



"Training of Trainers for Strengthening of Blood Services & e-Rakt Kosh"

Training Manual



**Ministry of Health & Family Welfare
Government of India,
India**



Honourable Health Secretary *Shri C K Mishra*, who is also a regular voluntary donor, donating Blood in a voluntary blood donation camp held at Ministry of Health and Family Welfare, Government of India, Nirman Bhavan, New Delhi





"Training of Trainers for Strengthening of Blood Services & e-Rakt Kosh"

TRAINING MANUAL



Blood Cell

National Health Mission

Ministry of Health & Family Welfare

Government of India



National Institute of Biologicals

Ministry of Health & Family Welfare

Government of India

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जगत प्रकाश नड्डा
Jagat Prakash Nadda



MESSAGE

स्वास्थ्य एवं परिवार कल्याण मंत्री
भारत सरकार
Minister of Health & Family Welfare
Government of India

National Health Mission (NHM) has recently taken numerous steps towards a comprehensive and total quality management approach for blood services by not only leveraging the use of ICT but also by providing the technical and financial assistance to the States/UTs to modernize their blood banks. The e-Rakt Kosh, a Centralized Blood Bank Management Information System has been conceptualized and developed as a comprehensive IT solution for streamlining the workflow of blood banks across the country as per standard operating procedures and fulfils the need of diverse stakeholders. This web based mechanism inter-connects all the Blood Banks of the State into a single network and provides key information regarding availability of blood by type, location of Blood Banks, etc.

While the Country has made significant progress in many RCH indicators that progress has not been commensurate in putting in place the requisite blood service infrastructure and a modern transfusion services network. Infrastructural modernization and the technical upgrading of skills in the blood banks would facilitate access to improved blood services along with a dynamic and modern transfusion services network.

I am happy to note that the National Health Mission along with National Institute of Biologicals has developed a training manual for E-Rakt Kosh services and strengthening of blood services.

I hope that the States will find the manual useful in strengthening the blood services in their States.

(Jagat Prakash Nadda)



सी.के.मिश्रा
सचिव
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भारत सरकार
स्वास्थ्य एवं परिवार कल्याण विभाग
स्वास्थ्य एवं परिवार कल्याण मंत्रालय
Government of India
Department of Health and Family Welfare
Ministry of Health & Family Welfare

MESSAGE

I am glad to know that National Health Mission, Government of India, in collaboration with National Institute of Biologicals (NIB) is conducting Six Day Residential training programme on “Training of Trainers for e-Rakt Kosh software training & strengthening of Blood Services” for Blood Bank officials of the eleven states; Assam, Bihar, Chhattisgarh, Gujarat, Jharkhand, Madhya Pradesh, West Bengal, Uttarakhand, Uttar Pradesh, Tamil Nadu, Telangana from 07.11.2016 to 12.11.2016. The Programme aims at strengthening blood services in these states in the areas of e-Rakt Kosh software for transparent & streamlined workflow of the blood services, Transfusion Transmitted Diseases, Blood Group Serology, Equipment Maintenance and their Quality Assurance, Haemovigilance, Analysis of gaps in Blood Bank Management and Total Quality Management Systems. The basic objective of this training is to improve the standards of Blood services in our country.

This training programme has been initiated keeping in mind the convergence with “Pradhan Mantri Kaushal Vikas Yojana (PMKVY)” which emphasizes on ‘Skill Development’. I am sure, this will help facilitate in building up a ‘National Talent Pool of Skilled and Trained Manpower’ to improve the quality, safety and efficacy of blood and blood products.

I am confident that these training programmes will help Blood Banks to improve their standards and enable them to provide excellent services for safeguarding public health.

I wish all success for the training programmes.


(C.K. Mishra)



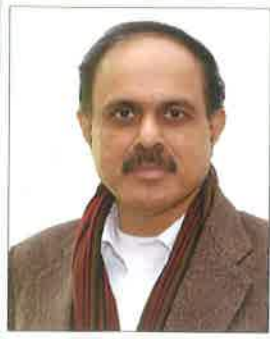
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4.11.2016

MESSAGE

Blood is essential for human life and has no substitutes. Throughout the world, the blood services aim provide a lifesaving service by ensuring an adequate supply of safe blood. The crying need is to ensure the provision of safe blood and its components. There is need of skilled and Trained Manpower to improve the quality, safety and efficacy of blood and blood products by adhering to the norms of good laboratory practice (GLP), good manufacturing practices (GMP). This requires capacity building. A trainer may encounter resistance from both employees and managers. However, a trainer can combat this by demonstrating that training is actually a crucial part of employees' and managers' work.

To improve the standards of Blood services in the country National Health Mission, Government of India, in collaboration with National Institute of Biologicals, Noida is conducting six day residential training programme on "Training of Trainers for e-Rakt Kosh software training & Strengthening of Blood Services" for Blood Bank officials for eleven states from 07.11.2016 to 12.11.2016.

This training will improve the skills of blood bank officials of the states for strengthening the blood services and further enable them to provide excellent services to the society.


(Dr. Arun Kumar Panda)

Healthy Village, Healthy Nation



एड्स - जानकारी ही बचाव है
Talking about AIDS is taking care of each other



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MESSAGE

Blood Services are a crucial component of curative healthcare services. Adequate and safe supply of blood and blood components is essential to enable care of critical patients in the hospitals.

Blood cell NHM envisions comprehensive and well integrated and sustainable blood banking services in the country with availability of safe blood which is accessible to all. Capacity building in the field of blood services is an important component for ensuring such blood services.

Access to safe blood in rural areas of India continues to be a challenge. Blood banks and blood transfusion centres operate in total isolation; their standards vary from from centre to centre .

To maintain universal basic standards across the country a training manual with several consultations with the experts from Blood Transfusion, CDSCO, NIB and NHM has been prepared for dissemination amongst stakeholders.

I hope the Six Day Residential training programme organized by National Health Mission, Government of India, in collaboration with National Institute of Biologicals (NIB) for "Training of Trainers for e-Rakt Kosh software training & Strengthening of Blood Services" for Blood Bank officials will help in strengthening of the blood services in the country.

(MANOJ JHALANI)

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Director

Message

National Institute of Biologicals, an autonomous institute under Ministry of Health and Family welfare ensures quality of biologicals and vaccines in the country. The institute responsibly assures and reviews the quality of number of Biological products available through domestic manufacturers or imports. The operations are carried out in close coordination with Government of India regulatory authorities as Office of Drug Controller of India, Indian Pharmacopoeia Commission.



National institute of Biologicals and National Health Mission are organizing six days residential training programme on "Training of Trainers for Strengthening of Blood Services & e-Rakt Kosh" for Govt. Blood Bank Officials of different States across the country at NIB, NOIDA.

One of the important mandates of the institute is to provide scientific trainings to disseminate the knowledge & expertise in quality control of Biologicals. The institute regularly imparts Hands on Training in the areas of Transfusion Transmitted Infections, Blood Group Serology & its EQAS, Total Quality Management System (TQMS), Haemovigilance Programme of India (HvPI) to improve the standards of Blood Banks and the Blood Transfusion services in our country.

The Hands-on-Training imparted to the trainees in the NABL-accredited and CDL-notified Laboratories of NIB will be a right step in this direction. The training sessions include lectures and presentations from eminent Speakers & Senior Faculty drawn from the Institutes, Academia and Transfusion Medicine Departments across the country.

Given these inputs, I am confident that these training programmes will help to strengthen the standards of Blood Service and Protect & Promote Public Health by Safe Blood Transfusion Practices.

Dr. Surinder Singh

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Abbreviation

Ab	Antibody
ACD	Acid Citrate Dextrose
ADRRF	Adverse Donor Reaction Reporting Form
Ag	Antigen
AHTR	Acute Hemolytic Transfusion Reaction
AMC	Annual Maintenance Contract
BSA	Bovine Serum Albumin
BTS	Blood Transfusion Services
BTI	Blood Time Temperature Indicators
CAPA	Corrective and Preventive Action
CBMWF	Common Biomedical Waste Treatment Facility
CDAC	Centre for Development of Advanced Computing
CDSCO	Central Drugs Standard Control Organization
CLIA	Chemiluminescent Immunoassay
CMC	Comprehensive Maintenance Contract
CPD	Citrate Phosphate Dextrose
Cryo	Cryoprecipitate
CUE	Confidential Unit Exclusion
D&C Act	Drugs and Cosmetic Act
DEO	Data Entry Operator
DGHS	Directorate General of Health Services
DHTR	Delayed Haemolytic Transfusion Reaction
DQ	Design Qualification
ELISA	Enzyme Linked Immunosorbent assay
EMMS	Equipment Management & Maintenance System
EQAS	External Quality Assurance Scheme
FFP	Fresh Frozen Plasma



FNHTR	Febrile Non Hemolytic Transfusion Reaction
GLPs	Good Laboratory practices
HA	Haemagglutination
HBV	Hepatitis B Virus
HCFs	Health care facilities
HCV	Hepatitis C Virus
HER	Electronic Health Records
HIV	Human Immunodeficiency Virus
HOD	Head of Department
HTC's	Hospital Transfusion Committees
HvPI	Haemovigilance Programme of India
IAT	Indirect Antiglobulin Test
ICT	Information and Communications Technology
ICTC	Integrated Counseling & Testing Centre
IHN	International Haemovigilance Network
IQ	Installation Qualification
ISBT	International Society of Blood Transfusion
LISS	Low-ionic strength solution
MO Incharge	Medical Officer Incharge
MTP	Massive Transfusion Protocol
NABH	National Accreditation Board for Hospitals & Health Care Providers
NACO	National AIDS Control Organization
NAT	Nucleic Acid Amplification Technology
NBDVP	National Blood Donor Vigilance Programme
NCC	National Coordinating Centre
NIB	National Institute of Biologicals
OQ	Operational Qualifications
PA	Particle Agglutination



PEG	Polyethylene glycol
PQ	Performance Qualification
PRBC	Packed Red Blood Cell
PRP	Platelet Rich Plasma
PT	Proficiency Testing Programme
PvPI	Pharmacovigilance Programme of India
QMS	Quality Management System
RCF	Relative Centrifugal Force
RDP	Random Donor Platelets
SDP	Single Donor Platelets
SOPs	Standard Operating Procedures
TACO	Transfusion Associated Circulatory Overload
TAD	Transfusion Associated Dyspnea
TRALI	Transfusion-Related Acute Lung Injury
TRRF	Transfusion Reaction Reporting Form
TTI	Transfusion Transmitted infections
VNRBD	Voluntary non-remunerated blood donors
WB	Whole Blood
WHO	World Health Organization



Vision & Mission

Blood Cell:

Government of India is responsible for assessing and consolidating the demand for blood to ensure that the essential requirements are met in the most efficient manner. There is a special emphasis on prevention and management of various Haemoglobinopathies. In view of this the Minister of Health and Family Welfare (MH&FW) has set up a Blood cell under NHM to ensure the accessibility, adequacy, safety and quality of blood is maintained, prevention and control of Haemoglobinopathies and a stem cell registry is being initiated and implemented in co-ordination with different arms of Ministry for improvement of the health care systems.

Mission Statement:

A coordinated long range planning for the development and integration of such diverse activities together with careful considerations of priorities and optimal use of resources and funds to implement the blood services, manage haemoglobinopathies and maintain a stem cell registry at the National level with their counter parts at the state level to ensure an effective functional program.

Chapter 1

e-Rakt Kosh

Blood transfusion is an indispensable component of health care. It contributes to saving millions of lives each year in both routine and emergency situations, permits increasingly complex medical and surgical interventions and dramatically improves the life expectancy and quality of life of patients with a variety of acute and chronic conditions. Patients who require transfusion as part of their clinical management have the right to expect that sufficient blood will be available to meet their needs and to receive the safest blood possible. The timely availability of safe blood and blood products is essential in all health facilities.

Most of the Blood Banks and blood transfusion centres are operating in isolation. Many blood banks are hospital based and often operate with minimal infrastructure and an inadequate supply of blood. The major concern of Blood Banks is to ensure efficient and safe collection and maintenance of quality blood stock. There is a need to phase out replacement donation and curb the malpractices of professional/paid donations. This becomes crucial as the span of time for delivery of blood in emergency situation, is very narrow. Moreover, blood banks across the state & districts are not able to utilize the available blood stock appropriately due to lack of regulation, connectivity and time taken to propagate information via conventional channels. Drugs & Cosmetics Act & Rules, DGHS manual for Blood Transfusion, NACO (National AIDS Control Organization) and NABH (National Accreditation Board for Hospitals and Health care Providers) have provided standards to ensure the quality of blood. To ensure effective enforcement and adherence to these guidelines, a need for Centralized Blood Bank Information Management System was felt. A comprehensive IT solution, '**e-Rakt Kosh**' was envisioned in an attempt to address these problems by providing means to connect, digitize and streamline the work flow of blood banks in India. Objective was to revise the existing systems, to bring some process re-engineering and to automate data entry, search and accessibility.

Objective of e-Rakt Kosh:

Ministry of Health and Family Welfare (MoHFW) has now adopted a comprehensive and total quality management approach by not only leveraging the use of Information and Communications Technology (ICT) but also simultaneously taking a number of steps towards the modernization of blood banks in the States/ Union Territories (UTs) by providing the critical inputs under the blood services program. e-Rakt Kosh is a Centralized Blood Bank Management



Information System that has been conceptualized and developed after multiple consultations with all stakeholders and MoHFW.

e-Rakt Kosh, is identified as a comprehensive IT solution attempting to address the problem by providing the guidelines and streamlining the workflow of blood banks & storage centres across the nation. This web based mechanism inter connects all Blood Banks of the nation into a single network. The Integrated Blood Bank MIS incorporates the acquisition, validation, storage and circulation of various live data and information electronically, regarding blood donation and transfusion services. Such system is able to assemble heterogeneous data into legible reports to support decision making from effective donor screening to optimal blood dissemination in the field. These electronic processes will help the public to easily access the blood availability status and can make requisition of a particular blood group specific blood component in nearby blood banks (especially rare groups). It includes online tracking and trailing system of the blood and blood products (components of blood), by the state level administrators.

The e-Rakt Kosh application facilitates compliance with the regulatory requirements of the Drugs & Cosmetics Act and Rules as well as DGHS guidelines. This application will also adhere to the notified Electronic Health Record (EHR) standards so as to ensure consistency with other e-Health systems. It is envisaged to integrate e-Rakt Kosh with Inventory Management Systems and EMMS (Equipment Management & Maintenance System). This will aid in management of consumables and maintenance of equipment respectively. Considering the national roll out, e-Rakt Kosh has been developed with modular and scalable approach with configurable rule based architecture allowing customization to easily incorporate specific requirements from nationwide stakeholders.

The key objectives of the system are briefed below

- Adhere to Drugs & Cosmetics Act, DGHS manual and NACO guidelines
- Transparent and streamlined workflow of the State Blood Services
- Real time blood stock availability to the service providers and beneficiaries
- Minimize wastage of blood due to expiry
- Restrict professional blood donors and ensure donation of quality blood by introducing biometrics
- Informed decision making by data analysis
- Networking of Blood Banks
- Reduced turnaround time for arrangement of blood/blood components
- Automated generation of statutory reports
- Enable to create State-wise / District-wise donor repository



- Statistical Analysis and dashboards
- Mobile based application for administrators, service providers and end users

Modules for Blood Bank and Blood Storage Units:

In order to accommodate the workflow of the Blood Banks and Blood Storage Units,

e-Rakt Kosh has the following main modules:

Sr. No	Module Name	Usability		
		Blood Bank	Storage Unit	State/National Authorities
1.	Donor Management	Yes	No	No
2.	Camp Management	Yes	No	No
3.	Blood Stock Management	Yes	Yes	No
4.	Blood Grouping	Yes	Yes	No
5.	Investigations	Yes	Yes	No
6.	Requisition & Issue	Yes	Yes	No
7.	Billing	Yes	Yes	No
8.	Enquiry	Yes	Yes	No
9.	Quality Control	Yes	Yes	No
10.	Inventory	Yes	Yes	No
11.	Bio Medical Waste	Yes	Yes	No
12.	Equipment Management	Yes	Yes	No
13.	Reports / Dashboards	Yes	Yes	Yes
14.	Web Portal	Yes	Yes	Yes
15.	Mobile Apps	Yes	Yes	Yes

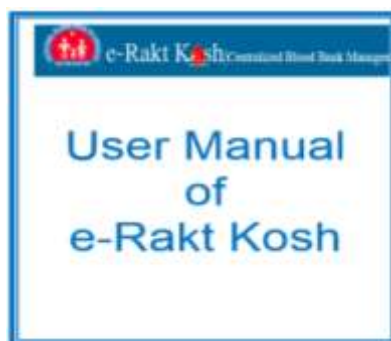
Where to Get User Manuals & Training Videos:

You can download the user manual and training videos from the following link:

<https://drive.google.com/open?id=0B95NRpEAW41bWDh2Z2pKLVREems>

or

<https://goo.gl/Jt29SW>



User: Refers to Blood Bank & Storage Unit staff who interact with the e-Rakt Kosh software

Training Module 1

How to Access e-Rakt Kosh:

- Pre-requisite: Mozilla Firefox should be available on the system. You may download it from download section of e-Rakt Kosh or by directly accessing the link: <https://www.mozilla.org/en-US/firefox/new>
- Every user will have his/her own User ID and Password according to their working role assigned to access the e-Rakt Kosh Application.
- To access e-Rakt Kosh application click on Browser (Mozilla Firefox) and enter the link www.eraktkosh.in Home page will be displayed, click on the image displayed in the following figure to login in to e-Rakt Kosh application.

For Further Details Please Refer User Manual

Click here to login in
e-Raktkosh application

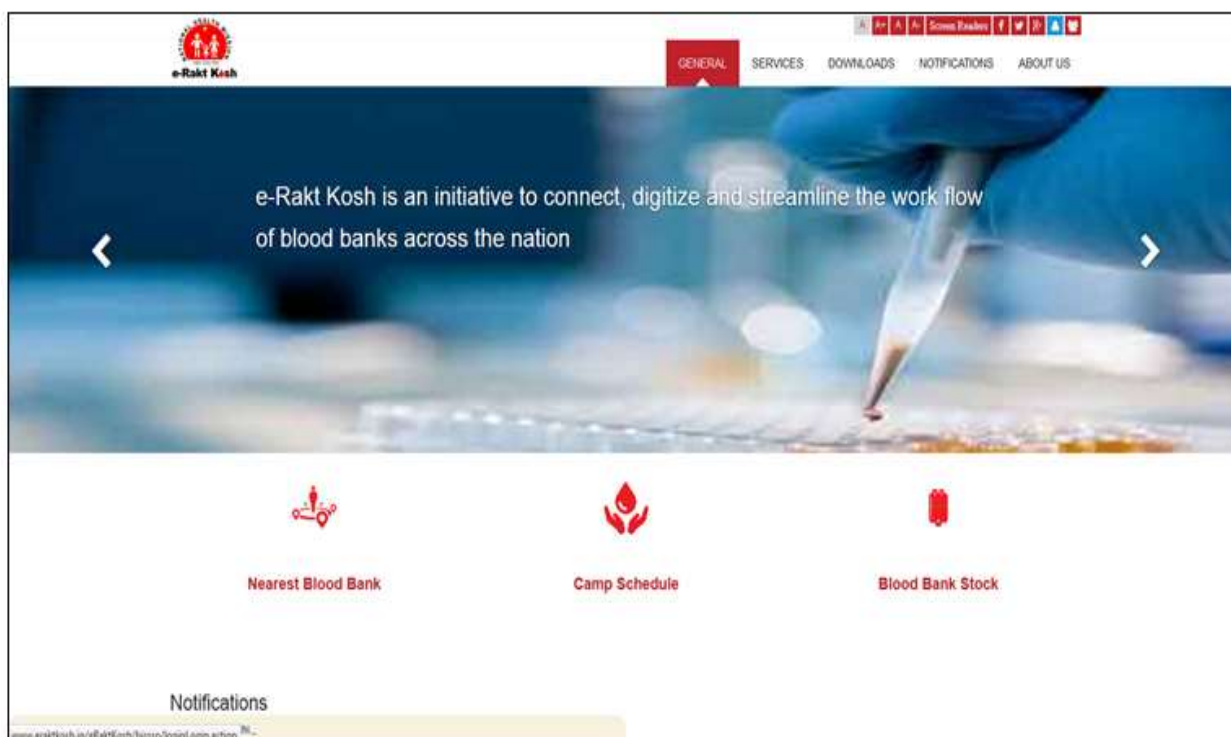


Fig: e-Rakt Kosh Login

Donor Management

Donor Management handles the in-house donation process. It captures the Donor registration details, donor counselling, physical examination, donation details etc.

This Training module covers the following processes, for details please refer to User Manual. Medical Officer In-charge has access to all the modules and decides access rights of staff to the modules.

S. No	Process Name	Access By	Description
1.	*Donor Registration & Consent	DEO/Social Worker /Clerk/ Counsellor/ Nurse	This process is used to register the in-house donor (voluntary/ replacement/ autologous/ family) for whole blood / apheresis donation.
2.	*Physical Examination	Doctor/Nurse	This process is used to do pre-donation counselling and record the physical examination and fitness details. There is a provision to print the consent and questionnaire.
3.	*Donation Detail	Nurse/ Technician/Doctor	This process is used to capture the donation details. On selection of bag type, barcode label will be generated. Generated number will be used as donor number/bag number. It captures complete donation details like blood volume, donation status etc.
4.	Apheresis Donation	Nurse/ Technician/Doctor	This process is used in blood banks where we have apheresis units. It captures the bag label details, donation details, apheresis process parameters.
5.	Donor Demographic Modification	DEO/Social Worker /Clerk/ Nurse	This process is used to update the donor demographic and address details.
6.	Bag Detail Modification	Nurse/Technician	This process is used to update/correct bag details like bag type, tubing no, volume etc. after donation.
7.	Donor Refreshment Detail	DEO/Social Worker/Clerk/ Counsellor/ Nurse	This process is used to capture the refreshment details of a donor.
8.	Donor Adverse Reaction	Nurse/Doctor	This process is used to capture donor's adverse reaction.
9.	Donor Counselling	Counsellor/ Social Worker/Doctor	This process is used to capture the post-donation counselling in case of reactive & non-reactive donor. Provision is given to refer the donor to speciality hospital, ICTC, etc.
10.	Label Printing	Nurse/ Technician	This process is used to print labels for bags.

***Major Processes to complete the Donor workflow. Other processes may be utilized as and when required.**



Camp Management

This module is used to capture the complete workflow of Camp. It handles the camp requisitions, camp approval, bag generation for camps, camp-wise donor registration etc.

This Training module covers the following processes, for details please refer User Manual.

S. No	Process Name	Access By	Description
1.	Camp Requisition	Social Worker/Clerk	This process is used to plan/request a camp on the basis of blood requirements. Requests can be in-house or external i.e. from other organisations. It has provision to schedule camp for future if required.
2.	Camp Requisition Approval	HOD	This process is used to change/ approve/ cancel the camp request done through Camp Requisition process.
3.	Bag Number Generation	Nurse/Clerk/ Technician	To ready & print the Bag labels for Camps.
4.	Resource Allocation	Nurse/Clerk/ Technician	This process is used to allocate resources/staff for camp & assign roles/responsibilities to them. Provision to print checklist is also available.
5.	Camp Bag Entry	DEO/ Nurse/ Technician	This process is used to make entry of bags which are used in camps for further processing in blood bank.
6.	Post Camp Detail	Nurse/Technician/Social Worker/ DEO	This process is used to capture post camp details and close the camp. It has provision to send the unused bags for in- house/other camp.
7.	Camp Donor Registration	Nurse/Technician/Social Worker/ DEO	This process is used to register a camp donor.

Grouping

This section is used by technicians for the entry of blood group of donor as well as patient samples. User has option to enter the details separately for Cell and Serum grouping or they can enter it through a single process. ***If equipment is capable of interfacing, then blood group data will be automatically available for group validations.***



This Training module covers the following processes, for details please refer User Manual.

S. No	Process Name	Access By	Description
1.	Donor Grouping	Technician	To capture the cell & serum grouping details of donor. In case automated bidirectional machine is available, then this process will work to send the request to equipment.
2.	Donor Grouping Confirmation	Technician	To verify and confirm donor's blood group.
3.	Patient Grouping	Technician	To capture the cell & serum grouping details of patient. In case automated bidirectional machine is available, then this process will work to send the request to equipment.
4.	Patient Grouping Confirmation	Technician	To verify and confirm patient's blood group.

TTI Screening

This section is used to capture the Investigation details of donor sample. It is one of the sensitive sections which require monitoring as well as maintenance of the confidentiality in case the tests results are positive. This section is used by Technicians/MO In-charge to enter the result of investigations. User has various options to capture the result in e-Rakt Kosh. ***If Medical equipment is capable of interfacing with e-Rakt Kosh then result will be automatically available in e-Rakt Kosh for validation.***

This Training module covers the following processes, for details please refer User Manual.

Medical Officer In-charge has access to all the modules

S. No	Process Name	Access By	Description
1.	Date wise Investigation	Technician	This is used to capture all TTI screening results of particular donation date for multiple bags.
2.	Bag wise Investigation	Technician	This is used to capture all TTI screening results for a particular bag.
3.	Performa Test Detail Entry	Technician	This is used to capture TTI screening results of particular test for multiple bags by machine interfacing.
4.	Parameter wise with Kit Details	Technician	This is used to capture the TTI results parameter-wise i.e., reactive/non-reactive status for particular test.
5.	Final Validation of Bags	Technician	This is used to finally validate the result entered from above process or result received from medical equipment.
6.	Repeat Investigation	Technician	This is used to capture the repeat test details with reason.



7.	Investigation Report Printing	Technician/ DEO/Social Worker/Clerk	This process is used to print the TTI Screening Report.
8.	Donor Antibody Screening/ Identification	Technician	This is used to identify & capture details of donor's antibody screening.
9.	Patient Antibody Screening /Identification	Technician	This is used to identify & capture details of patient's antibody screening.

2.1 Stock Management

This section is used to manage the Blood Stock in Blood Banks and Blood Storage Units. According to the need of the Blood Bank/Storage Units, these processes will be used. This module helps staff to manage the Blood Stock.

This training module covers the following processes, for details please refer User Manual.

S. No	Process Name	Access By	Description
1.	*Component Separation	Technician	This is used to capture details of separated components.
2.	*Labelling & Shifting	Technician	This is used to capture details of labelling & shifting of bags.
3.	Bag Storage & Movement	Technician	This is used to change the storage/shelf details of particular bag.
4.	Child Unit	Technician	This is used to generate the paediatric/ child bags having less volume than the actual bag.
5.	Bag Reserve	Technician	This is used to reserve a bag of particular component.
6.	Bag Unreserved	Technician	This is used to unreserved the reserved bag.
7.	Bag Cancellation	Technician	This is used to cancel the donated bag & to capture the cancellation details of bag along with reason.
8.	Bag Cancellation Confirmation	Technician	This is used to validate the Cancellation Request.
9.	Waste Generation (Bag Discard)	Technician	This process is used for discarding the cancelled, expired, reactive & therapeutic bags
10.	Bulk Component Separation		This is used to separate blood components of multiple bags at a time i.e., in bulk.

***Except Process 1, 2 and 10 other processes may be utilized in Blood Storage Unit as and when required. In Blood Bank all process will be utilized as and when required.**



Training Module 2

Component Requisition

This section handles the patient centric request to issue the blood component. Request can be received from in-house ward or from external hospital. This section covers the requisition and authorization of process.

This Training module covers the following processes, for details please refer User Manual.

S. No	Process Name	Access By	Description
1.	*Component Request	DEO/Clerk/Nurse/ MO In-charge In charge	This is used to generate component request for patient and capture patient's blood sample & other details.
2.	Authorization of Requisition	HOD/Sr. Technician/Sr. Clerk	This is used to approve the request of components.
3.	Requisition Modification	DEO/Clerk	To modify the details of patient entered during Component Request process.
4.	Patient Sample Acceptance	Technician	This is used to capture the patient sample details.
5.	Voluntary Card	DEO/Clerk	To get a blood unit on the basis of Voluntary Donation Card
6.	Requisition Cancellation	DEO/Clerk	This is used to cancel/ postpone the patient's request with reason.

***Major Processes to complete the Requisition workflow. Other processes may be utilized as and when required.**

Cross match and Issue

This section is used by technician to cross match patient blood sample with blood bags.

This Training module covers the following processes, for details please refer User Manual.

S. No	Process Name	Access By	Description
1.	*Patient Grouping	<i>Already covered in Grouping Section. Section 2.4</i>	
2.	*Cross Match	Technician	This is used to capture the cross matching details. Have provision to add & cross match for multiple bags at a time.
3.	*Billing	Clerk/ Technician	This is used to capture the billing details while issuing bags. Depending on billing request for bags, billing is generated for particular



			components.
4.	*Component Issue	Technician	This is used to issue cross matched & without cross matched bags. Compatibility report is generated after issuing bag which includes all details of bag.
5.	Ready To Issue	Technician	This process is used to issue tested bags without cross matching.
6.	Cross Match Cancellation	Technician	This is used to cancel the issue of cross matched bags with reason.
7.	Cross Match Cancellation Validation	Technician	This is used to validate the cross match cancellation details.
8.	Bag Return	Technician	This is used to return issued bag to stock or to discard issued bag as per requirement.
9.	Thalassemia/Multi transfused Patient Registration	Clerk/ Technician	This is used to capture details of thalassemia patient.
10.	Thalassemia/Multi transfused Patient Requisition	Clerk	This process is used to raise the blood component request for thalassemia patients.

3.1 Stock Transfer

This section is used by blood banks to transfer the blood and components to blood storage units and other blood banks.

This Training module covers the following processes, for details please refer User Manual.

S. No	Process Name	Access By	Description
Stock Transfer – Offline (Other Blood Banks, not a part of e-Rakt Kosh)			
1.	Requisition To Other Blood Bank	DEO/Clerk/ Technician	This is used to raise request to other blood banks in case of shortage of blood
2.	Bag Receive From Other Blood Banks	DEO/Clerk/ Technician	This process is used to enter the blood components in the blood bank stock which have been received from other blood banks
3.	Requisition From Other Blood Bank	DEO/Clerk/ Technician	This process is used to capture the blood component requirement details from storage units or other blood banks.
4.	Bulk Issue	DEO/Clerk/ Technician	This process is used to issue the blood components to storage units / blood banks.



Training Module 3

Enquiry

This section is used to verify & enquire about blood bags & their components.

This Training module covers the following processes, for details please refer User Manual.

S. No	Process Name	Access By	Description
1.	Blood Inventory Details	Technician/ MO In-charge	This is used to enquire about tested, untested, cross matched, reserved, paediatric & to be expired bags in stock.
2.	Discarded Blood Details	Technician/ MO In-charge	This is used to enquire about discarded bags in a stock i.e., reactive, cancelled & expired bags.
3.	Camp Details	Technician/ MO In-charge	This is used to enquire about all the held/ cancelled camps.
4.	Voluntary Donor Details	Technician/ MO In-charge	This is used to enquire about all the voluntary donors & their details.
5.	HOD Dashboard	Technician/ MO In-charge	This is used to display all the statistics of requisitions & donations in numeric & graphical formats.
7.	Guidelines for SOP	Technician/ MO In-charge	This is used to provide guidelines for Standard Operating Procedure.
8.	Bag Tracking	Technician/ MO In-charge	This is used to track all details of any bag.

Training Module 4

Citizen Centric Portal

This section covers the portal related services. It is used by citizens to get the information about nearest blood banks, their stocks and the camp schedule.

This Training module covers the following processes, for details please refer User Manual.

S. No	Process Name	Description
1.	Nearest blood bank enquiry	This is used to know the nearest blood banks in the location.
2.	Blood bank stock enquiry	This is used to enquire whether particular blood group or component is available at the blood bank.
3.	Camp schedule enquiry	This is used to enquire about the scheduled camps.



State/Blood Bank Portal User

This section covers the portal related services used by the blood bank. This covers services about verification of blood bank information, stock entry, camp schedules so that they will be available to citizens.

This Training module covers the following processes, for details please refer User Manual.

S. No	Process Name	Description
1.	Managed Blood Bank (State Level)	Blood cell nodal officer can manage its state blood banks. He can add, modify and verify the blood banks. Also create portal user of specific blood bank.
2.	Manage Nodal Officer	This is used to capture the details of nodal officers and master trainers.
3.	State -Manage Profile	This is used to change the password, email id etc. of Blood cell nodal officer .
4.	Blood Bank Portal User- Manage Stock	This is used to update the stock information so that it is available at the e-Rakt Kosh application.
5.	Blood Bank Portal User- Manage Camp	This is used to provide the camp schedule.
6.	Blood Bank Portal User- Manage Blood Bank	This is used by blood bank to update its information.

Mobile Apps

This section covers mobile apps for citizen centric services. Apps are available for windows, android and iOS platforms.

Process No	Process Name	Description
1.	Nearest blood bank enquiry	This is used to know the nearest blood banks in the location.
2.	Blood bank stock enquiry	This is used to enquire whether particular blood group or component is available at the blood bank.
3.	Camp schedule enquiry	This is used to enquire about the scheduled camps.

SMS Generated from application

Various SMS are being sent from the e-Rakt Kosh application for informing user about various activities. Some of the activities are listed below

S. No	Recipient	Purpose	Message
1	Donor	Sent At the time of Successful registration of donor	Dear Donor, Thank You for registering with us!!! Your Donor Registration Number is 191011600443. e-Rakt Kosh Team
2.		When blood donation is completed successfully	Dear Donor, We thank you for saving life by donating blood. Your donor no is 1611158



3	HOD	Expiry of Bags	Dear Sir/Madam, Near Expiry blood bags (10 days) in the stock are WB-10, RBC-5. Please take corrective actions
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Training Module 5

Quality Control

This section covers the quality related process used in Blood Bank. This can be used for quality conformance of blood bags, reagents, kits in blood bank.

This Training module covers the following processes, for details please refer User Manual.

S. No	Process Name	Access By	Description
1.	Quality Control	Technician	This is used to capture the Quality of blood components.
2.	Quality Report	Technician	This is used to display captured details of blood component's quality.
3.	Temperature Recording	Technician	This is used to capture the temperature of storage.

Reports/Formats

This section covers the different reports used by blood banks and Storage unit staff for day-to-day purpose. It also contains various administrative and statutory reports for the effective monitoring.

This Training module covers the following processes, for details please refer User Manual.

S. No	Process Name	Description
1.	Blood Donor Record	This report displays list of registered donors
2.	Donor Master Register	This report displays list of donations
3.	Donor Statistics	This report displays statistics of registered donors
4.	Donor Blood Grouping	This report displays donor's blood group details
5.	Camp Donor Detail	This report displays camp donor details
6.	Camp Detail	This report displays list of camps held
7.	List of Blood Requisitions	This report displays list of blood requisitions from internal/ external patients
8.	Cross Match Register	This report displays list of cross matched bags details
9.	Issue Register	This report displays list of blood bags issued to patients
10.	Expiry Blood Bag Listing	This report displays list of expired blood bags
11.	Temperature Charting Report	This report displays temperature recording of blood storage equipment



12.	Thalassemia/ Multi Transfused Booking Register Report	This report displays blood requirement details of registered thalassemia patients
13.	Individual Blood Bank Statistics Report	This report displays the statistics of individual blood bank
14.	Camp Statistics	This report displays total no. of camps held / cancelled
15.	Donor Statistics	This report displays total no. of successful/ unsuccessful donations
16.	Issue Statistics	This report displays total no of bags issued

Some of the report formats are provided for reference. There are various other report formats which can be generated from the e-Rakt Kosh application.

