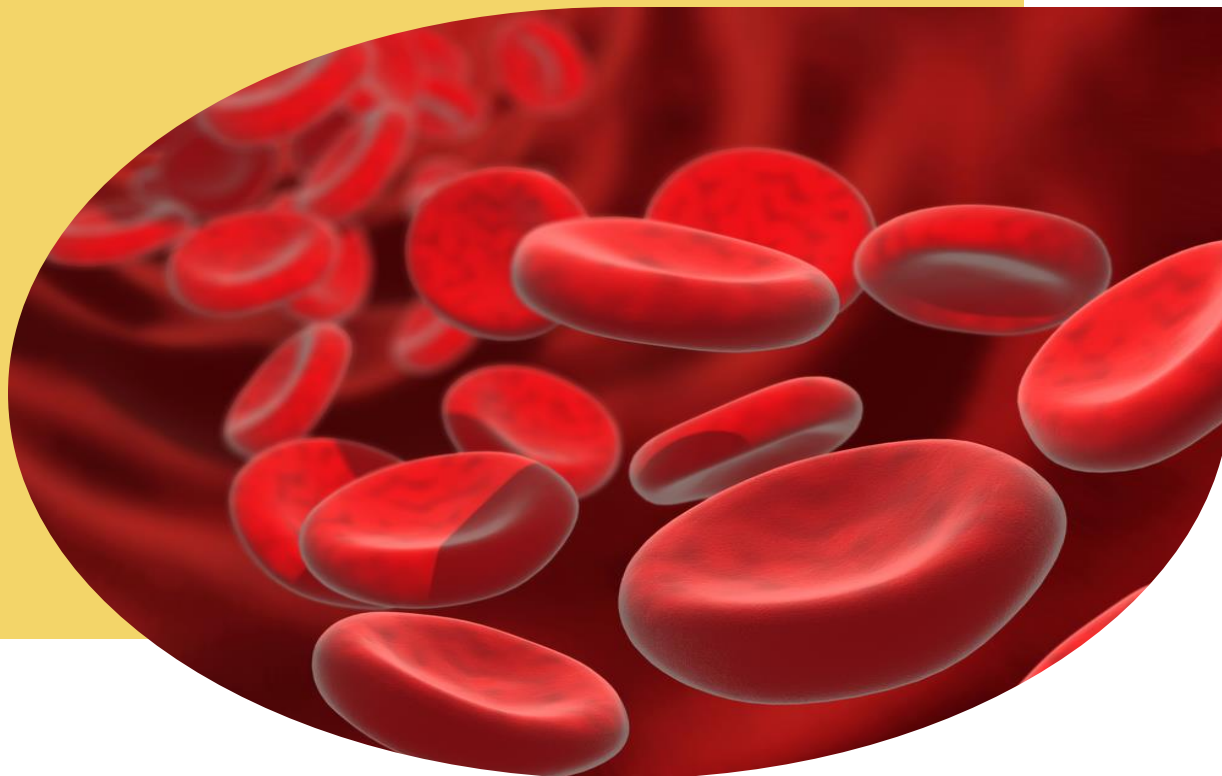




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Azadi Ka
Amrit Mahotsav



Good Blood Transfusion Practices

- Guidance for Rational use of blood

Blood Transfusion Practice & Haemovigilance Guidelines for Practicing Clinicians, Residents, Nurses, Technicians and Students

National Institute of Biologicals, NOIDA,
Ministry of Health & Family Welfare, Government of India

2022

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Dr. Anup Anvikar
Chairperson, Core Group- Haemovigilance Programme of India
& Director, National Institute of Biologicals
A-32, Sector-62
NOIDA-201309

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FOREWORD

Strengthening of blood transfusion services in a country is the utmost need for the health system. In blood transfusion services there should be a comprehensive quality system in place and haemovigilance should be embedded within this system.

Effective national haemovigilance system is one of the essential modules for strengthening blood transfusion services in a country by ensuring safe blood practices. The fundamentals for an effective national haemovigilance system are required to be set by the countries for successful implementation of Haemovigilance Programme.



Haemovigilance is an important tool for improving safe blood transfusion practices in a country. The Haemovigilance Programme of India has entered into its tenth year, and has evolved over the decade. In the initial years, it focused on the recipient safety monitoring. However, in recent years, the donor haemovigilance has also become an integral part of the programme. While the programme is doing well, lot needs to be done in order to include more and more blood centres.

The program is analyzing the reactions being submitted online by Blood Centres through indigenously developed haemovigilance software by NIB. Data analysis reports under the programme with recommendations for stakeholders are being published from time to time. Such information is a key to introduce required changes in the applicable policies, improve standards, system, processes and assist in the formulation of guidelines.

I am immensely pleased to inform that National Institute of Biologicals, NOIDA, Ministry of Health and Family Welfare, Government of India is bringing out the “Good Blood Transfusion Practices- Guidance for Rational use of Blood” for Blood Transfusion Practice & Haemovigilance Guidelines for Practicing Clinicians, Residents, Nurses, Technicians and Students.

I would like to commend the efforts of all the experts of HvPI who have been involved in bringing out this guideline.

I also compliment the entire team of HvPI, NIB responsible for bringing out this publication & wish them all success in their endeavor.

Further, I wish that this guideline will be widely disseminated among the stakeholders all across the country.

(Dr. Anup Anvikar)
Director, NIB

Dated: 11.11.2022

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It was decided to prepare the Good Blood Transfusion Practices guidelines in the meeting of National Executive Committee of HvPI held on 19th September, 2018 at NIB.

Subsequent to this the draft of Good Blood Transfusion Practices – Guidance for Rational use of Blood has been prepared, reviewed & finalized by the core team members. National Institute of Biologicals (NIB), NOIDA, Ministry of Health & Family Welfare, Government of India acknowledge the sincere contribution made by the Core Team along with the group of clinicians who have reviewed & provided their valuable inputs in bringing out the **“Good Blood Transfusion Practices- Guidance for Rational use of Blood” 2022** for Blood Transfusion Practice & Haemovigilance Guidelines for Practicing Clinicians, Residents, Nurses, Technicians and Students.

Core Team:

1. Dr. Neelam Marwaha,
Chairperson, National Executive Committee (NEC)- Haemovigilance Programme of India and
Former Professor & Head, Department of Transfusion Medicine,
Post Graduate Institute of Medical Education and Research (PGIMER), Chandigarh.
2. Prof. Debasish Gupta,
Head, Department of Transfusion Medicine,
Sree Chitra Tirunal Institute for Medical Sciences and Technology (SCTIMST), Thiruvananthapuram,
Kerala.
3. Prof. Ravneet Kaur,
Head, Department of Transfusion Medicine,
Government Medical College and Hospital (GMCH), Chandigarh.
4. Dr. Naveen Agnihotri,
Director, Blood Transfusion Medicine Consulting Services LLP, New Delhi
5. Dr. Lakhvinder Singh,
Associate Professor, Department of Transfusion Medicine,
PGIMER, Chandigarh.
6. Dr. Akanksha Bisht,
Scientist Grade-II & Head- HvPI,
NIB, NOIDA.

Clinicians Group:

1. Dr. Padmaja Samant,
Additional Professor, Dept. of Obstetrics and Gynaecology,
Seth GS Medical College & KEM Hospital, Parel, Mumbai.
2. Dr. Gaurav Parkash,
Professor, Department of Clinical Hematology and Medical Oncology,
PGIMER, Chandigarh.
3. Prof. (Dr.) Suchandra Mukherjee,
Head Dept. of Neonatologist, IPGIMER, Kolkata.

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1. Prof. (Dr.) Shakti Gupta,
Director, All India Institute of Medical Sciences (AIIMS), Jammu, J & K
2. Prof. U.B. Mishra,
Professor & Head, Hospital Administration and Principal,
Hind Institute of Medical Sciences, Sitapur, Lucknow, Uttar Pradesh
3. Dr. Vinod Kumar Panicker,
Professor & Head, Dept. of Transfusion Medicine,
Saveetha Medical College and Hospital, Chennai
4. Dr. R.K. Chaudhary,
Head, Department of Transfusion Medicine,
Sanjay Gandhi Postgraduate Institute of Medical Sciences, Lucknow, Uttar Pradesh
5. Dr. Nabajyoti Choudhury,
President of the Asian Association of Transfusion Medicine,
Assam Cancer Care Foundation, AMCH Campus Dibrugarh, Assam
6. Dr. Sadhana Mangwana,
Sr. Consultant & Head - Transfusion Medicine & Immunohematology,
Sri Balaji Action Medical Institute, New Delhi
7. Dr. Prasun Bhattacharya,
Professor & Head, Dept. of Immunohaematology and Blood Transfusion Medical College Hospital,
Kolkata, West Bengal
8. Sh. Suresh Kumar Kalwaniya, Drugs Inspector, Central Drugs Standard Control Organization, North Zone
9. Dr Punam Bajaj, Director, National Accreditation Board for Hospitals & Healthcare Providers (NABH), New Delhi
10. Dr. Satish Gupta,
Former Controller, Drugs and Food Organization, Jammu, J&K
11. Dr. G. Selvaraj,
Former Director Drugs Controller, Chennai, Tamil Nadu

TABLE OF CONTENTS

Chapter	Topic	Page number
1	LAW GOVERNING BLOOD TRANSFUSION IN INDIA	8
2	CONSENT FOR BLOOD TRANSFUSION	9-10
3	REQUISITIONING FOR BLOOD - BLOOD ORDERING AND SAMPLE REQUIREMENTS	11-16
4	BLOOD COMPONENTS AND INDICATIONS	17-33
5	TRANSPORT AND STORAGE OF BLOOD COMPONENTS OUTSIDE BLOOD CENTRE	34
6	ADMINISTRATION OF BLOOD COMPONENTS	35-40
7	MASSIVE TRANSFUSION AND SPECIAL SITUATIONS IN BLOOD TRANSFUSION	41-44
8	BLOOD TRANSFUSION REACTIONS	45-56
9	PATIENT BLOOD MANAGEMENT	57-60
10	TRANSFUSING CLINICIAN & BLOOD CENTRE	61
11	DOCUMENTATION IN BLOOD TRANSFUSION.	62
12	REFERENCES	63-64
13	LIST OF ANNEXURES	65-89

ABBREVIATIONS

AABB	(formerly) American Association of Blood Banks
AST	Aspartate Aminotransferase
aPTT	Activated Partial Thromboplastin Time
BJH	British Journal of Haematology
BT	Blood Transfusion
CPDA1	Citrate Phosphate Dextrose Adenine
CVS	Cardiovascular System
DH/STR	Delayed Hemolytic/Serological Transfusion Reaction
DIC	Disseminated Intravascular Coagulation
EACTS	European Association for Cardio-Thoracic Surgery
EACTA	European Association of Cardiothoracic Anaesthesiology
ECMO	Extra Corporeal Membrane Oxygenation
FFP	Fresh Frozen Plasma
FOCUS	Functional Outcomes in Cardiovascular Patients Undergoing Surgical Hip Fracture Repair Trial
FOGSI	Federation of Obstetric & Gynaecological Societies of India
Hb	Hemoglobin
HbS	Hemoglobin Sickle (Sickle cell disease)
HCW	Health Care Worker
HIV	Human Immunodeficiency Virus
HTC	Hospital Transfusion Committee
HTR	Hemolytic Transfusion Reaction
IACTA	Indian Association of Cardiovascular Thoracic Anaesthesiologists
ICCA	Indian College of Cardiac Anesthesia,
ICOG	Indian College of Obstetricians and Gynecologists
ID	Identification
IHN	International Haemovigilance Network
INR	International Normalized Ratio
ISBT	International Society of Blood transfusion
LD	Leukodepleted
LDH	Lactate Dehydrogenase
MSBOS	Maximum Surgical Blood ordering schedule
MT/MTP	Massive transfusion/Massive Transfusion Protocol
NCDRC	National Consumer Disputes Redressal Commission
OT	Operation Theater
PABD	Predeposit Autologous Blood Donation
PRBC	Packed Red Blood Cells/ Corpuscles
PBM	Patient Blood Management
PPI	Positive Patient Identification
PTP	Post Transfusion Purpura
RDP	Random Donor Platelets (prepared from 1 unit of whole blood)
RCOG	Royal College of Obstetricians and Gynecologists, United Kingdom.
SBOE	Surgical Blood Ordering Equation
SDP	Single Donor Platelet (prepared by apheresis technique)
TAGVHD	Transfusion Associated- Graft Versus Host Disease
TACO	Transfusion Associated Circulatory Overload
TAD	Transfusion Associated Dyspnoea
TAH	Transfusion Associated Hypotension
TRALI	Transfusion Related Acute Lung Injury
WHO	World Health Organization

1. LAW GOVERNING BLOOD TRANSFUSION IN INDIA

a. Background

Blood transfusion (BT) is one of the most common procedures performed in the hospitals today. It involves not just the Transfusion Medicine team in the blood centre but multiple healthcare professionals and stakeholders throughout the hospital. BT can be lifesaving but just like the proverbial double edged sword, it can also be associated with life threatening complications.

If blood as a lifesaving elixir is the vehicle, the clinician is the alert driver required to move it in the right direction. To optimize the blood collection and transfusion practices in India, National Blood Policy was mooted in the year 2002. One of the prime objective of this policy is to encourage appropriate clinical use of blood and blood products¹ in India. A key strategy (5.2 of Objective 5) to achieve this objective is by way of guidelines on “Clinical use of blood” being made available to the stakeholders. This handbook is an effort in this direction, though not an exhaustive one, it does touch upon the important topics of relevance to a practicing clinician.

b. Law governing blood transfusion in India

The Drugs and Cosmetics Act, 1940 and the Rules thereof (with amendments from time to time) provide the legal framework for the blood transfusion services in India. This law provides the legal framework for blood centre operations like blood collection, storage, processing, transport, compatibility testing, documentation in blood centre, blood transfusion to the patients, etc. Additionally, judgments by various civil, consumer and criminal courts have added to these regulations for blood transfusion procedure in the patients from time to time.

2. CONSENT FOR BLOOD TRANSFUSION

Need

Internationally, blood transfusion is considered as an invasive medical procedure, performed on a live body. Therefore the doctor is bound to disclose to the patient the associated benefits, risks and alternatives to blood transfusion, and it is now an accepted medical norm to obtain informed consent of the patient before a blood transfusion

Law and regulations governing consent

Blood transfusion to a patient without obtaining a valid consent is considered as an unauthorized act amounting to “a tortious act of assault and battery” and hence, deficiency in service. NCDRC in *M. Chinnaiyan v/s Sri Gokulam Hospital & Anr* (Annexure 1) case brought forward the need to obtain a separate consent for blood transfusion. In this case, the honorable court clarified that since blood transfusion involves an additional risk, **a separate consent of the patient is required for the transfusion of the blood**. In cases of children, unconscious and insane patients, consent is required to be taken from the legal guardian. Recently, National Consumer Disputes Redressal Commission (NCDRC 2016) ordered a hospital in Mumbai to pay a patient Rs. 12000 per month till her death just because an informed consent was not taken before a blood transfusion, through which she allegedly acquired an HIV infection².

Sample/ Model consent form – Based on the sample consent form in the Training module for blood bank medical officers and laboratory technicians ³(Annexure 2)

Ethics regarding consent for blood transfusion

Ethics underpin all the procedures and process carried out in a healthcare setup. Healthcare personnel are bound by the ethical code for Blood Transfusion formulated by International Society of Blood Transfusion in 1980⁴ and currently revised in the year 2017 (**Annexure 3**). This ethical code which includes the recommendations contained in the World Health Assembly Resolution (WHA28.72) on the utilization and supply of human blood and blood products mandates that:

- Patients are informed of the known risks and benefits of blood transfusion and/or alternative therapies and have the right to accept or refuse the procedure. Any valid advance directive is respected.
- In the event that the patient is unable to give prior informed consent, the basis for treatment by transfusion must be in the best interests of the patient.
- Transfusion therapy is given under the overall responsibility of a registered medical practitioner.

- Genuine clinical need is the only basis for transfusion therapy.
- There is no financial incentive to prescribe a blood transfusion.
- As far as possible the patient receives only those particular components (cells, plasma, or plasma derivatives) that are clinically appropriate and afford optimal safety.
- Wastage is avoided in order to safeguard the interests of all potential recipients and the donor. Blood transfusion practices established by national or international health bodies and other agencies competent and authorized to do so should be in compliance with this code of ethics

3. REQUISITIONING FOR BLOOD – BLOOD ORDERING AND SAMPLE REQUIREMENTS

Need

Patients undergoing elective surgical procedures often need red cell and other blood components intraoperative or post operatively. The preoperative request for blood units is often based on worst case assumptions, with potential for exhaustion of the blood centre resources. These blood requests frequently overshoot the actual need resulting in unnecessary crossmatching. Blood components are a scarce resource and there is a need to establish Blood ordering schedule to promote rational blood use and minimize its depletion.

Maximum Surgical Blood Ordering Schedule (MSBOS)

A MSBOS is a list of common elective surgical procedures performed, along with the maximum number of blood units being cross-matched preoperatively for each procedure.

Mead's criteria⁵: $MSBOS = 1.5 \times \text{transfusion index (No. of units transfused/no. of patients transfused)}$.

For example: In 100 patients undergoing a particular surgery, 204 units were transfused.

$MSBOS = 1.5 \times (204/100) = 3.06$. It implies that three blood units should be crossmatched for the patients undergoing this particular surgery.

SBOE: Surgical blood ordering equation is a comprehensive MSBOS, which includes patient and surgery specific variables such as preoperative and postoperative hemoglobin levels of the patient and amount of surgical blood loss during each surgical procedure. It is calculated in two steps⁶

Step 1: Predicted Hb fall during a surgical procedure is calculated by retrospective analysis of the pre and post Hb for that particular surgery. For example: In 100 surgeries the mean pre op Hb is 11 gm/dl and mean post op Hb is 8. And the patients required an average of 2 units during the surgery.

