. http://nabh.co.in

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BLOOD STORAGE ROOM


COUNSELLING ROOM


BLOOD COLLECTION ROOM


DONOR REFRESHMENT


BLOOD CENTRE
BLOOD ISSUE


DONORS REFRESHMENT ROOM
REGISTRATION


BLOOD GROUPING & SEROLOGY ROOM


तेरापंथ युवक परिषद, नगाँव
MEGA BLOOD DONATION DRIVE


GIVE THE GIFT OF LIFE TO OTHERS.
DONATE BLOOD !
A SINGLE DROP OF BLOOD CAN MAKE A HUGE DIFFERENCE.

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ASSAM STATE BLOOD TRANSFUSION COUNCIL
KHANAPARA, GUWAHATI – 22