Donor Register

Report Date & Time : 25-Dec-15 13:37 PM

Indian Red Cross Society Nhq Blood Bank

1, Red Cross Road, New Delhi, Central, Delhi, India

Phone: 91123775551 Fax: 91123775554 Email: drcsindia2000@yahoo.co.in

Blood Donor Record

From : 15-Dec-2015 To : 18-Dec-2015

S. No.	Donor No.	Time	Bag Type	Tubing No.	Batch No.	Date	Name	Age	Gender	Address	Mobile	Weight	BP	Pulse	H.B.	Blood Group	Medical Examination report	Donor Catg. (V.D.R.L.)	Patient Details for whom Donation is		
																			Name	Hospital Name	Blood
1	16RC3987	01:12	Double (450) Cpts	GD866511	-	15-Dec-2015	Parvath	24 Yr	M	Rajiv Garden Shakiri Nagar Central Delhi	92109993	74	120/84	72	15.6	A+Ve	Fill Donated	Replacement	SHYAM B A B U	Lata Hospital	O+Ve
2	16RC3988	01:12	Double (450) Cpts	GD864777	-	15-Dec-2015	Geetan	27 Yr	M	A-1 Bhagirath Vihar Delhi Central Delhi	70801079	85	120/90	70	10.7	O+Ve	Fill Donated	Replacement	CHANDN	Chacha Nahru Ba Chikitsalaya	-
3	16RC3989	06:12	Double (450) Cpts	gd866395	-	16-Dec-2015	Smah Jan	35 Yr	M	Shri Man Road Patodi Drive Delhi NCT	90100080	78	130/78	74	13.9	B+Ve	Fill Donated	Voluntary	null	null	-
4	16RC3990	06:12	Double (450) Cpts	GD866480	-	16-Dec-2015	Devender Kumar Gupta	57 Yr	M	A.C. 18 Tector Garden New Delhi 27 New	95000094	88	130/84	80	14.5	B+Ve	Fill Donated	Voluntary	null	null	-
5	16RC3991	06:12	Double (450) Cpts	GD867387	-	16-Dec-2015	M.S. Sengupta	36 Yr	M	9061110 Sanshodh Apartments	90101004	82	120/90	72	15.6	B+Ve	Fill Donated	Voluntary	null	null	-
6	16RC3992	06:12	Double (450) Cpts	GD866557	-	16-Dec-2015	K.S. Dhillon Vashist	45 Yr	M	D-118 K.M Pur Road New Delhi New	92109973	102	130/84	78	14.3	A+Ve	Fill Donated	Voluntary	null	null	-
7	16RC3993	06:12	Double (450) Cpts	GD866948	-	16-Dec-2015	Anil Kumar Gupta	46 Yr	M	B-110 Sachdev Jang Enclave New Delhi Delhi	90100080	95	124/80	70	14.3	A+Ve	Fill Donated	Voluntary	null	null	-
8	16RC3994	06:12	Double (450) Cpts	HQ952134	-	16-Dec-2015	Deepa Choudhary	19 Yr	F	B-110 Shakti Nagar New Delhi New Delhi Delhi	90000070	65	124/82	72	12.9	B+Ve	Fill Donated	Voluntary	null	null	-

Figure 1: Blood Donor Record Report

Donor Statistical Report

Report Date & Time : 29-Dec-16 11:57

Indian Red Cross Society Nhq Blood Bank
1, Red Cross Road, New Delhi, Central, Delhi, India
Phone: 01123775551 Fax: 01123775554 Email: drcsindia2000@yahoo.co.in

Donor Statistical Report
From : 01-Dec-2015 To : 29-Dec-2015

Donor Type	In-House			Camp			Grand Total
	Male	Female	Total	Male	Female	Total	
Voluntary	198	5	204	865	60	925	1129
Replacement	210	3	213	0	0	0	213
Total	408	9	417	865	60	925	1342

Figure 2: Donor Statistical Report

Cross Match Register

Report Date & Time : 29-Dec-16 12:41

Indian Red Cross Society Nhq Blood Bank
1, Red Cross Road, New Delhi, Central, Delhi, India
Phone: 01123775551 Fax: 01123775554 Email: drcsindia2000@yahoo.co.in

Cross Match Report
From : 16-Dec-2015 To : 29-Dec-2015

S. No.	Test Date	Patient Details	Bag No.	Tube No.	Component Type	Collection Date	Donor Blood Group	Minor tps	Major tps	Minor tps	Major tps	Compatibility	Crossmatch Result	Sign of Lab. Test	Sign of RBC
1	20-Dec-2015	Anand Kumar	-	16RC4625	328132183	Paired Red Blood Cells	20-Dec-2015	O+Ve	-	-	-	-	Yes	Normal	
2	30-Dec-2015	Anand Kumar	-	16RC4614	635131174	Paired Red Blood Cells	30-Dec-2015	O+Ve	-	-	-	-	Yes	Normal	
3	19-Dec-2015	Anand Kumar	-	R00581	Q0697145	Paired Red Blood Cells	30-Dec-2015	O+Ve	-	-	-	-	Yes	Normal	
4	26-Dec-2015	Maya Prasad	Janakpur Super Speciality Hospital	R116289	534121286	Paired Plasma Plasma	-	SA	-	-	-	-	Yes	Normal	
5	25-Dec-2015	Maya Prasad	Janakpur Super Speciality Hospital	R116289	51100542	Paired Plasma Plasma	-	SA	-	-	-	-	Yes	Normal	
6	26-Dec-2015	Maya Prasad	Janakpur Super Speciality Hospital	R116289	413287174	Paired Plasma Plasma	-	SA	-	-	-	-	Yes	Normal	
7	20-Dec-2015	Maya Prasad	Janakpur Super Speciality Hospital	R117623	51100544	Paired Plasma Plasma	-	SA	-	-	-	-	Yes	Normal	
8	25-Dec-2015	Maya Prasad	Janakpur Super Speciality Hospital	R0004044	54113355	Paired Red Blood Cells	22-Dec-2015	B+Ve	-	-	-	-	Yes	Normal	
9	26-Dec-2015	Maya Prasad	Janakpur Super Speciality Hospital	R0004044	Q0000489	Paired Red Blood Cells	23-Dec-2015	B+Ve	-	-	-	-	Yes	Normal	
10	20-Dec-2015	Maya Prasad	National Institute of Tuberculosis and Respiratory	R00052	Q0695951	Whole Blood	21-Dec-2015	A+Ve	-	-	-	-	Yes	Discontinued	
11	27-Dec-2015	Aravind Kumar	East West Medical Centre	R00462	51100522	Paired Red Blood Cells	29-Dec-2015	B+Ve	-	-	-	-	Yes	Discontinued	
12	27-Dec-2015	Aravind Kumar	East West Medical Centre	R00445	534132576	Paired Red Blood Cells	24-Dec-2015	B+Ve	-	-	-	-	Yes	Discontinued	
13	27-Dec-2015	Aravind Kumar	East West Medical Centre	R00444	534132734	Paired Red Blood Cells	24-Dec-2015	O+Ve	-	-	-	-	Yes	Discontinued	
14	28-Dec-2015	Aravind Kumar	East West Medical Centre	R00439	534132732	Paired Red Blood Cells	24-Dec-2015	O+Ve	-	-	-	-	Yes	Normal	
15	28-Dec-2015	Aravind Kumar	East West Medical Centre	R00455	534132731	Paired Red Blood Cells	25-Dec-2015	O+Ve	-	-	-	-	Yes	Normal	

Figure 3: Cross Match Register



Issue Register

Report Date & Time : 28-Dec-16 5:51 PM

Indian Red Cross Society NRI Blood Bank
1, Red Cross Road, New Delhi, Central, Delhi, India
Phone: 01123711001 Fax: 01123711404 Email: drvr@redcrossnri.org

Issue to Patient Register Report
From : 03-Dec-2016 To : 03-Dec-2016

S. No.	Date of Issue	Time of Issue	Name of Patient	Name of Hospital	Father Name	Patient Blood Group	Bag No.	Tabing No.	Particular of product supplied	Quantity in ml	Issued Blood Group	Thot. Card No.	Cs. No./Admission No.	Is Crossmatched	Paid Free	Recipient Name	Issued Against	Issued By	Remarks
1	03-Dec-2016	03:53 PM	Mansi Manchanda	Sr Gangaani Hospital	Chetan Manchanda	B+Ve	R18614	4X31723	Packed Red Blood Cells	230	B+Ve	185	-	No	Free	Mansi	-	manish	
2	03-Dec-2016	03:53 PM	Mansi Manchanda	Sr Gangaani Hospital	Chetan Manchanda	B+Ve	R18613	4X31868	Packed Red Blood Cells	230	B+Ve	185	-	No	Free	Mansi	-	manish	
3	03-Dec-2016	03:54 PM	Ramesh Chandra	Hindu Rao Hospital	Manoj K Chhabra	B+Ve	16RC3718	4X67502	Packed Red Blood Cells	200	B+Ve	320	-	No	Free	Ramesh	-	manish	
4	03-Dec-2016	03:54 PM	Ramesh Chandra	Hindu Rao Hospital	Manoj K Chhabra	B+Ve	R18346	4X316333	Whole Blood	350	B+Ve	320	-	No	Free	Ramesh	-	manish	
5	03-Dec-2016	03:57 PM	Sanjay Chugh	Hindu Rao Hospital	Vijender K Chugh	B+Ve	R18625	4X31589	Packed Red Blood Cells	230	B+Ve	219	-	No	Free	Sanjay Chugh	-	manish	
6	03-Dec-2016	03:57 PM	Sanjay Chugh	Hindu Rao Hospital	Vijender K Chugh	B+Ve	R18638	4X31848	Packed Red Blood Cells	230	B+Ve	219	-	No	Free	Sanjay Chugh	-	manish	
7	03-Dec-2016	03:58 PM	Sunil Jain	Smt Sucheta Nigam Hospital	Vijender Anand	O+Ve	16RC3665	Q1755740	Packed Red Blood Cells	250	O+Ve	362	-	No	Free	Sunil	-	manish	
8	03-Dec-2016	03:58 PM	Sunil Jain	Smt Sucheta Nigam Hospital	Vijender Anand	O+Ve	R18429	5553089	Packed Red Blood Cells	270	O+Ve	362	-	No	Free	Sunil	-	manish	
9	03-Dec-2016	03:58 PM	Sandeep Dandia	Nilok	Gur Deyal Seodia	O+Ve	16RC3714	Q1751994	Packed Red Blood Cells	250	O+Ve	186	-	No	Free	Sandeep	-	manish	
10	03-Dec-2016	03:59 PM	Disha Jain	Nilok	Naveen Kumar Jain	O+Ve	16RC3708	Q1753198	Packed Red Blood Cells	250	O+Ve	7	-	No	Free	Disha	-	manish	

Figure 4: Issue Register

Camp Statistical Report

Indian Red Cross Society NRI Blood Bank
1, Red Cross Road, New Delhi, Central, Delhi
Phone: 01123711001 , Fax: 01123711404, Email: drvr@redcrossnri.org
Metropolis Mall
Camp Blood Donor List
Camp Date : 25-DEC-16

S. No	Bag No	Name	Age/Sex	Address	Mobile	Blood group	Reason
1	R20661	Sandeep Roy	32 YnM	678, Saraswati Vihar Gurgaon Haryana	-	B+Ve	-
2	R20662	Ranjit Singh	24 YnM	Ploy No 35, Gurgaon Gurgaon Haryana	8100000099	O+Ve	-
3	R20663	Rishi Sahoo	33 YnM	369, Saraswati Vihar, Gurgaon Gurgaon Haryana	9900000335	B+Ve	-
4	R20664	Anoop Tiwari	27 YnM	137, Vip Road Kolkata Gurgaon Haryana	9800000440	A+Ve	-
5	R20665	Sandeep Jain	50 YnM	Gurgaon Gurgaon Haryana	9800000634	A+Ve	-
6	R20666	Prakash Sural	22 YnM	Kolkata Gurgaon Haryana	7500000587	A+Ve	-
7	R20667	Anoop Shukla	22 YnM	Delhi Gurgaon Haryana	9500000495	O+Ve	-
8	R20668	Rishi Sharma	31 YnM	Gurgaon Gurgaon Haryana	8100000551	O+Ve	-
9	R20669	Anoop Gulati	28 YnM	H.P. Gurgaon Haryana	7040000044	O+Ve	-
10	R20670	Anoop Sahoo	25 YnM	Grissa Gurgaon Haryana	8650000015	A+Ve	-
11	R20671	Srinangi Bikra	25 YnF	3349b, Gurgaon Gurgaon Haryana	8160000075	B+Ve	-
12	R20672	Anoop Verma	22 YnF	Uttarakhand Gurgaon Haryana	9900000092	B+Ve	-
13	R20673	Sandeep Singh	25 YnF	Gurgaon Gurgaon Haryana	8400000010	O+Ve	-
14	R20674	Vinod Gautam	23 YnF	Sangam Vihar Gurgaon Haryana	9800000134	O+Ve	-
15	R20675	Rishi	19 YnM	Sonapat, Haryana Gurgaon Haryana	9910000058	AB+Ve	-
16	R20676	Anoop Tiwari	23 YnM	Ram Kishan Colony Gurgaon Haryana	9800000121	AB+Ve	-
17	R20677	Rishi Gangawat	24 YnM	Gurgaon Gurgaon Haryana	8400000010	A+Ve	-
18	R20678	Prakash Singh	27 YnM	Gurgaon Gurgaon Haryana	9750000044	O+Ve	-
19	R20679	Sandeep Verma	29 YnM	Gurgaon Gurgaon Haryana	9550000051	B+Ve	-
20	R20680	Rishi Singh	31 YnM	Gurgaon Gurgaon Haryana	9310000054	A+Ve	-

Figure 5: Camp Statistical Report



Invoice

BILLING SERVICES RECEIPT			
Lic No. 507			
INDIAN RED CROSS SOCIETY DRUG BLOOD BANK			
Certified by ISO 9001:2008, Accredited by NABH & NABL			
1. Red Cross Road			
, NEW DELHI, Delhi-110001			
Phone No: 01126111551, Email Id: dr@redcross2002@yahoo.co.in			

REQ No. : 97101160008028	DATE&TIME : 28/12/2016 17:40:45	BILL No. : 97101160000458/1	
NAME : SUMAN	AGE/SEX : 25 YR/FEMALE	BLD GROUP : -	
REQ HOSP. : Pt. Madan Mohan Malviya Hospital			

S.No.	SERVICE NAME	RATE (Rs.)	QTY. AMOUNT (Rs.)
1	WHOLE BLOOD WITHOUT CROSS MATCH	1050.00	2 2100.00
			TOTAL AMOUNT 2100.00

		BILLED AMT (Rs.)	2100.00
		CONCESSION AMT (Rs.)	0.00
		COLLECTED AMT (Rs.)	2100.00
RUPEES (IN WORD) : TWO THOUSAND ONE HUNDRED RUPEES ONLY			
Mode Of Payment: Cash/Cheque			
Cheque Details:			
			ADMIN
			Authorized Signatory

Figure 6: Billing Report

7. Samples

Print	Cancel
	
9410116000375	9410116000375
Donation Date: 17-Oct-2016	Donation Date: 17-Oct-2016
Use Upto: 17-Oct-2017	Use Upto: 17-Oct-2017

Figure 7: Sample Label

Training Module 6

Inventory

This section is used by stores for management of their inventory. The entire inventory related to blood bank like blood bags, kits, reagents etc. can be indented, issued through this section.

This Training module covers the following processes, for details please refer User Manual.

S. No	Process Name	Access By	Description
1.	Indent Desk	Staff (Indenter)	This is used to raise demand store-wise.
2.	Issue Desk	Store Keeper/ Store Clerk	This is used to issue the items against demand/indent generated.
3.	Approval Desk	Store Keeper/ Store Clerk	This is used to approve/ reject the generated indent.
4.	Acknowledge Desk	Staff (Indenter)	This is used to acknowledge the received items.
5.	Item Inventory	Store Keeper/ Store Clerk	This is used to show the current item stock, entry of offline stock.

Equipment Management

This section is used to maintain the equipment details of the blood bank like refrigerators, their maintenance, complaints etc.

This Training module covers the following processes, for details please refer User Manual.

S. No	Process Name	Description
1.	Equipment Inventory Desk	This is used to display/ add equipment stored in hospital Inventory.
2.	Centralized Equipment/Warranty & Maintenance	This is used to capture the equipment details like warranty, AMC details.
3.	Equipment Complaint Desk	This is used to request a complaint for equipment.
4.	Complaint Approval	This is used for approving of equipment complaint. Complaint is finally closed from this process only when all processing is done.



Bio Medical Waste

The management of waste generated in the blood banks like blood bags, their treatment and discard will be handled through this process.

This Training module covers the following processes, for details please refer User Manual.

S. No	Process Name	Access By	Description
1.	Waste Generation	Technician	This is used to collect & save generated waste details like waste category, weight of waste etc.
2.	Waste Treatment	Technician	This is used to provide treatment to the generated waste as per biomedical wasteguidelines.
3.	Waste Handover to Third Party	Technician	This is used to give waste details to third party
4.	Inspection Scheduling	Technician	This is used to schedule the inspection for waste generation area.
5.	Inspection Details	Technician	This is used to record details of inspection - inspection date & time, team members, etc. & its result.
6.	Prevention of Injury Details	Technician	This is used to record injury/ prevention details of any employee of hospital.

Pre-requisites for e-Rakt Kosh Implementation

To start e-Rakt Kosh in Blood Bank these are following Pre-requisites:

Identification of Master Trainer

Master Trainer: For every state a master trainer will be identified by state officials. Master trainer should have knowledge of Blood Bank processes as well as computer operations. The role of master trainer will be

- To get e-Rakt Kosh training from CDAC
- Understand the e-Rakt Kosh Application
- Coordinate with Blood Bank nodal officers
- Provide training to nodal officers
- In case of any gap in e-Rakt Kosh inform the same to CDAC team



Identification of Blood Bank Nodal Officer

For every blood banks or storage unit, a nodal officer will be identified to handle the further training and support to internal staff for the use of e-Rakt Kosh.

The role of nodal officer will be

- Provide master data for e-Rakt Kosh configuration
- To get e-Rakt Kosh training from Master Trainer
- Understand the e-Rakt Kosh Application
- Provide training to blood bank staff
- In case of any gap in e-Rakt Kosh, inform the same to master trainer

Infrastructure Readiness in Blood Banks

1. HARDWARE INFRASTRUCTURE REQUIRMENT FOR END USERS

The required hardware infrastructure at a blood bank includes the Desktops, Bar code Printers and Bar Code scanners, etc. Additionally, internet connection is also a mandatory requirement. Following are the details of the required IT infrastructure across all blood banks. The picture below shows a typical hardware setup required in a blood bank.

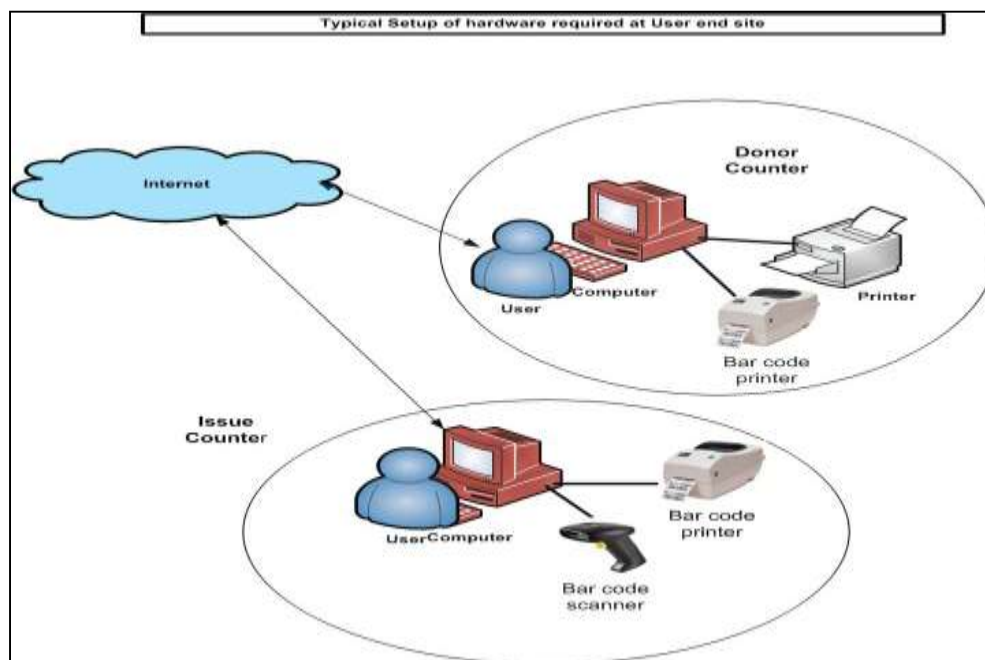


Figure 8: Hardware (HW) Setup at Blood Bank

2. MINIMUM INFRASTRUCTURE AT EACH BLOOD BANK

Table: Hardware requirements at end user site

S. No.	Name of Item	Min. Quantity	Indicative requirements
1	Desktop/ Thin client	2	a. For New Desktop purchase: A computer or laptop with i3 equivalent processor or Higher processor, Min. 1 GB RAM or higher with WIN 7 or higher or Linux. b. For existing Computer: Any existing computer with P-IV or equivalent processing capacity with Min. 1 GB RAM with windows XP/ Win7/ Win 8 or Linux OR c. Thin-client: Dual core Processor with 4 GB DDR II with 6 USB ports. With Embedded Windows/ Linux OS.
2	Browser	On every computer	Firefox Mozilla Ver. 24 or higher
3	Printers	1	Laser jet printer, paper size: A4,
4	Barcode Printer	2	With Bar code: 1D, 2D
5	Barcode Reader	1	Scanner type: Linear Imager, Interface: USB/Keyboard,
6	Internet Connection	1	Internet bandwidth using broadband, leased line or data card of 2-4 Mbps Bandwidth per site.
7	Manpower	2	Computer operators- Existing or New

Note: Requirements mentioned in table above are minimum requirements at a location. These may slightly vary depending upon size of blood bank.

3. INTERNET / NETWORKING

Broadband or lease line internet connection is required for faster and reliable data communication. The internet bandwidth should be at least 1 Mbps dedicated link either from SWAN network or from a local Internet Service Provider (ISP). Alternatively Data cards can also be used.



4. RATIONALE FOR USAGE OF COMPUTING HARDWARE AT USER END

Table: Rationale for usage of hardware

Desktops/Computers	Desktops are required for entry of records for different processes in BBMS, printing of reports and doing analysis.
Printers	Printers are required to print reports at blood bank
Bar code printer	Bar code printer is required for printing of blood bag label's
Bar code scanner	Bar code scanner will be required in scanning bar code from blood bags
Internet bandwidth	Internet connection using leased line or data card or broadband is required at all locations

5. Stationery Requirement

Sr. No	Document	Stationary	Size
1	Questionnaire	Blank Sheet	A4
2	Compatibility Report	Blank Sheet	A4
3	Bulk Issue Report	Blank Sheet	A4
4	Sample Label	Barcode Label	5 cm X 2.5 cm
5	Cross Match Label/ Labelling Labels	Barcode Label	10 cm X 5 cm
6	Colour Stickers –Small Blood Group Wise – Pre printed	Barcode Label(Pre Printed)	4.4 cm X 3.5 cm



Annexure: A

PROPOSED HARDWARE SPECIFICATIONS

The below mentioned specifications are ideally suggested if new hardware is to be purchased. However hardware items with lesser configuration may also be sufficient as mentioned in table no. 1 above.

1.	Desktops
Item	Description of Requirement
Mandatory Certifications	OEM – ISO 9001 Manufacturer, Certified on supplied OS, DMI 2.0 compliance and support, Energy Star 5, UL certification
Processor	Intel Core i3-3rd Generation, clock speed- min 2.9Ghz series or higher
Core / Thread	2 Core / 4 Thread
Cache	4 MB L2 or higher
Chipset	Intel H55 Chipset or equivalent or higher
Memory	Min. 1 GB DDR3 RAM 1066 MHz
HDD	320 GB SATA 7200 HDD
Monitor	17” Wide TFT Monitor or higher
Keyboard	Min. 101 keys OEM Key board USB/ PS2
Mouse	Two button Optical Scroll Mouse USB/ PS2
Cabinet	Micro ATX/ATX
USB	Min. 6 USB (min. 2 in front) latest version.
Network Features	10/100/1000 LAN Controller
Ports	Minimum 1 Serial, 1 Parallel and PS/2 for key board & Mouse
Operating System	Pre-installed Microsoft Windows 7 Professional or above with Media and documentation (With recovery CD as case may be)/ Preinstalled Linux
Antivirus	Anti-Virus Client with license
2.	Laser Printer
Item	Description of Requirement
Print speed	Up to 20 ppm (A4)
Print Resolution	Up to 600 x 600 dpi
Duty cycle (monthly)	Up to 3000 pages
Duplex print option (A4)	Yes
Features	Print
Network Enabled	Yes
Energy Star	Yes
Standard memory	Min. 128 MB
Processor	500 MHZ
Compatible operating systems	All Win OS & Linux
Accessories	USB & power cable



Table: Recommended specifications of Desktop & Printer

3.	BAR CODE READER/ SCANNER
Item	Description of Requirement
Scanner Type	Linear Imager, QR Code
Light Source:	Red LED 610-650 nm
Scan Rate	270 reads/sec
Working Distance	From contact to 12” on 100%U.P.C./EAN Symbols
Print Contrast	15% minimum reflective difference
Roll (Tilt):	+/- 45 degrees
Pitch	+/- 65 degrees
Skew (Yaw):	+/- 60 degrees
Interface	USB / Keyboard wedge cable with all peripheral cables.
Decode capability	Auto discriminates all standard 1D & 2D codes including GS1 Data Bar, GS1 Data Bar Stacked; GS1 Data Bar Stacked Omni directional; GS1 Data Bar Expanded Stacked.GS1-1D & 2D
Weight	< 250 gm.
Power Source	Host power or External Power supply (through Mains / Battery box)
Others	Should come with drivers (on CD/DVD) for Windows and Linux OS
Operating Systems	Windows XP Professional, Windows 7 or Higher versions or Linux
4.	BAR CODE PRINTER
Item	Description of Requirement
Make & Model	
Printing Technology	Thermal Transfer
Print Speed	2 ips
Print Width	105 mm(4.09”)
Print length	1000 mm(39.33”)
Ribbon length	Minimum 300 mtrs.
Ribbon	With ARCP- Automatic Ribbon Control & Positioning System - For Wrinkle free printing by automatic ribbon tension control
Label Sensor Type	Fully adjustable Sensor with Label gap, card notch & reflective black mark
Label Roll Capacity	Internal - 125 mm OD External- 200 mmOD
Memory	Flash - 2 MB DRAM - 6 MB
Interface	RS-232/ Parallel Port, USB 2.0 or above
Bar Code	1Dbarcodes: Min. 12 standard barcodes
	2Dbarcodes: Min. PDF-417,Maxicode, Data matrix
Media Type	Roll-fed, Fanfold, Continuous, Die cut, black mark, ticket, tag
Accessories	With all accessories for peripherals



Table: Recommended specifications of Barcode and Thin client

Thin client	
Item	Description of Requirement
LTSP 5.x support	Required
LAN port	Gigabit Ethernet RJ-45 LAN Port with LAN (iPXE / gPXE / Ether boot)
Embedded Thin Client OS	Yes Required with full support for latest supported version of Embedded Windows pre-installed/ Or Linux
CPU	Intel Dual Core 1.86GHz or EQUIVALENT or higher
Memory	4GB DDRII
Output Device/ Monitor	Dual digital Monitor (DVI-D + DVI-I, VGA with Adapter)
Sound	Internal Speaker with Line Out, Mic In
Keyboard	USB or PS2
Mouse	USB or PS2
USB	Min. 4 USB Hi Speed USB 2.0 port, Min 2 USB 3.0 Ports
Warranty	3 Year on-site warranty 24x7, 4 hours response time with 72 hours part replacement
Certification	Energy star & EPEAT gold registered.
Accessories	All accessories and power cable

Master Data of Blood Bank

To configure the e-Rakt Kosh for Blood Bank, following minimum master data set will be required. Nodal Officer is requested to fill these sheets and mail to CDAC NOIDA for configuration purpose.

1. Blood Bank Information

Blood Bank Name			
Short Name			
License Details	No:	Valid From:	Valid To:
NABH Accreditation if Available	No:	Valid From:	Valid To:
Category	Tick or Add 1. Govt 2. Red Cross 3. Charitable 4. Private 5. Other (please mention)		
Location	Tick or Add 1. Medical Hospital 2. District or Sub District Hospital 3. CHC 4. PHC 5. Stand Alone Blood Bank 6. Other (please mention)		
Address 1			
Address 2			



City	
District	
State	
Pin code	
Contact Person/HOD	
Phone No's	
Fax No's	
E-mail	
Web Site	
Any Other Information	

2. Donor Types Supported by Blood Bank

Sr. No	Donor Type	Tick
1.	Voluntary	
2.	Replacement	
3.	Family Donor	
4.	Directed	
5.	Autologous	
6.	Other (Specify)	
7.		
8.		
9.		
10.		

3. Donation Types Supported by Blood Bank

Sr. No	Donor Type	Tick
1.	Whole Blood	
2.	Plasma Apheresis	
3.	Platelet Apheresis	
4.	Other (Specify)	
5.		
6.		
7.		

4. Components Supported by Blood Bank

Sr. No	Component Name	Tick
1.	Whole Blood	
2.	Packed Red Blood Cell (PRBC)	
3.	LR- Packed Red Blood Cell (LR-PRBC)	
4.	Random Donor Platelet (RDP)	
5.	Single Donor Platelet (SDP)/ Apheresis Platelet	
6.	Platelet Rich Plasma (PRP)	
7.	Fresh Frozen Plasma	
8.	Cryoprecipitate	
9.	Cryo Poor Plasma	
10.	Other (Specify)	
11.		
12.		
13.		

5. Bag Type Supported by Blood Bank

Sr. No	Bag Type	Tick
1.	Single (350/450ml)	
2.	Double (350/450ml)	
3.	Triple (350/450ml)	
4.	Quadruple (450 ml) with inline filter	
5.	Quadruple (450 ml) without inline filter	
6.	Penta Bag (450 ml)	
7.	Transfer Bags	
8.	Apheresis Kits	
9.	Other (Specify)	
10.		

6. TTI Parameters Supported by Blood Bank

Sr. No	TTI Parameters	Tick
1.	HIV 1&2	
2.	Hepatitis-B	
3.	Hepatitis-C	
4.	Syphilis	
5.	Malaria	
6.	Other (Specify)	
7.		
8.		
9.		
10.		



7. Refreshment Details

Sr. No	Item Name	
1.		
2.		
3.		

8. Charge Details

Sr. No	Component/Tariff Name	Charges in Rs.
1.		
2.		
3.		
4.		
5.		
6.		
7.		
8.		
9.		
10.		

9. Blood Area Details

The Following details of Blood bank area need to be entered in the Format enclosed.

Area Usability can be:

1. Registration Room
2. Medical Examination Room
3. Counsellor Room
4. Donation Room
5. Refreshment Room
6. Serology Laboratory
7. Component Lab
8. TTI Lab
9. Receipt and issue counter
10. Store
11. MO In-charge Room



12. Record Room
13. Quality Control Lab
14. Washing & Sterilization Area
15. Other (Specify)

Sr. No	Area Name	Area Usability	Room No	Location
1.				
2.				
3.				
4.				
5.				
6.				
7.				

11. Blood Storage Details

Storage Type can be

1. Untested bags
2. Tested bags
3. Cross Matched Bags
4. Expired bags/discarded bags

Sr. No	Storage/ Equipment Name	Storage Type	Area	Specific for Components	Specific for ABO
1.					
2.					
3.					
4.					
5.					
6.					
7.					



11. Other Blood Bank / Storage associated with Blood Bank

S. No	Blood Bank/ Storage Unit Name	Storage Unit Yes/No	Address	License Details
1.				
2.				
3.				
4.				
5.				
6.				
7.				
8.				

Contact Us

You can e-Mail us at eraktkosh@cdac.in

Chapter 2

BLOOD DONOR SCREENING, COUNSELLING AND COLLECTION OF BLOOD

Donor Management

Blood transfusion service is an essential element of a health-care system and individuals who donate their blood provide a unique contribution to saving lives and improving patient health. To provide a safe and sufficient blood supply, the Blood Transfusion Services should build and maintain a pool of safe, voluntary non-remunerated blood donors. Blood donors should be provided with high standards of care and assurance of their health and safety.

Counselling is an integral part of the Blood Transfusion Services. Blood donor counselling is a confidential dialogue between a blood donor and a trained counsellor about issues related to the donor's health and the donation process. It should be provided before and after blood donation. It minimizes the unnecessary loss of suitable donors while maximizing the retention of donors, including those who are temporarily deferred.

Counselling provides an opportunity for the blood bank to assist donors to provide informed consent for blood donation and to defer unsafe donors. It also aids donors to self-defer if they are aware of having been exposed to any risk of TTI or have a known health condition or have had a treatment that could influence their suitability to donate blood. Blood donor counselling contributes to blood safety by reducing the prevalence of TTI in donated blood and assists in maintaining a pool of safe, healthy and reliable voluntary non-remunerated blood donors (VNRBD). This is particularly valuable for blood bank in the process of transition from a reliance on first-time or family replacement donors to regular VNRBD.

Pre-donation information

It is an important first step in informing and educating donors about the blood donation process, including donor selection criteria and deferral or self-deferral, blood screening for TTI, blood grouping, counselling and referral. Pre-donation information may be provided verbally or through printed, graphic, audio-visual and online materials and should be presented in a simple and clear format. It is usually made available to prospective donors at the same time as the donor questionnaire during the process of registration for blood donation.



Pre-donation Counselling should aim at eliminating fear through information and education. This should include safety of blood donation, blood volume in human body, amount of donation, recuperative power of human body, principles of donor selection, blood communicable diseases, safe blood transfusion, safety of blood donor, safety of recipient and need of self-exclusion by the prospective donors when one is not fit to donate blood. Pre-donation counselling should be provided before donation, maintaining confidentiality and privacy. Need for honest and truthful reply should be stressed.

Donors should be advised to contact the blood transfusion services (BTS) and provide post donation information if they become unwell, particularly with an illness that they might have been incubating at the time of donation (usually within 28 days of donation), or remember important information about a past illness or their risk for a TTI that should have been declared before donation. All donors should be provided with information on post-donation care to reduce the risk of adverse donor reactions and be advised to provide the BTS with any additional information that may affect the safety of the blood for transfusion. Planning of voluntary donor badge at the end of the donation by the Social Worker and a smiling “thank you” before the donor leaves the bed, pay enormous dividends to retain donors.

The donor should be served refreshment after blood donation. Refreshment and drinks should be served neatly and cordially with a smile. Giving company and advising about do's and don'ts for the next few hours are part of donor care.

In the post donation stage, Donor Certificate and Blood Donor Card should be handed over to respective donor so that the donor can know his/her blood group. The donor has to be informed regarding

- The window period for TTI
- How to remain safe blood donor
- Need for safe blood donor base
- How to be a regular donor.

In case of any high risk behaviour/history - **Confidential unit exclusion (CUE)** allows donors to inform the BTS, in a confidential manner, whether to use their blood for transfusion or not. The donor should be informed of the process of CUE, if this system is in place in the BTS.



Donor Notification

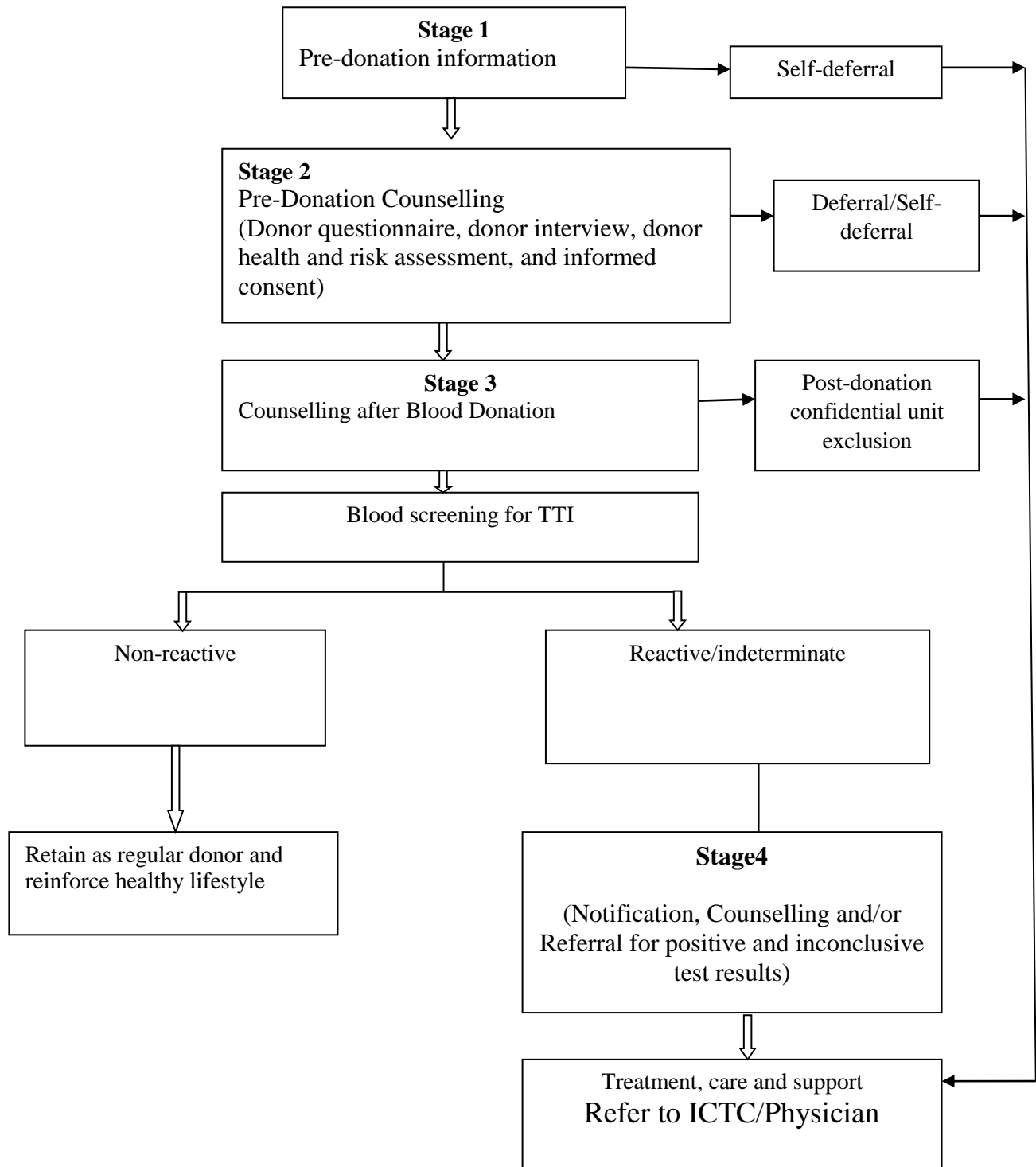
As per the govt. guidelines*

- Specific informed consent should be taken from the donor at the time of registration to inform the donor of results for TTI testing
- Pre-donation counselling essential
- In case of sero-reactive donor- Blood Bag to be discarded
- Donor to be informed that tests are not conclusive and need to be confirmed

Strict confidentiality has to be maintained while informing the donor of sero-positivity in TTI testing. The results should not be given through letter/mail. Only mention that some abnormality in results has been found and the donor may contact the blood bank. On contact with blood bank counsellor, the results should be revealed after proper counselling with a clear statement that the test done was only a screening test and confirmation needs to be done.

The donor should be referred to the nearest ICTC/Physician for confirmation of screening results and further management. Proper Counselling and care of blood donors with courtesy, concern, care and sincerity may inspire many onlookers and voluntary donors to become blood donors for the first time and one time donors to become regular repeat donors to strengthen the healthy voluntary donor base.

Stages of Blood Donor Counselling



* [An Action Plan for Blood Safety 2007, NACO, MH&FW, GOI. Point No. 4.13-4.16]



CRITERIA FOR SELECTION OF BLOOD DONORS

The purpose of donor selection is to identify any factors that might make an individual unsuitable as a donor, either temporarily or permanently.

The Medical Officer/Staff Nurse/Lab Technician on duty determines the suitability of donor for blood donation and should confirm that the criteria are fulfilled after evaluation of health history questionnaire and medical examination including the results of pre donation screening tests.

A. Accept only voluntary/replacement non-remunerated blood donors if following criteria are fulfilled.

The interval between blood donations should be no less than three months. The donor shall be in good health, mentally alert and physically fit and shall not be a jail inmate or a person having multiple sex partners or a drug-addict. The donors shall fulfil the following requirements, namely:

The donor shall be in the age group of 18 to 65 years (**“The gazette of India” Extraordinary part II section 3- sub section (i) published by authority dated 18th Feb 2011**)

B. Physical Examination

Criteria	
General Appearance	The prospective donor must appear to be in good health
Age & Weight	
	18 to 65 years
	>45kg
Whole Blood Volume Collected	Maximum of 10 ml per kilogram of donor weight, including samples
Donation Interval	Three months after whole blood donation
	>72 hours after platelet pheresis (and not more than twice a week)
Blood Pressure (Control without Medicine)	Within normal range
Pulse	Within normal range
Temperature	<37.5 °C if measured orally, or equivalent if measured by another method
Haemoglobin/Hematocrit	>12.5 g/dl/>38%

Occupation Hazard

Air Crews, drivers of long-distance-heavy-duty vehicles and construction workers on high building are advised not to proceed for the duty within 12 hours of blood donation.