Predicted Hb fall = (pre op Hb - post op Hb) + number of red cell transfused. Hence, in surgery Y, predicted Hb fall is 5 gm/dl.

Step 2: Red cell units required for a patient undergoing surgery Y with a pre Hb of 11 gm/dl and minimal acceptable Hb for this patient is 7 considering the RBC transfusion threshold (depending on the patient age and any co-existent condition).

Red cell units required = predicted Hb loss - (Pre Hb - minimal acceptable Hb).

Hence in this patient, red cell units required are $5-(11-7) = 1$. For this patient undergoing surgery Y shall require 1 unit of blood.

Institute specific MSBOS : MSBOS should be based on institution specific blood utilization data not on consensus opinion. Table no.1 shows an institution specific MSBOS which guides the transfusion requirement of that institute. The blood requirement for a particular surgery may vary from among institutes.

Table 1: MSBOS derived by blood utilization data of an institute

Surgical procedure	Blood units requirement	Surgical procedure	Blood units requirement
1. Liver transplant	6 units	1. Liver resection	2 units
2. Heart or lung transplant	4 units	2. Whipple's	2 units
3. Cardiac major vascular	4 units	3. Intracranial tumour or aneurysm	2 units
4. Vertebral fusion	4 units	4. Total hip arthroplasty	2 units
5. Pelvic orthopaedic	4 units	5. Carotid body tumour	2 units
6. Major Vascular	4 units	6. Intraabdominal GI	2 units
7. Complex cesarean (accrete, percreta)	4 units	7. Repeat cesarean	2 units

Request for Blood and its components

A requisition for blood component must be received by the blood centre along with properly labelled recipient blood sample before testing or the issue of blood components. Incompletely filled requisitions forms and samples with labelling error are liable to be rejected by the Blood centres.

For transfusion requisition, a dedicated form is recommended (**Annexure 4**).

Blood requisition should contain the following information ^{7,8}:

Mandatory requirement: This information must be mentioned on the requisition form. Without this information, blood centres can reject the blood component requisition form.

Recipient name

Name of hospital/hospital registration number

Age, Sex, ward and bed number

Name of the clinician

Amount of blood/component needed

Date and time of blood/component required

Routine/emergency

Diagnosis

Reason for transfusion, hemoglobin/ platelet count

Signature of the medical officer

Name and signature of the phlebotomist collecting the sample

Signature and contact details of the phlebotomist/clinician

Any blood component modification if required

Desirable requirement: The following information should also be provided if available. It helps the blood centres to decide the type of blood component best suited for the patient.

Blood group of the recipient if done earlier

Presence of any antibody

History of previous transfusion

History of any previous transfusion reactions

Obstetric history in case of female patients

Other relevant medical or surgical history.

Informed consent should be taken as detailed in chapter no 2.

Emergency issue of blood: In case of emergency, blood can be issued with immediate spin crossmatch. Certain conditions like massive haemorrhage due to trauma, obstetric bleed and gastrointestinal bleeds where patient may require life-saving transfusion before the usual compatibility tests can be performed. In this case, clinician has to give the consent for emergency crossmatch stating that he gives consent for immediate issue of blood as the patient is critical and requires blood transfusion as a life saving measure. All hospitals should have a standard operating procedure (SOP) for issue of blood during such critical emergency cases. If group specific blood unit is not available, O Rh(D) neg unit can be used. Regarding emergency issue of blood, AABB⁹ states that uncrossmatched O group red cell units if recipient blood group is unknown. Rh(D) neg red cell units are preferred in females of child bearing potential. If there has been time to test only the blood group, then uncrossmatched blood group matched blood should be issued as per international guidelines.

Blood Samples for ordering Blood

Need : All requisitions for blood component should be accompanied by a properly labeled blood sample.

Tests done on the blood sample

ABO (both forward and reverse grouping) and Rh(D) grouping.

Crossmatch (emergency and complete crossmatch).

In case of incompatible crossmatch, sample is required for further work up which includes phenotyping, antibody screen and identification of the antibody causing incompatible blood.

In case of autoimmune hemolytic anemia, large amount of red cells are required for special techniques like adsorption elution. Hence, repeat sample with large volume (5-10) ml may be required.

Neonatal sample: All neonatal sample should be accompanied by maternal blood sample. Blood issued to neonates should be checked for compatibility with the maternal blood sample also. If mother is not available, it should be documented on the blood requisition form. For Intrauterine transfusions and if the blood is made available for exchange transfusion before the delivery of isoimmunized child, O Rh(D) negative red cells compatible with maternal serum are issued.



Positive patient identification before blood sample collection

Positive patient identification (PPI) is actively identifying a patient by asking to confirm name/ father's name/ other (if conscious and communicating) or checking IDs attached to the patient (e.g. wrist band). Relying on files/ records at patient bedside or confirmation by a third person only is passive identification and can be dangerous. Just like pre-transfusion sample collection requires a PPI, confirming it just before a BT is commenced is equally essential.

Few important points to remember about PPI are:

Even if you know your patient, patient's identification on patient file should be checked to make sure it is correct.

Two marks of identification are required

Include your patient in the identification process by asking specific questions:

What is your name

'How do you spell your name?'(wherever possible)

AVOID questions that require only a 'Yes' or 'No' eg. Are you Mr.XYZ?

After drawing the sample(s), label the tubes before leaving the patient.

Labelling samples away from the patient greatly increases the risk of mislabelling.

Document that you drew the blood sample. Never sign for anyone else's work!

If any discrepancies are discovered they must be satisfactorily resolved prior to collecting a pre-transfusion sample.

Blood sample is to be collected at the bed side after proper identification of the patient and the sample label should contain the following information.⁷

Patient's/recipient full name

Hospital identification number

Name of hospital

Ward

Date and time

A qualified person of the blood centre staff receives the sample and checks the information on the form and sample. In case of any discrepancy, the requisition should not be accepted.

In case of a need for transfusion after 72 hrs of sample collection, a fresh sample is to be sent for crossmatch because a recent transfusion or pregnancy may stimulate production of unexpected antibodies.

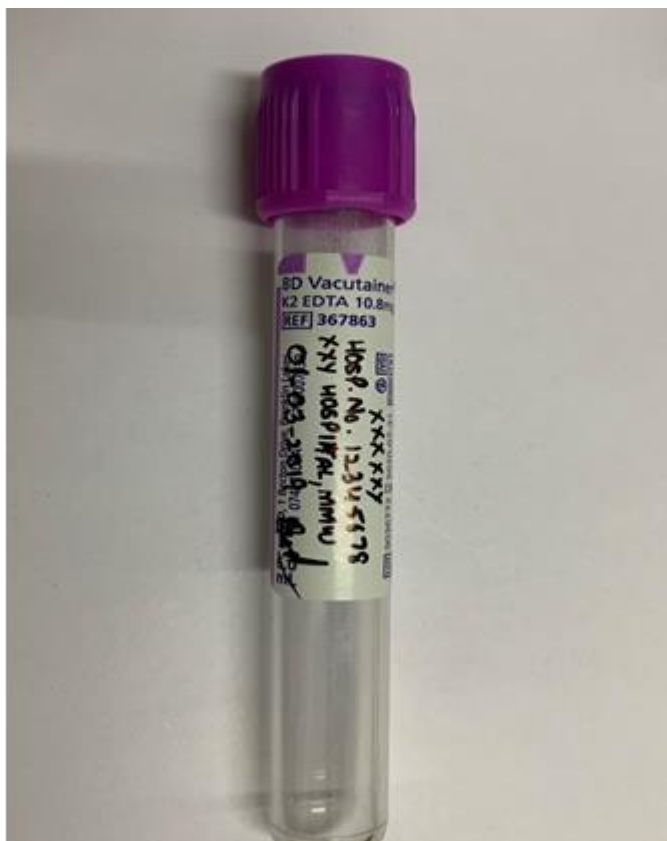
Use of hemolyzed are not accepted and discarded. It may create difficulties in evaluating test results.

Avoid taking sample from the same extremity in which there is an intravenous infusion.

Sample collected should be sent immediately to the blood centre.

Avoid sending preserved samples to the blood centre as it has high rate of error.

Blood samples are stored at 4-6°C for seven days in the blood centre to evaluate any adverse event in the recipient.



This picture shows properly labelled blood sample for Blood component requisition

Do's and Don'ts for Bed side transfusion practices

Do's	Don'ts
Always label the blood sample at the patient bedside	Don't sign for anyone else's work (sampling)
Label the sample immediately before/after taking the blood sample. It should be an uninterrupted continuous event	Don't take sample from the arm in which there is intravenous infusion
Requisition form should be filled completely	Don't fill any wrong information on the form.
Any discrepancy during sample collection, resolve it before sending the sample for transfusion	Don't send any unidentified sample lying on the bedside of patient for transfusion requisitions.

4. BLOOD COMPONENTS AND THEIR INDICATIONS

<p>Appropriate and rational blood use</p> <ul style="list-style-type: none"> - World Health Organization (WHO) 	<p>The appropriate use of blood and blood products means the transfusion of safe blood products only to treat a condition leading to significant morbidity or mortality that cannot be prevented or managed effectively by other means.</p> <p>Rational use of blood and blood products is to reduce unnecessary transfusions and minimize the risks associated with transfusion, the use of alternatives to transfusion where possible, and safe and good clinical transfusion practices, including patient blood management.</p>
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Various blood components – contents, storage and indication^{7,10}

A blood component is a constituent of blood which is separated from whole blood for e.g. red cell concentrate, platelet concentrate, fresh frozen plasma, etc. Table given below gives a snapshot of most commonly used blood components:

Name of the component	Approximate volume (ml)	Shelf life	Storage temperature
PRBC	150 - 250 ($\pm 10\%$)	35 - 42 days	2 - 6°C
FFP	180 - 300	1 year	Below minus 30°C
RDP	50 - 70	5 days	20 - 24°C
SDP (single donor platelet)	200	5 days	20 - 24°C
Cryoprecipitate	10 - 20	1 year	Below minus 30°C
Whole Blood	365 to 560	21 - 35 days	2 - 6°C

a. Whole blood

<i>Approximate Volume:</i>	365 to 560 ml (including the anticoagulant-preservative and acceptable variation of $\pm 10\%$ during collection of 350 – 450 ml whole blood from the donors)
<i>Hematocrit:</i>	30 – 40%
<i>Storage Conditions:</i>	2-6°C in a monitored blood refrigerator
<i>Special Treatment:</i>	Leukocyte reduction, washing, irradiation,
<i>Crossmatch:</i>	REQUIRED.
<i>Compatible alternate blood groups</i>	NIL. Only patient's blood group can be used for whole blood. O negative whole blood CANNOT be used as a universal donor.
Indications: <ol style="list-style-type: none"> Exchange transfusion in neonates. When packed red blood cells are not available, whole blood can be used in acute bleeding conditions when there is also a need to correct hypovolemia, e.g. battle field injuries, road traffic injuries, etc. 	

Rationality of use



Rationale blood transfusion not only decreases the cost, it also affects the patient outcomes!

The appropriate use of blood and blood products means the transfusion of safe blood products, only to treat a condition leading to significant morbidity or mortality that cannot be prevented or managed effectively by other means¹⁰. With red cell concentrate replacing the whole blood in most of the situations, there are very few clinical and practice circumstances where whole blood use can be justified as mentioned in the table above. Platelet function is rapidly lost during the whole blood storage and there is no useful platelet function left after 24 hours of cold storage. Routine use of whole blood should thus be discouraged, as better and more specific therapy in the form of component transfusion is available.

Whole blood - the current update

Since late 1960s component therapy has increasingly been used in the developed world, rapidly replacing the whole blood usage. However, in developing countries like India, whole blood is still used in many centres, mostly due to the lack of availability of blood components. Barring few studies (primarily in combat settings) done on small number of patients, there are still no randomized clinical trials or studies on large patient groups to validate the usefulness and safety of whole blood use. Hence, blood component therapy with a proven track record in terms of safety, efficacy, efficiency and usefulness is still the benchmark and whole blood use has to be discouraged in routine clinical practice.

b. Packed Red Blood Cells

Annually more than 80 million units of red cells are transfused globally and a wide variation in transfusion threshold and practices is seen for this particular blood component.

<i>Approximate Volume:</i>	Minimum 250 ml \pm 10% from 450 ml bag Minimum 150 ml \pm 10% from 350 ml bag. (This volume is exclusive of any additive solution added to the PRBC)
<i>Hematocrit:</i>	65-70% when stored in CPDA1 solution 50-60% when stored in additive (SAGM/Adsol/etc) solution
<i>Storage Conditions:</i>	2-6°C in a monitored blood refrigerator
<i>Special Treatment:</i>	Leukocyte depletion: Leucocytes in the final PRBC should be less than 5×10^8 when intended to prevent febrile reactions and less than 5×10^6 when required to prevent alloimmunization or cytomegalovirus infection. For achieving a level of less than 5×10^6 , use of leucocyte filters is usually necessary. Saline washing: Red cells are washed with sterile Normal Saline by centrifugation at 2 to 8 degrees centigrade to remove residual plasma and other additives/ preservatives suspected of causing allergic/ anaphylactic reaction in select patients. Irradiation: Done using gamma rays or x-ray irradiation at 25 Gray to prevent graft versus host disease due to proliferation of lymphocytes Freezing: Cryoprotective substance is added to the PRBCs for extended storage between minus 80 to minus 196 degrees centigrade.
<i>Crossmatch:</i>	Required.

Compatible alternate blood groups

See table in below.

Indications and dosage^{11,12}: [References: Clinical Practice Guidelines From the AABB (2016) & National institute for health and care excellence (NICE 2015) guidelines on blood transfusion]

- PRBC transfusion is not indicated until the Hb level is **7 g/dL (restrictive transfusion threshold)** and is recommended for hospitalized adult patients who are **hemodynamically stable, including critically ill patients** (strong recommendation, moderate quality evidence).
- A restrictive RBC transfusion threshold of **8 g/dL** is recommended for patients undergoing orthopedic surgery, cardiac surgery and those **with preexisting cardiovascular disease** (strong recommendation, moderate quality evidence).
- Above recommendations do not apply to the patients with acute coronary syndrome, severe thrombocytopenia and chronic transfusion-dependent anemia.**
- Patients, including neonates, should receive PRBC units, irrespective of duration of storage in blood centre, rather than limiting patients to transfusion of only fresh PRBC units (strong recommendation, moderate quality evidence).
- Adults without any active bleeding should be transfused single-unit red blood cell transfusions (or equivalent volumes calculated on the body weight basis for children or low body weight adults). In these patients, clinical reassessment and Hb levels should be done before further transfusions are given.

Compatible blood groups for PRBC transfusion

The below grid is for the **PACKED RED BLOOD CELLS transfusion ONLY** as there is no alternate choice of blood groups for the whole blood transfusion.

Patient's Blood Group	1 st choice for PRBC	2 nd choice for PRBC	3 rd choice for PRBC	4 th choice for PRBC
"A pos"	"A pos/ neg"	"O pos/ neg"		
"B pos"	"B pos/ neg"			
"O pos"	"O pos/ neg"			
"AB pos"	"AB pos/ neg"	"B pos/ neg"	"A pos/ neg"	"O pos/ neg"
"A neg"*	"A neg"	"O neg"		
"B neg" *	"B neg"			
"O neg" *	"O neg"			
"AB neg" *	"AB neg"	"B neg"	"A neg"	"O neg"

[pos = Rh(D) positive; neg = Rh(D) negative]

* Rh positive Packed RBCs can be transfused to Rh negative patients (post menopausal females, elderly men) when antibody screen is negative and only as a life saving measure. Informed consent from the patients/ relatives should be taken by the treating doctor/ transfusion medicine physician.

There are many existing international guidelines recommending RBC transfusions for various category of patients. Although decision to transfuse should be individualized according to the patient's condition, below mentioned indications are based on the latest scientific evidence and shall help in standardizing the blood transfusion practices in patients. Hemoglobin level is one of the critical factor used daily by the doctors to make a decision to transfuse and thus below mentioned guidelines incorporate Hb as one of the triggers wherever feasible.

1. Rationale PRBC use in Obstetrics and Gynecology

The WHO guidelines for blood transfusion in Obstetric patients published more than 15 years back recommended that blood transfusion should not be based on the Hb levels alone. There were no specific recommendation regarding the trigger for blood transfusion in these patients. In view of absence of any specific recommendations/ guidelines from the Indian obstetrics and gynecology bodies/ societies (e.g. FOGSI, ICOG) till December 2019, the below mentioned practice points have been taken from the RCOG, UK guidelines (2018)¹³.

- For normocytic or microcytic anemia, a trial of oral iron should be considered as the first step and further tests should be undertaken if there is no demonstrable rise in Hb at 2 weeks and compliance has been checked.
- Pregnant women should be offered screening for anemia at booking and at 28 weeks. Women with multiple pregnancies should have an additional full blood count done at 20–24 weeks.
- Parenteral iron is indicated when oral iron is not tolerated or absorbed or patient compliance is in doubt or if the woman is approaching term and there is insufficient time for oral supplementation to be effective.
- All women should have their blood group and antibody status checked at booking and at 28 weeks of gestation.
- Pre-delivery autologous blood deposit is not recommended.
- There should be a clear local protocol on how to manage major obstetric hemorrhage.
- There are no firm criteria for initiating red cell transfusion. The decision to provide blood transfusion should be made on clinical and hematological grounds. FFP at a dose of 12–15 ml/kg should be administered for every 6 units of red cells during major obstetric hemorrhage. Subsequent FFP transfusion should be guided by the results of clotting tests. Aim to maintain the platelet count above 50,000/ microliter in the acutely bleeding patient. A platelet transfusion trigger of 75,000/ microliter is recommended to provide a margin of safety.
- Anemic women who are not actively bleeding intrapartum or immediate post-partum, an Hb less than 7gm/dl is an indication for PRBC transfusion. For actively bleeding patients, follow with major obstetric protocols or massive transfusion protocol developed locally by the Hospital Transfusion Committee.

- The use of rFVIIa may be considered as a treatment for life-threatening postpartum hemorrhage (PPH), but should not delay or be considered a substitute for a life-saving procedure such as embolisation or surgery, or transfer to a referral centre.
- During major obstetric hemorrhage or with clinically diagnosed PPH, in addition to the standard care, early (within 3 hours of birth) use of intravenous Tranexamic acid is recommended (WHO 2017).

2. Rationale PRBC use in intensive care units[source: Red Blood Cell Transfusion: 2016 clinical practice guideline from AABB. Transfusion. 2016 Oct;56(10):2627-2630¹¹]

Sr. No	Clinical condition	Transfusion trigger	Strength of recommendation	Quality of evidence
1	Hemodynamically stable adult or pediatric patient	Hb \leq 7gm/ dl	Strong	High
2	Post-operative surgical patients	Hb \leq 8 gm/ dl Or symptoms like chest pain, orthostatic hypotension, tachycardia	Strong	High
3	Hemodynamically stable patients with pre-existing cardiovascular disease	unresponsive to fluid resuscitation or congestive heart failure	Weak	Moderate
4	Hemodynamically stable patients with acute coronary syndrome	No recommendation for or against a liberal or restrictive RBC transfusion threshold	Uncertain	Very low

3. Rationale PRBC use in Surgery & orthopedics

Effective and rationale BT involves pre-operative optimization of the patient, minimizing blood loss during surgery and avoiding unnecessary transfusions after the surgery. Clinical practice guidelines by AABB are relevant for BT in surgical and orthopedic patients (refer to the Rationale use in intensive care units section above). Additionally, the outcomes from the landmark FOCUS trial¹⁴ which included only the hip fracture patients with co-existing cardiovascular (CVS) disease or CVS disease risk factors, groups previously thought to require aggressive anemia management, made it amply clear that restrictive transfusion strategy is safe. Briefly:

- There was no difference in rates of mortality or mobility limitation at 60 days when patients with CV disease/ risk received BT at Hb of \leq 8 g/dl versus those who received BT at Hb of \leq 10 g/dl.

- Transfuse if symptomatic anemia, e.g. chest pain, tachycardia unresponsive to fluid resuscitation, orthostatic hypotension or congestive heart failure is present.
- The same thresholds can be safely applied to the patients with stable cardiovascular disease.
- Patients who are not actively bleeding should be transfused with a single unit of red cells and then reassessed before further blood is given.

It is commonly believed, that the surgeons and orthopedics prefer liberal blood transfusion strategy over a restricted one. However, there is now ample evidence that adhering to restrictive transfusion strategies and lower Hb thresholds (7-8 g/dl) is safe, effective as well as cheaper.

4. Rationale PRBC use in Cardiac surgery

Cardiac surgeries have traditionally been considered as big consumers of blood and blood components with incidence of peri-operative blood transfusion ranging from 40-90%¹⁵. However, with increased awareness of adverse outcomes associated with BT and additional cost, it is now realized that transfusions should be done optimally. Indian professional bodies like ICCA and IACTA have not yet officially endorsed (till Jan 2020) any guidelines for blood use in cardiac surgery in India.

Pre-operative transfusion (EACTS & EACTA 2017 guidelines) -Preoperative erythrocyte transfusion is not routinely recommended in preoperative anemic patients to prevent postoperative AKI¹⁶. However, in the case of emergency surgery and life-threatening anemia, it is legitimate to use preoperative blood transfusions to increase the Hb levels.

Oral or intravenous iron alone may be considered in mildly anemic patients (women, Hb 10-12 g/dl; men, Hb 10-13 g/dl) or in severely anemic patients (both genders, Hb \leq 10 g/dl) to improve erythropoiesis prior to cardiac surgery. Erythropoietin with iron supplementation should be considered to reduce postoperative transfusions in patients with noniron deficiency (e.g. EPO, vitamin D or folate acid deficiency) anemia, undergoing elective surgery.

Pre-operative autologous blood donation - In patients posted for elective surgery with Hb > 11 gm/dl and without severe aortic stenosis or an acute coronary syndrome within 4 weeks, PABD may decrease the number of postoperative BT. Acute normovolemic hemodilution (ANH) has not shown much advantage in cardiac surgery patients.

Quality of blood - The use of PRBCs of all ages is recommended, because the storage time of the PRBCs does not affect the outcomes (Class I, level A evidence). The use of leucocyte-depleted PRBCs is recommended to reduce infectious complications (Class I, level B evidence).

Hemoglobin trigger – The Society of Thoracic Surgeons and Society of Cardiovascular Anesthesiologists 2011 guidelines recommended RBC transfusion for Hb <6 g/dL during cardiopulmonary bypass and <7 g/dL post-operatively, except in patients at risk for decreased cerebral oxygen delivery, for whom a higher Hb level was recommended¹⁷. However, 2017 EACTS & EACTA guidelines recommend that instead of a fixed Hb threshold, BT should be based on the clinical condition of the patient (Class I, level B evidence). A restrictive Hb of 7-8 gm/dl (Hct 21-24%) with patient maintaining adequate DO_2 (> 273 ml O_2 /min/ m^2) level can be considered during cardiopulmonary bypass (Class IIb, level B evidence). Most cardiac anesthesiologists now agree that it is reasonable to transfuse blood with Hb <7 g/dl and transfusion is unnecessary when Hb is >10 g/dl¹⁸. The individualized approach used in between these two triggers (Hb between 7-10 g/dl) should be based on a restrictive strategy, with a focus on the improved clinical outcome along with the additional cost and risk of a BT.

5. Rationale PRBC use in neonates and pediatric patients [Source: Technical Manual. 19th ed. Bethesda, Maryland: AABB; 2017. p. 505 – 26]¹⁹

Age appropriate hemoglobin levels, the ability to tolerate blood volume loss and total blood volume differs in pediatric patients as compared to adults. Following are the indications of RBC transfusion in pediatric patients:

Infants less than 4 months of age:

Category	Recommendation for RBC transfusion @10-15ml/ kg
Symptomatic anemia (tachycardia, tachypnea, poor feeding)	Maintain Hb above 7 gm/dl
On oxygen (cannula/ hood) or mechanical ventilation, significant tachycardia (>180 beats/ min) or tachypnea (>80 breaths/ min) or apnea or bradycardia	Keep Hb > 10 gm/dl
On >35% oxygen by hood or on CPAP/ IMV* with mean airway pressure \geq 6-8cm of water	Keep Hb > 12gm/ dl
Congenital cyanotic heart disease or on ECMO	Keep Hb > 15 gm/ dl

* CPAP continuous positive airway pressure IMV intermittent mandatory ventilation

Infants older than 4 months and children

Category	Recommendation for RBC transfusion
Intraoperative blood loss > 15% of blood volume, Perioperative anemia, chemotherapy, radiotherapy, chronic congenital or acquired symptomatic anemia	Maintain Hb above 8gm/ dl
Severe pulmonary disease, ECMO	Keep Hb > 13 gm/ dl
Sickle cell disease for surgery under general anesthesia	Keep Hb > 10gm/ dl
Acute blood loss with unresponsive hypovolemia	Any Hb level

6. **Rationale PRBC use in common Hemoglobinopathies in India**[Source: Guidelines for screening, diagnosis and management of Hemoglobinopathies. Indian J Hum Genet. 2014;20(2):101-19]²⁰ -

Thalassemia and Sickle cell diseases are two common Hemoglobinopathies in India that require long and specialized treatment. Despite many advancements in the diagnosis and management of these diseases, it is unfortunate that still most of the patients in India are dependent mainly upon repeated blood transfusions.

Blood transfusion in Thalassemia

In thalassemia, excess iron due to these repeated blood transfusions, needs to be removed by the use of the expensive chelation treatment.

Thalassemia intermedia and Hb E thalassemia patients may not need regular red cell transfusions. Even in thalassemia major patients, regular transfusions are not justified only on the basis of Hb levels. Clinical parameters should be assessed before advising a chronic transfusion therapy because of grave risks with chronic BT therapy²¹. Following parameters suggest that the patient will need chronic red cell transfusions.

- Hb level <7 g/dl on two successive occasions separated by at least 2 weeks (the patient should be on folic acid replacement and there should be no other aggravating cause, i.e. infection, bleeding, etc.)
- Patient's growth, activity, academic performance, zeal, etc., are hampered
- Unnatural bony growth due to marrow expansion
- Development of organ failure such as cardiac failure, edema.
- Even if Hb level is >7 g/dl and <10 g/dl, and above clinical features are present, the patient may need chronic transfusion therapy.

Objectives of chronic red cell transfusions is to ensure adequate Hb level so that O₂ delivery to the tissue is not hampered. This will be indicated by:

- Normal growth spurt.
- Increased zeal, energy, enthusiasm, and improved academic performance.

- Improved appetite.
- Suppressed over active erythropoiesis leading to bone deformities.

Red cell transfusions should be given at an interval of 2-5 weeks. This interval is optimized based on:

- The amount of red cells transfused so that pre-transfusion Hb remains >9 g/dl but post-transfusion Hb does not go above 12 g/dl
- There is no fluid overload.
- Transfusion process is over within a reasonable time (within 4 hours).
- Frequency of transfusions is not such that it interferes with patient's normal activities.
- Reducing the number of venipuncture (as lifelong transfusion is needed, peripheral veins need to be preserved well).

Suitable blood components for transfusion:

- Red cell concentrates (hematocrit around 0.65) is suitable
- Leucodepleted (prestorage) blood is desirable.

Amount of PRBC to be transfused:

- Pretransfusion Hb is to be estimated along with the weight of the patient and recorded.
- If the hematocrit of the red cell concentrate used is 0.65, then 3-4 ml/kg will raise the Hb by 1 g/dl in the absence of hypersplenism.
- Generally in a single transfusion an attempt is made to raise the Hb by 4 g/dl if transfusions are scheduled at 3- to 5 weekly intervals.
- Below mentioned grid can be used to guide the volume of transfusion based on the desired Hb increase in the patient and the hematocrit of the blood bag²¹:

Target increase in Hb level	Hematocrit of the blood bag			
	50%	60%	75%	80%
1 g/dl	4.2 ml/kg	3.5 ml/kg	2.8 ml/kg	2.6 ml/kg
2 g/dl	8.4 ml/kg	7.0 ml/kg	5.6 ml/kg	5.2 ml/kg
3 g/dl	12.6 ml/kg	10.5 ml/kg	8.4 ml/kg	7.8 ml/kg
4 g/dl	16.8 ml/kg	14.0 ml/kg	11.2 ml/kg	10.4 ml/kg

Pre-transfusion testing should be done before starting chronic transfusion therapy as follows:

- Irregular antibody screening at regular intervals in necessary and should be done during pre-transfusion testing. Once an alloantibody is detected, it should be identified and antibody negative blood should be crossmatched.

- Extended phenotyping of patient's red cells is desirable. If possible, an extended phenotype of the patient should be done and record kept for any future need.
- If the family is interested in stem cell transplantation, then counseling and early referral to such a centre should be done.
- Serum ferritin level is not needed if the child is <2 years
- Serum ferritin levels should be recorded at regular intervals (3 months) after first 10 units of red cells have been transfused and iron chelation should be started and the dose should be adjusted so as to maintain serum ferritin between 500 and 1000 ng/ml.
- Before starting chronic red cell transfusions, hepatitis B vaccination should be completed.
- Every 3 months, virus serology should be done to detect viral infection at the earliest.
- Patient should receive NAT tested blood components as far as possible.
- Detailed record of red cell transfusions, complication, management, etc should be kept.
- Close relative's blood should not be transfused.

Blood transfusion in Sickle cell disease

- PRBC transfusions play an important role in the treatment of some acute illnesses in patients with sickle cell disease. Timely BT may be lifesaving in severe complications.
- PRBC should be transfused if the Hb is $\geq 1-2$ g/dl, below baseline and the patient shows any signs of cardiovascular compromise.
- Indications for red cell transfusions include acute exacerbation of the patient's baseline anemia (e.g. hyperhemolysis, hepatic sequestration, splenic sequestration, aplastic crisis) that requires increased oxygen carrying capacity, acute life or organ-threatening vaso-occlusive episodes (e.g. stroke, acute chest syndrome, severe infection, multiorgan failure, etc.) and preparation for surgical or radiographic procedures.
- Leukocyte-depleted, packed RBCs are recommended and where available Rh, Kell antigen matched, sickle-negative cells are preferred.
- Slow correction of the anemia, for example, 4-5 ml/kg PRBC over 4 h often with furosemide or isovolemic partial exchange transfusion may be needed to prevent precipitation of heart failure.
- Simple transfusion with 10 ml/kg of PRBC typically raises the Hb by about 2 g/dl.
- PRBC transfusion in a dose of 10 ml/kg for Hb <4-5 g/dl and signs of cardio vascular compromise should be done. Transfusion may be needed for Hb <7-8 g/dl for patients with relatively high baseline Hb Sickle levels. In severe cases, urgent initiation of transfusion prior to inpatient admission may be life-saving. A post-transfusion Hb level <8-9 g/dl is generally recommended to avoid the risk of hyperviscosity that may occur several days later when RBCs sequestered in the spleen may return to the circulation and increase the Hb 1-2 g/dl above the post-transfusion levels.

- Since sickle red cells are poorly deformable, simple red cell transfusions that increase the Hb levels to >10-11 g/dl may cause hyperviscosity in patients not receiving chronic transfusions and should be avoided.
- Partial exchange transfusion, generally by erythrocytapheresis (using apheresis technology), may be needed for severe life-threatening illness or in situations where a relatively high baseline Hb precludes a simple transfusion that would lead to the risk of hyperviscosity.
- Partial exchange transfusion or erythrocytapheresis to achieve Hb 10 g/dl and keep Hb Sickle (patient's RBC) <30%. Remove femoral or central venous catheter as soon as possible after exchange transfusion to reduce risk of thrombosis.
- Simple transfusion with PRBCs to achieve post-transfusion Hb approximately 10 g/dl may be considered as an alternative to partial exchange transfusion for stable patients with Hb 6-7 g/dl (do not transfuse acutely to Hb >10 g/dl, Hct >30%)

NICE guidelines published in 2015 recommend that individual thresholds and Hb targets should be set for each patient who needs regular blood transfusions for chronic anemia as seen in Hemoglobinopathies¹².

Modification of PRBC – leukodepletion, irradiation, volume reduction.

Leukodepletion, irradiation and volume reduction are one of the most common blood unit manipulations done in a blood centre to enhance blood safety for select category of patients.

Leukocyte depletion or leukodepletion (LD) is the process of removing leukocytes (mostly before storage of blood) from whole blood or platelets to prevent:

- Transfusion transmitted cytomegalovirus transmission
- HLA immunization
- Febrile non-hemolytic transfusion reactions
- Platelet refractoriness (failure to increase platelet count in a patient after repeated platelet transfusions)

Blood centre supplying the blood units can be asked about the availability of LD blood units.

Irradiation is done on the cellular blood components like RBC, platelets and granulocytes to prevent a fatal blood transfusion reaction called TA-GVHD (transfusion associated graft versus host disease) in at risk patients. When the blood donor/ unit is a blood relative of the transfusion recipient or the product is HLA matched, the recipient is at high risk for TA-GVHD. Acellular blood components like plasma and cryoprecipitate do not require irradiation treatment.

Volume reduction is preparing smaller aliquots for blood transfusion. This is most commonly done for the neonates and infants and may be required in the patients at risk of transfusion associated circulatory overload.

All the blood components can be volume reduced to suit the patient requirement. If done in a sterile manner (e.g. using sterile connecting device), there is no change in the original expiry and remaining aliquots can be used till the expiry of the original blood component. This is particularly useful in decreasing donor exposure in neonates and infants.

c. **Fresh Frozen plasma (FFP)**

FFP is conventionally transfused to patient with active bleeding or prophylactically to patients with modest to severe abnormality in the various coagulations tests like Prothrombin time, International normalized ratio (INR) and activated partial thromboplastin time (aPTT).

Indications of FFP transfusion (British Journal of Haematology guidelines 2018)²²

1. **Therapeutic Indications with Active bleeding :**

- Patient with massive bleed like trauma or obstetric cases may develop multiple coagulation factor deficiency require FFP transfusion along with other blood components for maintaining the hemostatic and hemodynamic stability. details regarding massive transfusion are covered in chapter on massive transfusion
- Disseminated Intravascular Coagulation or consumptive coagulopathy with active bleeding.
- Immediate correction of Vitamin K deficiency and warfarin reversal
- Thrombotic thrombocytopenic Purpura
- Patient with congenital factor deficiency like factor V deficiency when no alternative therapies are available

2. **Prophylactic Indications abnormal coagulation tests (INR >1.5) in the absence of bleeding:**

- FFP transfusion before an invasive procedure : Abnormal coagulation test are poor predictors of bleeding risks in non-bleeding patients prior to an invasive procedure (2C). Various studies have shown that mild to moderate abnormalities in the coagulations tests is not associated with bleeding and prophylactic plasma transfusion in these patients does not affect bleeding outcomes (AABB). BCSH recommends that coagulations tests should be considered in patients undergoing procedures with a moderate or high bleeding risk, any patient on anticoagulant , or those who have a personal/family bleeding history (1B).
- Patients on anticoagulants like warfarin to correct the INR prior to an invasive procedure.