Respiratory Infection

Cold, Flu, cough, sore throat or acute sinusitis	Defer until all symptoms subside and temperature is normal
Chronic Sinusitis	No deferral unless using antibiotics
Asthmatic attack	1 week after last attack if chest is clear
Asthmatics on steroids	Defer

Pregnancy and abortion

Pregnancy or recently delivered	Defer for 6 months after delivery
Abortion	Defer 6 months after abortion
Breast feeding	After baby weaned

Surgical Procedures

Major Surgery	Twelve Months after recovery
Minor Surgery	3 Months after recovery
Open heart surgery including By-Pass Surgery	Permanently defer
Cancer Surgery	Permanently Defer
Localized Skin Cancer that was removed	6 months after removal
Tooth extraction or dental manipulation	Defer for 3 days
Dental Surgery under anaesthesia	Defer for one month

Heart Disease

Has any active symptom (chest pain, shortness of breath, swelling of feet)	Permanently defer
Restricted activity	Permanently defer
Cardiac medication (digitalis nitro glycerine)	Permanently defer
Myocardial Infarction	Permanently defer
Coronary artery disease	Permanently defer
Angina Pectoris	Permanently defer
Rheumatic heart disease with residual damage	Permanently defer

Convulsions and Epilepsy	Permanently defer
Endocrinal Disorders	Permanently defer



Infectious Disease

Donors should be free from infectious diseases known to be transmissible by blood, so far as can be determined by usual examination and history.

Viral Hepatitis

Has had hepatitis (jaundice other than Hepatitis A) Hepatitis B (HBsAg), Hepatitis C (HCV)	Permanently defer
Exposure to hepatitis by tattoos, Acupuncture or body piercing	Defer for 12 months
Worked in renal dialysis	Defer for 12 months
Received transfusion of blood and its components	Defer for 12 months
Close contact with individual suffering with hepatitis	Defer for 12 months

Jaundice

Has ever had jaundice associated with

New born	No deferral
Rh Disease	No deferral
Gall Stone	No deferral
Mononucleosis	No deferral

HIV Infection/AIDS

High risk group for HIV infection	Permanently Defer
Anti HIV positive person	Permanently Defer
Donors having symptoms of AIDS	Permanently Defer

Malaria

History of malaria in endemic area but duly treated and free from any symptoms	Accepted 3 months after treatment
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Tuberculosis

Tuberculosis	Defer for five years after cessation of symptoms and completion of treatment
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Syphilis

Genital sore or generalized skin rashes	Defer for 12 months after rashes disappear and completion of therapy
---	--

Fever

Had prolonged or Rheumatic fever	Defer till fully recovered and off medication
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Kidney disease

Acute infection of kidney (pyelonephritis) or acute infection of bladder(cystitis)	Defer for 6 months after cessation of treatment
Chronic kidney disease/failure	Permanently defer

Digestive System

Stomach ulcer with symptoms or with recurrent bleeding	Permanently defer
Chronic liver disease/failure	Permanently defer

Vaccination and inoculation

1. No waiting period(if symptoms free)	
Inoculation with toxin or a killed viral/bacterial vaccine	
Typhoid	Paratyphoid
Cholera	Influenza
Diphtheria	Pertussis
Tetanus	Polio (Salk vaccine, injection)
Plague	Rabies as prophylactic
Prophylactic Hepatitis B	Gamma globulin
2. Two weeks deferral after vaccination	
Polio oral (Sabine vaccine, oral)	Measles (rubella)
Mumps	Yellow fever
3. Four-weeks deferral from time of vaccination	
Anti-tetanus serum	Anti- venom serum
Anti-diphtheria serum	Anti-gas gangrene serum
Rubella(German measles)	
4. Twelve-months deferral from time of vaccination	
Anti-rabies vaccination as a result of animal bite	
HBIG (hepatitis B immune globulin)	
Immunoglobulins	



Medication

If a donor is taking some medicine it may not be in his/her own interest to donate blood and may also affect the patient/recipient who would receive the blood.

Medicines	Accepted/Deferred
Oral Contraceptive	Accepted
Analgesics	Accepted
Vitamins	Accepted
Mild sedative and tranquilizers	Accepted
Salicylates(aspirin) taken in last three days	Not accepted if blood be used for preparing platelets
Isotretinoin (Accutane) Used for acne	Defer for 1 month after the last dose
Finasteride (e.g Proscar) used to treat benign prostate hyperplasia	Defer for 1 month after the last dose
Oral anti-diabetic drugs with no vascular complication	Acceptable
Diabetics on insulin	Defer while taking the drug
Antibiotics(Oral)	Defer for 3 days after last dose and till symptoms free
Antibiotics(Injection)	Defer for 4 days and till symptoms free/after the last injection
Cortisone	Defer for 7 days after the last dose
Medicine to treat Hypercholesterolemia	Accepted

Donors taking following medicines are permanently rejected:

Anti-arrhythmics	Immunosuppressants
Anti- convulsants	Pituitary growth hormones of human origin
Anticoagulants	Sedatives or tranquilizers in high dose
Anti-thyroid drugs	Vasodilators
Cytotoxic drugs	Etretinate to treat psoriasis. It is teratogenic
Digitalis	Drugs for Parkinson's Disease
Dilantin	



Other conditions requiring Permanent deferral

No person shall donate blood and no blood bank shall draw blood from person, suffering from any of the disease mentioned below, namely:-

- Cancer
- Abnormal bleeding tendencies
- Unexplained weight loss
- Polycythemia Vera
- Leprosy
- Schizophrenia
- Severe allergic disorders

BLOOD COLLECTION

Blood Bank collects the blood from the voluntary blood donors in blood donation camps and in-house. However, blood is also taken on replacement basis. As per Drugs and Cosmetics Act and Rules there under, a Blood Donation Camp with expected 50-70 blood units in about three hours or from 100 to 120 donors in five hours the following requirement shall be fulfilled

- One Medical Officer
- Two nurses or phlebotomists for managing six to eight donor tables
- Two medical Social Workers
- Three blood bank technicians
- Two Lab. Attendant
- Vehicle having a capacity to seat 8-10 person with provision of carriage of equipment and materials.

Blood donor is registered and asked to fill a questionnaire to elicit medical history. Donor is counselled by the counsellor for ensuring safe blood supply.

Pre-donation Tests - Haemoglobin determination equipment or copper sulphate is used to obtain a haemoglobin value. A Medical Officer/nurse interviews the prospective donor and measures his / her blood pressure, temperature, while eliciting medical history and any event related to previous blood donation. Donors found fit on screening are accepted for blood donation. The Staff Nurse/ phlebotomist prepares the phlebotomy site.

- Staff nurse/ phlebotomist collects the blood from the donor in accordance with SOPs and in the presence of doctor.

Blood can be collected in either 350 ml or 450 ml blood collection bags, depending upon weight of the donor.



PROCEDURE:

After selection of the vein for venepuncture, apply 70% alcohol , povidone-iodine and finally 70% alcohol swab in this sequence at the phlebotomy site. Start disinfection of the skin of about an area of 5 cm diameter from the centre outwards in a circular motion. Scrub the povidone-iodine vigorously for at least 30 seconds or till froth forms. Do not touch the site prepared for venepuncture. If the puncture site is touched, repeat skin preparation procedure as detailed earlier.

Discreetly check the used swab. If it is physically soiled/ contaminated, take a new swab and repeat skin preparation procedure as detailed earlier.

Dispose off used swab(s) into a waste bin meant for bio-hazardous materials. Allow the skin to air dry. Do not wipe the area with cotton wool, fan or blow on it.

Perform phlebotomy as per the SOP.

Post-donation - The donor is advised to rest and replenish fluids after donating blood and a history of the donation is recorded on a donation card, which is returned to the donor. Feedback form is filled by the blood donor. Blood donor and donation record is maintained.

Post Donation Care

The donor needs to be observed after blood collection, in order to attend to any adverse reactions in the immediate post-donation period.

Following blood donation, serve refreshment with warm hospitality. Whatever be the items of refreshment and drinks, they should be served nicely with a smile. This leaves a permanent impression on the donor. Thanking the donor with a request to donate again after 3 months inspires a donor for a repeat donation.

Conversation with the blood donors is very important to retain the donor as a regular blood donor.

Watch out for following signs of minor reactions:

- Restlessness / giddiness
- Perspiration on forehead
- Pale colour
- Tendency to faint
- Lack of willingness to communicate
- Hyper ventilation



To prevent adverse reactions like giddiness ask the donor not to get up from the chair/cot for 5 minutes even if he feels perfectly all right. Observe for another 10 minutes in the refreshment area whilst having refreshment. It is important that any reaction be spotted as soon as possible and measures taken to prevent the reaction from continuing or becoming more severe. When an adverse donor reaction occurs, the social worker should remain cool and call the Medical Officer.

If the blood donor becomes pale and /or light headed, the social worker should act promptly to prevent the donor from falling. The social worker should help the donor to lie down with legs slightly raised. In case of bleeding from the site of venepuncture, finger pressure can be applied on the cotton wool pad till the medical officer arrives.

Inspect the venepuncture site before the donor leaves the donor room. Apply a Band aid tape only after oozing stops. If there is persistent oozing at the site of venepuncture, apply pressure with a dry, sterile cotton swab. If there is haematoma apply pressure gently over the area after 5 minutes. Inform the donor about the expected change in skin colour. If the pain persists, ask him/her to apply ice.

The blood donor should always be requested to remain in the refreshment room for at least 15 minutes. This is not only for hospitality reasons but this time frame is to watch out for any possible donor reaction in the immediate post donation period. The blood donor may be advised to increase their liquid consumption (non-alcoholic) during the day. The blood donor should also be instructed to refrain from smoking and to avoid strenuous activities like jogging, going to the gym, etc.

National Blood Donor Vigilance Programme (NBDVP)

The recipient's part i.e. Reporting of Adverse Reactions w.r.t Blood Transfusion in the patient was covered under **Haemovigilance Programme of India (HvPI)** with the launch of the programme on 10th December 2012 in the country & the donor's part i.e. Reporting of Adverse Reactions associated with Blood Donations is to be covered under **NBDVP** which was launched on 14th June 2015 on World's Blood Donor Day at Science City Kolkata under the ambit of Haemovigilance Programme of India.

The objectives of NBDVP are to:

- Improve donor safety and satisfaction through monitoring, analysing and researching adverse events
- Analyze risk factors , implement and evaluate preventive measures
- Provide evidence based support for Blood Donation Process improvement



- Reduce the frequency of adverse events
- Increase donation frequency

A one page Adverse Donor Reaction Reporting Form (ADRRF) has been devised to capture information about adverse reactions or complications related to blood donation. The form is in line with the complications defined in the Standard for Surveillance of Complications Related to Blood Donation by working group on “donor vigilance” of the International Society of Blood Transfusion of Haemovigilance (ISBT) Working Party on Haemovigilance, December 11, 2014. The centers enrolled under the HvPI will collect data in respect of adverse reactions associated with blood donation. The information collected in ADRRF will be forwarded to the coordinating center, i.e., the National Institute of Biologicals (NIB) through a software i.e. Donor-Vigil Software for National Blood Donor Vigilance was indigenously developed by Software Development Team of NIB, which was launched on 14th June, 2016 on World’s Blood Donor Day at Darjeeling. This data will be collated and analyzed to identify trends and recommend best practices and interventions required to improve donor safety. These recommendations will be forwarded to the Drugs Controller General (India), Central Drugs Standard Control Organization, to formulate safety-related regulatory decisions to improve donor safety and satisfaction.

National Blood Donor Vigilance Programme (NBDVP) is an integral part of the HvPI and is a comprehensive, centralized, and well-structured approach to collect, collate, and analyze data to continuously improve donor safety and satisfaction so that the blood donors have a feeling of being well-treated and well taken care of that may cause blood donors to continue as repeat donors and will have an positive impact **Excluded:** when there is conclusive evidence beyond reasonable doubt that the complication can be attributed to causes other than the donation.





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I) Donor Information	
Donor Id _____ Sex _____ Weight of Donor (KG) _____ Age/Date of Birth _____	Type of Donation: (a) Whole Blood, (b) Apheresis — (1. RBC, 2. Platelets, 3. Plasma, 4. Plasma + Platelets) Donor Type: (a) Voluntary, (b) Replacement, (c) Voluntary Family Donor (1. first-time, 2. repeat) Venipuncture: (a) 1, (b) 2, (c) >2 Data Captured: (a) Onsite, (b) Call back by donor, (c) Call back by Blood Centre Site of Donation: (a) Camp (b) Blood Centre
II) Details of Blood Collected	
Lot No. of Blood Bag _____ Manufacturer of Blood Bag _____ Date & Time of Donation _____	Volume of Blood Collected (ml) _____ Expiry date of Blood Bag _____ Date & Time of Reaction _____
III) Type of Complications (Refer Annexure I)	
<p>A1-Complications mainly characterized by the occurrence of blood outside the vessels</p> <p>(a) Haematoma (bruise) (b) Arterial puncture (c) Delayed(bleeding/Re-bleeding)</p> <p>A2-Complications mainly characterized by pain</p> <p>(a) Nerve injury/irritation (b) Other Painful arm</p> <p>A3-Localised infection/inflammation along the course of a vein</p> <p>(a) Thrombophlebitis (b) Cellulitis</p> <p>A4- Other major blood vessel injury -Serious conditions needing specialist medical diagnosis and attention.</p> <p>(a) Deep venous thrombosis (DVT) (b) Arteriovenous fistula (c) Compartment syndrome (d) Brachial artery pseudoaneurysm</p> <p>B-Complications mainly with generalized symptoms: Vasovagal reactions</p> <p>(a) LOC(Loss of Consciousness) < 60 sec (b) LOC(Loss of Consciousness) > 60 sec (c) Without loss of consciousness (LOC) (d) With injury (e) Without injury (f) Within Blood collection facility (g) Outside blood collection facility</p> <p>C-Complications related to apheresis</p> <p>(a) Citrate reaction (b) Haemolysis (c) Air embolism (d) Infiltration of IV fluids</p> <p>D-Allergic reactions</p> <p>(a) Allergy (local) (b) Generalised allergic reaction (anaphylactic reaction)</p> <p>E-Other serious complications related to blood donation</p> <p>(a) Acute cardiac symptoms (b) Myocardial infarction(MI) (c) Cardiac arrest (d) Transient Ischemic Attack(TIA) (e) Cerebrovascular Accident (f) Death</p> <p>F-Other Reactions</p>	
IV) Outcomes	
<div style="display: flex; justify-content: space-between;"> <div style="width: 48%;"> <input type="checkbox"/> Resolved <input type="checkbox"/> On Follow Up <input type="checkbox"/> Recovered with Sequelae <input type="checkbox"/> Permanently Disabled <input type="checkbox"/> Death following the Adverse Reactions <input type="checkbox"/> Unknown </div> <div style="width: 48%;"> <input type="checkbox"/> Definite (Certain) <input type="checkbox"/> Probable (Likely) <input type="checkbox"/> Possible <input type="checkbox"/> Unlikely (Doubtful) <input type="checkbox"/> Excluded </div> </div>	
V) Imputability (Refer Annexure II)	





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Annexure I

Donor Complication Form

Reference Document (Type of complication)

☐ **A 1. Complications mainly characterized by the occurrence of blood outside the vessels.**

☐ **a) Haematoma (bruise)**

☐ Bruising/discolouration ☐ Redness/warmth ☐ Swelling ☐ Local pain/tenderness

☐ Nerve irritation/injury

☐ **b) Arterial puncture**

☐ Bright Red blood ☐ Pulsating needle/tubing. ☐ Blood bag fills rapidly (< 4 min).

☐ Weak pain (elbow). ☐ Radial pulse weak/absent.

☐ **c) Delayed bleeding/ Re-bleeding)**

☐ Inadequate Pressure at venipuncture site ☐ Inadequate duration of pressure (< 10 min)

☐ Heavy lifting or strain to the donor's arm. ☐ Donor medications (anticoagulants/aspirin)

☐ **A2. Complications mainly characterized by pain**

☐ **a) Nerve injury/irritation**

☐ Radiating, sharp pain moving away from the venepuncture site,

☐ Paraesthesias- tingling, burning sensations in the hand, wrist or shoulder area

☐ Onset of symptoms-on needle insertion or withdrawal

☐ Delayed pain when accompanied by haematoma.

☐ Worsening of symptoms in certain positions or with certain arm motions.

☐ **b) Other Painful arm**

☐ Arm pain described as ache or heaviness in the arm(Like vaccination)

☐ Absence of nerve irritation

☐ **A 3. Localised infection/inflammation along the course of a vein**

Symptoms localized to phlebotomy site

☐ Warmth ☐ tenderness ☐ Local pain ☐ Redness ☐ Swelling (at the site of phlebotomy)

☐ Fever Present/absent

☐ **a) Thrombophlebitis:** Symptoms along course of vein

☐ **b) Cellulitis:** The redness, swelling and tenderness affect the soft tissues

☐ **A4. Other major blood vessel injury -Serious conditions needing specialist medical diagnosis and attention**

☐ **a) Deep venous throosis (DVT)** ☐ Swelling and Pain in upper arm ☐ Signs of superficial inflammation/thrombosis(See A3) ☐ Additional risk factor of thrombosis(ExOC pills)

☐ **b) Arteriovenous fistula** ☐ Pulsating mass ☐ Palpable thrill/Associated bruit

☐ Affected area-warm ☐ Distal area -feels cool ☐ Distal veins-dilated& pulsatile

☐ Related to arterial puncture ☐ Related to venous laceration.

☐ **c) Compartment syndrome** ☐ Painful arm ☐ Swelling(Haematoma) ☐ Paresthesias

☐ Partial paralysis. ☐ Muscle and soft tissue necrosis.

☐ **d) Brachial artery pseudoaneurysm**

☐ Pulsating mass in the arm. ☐ Pain and paraesthesias. ☐ Haematoma(large)

☐ May follow Arterial puncture (A1)





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B. Complications mainly with generalized symptoms: Vasovagal reactions

- ☐ Generalized Weakness ☐ Anxiety ☐ Dizziness ☐ Nausea ☐ Vomiting
☐ Pallor (Skin and lips) ☐ Cold extremities ☐ Hyperventilation ☐ Hypotension ☐ Vomiting
☐ Rapid Pulse ☐ Low Vol Pulse ☐ Feeling of warmth ☐ Vomiting
☐ Convulsions ☐ Tetany ☐ Twitching ☐ Vomiting
a) ☐ LOC (Loss of Consciousness) < 60 sec b) ☐ With injury c) ☐ Within Blood collection facility
☐ LOC (Loss of Consciousness) > 60 sec ☐ without injury ☐ Outside blood collection facility
☐ Without loss of consciousness (LOC)

C. Complications related to apheresis

☐ a) Citrate reaction

- ☐ Numbness/tingling/vibrations-lips, fingers ☐ Metallic taste ☐ Vomiting
☐ Chills/ shivering ☐ light-headedness ☐ Muscle twitching ☐ Carpopedal spasm
☐ rapid or slow pulse, ☐ Irregular Pulse ☐ shortness of breath.
☐ Tetany(generalized muscle contractions) ☐ Shock ☐ Cardiac arrest

☐ b) Haemolysis

- ☐ Pink or red plasma ☐ Blood in lines ☐ Pink or red urine

☐ c) Air embolism

- ☐ Bubbling sound or feeling at venipuncture
☐ Cough ☐ Dyspnea ☐ Apprehension ☐ Sweating ☐ Chest pain ☐ Confusion
☐ Tachycardia, ☐ Hypotension, ☐ Nausea ☐ Vomiting.

☐ d) Optional category: Infiltration of IV fluids ☐ Swelling at venipuncture site

D. Allergic reactions

☐ a) Allergy (local)

- ☐ Itching and redness at the ()venepuncture site ()Bandage site or () Skin disinfection area. ☐ Raised rash or hives that may expand to cover a larger area of the arm.
☐ Occurrence ()Soon after donation () Hours later () Days later.

☐ b) Generalised allergic reaction (anaphylactic reaction)

- ☐ Occurs soon after reaction ☐ Cardiac arrest
☐ Apprehension/Anxiety ☐ Flushing, swelling of eyes, lips or tongue ☐ cyanosis ☐ cough
☐ wheezing ☐ Dyspnea ☐ Chest tightness ☐ cramps, nausea, vomiting, diarrhoea,
☐ tachycardia ☐ Hypotension ☐ altered mentation.

E. Other serious complications related to blood donation

Major cardiovascular event (MCE) (Upto 24hours after donation.

- a) ☐ Acute cardiac symptoms (other than myocardial infarction or cardiac arrest).
b) ☐ Myocardial infarction(MI) c) ☐ Cardiac arrest ☐ Transient Ischemic Attack(TIA)
d) ☐ Cerebrovascular accident e) ☐ Death





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Annexure II

IMPUTABILITY LEVELS (Grading of complication severity and Imputability strength of relation between donation and complication)

The Imputability levels are given below:

- **Definite (Certain):** when there is conclusive evidence beyond reasonable doubt for the relation.
- **Probable (Likely):** when the evidence is clearly in favour of a relation.
- **Possible:** when the evidence is indeterminate for attributing the complication to the donation or an alternative cause.
- **Unlikely (Doubtful):** when the evidence is clearly in favour of attributing complication to other cause.
- **Excluded:** when there is conclusive evidence beyond reasonable doubt that the complication can be attributed to causes other than the donation.



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Denominator Data About All Donor		
1. Total donations in the month (of reporting)		
Whole blood[] Apheresis[] If apheresis RBC[] Platelets[] Plasma [] Plasma + Platelets[]		
2. Gender of Donor (Total) Male [] Female []		
3. Donor Types (Total) First-time donors [] Repeat donors []		
4. Volume of donation		
No of 350 ml donations []	No of 450 ml donations[]	others



Chapter 3

Blood Component Preparation and Quality Control

Blood component is a constituent of blood, separated from whole blood e.g. red cells, platelets, FFP

Use of components ensures rational use of blood

- Component separation allows optimal survival of each constituent of blood
- Each component meets specific need of patient
- Avoids exposure to unnecessary constituents and complications
- Conserves blood, more than one patient may benefit
- Supplements blood supply and results in better blood inventory management

Component preparation is based on differences in size and density (specific gravity) of blood cells.

Plasma – sp. Gr. 1.02-1.03

Platelet-sp. Gr. 1.03- 1.04

RBC- sp. Gr. 1.08-1.09

Cellular Components

- Packed Red Cells
- Leucoreduced Red Cells
- Platelet concentrates (Random donor)
- Leucoreduced Platelet Concentrates
- Single Donor Platelets (Aphaeresis)
- Granulocytes (Aphaeresis)
- Stem Cells (Aphaeresis)

Plasma Components

- Fresh Frozen Plasma/ FFP
- Cryoprecipitate
- Cryo Poor Plasma



PREPARATION OF COMPONENTS:

PRINCIPLE:

Components of blood have different specific gravities. Due to differences in specific gravity, they can be separated by centrifuging at different centrifugal forces for different durations of time. Availability of multiple bags system (Double, triple, Quadruple, etc.) allows separation of components after centrifugation while maintain a closed system.

Blood bags used for component preparation should be able to withstand centrifugation at 5000g for 30 minutes at 4°C and 37°C without any leakage. They should be sterile and should have good quality needle (16-G) with no burrs. These bags should be able to withstand temperature from -80°C to +50°C.

Steps involved in blood component preparation

- Donor screening and selection
- Blood collection in multiple bags
- Centrifugation +/- Filtration; sedimentation
- Separation of components into satellite bags
- Storage

Materials and Equipment:

- Multiple blood bags system (Double, triple, Quadruple, etc.)
- Refrigerated Centrifuge
- Weighing balance
- Two pan balance
- Laminar air flow bench
- Blood Bank Refrigerator, 2-6°C
- Deep freezers (-40°C, -80°C)
- Platelet agitator and incubator
- Water bath
- Plasma expressor
- Tube sealer
- Stripper
- Thin board boxes for storing plasma in freezer
- Plastic over raps for blood bags (preferably)



- Appropriate labels (sticker) and instructions for each component
- Transfer packs

Additional/Optional

- Sterile connecting device
- Cryoprecipitate bath 4°C
- Gamma irradiator
- Cell separator

KEY ELEMENTS IN BLOOD COMPONENT PREPARATION

- Adequate premises and space (+50 m²)
- Suitable equipment and services
- Correct materials, containers and labels
- Approved procedures and instructions with Clearly Defined Processes
- Qualified and trained staff

Factors affecting Quality of blood component preparation

Collection of blood

- Proper selection of donor: Donors who are taking aspirin or other Antiplatelet drug therapy should be deferred for 72 hours
- Clean and aseptic venipuncture site to minimize bacterial contamination
- Clean venipuncture with minimum tissue trauma and free flow of blood
- The flow of blood should be uninterrupted and continuous. If any unit takes more than 8 minutes to draw, it is not suitable for preparation of platelets concentrate, fresh frozen plasma or cryoprecipitate. Bad venipuncture, hematoma, double pricks or over/under collections are not optimal for component harvesting.
- A correct amount of blood proportionate to anticoagulant should be collected in primary bag that has satellite bags attached with integral tubing. Commonly used Anticoagulant and preservative solutions include
 - CPDA-1
 - CPD–SAGM (Saline, adenine, glucose, mannitol)
 - CPD-ADSOL

49 ml of anticoagulant is required for 350 ml of blood collection, whereas for 450 ml blood collection, 63 ml of anticoagulant is required.



- 350ml of Blood weighs 367.5gm whereas 450ml of Blood weighs 472.5 gm (1ml of Blood=1.05 gm of blood)

(Total wt of Blood Bag=Volume of Blood x 1.05 + wt of empty bag)

- Monitor the collection of blood with Automatic Mixer/Scale which is used for collecting the desired amount of blood and mixing the blood with the anticoagulant.
- If platelets are to be harvested the blood bag should be kept at room temperature 20-24°C until platelets are separated. Platelets should be separated within 6-8 hours from the time of collection of blood.

Component preparation should be done within 6-8 hrs of blood collection

- Triple packs system with two attached bags makes it possible to make red cells, platelet concentrate and fresh frozen plasma.
- Quadruple packs system with three attached bags are used for preparing red cells, platelet concentrate, cryoprecipitate (factor VIII) and cryo- poor plasma.
- Double bags are used for making red cells and plasma only.
- All the satellite bags should be labeled appropriately.

UTMOST CARE DURING BLOOD COLLECTION IS THE KEY TO GOOD QUALITY OF BLOOD COMPONENTS

Pre-centrifugation Storage

- Critical elements – Time and storage conditions prior to separation
- Maintain Temperature Between 20 – 24 °C for Platelet preparation
- Maintain Temperature at 4 °C for Red Cell preparation

CENTRIFUGATION

- Balance 2 bags (with satellite bags) accurately and place in diagonally opposite cups, to ensure good Interface and consistent Yield. This minimizes WBC contamination and enhances life of equipment. Unequal weights place excessive eccentric loads on rotor of centrifuge, which cause irregular wear and tear and eventual breakage.
- Rubber discs / or soft plastic should be used for balancing. No sharp objects should be used for balancing
- The bags should be so placed that its broad side/label faces the outside wall of the cup. Bags should be well packed in cups. Tap the port end of bags to remove red cells sticking to ports



- Plastic over wears for bags may be used (optional).
- Correct speed of centrifugation and time must be maintained as they are the most critical factors in component preparation and dictate degree of separation. The blood components are prepared by centrifuging at different relative centrifugal force in g at different time. Conversion of relative centrifugal force (RCF) to rpm depends upon the radius of centrifuge rotor.

It can be calculated by:

- Nomogram
- Centrifugal Force in g = $28.38R(\text{rpm}/1000)^2$
R= Radius of the centrifuge rotor in inches
Light Spin: 2000g x 3min
Heavy Spin: 5000g x 5min

Each centrifuge should be calibrated for optimum speeds and times of spin for the preparation of each component

- Programme Display panel in Refrigerated Centrifuge shows:
 - Programme No
 - Acceleration
 - Deceleration
 - Speed(RPM)
 - Time(minutes)
 - Temperature
- Temperature for centrifugation-
 - 4°C for Packed Red Cells
 - 22 °C for PRP, Platelets
- Observe for any abnormal vibration till the required speed is attained, if there is any, stop the centrifuge and check the weight of the opposite cups with bags.
- In centrifuged unit, Components settle in layers, depending upon the speed and time of Centrifuge. Gentle Handling of centrifuged units prevents mixing at interface

PREPARATION OF RED CELLS AND FFP

- 1 Collect appropriate volume of donor blood in CPDA double bag.
- 2 Store at 2-6°C till processed.



- 3 Place bags in the buckets of refrigerated centrifuge and balance the opposite bags accurately.
- 4 Centrifuge at heavy spin (5000 x g) for 5 minutes at 2-6 °C.
- 5 Place the primary bag on plasma expessor and allow the plasma to flow into one of the satellite bags. Leave appropriate amount of plasma in primary bag to maintain the hematocrit of 80%. Seal the tubing and separate the bags.
- 6 Label the plasma bag and is rapidly frozen. This should be done as soon as possible after collection, in any case within 6-8 hours. The complete freezing process should be as short as possible and preferably should not take more than one hour.
- 7 FFP should be frozen immediately and kept in cardboard boxes in horizontal position with a Rubber band to make an indentation on FFP and once frozen should be stored in vertical position in deep freezer below -18°C

PREPARATION OF PLATELETS

Platelets can be prepared by platelet rich plasma (PRP) method or by Buffy Coat method. In PRP method, whole blood undergoes 'light spin' to separate the platelet rich plasma. This PRP subsequently undergoes heavy spin to get platelet Concentrate.

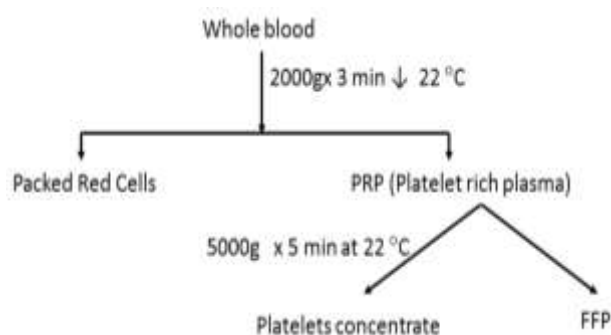
It is prepared from 450 ml whole blood kept at room temperature (22-22°C) and within 6 to 8 hours of collection.

Procedure:

- 1 Collect 450 ml blood by a clean, single venipuncture into 450 ml CPDA or ADSOL / SAGM triple bags system.
- 2 Keep the blood bag at room temperature (20-22°C) before preparing platelets, for not more than 6 hours. Do not chill at any time before or during platelet separation.
- 3 Centrifuge the blood bags at 20-24°C at light spin for appropriate time (2000 x g for 3 minutes).
- 4 Separate 4/5 of the platelet rich plasma (PRP) into one satellite bag if CPDA triple bags systems are used. Double seal the tubing between the primary bag and the satellite bags. Separate the primary bag with red cells. One of the satellite bags contains PRP. If the ADSOL /SAG -M triple bags system is used, transfer all PRP into empty satellite bag and add additive solution in to red cells. Double seal the tubing of the bag with red cells and separate it from the satellite bags. One of the satellite bags contains PRP. PRP may be used as such or processed further to prepare platelet Concentrate (PC).



- 5 Centrifuge the bag with PRP and another satellite bag at 20-24°C at 'heavy spin' for appropriate time e.g. 5000xg for 5 minutes.
- 6 Express supernatant platelet - poor plasma into another empty satellite bag.
- 7 Leave approximately 50 ml of plasma with the platelets and label it.

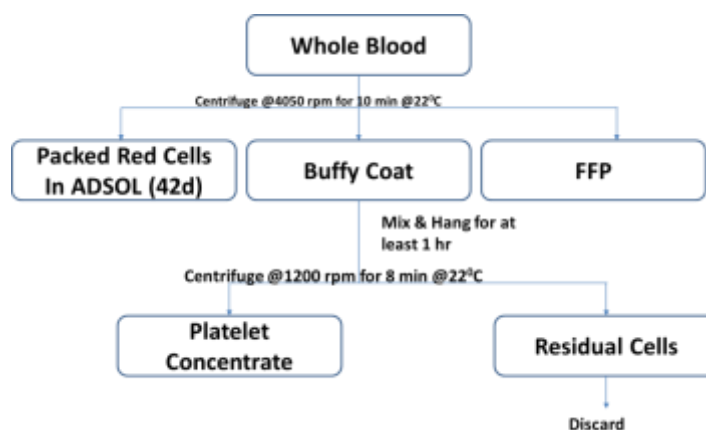


- **Platelet concentrates** are kept for 60 min in laminar flow hood, with the label side down
- Mix the contents of the bag manually before placing the unit in platelet incubator

BUFFY COAT METHOD:

Whole blood is centrifuged at high speed to separate the buffy coat. Buffy coat is centrifuged at low speed to concentrate platelets

- Whole blood should be stored at 20-24°C till processing
- Centrifuge at high speed. Remove supernatant plasma from top and red cells from bottom of 'Top and bottom bags'. Leave Buffy coat in the primary bag.
- The primary bag with buffy coat and plasma with satellite bag is left hanging for about 2 hours at room temperature (22°C) and then centrifuged at light spin at 22°C.



- Store platelet at 20-22°C under constant agitation in platelet incubator with agitator till used. The shelf life is 3-5 days depending on the type of plastic bags used.



Cause of Platelet Aggregates

- Excessive Agitation- Late
- Poor Re-suspension- Early
- Insufficient Rest Period
- Disrupted Platelet Button

Causes of Bloody Platelets

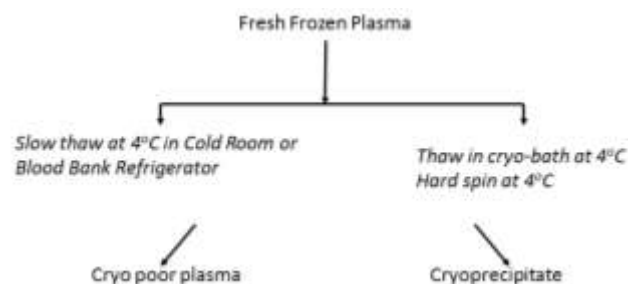
- Insufficient Centrifugation
- Cups Not Balanced- Disturb Interface
- Rough Handling- Disturb Interface
- Excessive Expression

CRYO PRECIPITATE

Cryoprecipitate are precipitated proteins of plasma, rich in Factor VIII and fibrinogen, obtained from a single unit of fresh plasma (approximately 200 ml) by rapid freezing within 6 hours of collection.

Thaw frozen plasma either at 4°C in a cold room (air thaw) or at 4°C in circulating water bath.

- If FFP is thawed in a cold room, hang the bag in an inverted position with ports lower most and place the second satellite bag on a lower shelf. Observe the pack frequently to make sure the thawed plasma is flowing in to the satellite bag. When 10-15 ml of plasma remain with cryoprecipitate seal the tubing and separate bags.
- If FFP is thawed in 4°C water bath, centrifuge the bag when the plasma is slushy at 5000 x g for 5 minutes at 4°C. Then supernatant cryo-poor plasma is siphoned out in the satellite bag, leaving 10-15 ml plasma with cryoprecipitate. Seal the tubing and separate the bags. Label bags.
- Store the bag with cryoprecipitate at -18°C



LEUKOREDUCTION

- Whole blood contains approximately 10^9 leukocytes. Reduction of leukocytes in whole blood to one tenth (10%) of the original to 10^8 is 1 log reduction i.e., removal of 90% leukocytes. This can be achieved by Buffy coat removal.
- Reduction of leukocytes to one thousandth of the original to 10^6 is 3 log reduction i.e. removal of 99.9% leukocytes.
- Leukoreduced components should have $<5 \times 10^6$ WBC/unit (red cell loss not more than 10%)

Leukoreduction can be achieved by:

- Specific leucodepletion filters
- Apheresis devices (cell separators)

Leucocyte filters are most efficient – 99.99% (4 log depletion)

- Leucocyte filters can be Red cell filters or Platelet filters
- Leucofiltration can be done
 - At the bedside
 - In the blood bank before issue
 - At the time of component preparation

Irradiated Blood Components

Blood irradiated with 25 Gy destroys ability of donor lymphocytes in blood product to proliferate in the recipient and cause GVHD

- Blood products requiring irradiation: Whole Blood (WB), Packed Red Cell (PRBC), Random Donor Platelets (RDP), Single Donor Platelets (SDP)
- Fresh Frozen Plasma (FFP) and Cryoprecipitate (CRYO) need not be irradiated

INDICATION

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



Component	Storage temp	Shelf life	Compatibility
Red cells	+ 2°-6°C	35 days	ABO / Rh
Red cells with additive solution	+ 2°-6°C	42 days	ABO / Rh
FFP	- 18°C	1 year	ABO
CPP	- 18°C	5 year	ABO
Platelets	+ 22°C	5 days	preferably ABO match, but any group is acceptable
Cryoprecipitate	- 18°C	1 year	any group

Quality Control of Blood Components

- 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

Volume

$$\text{Volume (ml)} = \frac{\{\text{Weight of bag + blood components (gm)}\} - \text{wt of empty bag}}{\text{Specific gravity of component}}$$

Volume should be recorded on all units

- Appropriate labels should be put
- For Quality Control, Non-destructive sampling methods is used, usually involve use of pack tubing
- Mixing of product and stripping of lines are vital and methods need to be standardised
- For platelet count samples should be taken into a dry EDTA tube, to induce disaggregation
- Sampling methods must be validated to ensure that they produce consistent samples, regardless of the operator

Quality Control of Whole Blood

Parameter	Quality Requirement	Frequency of Control
Volume	350/450 ml \pm 10 %	1 % of all units
Anticoagulants*	49/63 ml	All units
PCV(Hct)	30 to 40%	4 units per month
HBs Ag	Negative by ELISA	All units
Anti-HCV	Negative by ELISA	All units
Anti-HIV I&II	Negative by ELISA	All units
Syphilis	Negative by Screening test	All units
Sterility	By culture	Periodically (1% of all units)



Quality control of red cells concentrates (Prepared from 450ml Blood)

Parameter	Quality requirement	Frequency of control
Volume	280 ± 40 ml	1 % of all units
PCV (Hct)	70% ± 5 %	Periodically

Quality control of red cells in preservative sol. (ADSOL/SAGM)

Parameter	Quality requirement	Frequency of control
Volume	350 ± 20 ml	1% of all units
PCV(Hct)	55-65%	Periodically

Quality control of platelet concentrate.**Quality control of platelet concentrate prepared from 450 ml of whole blood**

Parameter	Quality Requirements	Frequency of control
Volume	50-70 ml	All units
Platelets count	$>5.5 \times 10^{10}$	4 units per month
pH	>6.0	4 units per month
RBC contamination	0.5 ml	4 units per month
WBC contamination	$5.5 \times 10^7 - 5 \times 10^8$	4 units per month

Quality control of platelet concentrate prepare from buffy coat

Parameter	Quality requirement	Frequency of control
Volume	70-90 ml	4 units per month
Platelet count	$6-9 \times 10^{10}$	4 units per month
pH	>6.0	4 units per month
WBC contamination	$<5.5 \times 10^6$	4 units per month
RBC contamination	Traces to 0.5 ml	4 units per month

On visual inspection of unit: If no pink or red discoloration, it may be assumed to contain insufficient red cells to cause immunization.

All units should show ‘swirling’ effect

‘Absence of swirling in platelet concentrates is highly predictive of poor post-transfusion platelet count increments and increased risk of bacterial contamination’. For platelet products QC should be done on expiry date (end of storage period) of the component.

Quality control of Fresh Frozen Plasma (FFP)

Parameter	Quality control	Frequency of control
Volume	200-220 Plasma	4 units per month
Stable coagulation factors	200 units of each factor	4 units per month
Factor VIII	0.7 units/ml	4 units per month
Fibrinogen	200-400mg	4 units per month



Quality Control of Cryoprecipitate

Parameter	Quality control	Frequency of control
Volume	10-20 ml	Occasionally
Factor VIII	80-120 units	Occasionally
von-Willebrand factor	40-70% of the original	Occasionally present.
Factor XIII	20-30% of the original	Occasionally
Fibrinogen	150-250 mg	Occasionally
Fibronectin	55 mg	Occasionally

75% units sampled and tested should have the values indicated above.

Factors Affecting the Quality of Blood Components.

1. Selection of donor
2. Quality of blood bag and anticoagulant preservative solution used
3. Techniques of phlebotomy (already discussed)
4. Time period: separation should be done within 8 hrs of collection
5. Transit temperature: 20-24°C for not more than 8 hours
6. Refrigerated centrifuge calibration for maximum yield in minimum time
 - Critical variables – speed, temp, duration, rotor size
 - Accurate balancing – dry weight preferred
 - Bag position
 - Swinging cups better than fixed angle cups
7. Storage temperature
 - 4±2°C = Whole Blood (WB), Packed Red Cell (PRBC)
 - 20°C-24°C = Platelet Concentrate prepared by PRP method, Buffy Coat method and Apheresis (PRP-PC, BC-PC, AP-PC)
 - ≤ -18°C = FFP, Cryoprecipitate
8. Uninterrupted, gentle flat bedded platelet incubator/agitator
 - 60-70 cycles /min
 - 1½ inch movement on either side



Chapter 4

BLOOD GROUP SEROLOGY

ABO and Rh Blood group system

The purpose of this section is to help you to understand the ABO and Rh blood group system and its importance in blood transfusion. The ABO blood group system is the most important blood type system (or blood group system) in human blood transfusion. The ABO blood group system is widely credited to have been discovered by the *Austrian scientist Karl Landsteiner*, who identified the O, A, and B blood types in 1900. He showed that by cross-testing one blood sample with another, some samples would mix successfully with no visual signs of reaction while others would react strongly, causing agglutination, which is a massive clumping of the red cells. The presence of anti-A and anti-B antibodies in the serum differs according to the AB antigens present on the red cells (Figure 1).



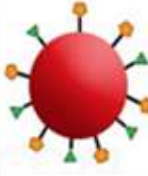







	Group A	Group B	Group AB	Group O
Red blood cell type				
Antibodies in Plasma	 Anti-B	 Anti-A	None	 Anti-B and Anti-A
Antigens in Red Blood Cell	 A antigen	 B antigen	 A and B antigens	None

Figure 1

Rh blood group system

Unlike the ABO antigens, Rh antigens are fully developed in early fetal life and remain so throughout adult life. Cord and newborn infants' red cells will therefore Rh type as strongly as normal adult blood. Rh factor in blood types stands for "Rhesus Factor". People who have D antigen are said to be Rh (D) positive (Rh+), while those who do not have are Rh (D) negative (Rh -).



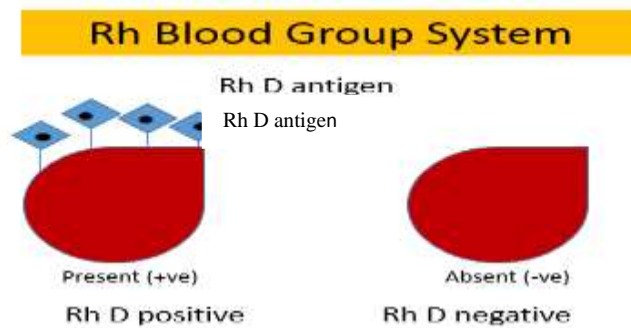


Figure 2

ABO grouping and Rh-D typing

Forward or Cell grouping: It is based on an agglutination reaction between A and B antigens present on the red blood cells with the commercially available Anti-A and Anti- B antisera.

Reverse or Serum grouping: It is based on an agglutination reaction between naturally occurring Anti-A and Anti-B antibodies in serum /plasma with reagent A, B or O red cells.

Rh typing: Routine Rh grouping of red cells involve D-antigens testing in patients and Rh (D) and weak D (D^u) antigens testing in donors. The test for other Rh antigens (C, c, E, e) are done for thalassemic and other multi transfused patients.

Anti-A₁ Lectin and Anti-AB in blood grouping reagents

- (a) Anti-A₁ Lectin obtained from the seeds of the plant *Dolichos biflorus* agglutinates only A₁ and A₁B cells but not A₂ and A₂B.
- (b) Anti-AB - It is usual to include Anti-AB as part of standard blood grouping tests on donors to ensure that the weaker group A and group B antigens are not missed. Anti-AB is not required for testing patients' red blood cells, but it is recommended for donor blood grouping. Table 1 shows the serological reactions with Anti-A, Anti-AB and Anti-A₁ Lectin.

Table 1

Antisera	Red Cells			
	A ₁	A ₂	A ₁ B	A ₂ B
Anti-A	Positive	Positive	Positive	Positive
Anti-AB	Positive	Positive	Positive	Positive
Anti-A ₁ Lectin	Positive	Negative	Positive	Negative

**Anti-A₁ is found in 1-8% of A₂ and 22 to 30% of A₂B individuals. It is usually active at room temperature or below and is rarely clinically significant, but when it reacts at 37°C it is clinically significant.*



Preparation of cell Suspension

- Wash red blood cells 3 times till the supernatant is clear.
- Prepare 40%, 2-5% and 0.8% red cells suspension in normal saline for slide, tube and gel card method respectively.

To prepare 100µl of required suspension, mix Normal Saline & packed RBC as given below in Table 2

Table 2 - Red Blood Cell Suspension (%)

% of cells	Vol. of N. S (µl)	Vol. of Washed, packed RBC (µl)
1%	99	1
2%	98	2
3%	97	3
4%	96	4
5%	95	5
40%	60	40

Slide technique:

1) Slide testing

The glass slide method is insensitive and leads to errors. This technique may be used for emergency ABO grouping tests or for preliminary grouping particularly in an outdoor camp. Slide method is not recommended for routine use because it is not reliable for

- Weakly reactive antigens on cells
- Serum grouping with low titre anti-A or anti-B

Advantages

1. Can be used in emergency and blood camps for preliminary blood grouping.
2. Easy to perform
3. Quick results

Disadvantages

- Less sensitive than the tube test
- Drying up of the reaction mixture can cause aggregation of cells, giving false positive results
- Weaker reactions are difficult to interpret.



Material required

1. Glass slides
2. Marker pen
3. Pipettes
4. Pipette tips
5. Mixing stick

Reagents required

1. Monoclonal Anti -A, Anti- B
2. Monoclonal Anti- D (IgM) or Blend of IgM and IgG monoclonal

Method

1. Label left side of the glass slide as A for Anti-A and right side with B for Anti-B.
2. Label another slide as D for Anti-D.
3. Put one drop of Anti- A on the side labeled as A and one drop of Anti- B on the side labeled as B followed by one drop of Anti -D on the slide labeled as D.
4. Add one drop of 40% red cell suspension to each of the antisera.
5. Mix the cells and antisera to an area with a diameter of 2 cm. Then gently rock the slide, look for agglutination. Read the reactions within two minutes, otherwise the drying of the reagents will give a false-positive reaction.
6. Record the results.

Interpretation

Agglutination indicates a positive result and free red cells indicates a negative reaction (Figure 3).

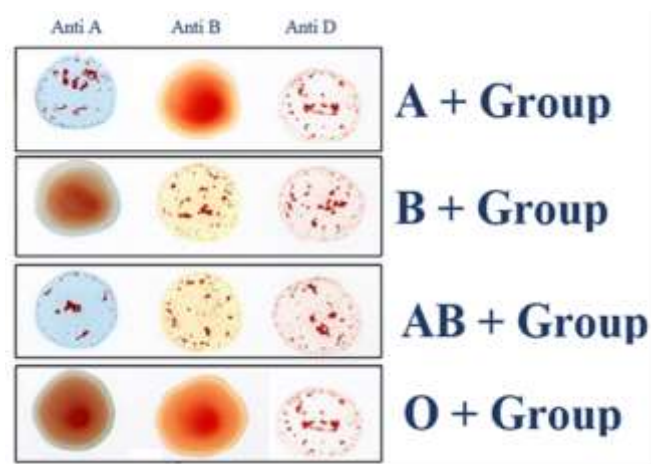


Figure 3 Interpretation for Slide method



Tube technique:

This technique is the recommended for grouping & treated as a “Gold Standard method”. It involves

1. Forward grouping or Cell grouping: testing test red cells with known antisera.
2. Reverse or serum grouping: testing serum of donor/patient with known A, B, O cells.

Advantages

1. Easy to perform
2. Accurate
3. The cell mixture can be incubated for a long time without drying.
4. The centrifugation used enhances the reaction and hence even weak antigens/antibodies can be detected.
5. Uses smaller quantity of reagents.

Materials required

1. Absorbent sheets
2. Tissue paper rolls
3. Marker Pens
4. Glass beakers (100ml)
5. Measuring cylinders (500ml, 1000ml)
6. View box
7. Test tubes (10 x 75mm)
8. Test tube racks
9. Micropipettes
10. Pipette tips
11. Normal Saline (0.9%)

Equipment required

1. Centrifuge
2. Microscope
3. Incubator
4. Refrigerator to store samples & reagents at 2 – 6°C.

Reagents required:

1. Monoclonal antisera (Anti-A, Anti-B, Anti-AB, Anti-D (IgM) or Blend of IgM and IgG from two different manufacturers)
2. Polyspecific Anti Human Globulin



3. Anti-A₁ Lectin and Anti-H Lectin - optional
4. 2-5% red cell suspension of the samples to be grouped
5. 2-5% of Reagent cells (A , B and O cells) washed in normal saline

Cell or forward grouping

In this the donor/patient red cells are tested with known antisera.

Method

1. Label five tubes as Anti-A, Anti-B, Anti-AB, Anti-D1 and Anti-D2.
2. Add one drop of Anti-A to tube labeled Anti-A, one drop of Anti-B to tube labeled Anti-B, one drop of Anti-AB to tube labeled Anti-AB and one drop each of Anti-D to tube labeled D1 and D2 respectively.
3. Add one drop of 2-5% red cell suspension of donor/patient to each tube.
4. Mix gently and leave at room temperature for 30-45 minutes or centrifuge at 1000 rpm for 1 minute after 5-10 minutes.
5. Resuspend the cell button and check for agglutination/ hemolysis.
6. Record the results.
7. If no agglutination is seen, the contents of the tube must be examined microscopically.
8. All negative results obtained with D1 and D2 should be further tested by IAT (refer to chapter for Indirect Antiglobulin Test) for weak D.
9. An auto-control (patient's serum and cells) can be set up in grouping. No agglutination should be seen in this tube.

Serum grouping

In this the serum/plasma of the donor/patient is tested with known reagent red cells. The A-cells, B-cells and O-cells are obtained by pooling fresh group A, B and O cells from at least 3 individuals.

Method

1. Label three tubes as A, B and O cells.
2. Place two drops of the donor/patient serum/plasma in each tube.
3. Add one drop of A-cells to tube marked A, one drop of B-cells to tube marked B and one drop of O cells to tube marked as O.
4. Mix the contents by gentle shaking.
5. Incubate the tubes at room temperature for 5-10 minutes.



6. Centrifuge at 1000 rpm for 1 minute.
7. Check for agglutination / hemolysis.
8. If no agglutination is seen, the contents of the tube must be examined microscopically.
9. Record the results immediately (refer Table 3 and Figure 4).

Grading of the reaction by tube method shown in Figure- 4

Presence of agglutination or hemolysis is a positive result.

A smooth red cell suspension after the button is re suspended is a negative result.

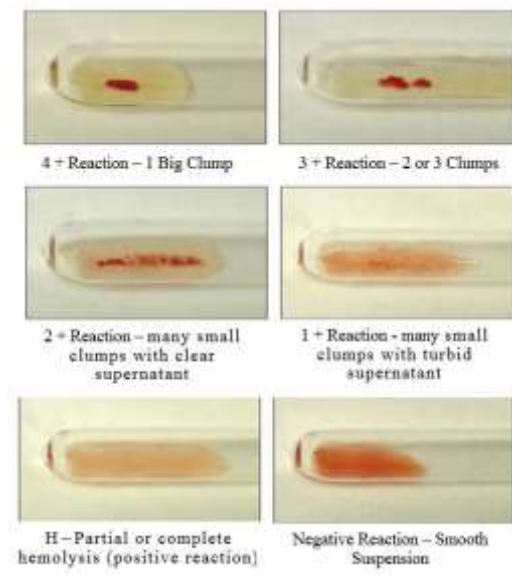


Figure: 4 Grading of agglutination by tube method

Table: 3 Interpretation of results for Forward and Reverse grouping

Blood Group	Forward grouping					Auto control	Reverse grouping		
	Anti-A	Anti-B	Anti- AB	Anti- D1	Anti- D2		A cells	B cells	O cells
A ₁ Pos	3 to 4+	Neg	3 to 4+	3 to 4+	3 to 4+	Neg	Neg	3 to 4+	Neg
A ₁ Neg	3 to 4+	Neg	3 to 4+	Neg	Neg	Neg	Neg	3 to 4+	Neg
B Pos	Neg	3 to 4+	3 to 4+	3 to 4+	3 to 4+	Neg	3 to 4+	Neg	Neg
B Neg	Neg	3 to 4+	3 to 4+	Neg	Neg	Neg	3 to 4+	Neg	Neg
A ₁ B Pos	3 to 4+	3 to 4+	3 to 4+	3 to 4+	3 to 4+	Neg	Neg	Neg	Neg
A ₁ B Neg	3 to 4+	3 to 4+	3 to 4+	Neg	Neg	Neg	Neg	Neg	Neg
O Pos	Neg	Neg	Neg	3 to 4+	3 to 4+	Neg	3 to 4+	3 to 4+	Neg
O Neg	Neg	Neg	Neg	Neg	Neg	Neg	3 to 4+	3 to 4+	Neg

Gel card method for blood grouping

Microtubes containing sephadex gel prepared in a buffer solution such as LISS (low ionic strength saline) or saline are available. Gel cards used for blood grouping may contain red cell specific antisera for grouping , sedimenting agents like bovine serum albumin and preservative such as sodium azide etc. Each card contains six such microtubes.

Materials required

1. “ABO/D + reverse typing gel cards” containing monoclonal Anti-A, Anti-B and Anti-D within the gel matrix. The microtube control is the negative control. Two microtubes with neutral gel serve for reverse grouping with A & B cells.
2. Diluent (modified low ionic strength saline)
3. Reagents cells – A and B cells in a 0.8% \pm 0.1% suspension or as per manufacturer’s protocol.
4. Pipette
5. Pipette tips
6. Centrifuge for Gel cards

Procedure

1. Identify the gel card with unique patient/donor no.
2. Remove the aluminum foil from as many microtubes as required by holding the card in upright position.
3. Pipette 50 μ l (or as per manufacturer’s protocol) of patient’s serum/plasma to both microtubes 5 & 6.
4. Pipette 25 μ l (or as per manufacturer’s protocol) reagent cell A₁ to microtube 5.
5. Pipette 25 μ l (or as per manufacturer’s protocol) reagent cell B to microtube 6.
6. Pipette 50 μ l (or as per manufacturer’s protocol) of patient’s red cell suspension to microtubes 1-4 (A,B,D, ctrl)
7. Incubate at room temp for 10 minutes (or as per manufacturer’s protocol)
8. Centrifuge the Gel Cards for 10 minutes (or as per manufacturer’s protocol).
9. Read and record the results (as per Table 4 & Figure 5- 6).



Table: 4 Grading of the reaction for gel cards:

4+ reaction	Represented by a solid band of agglutinated red cells at the top of the gel column. Usually no red cells are visible in the bottom of the microtube.
3+ reaction	Represented by a predominant amount of agglutinated red cells toward the top of the gel column with few agglutinates staggered below the thicker band. The majority of agglutinates are observed in the top half of the gel column.
2+ reaction	Characterized by red cell agglutinates dispersed throughout the gel column with few agglutinates at the bottom of the microtube. Agglutinates should be distributed through the upper and lower halves of the gel.
1+ reactions	Characterized by red cells agglutinates predominantly observed in the lower half of the gel column with red cells also in the bottom. These reactions may be weak, with a few agglutinates remaining in the gel area just above the red cells pellet in the bottom of the microtube.
Negative reaction	Represented by red cells forming a well-delineated pellet in the bottom of the microtube. The gel above the red cell pellet is clear the free of agglutinates.
Mixed-field reactions	May be recognized as a layer of red cell agglutinates at the top of the gel accompanied by pellet of unagglutinated cells in the bottom of the microtube.

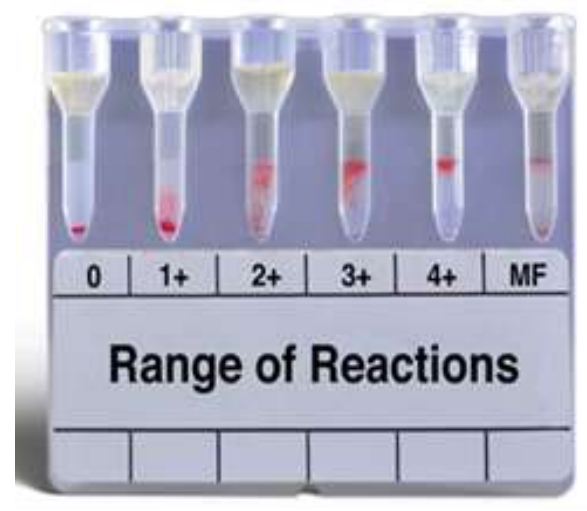
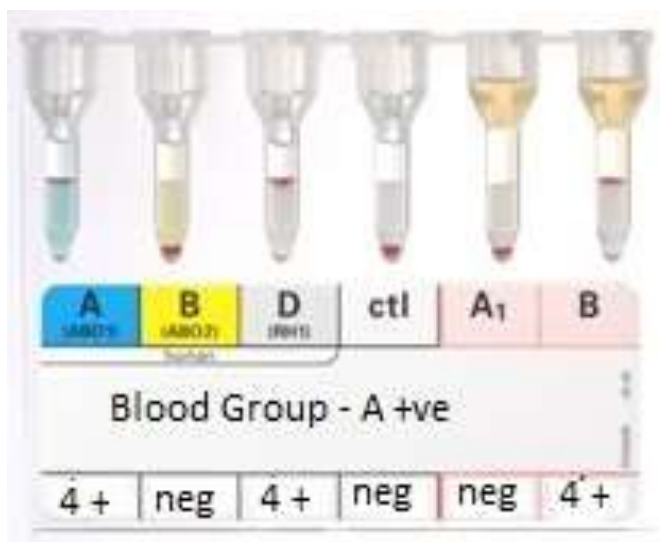


Figure:5 Gel card for Forward and Reverse grouping

Figure: 6 Grading of reaction in Gel cards

Precautions in blood grouping

1. Perform the grouping at room temperature (20-24°C).
2. Include both cell and serum grouping as this serves as a check.
3. Use antisera as per manufacturer's instructions.
4. Store antisera in the refrigerator when not in use.
5. Check the antisera regularly with known cells.
6. All glassware must be dry and clean.
7. Label all tubes accurately.
8. Record results immediately.
9. Use correct speed and time of centrifugation.

Indirect antiglobulin test (IAT)

IAT is used to determine in vitro sensitization of red cells with IgG or Complement

Used for

- Antibody screening
- Antibody identification
- Crossmatching
- Typing of minor red cell antigens such as Duffy, Kell, Kidd
- Detection of weak D (Du test)
- Titration of antibodies (Anti-D in maternal serum in HDN)

MATERIAL REQUIRED:

Equipment:

- Refrigerator to store samples & reagents at 2 – 6°C.
- Serology water bath/ Incubator
- Tabletop centrifuge.
- Microscope.

Specimen:

Serum or plasma of donors/patients.

Reagents:

- Antibody-screening reagent red blood cells (two or three cells)/ Group O pooled cells.
- Antihuman globulin reagent (anti-IgG+anti-C3d).
- IgG coated O Rh(D) pos red cells/ sensitized red cells/check cells.



- Normal saline (0.9%)
- LISS
- 22% Bovine albumin

Glassware:

- Test tubes.
- Automated Pipettes
- Pasteur pipettes.
- Glass slides.

Miscellaneous:

- Permanent marker pens.
- Rubber teats.
- Disposal box.
- Glass beakers.
- Test tube racks.
- Plastic box filled with hypochlorite.

Principle:

The indirect antiglobulin test is used for the detection of IgG antibodies, which are not detectable in saline phase but are detectable with use of AHG serum. In this test, pooled O cells or the antibody-screening reagent red blood cells or donor or test cells are combined with serum/plasma under investigation. The addition of a potentiating medium enzyme / albumin helps to promote the interaction of red cells and antibodies allowing antibody/antigen reactions to occur. Positive reactions (haemolysis or agglutination) in any tests indicate the presence of alloantibody or auto antibody in the serum.

PROCEDURE:

Indirect Antiglobulin Test:

1. Label tubes appropriately.
2. Add two drops of test serum/plasma to each tube.
3. Add 1 drop of 2%-5% saline suspended reagent/pooled O red cell suspension/donor cells/test cells.
4. Incubate at 37°C for 30-60 minutes.
5. Centrifuge and observe for hemolysis/ agglutination.
6. Wash the red cells 3 or 4 times with saline, and completely decant the final wash.
7. Add one drop of AHG reagent to cell button and mix well.
8. Centrifuge and observe for agglutination.



9. Read and record the results.
10. Negative results should be confirmed by adding 1 drop of check cells. If positive, it is a valid test. However, if negative after adding check cells, test is invalid.

Albumin or LISS Additive Indirect Antiglobulin Test:

1. Add two drops of serum/plasma to properly labelled tubes.
2. Add an equivalent volume of 22% bovine albumin or LISS additive.
3. Add 1 drop of 2%-5% saline suspended reagent/pooled O red cell suspension/donor cells/test cells to each tube and mix. Incubation times are as shown in the table
4. Centrifuge and observe for hemolysis/ agglutination
5. Follow steps 6-9 as in routine IAT procedure as given above.

Test	Incubation Temperature	Ideal Incubation Time
Saline	37 ⁰ C	30-60 minutes
Albumin	37 ⁰ C	15-30 minutes
LISS	37 ⁰ C	15 minutes
Follow manufacturer's directions when using commercial reagents.		

LISS Indirect Antiglobulin Test Procedure

1. Wash reagent or donor cells three times in Normal saline, and completely decant the saline.
2. Resuspend the cells to 2-3% suspension in LISS.
3. Add two drops of serum/plasma to properly labelled tubes.
4. Add 2 drops of LISS suspended red cells, mix and incubate at 37°C for 10-15 minutes.
5. Centrifuge and observe for hemolysis/ agglutination
6. Follow steps 6-9 as in routine IAT procedure as given above.

Interpretation:

1. Hemolysis or agglutination in any test may indicate the presence of an unexpected antibody.
2. The absence of agglutination and hemolysis in all tests is a negative test result.
3. After addition of IgG-sensitized cells to a negative test, the presence of agglutination indicates that the AHG serum added was capable of reacting and that the negative antiglobulin test is valid.



4. If IgG-sensitised cells added to confirm the activity of the anti-IgG show only weak or no agglutination after centrifugation, the test is invalid and must be repeated.

DOCUMENTATION:

Documentation of all the results should be done in respective registers. All records are initialled by the technician who has performed the test and by the technician who has checked the results.

Factors affecting IAT

- Temperature - 37°C
- Ratio of serum to cells – 2:1 (Increasing serum to red cell ratio increases the sensitivity of IAT)
- Incubation time- 60 min
- Suspending medium –Saline/ LISS
- Washing of cells – 3 to 6 times: Inadequate washing results in false negative reaction due to neutralization of AHG by unbound antibody.
- Addition of AHG reagent – Failure to add AHG reagent results in false negative result.
- Centrifugation for results – Proper speed & time
- Quality of AHG reagent – QC of reagent
- **Sources of False negative Result**
- Inadequate washing of red cells.
- Test is interrupted or delayed.
- Improper procedure
- Problems with AHG reagent
 - Bacterial contamination of reagent
 - Improper storage.
 - Failure to add AHG reagent.
 - Decreased reactivity of AHG reagent.

Sources of False Positive Result

- Autoagglutination or polyagglutination of red blood cells.
- Improper washing of glassware.
- Over centrifugation.
- Presence of other antibodies in the AHG reagent.



- Contaminated reagents
- Saline contaminated by heavy metals or colloidal silica.
- Using DAT positive cells
- Samples not in EDTA (Complement may attach to red cells in vitro)

ANTIBODY SCREEN

Purpose of antibody screen is to detect unexpected red cell antibodies (other than anti A and Anti B).

Antibody screening is required for

- Pretransfusion testing of donor blood
- Pretransfusion testing of recipient blood
- Serological changes in antenatal period
- Investigation of Hemolytic anemia
- Transfusion reaction workup.

Principle:

The antibody screen test is used in the detection of unexpected blood group antibodies. In this test, serum under investigation is reacted with pooled O cells or 2/3 reagent red blood cells. The addition of a potentiating medium enzyme / albumin helps to promote the interaction of red cells and antibodies allowing antibody/antigen reactions to occur. Positive reactions (haemolysis or agglutination) in any tests indicate the presence of alloantibody or auto antibody in the serum.

- Pooled O cells are used only for testing samples from blood donors. For patient samples or antenatal samples, 2/3 cells reagent panel should be used.
- Group O red cells are used for antibody screening because they lack both A and B antigens. Hence, naturally occurring anti-A or anti-B do not interfere with detection of unexpected antibodies
- For antibody screening of patients, Un-pooled cells from a minimum of two donors must be used.
 - One reagent red cell should be R_1R_1 and other R_2R_2 .
 - Must express clinically significant antigens of Rh, Kell Duffy, Kidd, MNSs, P and Lewis system.
 - Homozygous expression of some of these antigens is essential for reliable detection of weak antibodies.



- Cell panels are commercially available. Institutions can also prepare their own cell panel.
- An anti-gram listing the antigen makeup of each cell provided with each lot of screening cells.
- Antibody screening is done at room temperature in saline phase and at 37⁰ C, in AHG phase.
- For pre-transfusion testing, goal is to detect clinically significant antibodies; which can cause Hemolytic disease of fetus and newborn or Hemolytic transfusion reaction.
- Potentiators can be used in antibody screening and identification to enhance antigen-antibody reaction
 - Low-ionic strength solution (LISS)
 - Bovine serum albumin (BSA)
 - Polyethylene glycol (PEG)
 - Proteolytic enzymes
 - Papain
 - Ficin
 - Bromelain
- 11 cell panel is used for antibody identification
 - Rules for antibody Identification
 - 3 pos should give pos reaction
 - 3 neg should give negative reaction
 - All major significant antibodies ruled out
 - Patient must lack corresponding antigen

MATERIAL REQUIRED:

Equipment:

- Refrigerator to store samples & reagents at 2 – 6 °C.
- Serology water bath/ Incubator
- Tabletop centrifuge.
- Microscope.

Specimen:

Serum or plasma of donors/patients.



Reagents:

- Antibody-screening reagent red blood cells (two or three cells)/ Group O pooled cells.
- Antihuman globulin reagent (anti-IgG+anti-C3d).
- IgG coated O Rh (D)pos red cells/ sensitized red cells/check cells.
- Normal saline (0.9%)
- LISS
- 22% Bovine albumin

Glassware:

- Test tubes.
- Automated Pipettes
- Pasteur pipettes.
- Glass slides.

Miscellaneous:

- Permanent marker pens.
- Rubber teats.
- Disposal box.
- Glass beakers.
- Test tube racks.
- Plastic box filled with hypochlorite.

PROCEDURE:**Antibody Screen (by IAT method, at 37°C):**

1. For antibody screening, arrange 3/2/1 test tubes for each patient or donor (depending upon whether 3cell/2cell reagent panel/pooled O cells are being used). For antibody identification, arrange 11 tubes for 11 cell panel and 1 tube for auto control.
2. Label tubes appropriately.
3. Add two drops of test serum/plasma to each tube.
4. Add 1 drop of 2%-5% saline suspended reagent/pooled O red cell suspension.
5. Incubate at 37 °C for 30-60 minutes.
6. Centrifuge and observe for hemolysis/ agglutination.
7. Wash the red cells 3 or 4 times with saline, and completely decant the final wash.



8. Add one drop of AHG reagent to cell button and mix well.
9. Centrifuge and observe for agglutination.
10. Negative results should be confirmed by adding 1 drop of check cells. If positive, it is a valid test. However, if negative after adding check cells, test is invalid.

For Albumin/ LISS additive procedure or LISS antibody screening method, follow the IAT method for these (as given in procedure of Indirect Antiglobulin test).

Interpretation:

1. Hemolysis or agglutination in any test may indicate the presence of an unexpected antibody.
2. The absence of agglutination and hemolysis in all tests is a negative test result.
3. After addition of IgG-sensitized cells to a negative test, the presence of agglutination indicates that the AHG serum added was capable of reacting and that the negative antiglobulin test is valid.
4. If IgG-sensitised cells added to confirm the activity of the anti-IgG show only weak or no agglutination after centrifugation, the test is invalid and must be repeated.

DOCUMENTATION:

Documentation of all the results should be done in respective registers.

All records are initialled by the technician who has performed the test and by the technician who has checked the results.



SALINE CROSS-MATCH/ IMMEDIATE SPIN CROSS-MATCH

Principle:

The major cross-match is used to detect IgM antibodies in patient's serum against antigens on donor cells. It can detect ABO grouping errors but is inadequate for detection of clinically significant IgG antibodies

MATERIAL

Equipment:

- Refrigerator to store samples & reagents at 2 – 6°C.
- Serology water bath/ Incubator
- Table top centrifuge.
- Microscope.

Specimen:

- Serum or plasma of patient/ recipient
- Donor red cells suspended in saline.

Reagents:

- Normal saline (0.9%)

Glassware:

- Test tubes.
- Automated Pipettes
- Pasteur pipettes.
- Glass slides.

Miscellaneous:

- Permanent marker pens.
- Rubber teats.
- Disposal box.
- Glass beakers.
- Test tube racks.
- Plastic box filled with hypochlorite.



PROCEDURE:

Cross-match:

1. Label 1 tube for each saline cross match to be done.
2. Add 2 drops of patient's serum to the labelled tube.
3. Prepare 1 drop of 2%-5% donor red cell suspension.
4. Mix the contents of tubes gently and incubate for 5-10 minutes (spin method) or incubate for 30-60 minutes (sedimentation method) at Room temperature.
5. Centrifuge the tubes at 1000 rpm for 1 minute in spin method (after 5-10 minutes incubation). Centrifugation is optional in sedimentation method.
6. Examine for hemolysis.
7. Gently resuspend red cell button and examine for agglutination.
8. Examine all visually negative reactions under microscope.
9. Grade and record test results immediately.
10. Let a second technician check the results.

Interpretation:

1. Hemolysis or agglutination in any test indicates incompatibility.
2. Absence of hemolysis / agglutination in all tests indicates compatibility.

Limitations:

The saline / enzyme cross match will not any IgG antibodies or error in Rh typing

DOCUMENTATION:

- Enter results in cross-match register and compatibility report form.
- All records are initialled by technician who performed the test and the technician who has checked the results.

ANTIGLOBULIN CROSS-MATCH

Principle:

The cross match through the anti-globulin phase permits detection of clinically significant incompatibilities caused by incomplete antibodies that sensitise cells at 37°C, but do not directly cause agglutination.



MATERIAL REQUIRED:

Equipment:

- Refrigerator to store samples & reagents at 2 – 6°C.
- Serology water bath/ Incubator
- Tabletop centrifuge.
- Microscope.

Specimen:

- Serum or plasma of patient/ recipient
- Donor red cells suspended in saline.

Reagents:

- Antihuman globulin reagent (anti-IgG+anti-C3d).
- IgG coated O Rh(D)pos red cells/ sensitized red cells/check cells.
- Normal saline (0.9%)
- LISS
- 22% Bovine albumin

Glassware:

- Test tubes.
- Automated Pipettes
- Pasteur pipettes.
- Glass slides.

Miscellaneous:

- Permanent marker pens.
- Rubber teats.
- Disposal box.
- Glass beakers.
- Test tube racks.
- Plastic box filled with hypochlorite.

PROCEDURE:

Anti-Globulin Cross-Match:

1. Label tube with patient/unit identification.
2. Add two drops of patient serum to each tube.
3. Prepare a 2%-5% cell suspension in saline from each donor unit segment.
4. Add 1 drop of donor's red cell suspension to the tube and mix well.
5. Incubate at 37°C for 30-60 minutes.
6. Centrifuge at 1000 rpm for 1 minute and observe for hemolysis/ agglutination (after gently shaking the tube and dislodging the cell button).



7. Wash the cells at least 3 times with saline. Decant completely after last wash. (washing can be done manually or in automated cell washer).
8. Add two drops of antihuman globulin reagent to the dry cell button.
9. Mix well and centrifuge at 1000 rpm for 1 minute.
10. Resuspend and read for agglutination against well lighted background.
11. Grade and record test results immediately.
12. To all negative tests, add 1 drop of IgG-sensitised check cells. Mix, centrifuge, resuspend and read for agglutination. Grade and record test results. After the addition of IgG-sensitised control cells to a negative test, the presence of agglutination indicates that the AHG serum added was capable of reacting and that the negative antiglobulin test is valid. However, after adding check cells, if there is no agglutination, test is invalid.

Interpretation:

1. Hemolysis or agglutination indicates the presence of a serologically incompatible cross-match. This result is interpreted as **Incompatible**.
2. Absence of agglutination and hemolysis is a negative test result and indicates a serologically compatible crossmatch. This result is interpreted as **Compatible**.
 - i. If the IgG-sensitised control cells added to confirm the activity of the Polyspecific reagent show only weak or no agglutination the test is invalid and must be repeated.

Limitations:

The anti-globulin cross- match will not:

1. Detect error in Rh typing.
2. Prevent isoimmunisation of the recipient.
3. Detect some weakly reactive antibodies.

DOCUMENTATION:

Document results in cross-match register and compatibility report form. All records are initialled by the technician who has performed the test and by the technician who has checked the results.



PREPARATION OF O Rh (D) POSITIVE SENSITIZED RED CELLS/ CHECK CELLS

MATERIAL REQUIRED:

Equipment:

- Refrigerator to store samples & reagents at $2^{\circ} - 6^{\circ}\text{C}$.
- Serology water bath/ Incubator
- Tabletop centrifuge.

Reagents:

- Normal saline (0.9%)
- Polyspecific AHG
- Monoclonal Anti D(IgG)
- O Rh(D) pos red cells

Glassware:

- Test tubes.
- Automated Pipettes
- Pasteur pipettes.

Miscellaneous:

- Permanent marker pens.
- Rubber teats.
- Disposal box.
- Glass beakers.
- Test tube racks.
- Plastic box filled with hypochlorite.

PROCEDURE

- Perform doubling dilution of commercially available monoclonal anti-D (IgG)
- Select the highest dilution which coats O RhD positive red cells (sensitize) but does not agglutinate them.
- For eg. For dilution of 1:64, add 630 μl of NS to 10 μl of undiluted anti-D
- Take one volume of diluted anti-D to which add equal volume of pooled O RhD positive red cells
- Incubate at 37°C for 45 min
- Wash 3 times with Normal saline
- Add 1 drop of AHG to 1 drop of 5% suspension of washed red cells
- Mix, spin at 1000 rpm for 1 minute. Cells should show 2+ agglutination.
- Check cells can be stored in Alsever's solution for 1 week at 4°C



ANTIBODY TITRATION PROCEDURE

Principle:

Titration is a semi-quantitative method to determine the concentration of antibody in a serum sample or to compare the strength of antigen expression on different red cell samples.

Equipment:

- Refrigerator to store samples & reagents at 2 – 6°C.
- Serology water bath/ Incubator
- Tabletop centrifuge.

Reagents:

- Normal saline (0.9%)
- 2% to 5% saline suspension of red cells that express the antigen corresponding to antibody.
- Polyspecific AHG

Glassware:

- Test tubes.
- Automated Pipettes
- Pasteur pipettes.

Miscellaneous:

- Permanent marker pens.
- Rubber teats.
- Disposal box.
- Glass beakers.
- Test tube racks.
- Plastic box filled with hypochlorite.

PROCEDURE:

- Label 10 test tubes according to the serum dilution (1:1;1:2;1:4;1:8 and so on)
- Add one volume of saline to all the test tubes except the first.
- Add one volume of serum to first and second test tube. (1:1 and 1:2, respectively).
- Mix and transfer one volume from 2nd test tube to 3rd; from 3rd to 4th and so on.
- This gives the doubling dilution of serum.
- Label 10 fresh tubes for the appropriate dilutions.