3. **Other Indications:**

- As replacement fluid during therapeutic plasma exchange procedures for TTP and HUS
- In patients with liver disease, abnormal coagulation tests should be interpreted with caution as some of the patient may have prothrombotic tendency with elevated prothrombin time. Fresh frozen plasma transfusion is recommended only if active bleeding is present or prophylactically for high bleeding risk invasive procedures.

- Cardiopulmonary bypass surgery – use in the presence of bleeding but where abnormal coagulation is not due to heparin. Routine perioperative use is not indicated
- Severe sepsis, particularly in neonates (independent of DIC).

Dosage of FFP²²

1. FFP are transfused using weight based dosing of 10-15 ml/kg of recipient weight.
2. During massive transfusion, FFP transfusion may be given in a fixed ratio with red cell transfusion as per the massive transfusion protocol
3. As per BCSH, Patients with high bleeding risk during a procedure, starting dose of 15ml/kg body weight can be considered, although this is not evidence based.

Inappropriate use of FFP²³

Plasma products are associated with the highest rate of inappropriate utilization (upto 50%) with evidence of inappropriate practice based on local audits. The main reason for this inappropriate use of FFP is non availability of national/local guidelines in various countries like India. Even in countries with national guidelines, the compliance is really poor as per the published studies or audits.

FFP transfusion is not indicated in the following conditions:

1. Use of FFP for volume replacement in patients who are not bleeding.
2. Use of FFP for nutritional purposes like hypoproteinemia.
3. Lack of evidence based local guidelines for FFP transfusion
4. Prophylactic FFP transfusion for invasive procedures with normal or mildly (INR <1.5) deranged coagulation tests.
5. FFP transfusion in patient with bleed with normal coagulation tests.

d. Platelet components

Platelet components are required for patients with bleeding due to thrombocytopenia. However, they are also given prophylactically in conditions with low platelet count with the potential to cause bleeding.

- **Dosage:**

1 unit of platelet concentrate/10 kg; for an adult of 60-70 kg, 4-6 single donor units containing at least 240×10^9 platelets should raise the platelet count by $20-40 \times 10^9/L$.

Increment will be less if there is splenomegaly, disseminated intravascular coagulation (DIC) or septicaemia.

- **Indications:**

Treatment of bleeding due to:

- Thrombocytopenia.

- Platelet function defects.
- Prevention of bleeding due to thrombocytopenia as in bone marrow failure.

- **Contraindications:**

- **Absolute :** Thrombotic thrombocytopenic purpura (TTP). British Journal of Haematology recommends platelet transfusion in cases of TTP only during life threatening bleeds.
- **Relative :**
 - Idiopathic autoimmune thrombocytopenic purpura (ITP).
 - Untreated DIC.
 - Thrombocytopenia associated with septicaemia, or in cases of hypersplenism.

Transfusion triggers (Platelet count below which platelet transfusion is indicated) for prophylactic platelet transfusion (BJH guidelines 2017)²⁴

Clinical condition	Platelet transfusion triggers for prophylactic transfusion
Reversible bone marrow failure where recovery is anticipated	<ul style="list-style-type: none"> • 10,000/μl in non-bleeding, non-infected patient • Threshold for patient with increased risk of bleeding can be increased to 10-20,000/μl
Chronic bone marrow failure where recovery is not anticipated	<ul style="list-style-type: none"> • No prophylactic platelet is recommended • Manage patient according to severity of their sign and symptoms.
Critical illness with no bleeding	10,000/ μ l in non-bleeding, non-infected patient
venous central lines	10,000/ μ l
Lumbar Puncture	40,000/ μ l
Insertion removal of epidural catheter	40,000/ μ l
Major surgery	40,000/ μ l
Neurosurgery/ophthalmic surgeries	1 lac/ μ l
Percutaneous liver biopsy	50,000/ μ l
Renal Biopsy	<ul style="list-style-type: none"> • Avoid platelet transfusion because infused platelet will acquire a dysfunction similar to patient own platelets • consider desmopressin
Bone marrow aspirate, trephine biopsy, peripheral catheter insertion and cataract surgery	No prophylactic platelet required

Transfusion triggers for Therapeutic platelet transfusion (BJH guidelines 2017)²⁴

Clinical condition	Platelet transfusion trigger for therapeutic transfusion.
Severe bleeding (Massive transfusion)	50,000/ μ l
Multiple trauma, traumatic brain injury or spontaneous intracerebral haemorrhage	1 lac/ μ l
Non severe bleeding	30,000/ μ l
DIC in presence of bleeding	30,000/ μ l

Use in cardiopulmonary bypass surgery:

Platelet function defects and thrombocytopenia often occur after cardiac bypass surgery.

Platelet transfusion is recommended for patients with bleeding not due to surgically correctable causes (closure time done by Platelet Function Analyzer – PFA-100/Innovance PFA-200/ Sonoclot-provides global indication of platelet function). Prophylactic platelet transfusions are not required for all bypass procedures.

e. Cryoprecipitate

Cryoprecipitate is a blood component which is derived from FFP. It has relatively higher concentration per milliliter for fibrinogen, factor VIII, Von Willebrand factor (vWF), factor XIII and fibronectin

<i>Approximate Volume:</i>	10 – 20 ml
<i>Storage Conditions:</i>	Below minus 30°C in a blood centre freezer. It should be immediately transfused after thawing however, it can be stored at 2 - 6°C for a maximum duration of 6 hours post thawing, if not immediately transfused.
<i>Special Treatment:</i>	nil

<i>Crossmatch:</i>	NOT REQUIRED.
<i>Compatible alternate blood groups</i>	Although blood group specificity is preferred it is not mandatory especially in adults. However in neonates or small children it is desirable to give blood group specific or neutral (AB) group cryoprecipitate. The Rh type can be ignored if there is no red cell contamination of the product.
<i>Indications:</i> <ol style="list-style-type: none"> Hemophilia A (when pathogen inactivated antihemophilic concentrate factors are not available) Von Willebrand's disease Congenital or acquired fibrinogen deficiency (when pathogen inactivated fibrinogen is not available or cannot be used) Acquired factor VIII deficiency (when pathogen inactivated antihemophilic concentrate factors are not available) Factor XIII deficiency As a source of fibrin glue for preparing topic hemostatic agent in surgical procedures when pathogen inactivated fibrinogen is not available or cannot be used. 	

5. TRANSPORT AND STORAGE OF BLOOD COMPONENTS OUTSIDE BLOOD CENTRE

Transport of blood components from blood centre to patient area should be in well insulated transport boxes which are validated to maintain required storage temperature.

Maintenance of appropriate temperature requirements allows for the possibility of returning the components to inventory if they are not transfused.

Transport temperature for various components as per WHO recommendations are :

- Red cell components : 2 to 10 degrees celsius
- Plasma components* : less than -20°C
- Platelet components : 20 to 24 degrees Celsius

Some blood centres issue Plasma components after thawing at 37° C, then it should be transfused immediately or store at 2 to 10 degrees Celsius if required.

When the blood product that was ordered arrives, transfuse it as soon as possible to avoid having to store it. However, if the blood product is not used immediately, store it under the correct storage conditions. For example: red cell units should be stored in blood storage refrigerators only maintaining the appropriate temperature of 2 to 6 degrees celsius

Storage of blood components in domestic refrigerators should be discouraged

- Do not store blood units in freezer compartment or chill tray of the refrigerator. Red cells will haemolyse.
- Do not refrigerate Platelet Concentrates. They become non-viable on refrigeration and have no therapeutic value.

Type of Blood Component	As per WHO recommendation ⁸ , the blood component after issue from the blood centre should be transfused within:
Red cell components	30 minutes
Plasma components (thawed)	30 minutes
Platelet components	immediately

Holding blood components that have been dispensed from the blood centre in other hospital areas before transfusion is considered to be storage

Receive back of blood: After issue of blood from the blood centre, if not transfused should be returned back to blood centre immediately and certify that cold chain was maintained during the storage outside blood centre. If the blood unit shows any sign of hemolysis or any sign that the bag has been opened, it is discarded. However, blood centre can have their own policy on receive back and reissue of unused units.

6. ADMINISTRATION OF BLOOD COMPONENTS

Administration of blood components²⁵



All blood components except hematopoietic precursor cells, MUST be transfused using a BT set with 170-200

a. Venous access: Cannula

Urgency	Adult	Pediatric	Remarks
Routine	18-20 G	20-24 G	Choose size as per flow requirements; in difficult and poor veins a smaller cannula with low flow rates may be used. Most central venous access devices have sufficient diameter for adequate flow.
Emergency	Large diameter and additional IV access may be used to achieve adequate flow rate and concurrent blood component transfusions.		

b. Blood transfusion sets (BT set):

- i. **Priming:** Use either 0.9% normal saline or blood component. Do not mix medications and fluids (other than normal saline) in the same line/ blood bag. Other ports/ lumens may be used to administer medications/ fluids.
- ii. **Re-use:** As per the manufacturer instructions or for the same type of blood component (any number of units) up to 12 hours same BT set may be used. Do not use same BT set for different type of blood components, e.g. do not transfuse platelets through a BT set used earlier for packed red blood cells or whole blood.

c. Infusion devices:

- i. **Infusion pumps and syringe drivers:** These are commonly used in the neonates and intensive care settings. Blood must first pass through the standard 170-200 micron filter even when infusion pumps are used. There must be a regular maintenance program for such devices.
- ii. **External pressure devices:** These are used for rapid infusions of large volume of blood components. A large bore cannula must be used with these devices to avoid hemolysis. These should exert a uniform pressure on the blood bag and have a gauge to measure the pressure. The maximum pressure should not exceed 300 mm Hg

d. **Blood warmers and indications:** For blood and patient safety it is very important that hospitals using blood warmers ensure their regular upkeep and maintenance. Appropriate devices, with alarm and temperature indicator, for blood warming should be used and improvised blood warming techniques may do more harm than good to the patient. A blood warmer may be used for:

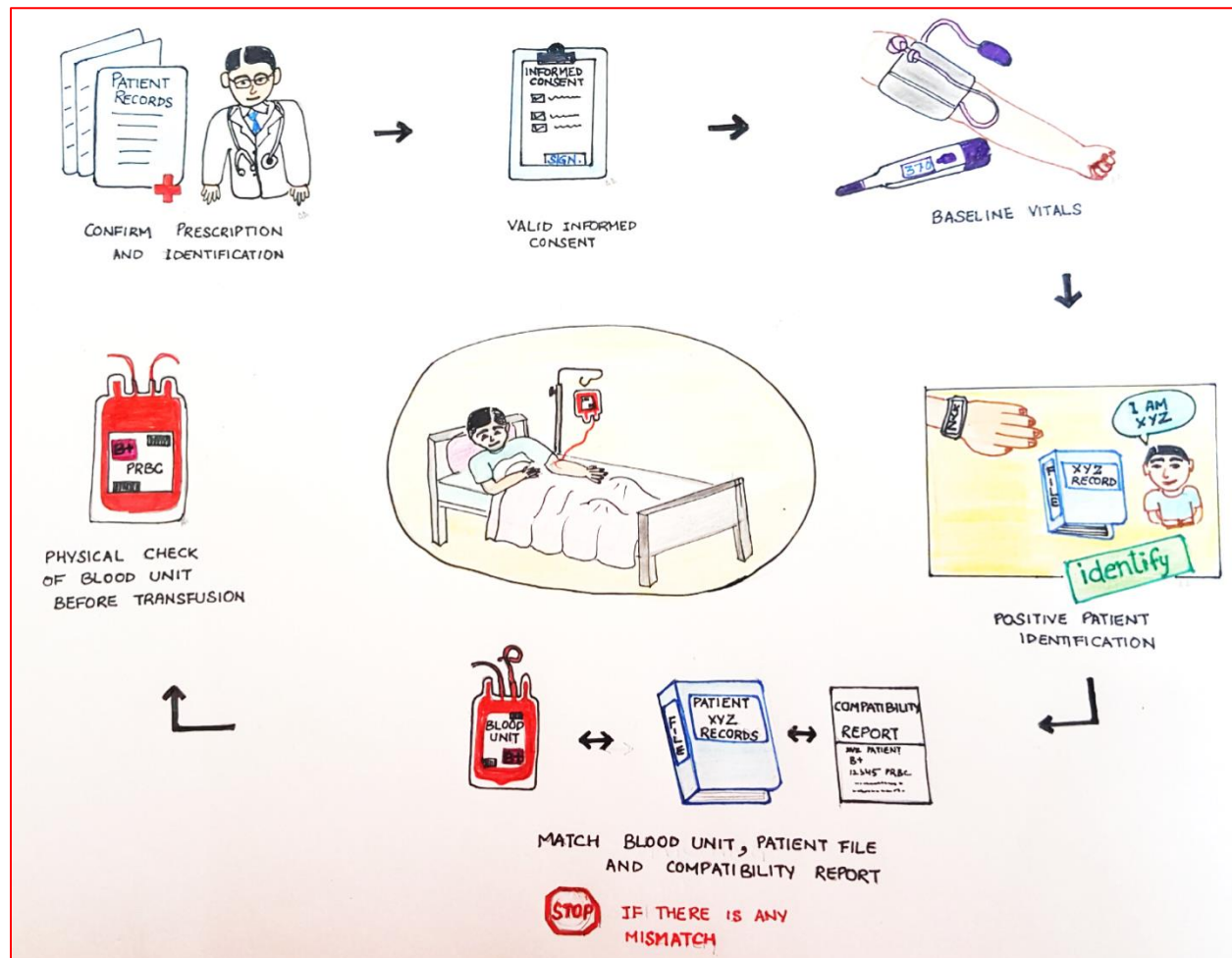
- i. Exchange transfusion and intrauterine transfusion
- ii. Patients with clinically significant cold antibodies
- iii. Rapid transfusion of large blood volumes (>50ml/kg/hour in adults and > 15ml/ kg/ hour in pediatric patients)
- iv. Plasma exchange in therapeutic apheresis
- v. Blood transfusions in hypothermic patients

e. **Fluids and medications compatible with blood components**

Solution	Compatibility	Remarks
0.9% Normal Saline	Compatible	As far as possible IV fluid solutions should not be co-administered with blood and components, however, 0.9% NS may be given when required.
Calcium containing electrolyte or colloid solution (like lactated Ringer's solution, Haemaccel®)	incompatible	Should NOT be co-administered with blood or in the same IV line.
5% dextrose in water	Incompatible	Not compatible with whole blood and PRBC transfusion, as it may lead to hemolysis.
Hypotonic sodium solutions		

Additionally, it is not advisable to transfuse two different type of blood components (e.g. plasma and packed red cells) simultaneously, even via separate IV access lines. This is to avoid any uncertainty arising in case of a blood transfusion reaction, however, this rule may not apply in emergency and lifesaving situations.

f. Blood Transfusion process in a snapshot:

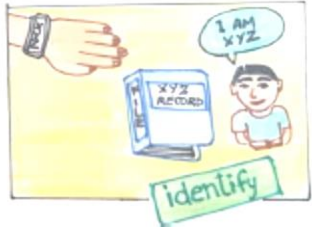


g. Checklist when receiving a blood component from blood centre²⁶:

A very common reason for mismatch blood transfusion to a patient is **INCORRECT IDENTIFICATION OF BLOOD UNIT AND/ OR THE PATIENT**. Following a proper protocol as outlined below is critical to the patient safety:

- ✓ While asking for blood from the blood centre, send a proper identification of the patient for whom blood is required. This should contain at least 2 unique identifiers of the patient, e.g. name and registration number of the patient. It is desirable to have additional patient information like age, gender, location etc.
- ✓ The blood unit should be transported in an insulated container so that an appropriate temperature is maintained in transit.
- ✓ Upon receiving the blood unit at the patient location, check the details on the blood unit - they should match the patient details to whom blood transfusion is to be given. Check the accompanying compatibility report also for correctness of the patient details.
- ✓ Get the blood units issued only when transfusion is imminent. **NEVER STORE BLOOD IN WARDS/ ICUs/ OTs** as far as possible. Blood can be returned to the blood centre for a later release in case blood transfusion is not possible immediately.

h. Positive patient identification and vital examination before blood transfusion



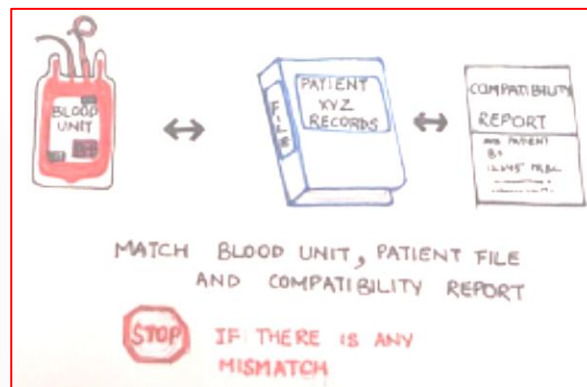
Positive patient identification (PPI) is actively identifying a patient by asking to confirm name/ father's name/ other (if conscious and communicating) or checking IDs attached to the patient (e.g. wrist band). Relying on files/ records at patient bedside or confirmation by a third person only is passive identification and can be dangerous. Just like pre-transfusion sample collection requires a PPI, confirming it just before a BT is commenced is equally essential.

i. Identification bands

Patients receiving a blood component must be positively identified and should have an identification (ID) band attached to their body with at least name, unique identification number (e.g. medical registration number) and/ or date of birth/ age. Hospitals transfusing blood should have a policy on how a patient would be positively identified in conditions when this ID band is not on the patient, e.g. in OTs, burn patients, neonates, orthopedic surgeries, emergency room, etc.

j. Pre-transfusion checking

- Verify if a valid informed consent for blood transfusion is available.
- The final check should be done at the patient bed side and not the nursing counter. This should be done immediately before starting the blood transfusion. Should preferably be done by 2 trained persons of the medical team **INDEPENDENTLY** and one of them should be a medical doctor. This exercise should be documented for any (later) validation and training purpose. There should not be a discrepancy between the information on the blood unit, patient (records) and the accompanying compatibility report as detailed below. In case there is any discrepancy, it should be considered an emergency and blood centre should immediately be informed. There may be a 2nd wrong blood transfusion about to happen.



All the 3 of below mentioned details should be checked and tallied before transfusion:

Blood unit	Compatibility report	Patient details
<ul style="list-style-type: none"> ✓ Unique unit ID ✓ Type of blood/ component ✓ Volume of blood/ component ✓ Blood group - should be identical or compatible with the patient ✓ Date of expiry ✓ Check the blood unit for any signs of deterioration, e.g. clumps, leak. 	<ul style="list-style-type: none"> ✓ Unit ID(s) ✓ Name of blood/ component(s) ✓ Volume of blood/ component(s) ✓ Expiry date of unit(s) - should be 'in-date' ✓ Compatibility status of unit(s) ✓ Negative for infectious disease markers (e.g. HIV, HBsAg, etc.) ✓ Name & signature of person performing the compatibility testing. ✓ Format for reporting any adverse reaction to blood/ component. 	<ul style="list-style-type: none"> ✓ The component prescribed by the treating doctor. ✓ Any special requirement, leukodepletion, warming, medications before transfusion, etc. ✓ Confirm patient's name and at least a 2nd identifier from patient or an identity attached to the patient, e.g. wrist band. ✓ Re-check patient vitals and document. ✓ Document the time of starting the BT.

k. Blood transfusion rates

The blood transfusion (or infusion) rate depends on the clinical condition, age and cardiac status of the patient being transfused. For patients at risk of circulatory overload (hypoalbuminemia, cardiac failure, age above 65 years, etc) transfuse slowly with more frequent monitoring. It may be necessary to use a diuretic wherever indicated in such cases. The below mentioned rates are for a hemodynamically stable, non-bleeding adult patient.

Blood component	Transfusion rate [#] (ml/hour)	Maximum time to transfuse a unit
Whole Blood	150 - 200	240 minutes
Packed Red Blood Cells/ Red cells	100 - 150	240 minutes
Random donor platelets	150 - 300	30 minutes
Single donor platelets	150 - 300	30 minutes
Fresh frozen plasma/ plasma	150 - 300	30 minutes
Cryoprecipitate	150 - 300	30 minutes
Granulocytes	Determine locally	240 minutes

[#] WHO: Guidelines for medical interns, Bangladesh



For stable patients, start each unit at a very slow rate (e.g. @1 ml/ minute) for the initial 15 minutes with frequent monitoring and recording of vitals as per the institutional policy. Rate can be increased after 15 minutes if patient tolerates the transfusion

l. Observation and monitoring during blood transfusion

At no moment patient should be left alone and frequent visual observation of the patient for the entire duration of the transfusion must occur. Except for patient with serious co-morbidities where more frequent vital recording may be required, for all patients receiving a BT, vitals (temperature, BP, pulse and respiration rate/ and or oxygen saturation), must be recorded at a minimum as follows:

- i. Before start of each unit
- ii. 15 minutes after starting of each unit
- iii. If uneventful, 30-60 minutes thereafter till completion of the unit.
- iv. After the unit is completely transfused.
- v. Whenever, there is any adverse reaction to the BT.

m. Documentation in patient records before, during and after a blood transfusion:

Before BT	During BT	After BT
<ul style="list-style-type: none"> ✓ Valid indication and relevant investigations. ✓ Doctor's prescription for type & quantity of blood component(s) in patient's record/ file. ✓ Valid and signed informed consent or its refusal. ✓ Correct date, time and signature for all of the above 	<ul style="list-style-type: none"> ✓ Signature(s) and identification of HCW involved in BT. ✓ Starting date & time. ✓ Vitals during BT at appropriate intervals (as mentioned above) ✓ Any adverse effect/ reaction ✓ Any medication administered during BT 	<ul style="list-style-type: none"> ✓ Completion date & time ✓ Vitals at finish and after 30-60 minutes ✓ Completed transfusion reaction form (document NIL reaction in case no reaction happened) ✓ File/ paste relevant documents in patient's file (e.g. compatibility sticker/ report, etc.) ✓ Any adverse effect/ reaction

7. MASSIVE TRANSFUSION AND SPECIAL SITUATIONS IN BLOOD TRANSFUSION

Massive transfusion

Introduction : Massive hemorrhage is a common complication in a number of clinical settings. In traumatic injury, hemorrhage is a major cause of morbidity and is responsible for almost 50 % of the deaths occurring within 24 hrs of injury and upto 80% of intraoperative trauma mortalities. Other causes of massive bleed requiring massive transfusion includes cardiovascular and hepatobiliary procedures, obstetric bleeds and GI bleeds. Early, aggressive, and ratio based blood component as per the massive transfusion protocol resuscitation provides improved outcomes. Despite the need for consensus on the management of patients with massive bleeding, currently, no such consensus exists. Various international scientific bodies have published guidelines for massive transfusion protocol. In India, no massive transfusion protocol exists for the management of clinical situations with massive bleeds. Hence, there is need for Indian hospitals to formulate Massive transfusion protocol suited to their need and resources to improve survival in massive blood loss

Definition : Massive blood transfusion is defined as the administration of 8 to 10 PRBC units in an adult recipient in 24 hours or acute administration of 4 to 5 PRBC units within one hour or replacement of more than one blood volume in 24 hours or more than 50% of blood volume in 4 hours (adult blood volume is approximately 70 mL/kg)²⁷

- Replacement of a blood volume equivalent within 24 hours.
- >10 units within 24 hours.
- Transfusion >4 units in 1 hour.
- Replacement of 50% of blood volume in 3-4 hours.
- A rate of loss >150 ml/hour.

Goals of massive transfusion protocol:

- Early resuscitation with recognition of blood loss and activation of massive transfusion protocol
- Maintenance of tissue perfusion
- Oxygenation by restoration of blood volume and Hb
- The cessation of bleeding by several means including early surgical or radiological intervention
- Judicious use of blood component therapy to correct coagulopathy.

Complication of massive transfusion^{7,8,22}

Massive transfusion (MT) is a lifesaving treatment, but can be associated with significant complications. The lethal triad of acidosis, hypothermia, and coagulopathy associated with MT is associated with a high mortality rate.

- **Acidosis:** Acidosis in a patient receiving a large volume transfusion is more likely to be the result of inadequate treatment of hypovolaemia than due to the effects of transfusion. Under normal circumstances, the body can readily neutralize this acid load from transfusion. The routine use of bicarbonate or other alkalizing agents, based on the number of units transfused, is unnecessary.
- **Coagulopathy :** dilution of the platelets and coagulation factor with initial resuscitation of bleeding patient is done with excessive crystalloids and red cell transfusion. Coagulopathy is ascribed to loss of hemostatically active blood , dilution factor, acidosis and hypothermia which reduces the enzymatic activity leading to destabilization of coagulation complexes. Hence it becomes a vicious circle where acidosis and hypothermia causes coagulopathy and coagulopathy leads to increase bleeding causing tissue hypotransfusion leading to acidosis and hypothermia. Hence, active initial management with ratio based transfusion therapy avoiding blood dilution and providing extracorporeal blood warming allows many trauma patients survive.
- **Hypothermia**
- **Hyperkalaemia/Hypokalaemia:** The storage of blood results in a small increase in extra-cellular potassium concentration, which will increase the longer it is stored. This rise is rarely of clinical significance, other than in neonatal exchange transfusions. Hypokalemia is more frequent than hyperkalemia and is due to inward shift of potassium ions in red cells due to citrate toxicity and aldosterone induced urinary loss.
- **Citrate toxicity and hypocalcaemia:** Citrate toxicity is rare, but is most likely to occur during the course of a large volume transfusion of whole blood. Hypocalcaemia, particularly in combination with hypothermia and acidosis, can cause a reduction in cardiac output, bradycardia, and other dysrhythmias. Citrate is usually rapidly metabolized to bicarbonate. It is therefore unnecessary to attempt to neutralize the acid load of transfusion.
- **Air embolism**

Massive transfusion protocol: Massive transfusion protocols (MTPs) are established to provide rapid blood replacement for the patients with massive blood loss. Early optimal blood transfusion is essential to sustain organ perfusion and oxygenation. There are many variables to consider when establishing an MTP, and studies have prospectively evaluated different scenarios and patient populations to establish the best practices to attain improved patient outcomes. Initial resuscitation should be started immediately in a ratio based blood component therapy. The most accepted ratio based protocol is as given by BCSH guidelines recommends blood components to be transfused in equal ratios.

After initial resuscitation, following parameters should be evaluated while guiding the further therapy:

- Temperature $>35^{\circ}\text{C}$
- Acid-base status: pH >7.2 , base excess < -6 , lactate <4 mmol/L
- Ionised calcium (Ca) >1.1 mmol/L
- Haemoglobin (Hb): This should not be used alone as a transfusion trigger; and, should be interpreted in context with haemodynamic status, organ and tissue perfusion
- Platelets (Plt) $\geq 50 \times 10^9 /\text{L}$
- PT/APTT (activated partial thromboplastin time) ≥ 1.5 x of normal
- Fibrinogen

Role of Visco-Elastic Assays : These are point of care tests available to monitor the coagulation status in a patient. These tests can be used to guide appropriate transfusion therapy in a patient requiring blood transfusion by localizing the defect in the coagulation. There are various type of visco-elastic assay available like thromboelastography, rotational thromboelastometry and sonoclot. These assays are better than the conventional coagulation tests as Whole blood is used for testing and effect of platelets is also studied. It can also differentiate between the hypofibrinolytic and hyperfibrinolytic state trauma induced coagulopathy.

The best practice for massive transfusion (MT) includes an established institutional definition of massive transfusion protocol, an accurate method for predicting which patients will require MT so therapy can be promptly initiated and over-utilization can be avoided, and finally, an established MT protocol with a clear plan for activation and use of appropriate blood products to maintain hemostasis. Adherence to the established protocol is critical to extract the full clinical benefit of an MTP for treating either trauma or non-trauma patients.

Massive transfusion In trauma : Adult trauma patients with, or at risk of, massive haemorrhage should initially be transfused empirically with a 1:1:1 ratio of plasma: red cells: platelets. These patients with, or at risk of major haemorrhage, should be given tranexamic acid as soon as possible after injury.

Massive transfusion in obstetric patients: blood component therapy should be same as in non pregnant patients except that fibrinogen supplementation with cryoprecipitates should be considered at fibrinogen levels are <2.0 gm/dl. Tranexamic acid may also be considered post partum.

Special situations in blood transfusion

a. Unconscious or anesthetized patients

Such patients pose peculiar problems during

- i. **Sample collection and blood ordering** – If a given name cannot be assigned to the blood request form and the blood sample, UNKNOWN with unique hospital registration number can be used rather than mentioning no name. When more than one such patients are present, they can be labeled as UNKNOWN 1, UNKNOWN 2, etc.
- ii. **Informed consent** – 2 independent doctors (one of whom is unrelated to the patient care) can authorize/ consent for a blood transfusion in an unconscious patient with no friend/ relative/ next of kin available in an emergency situation.
- iii. **Blood transfusion** – closer observation during transfusion is required as patient is unable to verbalize the symptoms. Besides above mentioned conditions, this may also happen with anesthetized/ sedated patients. Signs and symptoms would present differently and may present as hypotension, uncontrolled bleeding, generalized oozing during a surgical procedure, hemoglobinuria or oliguria. Sudden deterioration in the patients ventilator setting or oxygen saturation may be a pointer towards an acute transfusion reaction.

b. Blood transfusion in pediatric patients:

- i. **Sample collection and blood ordering** – All the patient care areas dealing with pediatric patients should have an inhouse policy for amount of sample for pediatric (including neonates) blood transfusion. Since blood sampling is a known cause of anemia in low weight children, repeat samples can be avoided for transfusion of plasma, platelets, cryoprecipitate, etc. where cross-matching is not required. However, patient's blood group should have been done/ documented at least once in such situations. Pediatrician can discuss blood sample requirement and policies like 'type and screen' for pediatric patients. Type and screen is a policy where repeated cross-matches need not be done, once antibody screening has been done and no irregular antibodies are found in the patient's blood.

Children less than 20 kg should preferably be prescribed and issued blood in milliliters (ml) to avoid complications like volume overload.

- ii. **Informed consent** – Parents/ guardians/ relatives should consent for blood transfusion in pediatric patients.
- iii. **Blood transfusion** – besides routine observation as in adult patients, these patients should be closely observed for signs and symptoms of adverse transfusion reactions. Irritability, agitation and inconsolability by the parent or main caregiver may be the sole symptoms of an adverse transfusion reaction in pediatric patients. Age-appropriate activities can be provided during the transfusion for a better care. Syringe drivers and volumetric infusion pumps (approved for the purpose) should be used wherever possible to ensure accurate rates in younger children.

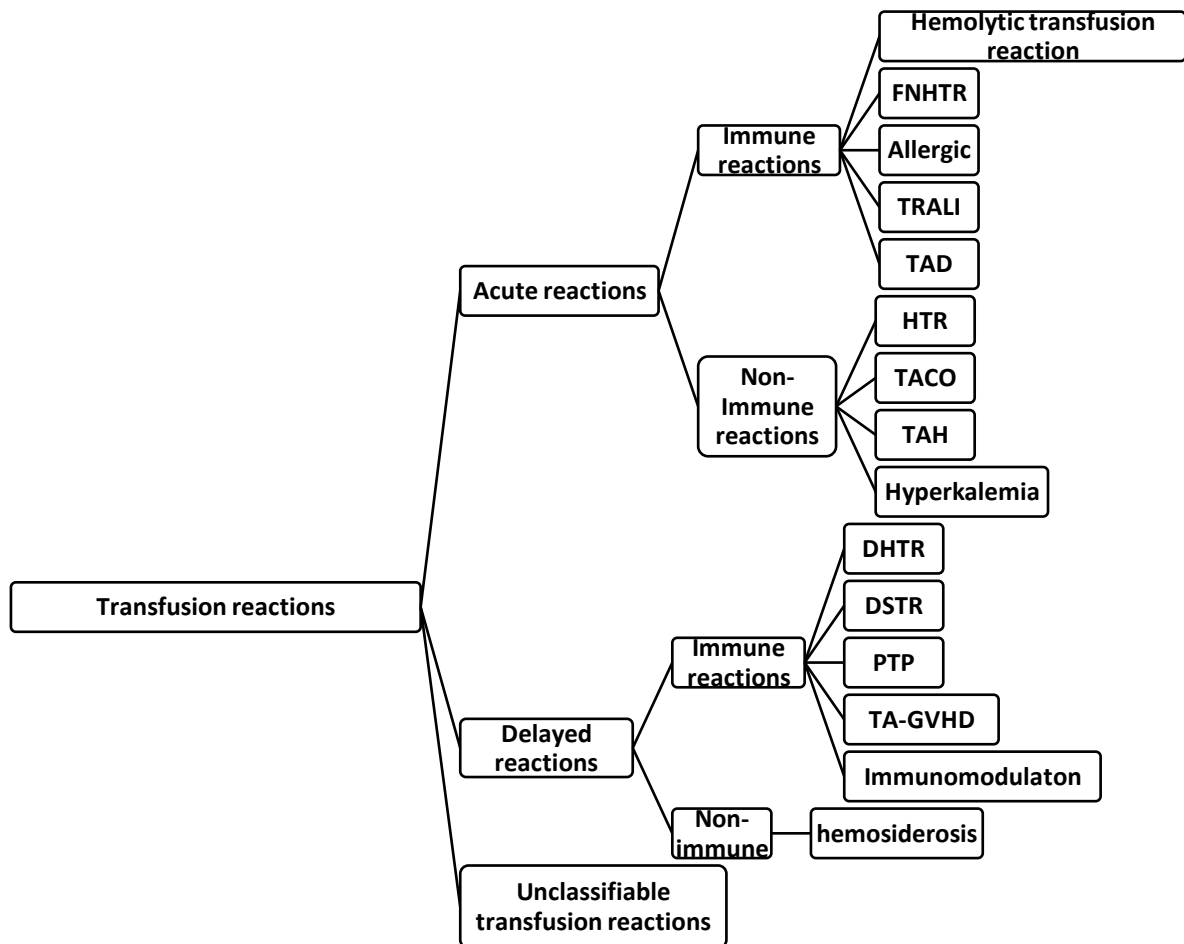
8. BLOOD TRANSFUSION REACTIONS

Risks of blood transfusion: Transfusion therapy with red blood cells and other blood products are integral in the management of various group of patients. In addition to the beneficial effects, the blood transfusion is associated with various adverse effects also which may range from mild reactions like allergic reactions to life threatening reactions like HTR and TRALI. As per the UK shot report 2016, errors associated with the patient identification are the most common cause of serious adverse reactions.

Adverse Transfusion reaction : It is an undesirable response or effect in a patient temporally associated with the administration of blood or blood components.

Classification of adverse reactions: As per ISBT standard definitions²⁸, also adopted by Haemovigilance Programme of India, the transfusion reactions may be broadly divided into two main categories :

1. Non infectious complications of transfusion: these reactions can be further divided into acute reaction occurring during or within 24 hours of transfusion and delayed reactions occurring after 24 hours of transfusion. Transfusion reaction which does not fit into the criteria of any of the defined transfusion reactions are labeled as unclassifiable transfusion reactions as shown in the figure below:



Classification of Transfusion Reactions

Classification of transfusion reactions based on their time of onset

Acute transfusion reactions	Onset during or within	Type of reaction
	1 hour	TAH
	4 hours	FNHTR, Allergic reaction
	6 hours	TRALI
	12 hours	TACO
	24 hours	HTR, TAD
Delayed transfusion reactions	Onset between	Type of reaction
	24 hrs-28 days	DHTR, DSTR
	5-12 days	Post transfusion Purpura
	7-42 days	TA-GVHD

2. **Infectious complications of transfusion:** It includes the transfusion transmitted bacterial, viral and other parasites like malaria and babesia infections. The clinical presentation of these transfusion hazards is variable depending upon the type of organisms transmitted through blood transfusion. In transfusion transmitted bacterial infection, the clinical picture may range from asymptomatic to fever to acute sepsis, hypotension and death. Various viral TTI's may present acutely or have a chronic presentation.