- Using separate pipettes for each dilution, transfer 2 drops of diluted serum into correspondingly labelled test tube. Add 1 drop of 4-5% red cell suspension.
- Mix each tube properly and test by serologic technique appropriate for antibody (saline method for IgM and IAT method for IgG antibody).

INTERPRETATION:

- The reciprocal of the highest dilution which gives 1+ macroscopic agglutination is reported as titer. (e.g. titer of 16 if 1+ agglutination is seen in 1:16 dilution)
- If there is agglutination in the tube containing most dilute serum, end point has not been reached and additional dilutions need to be prepared.



QUALITY CONTROL AND EVALUATION OF BLOOD GROUPING REAGENTS

The purpose of Quality Control of Blood grouping reagents is to ensure standard quality of blood grouping reagents to be used by Blood Transfusion Services.

Material required:

1. Marker Pens
2. Test tubes 5ml (12 x 75mm)
3. Test tubes 10ml (16 x 100mm)
4. Test tube racks
5. Glass Slides
6. Cover Slips
7. Beakers (100ml)
8. Plastic box with 1% Hypochlorite solution

Equipment required:

1. Centrifuge
2. Microscope
3. Micropipettes
4. pH-Meter
5. Stop watch
6. Refrigerator
7. Incubator

Reagents required:

1. Red Blood Cells suspension: 2-5% cells.
2. Normal Saline.
3. Low Ionic Strength Solution.(if recommended by the manufacturer)

Pre-Test Preparation

Keep the bench ready and bring all the reagents to be tested at room temperature.

1. Check the reagent for physical appearance and color
2. Prepare bench protocol for procedure to be followed for Titre, Specificity, Avidity, Intensity, Rouleaux and prozone testing.
3. Use normal saline or any other diluent as per standard instructions.













4. Use fresh pipette tip for each dilution to avoid carryover of reagent to next higher dilution.

Test Procedure for Anti-A, Anti-B, Anti-AB, Anti-D (IgM) and Anti-D (IgG + IgM)

PREPARATION OF MASTER DILUTION OF REAGENT UNDER TEST

- i. Arrange and label one row each of test tubes from 1: 2 to 1: 2048 for master dilution for reagent under test.
- ii. Beginning with the undiluted reagent, prepare a twofold master serial dilutions (1:2, 1:4 etc. till 1: 2048) for test reagent.
- iii. Prepare a total of 400ul of each dilution as depicted in the diagram below keeping 100ul extra volume for each dilution as buffer volume for pipetting : -
 - a) Add 400ul of reagent diluent (Normal Saline or as per instructions) and 400ul of reagent to tube no 1.
 - b) Mix and transfer 400ul to next tube.
 - c) Repeat step two till tube no.11 as above.

	400ul	400ul	400ul	400ul	400ul	400ul	400ul	400ul	400ul	400ul	400ul
											
Master Dilution	1:2	1:4	1:8	1:16	1:32	1:64	1:128	1:256	1:512	1:1024	1:2048
Tube No	1	2	3	4	5	6	7	8	9	10	11

Titration and Specificity:

1. Arrange and label as many rows of test tubes as the number of reagent red cells, to be used for titration of test reagent as above.
2. Dispense 100ul of each dilution from respective master dilution tube and neat reagent from the reagent vial to tube labelled Neat for each reagent red cells.
3. Arrange and label the tubes for negative control cells for specificity testing of reagent under test. Use undiluted (100ul neat) reagent for specificity testing for each negative control cell.
4. Dispense 100ul of reagent red blood cell suspension of positive control cells and negative control cells to the respective rows of tubes for reagent under test.
5. Gently shake test tube stand to mix the contents thoroughly (in case of Anti-D (IgG + IgM) also incubate one set of row at 37°C for 30minutes).
6. Centrifuge for 1 minute at 1000rpm.



7. For specificity, observe all the negative control tubes under the microscope for clear-cut negative reaction.
8. Gently dislodge the cell buttons of each test tube and examine grade of reaction macroscopically (as per Figure 4 on page 73) and record the readings.

Titre

1. The test results should show at least one tube with no agglutination after the end point.
2. The Cell control / Diluent control should show negative reaction.

Specificity: Clear cut reaction with red cells having corresponding antigen(s); and no reaction with negative control.

Avidity & Intensity testing by Slide method (at room temperature)

1. Reagent Red Cell Preparation: Prepare 40-50% of reagent red cells suspension
2. Dispense an equal volume of reagent under test (20-50ul) and reagent red blood cells (40-50%) on clean glass slide, adjacently.
3. Mix reagent and cells rapidly in a circular manner using a mixing stick and spread over 1-3 mm diameter area on slide.
4. Observe and measure the time for appearance of the first visible agglutination.
5. For each reagent cell repeat steps 2 to 4 three times and calculate mean of three observations.
6. Mix the contents for 2 minutes by moving slide gently in an orbital manner and record the intensity or the grade of the reaction.

REACTIVITY

Haemolysis: Observe all tubes for absence of haemolysis.

Rouleaux: Check the contents of all the negative control tubes microscopically for absence of rouleaux. Place about 5ul of the mixed contents on a slide and cover with cover slip and observe under the microscope.

Prozone:

- **NO PROZONE is present - if the reaction grades are the same or increase as the incubation time increases,**
- **PROZONE is present - If the reaction grade decreases as the incubation time increases.**

Recording of Results: Record all the raw data, test results and observations



a) Acceptance Criteria for Anti-A (Monoclonal)

Name and type of the Reagent	Physical Appearance and Color	Type of Red Cells	Titre	Avidity (time in Seconds)	Intensity	Specificity	Reactivity (Rouleaux Haemolysis Prozone)
Anti- A (Monoclonal)	Clear, No turbidity, precipitate, particles or gel formation by visual inspection and blue colored liquid	A ₁	≥1:256	3 - 4 sec	3+	Positive	<div style="text-align: center;"> ↑ Absent ↓ </div>
		A ₂	≥1:128	5 – 6 sec	2+ to 3+	Positive	
		A ₂ B	≥1:64	5 – 6 sec	3+ to 4+	Positive	
		B	---	---	---	Negative	
		O	---	---	---	Negative	

b) Acceptance Criteria for Anti-B (Monoclonal)

Name and type of the Reagent	Physical Appearance and Color	Type of Red Cells	Titre	Avidity (time in Seconds)	Intensity	Specificity	Reactivity (Rouleaux Haemolysis Prozone)
Anti- B (Monoclonal)	Clear, No turbidity, precipitate, particles or gel formation by visual inspection and blue colored liquid	B	≥1:256	3 - 4	4+	Positive	<div style="text-align: center;"> ↑ Absent ↓ </div>
		A ₁ B	≥1:128	5 – 6	2+ to 3+	Positive	
		A ₁	---	---	---	Negative	
		O	---	---	---	Negative	

c) Acceptance Criteria for Anti-AB (Monoclonal)

Name and type of the Reagent	Physical Appearance and Color	Type of Red Cells	Titre	Avidity (Seconds)	Intensity	Specificity	Reactivity Rouleaux/ Haemolysis/ Prozone
Anti- A,B (Monoclonal)	Clear, No turbidity, precipitate, particles or gel formation by visual inspection and colorless or cherry colored liquid	A ₁	≥1:256	3 - 4 sec	4+	Positive	<div style="text-align: center;"> ↑ Absent ↓ </div>
		B	≥1:256	3 – 4 sec	4+	Positive	
		A ₂	≥1:128	5 – 6 sec	3+	Positive	
		A _x	---	---	---	Positive	
		O	---	---	---	Negative	



d) Acceptance Criteria for Anti-D (IgM) Monoclonal

Name and type of the Reagent	Physical Appearance and Color	Type of Red Cells	Titre	Avidity (Seconds)	Intensity	Specificity	Reactivity (Rouleaux, Haemolysis Prozone)
Anti-D (IgM) Monoclonal	Clear, No turbidity, precipitate, particles or gel formation by visual inspection and colorless liquid	O +ve R ₁ r (or) R ₁ R ₁	Room temp - 1:64 to 1:128	5 - 10 sec	3+	Positive	<div style="text-align: center;"> ↑ Absent ↓ </div>
		O-negative* (rr / r'r / r''r)	---	---	---	Negative	

* O negative cells should be confirmed as weak D negative by IAT

e) Acceptance Criteria for Anti-D (IgM + IgG) Monoclonal

Name and type of the Reagent	Physical Appearance and Color	Type of Red Cells	Titre	Avidity (Seconds)	Intensity	Specificity	Reactivity (Rouleaux, Haemolysis Prozone)
Anti-D (IgG+IgM) Blend Monoclonal	Clear, No turbidity, precipitate, particles or gel formation by visual inspection and colorless liquid	O +ve R ₁ r (or) R ₁ R ₁	Room temp - 1:32 – 1:64 37°C x 30' 1:128 to 1:256	10 - 20 sec	3+	Positive	<div style="text-align: center;"> ↑ Absent ↓ </div>
		O-negative* (rr / r'r / r''r)	---			Negative	

* O negative cells should be confirmed as weak D negative by IAT

f) Acceptance Criteria for Anti-D (IgG) - Monoclonal

Name of the Reagent and Type of the Reagent	Physical Appearance and Color	Type of Red Cells	Titre	Specificity	Reactivity (Rouleaux, Haemolysis)
			37°C x 30'		
Anti-D (IgG)	Clear, No turbidity, precipitate, particles or gel formation by visual inspection and Straw Colored liquid	O +ve R ₁ r and R ₀ r	≥1:32	Positive	<div style="text-align: center;"> ↑ Absent ↓ </div>
		O-negative* (rr / r'r / r''r)	---	Negative	

* O negative cells should be confirmed as weak D negative by IAT



g) Acceptance Criteria for Polyspecific Anti-Human Globulin reagent (AHG)

Name of the Reagent and type of reagent	Physical Appearance & Color	Type of Red Cells	Titre	Specificity	Reactivity (Rouleaux Haemolysis Prozone)
Anti-Human Globulin (Polyspecific)	Clear, No turbidity, precipitate, particles or gel formation by visual inspection and colourless / Green Coloured liquid	O +ve R ₁ r /R ₀ r (IgG Sensitized cells)	≥1:64 (1+)	Positive	↑
		O +ve (C3d sensitized Cells)	≥1:4 (1+)	Positive	Absent
		O +ve R ₁ r /R ₀ r (unsensitized cells)	---	Negative	↓

h) Acceptance Criteria for 22% bovine serum albumin (BSA)

Name of the Reagent and type of reagent	Physical Appearance & Color	Type of Red Cells	Titre	Purity	Specificity	Reactivity (Rouleaux Haemolysis Prozone)
Bovine Serum Albumin (22%)	Clear, No turbidity, precipitate, particles or gel formation by visual inspection and straw Coloured Liquid	O +ve R ₁ r (Anti-D(IgG) Sensitized)	1:32 to 64(1+)	>98% albumin, as determined by electrophoresis	Positive	↑
		O +ve R ₁ r (unsensitized cells)	---		Negative	Absent ↓



CHAPTER-5

TRANSFUSION TRANSMITTED INFECTIONS (TTI)

The screening of all donated blood unit for TTI agents prior to release for clinical use is an important activity for every blood transfusion service to safeguard the public health. The first line of defence in providing a safe blood supply and minimizing the risk of TTI, is to collect blood from well-selected, repeat voluntary non-remunerated blood donors.

As per Drugs and Cosmetics Act 1940 and Rules 1945 each blood units shall be free from:

- HIV I & II Antibody
- Hepatitis B surface antigen,
- Hepatitis C virus Antibody
- VDRL/RPR
- Malarial parasites

REGULATIONS REGARDING TTI TESTING:

Organization and management of TTI screening in blood transfusion services

Each blood transfusion service requires suitable infrastructure, reliable power and water supply, well maintained equipment and efficient transportation and telecommunication system. The blood bank staff must be qualified, experienced with regular proficiency testing in relation to TTI screening.

Procurement and supply of Assays and reagents

Continuous uninterrupted supply of assay kits and reagents is necessary.

Storage and Transportation

The kits should be stored and transport as per the manufacturer kit insert / instructions for use.

BLOOD SCREENING, QUARANTINE AND RELEASE

Blood Screening and Approaches

The screening of donated blood and the quarantine of blood and blood components represent critical processes that should be followed to ensure that blood units are safe. Based on the screening results, they should either be released for clinical or manufacturing use or be discarded. Laboratory screening for TTI should be performed on blood samples collected at the time of donation. All tests



on blood samples should be performed and recorded in accordance with standardized procedures in laboratories that are properly equipped to undertake them.

All blood samples, donations and components should be correctly labelled to ensure correct identification throughout the screening process. The BTS should also have appropriate, validated systems for linking all test results to the correct donations and donors, so that donors' records can be reviewed each time they come to donate. These systems will ensure that the correct results are allocated to each donation and prevent errors resulting in the transfusion of an unsafe unit.

1. Test each blood sample in accordance with standard operating procedures. The assay should have been validated for the specific TTI.
2. Collate and analyze the results of the assay. If a result is nonreactive, the blood unit can be released for clinical use.
3. If a blood sample is reactive for a TTI, immediately segregate and then discard the blood donation and all blood components derived from it.

If any discrepancy in the results is identified, a thorough investigation should be undertaken and corrective action taken to prevent the release of an unsafe unit of blood.

SCREENING ASSAYS

Types of Assays

The main types of assay used for blood screening are:

- I. Immunoassay (IA):
 - a. Enzyme Linked Immunosorbent assay (ELISA)
 - b. Chemiluminescent immunoassay (CLIA)
 - c. Haemagglutination (HA)/particle agglutination (PA) assay
 - d. Rapid/simple single-use assay (rapid tests-immunochromatography etc.,)
- II. Nucleic acid amplification technology (NAT) assay (To pick up residual risk of TTI due to window period donation, are supplementary to immune assay)

Selection of Assays

In the context of blood screening, appropriate evaluation is required in selecting the type of assay for each TTI, based on critical assay characteristics, such as sensitivity and specificity, as well as cost



and ease of use, lab specific factors like number of samples tested, staff levels, staff competence, available equipment, logistics like cost, procurement system, shelf life, infrastructure.

Instructions and Procedures:

Some instructions for handling of kit(s) etc. are given below and needs to follow universal safety precautions

- Wear laboratory coat and gloves.
- Do not eat, drink, apply cosmetics or handle contact lenses in areas where specimens are handled
- Do not pipette by mouth
- Do not use kits/ reagents beyond the expiry date
- Do not mix reagents from different lots
- All reagents to be used (neat or reconstituted) strictly as per the manufacturer's instructions given in the kit insert
- Kit should be used for testing samples only when it has reached room temperature (25°C) after being brought of storage area (fridge or cold room).
- Decontaminate and dispose all specimen, reagents, and device as per bio- safety norms.
- Put back remaining components of the kit in appropriate storage conditions after use
- Do not freeze reagents.

Pre- Assay Activity

- Spread filter paper sheets on the work bench
- Keep a disposal box quarter- filled with a disinfecting solution (1% sodium hypochlorite) for disposing tips, vials, Cassettes, reagent bottles and used test devices.
- Keep a 'BIOHAZARD' marked bag ready for disposal of dry waste.
- Keep disinfectant (70% alcohol) swabs ready in a closed container.
- Keep all accessories required for testing (single channel micro- pipettes/ droppers, marker- pen, stop watch, scissors) ready on the filter sheet i.e. testing area.
- Keep sample deposition plan, kit details proforma and bench protocol of the prescribed procedure attached to clip boards on the workbench; outside the testing area but in clear view of the test performer.



Post Assay Activity

- After the assay, discard the test devices / ELISA plate, tips, reagents/reagents bottles in the box containing 1% available sodium hypochlorite (freshly prepared).
- Discard the used soiled spread filter sheet, used alcohol and sodium hypochlorite swabs, used gloves etc. according to Biosafety guideline 2016.
- Wipe all the used accessories (single channel pipettes, tip boxes, marker pens, forceps, and scissors), all the instruments touch points, fridge handles etc. with 70% alcohol swabs.

TESTING PROCEDURE

Every assay to be set up strictly following the manufacturer's instructions given in the kit insert/ instruction of use.

A model procedure for Rapid Assay for HIV-Ab, HCV-Ab, HBsAg & Malaria is below.

Materials Required

- Absorbent paper
- Latex gloves
- Discard jar with discard solution
- Single channel pipettes (2-20 µl, 10-100µl)
- Pipette tips
- Wash bottles
- Stop watch/Timer
- Every assay to be set up strictly following the manufacturer's instructions given in the kit insert / Instructions for use (IFU).

Procedures:

- Perform test as per manufacturer's instructions given in the package/ kit insert.
- Take the required number of devices/ strips and label them appropriately
- Tear off /cut the pouch and take test devices/ strips/comb/ slides & write the patient sample ID number to be tested on the rapid test and place them on the spread filter sheet. Add samples into the device having same patient ID number.
- Add reagents (if required).
- Add reagents and Washing solution as per the kit insert (if required)
- Read results within stipulated time as per the kit insert and record.



Validity of the test

- Appearance of Control line/ spot indicate valid test.
- Non-appearance of control line/spot indicate invalid test

Interpretation of Results

- Reactive: Both control and Test line/spot appear
- Non-Reactive: Only control line/spot to appear

Advantages

- Easy and rapid performance with few steps involved in the test
- Can be stored at temperature as recommended by manufacturer
- Does not require any equipment
- Test can be performed by staff with no formal laboratory training
- Interpretation is visual and simple, Validation as per the in- built control

Disadvantages

- Cost of individual test high
- No permanent record of results
- Less sensitive in picking up a sample from the window period of infection

Note: Besides rapid assays – Syphilis may be screened using RPR/VDRL/TPHA and Malaria may be screened using microscopy.

Rapid Plasma Reagin Test for Syphilis

Principle: - Syphilis produce antibodies that react with cardiolipin antigen in a slide flocculation test. It is not known if the antibodies that react with cardiolipin are produced against some lipid component of *Treponema pallidum*.

Materials Required

- Reagent kit.
- Micropipette (50 µl).
- Disposable tips.
- Mechanical rotator.
- Disposable gloves.
- Containers for discarding.



Method

- Bring all reagents and sample to room temperature.
- Place 50µl of serum in to circle of RPR test card using disposable dispenser or a safety pipetting device.
- Gently shake the antigen dispensing bottle to resuspend the particles.
- 1 drop of antigen suspension is added to each circle containing serum.
- Place the card on mechanical rotator. Rotate the card for 8 minutes at 180+2 rpm.
- Immediately remove the card from the rotator, rotate and tilt the card by hand to aid in differentiating non reactive from minimally reactive results.
- Read the test reaction in the wet static.

Interpretation:

Medium or large clumps	-	Reactive
Small clumps	-	Weakly reactive
No clumping	-	Non reactive

Validation:

- There should be agglutination in positive control.
- There should be no agglutination in negative control.

Microscopy for Malarial Parasite detection

Materials required:

1. **Reagents:** Leishman Stain. Buffer
2. **Requirement :** Microscope, Slides, Slide rack
3. **Sample:** Donor blood in EDTA vial

Method:

1. Take a clean slide
2. Transfer a small drop of blood near the edge of slide
3. Make a thin smear
4. Also make thick smear by taking a drop of blood in centre
5. Dry the smear at room temperature
6. Cover the smear with the staining solution by adding 10-15 drops on the smear. Wait for one minute.



7. Add equal number of the drops of buffer solution. Mix the reaction mixture adequately by blowing on it through a pipette. Wait for 10 minutes.
8. Wash the smear using tap water, stand the slide in a drawing rack
9. Examine the slide under low power 10x and high power objective 45x and 100x at least for 100 fields.
10. Examine the slide for trophozoites, schizont or gametocyte of Malaria Parasite

Interpretation:

Presence of trophozoites, schizont or gametocyte of Malaria Parasite indicates a positive result.

Rapid Test for Malaria:

Tests for Malaria antibody and tests for malaria antigen detection are available. Malaria antigen detection is the method of choice. The malaria antigen Test consists of a membrane strip which is pre coated with two monoclonal antibodies as two separate lines across a test strip

Model Test Procedure for Malaria antigen:

1. Add the donor blood sample into sample well on the test strip
2. Add assay buffer to the sample well
3. Read result after 20 minutes

Interpretation:

1. Presence of only control band indicates negative result
2. Absence of control band indicates invalid test
3. Presence of control and test band indicates positive result.
4. Interpretation of the strip for identification of different species of Plasmodium must be done as per the manufacturer's instructions.

I. A model procedure for Sandwich ELISA Assay for HIV-Ab, HCV-Ab and HBsAg

Materials Required:

- All as mentioned in Rapid assay

Equipment:

- ELISA Reader
- ELISA Washer
- Incubator
- Refrigerator



PROCEDURE

- Add controls and samples in to the respective wells.
- Cover the plate with plate sealer and incubate at temperature mentioned in the respective manufacturer kit insert.
- Wash the plate either using ELISA plate washer or manually (dispense the required volume of diluted wash buffer into all the well with the help of multichannel pipette, discard the tips and then use fresh tips for aspirating the whole volume of the wash buffer, repeat the above cited step as per manufacturer kit insert and then cover the plate with absorbent paper and tap inverted plate on the work bench).
- Add conjugate in the each well as per respective manufacturer kit insert.
- Cover the plate with plate sealer and incubate at temperature mentioned in the respective manufacturer kit insert.
- Wash the plate as per manufacturer kit insert.
- Add substrate solution in the each well as per respective manufacturer kit insert.
- Incubate in the dark at temperature mentioned in the respective manufacturer kit insert.
- Add stop solution in the each well as per respective manufacturer kit insert.
- Select absorbance as per respective manufacturer kit insert and read accordingly.

Troubleshooting of ELISA

- If negative controls are giving positive results, there may be contamination of substrate solution, or contamination of enzyme-labelled antibody, or of control themselves.
- If no colour developed for the positive controls or for the samples, check all reagents for expiry date, concentration of reagents, and storage conditions. Check the integrity of the antibody reagent.
- If very little colour has developed for positive controls and test samples, check the dilution of the enzyme labelled antibody, and the concentration of substrate.
- If colour has developed for test samples but not the positive or negative controls, check the source of the positive controls, their expiration date and their storage.
- If colour can be seen, but the absorbance is not as high as expected, check the wavelength setting of the ELISA reader.
- When rerunning an assay while troubleshooting, change only one factor at a time.



- Other errors that may lead to low absorbance may include improper washing of the plates, improper pipetting (operator related/calibration related).
- Errors may also occur because of improper calibration of reader.
- For Errors and remedy please check operating manual of the respective ELISA reader

Importance of Specimen quality

- Lipemic, hemolysed and contaminated specimens do not yield reliable results
- Bio-safety measures are very crucial to prevent laboratory infections - handling and disposal.
- Avoid adding preservatives - some interfere with test results

DIFFERENCE BETWEEN RAPID AND ELISA

Sample	Serum, Plasma, Whole blood	Serum and Plasma
Testing	Individual	Batch
Infrastructure	Minimal	Specialized set up
Quality control	Difficult to perform	Possible
Time Required	< 30 minutes	>more than 2 hours
Storage	Can be stored at RT	Stored at 2 to 8°C

MONITORING ASSAY PERFORMANCE

In blood screening, assay performance should be continually monitored in order to identify any changes in performance that are occurring. Performance is usually assured by monitoring one or more parameters that can reasonably be expected to change relatively quickly as a result of any change in the performance or use of the assay. These parameters include:

1. Quality control sample results
2. Assay control values
3. Repeat reactivity.

Controls may be blank well, Negative controls, positive controls or reactive border line controls used for drawing up of an LJ chart. Westgard criteria may be utilized as a better indicator to assess the validity of an assay in addition to the qualification of controls. LJ Chart can be used to detect systemic variation, random variation, lot to lot variation & day to day variation.



USE OF AUTOMATION FOR PERFORMING ASSAYS

The use of automation is a major consideration for blood transfusion services that perform a large number of screening tests. While all ELISA need a basic level of automation (automated plate washers and readers), highly sophisticated automated screening systems are available that can perform all aspects of an immunoassay from sampling through to the final analysis of the results. These systems perform immunoassays from any major manufacturer and are referred to as “open” systems; they are generally microplate-based and the equipment and assays are not linked. Dedicated systems, known as “closed” systems, are fully automated and use only specific, dedicated assays with all the necessary reagents and controls produced by or in collaboration with the equipment manufacturer.

NEWER TECHNOLOGIES

New blood safety technologies are constantly becoming available which may offer new opportunities to blood screening programmes. Newer generations of immune assays and NAT are being continuously developed incorporating more and more mutant strains which can detect various escape mutants and simultaneously reduce window period.

QUARANTINE OF BLOOD AND BLOOD COMPONENTS

A system should be in place to ensure that screened and unscreened units are stored in separate blood storage equipment to prevent the issue of unscreened units. All reactive or positive donations and all components derived from these donations should be labelled “Not for Transfusion” and segregated for discard or non-clinical use.

RELEASE OF BLOOD AND BLOOD COMPONENTS

When all the required blood screening tests have been performed, the results have been checked and any other required checks have been made, formal release procedures can be undertaken to release quarantined units and physically move the released blood stock from one location to another. The BTS should have appropriate systems for labelling the blood and blood components as ready for clinical use. The label on each blood unit should contain the relevant details of the donation and the tests carried out on the donation. When this has been carried out, the screening process is considered to be complete.



MANAGEMENT OF REACTIVE DONORS

Linking to Referral Centres

The donors pertaining to reactive units may be called back and informed as to the inability to utilise the unit, if the donor consented for knowing any abnormal test report. The reactive donors must be linked to ICTC centres in cases of HIV, to STI clinics in case of Syphilis, may be linked to medical OPD/medical GE OPD as the case may be in case of HBV, HCV and malaria.

Post-Test Counselling

Any of the donor found reactive to be notified and counselled (Referred to 'Donor Notification' in chapter 1).

QUALITY MANAGEMENT IN TTI TESTING

Elements of quality systems

Key elements of a quality system for blood screening include organizational management, quality standards, documentation, traceability, training, assessment and maintenance and calibration. All screening tests should be performed in accordance with defined quality requirements, and all blood donations and blood components prepared from them should be handled appropriately before, during and after laboratory testing. It is the responsibility of the blood transfusion service as well as individual laboratories to implement these standards consistently.

A quality system in a laboratory defines all processes and procedures that should be put in place to ensure effective blood screening. Its implementation minimizes errors and ensures that:

- Appropriate tests are performed on the correct samples
- Accurate results are obtained
- Only screen non-reactive blood and blood components are released for transfusion or manufacturing use
- Screened blood and blood components are available in the blood inventory at all times.
- Errors often result from a combination of factors, with the original error being compounded by inadequate checking procedures in the laboratory.

Documentation

All processes carried out by the laboratory should be documented and the records kept for traceability. Records include test results, quality control results, batches of test kits and expiry dates.



There should be a document management system in place for the safe storage, retrieval, archiving and disposal of documents. This system should also ensure confidentiality of records.

The records of donors whose test results are reactive, inconclusive or positive should be marked or flagged to prevent further donations or for further action to be taken, such as follow-up for further investigation or recall for future donations.

Maintenance of records as per Drugs and Cosmetics Rules, 1945 the following documents are mandatory

The records which the licensee is required to maintain shall include inter alia the following particulars, namely:

- 1 Blood donor record: It shall indicate serial number, date of bleeding, name, address and signature of donor with other particulars of age, weight, haemoglobin, blood grouping, blood pressure, medical examination, bag number and patient's detail for whom donated in case of replacement donation, category of donation (voluntary / replacement) and deferral records and signature of Medical Officer In-charge
- 2 Master records for blood and its components: It shall indicate bag serial number, date of collection, date of expiry, quantity in ml. ABO/Rh Group, results for testing of HIV I and HIV II antibodies, Malaria, V.D.R.L. [(Hepatitis B surface antigen and Hepatitis C Virus antibody)] and irregular antibodies (if any), name and address of the donor with particulars, utilization issue number, components prepared or discarded and signature of the Medical Officer in charge.
- 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 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 Blood bank must issue the cross matching report of the blood to the patient together with the blood unit.
- 8 Transfusion adverse reaction records.
- 9 Records of purchase, use and stock in hand of disposable needles, syringes, blood bags, shall be maintained.

NOTE: The above records shall be kept by the licensee for a period of five years.

Traceability

Traceability is a critical part of the quality system in a blood transfusion service. All activities and actions associated with the handling, testing and processing of each donation should be recorded completely and fully linked to the donation, the donor, the fate of the donation and the patient. A fully documented audit trail should be available to demonstrate that each donation has, in fact, been tested and handled correctly and that all test results are valid. To provide this evidence, records and other documents should be stored for a defined period of time; that is 5 years as per D&C Act

QUALITY ASSURANCE IN TTI TESTING

Definition: Quality Assurance program is related to sampling, specifications, testing and also with the process, documentation, and reporting in order to ensure that adequate and relevant steps have been taken for achieving satisfactory quality.

Quality assurance consists of two components:

1. Internal Quality Control
2. External Quality Assessment

Internal Quality Control (IQC): Internal quality control includes measures that are introduced during each assay to minimize random and systemic error occurring during testing. They are the set of procedures followed by laboratory personnel for release of reliable results on day to-day basis. IQC is a concurrent and continuous process.

External Quality Assessment (EQA): External quality assessment refers to a system of assessing the performance of a laboratory by an external agency. It is done by an independent agency and a laboratory that is able to produce accurate, reliable and reproducible results and is considered as a good testing facility. The aim of EQA is to ensure inter-laboratory comparability and the assessment



is retrospective as well as periodic in nature. The proficiency samples are provided by the external agency to all the participating laboratories.

Requirements of EQAS programme

1. The proficiency panels supplied:
 - a) All participating laboratories should receive materials from the same source.
 - b) The materials should remain stable through the transit from the organizing to the participating laboratory.
2. Documentation for the specimens:
 - a) The specimens should be accompanied by instruction sheets enumerating the tests and the method of analyses of results that need to be performed by the participating laboratories in order to fulfil the terms and conditions of participation.
 - b) Clear instructions on the method of sending the report, address for sending the report and the turnaround time for sending the report should also be given to the participating laboratory.
3. Testing of the specimen: The specimen should be tested in the participating laboratory in a manner similar to that which is adopted for testing the routine samples.
4. Number of participating laboratories:
 - a) More number of laboratories should participate in the EQA program.
 - b) When the number of participating laboratories is more, the results can be better subdivided according to the analytical technique used by the laboratories.
5. Statistical analysis of results:
 - a) The laboratories are assessed for individual determinations as well as for all determinations collectively.
 - b) This is done over a period of time for each as well as several distributions.
 - c) Results assessing the quality of testing of the participating laboratories must be sent to them confidentially along with a remark whether it is Satisfactory/unsatisfactory or discordant.
6. Turnaround time and frequency:
 - a) This is the time period between sending the samples to participating laboratories and receiving the results back from all of them. This should be as short as possible
 - b) A short turnaround time helps to take relevant action in case of any unsatisfactory performance.
7. Anonymity of participating laboratories;



- a) Each participating laboratory should be given an Identity Code number by the assessing laboratory.
- b) A well designed scoring scheme for assessment contributes to the overall success of the EQA in stimulating improved performance by the participating laboratories.

For any laboratory, its Internal Quality Control program and participation in External Quality Assessment are complementary for ensuring the reliability of its procedures, results and quality of its output.

Objective and benefits of EQAS

The overall objective of EQA is to improve standards of performance in blood transfusion laboratories. This can be achieved by raising awareness of the need for improvement, demonstrating the benefits of best practice and providing information, education and support for improvement.

Benefits to participating laboratories

The benefits of EQA to participating laboratories include: Comparison of their own performance with the performance of other participating laboratories competency assessment: Process to assess an individual's skill and ability in performing a single procedure or set of related procedures. Identification of problems relating to laboratory processes, techniques and reagents. Provision of information and education to improve performance Encouragement of best practice Opportunities to enhance the credibility of the laboratory and increase public confidence Access to a network of laboratories for the exchange of information.

Benefits to health and regulatory authorities The benefits of EQA to health and regulatory authorities include: Establishment of a network of blood transfusion laboratories with a known standard of performance, Provision of useful information to assist in: Setting standards, Reviewing testing strategies and technologies, Using resources effectively, Improving public confidence in the blood transfusion service, Supporting systems of accreditation.

EQA Schemes

EQA should be organized as a formal and structured scheme in order to ensure effective planning and organization. This will ensure the uniform provision of samples for testing and a standardized approach to both the analysis and reporting of results and the monitoring of the performance of participating laboratories.



EQA should be made available to all laboratories in which blood group serology is performed, regardless of their size, workload or the complexity of the tests performed. Depending on the policy and regulatory systems currently in place, laboratories could participate in EQA on either a voluntary or a mandatory basis. Where participation is voluntary, laboratories should be actively encouraged to register for EQA of all tests that they routinely perform.

MAINTENANCE OF COLD CHAIN

Cold Chain for Blood Storage and Transportation

The blood cold chain is a systematic process for the safe storage and transportation of blood from its collection from the donor to its administration to a patient who requires transfusion. It is referred to as a 'cold chain' because blood, being a biological substance, must be kept cold in order to reduce bacterial contamination and to prolong its life

The blood cold chain begins at the time the blood is collected and continues until it is transfused

Difficulty in maintaining cold chain

- Instead of purpose-designed blood bank equipment, domestic refrigerators and freezers are often used for the storage of blood and blood components.
- Frequent power cuts /power surges leading to use of generators especially in remote rural areas hospitals/blood collection and storage units cause sensitive blood bank refrigerators, to get damaged.
- Adverse environmental conditions e.g. high ambient temperature and humidity further put stress on the equipment.

Table: Ideal storage temperature for blood components

Component	Storage	Transport	Expiration	Additional criteria
Whole blood	1-6°C	Cooling towards 1-10°C If intended for platelet preparation(as close to 20-24°C	21 days (ACD/CPD/CP2D) 35days (CPDA-1)	
Red blood cells	1-6°C	1-10°C	21 days (ACD/CPD/CP2D) 35days (CPDA-1) Additive solution:42 days Open system:24 hrs	
RBC Leucocyte reduced	1-6°C	1-10°C	21 days (ACD/CPD/CP2D) 35days (CPDA-1) Additive solution:42 days	
RBC Washed	1-6°C	1-10°C	24 Hours	



Platelets	20-24°C with continuous gentle agitation	20-24°C (as close to as possible)	24 hours to 5 days depending on collection system	Maximum time 24 hours without agitation
Platelets pooled or open system	20-24°C with continuous gentle agitation	20-24°C (as close to as possible)	4 hrs	
Plateletpheresis	20-24°C with continuous gentle agitation	20-24°C (as close to as possible)	24 hours to 5 days depending on collection system	Maximum time 24 hours without agitation
Cryoprecipitate AHF	≤ -18°C	Maintain frozen state	12 months from original collection	Thaw the FFP at 1-6°C Refreeze cryoprecipitate within 1 hour
Cryoprecipitate AHF Thawed	20-24°C	20-24°C (as close to as possible)	Open system or pooled :4hours	Thaw at 30-37°C
FFP Fresh Frozen Plasma	≤ -18°C	Maintain Frozen state	12 months	Placed in freezer within 6-8 hrs of collection in CPD,CP2D,CPDA-1 or ACD
FFP Thawed	1-6°C	1-10°C	24 hours	Thaw at 30-37°C

Main activities involved in cold chain process

Three main activities involved in the blood cold chain process:

- **Storage:** Which keeps blood at the correct temperature from the time it is collected up to the time it is transfused.
- **Packing and transportation:** This includes equipment and materials needed to move blood components safely through the blood cold chain
- **Maintenance of equipment:** This provides the proper management, infrastructure and backup needed to ensure a reliable, sustainable and safe blood supply.



Equipment required to maintain cold chain

BLOOD BANK REFRIGERATOR

- They have heavier insulation all round to enable a longer holdover time
- A cooling fan to enable even distribution of air in the cabinet.
- Temperature monitoring devices, with an external temperature display and an alarm system
- Scratch resistant internal lining of the cabinet (stainless steel or aluminum).
- Glass front door to enable the user to view the contents in the cabinet
- Roll out drawers or shelves for holding the blood.

The key limitations for optimal performance are the hold-over time during power failure in the absence of a standby generator and also the cooling down time.

“Holdover time”-- The time it takes for the temperature of blood to rise above +6⁰C when the power supply to the equipment is cut off.

- Depends on the quality of the insulation of the cabinet and the frequency of door openings.
- The longer the hold-over time, the safer the blood will be during power cuts.
- The hold-over time is less critical for plasma freezers.

“Cool down time”-- The time taken to cool down a load of blood or plasma packs to the temperature of the refrigerator or freezer respectively is referred to as the “cool down time”.

- The cool down time depends on the temperature of the components when introduced into the cold chain equipment
- Capacity of the equipment to achieve the desired temperature.
- Quantity of blood components introduced at any one time

Refrigerators for blood components should ideally be connected to a reserve power unit, as well as to the main supply.

Domestic refrigerator is not suitable for storage of blood component

- Usually poorly insulated
- Warm up quickly when electricity fails
- Temperatures often fall below freezing in areas close to the freezing compartment,
- The doors are poorly insulated
- Temperature monitoring devices are not routinely fitted



Alternatives to a standard blood bank storage refrigerator

Solar powered blood bank refrigerators

- Suitable in areas with a sufficient quantity of sunshine throughout the year
- Designed as chest type (top opening door) and there is no internal light in the cabinet

Ice-lined blood bank refrigerators

- These are especially designed to have a longer hold-over time. i.e. temperature below $+10^{\circ}\text{C}$ for up to 72 hours following a power cut.
- Lining of the cabinets done with water/ice containers or freezer sections ice packs positioned adjacent to the blood storage area.

DEEP FREEZER

- “Compression type” plasma freezers are suitable for the storage of plasma (FFP) and cryoprecipitate
- The general construction of a plasma freezer is similar to that of a blood refrigerator, except that there is more insulation
- The hold-over time is at least 24 hours unless the freezer door is opened frequently
- A plasma freezer is expected to operate at a temperature of below -18°C .

PLATELET AGITATOR

Platelet agitators are designed for the storage of platelets at a temperature of between 20°C – 24°C .