Definition and diagnosis of transfusion reactions:

1. **Hemolytic transfusion reaction:** A hemolytic transfusion reaction is characterized by clinical and laboratory signs of increased red cell destruction produced by blood transfusion. Hemolysis can occur intravascularly and extravascularly.
 - 1.1 **Acute hemolytic transfusion reaction (AHTR):** It has its onset during or within 24 hours of transfusion.
 - 1.1.1 **Immune AHTR:** AHTR is immune if there is positive serology with ABO incompatible transfusion, Incompatible crossmatch, Direct antiglobulin test positive with or without positive antibody screen.
 - 1.1.2 **Non - Immune :** if the serology is negative and physical cause of red cell hemolysis is present.

Clinical signs of red cell destruction:

1. Fever
2. Chills/rigors
3. Chest pain
4. Facial Flushing
5. Abdominal pain
6. Back/flank pain

7. Nausea/Vomiting
8. Diarrhoea
9. Hypotension
10. Pallor
11. Jaundice
12. Oligo/anuria
13. Diffuse Bleeding
14. Dark urine (Cola colored)

Laboratory features of red cell destruction

1. Increased Plasma Hb
2. Hemoglobinuria
3. Decreased serum haptoglobin
4. Unconjugated hyperbilirubinemia
5. Increased LDH/AST levels
6. Decreased Hb
7. Decreased fibrinogen
8. Spherocytes on Blood film.

Not all clinical or laboratory features are present in cases of hemolytic reactions

1.2 Delayed Hemolytic Transfusion Reaction (DHTR):

It usually manifests between 24 hours and 28 days after a transfusion.

- Clinical and laboratory features of red cell destruction are usually present but are less severe
- It may manifest as an inadequate rise of post-transfusion hemoglobin level or unexplained fall in hemoglobin after a transfusion
- Blood group serology usually shows positive direct antiglobulin test and positive antibody screen either due to newly formed alloantibody or preexisting alloantibody missed on pre transfusion testing.

Grades of severity : same as AHTR

- 1.3 **Delayed Serological Transfusion Reaction (DSTR)** : It is completely a laboratory diagnosis and has no clinical presentation and is characterized by demonstration of clinically significant alloantibodies against red blood cells which were previously absent(as far as is known) with absence of clinical and laboratory features of hemolysis.

2. **Pulmonary Transfusion reactions:** Pulmonary transfusion reactions are characterized by respiratory distress or pulmonary edema due to pulmonary damage produced by blood transfusion. These reactions which includes TRALI, TACO and TAD are considered as primary pulmonary reactions. Secondary pulmonary reactions occur in the wake of another transfusion reactions in which lung is not the mainly affected tissue. These include hypotensive/anaphylactic reactions, hemolytic transfusion reactions and TTBI's.

2.1 Transfusion Related Acute Lung Injury (TRALI)²⁹

2.1.1 TRALI Type - 1: Patients who have no risk factors for ARDS and meet the following criteria:

- a.
 - i. Acute onset
 - ii. Hypoxemia ($P/F \leq 300$ or $SpO_2 < 90\%$ on room air)
 - iii. Clear evidence of bilateral pulmonary edema on imaging (e.g., chest radiograph, chest CT, or ultrasound)
 - iv. No evidence of LAH or, if LAH is present, it is judged to not be the main contributor to the hypoxemia
- b. Onset during or within 6 hrs of transfusion
- c. No temporal relationship to an alternative risk factors for ARDS.

Alternate risk factors for ALI are:

- Direct Lung Injury
 - Aspiration of gastric contents
 - Pneumonia
 - inhalational injury
 - Lung contusion
 - Near drowning
 - Pulmonary vasculitis
- Indirect Lung Injury
 - Non pulmonary sepsis
 - Non cardiogenic Shock
 - Major trauma
 - Severe Burns
 - Acute pancreatitis
 - Cardiopulmonary Bypass
 - Drug Overdose

2.1.2 **TRALI** type 2 : patients who have risk factors for ARDS (but who have not been diagnosed with ARDS) or who have existing mild ARDS (P/F of 200-300), but whose respiratory status deteriorates and is judged to be due to transfusion based on:

- a. Findings as described in categories a and b of TRALI Type 1, and
- b. Stable respiratory status in the 12 hrs before transfusion

2.2 **Transfusion Associated Circulatory overload (TACO)** (IHN/ISBT working party on hemovigilance and AABB): It is characterized by presence of a total of 3 or more of the criteria below:

- **Acute or worsening respiratory compromise:** It is manifested by tachypnoea, shortness of breath, cyanosis and decreased oxygen saturation values. Clinical finding could include crackles on lung auscultation, orthopnea, cough, a third heart sound and pinkish frothy sputum in severe cases.
- **Radiographic chest imaging and/or other non-invasive assessment of cardiac function e.g. echocardiogram.** The findings which suggest pulmonary oedema from circulatory overload include presence of new or worsening pleural effusions, widened vascular pedicle, progressive lobar vessel enlargement, peribronchial cuffing, bilateral Kerley lines, alveolar oedema with nodular areas of increased opacity and/or cardiac silhouette enlargement.
- **Evidence of cardiovascular system changes not explained by the patient's underlying medical condition,** including development of tachycardia, hypertension, widened pulse pressure, jugular venous distention, enlarged cardiac silhouette and/or peripheral oedema.
- **Evidence of fluid overload** including any of the following: a positive fluid balance; response to diuretic therapy e.g. from diuretic therapy or dialysis combined with clinical improvement; and change in the patient's weight in the peri-transfusion period
- **Supportive result of a relevant biomarker e.g. an increase of B type natriuretic peptide level** (e.g., BNP or NT-pro BNP) above the age group-specific reference range and greater than 1.5 times the pre transfusion value. A normal post-transfusion NP level is not consistent with a diagnosis of TACO; serial testing of NP levels in the peri-transfusion period may be helpful in identifying TACO.

Occurring during or up to 12 hours after transfusion

2.3 **Transfusion associated dyspnoea (TAD):** It is characterized by respiratory distress within 24 hours of transfusion that does not meet the criteria of TRALI, TACO, or allergic reaction.

Grades of severity : same as AHTR

3. **Cardiovascular Transfusion reactions:** Cardiovascular transfusion reactions are characterized by change in Blood pressure and pulse rate. Hypotension, tachycardia and hypertension are generally secondary to other transfusion reactions or may be associated with anxiety. Hence, other transfusion reactions should be excluded before making a diagnosis of cardiovascular involvement. The only primary cardiovascular transfusion reaction known is Hypotensive transfusion reaction.

3.1. **Hypotensive transfusion reaction:** This reaction is characterized by hypotension defined as a drop in systolic blood pressure of more than or equal to 30 mm Hg occurring during or within one hour of

completing transfusion and a systolic blood pressure less than or equal to 80 mm Hg and all other transfusion reactions presenting with hypotension are excluded.

- Most reactions do occur very rapidly after the start of the transfusion (within minutes). This reaction responds rapidly to cessation of transfusion and supportive treatment.
- Hypotension is usually the sole manifestation but facial flushing and gastrointestinal symptoms may occur. It is more frequently seen in patients on ACE Inhibitors.

4. **Systemic Transfusion reactions :** These transfusion reactions are characterized by general physical signs and symptoms and may involve multiple organ systems.

1.1 Febrile non hemolytic transfusion reaction (FNHTR)

Presence of one or more:

- Fever ($\geq 38^{\circ}\text{C}$ / 100.4°F oral or equivalent and a change of $\geq 1^{\circ}\text{C}$ / 1.8°F from pre-transfusion value)
- Chills/rigors

This may be accompanied by nausea and headache.

Occurring during or within 4 hours following transfusion.

Without any other cause such as hemolytic transfusion reaction, bacterial contamination or underlying condition.

FNHTR Could be present in absence of fever (chills and rigor present)

1.2 Allergic reaction

It may present only with mucocutaneous signs and symptoms:

- Morbilliform rash with pruritus
- Urticaria
- Localized angioedema
- Edema of lips, tongue, uvula
- Periorbital pruritus, erythema and edema
- Conjunctival edema

Occurring during or within 4 hours of transfusion.

TA-GVHD: TA-GVHD is a clinical syndrome characterized by symptoms of fever

- Characteristic rash : erythematous, maculopapular eruption centrally that spreads to extremities and may, in severe cases, progress to generalized erythroderma and haemorrhagic bullous formation

- Liver dysfunction
- Diarrhea
- Pancytopenia
- Characteristic histological appearance on biopsy
- Occurring 1-6 weeks following transfusion with no other apparent cause.
- The diagnosis of TA-GVHD is further supported by the presence of chimerism.

4.4 Post transfusion Purpura:

PTP is characterized by thrombocytopenia arising 5-12 days following transfusion of cellular blood components with finding of antibodies in the patient directed against the human platelet antigen(HPA) system.

Do's after an acute transfusion reaction:

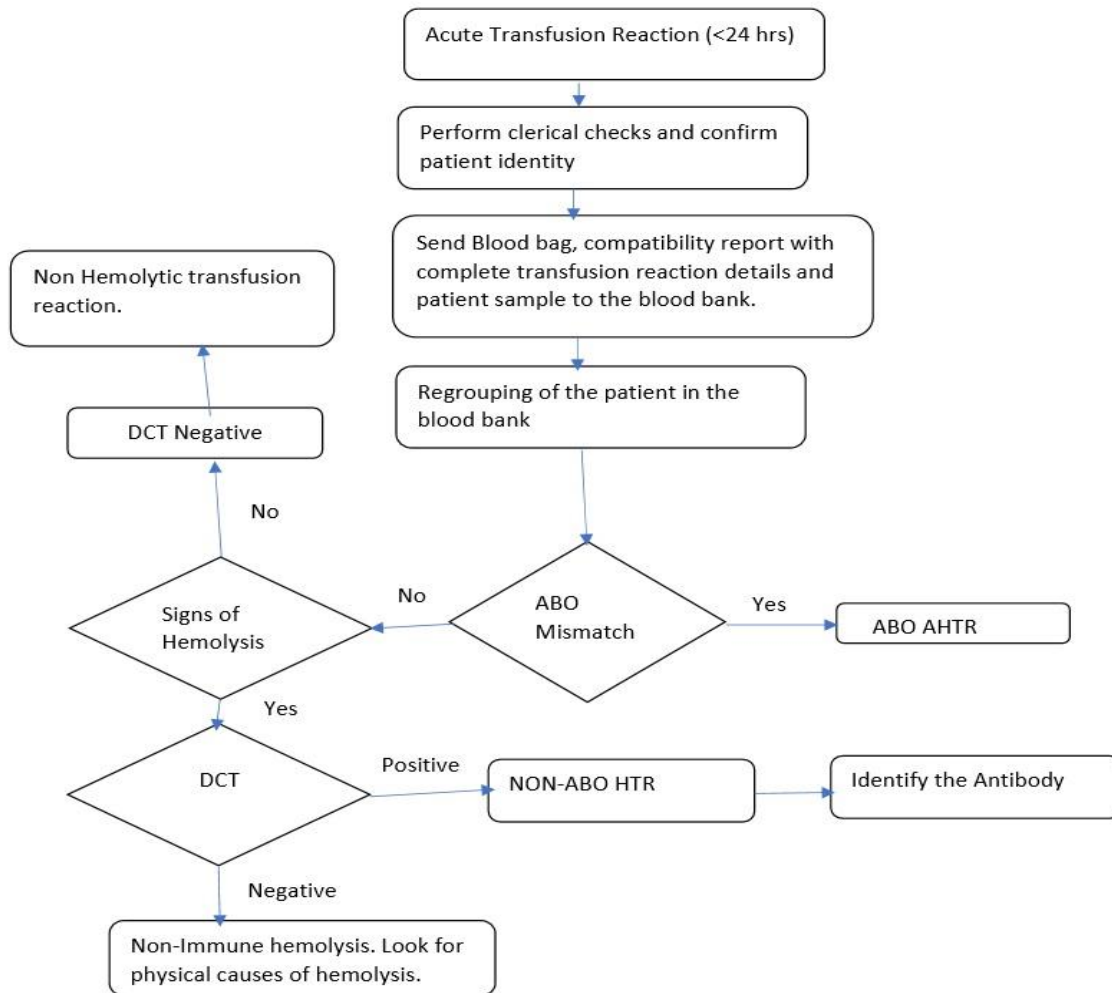
1. Identify the patient to rule out any mismatched transfusion
2. Take immediate note and inform blood centre
3. Do not restart the transfusion from the same bag
4. Record the vitals : temperature, pulse rate, respiratory rate, Blood pressure and oxygen saturation.
5. If the patient is on ventilator, record the ventilator setting pre and post transfusion.
6. Complete the transfusion reaction form and appropriately record the following:
 - a. Clinical sign and symptoms
 - b. Time after the start of transfusion to the occurrence of reaction
 - c. Unit no. and volume of component transfused
7. Send clotted and EDTA samples along with BT Set (if available) to the blood centre for immunohematological work up to rule out any immune cause of hemolysis
8. Investigations:

Type of transfusion reactions	Investigations to be sent
Universally indicated to be sent in all cases of transfusion reactions	Repeat blood grouping Direct coombs test (DCT) Complete blood count
Febrile reactions and suspected TTBI	Blood culture of the bag and patient.
Hemolytic transfusion reaction	Plasma and urine haemoglobin Renal function test Liver function test Coagulation screen
Respiratory transfusion reactions	Chest X-ray, B-type natriuretic peptide level

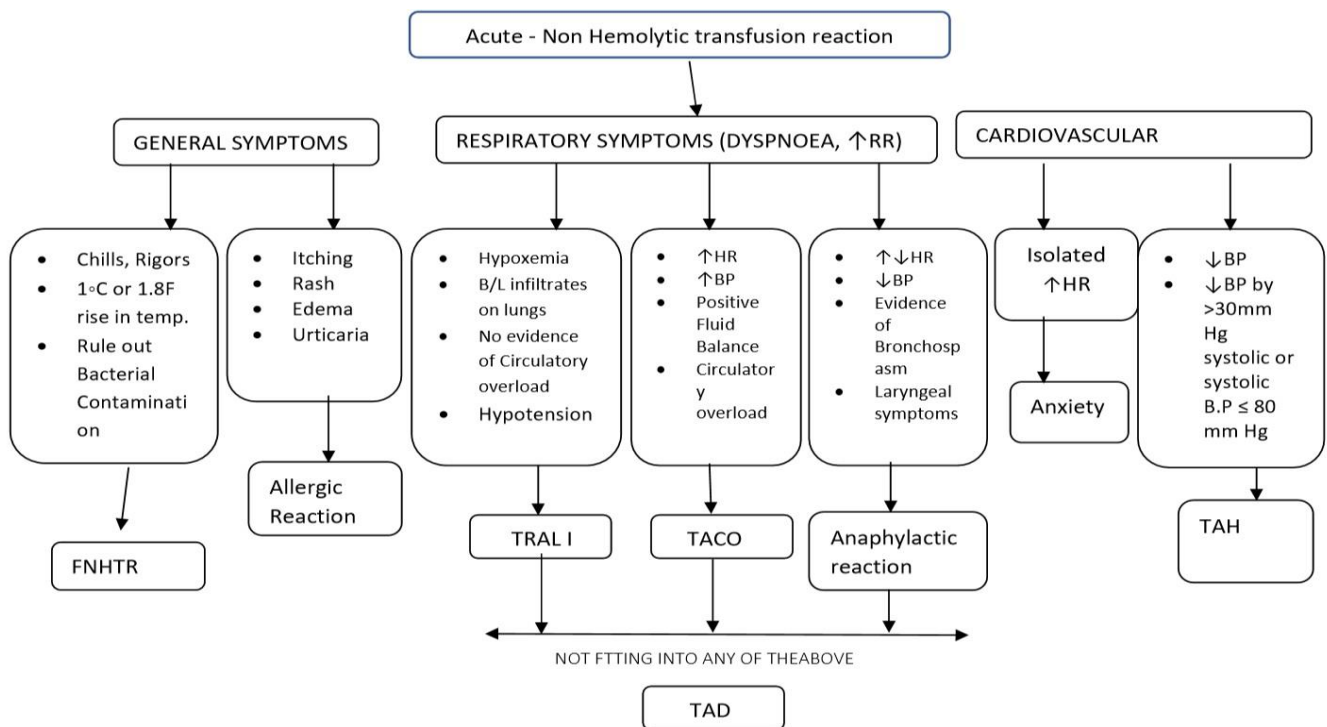
9. Identify and diagnose the reaction based on clinical evaluation.

Below diagram shows common clinical sign and symptoms and their differential diagnosis

Clinical symptoms	AHTR	FNHTR	Allergic	Anaphylaxis	TACO	TRALI	Bacterial sepsis
Fever	+	+	-	-	-	+	+
Hypotension	+	-	-/+	+	-	+	+
Urticarial rash	-	-	+	+	-	-	-
Resp. Distress	+	-	-	+	+	+	+
Hemoglobinuria	+	-	-	-	-	-	-
Urine output	+	-	-	-	+	-/+	-/+
Non Specific Symptoms	+	-	-	-	+	-	-



Flowchart 1. An aid to exclude hemolysis as a cause of transfusion reaction.



Flowchart 2 Differential diagnosis of Acute non hemolytic transfusion reactions

Management of Transfusion Reactions⁶:

1. Transfusion should be stopped immediately
2. Start symptomatic treatment like in febrile and allergic reactions, antipyretics and anti-histaminics are given respectively. If not controlled, corticosteroid can be given.
3. In cases of life threatening reactions, the treatment should be initiated immediately based on clinical sign and symptoms:
 - keep IV line open with normal saline in another site.
 - Infuse normal saline to maintain systolic BP.
 - Maintain airway and give high flow oxygen by mask.
 - Give IV corticosteroids and bronchodilators if there are anaphylactic features.
 - Adrenaline (as 1:1000 solution) 0.01 mg/kg body weight by slow intramuscular injection is given for severe anaphylactic reaction not controlled by corticosteroids.
 - Give diuretic if hypertensive with respiratory difficulty (TACO): e.g. frusemide 1 mg/kg IV or equivalent.
 - Check a fresh urine specimen visually for signs of haemoglobinuria.
 - Notify the blood centre immediately.

- Maintain fluid balance chart.
- Assess for bleeding from puncture sites or wounds. If there is clinical or laboratory evidence of DIC, give platelets (adult: 4-6 units) and either cryoprecipitate (adult: 12 units) or FFP (adult: 3 units).
- Reassess. If hypotensive:
 - Give further saline.
 - Give inotrope, if available.
- If urine output falls or there is laboratory evidence of acute renal failure (rising K⁺, urea, creatinine)
 - Maintain fluid balance accurately.
 - Give further diuretic: e.g. frusemide 1 mg/kg IV or equivalent.
 - Consider dopamine infusion, if available.
 - Seek expert help: the patient may need renal dialysis.
- If bacteraemia is suspected (rigor, fever, collapse, no evidence of a haemolytic reaction), start a broad-spectrum antibiotic IV.

With the exception of urticarial allergic and febrile non-haemolytic reactions, all are potentially fatal and require urgent treatment. The severity of the reaction and the degree of morbidity is usually related to the volume of blood transfused.

Grades of severity of transfusion reactions (ISBT)

Grade 1 (Non Severe): the recipient may have required medical intervention (e.g. symptomatic treatment) but lack of such would not result in permanent damage or impairment of a body function

Grade 2 (Severe): the recipient required in-patient hospitalization or prolongation of hospitalization directly attributable to the event OR persistent or significant disability or incapacity OR Medical or surgical intervention required to preclude permanent damage or impairment of a body function.

Grade 3 (Life threatening): the recipient required major intervention following the transfusion (vasopressors, intubation, transfer to intensive care) to prevent death.

Grade 4 (Death): the recipient died following an adverse reaction and the death is possible, probably or definitely related to transfusion.

If the recipient died of another cause, the severity of the reaction should be graded as 1,2 or 3

Imputability (ISBT) : This is, once the investigation of the adverse transfusion event is completed, the assessment of the strength of relation to the transfusion of the ATE.

Definite (certain): when there is conclusive evidence beyond reasonable doubt that the adverse event can be attributed to the transfusion

Probable (likely): when the evidence is clearly in favor of attributing the adverse event to the transfusion

Possible: when the evidence is indeterminate for attributing the adverse event to the transfusion or an alternate cause

Unlikely (doubtful): when the evidence is clearly in favor of attributing the adverse event to causes other than the transfusion

Excluded: when there is conclusive evidence beyond reasonable doubt that the adverse event can be attributed to causes other than the transfusion

Key Points :

1. All the adverse transfusion reactions should be reported to the Blood centre for further investigation to rule out hemolysis occurring due to blood transfusion.
2. Complete and accurate report of transfusion reaction helps blood centres to provide modified blood components to prevent recurrence of the reaction.
3. Transfusion reaction can develop during or after the blood transfusion.
4. Staff involved in monitoring of patients who have received blood transfusion should be trained to identify any adverse reaction and start timely treatment.

9. PATIENT BLOOD MANAGEMENT

Definition⁹: It is a patient-focused, multi-disciplinary, evidence-based and systematic approach to optimize the management of patient and transfusion of blood products for quality and effective patient care.

Essential elements of patient blood management:

1. Optimize a patient's blood levels before a surgical or medical treatment.
2. Appropriate diagnosis and optimal treatment.
3. Use of alternatives to transfusion.
4. Good surgical and anaesthetic techniques.
5. Use of alternatives to blood transfusion.
6. Blood conservation.
7. Physician Education and changing physician behaviour

Scope of PBM: The primary aim of PBM is to improve patient safety and clinical outcomes by appropriately managing the patient's own blood and by minimizing unnecessary exposure to allogenic blood products.

PBM in medical settings

1. Replacement fluids : crystalloid and colloid
2. Limit iatrogenic loss
3. Tolerate low haemoglobin, maximize oxygen delivery (hyperbaric Oxygen)
4. Monitor bleeding
5. Treatment and prevention of Anemia: Anemia in patients with medical disorders are multifactorial and may affect the prognosis. Potentially reversible causes of anemia like mineral/vitamin deficiencies, hypersplenism, malnutrition, alcohol induced marrow aplasia or anemia should be explored, diagnosed and managed appropriately to reduce the need for allogenic blood transfusion.¹³ (Gonzalez-Casas R)
6. Appropriate transfusion strategy in medical conditions requiring multiple blood transfusions.
 - a. Prophylactic FFP transfusion in liver disorders has been questioned by a large metaanalysis for its clinical effectiveness¹⁴.
7. Majority of national and international scientific societies recommends restrictive transfusion policy as various studies has shown its benefit in terms of patient outcome, minimizing need of transfusion and its associated complications.^{15,16}
8. Use of viscoelastic assay to guide the blood component therapy has also be shown to reduce the allogenic blood exposure.

9. Increasing Tolerance of Anemia

- a. Increasing oxygen delivery or decreasing oxygen consumption
- b. Optimize hemodynamic status and maintain normovolemia using vasopressors and appropriate ventilation
- c. Adequate pain control or sedation
- d. Maintaining normothermia and promptly treating infections.

PBM in Surgical (perioperative) setting: It can be categorized into three phases : pre-operative, intraoperative and post operative. Optimizing the patient's red cell mass, minimizing the blood loss and exploiting the capacity of the patient for tolerance of anemia are the three main strategies which can be implemented to minimize the allogenic blood requirement with better patient outcome as detailed in the table below:

	Optimize red cell mass	Minimise blood loss and bleeding	Harness and optimize physiological reserve of anemia
pre-operative	<ul style="list-style-type: none"> • Identification and management of any underlying condition causing anemia • treat suboptimal iron stores, iron deficiency, anemia of chronic disease and iron restricted erythropoiesis (pre-operative anemia clinics) • Treat other haematinic deficiencies 	<ul style="list-style-type: none"> • identify and manage bleeding risk • minimise iatrogenic blood loss • Appropriate procedure planning • Stop medications, including some natural and herbal medicines, which can increase the risk of bleeding. 	<ul style="list-style-type: none"> • Assess /optimize patient's physiological reserve and risk factors • compare estimated blood loss with patient specific tolerable blood loss • Acute normovolumic hemodilution
intra operative	<ul style="list-style-type: none"> • time surgery with haematological optimization 	<ul style="list-style-type: none"> • meticulous haemostasis and surgical technique • Blood sparing surgical devices • anaesthetic blood conserving strategies 	<ul style="list-style-type: none"> • optimize cardiac output • optimize ventilation and oxygenation

		<ul style="list-style-type: none"> • Autologous blood options • maintain normothermia • pharmacological and haemostatic agents like anti-fibrinolytics, Desmopressin and topical haemostatic agents • deliberate controlled hypotension. • Point of care testing(Visco-elastic assays) 	
post operative	<ul style="list-style-type: none"> • optimize erythropoiesis • Be aware of drug interactions that can increase anemia 	<ul style="list-style-type: none"> • vigilant monitoring and management of post operative bleeding • Avoid secondary haemorrhages • Rapid warming and normothermia • Autologous blood salvage • Minimise iatrogenic blood loss • Haemostasis/anticoagulation management • prophylaxis of upper GI haemorrhage • Avoid/treat infections promptly 	<ul style="list-style-type: none"> • maximize oxygen delivery • Minimise oxygen consumption • Avoid/treat infections promptly • Restrictive transfusion thresholds

Pre-operative Autologous Blood donation : Autologous blood is collected from the patient 3-4 weeks prior to the scheduled procedure. Patient should be in good health and fulfil the criteria for autologous donation. In the last several decades, PAD has declined in number due to associated high error rate and availability of better intraoperative blood salvage techniques.

Acute Normovolemic Hemodilution : it involves removal of patient own blood before or shortly after the beginning of the surgical procedure in which high blood loss(>1500ml) is anticipated and infusion of crystalloid and colloid to maintain the circulatory volume. This causes decrease in hematocrit of the patient and red cell loss during the surgical bleed is minimized. Patient own blood with high (pre-operative) hematocrit is transfused to maintain the haemostasis. Blood collected is stored at room temperature during the procedure, hence platelets and coagulation factors remain preserved in it.

Autologous blood recovery (Intraoperative and post-operative phase): In Autologous blood recovery, the shed blood during the surgical procedure is collected and reinfused after washing with normal saline. Washing removes plasma, platelets, red cell stroma, contaminants and anticoagulants. It is more efficacious in high blood loss surgeries with minimal risk of bacterial contamination like cardiothoracic, vascular, orthopedic surgeries. In case of cancer surgeries and obstetric bleed, there are chances of reinfusion of tumour cells and amniotic fluid which can be minimized by using double suction set up and leukocyte reduction filters. However, the risk is only theoretical not supported by any scientific evidence.

Role of hospital transfusion committee (HTC) in PBM :

1. Clinical practice guidelines: Various scientific bodies have given guidelines for blood component transfusion. Rational blood use as per the guidelines and following restrictive threshold leads to decrease in allogenic blood exposure and better patient outcome. For the implementation of these guidelines at the institutional level, approval from the HTC is required.
2. To improve awareness among HTC members to explore improvement in PBM within respective departments.
3. Transfusion Audits which include systematic review of the use of transfusion of blood products against the transfusion guidelines with the aim of improving the transfusion services in the institute.

Key points:

1. It is a patient-focused, multi-disciplinary, evidence-based and systematic approach to optimize the management of patient and transfusion of blood products for quality and effective patient care.
2. It promotes appropriate rational blood component transfusion and prevents its overutilization.
3. It reduces the transfusion associated risks and improves quality of care in patients requiring transfusion.
4. In India, we have high incidence of anemia especially in female population. Treating pre-operative anemia reduces the need for transfusion during the surgical procedure.
5. PBM is not limited to optimizing transfusion therapy. It involves the use of hemostatic drugs, blood recovery techniques, limiting surgical blood loss and medical education.
6. Role of HTC is critical for the implementation and success of the PBM programme in an institute.

10. TRANSFUSING CLINICIAN AND BLOOD CENTRE

a. Hospital transfusion committees (HTC)

HTC (also called as blood transfusion committee) is a body where all the key stakeholders involved in blood transfusion come together to decide, monitor and intervene for blood transfusion related policies and procedures in a healthcare organization. An HTC consists of blood centre doctor as the convener and major users of blood, like cardiac surgery, obstetrics department doctors as members along with an administrator, nursing head and laboratory doctors as key members. A chairman is selected from amongst the members. Annual and preferably a quarterly meeting of the HTC should be convened where members can decide on the best transfusion practices in their institute. HTC's utility in improving the blood transfusion practices in a healthcare setting is now internationally accepted. Formulation of a working HTC is also a regulatory requirement in India (Drugs and Cosmetics Act 1940 and rules thereunder). The HTC plays a key role in enhancing safety, efficacy, and efficiency of blood centre services³⁰. **Annexure 5** details the key members and the functions of an HTC in an institute.



The majority of research questions, priorities and strategies of Low-Medium Income Category (WHO classification) countries fall into the areas of: blood availability, blood transfusion safety, appropriate use of blood, quality systems, health

HTC works towards the best interests of the patient as well as healthcare provider. Few practical goals of any HTC should be:

- i. Enumerating clear, documented and authorized processes with assigned responsibilities in a blood transfusion chain.
- ii. Approving blood requisitioning process, blood sample requirement, blood reservation, transport conditions, rationale use, alternative blood groups, adverse reaction reporting and return of blood units for disposal.
- iii. Monitoring shortages and wastages of blood components.
- iv. Monitoring quality indicator for blood transfusion services.
- v. Research in blood transfusion as per the local needs

11. DOCUMENTATION IN BLOOD TRANSFUSION

Following documents form an essential part of blood transfusion in a patient:

- i. Indication for blood transfusion, supported by relevant clinical/ laboratory parameters.
- ii. Informed consent for blood transfusion
- iii. Written prescription by a registered medical practitioner.
- iv. Compatibility report and/ or label.
- v. Start and completion time of each blood unit.
- vi. Relevant vitals and patient condition before, during and immediately after transfusion.
- vii. Occurrence and management of any adverse transfusion reaction and reporting. **Annexure 6**
- viii. Documentation of outcome of blood transfusion (e.g. Hb increased, bleeding stopped, etc.) is desirable in patient records.

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LIST OF ANNEXURES

Annexure – 1: NCDR judgment regarding blood transfusion consent. (Attachment)

Annexure – 2: Model blood transfusion consent form.

Annexure - 3: ISBT code of ethics (attachment)

Annexure – 4: Model blood requisition form (attachment)

Annexure – 5: Hospital Transfusion Committee

Annexure – 6: Transfusion reaction and reporting form (TRRF): HvPI (attachment)

Annexure 1

M. Chinnaiyan vs Sri Gokulam Hospital And Anr. on 25 September, 2006

National Consumer Disputes Redressal

M. Chinnaiyan vs Sri Gokulam Hospital And Anr. on 25 September, 2006

Equivalent citations: III (2007) CPJ 228 NC

Bench: K G Member, P Shenoy

ORDER P.D. Shenoy, Member

1. Aggrieved and dissatisfied by the order of the State Consumer Disputes Redressal Commission, Chennai, which had dismissed his complaint, the complainant (husband of the deceased) has filed this appeal before us. The dispute in this case falls in narrow compass i.e. whether transfusion of two units of blood to the complainant's wife in the post-operative period in December 1990 could result in full blown AIDS in mid, June, 1994.

Briefly stated facts of the case are as under:

2. Smt. R. Lalitha while taking treatment for abdominal pain at Gokulam Hospital (1st opposite party) before the State Commission was advised to undergo hysterectomy, which was performed by Dr. P. Chellammal, Gynaecologist in December 1990. She was transfused two units of blood in the postoperative period in that hospital which was allegedly procured from Queen Mary's Clinical Laboratory, which is the second opposite party before the State Commission. In mid-1994 the patient developed recurrent loose motion, weight loss, respiratory infection and difficulty in swallowing, for which a blood test was done by the second opposite party which showed that HIV antibodies were present. Therefore she was referred to YRG Centre for AIDS Research and Education, wherein ELISA test was done in June 1994 which confirmed that complainant's wife was infected with HIV. She underwent medical treatment at YRG Centre. In July 1995, complainant's wife developed left sided hemiparesis, oral candidiasis and pulmonary tuberculosis. She was hospitalized at CSI Kalyani General Hospital, Madras in July 1995. As she became unconscious, a CT Scan was done and where the disease was diagnosed as glioma of the brain, for which she was admitted in Raju Hospital at Madras on 12.8.1995 where she died on 16.8.1995.

Case of the appellant:

3. In late 1990 R. Lalitha the complainant suffered from bleeding of uterus and was admitted to R1 - Sri Gokulam Hospital wherein hysterectomy was performed on 21.2.1990. Subsequent to the operation, two units of blood was transfused to the patient which was brought from R2 - Queen Mary's Clinical Laboratory which did not conduct any test to satisfy itself that it was free from infection like HIV, etc. The hospital authorities (R1) also did not cross check whether there is a certificate in this regard. The treating doctor should satisfy himself that the blood is free from infection which she did not do. In June 1994 when the patient suffered from multiple diseases for which she did not have immunity, blood was tested and found to be HIV+. This gap of 3½ years is categorized in medical texts as "Aid Symptomatic period". The blood was obtained by the first opposite party from the second opposite party's laboratory. But for the uterine problem the complainant's wife had no other illness. In mid-1994 she developed several problems. The complainant had paid the first and second opposite parties the surgery costs, postoperative care cost as well as the cost of the blood. The second opposite party which supplied the blood had not tested

M. Chinnaiyan vs Sri Gokulam Hospital And Anr. on 25 September, 2006

the blood to ensure that the blood was free from the deadly HIV. Any blood bank/laboratory supplying blood is duty-bound to ensure that the blood supplied is free from HIV and other infections. The second opposite party had failed to carry out the test required to ensure that the blood was not infected. The blood supplied by the second opposite party to the first opposite party for transfusion had HIV antibodies. The first opposite party also owed a duty to the patient to ensure that the blood which it was transfusing her was free from HIV/AIDS. There was thus a gross and patent negligence on the part of both the opposite parties while transfusing the blood with the result that the complainant's wife was infected with HIV by the transfusion of HIV contaminated blood. The complainant's wife lost her life on account of this negligence and deficiency in service on the part of the opposite parties.

4. Out of the three modes of transmission of HIV/AIDS the most dangerous one is through the transfusion of blood having the virus. The sole reason for the complainant's wife developing HIV/AIDS was the transfusion of the blood contaminated with the HIV virus done by the opposite parties after the operation in December 1990. The complainant's wife and the complainant have led clean lives and there was absolutely no other reason for her getting HIV infection which led to her death. The HIV infection developed into full blown AIDS 3% years later. It is well known that persons who are infected with HIV develop complications subsequently after the gestation period/window period. The virus remains dormant in the body and strikes the body's immune system later. The period between the entry of the virus and onset of the disease could be several years depending on several factors.