- The recommended type of agitator is a flatbed agitator with horizontal or vertical agitation as this ensures
 - No platelet clumps are formed
 - Enable gas exchange through the wall of the bag
 - Avoid folding of the bags
 - Have a set speed to avoid foaming
- The key operational factors of the agitator are the number of strokes per minute (ideally 65 to 75) and the amplitude of each stroke (ideally 3.6 to 4.0 cm)
- Used to store both single donor and random donor platelets.
- A motion failure alarm is critical for monitoring the agitator.
- Temperature monitoring device used is similar to that used in conventional blood storage refrigerators



BLOOD TRANSPORT BOX

- To carry whole blood/packed red cell from:
 - Blood donation camps to blood bank
 - Mother blood bank to satellite storage centers or point of use.
- **Cold life of a box:** cold life is based on the time period between loading a box with frozen ice packs and blood packs at +4°C and the warmest internal temperature to reach +10°C when the external temperature is held constant at +43°C.
- Cold life should be at least 24 hours using appropriate ice packing.
- An SOP for validation of cold life of a transport box should be made specific to climate and distance travelled while transporting blood in each area.
- Transport boxes designed to operate from the direct current of a motor vehicle battery or those which require a rechargeable battery to maintain the cold life for over 24 hours are also available.

BLOOD COOLANT

- The coolants are kept at +4°C when they solidify, and are ready for use after two hours at room temperature.
- More efficient than ice/water whose thermal phase change is at 0°C.
- The most efficient cooling is achieved when the coolant pouch is in direct contact with the blood or platelet pack
- Efficiency also depends on the insulating capacity of the blood transport box
- Ice Packs: those used for transporting vaccines are safe to use for the transport of blood and blood products, with the precaution that they should not come into direct contact with the unit of whole blood or packed red cells
- Pre-filled ice packs can be used for transporting plasma products but not whole blood or packed cell

PLATELET COOLANT

- Platelet coolants are different in that they are expected to maintain a temperature of approximately +20 °C to +24 °C as is required for platelet storage.
- Platelet coolants have to be maintained according to the manufacturer's instructions



Methods to record temperature

The temperature within the refrigerator should be continuously recorded. Temperature records are retained as part of the blood bank records.

- **Temperature recorders/thermographs**
 - Provide a permanent record of the temperatures achieved at any time usually 24 hours or seven days
 - Charts can be kept as a permanent record which is a requirement of the quality system.
- **Built-in temperature display units**
 - A light-emitting diode (LED) displays the temperature
 - Either portable with temperature probes and LED temperature display or fixed onto equipment with visual/audible alarm systems included.
- **Temperature data loggers**
 - These use computer software to record the temperature
 - Are useful when platelets are stored at room temperature
- **Manual recording of temperature**
 - If a continuous recording thermograph not available the temperature must be recorded manually
 - Preferably a chart or in a record book, 4 hrly along with the date and time it was taken and the position of the thermometer.
- **Blood Time Temperature Indicators (BTTI)**
 - Based upon the migration of a chemical through a paper wick, the BTTI is an indicator on a card that gets activated and changes colour when cumulative temperature of exposure becomes more than 100°C
- **Alarm systems**
 - Modern blood bank refrigerators are fitted with different types of alarms, e.g. for temperature, power failure or door-ajar alarms.
 - A warning light as well as a continuous sound is generated to alert the user
 - Visual or audible signals should be placed in an area that has adequate personnel coverage 24 hours a day, to ensure that immediate corrective action is taken
 - A rechargeable battery, or an independent electrical circuit served by an emergency generator, is essential as a back-up energy supply.



Cold chain in transportation of blood components

Critical stages in the movement of blood from collection to transfusion

- Receipt and handling of incoming, unprocessed blood and plasma derivatives.
- Receipt and handling of processed blood.
- Quarantine policies and procedures.
- Labelling of products.
- Method of storage of blood components in available stock.
- Release of blood components for use.
- Procedures for thawing of frozen plasma or cryoprecipitate.
- Procedures for the release of platelet concentrate.
- Discarded blood and its safe disposal.
- Monitoring the blood inventory.

Transport of unprocessed blood from a donation camp

- Time from the first collection to transport to a blood bank should not be more than 6-8 hrs if components are to be made and temperature should be as close to 20-24°C as possible
- If it is to be used as whole blood then collected blood can be immediately stored in cold box and transported at 6-8°C
- Check the temperature of the blood packs on receipt, e.g. from maximum/minimum thermometers placed in the transport boxes.
- All the components prepared are stored in quarantine till appropriate test results are available

Transportation of blood from main blood bank to satellite units

- Ensure that the transport box is at the desired temperature prior to loading the blood components.
- A temperature monitoring device such as an electronic temperature data logger or maximum/minimum thermometer should be placed in the transport box.
- Two persons to cross check the paper work in order to ensure that possible clerical errors are avoided.
- When withdrawing blood from the blood bank, the supervisor is responsible for a visual check of the blood component for acceptable appearance.
- Assuming an insulation thickness of about 8 cm all round, six ice packs are adequate to maintain a temperature below +10°C of 40 blood packs for up to 20 hours, *provided that* the



transport box and contents are already at +4°C at the time of packing, the ice packs are frozen solid, and the ambient temperature is between +20°C and +30°C

- If wet ice is being used for maintaining the temp during transportation at no point should ice be allowed to come into direct contact with the blood as the red cells nearest to the ice may freeze and haemolyse.
- In such situation temperature can be considered to be in the +2°C to +10°C range as long as unmelted ice is still present on arrival at destination.
- The temperature on receipt can be monitored as follows:
 - Take two bags from the container;
 - Place a thermometer between the bags and fix them together with rubber bands
 - Quickly place them back into the container and close the lid;
 - Read the temperature after 5 minutes
- **For transport of frozen plasma and cryoprecipitate** Ice packs are usually used for transporting frozen plasma
- Suitable quantity of dry or wet ice in well-insulated containers or standard transport cartons lined with insulating material such as plastic air bubble can be used
- There should be at least as much wet ice in the cold box as there is plasma
- A simple method to determine if plasma units have thawed and refrozen is to place a rubber band around the unit at the time of preparation. Once the unit freezes it leaves an indentation at the sides. If the unit has thawed, or thawed and refrozen, the indentation will not be there

For platelet transportation If outdoor temperatures are extremely high, special chemical, coolant pouches are available that may be transported with platelets and will maintain temperatures of approximately +20°C to +24°C for up to 12 hours.

- Also available are containers with a power source that maintains temperatures between +20°C and +24°C.
- Platelets should reach their destination within 24 hours, which is the maximum time allowed without agitation

Transport of blood components to transfusion /administration area

- Blood is released after receipt of a requisition detailing the quantity and type of product required
- To avoid wastage, only One unit of red cells should be removed from the blood bank refrigerator at a time unless the rapid transfusion of large quantities of blood is required
- The blood is then immediately removed from available stock and put in the cold transport box ready for dispatch



- The temperature of **whole blood and red cell components** must be kept at +2°C to +10°C during transport.
- **Frozen plasma or cryoprecipitate** may be thawed only when transfusion is absolutely necessary
- Thawed plasma may be kept for a maximum of 6 hours at +4°C before transfusion if it is to be transfused for coagulopathy, otherwise can be stored up to 24hrs at 4°C.
- **PLASMA SHOULD NEVER BE REFROZEN**
- **Platelet components** should be transported in an insulated container with temperature stabilizing elements that ensure transport temperature is maintained as close as possible to the recommended storage temperature.
- It is recommended not to exceed 24 hours if transported without agitation
- **PLATELETS SHOULD NEVER BE REFRIGERATED**
- **IF NOT IMMEDIATELY USED AFTER ISSUE RETURN TO BLOOD BANK FOR PROPER STORAGE AND REISSUE**

Reusability of an issued blood component

If a unit of blood is returned to the blood bank, the following checklist should be used to decide whether it should be put back into stock or discarded

- Check that the unit has been returned to the blood bank within 30 minutes of issue.
- If the “tagging” system was used, check the seal.
- Verify that the unit has not been opened, by squeezing it gently and looking for blood at the entry port.
- Check the temperature by hand or by folding the unit around a thermometer.
- After mixing the unit gently, keep it in the upright position while it ‘settles out’ in the refrigerator and look for signs of haemolysis or other signs of deterioration in the plasma and red cells.

The unit must be discarded if:

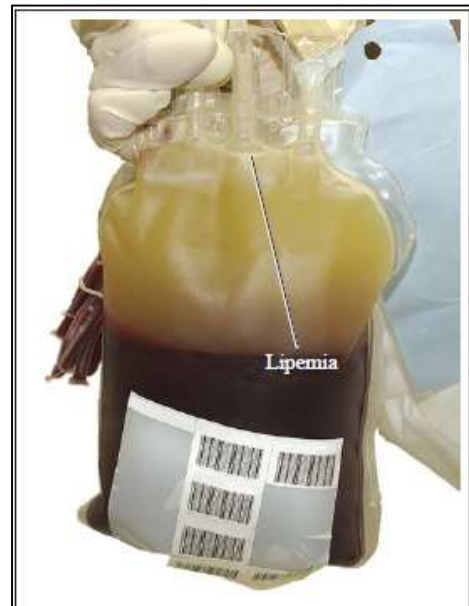
- It has been out of the refrigerator for longer than 30 minutes, or
- If the seal is broken, or
- There is any sign that the pack has been opened,
- There is any sign of haemolysis
- If the temperature is over +10 °C.



REFER TO VISUAL INSPECTION OF BLOOD COMPONENTS

VISUAL INSPECTION OF BLOOD COMPONENTS

WHOLE BLOOD /PACKED RED CELLS



A Layer of Lipemia present in centrifuged whole blood



Normal Packed Red Cells

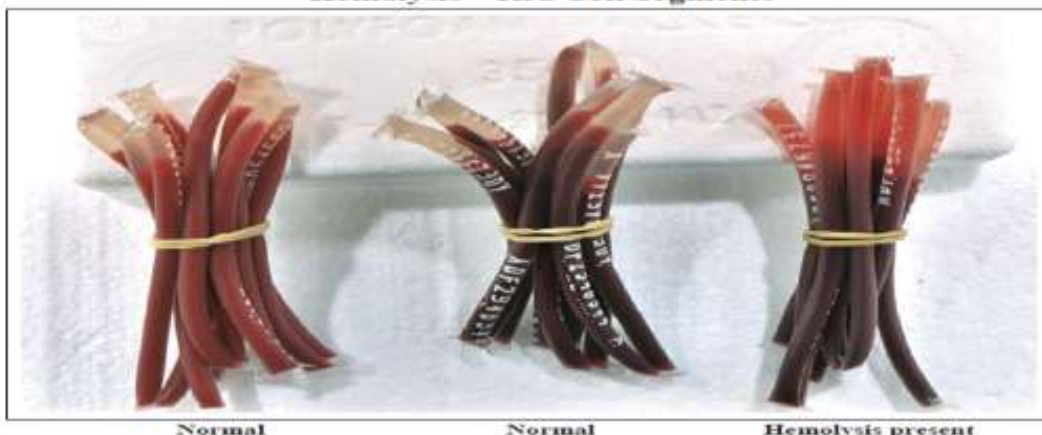


Clots remaining in the bag after filtration



White Particulate Matter in the Bag- Acceptable for transfusion
(Lipid rich matter dissipates with change in temp.)

Hemolysis – Red Cell Segments



Normal

Normal

Hemolysis present



0.11%

0.36%

1.14%

Supernatant of PRBC showing hemolysis

(Percent Hemolysis)



0

0.2

0.5

0.6

0.8

0.9

1.0

1.7

2.0

Percent Hemolysis

(Photograph for illustrative purposes only)

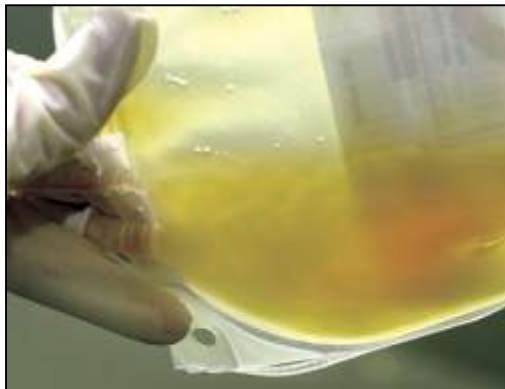
PLATELET CONCENTRATE



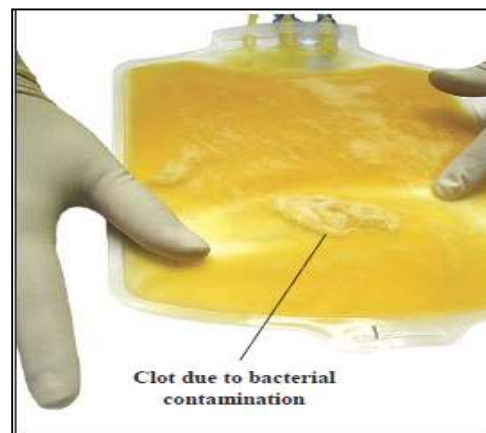
Typical Platelet
(Prepared by PRP method)



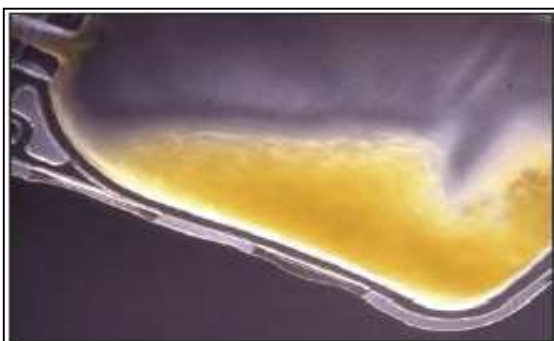
Red cell contamination in PRP
(0.5ml RBC)



Normal Platelet Concentrate



Clot in Platelet Concentrate
(Due to Bacterial contamination)



Swirling in Platelet Product



No swirling in Platelet Product

FRESH FROZEN PLASMA



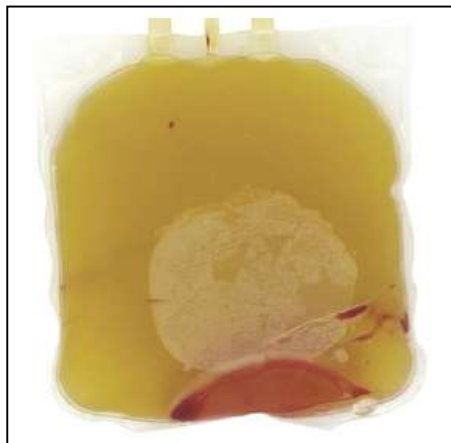
Typical Plasma



Icteric Plasma



Lipemic Plasma



Red cell in centrifuged Plasma



Yellow Clot in Plasma

CRYOPRECIPITATE PRODUCT



Source: American Red Cross Biomedical Services Job Aid: Visual Inspection Reference Guide 2006

Chapter 7

REQUISITION AND ISSUE OF BLOOD COMPONENTS

Transfusion decision

- Decision for transfusion and administration of blood is the responsibility of the treating doctor and other related staff.
- Need of blood/blood component transfusion to the patient should be weighed against the benefits of transfusion and risk involved.
- Patient should be informed about the decision to transfuse blood components.

It is mandatory to take informed consent of patient before transfusion

- Taking Informed Consent is a clinician's responsibility
- Patient should be explained about the benefits, risks, and alternative therapies of blood transfusion.
- It has to be taken in the language understandable by the patient.
- Patient should be given opportunity to ask questions.
- Patient and family should be educated regarding blood donation

Request for blood components

A requisition form completely filled and signed by the doctor on duty should be sent to the blood bank along with the blood samples.

Following details should be captured on the request form -

- Complete Name of patient
- Age and sex of patient
- Diagnosis of patient.
- Hospital's registration number unique to the patient
- Ward/Bed number.
- Name of blood/blood component required
- Special transfusion requirements for blood components to be arranged e.g. washing/CMV negative products/irradiated, etc.
- Quantity (units/volume) of blood/blood component required
- Date and Time of requirement



- Time of requirement of blood components should be mentioned on the requisition form(Immediate/Urgent/Routine)
- H/o previous transfusion if any
- Signature of the doctor

Blood sample details for pre transfusion testing

Sample Collection

- The collection of a properly labelled blood sample from the **correct** patient is **critical** to safe blood transfusion.
- Intended recipient/patient should be properly identified before collecting the sample.
- At least two identifier parameters must be used (for example complete name and hospital registration number) to identify the patient.
- Sample may be sent in plain tube or EDTA.
- For infants of less than 6 months of age, sample of mother is also required.
- After 72 hours of blood transfusion, a fresh blood sample should be sent for cross matching

Sample Labelling

- Sample tubes should be labelled at bedside just before collection of blood sample.
- Blood sample collection should be done one at a time for each patient to reduce the risk of error
- Phlebotomist must label the blood sample tubes with the following details: -
 - Name, age and sex of the patient
 - Hospital's Identification Number
 - Ward/Bed number.
 - Date of collection
 - Signature of the phlebotomist
- Manual method or imprinted labels may be used
- **Serum or EDTA plasma** may be used for pretransfusion testing.
- Samples should be transported in a secure manner which should include cold chain maintenance as well as safety issues



Pre transfusion compatibility testing

- Sample received in the blood bank is verified by a qualified technician.
- Information on the label and on the transfusion request form should be **identical**
- Specimen should not be grossly hemolysed or contaminated with IV fluid.
- Current mandated tests for pre-transfusion samples include

Donor Unit Testing

- ABO grouping: Forward and reverse
- Rh grouping : Rh(D)including weak D
- Mandatory TTI testing

Recipient Testing

- ABO grouping: Forward and reverse
- Rh grouping : Weak D is not required
- IAT testing: Antibody screen
(*Unexpected antibodies are those other than anti-A or anti-B.*)
- Cross match : Major and Minor

Selection of blood components

Whole blood /Packed Red Cell selection

- Whenever possible patients should receive blood components of their own **ABO group**.
- **D positive blood** should be selected for D positive recipients
- **D negative components** should be selected for D negative recipients
- When this is not possible, components of alternative ABO groups may be selected.
- The following is a list of acceptable alternatives **in the order of selection**:

ABO GROUP OF RECIPIENT

O
B
A
AB

ABO GROUP OF DONOR

O only
B, O
A, O
AB, A, O, B

If ABO compatible D negative components are not available treating doctor/doctor on duty should be informed



- If there is no alternative, give D positive, the risk of immunization must be weighed against the potential loss of the patient's life.
- Depending on the child bearing potential of the patient it may be appropriate to administer Rh Immune Globulin to recipients of D positive components (i.e. platelets).

Platelet selection

Platelets should ideally be the same ABO and Rh (D) type as the recipient .If not available non group specific platelet transfusion is an accepted practice.

When platelet concentrates from a Rh (D) positive donor are transfused to a Rh (D) negative recipient, and in particular females of childbearing age or female children, prophylactic Rh (D) immunoglobulin must be considered

ABO Compatibility of Plasma Components

PATIENT'S ABO BLOOD GROUP	ABO GROUP OF PLASMA COMPONENT *
Unknown	AB if urgent
O	O or A or B or AB
A	A or AB
B	B or AB
AB	AB (A if AB is unavailable)

*** Note: Individual plasma units of different blood groups must not be pooled**

Selection of Units in Massive Transfusion

- Defined as replacement of one or more blood volume(s) within 24-hours
- **OR** transfusion of about 10 units of whole blood of 450 ml each or 20 units of red cells within 24 hrs
- **OR** replacement of more than 50% of blood volume in 3 hours in an adult
- After one blood volume change, serological cross match has limited benefit.
 - **Pre-transfusion sample no longer represents currently circulating transfused blood.**
 - Only important to confirm ABO compatibility of subsequently transfused blood.

Massive transfusion protocol (MTP)

- In massive transfusion requirements in addition to RBCs transfusion of other components during this time are equally critical.



- Must take into consideration “dilutional coagulopathy. Giving RBCs plus IV solutions will NOT replace clotting factors or platelets.
- FFP and platelet transfusions should be based on evaluation of laboratory parameters (PT, APTT, Fibrinogen and Platelet count)
- Empirically trauma protocol for massively bleeding patients involves providing blood components in ratio of PRBC:FFP:PLATELET 1:1:1
- Repeat until bleeding is controlled.

Release of Blood in Urgent Situations.

- In immediate blood requirement cases doctor on duty should give in writing about the clinical urgency and it should be kept as a blood bank record
- Blood component issued should be properly labelled with donor blood group with indication **in BOLD LETTERS as UNCROSSMATCHED BLOOD** on the blood bag or component
- Compatibility testing must be started as soon as the specimen reaches the transfusion service
- Complete cross matches **promptly**. If incompatibility is detected at any state of testing, **immediately notify both doctor on duty and blood bank medical officer**

Provision of Red Cells in an Emergency

TESTS COMPLETED	UNITS SELECTED	AVAILABILITY
None	Emergency O Rh (D) Negative blood (uncrossmatched)	Immediate
Limited testing ABO/Rh(D) type only	ABO/Rh (D) group specific (uncrossmatched)	15 min
All testing Compatible Blood (Full ‘Group and Screen’)	ABO/Rh (D) group specific and compatible blood	45min to 1 hour

Issue of blood/blood components from blood bank in routine cases

Designated person will collect blood/blood component from the blood bank and take it to the patient.

Blood bank personnel should issue blood/blood component only after:

- An “Issue slip” having details of patient and blood/blood component required should be sent at the time of collecting blood/blood component from the blood bank.



- Verify the identity of the intended recipient by matching the particulars on issue slip and the blood request form with the two minimum identifiers defined earlier
- Visual inspection of the blood components being issued
- Ensure the right transportation conditions (including maintenance of cold chain).
- Blood sample of patient and donor is preserved in blood bank at 2- 6°C at least for 7days after issue.
- In any condition it should not be stored in domestic/unmonitored refrigerator.

Pre-transfusion Check at the Time of Infusion: -

The medical personnel administering the blood should check /verify the following information before transfusing the blood /blood components

- The name and identification number (hospital registration no.) of the patient, cross match report received and label on the bag (blood component)/container issued.
- It is desirable to ask the patient to state his or her name, if capable of doing so.
- Blood component issued to patient is same as that ordered
- The ABO and Rh type mentioned on bag and that on cross matching report is same.
- The expiry date of the bag should be verified as acceptable,
- Result of all transfusion transmissible infection testing should be checked and should be nonreactive.
- All identification attached to the bag/container must remain attached until the transfusion has been completed
- Visual inspection of blood components for hemolysis, change of colour, clots or aggregates etc. should be done.

Venous access

- For adult patients an 18-gauge needle is commonly used, however 23-gauge needles may be used for transfusions for paediatric patient

Use of blood administration set

- Standard blood transfusion set with filter with 170-260 micron pore size with drip chamber to be used for administration of all blood components
- Special leuco-reduction filters specific for red cell or platelet transfusion should be used with manufacturers instructions-commonly used for multiply transfused thalassemia or oncology patients



- Blood administration set may be primed with 0.9% saline
- IV fluids other than saline- Ringer's Lactate solution(may induce clot formation in the blood bag or BT set), 5% dextrose (may induce hemolysis) and hypotonic sodium chloride solutions should not be simultaneously administration via the same intravenous line
- ABO-compatible plasma, 5% albumin, or plasma protein fraction can be used with approval of the concerned clinician.
- Blood administration set should be changed every 12 hours.

Cold chain maintenance at blood administration site

- Red cell component should not be exposed to temperature above 10°C.
- Not to be warmed before transfusion in routine transfusion
- Kept at room temperature before starting of transfusion.
- Transfusion should start within 30 minutes of issue of blood from the blood bank.
- If delay in transfusion is anticipated blood should be returned to blood bank for proper storage till further transfusion
- Platelets to be transfused as fast as patient can tolerate (refer to table for rate of transfusion of blood components).
- FFP is thawed at 37°C hence transfusion should be started as soon as the product is received
- Blood components which cannot be transfused within the allowed time out of the storage temperature should be returned to blood bank for proper storage and reissue if required later on.

Rate of transfusion of various blood components

Red blood cell transfusion

1-2 ml/min for first 15 min followed by 2-5 ml/min

Transfusion should be completed within 4 hours

Platelet transfusion

2-5ml/min for first five minutes followed by 300 ml/min

Plasma transfusion

2-5 ml/min for first five minutes followed by
as fast as tolerated by patient approximately 300 ml/min



Monitoring of patient during and after transfusion

- Obtain patient baseline vital signs including blood pressure, temperature, pulse and respiration (BP/TPR) prior to administration
- ***Most reactions occur within 1st 15 to 30 minutes of administration.***
- Closely monitor the patient for the first 15 minutes
- Repeat vital signs and assess for transfusion/infusion reaction 15 minutes after initiation of transfusion/infusion and every 15 minutes thereafter TILL ONE HOUR
- Date and Time transfusion/infusion initiation and completion is recorded.



Chapter 8

HAEMOVIGILANCE

Blood transfusion is a lifesaving medical intervention. However, transfusion of blood and blood products may be associated with adverse effects such as transmission of blood borne pathogens including viruses, bacteria and parasites. Non-infectious hazards of transfusion can also harm the patients. Systematic and proactive surveillance of events during and after administration of blood products (Haemovigilance) helps to detect and identify adverse effects of blood transfusion and can be very effective in improving blood quality and safety.

Transfusion of blood and blood products is not without risks and it can lead to complications. Haemovigilance is a continuous process of data collection and analysis of Blood Transfusion related Adverse Reactions in order to investigate their causes and outcomes, and prevent their occurrence or recurrence. It includes the identification, reporting, investigation and analysis of Adverse Reactions and Events in recipients and blood donors as well as incidents in manufacturing processes, eventually errors and “near-misses”.

A Haemovigilance system is also an integral part of quality management in a blood system, triggering corrective and preventive actions for the continual improvement of the quality and safety of blood products and the transfusion process.

Haemovigilance is defined as: “a set of surveillance procedures covering the whole transfusion chain (from the collection of blood and its components to the follow-up of its recipients), intended to collect and assess information on unexpected or undesirable effects resulting from the therapeutic use of labile blood products, and to prevent their occurrence and recurrence”

IMPORTANCE

- Provides objective data on transfusion risks
- Increases awareness of transfusion and its complications among hospital staff
- Annual Haemovigilance reports - opportunities for education on transfusion risks
- Hospital Transfusion Committees (HTC's) can use data to review and improve processes involved in handling and administration of blood and components
- Identify potential hazards which may be present but unrecognized



NEED OF HAEMOVIGILANCE IN INDIA

Haemovigilance is required to identify and prevent occurrence or recurrence of transfusion related unwanted events, to increase the safety, efficacy and efficiency of blood transfusion, covering all activities of the transfusion chain from donor to recipient.

HAEMOVIGILANCE PROGRAMME OF INDIA (HvPI)

A centralized Haemovigilance Programme to assure patient safety & promote Public Health has been launched for the first time in the country on 10th December, 2012 in 90 Medical Colleges under Pharmacovigilance Programme of India (PvPI) for monitoring Adverse Reactions associated with Blood Transfusion & Blood Product Administration. National Institute of Biologicals (NIB), NOIDA is the National Coordinating Centre (NCC) for the Haemovigilance Programme of India (HvPI). The data in respect of Adverse Reaction associated with Blood transfusion & Blood Product administration is being collected from various Centres enrolled under HvPI in Transfusion Reaction Reporting Form (TRRF) via Haemo-Vigil software which has been developed in-house by IT Team NIB.

The recipient's part i.e. Reporting of Adverse Reactions w.r.t Blood Transfusion in the patient was covered under **Haemovigilance Programme of India** with the launch of the programme on 10th December 2012 in the country & the donor's part i.e. Reporting of Adverse Reactions associated with Blood Donations has been covered under **National Blood Donor Vigilance Programme (NBDVP)** which was launched on 14th June 2015 on World's Blood Donor Day at Science City Kolkata under the ambit of Haemovigilance Programme of India. NBDVP envisages to help analyse risk factors, implement and evaluate preventive measures, reduce frequency of adverse events and increase donor frequency. A dedicated software for Donor Vigilance is being used for reporting Adverse Reactions associated with Blood Donations.

Objectives of Haemovigilance Programme of India:

- Monitor Transfusion Reactions
- Create awareness amongst health care professionals
- Generate evidence based recommendations
- Advise CDSCO for safety related regulatory decisions
- Communicate findings to all key stakeholders
- Create National & International Linkages



Objectives of National Blood Donor Vigilance Programme:

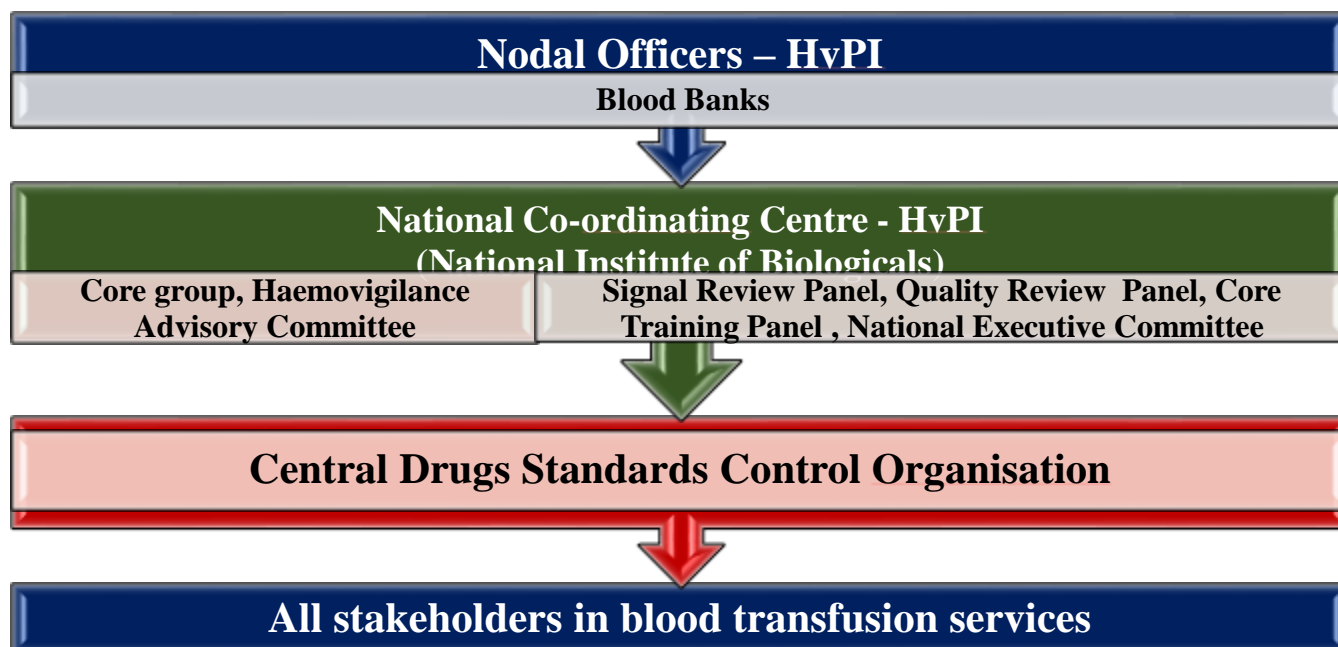
- Improve donor safety and satisfaction through monitoring, analysing and researching adverse events
- Analyse risk factors , implement and evaluate preventive measures
- Provide evidence based support for Blood Donation Process improvement
- Reduce the frequency of adverse events
- Increase donation frequency

CHARACTERISTICS OF HAEMOVIGILANCE PROGRAMME OF INDIA

HAEMOVIGILANCE PROGRAMME OF INDIA	
Non-punitive	Reporters are free from fear of retaliation against themselves or punishment of others as a result of reporting
Confidential	The identities of the patient, reporter and institution are never revealed to third party : Clause for confidentiality
Independent	The reporting system is independent of any authority with power to punish the reporter or the organization: NIB- Coordinating Centre between the Reporters and Regulators
Expert analysis	Reports are evaluated by experts who understand the clinical circumstances and are trained to recognize underlying systems causes: Core Group, National Executive Committee, Haemovigilance Advisory Committee, Quality Review Panel, Signal Review Panel, Core Training Panel
Credible	Traceability of events through proper documentation which in turn will lead to effective recommendations which are to be accepted and acted upon By defining responsibilities to all the key departments and also by defining systematic documentation process
Systems oriented	Recommendations focus on changes in systems & process rather than being targeted at individual performance
Responsive	Participating organizations commit to implementing recommendations whenever possible



HAEMOVIGILANCE PROGRAMME OF INDIA - ORGANOGRAM



REPORTING OF TRANSFUSION REACTIONS AND DONOR REACTIONS VIA HAEMOVIGILANCE SOFTWARES

The Centres (Medical Colleges/ Institutes/ Hospitals/ Blood Banks of India) that are enrolled under HvPI, report the Transfusion Reactions/Donor Reactions to the NCC-HvPI, NIB, NOIDA by entering the data into the Transfusion Reaction Reporting Form & Blood Donor Reactions Reporting Form via Haemovigilance Software.

Under Haemovigilance Programme of India following two software are available:

1. **Haemo- Vigil:-** (to capture transfusion reactions i.e. recipient Haemovigilance)
2. **Donor- Vigil:-** (to capture reactions during blood donation i.e. Donor Vigilance)

Link to NIB website for access of both the software is <http://nib.gov.in/>

- On click to above link, the homepage of National Institute of Biologicals (NIB) will be displayed.
- Click on the “**Haemovigilance Programme of India**” tab.
- On the right hand side of the page under **Software** tab both the software are present

(i) Haemo-Vigil Software (Recipient Haemovigilance)

(ii) Donor-Vigil Software (Donor Haemovigilance)



- Click on the desired Software tab for login page of the software.
- Enter “Username” and the “Password” in the required fields followed by the “Validation Code” and click on “**Sign In**”. By clicking on **Sign In** user is redirected to the home page of software having following five tabs:
 - a) **Transfusion Reaction Reporting Form / Donor Reaction Reporting Form:** to report the adverse transfusion / Donor reaction(s).
 - b) **Nil Reporting:** to report in case no adverse reaction has occurred in the particular month.
 - c) **Monthly Denominator Reporting Form:** To report the denominator details of the blood components/ products on monthly basis.
 - d) **Inbox:** to check the status of all information saved & submitted by the center.
 - e) **Edit Request:** to send the edit request & edit the TRRF in case the wrong information has been submitted.

ASSESSMENT OF TRANSFUSION/ DONOR REACTION REPORTS UNDER HvPI

The Reports submitted to National Coordinating Centre –HvPI, is assessed by HvPI Personnel to whom particular centre is allotted. Submitted Forms are assessed on the basis of following parameters:

1. Completeness
2. Correctness

Once the data is assessed NCC-HvPI forward it to the Quality Review Panel for the quality check, the data is further forwarded to the Signal Review Panel for the statistical analysis and also for the detection of “Signal”. Quality Review Panel and Signal Review Panel in turn provide their recommendations to the Core Group which are further presented to the Haemovigilance Advisory & National Executive Committee.

The recommendations from the Haemovigilance Committees are forwarded by the Core Group of HvPI to CDSCO.

CDSCO, Headquarter further takes regulatory decisions and forward them to the Stakeholders (Patients, Healthcare Professionals, Blood Banks, NACO, SBTC etc.).



INTERNATIONAL HAEMOVIGILANCE NETWORK

India has become a member of International Haemovigilance Network (IHN) in December 2014. IHN was established in the Year 2009. Presently 33 Countries are members of International Haemovigilance Network including India.

CREATING AWARENESS – IEC

Awareness about the Programme, its objectives and its non- punitive implications is being generated through publications in reputed journals/ magazines & Haemovigilance Newsletters and also by organizing CMEs on HvPI in different regions of the country. NCC, NIB organises various CMEs on Haemovigilance Programme of India all across the country. During CMEs, hands on training on Haemo-Vigil Software is also imparted to the participants w.r.t uplinking Haemovigilance Data in transfusion reaction reporting form (TRRF) via Haemo-Vigil software.

ADVERSE TRANSFUSION REACTION

Transfusion like other treatments can both benefit and do harm to the patient. Severe reactions are most likely to occur within 15 minutes of starting transfusion of each individual unit of blood products. If the patient experiences an adverse reaction during or following transfusion of a blood component, clinical staff must report this to the blood bank as soon as possible

Investigation of Adverse Transfusion Reaction form should be completed sent to the blood bank with any laboratory samples or remnants of transfused components (as indicated) for the investigation of the reaction

ACUTE HEMOLYTIC TRANSFUSION REACTION (AHTR)

- One of the most severe transfusion reactions is the AHTR.
- In this life-threatening condition, immune-mediated intravascular hemolysis occurs as recipient (host) IgM antibodies bind to donor RBCs and activate complement almost always because of an ABO mismatch.
- **The most common cause for AHTRs remains patient misidentification and clerical error.**
- The classical signs and symptoms of an AHTR include fever, chills and hemolglobinuria.
- In addition, the patient may develop hypotension, pain at the IV site, nausea/vomiting, dyspnea, renal failure or bleeding due to DIC.



- In a conscious patient even a few millilitres of ABO incompatible blood may cause symptoms within a few minutes of starting the transfusion
- In an unconscious or anaesthetised patient hypotension and uncontrollable bleeding due to DIC may be the only signs of an incompatible transfusion. Oliguria is common and is often followed by acute renal failure.
- A suspicion of AHTR may be confirmed by laboratory results showing a positive DAT, hemoglobinemia, hemoglobinuria, reduced haptoglobin, elevated bilirubin, elevated urine hemosiderin and renal abnormalities.

Treatment

- If an AHTR is suspected, the transfusion should be stopped immediately and a normal saline drip should be started to maintain IV access.
- The purpose of initial therapy is to maintain blood pressure and renal blood flow. As such, IV saline and a diuretic (if necessary) should be administered so that urine output is maintained at 100mL/hr. (Adequate urine output must be ensured as this dilutes the blood and helps to prevent acute tubular necrosis.)
- Additional treatment is supportive to manage complications such as bleeding caused by DIC.
- The patient's identity should be referenced to that on the blood product label to check for error.
- The blood bank should be notified and samples should be sent from the patient and the remaining blood product for testing.

FEBRILE NON HEMOLYTIC TRANSFUSION REACTION (FNHTR)

- Allergic reactions are common and are mediated by the recognition of donor plasma antigens by preformed recipient IgE antibodies.
- More severe allergic (anaphylactic) reactions can also occur. Symptoms of these reactions include hypotension and airway edema. These severe allergic reactions often occur when blood products are transfused to patients with IgA deficiency and who have antibodies directed against the IgA in these products.
- The second reaction associated with an isolated fever is likely a FNHTR.
- A FNHTR is defined as an otherwise unexplained rise in temperature of at least 10 C during or after transfusion with a blood product.



- This type of reaction may be due to cytokines from the plasma of the donor or to recipient antibodies directed against antigens on the cells of the donor.
- Treatment
- In a case of a suspected allergic reaction, the transfusion should be stopped and IV access maintained.
- Treatment for a simple allergic reaction includes administration of an antihistamine. More serious anaphylactic reactions should be treated with an antihistamine as well as with epinephrine, corticosteroids and vasopressors. Intubation may also be necessary. Prophylactic measures for future transfusions for these patients include antihistamines and corticosteroids before the transfusion.
- Treatment for a FNHTR is symptomatic with antipyretics. These may also be used prophylactically for future transfusion as well.

Transfusion-related acute lung injury (TRALI)

- TRALI is an acute respiratory distress syndrome secondary to transfusion of blood products and causes hypoxia and bilateral non-cardiogenic pulmonary edema.
- Its incidence is not precisely known, but is estimated between 1 in 1200 and 1 in 5000.
- Symptoms include dyspnea, hypoxemia, hypotension and fever. There is no evidence of CHF – there is no jugular venous distension and right arterial pressure is normal.
- The etiology of TRALI is unclear, however it is believed that there is either a transfer of biologically active lipids or a transfer of HLA/granulocyte antibodies from the donor to the recipient. (It is believed that multiparous female donors have an increased number of these antibodies as a result of previous pregnancies, and therefore receiving blood from these donors poses a greater risk of developing TRALI.)

Management of this type of transfusion reaction includes cessation of the transfusion, maintenance of the IV line with normal saline, as well as supportive care including oxygenation or mechanical ventilation, if necessary. CXRs must be performed and the blood bank notified. Steroids and diuretics are NOT indicated in the treatment of TRALI.

Transfusion Associated Circulatory Overload (TACO) symptoms and signs

- Symptoms --Non-productive, cough, dyspnea
- Signs -Tachypnea/orthopnea, pulmonary edema, raised jugular venous pressure,



- Cause Hypertension, cyanosis, and tachycardia volume overload , rapid infusion rate, complicating pre-existing patient condition
- Onset within 6 hours of completion of transfusion relates to patient's condition, volume administered and administration rate
- Frequency 1/700 transfusion recipients 1/100 "at-risk" patients (risk of cardiac overload, history of previous transfusion reactions, and/or unstable condition).
- Results of reaction acute pulmonary edema cardiac arrhythmia death
- "At-risk" patient Give each unit of red cells slowly (50 mL/hour)
 - maximum rate is 4 hours from removal from temperature controlled storage
 - units may need to be split
 - The patient may require additional diuretic therapy (for example I.V. furosemide).
 - Oxygen may be required.
 - Closely monitor the patient for signs and symptoms of TACO
- Differential diagnosis- TRALI, TAD

DELAYED HAEMOLYTIC TRANSFUSION REACTION (DHTR)

- DHTR is a haemolytic reaction occurring 24 hours or more following transfusion, in a patient that has been immunised to a red cell antigen by an earlier transfusion or pregnancy.
- The level of antibody may be so low that it cannot be detected in the pretransfusion sample.
- After transfusion of red cells bearing the target antigen a rapid, secondary immune response boosts the antibody level so that after a few days, transfused red cells bearing the relevant antigen may be rapidly destroyed
- Antibodies of the Kidd (Jk) and Rh systems are the most frequent cause of DHTR
- The signs of a delayed haemolytic transfusion reaction normally appear 1-14 days after transfusion.
- Usual features include fever, falling haemoglobin (or a failure of the haemoglobin to rise), jaundice and occasionally haemoglobinuria or renal failure.



TRANSFUSION TRANSMITTED INFECTIONS

Blood donors, like anyone else, can occasionally carry an infectious agent, sometimes for a long period, without having any clinical signs or symptoms. Donors are interviewed thoroughly as part of pre donation counselling to take high risk history or go for self exclusion. Tests are performed on every blood donation. No part of the donation should be released until all these tests are known to be clear. A good donor selection and testing procedures makes the risk of infection through the contamination of blood components and products extremely small.

Steps to follow when an Acute Transfusion Reaction is suspected:

- Firstly it is important to understand that early recognition and intervention will prevent morbidity and mortality,
- Once a reaction is suspected the nurse must initiate supportive care and summon support from attending medical officer **immediately**.

Actions:

- Stop Transfusion IMMEDIATELY!
- Commence normal saline infusion (**except in suspected TACO**) using a new intra-venous administration set.
- Ensure; airways are open, vital signs are stable, oxygen and emergency supplies available (crash cart in ready).
- Verify identity of patient; make certain that the unit being infused was unmistakably meant for that patient (review obligatory identifiers).
- Notify the blood bank and return unused blood component (with all tubing).
- **Collect blood and urine samples for the following:**
 - Group and cross match
 - Complete blood count
 - Coombs Tests (Direct and Indirect Antiglobin Tests)
 - Blood culture and gram stain
 - Urine for free haemoglobin
- Management as clinical scenario dictates, such as chest x-ray – All observations, actions and treatment must be fully documented in the medical record
- Further investigations (by blood bank and medical staff) of probable cause and implementation of corrective actions should be taken where warranted.





National Institute of Biologicals
Ministry of Health & Family Welfare, Govt. of India
(National Coordinating Center)
HAEMOVIGILANCE PROGRAMME OF INDIA



Transfusion Reaction Reporting Form (TRRF) For Blood & Blood Components & Plasma Products

* Mandatory Field

(A) Patient Information

Hospital Code No.:									
Patient Initials*:			Gender*:		Blood Group*:				
Hospital Admission No.*:				Age/Date of Birth*:		Yrs		Month	
						Days		Hrs	
Primary Diagnosis*:									
Medical History:									

(B) Transfusion Reaction Details*

Was the patient under anaesthesia during transfusion: Yes/No If Yes type : GA/Spinal/LA

Pre-transfusion Vitals:					Temp:	Pulse:	BP:	RR:	SPO2:
Vitals at the time of reaction:					Temp:	Pulse:	BP:	RR:	SPO2:

Please tick mark the relevant signs and symptoms listed below

Generalised		Pain	Respiratory	Renal	Circulatory
<input type="checkbox"/> Fever	<input type="checkbox"/> Anxiety	<input type="checkbox"/> Chest Pain	<input type="checkbox"/> Dyspnoea	<input type="checkbox"/> Haematuria	<input type="checkbox"/> Tachycardia
<input type="checkbox"/> Chills	<input type="checkbox"/> Itching (Pruritus)	<input type="checkbox"/> Abdominal	<input type="checkbox"/> Wheeze	<input type="checkbox"/> Haemoglobinuria	<input type="checkbox"/> Hypertension
<input type="checkbox"/> Rigors	<input type="checkbox"/> Edema (Site)	<input type="checkbox"/> Back/Flank Pain	<input type="checkbox"/> Cough	<input type="checkbox"/> Oliguria	<input type="checkbox"/> Hypotension
<input type="checkbox"/> Nausea	<input type="checkbox"/> Jaundice	<input type="checkbox"/> Infusion Site Pain	<input type="checkbox"/> Hypoxemia	<input type="checkbox"/> Other	<input type="checkbox"/> Raised JVP
<input type="checkbox"/> Urticaria	<input type="checkbox"/> Other	<input type="checkbox"/> Other			<input type="checkbox"/> Arrhythmias
<input type="checkbox"/> Flushing			<input type="checkbox"/> Bilateral infiltrates on Chest X-ray		<input type="checkbox"/> Other
<input type="checkbox"/> Restlessness					
<input type="checkbox"/> Vomiting			<input type="checkbox"/> Other		

Any Other(Specify) :

(C) Transfusion Product(s) Details*

Select*	Select Component	Select Indication	Date & Time of Issue of Blood Component	Date & Time of onset Transfusion	Unit Id (Transfused)	Blood Group	Volume Transfused (ml)	Expiry date of Blood Component	Manufacturer of Blood Bag	Batch / Lot No. of the Blood Bag	1st time/ repeat Transfusion
<input type="checkbox"/>	Whole blood										<input type="checkbox"/> 1st Time <input type="checkbox"/> Repeat 1 to 10 <input type="checkbox"/> Repeat > 10
<input type="checkbox"/>	Packed Red blood cells (PRBC)										
<input type="checkbox"/>	Buffy coat depleted PRBC										
<input type="checkbox"/>	Leucofiltered PRBC										
<input type="checkbox"/>	Random Donor platelets/ pooled										
<input type="checkbox"/>	Apheresis Platelets										
<input type="checkbox"/>	Fresh Frozen Plasma										
<input type="checkbox"/>	Cryoprecipitate										
<input type="checkbox"/>	Any Other										

Add New Plasma Product

Select	Plasma Product	Indication	Date of Administration	Manufacturer	Expiry Date of the Plasma Product	Batch No. / Lot No.	1st Time / Repeat
							<input type="checkbox"/> 1st Time <input type="checkbox"/> Repeat 1 to 10 <input type="checkbox"/> Repeat > 10

(D) Investigations									
<input type="checkbox"/> Clerical Checks		Specify Error Found if any:							
Investigation		Pre-transfusion sample				Post-transfusion sample			
		O+ /A+ /B+ /AB+ /O- /A- /B- /AB-				O+ /A+ /B+ /AB+ /O- /A- /B- /AB-			
<input type="checkbox"/> Repeat Blood Grouping		<input type="checkbox"/> Compatible <input type="checkbox"/> InCompatible <input type="checkbox"/> Not Done				<input type="checkbox"/> Compatible <input type="checkbox"/> InCompatible <input type="checkbox"/> Not Done			
<input type="checkbox"/> Repeat Crossmatch		<input type="checkbox"/> Negative <input type="checkbox"/> Positive <input type="checkbox"/> Not Done				<input type="checkbox"/> Negative <input type="checkbox"/> Positive <input type="checkbox"/> Not Done			
<input type="checkbox"/> Repeat Antibody screen		<input type="checkbox"/> Negative <input type="checkbox"/> Positive <input type="checkbox"/> Not Done				<input type="checkbox"/> Negative <input type="checkbox"/> Positive <input type="checkbox"/> Not Done			
<input type="checkbox"/> Antibody Identification		<input type="checkbox"/> Negative <input type="checkbox"/> Positive <input type="checkbox"/> Not Done				<input type="checkbox"/> Negative <input type="checkbox"/> Positive <input type="checkbox"/> Not Done			
<input type="checkbox"/> Direct antiglobulin test		<input type="checkbox"/> Negative <input type="checkbox"/> Positive <input type="checkbox"/> Not Done				<input type="checkbox"/> Negative <input type="checkbox"/> Positive <input type="checkbox"/> Not Done			
<input type="checkbox"/> Hemoglobin									
<input type="checkbox"/> Plasma Hemoglobin									
<input type="checkbox"/> Urine hemoglobin									
<input type="checkbox"/> Bilirubin (Total/conjugated)									
<input type="checkbox"/> Platelet count									
<input type="checkbox"/> PT/INR									
<input type="checkbox"/> Blood culture of Blood Bag		<input type="checkbox"/> Negative <input type="checkbox"/> Positive <input type="checkbox"/> Not Done				Specify Organism if positive			
<input type="checkbox"/> Blood culture of Patient		<input type="checkbox"/> Negative <input type="checkbox"/> Positive <input type="checkbox"/> Not Done				<input type="checkbox"/> Negative <input type="checkbox"/> Positive <input type="checkbox"/> Not Done			
		Specify Organism if positive				Specify Organism if positive			
<input type="checkbox"/> Chest X-ray of the patient in case of suspected TRALI									
In case of Non-immune hemolysis (which of the following was the case?)									
<input type="checkbox"/> Hemolysis due to freezing of PRBC Units									
<input type="checkbox"/> Hemolysis due to inappropriate warming of PRBC Units									
<input type="checkbox"/> Hemolysis due to infusion of any other fluid through same BT set. Specify Fluid: _____									
<input type="checkbox"/> Mechanical damage									
In Case of ABO Mismatch (which of the following was the case?)									
<input type="checkbox"/> Wrong Blood in tube									
<input type="checkbox"/> Grouping error									
<input type="checkbox"/> Labelling error									
<input type="checkbox"/> Wrong unit transfused									
(E) Nature of Adverse Reaction(s)*									
Select	Reaction		Date & Time of Onset of Reaction	Date & Time of Recovery	Outcome				
<input type="checkbox"/>	Febrile Non Haemolytic Reactions (FNHTR) 1° C rise in temperature <input type="checkbox"/> 2° C rise in temperature <input type="checkbox"/> Only Chills & Rigors <input type="checkbox"/>				<input type="checkbox"/> 1. Death following the Adverse Reaction(s)				
<input type="checkbox"/>	Allergic reaction				<input type="checkbox"/> 2. Recovered				
<input type="checkbox"/>	Anaphylaxis								
<input type="checkbox"/>	Immunological Haemolysis due to ABO Incompatibility								
<input type="checkbox"/>	Immunological Haemolysis due to other Allo-Antibodies								
<input type="checkbox"/>	Non Immunological Haemolysis								
<input type="checkbox"/>	Hypotensive Transfusion Reaction								
<input type="checkbox"/>	Transfusion Related Acute Lung Injury (TRALI) Definite <input type="checkbox"/> Possible <input type="checkbox"/>				<input type="checkbox"/> 3. Recovered with Sequelae				
<input type="checkbox"/>	Transfusion Associated Dyspnoea (TAD)								
<input type="checkbox"/>	Transfusion Associated Circulatory Overload (TACO)								
<input type="checkbox"/>	Transfusion Transmitted Bacterial Infection								
<input type="checkbox"/>	Transfusion Transmitted Parasitic Infection (Malaria)								
<input type="checkbox"/>	Post Transfusion Purpura								
<input type="checkbox"/>	Transfusion Associated Graft versus Host Disease (TAGvHD)				<input type="checkbox"/> 4. Unknown				
<input type="checkbox"/>	Other Reaction (s) Add New <input type="text"/>								
(F) Imputability Assessment*									
S. No.	Reaction Term	Transfusion Product/ Component	*Imputability Assessment (Please mention from the below list)						
*Imputability: 1. Definite (Certain), 2. Probable (Likely), 3. Possible, 4. Unlikely (Doubtful), 5. Excluded, 6. Not Assessed									
Monthly Denominator Reporting Form *									
Hospital Code :		Month/Year:							
Blood Component		No. of Units Issued							
1) Fresh Frozen Plasma									
2) Whole Blood									
3) Packed Red Blood Cells (PRBC)									
4) Buffy Coat Depleted PRBC									
5) Leucofiltered PRBC									
6) Random Donor Platelets/ Pooled									
7) Apheresis Platelets									
8) Cryoprecipitate									
9) Any Other									

Chapter 9

BIOSAFETY

Biosafety guidelines are provided for the protecting the diagnostic laboratory personnel while handling infectious materials/ agents of blood borne diseases such as HIV, HBV, and HCV etc. The risk of laboratory-acquired infection with blood borne diseases is primarily from contamination of hands, mucous membranes of eyes, nose and mouth by infectious blood and other body fluids. Though occupational risk is low, but the consequences of infection of blood borne diseases are dire. Since vaccines are not available for all the possible infections, safe work practices provide the best protection.

Following are the biosafety guideline procedures for serological assays:

1. Universal precaution for laboratory workers
2. Safe use of pipettes
3. ELISA washer and reader
4. Spill and accidents
5. Procedure for hand washing

Universal precaution for laboratory workers

- a) Wear good quality gloves when handling infectious material.
- b) Do not touch eyes, nose and other exposed membranes or skin with gloved hands.
- c) Do not leave the work place or walk around the laboratory wearing gloves.
- d) Wash hands with soap and water immediately after any contamination and after completion of work and removal of gloves.
- e) Wear laboratory apron when in laboratory.
- f) Restrict entry to the laboratory.
- g) Door to have a 'Biohazard' sign and 'Restricted Entry' labels.
- h) Keep laboratory clean, neat and free from extraneous material and equipment.
- i) Disinfect work surfaces at the end of procedures and each working day.
- j) Discard needles and other sharp instruments in a puncture- resistant container. Do not recap used needles and do not remove needles from syringes.
- k) Never pipette by mouth.
- l) Do not eat; drink, smoke and apply cosmetics or contact lens in the laboratory.
- m) Maintenance effective insect and rodent control programme.



Safe use of pipettes

- a) A pipetting aid should always be used
- b) Pipetting by mouth should be prohibited.
- c) All pipettes should have cotton plugs to reduce contamination of pipetting device.
- d) Air should never be blown through liquid containing infectious agents.
- e) Liquids should not be forcibly expelled from pipettes.
- f) To avoid dispersion of infectious material, a disinfectant soaked absorbent paper should be placed on the working surface.
- g) Contaminated pipettes should be completely submerged in a suitable disinfectant and left for 18- 24 hours before disposal.

ELISA Washer and Reader:

Washer

General: For daily operations, the instrument should be kept free of dust and liquid spills.

Daily: The contents of the waste bottle of water should be emptied into a dedicated decontamination flask.

The waste bottle should be filled with the deionised water and all tubes should be primed and rinsed with it before and after use. The purpose of this is to prevent any quantity of wash buffer from remaining in the tubing or in the manifold where it could dry and leave crystals which could in turn block the tubing for future use.

Reader

- a. The filters, lens surface and detectors should not be touched
- b. For daily operations, the optics should be kept free of dust and/or liquid spill

If by chance the surface of the instrument has been spilled with infectious agent it should be disinfected as follows

1. The power should be turned off and the instrument should be unplugged
2. In a well-ventilated area the spillage should be absorbed with filter paper.
3. The surface of the instrument should be cleaned with filter paper dampened in 2% glutaraldehyde solution or some other suitable laboratory disinfectant.
4. DO NOT use formaldehyde solution as a disinfectant, since even small traces of it might affect results in some ELISA tests.



Spill and Accidents


- a) Wear gloves.
- b) Spill of infected material to be covered with filter paper sheet or absorbent material.
- c) Pour 1% sodium hypochlorite disinfectant solution around and over the absorbent material and leave for 30 minutes.
- d) Clean the mixture of disinfectant and spilt material with filter paper or other absorbent material.
- e) Discard as per Biomedical Waste Management rule 2016.
- f) Wipe surface again with disinfectant.
- g) Broken glass/ plastic should be swept up with a dustpan and brush.
- h) Needle stick or other puncture wounds, cuts and skin contaminated by spills or splashes of specimen material should be washed thoroughly with soap and water.
- i) All spills and accidents should be reported to the laboratory supervisor.
- j) Records of spills and accidents should be maintained in the laboratory.
- k) Appropriate medical treatment should be provided to any affected laboratory personnel, in case of any accident.



Procedure for hand washing

How to Handwash?

WASH HANDS WHEN VISIBLY SOILED! OTHERWISE, USE HANDRUB

 **Duration of the entire procedure: 40-60 seconds**



Wet hands with water;



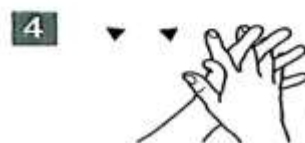
Apply enough soap to cover all hand surfaces;



Rub hands palm to palm;



Right palm over left dorsum with interlaced fingers and vice versa;



Palm to palm with fingers interlaced;



Backs of fingers to opposing palms with fingers interlocked;



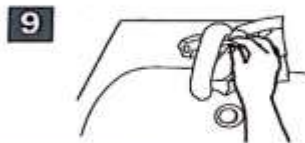
Rotational rubbing of left thumb clasped in right palm and vice versa;



Rotational rubbing, backwards and forwards with clasped fingers of right hand in left palm and vice versa;



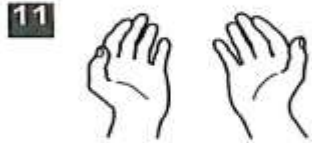
Rinse hands with water;



Turn off the tap.



Rinse your hands with 70% Ethanol and allow them to dry.



Your hands are now safe.



World Health Organization

Patient Safety

A Joint Venture for Safer Health Care

SAVE LIVES
Clean Your Hands

May 2009

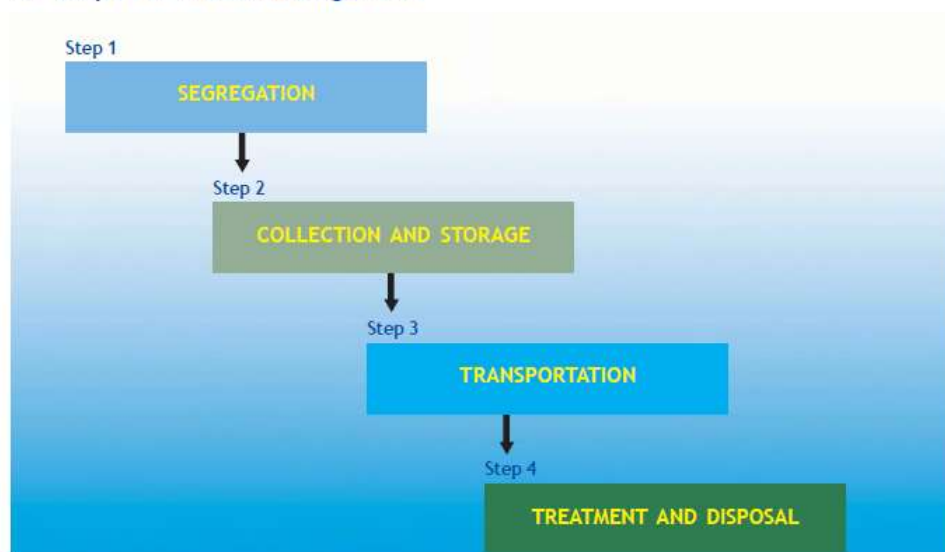


Chapter 10

BIOMEDICAL WASTE MANAGEMENT

“Bio-medical waste “means any waste, which is generated during the diagnosis, treatment or immunization of human beings or animals or in research activities pertaining thereto or in the production or testing of biologicals, or in health camps including categories mentioned in Schedule I of Ministry of Environment, Forests and Climate Change Bio-Medical waste Management Rules, 2016.”

1. Steps For Waste Management



CATEGORIES OF BIOMEDICAL WASTE DEFINED ACCORDING TO BIO MEDICAL WASTE MANAGEMNT RULES 2016

- The 2011 draft demarcated eight categories of biomedical waste (down from ten categories in the 1998 notification). The 2016 notification further brings down the number of categories to four.
- “Reduction in categories does not mean that a particular kind of biomedical waste is not being adhered to. What it means is that all types of wastes have been compiled in four categories for ease of segregation at a healthcare facility,”
- Health care facilities (HCFs) must segregate biomedical waste (the wastes involved in diagnosis, treatment and immunisation such as human and animal anatomical waste, treatment apparatus such as needles and syringes and cytotoxic drugs) at the individual level in colored bags—yellow, red, blue/white and black according to the category of the biomedical waste.



- They can store this waste for up to 48 hours after which they either treat it in-situ or a worker from a common biomedical waste treatment facility (CBMWF) comes to collect it. The CMBWF then treats the waste according to the colour of the bag. Different colours call for different types of treatments incineration, deep burial, autoclaving, shredding, chemical treatment, disposal in a landfill, etc. The bio-medical waste shall be segregated into containers or bags at the point of generation in accordance with Schedule I prior to its storage, transportation, treatment and disposal.
- The Bio-medical waste Management is subject to various regional, national, international regulations. The details in this complied document are as per the requirements laid down in Environment (Protection) Act. The “Act” means: the Environment (Protection) Act, 1986 (29 of 1986): Notification (Ministry of Environment, Forests and Climate Change Bio-Medical waste Management Rules, 2016.

SCHEDULE I: Part-1

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



Type of Waste	Type of Bag or Container	Treatment & Disposal options
Category: Yellow		
(a) Human Anatomical Waste: Human tissues, organs, body parts & fetus	Yellow coloured non-chlorinated plastic bags	Incineration or Plasma Pyrolysis or deep burial*
(b) Animal Anatomical Waste: Experimental animal carcasses, body parts, organs, tissues, including the waste generated from animals used in experiments or testing in animal houses		* Disposal by deep burial is permitted only in rural or remote areas where there is no access to CBWTF. This will be carried out with prior approval from the prescribed authority and as per the Standards specified in Schedule-III. The deep burial facility shall be located as per the provisions and guidelines issued by CPCB from time to time.
(c) Soiled Waste: Items contaminated with blood, body fluids like dressings,		Incineration or Plasma Pyrolysis or deep burial* In absence of above facilities, autoclaving



plaster casts, cotton swabs and bags containing residual or discarded blood and blood components		or micro-waving/ hydroclaving followed by shredding or mutilation or combination of sterilization and shredding. Treated waste to be sent for energy recovery
(d) Expired or Discarded Medicines: Pharmaceutical waste like antibiotics, cytotoxic drugs including all items contaminated with cytotoxic drugs along with glass or plastic ampoules, vials etc.	Yellow coloured non-chlorinated plastic bags or containers	Expired cytotoxic drugs and items contaminated with cytotoxic drugs to be returned back to the Mfr/ supplier for incineration at temperature >1200°C or to CBWTF or hazardous waste treatment, storage and disposal facility for incineration at >1200°C or Encapsulation or Plasma Pyrolysis at >1200°C. All other discarded medicines shall be either sent back to manufacturer or disposed by incineration.
(e) Chemical Waste: Chemicals used in production of biological and used or discarded disinfectants.	Yellow coloured containers or non-chlorinated plastic bags	Disposed of by incineration or Plasma Pyrolysis or Encapsulation in hazardous waste treatment, storage and disposal facility.
(f) Chemical Liquid Waste: Liquid waste generated due to use of chemicals in production of biological and used or discarded disinfectants, Silver X-ray film developing liquid, discarded Formalin, infected secretions, aspirated body fluids, liquid from laboratories and floor washings, cleaning, house-keeping and disinfecting activities etc.	Separate collection system leading to effluent treatment system	After resource recovery, the chemical liquid waste shall be pre-treated before mixing with other wastewater. The combined discharge shall conform to the discharge norms given in Schedule-III.
(g) Discarded linen, mattresses, beddings contaminated with blood or body fluid.	Non-chlorinated yellow plastic bags or suitable packing material	Non-chlorinated chemical disinfection followed by incineration or Plasma Pyrolysis or for energy recovery. In absence of above facilities, shredding or mutilation or combination of sterilization and shredding. Treated waste to be sent for energy recovery or incineration or Plasma Pyrolysis.
(h) Microbiology, Biotechnology and other clinical laboratory waste:	Autoclave safe plastic bags or containers	Pre-treat to sterilize with non-chlorinated chemicals on-site as per NACO or WHO guidelines thereafter for

Blood bags, Laboratory cultures, stocks or specimens of microorganisms, live or attenuated vaccines, human and animal cell cultures used in research, industrial laboratories, production of biological, residual toxins, dishes and devices used for cultures.		Incineration.
Category: Red		
Contaminated Waste (Recyclable) (a) Wastes generated from disposable items such as tubing, bottles, intravenous tubes and sets, catheters, urine bags, syringes (without needles and <i>fixed needle syringes</i>) and vacutainers with their needles cut) and gloves.	Red coloured non-chlorinated plastic bags or containers	Autoclaving or micro-waving/ hydroclaving followed by shredding or mutilation or combination of sterilization and shredding. Treated waste to be sent to registered or authorized recyclers or for energy recovery or plastics to diesel or fuel oil or for road making, whichever is possible. Plastic waste should not be sent to landfill sites.
Category: White (Translucent)		
Waste sharps including Metals: Needles, syringes with fixed needles, needles from needle tip cutter or burner, scalpels, blades, or any other contaminated sharp object that may cause puncture and cuts. This includes both used, discarded & contaminated metal sharps	Puncture proof, Leak proof, tamper proof containers	Autoclaving or Dry Heat Sterilization followed by shredding or mutilation or encapsulation in metal container or cement concrete; combination of shredding cum autoclaving; and sent for final disposal to iron foundries (having consent to operate from the State Pollution Control Boards or Pollution Control Committees) or sanitary landfill or designated concrete waste sharp pit.
Category: Blue		
(a) Glassware: Broken or discarded and contaminated glass including medicine vials and ampoules except those contaminated with cytotoxic wastes.	Cardboard boxes with blue colored marking	Disinfection (by soaking the washed glass waste after cleaning with detergent and Sodium Hypochlorite treatment) or through autoclaving or microwaving or hydroclaving and then sent for recycling.
(b) Metallic Body Implants		



SCHEDULE I: Part-2

1. All plastic bags shall be as per BIS standards as and when published, till then the prevailing Plastic
2. Waste Management Rules shall be applicable. Chemical treatment using at least 10% Sodium Hypochlorite having 30% residual chlorine for twenty minutes or any other equivalent chemical reagent that should demonstrate Log_{10} 4 reduction efficiency for microorganisms as given in Schedule- III.
3. Mutilation or shredding must be to an extent to prevent unauthorized reuse.
4. There will be no chemical pre-treatment before incineration, except for microbiological, lab and highly infectious waste.
5. Incineration ash (ash from incineration of any bio-medical waste) shall be disposed through hazardous waste treatment, storage and disposal facility, if toxic or hazardous constituents are present beyond the prescribed limits as given in the Hazardous Waste (Management, Handling and Trans-boundary Movement) Rules, 2008 or as revised from time to time.
6. Dead foetus below the viability period (as per the Medical Termination of Pregnancy Act 1971, amended from time to time) can be considered as human anatomical waste. Such waste should be handed over to the operator of CBWTDF in yellow bag with a copy of the official Medical Termination of Pregnancy certificate from the Obstetrician or the Medical Superintendent of hospital or healthcare establishment.
7. Cytotoxic drug vials shall not be handed over to unauthorised person under any circumstances. These shall be sent back to the manufactures for necessary disposal at a single point. As a second option, these may be sent for incineration at common bio-medical waste treatment and disposal facility or TSDFs or plasma pyrolysis at temperature $>1200^{\circ}\text{C}$.
8. Residual or discarded chemical wastes, used or discarded disinfectants and chemical sludge can be disposed at hazardous waste treatment, storage and disposal facility. In such case, the waste should be sent to hazardous waste treatment, storage and disposal facility through operator of common bio-medical waste treatment and disposal facility only.
9. On-site pre-treatment of laboratory waste, microbiological waste, blood samples, blood bags should be disinfected or sterilized as per the Guidelines of WHO or NACO and then given to the common bio-medical waste treatment and disposal facility.



10. Installation of in-house incinerator is not allowed. However in case there is no common biomedical facility nearby, the same may be installed by the occupier after taking authorisation from the State Pollution Control Board.
11. Syringes should be either mutilated or needles should be cut and or stored in tamper proof, leak proof and puncture proof containers for sharps storage. Wherever the occupier is not linked to a disposal facility it shall be the responsibility of the occupier to sterilize and dispose in the manner prescribed.
12. Bio-medical waste generated in households during healthcare activities shall be segregated as per these rules and handed over in separate bags or containers to municipal waste collectors. Urban Local Bodies shall have tie up with the common bio-medical waste treatment and disposal facility to pick up this waste from the Material Recovery Facility (MRF) or from the house hold directly, for final disposal in the manner as prescribed in this Schedule.

Types of infectious waste generated in a Blood Transfusion Service

(Reference: Guidelines for waste management in blood transfusion services: Manual, WHO, 2011)



Process	Sharps	Non-sharps	Effluents
Donor selection	<ul style="list-style-type: none"> • Broken slides and glassware • Lancets and needles • Cuvettes • Pipettes • Tiles • Micro-capillary tubes 	<ul style="list-style-type: none"> • Glassware • Filter paper strips for haemoglobin estimation • Gauze and swabs • Gloves 	<ul style="list-style-type: none"> • Used copper sulphate solution
Blood donation	<ul style="list-style-type: none"> • Broken glassware and ampoules • Broken test tubes and glass slides • Needles from blood collection bags and other used needles • Pairs of scissors 	<ul style="list-style-type: none"> • Gauze and swabs • Gloves • Blood units 	<ul style="list-style-type: none"> • Disinfectants
Post donation care		<ul style="list-style-type: none"> • Phlebotomy dressings, including plaster, bandages and swabs 	
Blood transfusion laboratory testing	<ul style="list-style-type: none"> • Broken glassware and ampoules • Test tubes and slides • Pipette tips 	<ul style="list-style-type: none"> • Blood sample tubes • Column agglutination cards • Gloves • Micro-plates • Used test kit materials 	<ul style="list-style-type: none"> • Liquids from cell washers • Blood and serum samples • Red cell suspensions for blood group serology testing

Process	Sharps	Non-sharps	Effluents
Component preparation and storage	<ul style="list-style-type: none"> • Wafers for sterile connecting devices 	<ul style="list-style-type: none"> • Blood units that are: <ul style="list-style-type: none"> – ruptured; – expired; – seroreactive; or – unsuitable due to other causes • Gloves • Transfer bags and accessories for component preparation • Segments from blood bag tubing • Leukoreduction filters 	
Transfusion in the clinical area	<ul style="list-style-type: none"> • Blood administration sets, intravenous sets and other disposable needles • Used syringes 	<ul style="list-style-type: none"> • Leukoreduction filters • Used blood bags 	

1% sodium hypochlorite solution

Store concentrated sodium hypochlorite in a cool place. Ensure the lid is tightly sealed after opening. To make a 200ml of a 1% sodium hypochlorite solution add the concentrated stock solution to water:

Stock concentration	3%*	3.5%*	4%*	4.5%*	5%*
Volume stock solution	67ml	57ml	50ml	44ml	40ml
Volume water	133ml	143ml	150ml	156ml	160ml
Final concentration	1%	1%	1%	1%	1%

* Consult the container for the concentration of the stock solution (It is typically 3% - 5%)



LABEL FOR TRANSPORTING BIO-MEDICAL WASTE BAGS OR CONTAINERS

DayMonth

Year

Date of generation

Waste category Number

Waste quantity.....

Sender's Name and Address Receiver's Name and Address:

Phone Number Phone Number

Fax Number..... Fax Number

Contact Person Contact Person

In case of emergency please contact :

Name and Address :

Phone No.

Note : Label shall be non-washable and prominently visible.

Chapter 11

EQUIPMENT MAINTENANCE AND USE

Equipment form a very important part of a blood bank resource involving heavy capital investment. It is essential to have an Equipment management program in place to ensure the following:

- Maintain a high level of performance
- Lengthen life of instrument
- Reduce interruption of services due to breakdowns and failures
- Improve customer satisfaction
- Improve the technologist's confidence and knowledge

Every blood bank/blood centre must have policies, processes, and procedures to ensure that calibration, maintenance, and monitoring of equipment conforms to these blood bank/blood centre standards and other specified requirement. There should be a proper need assessment and selection of the equipment. Facility requirements such as electrical, drains, plumbing, space and also manpower and availability of manufacturer technical support and service contracts should be ensured before procurement of equipment.

Selection and validation of equipment:

On installation and during routine use the equipment should show capability of achieving the performance required and should comply with specifications relevant to the examinations concerned. Blood centre should have a policy and procedure for calibration and validation of equipment to achieve the required performance that complies with standards.

Calibration:

Comparison of measurements performed by an instrument to those made by a more accurate instrument (standard) for the purpose of detecting, reporting & eliminating errors in measurement

MONITORING

Continuous observation & measurement of a variable, to check on a given condition.



Equipment Calibration:

It can be done by using calibrators or standards. Manufacturer's instructions must be followed.
Frequency of routine calibrations must be determined as per standards

VALIDATION:

Confirmation and provision of objective evidence that requirements for a specific intended use or application have been fulfilled

“Assurance that a specific process will consistently produce an outcome that meets its pre-established quality and performance specifications”

Validation of new equipment:

Validation of new equipment used in a process should include

- Design Qualification
- Installation Qualification
- Operational Qualification
- Performance Qualification

DESIGN QUALIFICATION (DQ)

Documented verification that the design (specifications) of the equipment and its components is adequate for your requirements

INSTALLATION QUALIFICATION (IQ)

Installation qualification demonstrates that the instrument is properly installed in environmental conditions that meet the manufacturer's specifications

IQ testing and documentation typically includes:

- Verification of the manufacturer
- Model no.
- Equipment no.
- Instrument calibration status,
- Equipment sop verification &
- Verification of critical installation parameters e.g. Equipment location,
- Major components and utilities



OPERATIONAL QUALIFICATION (OQ)

An Operational Qualification is a validation protocol that provides documented verification that equipment or a system functions according to written & pre-approved specifications.

It demonstrates that the installed equipment operates as intended.

It focuses on the capability of the equipment to operate within the established limits and specifications supplied by the manufacturer.

OQ testing and documentation typically includes

- Verification of the Operator Interface,
- Screen Menus,
- Alarms,
- Inputs and Outputs,
- Print Functions,
- Eventful & Uneventful Functions

PERFORMANCE QUALIFICATION (PQ)

PQ demonstrates that the equipment performs as expected for its intended use in the processes established by the blood centre and that the output meets the centre's specifications. It evaluates the adequacy of equipment for use in a specific process that uses the blood centre's personnel, procedures, and supplies in a normal working environment.

PQ testing and documentation typically includes

- Verification of the operator training,
- SOP approval
- Equipment or system process parameters.

PROCUREMENT AND RECEPTION OF EQUIPMENT

Every blood centre has established policy regarding funding agencies and protocol for procurement of its equipment and these are to be adhered. At the time of delivery the equipment is inspected as per specifications given in the supply order by the user department. On satisfactory receipt,



installation and commissioning of the equipment, a certificate to that effect is to be given by the user department. Ensure that the operational manual has been provided by the vendor or manufacturer.

Installation

The following steps should be taken during the process of equipment installation:

i. Prior to installation:

- Verify physical requirements have been met
For eg. safety checks, electrical, space, ventilation, water supply, ambient temperature, etc.
- Confirm responsibility for installation

ii. Upon receipt:

- Verify package contents
- Do not attempt to use prior to proper installation
- If required, ensure that the equipment is installed by the manufacturer

iii. After installation:

- Establish inventory record
- Define conditions
- Develop and implement protocols for calibration, performance verification, and operating procedures

USE OF EQUIPMENT

Only authorized person should operate the equipment. 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 so placed as to facilitate cleaning and maintenance. Manual for Standard Operating Procedure (SOP) and instructions for use and daily maintenance of all equipment should be available to personnel.

Training of User Staff

All relevant staff must be trained on the use of equipment. Training should include the following modules:

- Use & practice of equipment including proper handling of equipment
- Preventive maintenance and trouble shooting
- Following instruction manual in day-to-day use of equipment



- Common and recurrent causes of break-down
- Inspection and routine maintenance
- Calibration
- Testing and safety guidelines
- Basic concepts of physics and electronics as relevant to equipment
- Documentation of procedures (SOPs)
- Refresher training when new equipment is procured must be provided.

Equipment detail record, unique identification

Records about the identification of the equipment, manufacturer's name and contact person, date of receiving, maintenance work carried out, date of malfunction, modification, and repair etc. should be maintained.

Programme for calibration and maintenance of equipment

It includes establishing a programme that regularly monitors and demonstrates proper calibration and function of instruments, reagents and analytical system.

- Centre should have established or implemented procedure for calibration and regular monitoring
- It should also include program of preventive maintenance which contains recommendations of manufacturers / service report.
- Frequency of calibration of equipment is as per recommendation of manufacturer, or as per prevalent standards.
- Equipment that is used more frequently, should be calibrated more frequently
- Establish maintenance program
- Provide training for all operators

Breakdown of the Equipment

- Blood centre should have SOP for replacement/ repairing of defective equipment.
- The defective equipment is labeled and taken out of service.
- Once repaired it should be calibrated before putting in use and the procedure should be specified in a laid down SOP.
- For equipment which are non-functional a prominent label stating 'OUT OF ORDER' should be affixed.



- For equipment not in use a prominent label stating 'CURRENTLY NOT IN USE' is affixed.
- Blood bank should have a backup policy for shifting and storage of blood components in the event of breakdown of equipment.

IMPLEMENTING A MAINTENANCE PROGRAM

- Assign responsibility
- Oversight of all laboratory equipment
- Individual responsibilities
- Develop written policies and procedures
- Train staff
- Keep records

Maintenance contracts:

To ensure regular maintenance and prompt service and repair of equipment, in a cost effective manner, it is essential to have maintenance contracts. These are basically of two types

- Annual maintenance contract (AMC)
- Comprehensive maintenance contract (CMC)

Annual maintenance contract

A manufacturer company provides the service through AMC by themselves or with the help of service providers. The contract is usually for the period of 1 year after the warranty period is over and can be extended up to three years or five years as per the mutual understanding or agreement of both the parties.

Usually under AMC, the service providers give only service support and would charge separately for every replaced part of the equipment. However, in some cases, few parts are replaced during the visit by service engineer when it is mentioned in AMC contract that these limited parts will be replaced.

Comprehensive maintenance contract

It includes prompt service from the company or service providers. The contract is usually for the period of 1 year and can be extended up to three years or five years as per the mutual understanding of both the parties. It includes repairs and replacements of faulty parts. Having the contracts gives the benefits such as consumables (which are not part of contract) being available at reduced costs.



CMC is costlier than AMC because it includes the costs of spares as well.

Essential components of AMC & CMC:

- Name and address of both the parties
- Details of the equipment under contract
- Duration of contract
- Nature of AMC (comprehensive or non-comprehensive)
- Cost of the contract
- Number of visits and breakdown calls by the service engineer
- Payment terms
- Penalty clause
- Termination
- Signature
- Seal

ROUTINE MAINTENANCE

It is essential to carry out routine maintenance of equipment to ensure their long life and reliability of performance. Routine maintenance includes both preventive as well as corrective maintenance.

Any electronic product requires timely service to function properly. In hospitals, there is always a danger of undesirable machine breakdown. Preventive maintenance can save a lot of time and money. With the help of preventive maintenance services (PMS), it is possible to predict and identify parts which are at verge of collapse.

Preventive/planned maintenance

Written procedures must exist for planned maintenance of blood bank equipment.

Documents

Develop written procedures for all equipment. It should have step-by-step instructions for performing maintenance and function checks. Include a guide for troubleshooting.

Develop a problem log record for each piece of equipment with following entries:



- Date on which problem occurred/ removed from service
- Reason for breakdown or failure
- Corrective action taken
- Date returned to use
- Change in maintenance or function checks

Warranty of new equipment is for a sufficient time period to test performance of equipment. Safeguards for electronic equipment e.g. voltage stabilizer automatic switch over for emergency (generator) are to be ensured. Periodic checks and repairs should be carried out according to guidelines provided in the operational manual. A logbook for all critical equipment must be kept.

Preventive Maintenance Schedule of Equipment

This should be according to prescribed regulations or standards. A label with following information pasted on the equipment serves as a ready reference.

Name of the equipment	
Manufacturer & Model No.	
Name of supplier with contact No.	
Name of company to whom AMC given	
Contact person with phone no.	

Format for Equipment Service Record:

Visit for AMC on	Status of equipment on visit	Any recommendation	Equipment checked by	Next AMC due on



Corrective Maintenance

There should be a system in place for communicating defects in equipment which is known to all staff. Written procedures should exist for corrective maintenance of all essential blood bank equipment. It should include procedures for repair of equipment by outside agencies and in house and their records are to be maintained.

Response time of the supplier in case of necessary repairs can be recorded.

RETIRING EQUIPMENT / CONDEMNATION

When?

- When service engineer indicate not repairable
- Outmoded, will replace with new equipment
- Beyond economic repair

Why?

- Prevent inaccurate test results
- Free up valuable space
- Hazardous

How?

- Condemnation
- Salvage any useable parts
- Consider biohazard, follow safety disposal procedures (example: blood irradiator)
- As buy back discount for new equipment

Condemnation of Equipment

Procedures for condemnation and disposal of obsolete equipment must be laid down.

Criteria for condemnation and disposal of equipment should be defined, such as:

- Non-functional and beyond economical repair
- Non-functional and obsolete
- Functional but obsolete
- Functional but hazardous
- Functional but no-longer required



A well planned Equipment Maintenance Program provides several benefits like:

- Safety
- Fewer interruptions of work
- Lower repair costs
- Elimination of premature replacement
- Less standby equipment
- Identification of high maintenance cost
- Reduction of variation in test results
- Greater confidence in the reliability of results



Chapter 12

TOTAL QUALITY MANAGEMENT

Awareness on Quality:

The world has become aware of quality in all the fields, which can influence the people to change their mind set from traditional way of thinking to a systematic thinking and from Easy-to-go-approach to a disciplined approach for safe and effective collection, processing and disposition of blood and its components and subsequently safe and efficacious transfusion for treatment and patient care.

Quality: Quality is conformance to standards of performance or “fit for the purpose”

Total Quality Management: Total Quality management system is the integration of all functions and processes within an organization in order to achieve continuous improvement of the quality services that are important in fulfilling the customer satisfaction which is in turn benefit both the staff and society.

Plan, Do, Check and Act, which is also referred to as PDCA cycle or Deming Cycle.



PLAN- Planning Phase

Planning is the most crucial phase of total quality management for the objectives and processes necessary to deliver results in accordance with the expected target or goals. In this stage the plan of action and challenges which may come will be addressed.

DO-Doing Phase

This is the phase of implementation of the plan of action and execution of processes. These will provide a satisfactory service to the customers. In this doing phase, staff may develop solutions for the challenges/problems defined in planning phase or which are faced in the Doing phase.



Continuous collection of data and its analysis will help in the following stages of "CHECK" and "ACT" stages.

CHECK-Checking Phase

By studying/analysing the actual results and comparing against the targets or goals to ascertain the differences in the achievement of goals. The differences from the target/goals can be minimized by its root cause analysis. Charting data can make this much easier to see trends over several PDCA cycles and in order to convert the collected data into information. This information is what you need for the next step "ACT".

ACT-Acting Phase

By repeating the PDCA or Deming Wheel cycle as part of a continuous improvement in the organization will improve the process efficiency. This stage the decision of Management will be taken in to consideration in repeating the cycle.

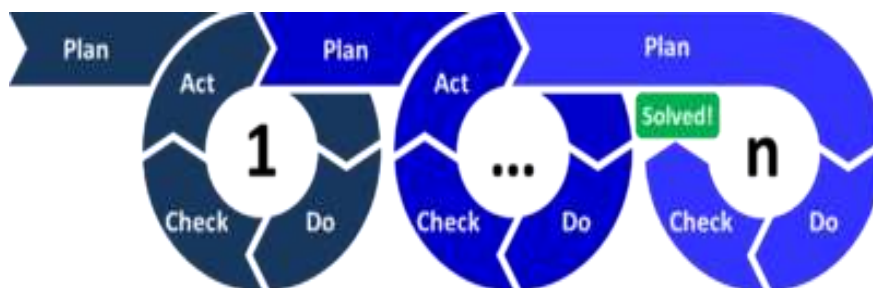


Fig. Multiple iterations of the PDCA cycle are repeated until the problem is solved.

Integration of processes related to Quality Management with Quality Control, Quality Assurance, Current Good Laboratory practices (cGLPs), Current Good Clinical Practices (cGCPs). The continuous improvement by knowledge management includes continuous education and training activities, data management through standard operating procedures, work instructions, reporting forms through digitalization of records etc. and the Stepwise Laboratory Improvement Process in Quality Management System leading to Accreditation.



Fig. Triangle of Wisdom

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

Quality policy: The overall intentions and direction of a laboratory related to quality as formally expressed by laboratory management.

Stakeholders in Quality Management System:

In order to achieve the quality objective the different stakeholders for implementation of QMS in Blood Services are as follows:

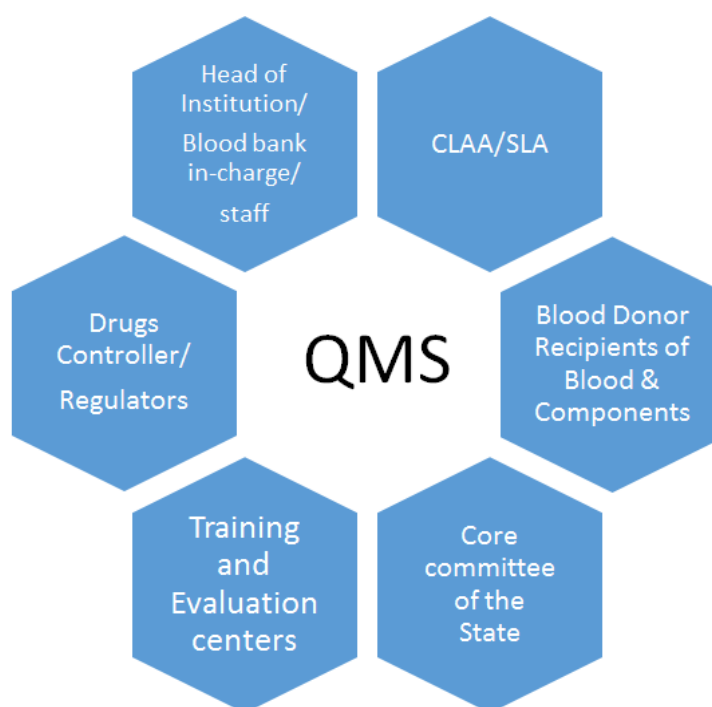


Fig. Stake holders of Quality Management System in Blood Services

1. MoHFW/State Health departments- by taking the initiative and drive for improving the quality of blood banks countrywide, formulating the training program and facilitating the training courses for implementation of QMS.
2. Head of institution- for Administrative and Financial support to Blood Services with willingness to improve quality in Blood Services

3. Drug controller: -for strict regulation on blood banks and ensure regulatory requirements are fulfilled by blood banks before grant/renewal of license.
4. Head of blood bank and staff –for making action plan, taking commitment from management and motivation of blood bank staff for implementation of QMS
5. Donor community- to provide support to blood bank by promoting voluntary blood donation for safe blood
6. Training centers-by providing infrastructure, imparting knowledge to participants on QMS.

Quality Management components as per NABH:

As per existing Standards of National Accreditation Board for Hospitals & Healthcare Providers (NABH), Quality Council of India, the Quality management system for Blood Banks is divided into eleven key components which will cover most of the processes in the blood bank.

The standards provide framework for quality assurance and quality improvement for blood banks. The standards focus on patient safety and quality of care. The standards call for continuous monitoring and comprehensive corrective action plan leading to building of quality culture at all levels and across all the functions. The standards are equally applicable to blood banks in the government as well as in the private sector.

An outline of NABH standards for Blood Banks

S.No.	QMS Component
1.	Organization and Management
2.	Accommodation and Environment
3.	Personnel
4.	Equipment
5.	External services and supplies
6.	Process Control
7.	Identification of Deviations and Adverse Events
8.	Performance Improvement
9.	Document Control
10.	Record
11.	Internal Audit and Management Review



Detailed components of QMS as follows:

1. Organization and Management:

- 1.1.** General: A senior official/competent authority should be responsible and provide directions to the activities of blood bank/blood Centre for its growth and development.
- 1.2.** Legal identity: A valid license issued by the regulatory authority as applicable for the blood bank/blood center should be available and displayed at the premises as per requirements of Drugs and Cosmetics Act 1940 & Rules 1945 made there under.
- 1.3.** Responsibility: The blood bank should have an organogram with defining designation as per hierarchies of the management and staff, available in the blood banks with indicating names as per their job responsibilities.
- 1.4.** Ethics: A display (Poster/Board) with the charges for availing the services in the blood bank should be displayed in the issue premises.
- 1.5.** Quality Policy: A blood bank should have defined quality policy and quality manual with incorporating eleven key components of Quality Management System as per governed Standards. Each blood bank should identify a. Quality Manager b. Technical Manager (Both cannot be the same person) can be with deputies and make responsible for the activities undertaken.
- 1.6.** Quality Manual: A quality manual shall describe the quality management system and the structure of the documentation used and shall include or make reference procedures including technical procedures.
- 1.7.** Blood Bank/ Blood Centre shall have defined emergency operation policies and procedures to respond to the effect of internal and external disaster.
- 1.8.** Standard Operating Procedures (SOPs):

The laboratory shall have a documented procedure to ensure that the following conditions are met.

 - a) All documents, including those maintained in a computerized system, issued as part of the quality management system are reviewed and approved by authorized personnel before issue.
 - b) All documents are identified to include:
 - A title;
 - A unique identification number on each page;
 - The date of the current edition and/or edition number;
 - Page number to total number of pages (e.g. "Page 1 of 5," "Page 2 of 5")



- Prepared by, verified by and Approved by signatures on each page.
- Any alteration in the procedure/text should be given as amendment and get should be approved by the competent person of the laboratory and change control should be maintained.

A typical structure of management system document hierarchy, generally followed, is given below:



Fig. A typical structure of document hierarchy

Documentation Structure

Describe the structure of documentation used in the management system. It shall include or make reference to the supporting procedures, including technical procedures, i.e., reference to supporting documents such as operating procedures etc. Pyramid structure for documentation may also be described here or referred. It shall include or make references to the supporting documents such as operating procedures, work instructions, forms, reports etc. This may also be described by a pyramid structure of management system document hierarchy along with criteria and requirements as per Drugs and Cosmetics Act: 1940 and the Rules 1945 therein with applicable amendments (if any).

2. Accommodation and environment:

Accommodation and Environment of a blood bank including component preparation and Apheresis and also for the outdoor blood donation camp should be as per standards laid down by Drugs and Cosmetics Act: 1940 and the Rules 1945 therein with applicable amendments (if any).

A blood bank should have an area of 100 sq. meter for its operations with smooth and easy workflow of all processes of the blood bank, 50 Sq.meter for blood component preparation and an additional 10 sq.meter required for apheresis procedure and desirably segregated with air lock to avoid contamination.



There shall be effective separation between adjacent sections of the blood bank/ blood centre in which there are incompatible activities. Measures shall be taken to cross- contamination.

The blood bank/ blood center shall be designed for the efficiency of its operation, to optimize the comfort of its occupants and to minimize the risk of injury and occupational illness. Patient/ recipients, employees and visitors shall be protected from recognized hazards including fire and non-fire hazards within the facility.

2.1. Health and Safety:

A designated staff should be responsible for health and safety officer and also have written procures and policies for health and safety, displayed in the appropriate work areas. A pre-employment medical examination and regular health check-up including Hepatitis B Vaccination shall be conducted on all the employees as per institutional policy. Health record of staff shall be kept confidential and in a safe place. Occupational health hazards are adequately addressed.

2.2.Environmental safety:

The blood bank in-charge should ensure fire safety measures in the blood bank including arranging the training of staff on fire precaution. A record of this training should be maintained. The working area in the blood bank is denoted as **Non-Smoking, No Food and No Drinks area.**

3. Personnel:

The personnel employed by the blood bank/blood center shall comply with the qualifications prescribed in Drugs and Cosmetic Act 1940 and Rules 1945 therein with amendments (if any).

3.1.Job Description, role responsibilities and training: There should be a written document with name, qualification, training attended management duties, expertise, responsibilities, further expertise/ training required should be available in the blood bank. A periodic competence report of each person for assigned job should be thereafter. The written policies on code of conduct on confidentiality regarding patient's information, donor and recipients information should be available.

The responsibilities of the blood bank/blood center Medical Director/ In-charge/ Medical officer shall include professional, scientific, consultative, advisory organizational, administrative and educational matters. These shall be relevant to the services offered by the blood bank/ blood center. In case blood bank operating 24 hrs of more than one Medical Officer in the blood bank/ blood center are required and the responsibility shall be defined by the Medical Director/ In-charge.



Technical Manager shall have overall responsibility for the technical operations and the provision of resources needed to ensure the required quality of blood bank/ blood center procedures.

Quality Manager has the responsibility and authority to oversee compliance with the requirements of the Quality Management System. The Quality Manager shall report directly to the level of management at which decisions are made on Blood Bank policy and resources.

In a blood bank/ blood center collecting less than 5000 units per year, same person can be designated as Technical Manager and Quality Manager.

Counsellor (Medical Social Worker) should be appointed for pre and post-test counselling, donor education, donor deferral, referral and linkages and for promoting voluntary non remunerated blood donation.

4. Equipment:

The blood bank should have minimal equipment as per Drugs and Cosmetic Act 1940 and Rules 1945 therein with amendments (if any) and should have a policy for the selection, specification, procurement, installation and use, maintenance. This mentioned procedures DQ, IQ, OQ and PQ as follows (In some cases: Not all stages of qualification may be required-Eg. Minor equipment).

- **Design qualification (DQ):** The equipment specifications with appropriate range and precision can be selected as per the user requirements and as per the space available in the blood bank.
- **Installation Qualification (IQ):** As per equipment pre-installation requirements given by the Supplier should be installed with proper electrical power requirements by physically verifying for its manage or any other discrepancies before installation may be checked and properly installed along with equipment safety measurements like UPS, Alarm systems.
- **Operational Qualifications (OQ):** It is essential in assuring equipment operational parameters under ideal conditions for its specification parameters and range. Eg., If you've specified that your equipment is going to run in a range of 50-150 RPM and will draw a specific amount of power, you want to verify that the equipment is achieving those operational requirements. So, review those parameters and challenge them. Again, make sure your equipment actually runs the way it's supposed to run.
- **Performance Qualification (PQ):** This will puts the equipment into the final test and refers to the test or validation protocol carried out by the user, offering documentary evidence that the



instrument is maintaining the agreed values in the form of Service reports should be available in the blood banks.



Fig. Equipment DQ, IQ, OQ, PQ and Maintenance cycle

4.1. Maintenance: Equipment are to be maintained with a unique identification number, date of installation, calibration date, calibration due date, preventive maintenance, Annual Maintenance Contract details with vendor details, contact person in case of breakage, authorized handling personnel list and instructions for use for daily maintenance should be available. A calibration schedule plan for each equipment should be maintained. A log should be maintained with all entries of log in and log out details with signatures and in case of any repairs, parts changed and service reports should be properly maintained in the file. The training of personnel and updating of knowledge over changing technologies to be documented.

There shall be a process to monitor and record the temperature of refrigerator or, freezers and platelet incubators continuously. The temperature will be recorded at least every 8 hours.

If blood or components are stored in an open storage area, the ambient temperature shall be maintained at $22^{\circ}\text{C} \pm 2^{\circ}\text{C}$.

Computer System: When computers or automated examination equipment are used for the collection, processing, recording, storage or retrieval of examination data, the blood bank/ blood center shall ensure that:

- a) Computer software, including that built into equipment is documented and suitably validated as adequate for use in the facility.
- b) Procedures are established and implemented for protecting the integrity of data at all times.
- c) Computer programmes and routines are adequately protected to prevent access alternation and destruction by unauthorized persons.
- d) An alternative system that ensures continuous operation shall be available in the event that computerized data and computer functions are unavailable. The alternative system shall be tested periodically.

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

In the event of breakdown of storage equipment the blood bank/ blood center shall have a policy for alternate storage of blood/ blood components.

S. No.	Equipment	Performance	Frequency for performance checking	Minimum frequency of calibration (outsourced or in house)
1	Temperature recorder (Display)	Compare against calibrated thermometer	Daily	Once in 6 months/year
2	Refrigerator/ Deep Freezer for storage of blood/ components	Compare against thermometer	Daily	Once in 6 months
3	Refrigerated blood bag centrifuge	Observe speed temperature and time	Each day of use	Once a year
4	Hematocrit centrifuge	Observe speed temperature and time	-	Once a year
5	General lab centrifuge	Observe speed temperature and time	-	Once a year



6	Automated blood typing	Observe control of correct result (QC samples)	Each day of use	Once a year
7	Haemoglobinometer	Standardize against cyanmethemoglobin standard	Each day of use	Once a year
8	Refractometer	Standardize against distilled water	Each day of use	Once a year
9	Blood container weighing device	Container of known calibrated weight	Each day of use	Once a year
10	Water bath	Observe temperature	Each day of use	Once a year
11	Autoclave	Observe temperature	Each day of use	Once a year
12	Serologic rotators	Observe control for correct result	Each time of use	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 weight of the first blood filled container for correct results	Once in 15 days	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 controls	Daily	Once a year
18	Pipettes	Volume	Once in a month	Once a year
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

Source: Accreditation Standards on Blood Banks/ Blood Centers and Transfusion Services, Third Edition, June 2016, NABH.

5. External services and supplies:

The blood bank should define and document its policies and procedure for selection and use of purchased external services, equipment, consumable supplies that affect the quality of its services. There shall be procedures and criteria for inspection, acceptance/rejection, and storage of



consumables. A blood bank should have a list of manufacturer, supplier and vendors of the reagents. The Purchased equipment and consumable supplies that affect the quality of the service shall not be used until they have been verified as comply with standard specification or requirements defined for the procedure concerned.

5.1. Inventory Control

There shall be an inventory control system for supplies. Appropriate quality records of quality control and external services offered, supplies and purchased product shall be established and maintained for period of time as defined in the quality management system.

This system shall include the recording of lot number of all relevant reagents, control materials and calibrators, the date of receipt in the blood bank/ blood center and the date the material was placed in service. All of these quality records shall be available for blood bank/ blood center management for review.

6. Process control:

In Blood Bank, process control incorporates every process and procedures as below;

1. Policies and validation of processes and procedures (Quality manual, Quality Policy, SOPs)
2. Donor Section (Motivation, Selection, Deferral, Retention etc.)
3. Component laboratory (Component preparation, Storage, Labelling, Storage and Quality control of Blood components)
4. Immunohaematology Section (Patient Sample receiving, Blood Grouping of patient and donor, Cross match, selection of Blood components for transfusion, issue of Blood component, Adverse transfusion reaction record/ Haemovigilance, Quality Control in Immunohaematology lab.)
5. TTI Laboratory (Methodology, Quality control of TTI testing, LJ Chart)
6. Bio-medical waste management
7. Laboratory safety

The laboratory shall have an Internal Quality Control (IQC) program to verify the quality of test results and processes. The frequency of QC of individual labs has been dealt with in respective chapters and should be as per SOPs.



6.1. Proficiency Testing Programme:

The blood bank/blood center shall participate in External Quality Assurance Scheme (EQAS)/ Proficiency Testing Programme (PT). It shall monitor the results of these programmes and participate in implementation of corrective action when control criteria are not fulfilled. Whenever a formal EQAS/ PT programme is not available, the blood bank/ blood centre shall develop a mechanism for determining the acceptability of procedures not otherwise evaluated. They can participate in suitable inter-laboratory comparison or adopt alternative methods to validate performance.

The blood bank/ blood center shall document, record and as appropriate, promptly act upon results from this comparison. Problems and deficiencies identified shall be acted upon and record of action retained.

The procedures for process control should be defined for all critical processes/parameters in the blood bank. The validation processes which are essential for equipment/processes will be followed to get accurate and reliable results.

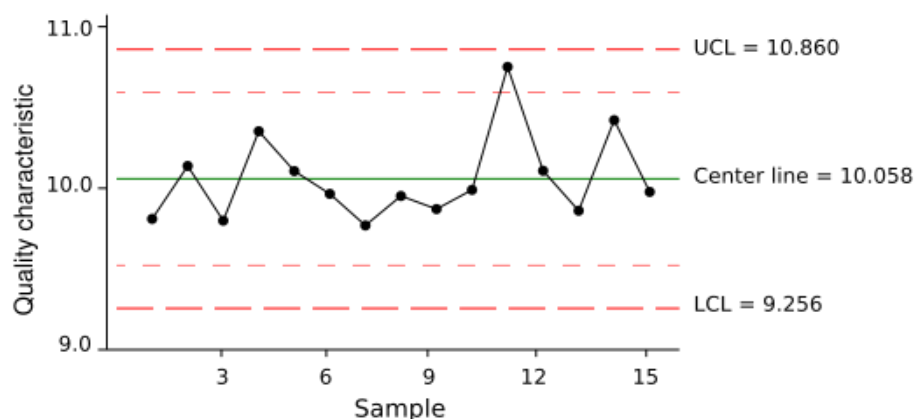


Fig. Example of process control chart

6.2. Laboratories are encouraged to participate in inter laboratory comparison programs to assess relative accuracy when they are unable to measure trueness. Use of reference materials is very expensive. Inter laboratory comparison programs offer a cost effective and reliable alternative.

7. Identification of deviation/out of specification and adverse events:

Blood bank should have a details of policy and procedure to address the out of specification (OOS) /deviations if any related to process or test analysis. A record should be maintained in respect of all the deviations and identifiable root cause analysis if any.



The blood bank should have a defined policy and procedure for reporting of adverse events such as: accidents, errors, incidents and near miss events and in documented format of such events.

The blood bank should define and implement procedure for release of results in case of nonconformities, including the review of such results. These events should be recorded.

8. Performance improvement:

The performance of the blood bank can be evaluated with the defined policy and procedures which will enable feedback mechanism in improving the process by corrective and preventive action (CAPA).

Corrective actions are implemented in response to customer complaints, out of specification results, non-conformance reports, issues identified during an internal audit or adverse or unstable trend in the testing process which can be used to improve the performance. Preventive actions are implemented in response to the identification of potential sources of non-conformity.

To ensure that corrective and preventive actions are effective, the systematic investigation of the root causes of failure is pivotal. CAPA is part of the overall Quality Management System (QMS). These can be used to indicate the performance improvement in the system.

9. Documentation and Document control:

Document: A "document" is any information or instructions, including policy statements, text books, procedures, specifications, calibration tables, biological reference intervals and their origins, charts, posters, notices, memoranda, software, drawings, plans and documents of external origin such as regulations, standards or examination procedures. Invalid or obsolete documents are promptly removed from all points of use, or otherwise assured against inadvertent use. Procedures shall be established to describe how changes to documents maintained in computerized systems are to be made and controlled.

All documents relevant to the quality management system should be uniquely identified. Quality documents shall be included title, edition or current revision date or revision number, number of pages, authority for issue and source identification. Retention time shall be defined by the nature of the examination or specifically for each record.

The blood bank should have a policy that defines the length of time various records pertaining to the quality management system. All records shall be legible and stored such that they are readily retrievable. Electronic Records: There shall be processes and procedures to support the



management of computer system. There shall be a process in place for routine backup of all critical data.

An alternative method to be used during system breakdown must be known. Hard copies (whenever necessary) should be available even when documentation is electronically maintained. Maintenance and continuous operations must be ensured. Procedures shall be in place to ensure that data are retrievable and usable. Personnel must be trained. Validation of system and integrity and security of data entry should be ensured. The records required by Drugs and Cosmetics Act shall also be maintained as hard copies.

10. Records and Test reports:

All the records and documents should be maintained as per Drugs and Cosmetics Act, 1940 and Rules, 1945 therein with amendments (if any). A foremost activity of data management is record keeping, which is essential for provision of services and activities carried out in a blood bank.

- I. Blood donor record
- II. Master records for blood and its components
- III. Issue register
- IV. Records of components supplied: quantity supplied; compatibility report, details of recipient and signature of issuing person.
- V. Records of ACD/CPD/CPD-A/SAGM bags giving details of manufacturer, batch number, date of supply, and results of testing.
- VI. Register for diagnostic kits and reagents used: name of the kits/reagents, details of batch number, date of expiry and date of use.
- VII. Blood bank must issue the cross matching report of the blood to the patient together with the blood unit.
- VIII. Transfusion adverse reaction records.
- IX. Records of purchase, use and stock in hand of disposable needles, syringes, blood bags, shall be maintained.
- X. Record of report sent to State AIDS Control Society/State Blood Transfusion Council
- XI. Record showing the daily temperature recordings.
- XII. Record of quality assurance (internal and external)
- XIII. Record of any adverse incident.
- XIV. Record of equipment maintenance.
- XV. Record of document control.



- XVI. Daily group-wise blood stock register (inventory) showing its receipt, issue and balance, units discarded with reason of discarding.
- XVII. Stock register of non-consumable articles.
- XVIII. Stock register of consumable articles.
- XIX. Documentation of staff qualifications and training.
- XX. Documentation of staff competency and proficiency tests.
- XXI. Staff attendance register or any other recording system.
- XXII. Grievance reporting register.
- XXIII. Transfusion Committee meeting minutes with Action Taken Report.

The records should be maintained for a period of five years as per Drugs and Cosmetic Act, 1940 and Rules, 1945 therein with amendments (if any).

11. Internal Audit and Management Review:

The blood bank should conduct scheduled internal audits and on management review at regular intervals to ascertain the performance of quality management system conformity to the standard procedures followed.

The internal audit programme shall address all elements of the quality system, including the testing and/or calibration activities. It is the responsibility of the quality manager to plan and organize audits as required by the schedule and requested by management. Such audits shall be carried out by the trained and qualified personnel who are, wherever resources permit, independent of the activity to be audited.

The blood bank should take appropriate corrective or preventive actions, which shall be documented and carried out within an agreed upon time. Follow-up audit activities shall verify and record the implementation and effectiveness of the corrective action taken.

The results of internal audits shall be submitted to laboratory management review. The Management review includes the process related to

- a. The suitability of policies and procedures
- b. Reports from managerial and supervisory personnel
- c. The outcome of recent internal audits
- d. Corrective and preventive actions
- e. Assessments by external bodies



- f. The results of inter-laboratory comparisons or proficiency tests
- g. Changes in the volume and type of the work
- h. Customer feedback
- i. Complaints
- j. Recommendations for improvement of blood bank
- k. Other relevant factors, such as quality control activities, resources and staff training

Findings from management reviews and the actions that arise from them should be recorded. The management should ensure that those actions are carried out within an appropriate and agreed timescale.

Definitions and terms:

- **Accuracy of measurement:** Closeness of the agreement between the result of a measurement and a true value of the measurement.
- **Agreement:** A contract, order, or understanding between two or more parties, such as between a facility and one of its customers.
- **Agreement review:** Systematic activities carried out before finalizing the agreement to ensure that requirements are adequately defined, free from ambiguity, documented, and achievable.
- **Blood:** Includes whole human blood, drawn from a donor and mixed with an anti-coagulant.
- **Blood bank/blood center:** A place or organization or units or institutions or others arrangements made by such organization, unit or institution for carrying out all or any of the operation for collection, apheresis, storage, processing and distribution of blood drawn from donors and/or for preparation, storage and distribution of blood components.
- **In-Charge blood bank/blood center Director:** Competent person (s) with responsibility for and authority over, a Blood bank/ Blood center.
- **Blood bank/ blood center Management:** Person (s) who manages the activity of a Blood bank/ Blood center headed by a blood bank/ blood center director.
- **Blood component:** A drug, prepared, obtained, derived or separated from a unit of blood
- **Blood product:** A drug manufactured or obtained from pooled plasma of blood drawn from donors by fractionation.
- **Closed system:** A system, the content of which are not exposed to air or outside elements during preparation and separation of components.



- **Collection facility:** A facility that collects blood, components or tissue from a donor.
- **Competence:** Ability of an individual to perform a specific task according to procedure.
- **Conformance:** Fulfillment of requirements. Requirements may be defined by customers, practice standards, regulatory agencies, or law.
- **Corrective action:** Action to eliminate the cause of a detected nonconformity by proper root cause analysis and also to protect the customer from receiving or using nonconforming product. It is the action to be taken to prevent recurrence.
- **Customer/ recipient:** The receiver of a product or service. A customer may be internal (i.e., another organization).
- **Disaster:** An event (internal, local, or national) that can affect the blood supply or the safety of staff, patient/ recipients, volunteers, and donors.
- **Document** (noun): Written or electronically generated information and work instruction. Examples of documents include quality manuals, procedures, or forms.
- **Document** (verb): To capture information for use in documents through writing or electronic
- **Equipment:** A durable item, instrument, or device used in a process or procedure.
- **Event:** A generic term used to encompass the terms ‘incident’, ‘error’, and ‘accident’.
- **Executive management:** The highest level personnel within an organization, who have the authority to establish or change the organization’s quality policy. Executive management may be an individual or a group of individuals.
- **Incident:** An unplanned deviation from a facility’s established policy, process or procedure.
- **Label:** An inscription affixed to unit of blood / component, or sample for indication.
- **Labeling:** Information that is required or selected to accompany a unit of blood, component, tissue, derivative or sample, which may include content, identification, and description of process, storages requirements, expiration date, cautionary statements, or indications for use.
- **Laboratory:** Laboratory for the biological, microbiological, immunological, serological, immune-hematological, hematological, or other examination of materials derived from the human body for the purpose of providing information for the diagnosis, prevention, pre-transfusion check and treatment of disease in, or assessment of the health of, human beings, and which may provide a consultant advisory service covering all aspects of laboratory investigation including the interpretation of result and device on further appropriate investigation.
- **Maintain:** To keep the current state.



- **Material:** A good or supply item used in the manufacturing process. Materials are a type of input product. Reagents are a type of material.
- **Measurement:** Set of operation having the object of determining a value or a quantity.
- **Non-conformance:** Failure to meet requirement.
- **Open system:** A system, the contents of which are expressed to air and outside elements
- **Organization:** An institution, or part thereof that has its own functions and executive management.
- **Policy:** A documented general principle that guides present and future decisions.
- **Pre-donation procedures:** It includes the mandatory process and activity done before proceeding with bleeding the donor.
- **Post donation procedures:** Activities, procedures, instructions carried out after bleeding donor.
- **Preventive action:** A proactive process for identifying opportunities for improvement, whenever they are identified either technical or concerning the management system. The action plan shall be developed, implemented and monitored to reduce the likelihood of the occurrence of such non-conformities. Procedures for preventive action shall include the initiation of such action and ensure that these are effective.
- **Procedure:** A series of tasks usually performed by one person according to instructions.
- **Process:** A set of related tasks and activities that accomplish a work goal.
- **Process Control:** The efforts to standardize and control processes in order to procedure predictable output.
- **Product:** A tangible result of a process or procedure.
- **Professional donor:** A person who donates blood for a valuable consideration, in cash or kind, from any source, on behalf of the recipient- patient/ recipient and includes a 'paid donor' or a 'commercial donor'.
- **Proficiency testing:** The structured evaluation of laboratory methods that assesses the suitability of processes, procedure, equipment, materials, and personnel.
- **Quality:** Characteristics of a unit of blood, component, sample, critical material, or service that bear on its ability to meet requirements, including those defined during agreement review.
- **Quality control:** Test routinely performed on materials and equipment to ensure proper function.



- **Measurement system:** The organizational structure, responsibilities, policies, processes procedures, and recourses established by executive management to achieve quality.
- **Quantity:** Attribute of a phenomenon, body or substance that may be distinguished qualitatively and determine quantitatively.
- **Quarantine:** To isolate nonconforming/ untested blood, components, tissue, derivatives, or materials to prevent their distribution or use.
- **Reference standards:** Reference standards define how or within what parameters an activity shall be performed and are more detailed than management system requirements.
- **Replacement donor:** A donor who is a family friend or a relative of the patient/ recipient.
- **Sample:** One or more parts taken from a system and intended to provide information on the system, often to serve as a basis for decision on the system or its production.
- **Supplier:** An activity that provides an input material or service.
- **Supplier qualification (Vendor evaluation):** An evaluation method designed to ensure that input materials and services (e.g. material, blood components, tissue and derivatives, patient/ recipient blood samples) obtained from a supplier meet specified requirements.
- **Traceability:** Property of the result of a measurement or the volume of a standard whereby it can be related to stated references, usually national or international standards, through an unbroken chain of comparisons all having stated uncertainties.
- **Transfusion service:** A facility that performs one or more of the following activities: compatibility testing, storage, selection, and issuing of blood and components to intended recipients. Transfusion services do not necessarily collect blood or process whole blood into components.
- **True positive:** A positive result on both the initial test and the confirmatory test.
- **Trueness of measurement:** Closeness of agreement between the average values obtained from a large series of result of measurements and a true value.
- **Uncertainty of measurement:** Parameter associated with the result of a measurement that characterized the dispersion of the values that could reasonably be attributed to the measurement.
- **Unit:** A container of blood or one of its components in a suitable volume of anticoagulant obtained from a collection of blood from one donor.



- **Validation:** Establishing recorded evidence that provides a high degree of assurance that a specific process will consistently produce an outcome, meeting its predetermined specifications and quality attributes.
- **Verification:** Confirmation by examination and provision of objective evidence that specified requirements has been met.
- **Voluntary blood donor:** A person who voluntarily donates blood after he/she has been declared fit after a medical examination, for donating blood, on fulfilling the criteria given hereinafter, without accepting in return any consideration in cash or kind from any source, but does not include a professional or a paid donor.

Benefit of Quality Management System:

Quality Management System is a continuous process and once a blood center has quality management systems there should be a self-assessment process in which you plan, do, check and take necessary corrective actions, thereby always striving to improve the quality.

An enhancement in quality of the blood bank increases the motivation of staff and increases confidence in their abilities which further improves donor, patient, clinician and community satisfaction. The donors develop confidence in the Blood Services, are satisfied and are more likely to become regular donors and promote voluntary non-remunerated blood donation.

An adequate and timely supply of products of defined standards builds the confidence of the clinician in the blood bank. Improved clinical outcomes with no adverse reactions in the patient post transfusion also contribute towards the same. Similarly the community at large seeing the performance of the blood bank, actively partners with it for voluntary blood donation camps, augmenting the blood safety.



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My message, especially to young people is to have courage to think differently, courage to invent, to travel the unexplored path, courage to discover the impossible and to conquer the problems and succeed. These are great qualities that they must work towards.



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