Submissions by the learned Counsel for the appellant:

5. The learned Counsel for the appellant submitted that blood transfusion was given without obtaining the consent of the patient.

6. The State Commission in its order had noted that complainant's wife and the complainant had led clean lives and there was absolutely no other reasons for her getting HIV infection which led to her death.

7. Under the Drugs and Cosmetics Rules, 1945, an amendment was introduced through which Rule 66A came into effect on 11.7.1989 which shows that every licensee of a blood bank shall get sample of every blood unit tested for freedom from HIV antibodies from such laboratories may be specified for the purpose by the Central Government. The date of performing such test shall be recorded on the label of the container also. As the blood was supplied in December 1990 respondent No. 2 was bound to comply with this legal requirement.

8. In the book under the caption 'HIV (Pathogenesis and Natural History)' by Howard Libman, MD and Harvey J Makadon, MD it has mentioned that the acute HIV syndrome has been documented between 6 and 56 days after a known exposure, with an average incubation of approximately 2 weeks. The duration of symptoms has ranged from 5 to 60 days, with reported averages ranging from 2 to 4 weeks (44-46, 51, 57, 64). Symptoms are usually acute in onset, and manifestations include fever, generalized lymphadenopathy, pharyngitis, headache, rash, myalgia and arthralgia.

M. Chinnaiyan vs Sri Gokulam Hospital And Anr. on 25 September, 2006

There is considerable variability in the clinical presentation.

9. Progression to Symptomatic HIV Disease - When the high viral levels associated with acute HIV syndrome are suppressed by the initial immunologic response, an infected person generally moves into an asymptomatic period that may range from several months to more than 10 years. Although symptoms are not present during this period of clinical latency, viral replication is ongoing, leading to a loss of approximately 10% of CD4 cells per year in most individuals.

10. Unguarded sex, use of same needle for injection, blood transfusion are the known causes of HIV infection, whereas percentage of certainty in the first two causes are low, but in the case of blood transfusion it is more than 99%. Therefore, learned Counsel submitted that it is necessary that the patient or the guardian be told about the risk of blood transfusion.

In *Chhatterton v. Gerson and Anr.* (1981) 1 ALL ER 257, it is held that-

The duty of a doctor was to explain to the patient what he intended to do and the implications of that action in a way that a careful and responsible doctor would do in similar circumstances; that where a patient had been given some explanation of the action proposed to be taken so that there was a real consent to the operation, an action would lie in negligence if there was a failure to inform the patient of the nature of the operation and its implications and the patient proved that, if a proper explanation had been given, she would not have consented to the operation; and that since the plaintiff had failed to prove that she had not been given details of the operation and its implications, her action both in trespass and negligence failed (post, pp. 442 H-443B, 445B) In *Reibl v. Hughes* (1997) 78 DLR (3d) 35 it stated that-

Action for damages for trespass to person and negligence. Plaintiff suffered severe headaches. Medical examination revealed plaintiff suffering from major occlusion of artery which should be surgically removed. During operation plaintiff suffered massive stroke. Held : Duty of surgeon to explain problems caused by such a complaint and to explain specific risks of surgery/of this kind. Duty also to explain risks of continuing without surgery. Defendant had only told plaintiff of mechanics of operation. Failed to communicate purpose or gravity of operation or risks involved. Defendant negligent in failing to carry out this duty. Liable also in battery. Plaintiff suffered permanent paralysis of right side of body, leaving him impotent, unfit for work and with no hope of working again. Was 44 years old at time of injury. Good work record. In expectation of substantial accident disability and retirement benefits if he had been able to remain with his employer for ten years. General damages of \$ 225,000.00 ACWS.

Submissions of the learned Counsel for respondent No. 1:

11. Learned Advocate for the respondent submitted that consent for the surgery was taken before operation was performed-

I am hereby giving my consent for doing operation in my wife for removal of her uterus after giving anesthesia.

M. Chinnaiyan vs Sri Gokulam Hospital And Anr. on 25 September, 2006

This consent note can be interpreted to include blood transfusion as the patient was suffering from anemia, it urgently require blood transfusion.

12. It is mentioned in the clinical note of the Gokulam Hospital on 29.12.1990 'reserve one bottle of blood' which was in the knowledge of the complainant. It is also mentioned in the nurses note dated 29.12.1990, 'Queen Mary's reserved one bottle of blood.' Hence, blood was obtained from Queen Mary's Clinical Laboratory and it was their responsibility to supply pure blood as it was a recognized laboratory. Dr. Chellammal has stated that as the laboratory was well established and Government approved blood bank and since the blood was certified to be free from infection it was administrated without any further second test. Complainant's wife perfectly recovered from the ailment and the wounds also had healed well. Further, Dr. Suniti Solomon has stated that it is medically impossible for her to say that the complainant's wife had acquired HIV through blood transfusion.

13. The complaint is time-barred as it was filed on 30.4.1996. Though she was operated in December 1990.

Submissions by the learned Counsel for the respondent No. 2 and his written arguments:

14. Learned Advocate for respondent No. 2 submitted that there are two issues which are involved in this case; one is whether R1 had obtained the consent of the complainant or his wife for conducting the surgery. R2 is not concerned with this. The second issue is whether R2 had supplied blood and if so whether it was impure. It is contended by R2 that no blood was supplied by R1 or R2. There is no proof and no receipt has been obtained. R1 has stated that she did not obtain the blood from R2 only the patient's attendant brought it from R2. The complainant has not produced the receipt for having made payment to R2 for obtaining the blood. The learned Counsel stated that he will submit the attested copy of the affidavit produced before the State Commission wherein it has been stated that this blood was not supplied by R2. Exh. A18 is a bogus and forged document. This is not issued by Queen Mary's Clinical Laboratory.

15. In his written arguments the learned Counsel for the respondent has submitted that the following facts will emerge from the stand taken by the parties:

(a) The complainant admittedly never procured two units of blood on his own, but says on oath that it was independently procured by the respondent No. 1

(b) The respondent No. 1 admittedly never procured the blood from the respondent No. 2 but states on oath that the complainant has independently procured the blood from respondent No. 2.

(c) The respondent No. 2 says that it has never supplied blood either to the complainant, or to the respondent No. 1 ever since its inception in the year 1987.

16. He further submitted that the complainant has not produced any receipt relating to the alleged purchase of any blood from any person, leave alone the respondent No. 2. The respondent No. 2 has filed documents/affidavits which are fabricated. A perusal of the same shows that it does not by any

M. Chinnaiyan vs Sri Gokulam Hospital And Anr. on 25 September, 2006

stretch of imagination shows the evidence of purchase of blood from respondent No. 2. No such ground has been taken by the appellant before this Commission, therefore, the complainant cannot make this as an oral submission at this stage of final arguments not having pleaded so. He also submitted that his institution strictly follows the procedure for the sale of blood as laid down in the Drugs and Cosmetics Act, 1940 and the Rules framed thereunder.

Analysis of evidence:

17. Dr. P. Chellammal, Gynaecologist who performed the operation at Gokulam Hospital in her counter affidavit had stated that it is not factually correct that the patient was administered with two units of blood during post-operative period, that too, without the consent of the patient. It is also false to say that the blood was obtained by the 1st opposite party from the 2nd opposite party. The doctor has further stated that none of the relatives, including the complainant could donate blood and they themselves have secured the blood from the 2nd opposite party which is a Government recognized approved blood bank and allegation is that the blood was secured from the 2nd opposite party by the 1st opposite party is false. Further it is stated that the 2nd opposite party is a recognized and Government approved blood bank and since it was certified that the blood supplied was free from any infection of communicable or transmittable disease the blood was not tested before transfusion. It is true that the blood banks are duty bound to supply blood which are free from any infections or communicable viruses.

18. As against this affidavit of the Gynaecologist who performed the surgery on the complainant's wife, the complainant has given his affidavit. The relevant extract is given below:

The complainant's wife was transfused two units of blood in the surgery. The blood was obtained by the first opposite party from the 2nd opposite party's laboratory. At the relevant time Thiru M Somasundaram was the Assistant in the 2nd opposite party's laboratory and he had delivered the blood to the first opposite party.

19. In the proof affidavit, Dr. P. Chellammal has stated that the 2nd opposite party is a renowned blood bank in Salem. It is a Government recognized blood bank. The 2nd opposite party has got a laboratory also and since the blood was certified that it was free from infection of any communicable or contagious diseases, there was no necessity to counter test the blood, nor was there any reason to suspect the correctness of the certificate. Hence, the 1st opposite party did not test the blood and she respectfully submits that it was not an act of negligence on her part.

Further it is pertinent to mention a vital fact that during the year 1990's HIV cases were not reported in Salem or for that matter in Tamil Nadu itself and therefore there was no occasion for the first opposite party to have any suspicion of infection of blood by HIV and in this case, the 3rd opposite party is a well established Government approved blood bank and since the blood was certified to be free from any infections, it was administered without any further second test. Therefore, there was no negligence on the part of the first opposite party in administering blood.

M. Chinnaiyan vs Sri Gokulam Hospital And Anr. on 25 September, 2006

It is more pertinent to mention another vital fact that if blood was taken from a person who was infected with HIV/AIDS virus immediately after infusion, the infection will not be able to be detected in testing by any method and the period during which such detection is not possible is popularly called as 'window period'. Medical Science has established that due to various reasons HIV some times will take even 4-10 years time to get fully grown up in the human bodies. Therefore, any donor or blood bank cannot detect the presence of any HIV virus during this period due to several scientific reasons.

Findings:

20. In the complaint before the State Commission, it is submitted as follows:

21. One of the modes of transmission of HIV/AIDS is through the transfusion of blood having the virus. The sole reason for the complainant's wife developing HIV/AIDS was the transfusion of the blood contaminated with the HIV virus done by the opposite parties after the operation in December 1990. The complainant's wife and the complainant have led clean lives and there was absolutely no other reason for her getting HIV infection which led to her death. The HIV infection development into full blown AIDS later. It is well known fact that persons who are infected with HIV develop complications subsequently. The virus remains dormant in the body and strikes the body's immune system later. The period between the entry of the virus and onset of the disease could be several years depending on several factors.

22. The second blood test was done in June 1994 which revealed that the patient was suffering from HIV. Hence, the complaint filed on 30.4.1996 is not time-barred. Blood transfusion is one of the methods through which a person can be infected with HIV.

23. No affidavit from the respondent No. 2 (laboratory) regarding non-supply of blood has been produced. The complainant had pointed out that the relevant document quoted below indicates that blood was obtained by the first opposite party from the second opposite party.

Patient's name:	Mrs Lalitha	Dated:28.12.1990
W/o		Age 48 years
Chinnaiyam		
Address :		SP No. 14448
Blood Group :	0	
Rh. Factor :	Positive	
		Sd/-
Ref. by		Queen Mary's Clinical
Dr. Sri Gokulam		Laboratory & Blood Bank
Hospital		19-c Sarada College Road
		Salem - 636 007 Phone: 62626,
		65282

M. Chinnaiyan vs Sri Gokulam Hospital And Anr. on 25 September, 2006

24. R. Lalitha, as seen from medical records was transfused two units of blood in December 1990. She acquired HIV through blood transfusion. In persons who acquire HIV through blood transfusions the disease manifests from two years to ten years of the transfusion. In Lalitha's case HIV manifested itself in mid-1994. Although HIV manifests two years or later, the antibodies to HIV can be detected in the blood from a few weeks of exposure to the virus. Any blood test done thereafter would have shown the presence of HIV.

25. Dr. Suniti Solomon who holds a Master's Degree in Medicines and the Director of Y R Gaitonde Medical Educational and Research Foundation Centre for AIDS Research and Education in her supporting affidavit has stated as follows:

R. Lalitha, as seen from medical records was transfused two units of blood in December 1990. She acquired HIV through blood transfusion. In persons who acquire HIV through blood transfusion the disease manifests from two years of the transfusion. In Lalitha's case HIV manifested itself in mid-1994. Although HIV manifests two years or later, the antibodies to HIV can be detected in the blood from 3-12 weeks to exposure to the virus. Any blood test done thereafter would have shown the presence of HIV.

This statement of Dr. Suniti Solomon has gone un rebutted.

26. The undisputed facts are that Smt. R. Lalitha had uterus problem and she was operated by Dr. P. Chellammal at Sri Gokulam Hospital on 29.12.1990. She was administered two units of blood. In the clinical notes of the hospital dated 29.12.1990 'reserve one bottle of blood' is mentioned. This is supplemented by nurse's report of the same date 'Queen Mary reserved one bottle of blood'. Consent of the patient is required for transfusion of blood. In this case, it is clear from the records that the complainant has given his consent only for hysterectomy operation to be performed under general anesthesia and not for transfusion of blood. Surgery involves risk and blood transfusion involves additional risk.

27. The Advocate for the R1 has brought to our notice the judgment rendered by this Commission I (1999) CPJ 13 (NC) : 1986-99 Consumer 3628 (NS) The Calcutta Medical Research Institute v. Bimalesh Chatterjee and Ors.:

Further the complainant has filed documents which are completely lacking in the essential technical details. We also find that the said patient ultimately died on 23.7.1997 which means he survived for four years after the treatment complained of. No evidence has been brought on record to link the blood transfusion with any of the resultant complications in the case. Nor has any evidence been led which would go to show the Hospital/appellant or any of its doctors had been negligent. In the absence of such evidence it cannot be held that the appellant or its doctors were guilty of any negligence or deficiency in service. The onus of proving negligence and resultant deficiency in service was clearly on the complainant which onus had not been discharged. In that view of the matter, the impugned order qua this appellant cannot be sustained and is hereby set aside. The result is that the appeal is accepted to the extent of the finding and the relief granted in the impugned order against the appellant and the impugned order to that extent is set aside. Rest of the

M. Chinnaiyan vs Sri Gokulam Hospital And Anr. on 25 September, 2006

order which is against the Insurance Company is upheld.

28. Though this case relates to blood transfusion, it does not pertain to HIV infection. In this case the allegation is of negligence of deficiency in service by transfusing wrong group of blood to the complainant/petitioner. In the aforesaid case National Commission has also stated as under:

We have heard at length arguments on both sides with regard to the amount of compensation of Rs. 2.00 lakh to be paid by the Calcutta Medical Institute, the appellant in the present case. The amount appears to have been awarded for negligence and deficiency in service in transfusing blood of wrong group to the complainant - respondent No. 1 before us. We find that reliance has been placed by the State Commission on a certificate issued by Dr. Sukumar Mukherjea who is neither the haematologist nor a pathologist. His opinion lacks in all requisite technical details and is absolutely vague. He does not mention the blood group of either the donee or the donor. This doctor who is only an MB (Calcutta) and ex-Senior House Surgeon, Calcutta Medical College Hospital, has no specialist qualification. He has talked of the blood picture without mentioning any detail thereof nor does he talk of having had a look at any blood picture. A patient is considered fit for kidney transplantation only when he has reached a critical stage and that stage is confirmed by the certificate issued by Woodlands Nursing Home which apart from giving estimate of the cost of the treatment and surgery also states the following:

This is to certify that Mr. Bimalesh Chatterjee, 33 years, 132-A Charu Chandra, Place East, Calcutta - 33 is suffering from End Stage Renal Disease and is undergoing Maintenance Haemodialysis in this centre. He has been advised to undergo a Renal Transplantation as a definitive form of treatment. This form of treatment is of a rather prolonged nature, and entails considerable expenses. An approximate estimate of the anticipated expenditure is given herewith....

(Emphasis supplied) Thus it is clear from this certificate that the patient was already suffering from End Stage Renal Disease and was undergoing Maintenance Haemodialysis which means he was already critical even in June 1993.

29. The above extracts indicate that patient was already suffering from End Stage renal disease at the time of admission for surgery for which blood transfusion took place. Secondly, whether transfused blood belonged to wrong grouping was based on a certificate by Dr. Sukumar Mukherjea who is neither a haematologist nor a pathologist. His opinion lacks in technical details and is absolutely vague. He does not mention the blood group of either the donee or the donor. Hence the above judgment has no relevance in the case under consideration.

Learned Counsel for the appellant brought to our notice the following judgment:

30. In *Malette v. Shulman* 72 OR (2d) 417 in Ontario Court of Appeal - Robins, Catzman and Carthy JJ. A the Court has ordered;

ROBINS J.A : The question to be decided in this appeal is whether a doctor is liable in law for administering blood transfusions to an unconscious patient in a potentially life-threatening

M. Chinnaiyan vs Sri Gokulam Hospital And Anr. on 25 September, 2006

situation when the patient is carrying a card stating that she is a Jehovah's witness and, as a matter of religious belief, rejects blood transfusions under any circumstances.

In the early afternoon of June 30, 1979, Mrs. Georgette Malette, then age 57, was rushed, unconscious, by ambulance to the Kirkland District Hospital in Kirkland Lake, Ontario. She had been in an accident. The car in which she was a passenger, driven by her husband, had collided head on with a truck. Her husband had been killed. She suffered serious injuries.

At about this time, a nurse discovered a card in Mrs. Malette's purse which identified her as a Jehovah's witness and in which she requested, on the basis of her religious convictions, that she be given no blood transfusions under any circumstances. The card, which was not dated or witnessed, was printed in French and signed by Mrs. Malette. Translated into English, it read:

No Blood Transfusion:

As one of Jehovah's witnesses with firm religious conviction, request that no blood or blood products be administered to me under any circumstances. I fully realize the implications of this position, but I have resolutely decided to obey the Bible command : "keep abstaining.... From blood." (Acts 15:28, 29). However, I have no religious objection to use the non-blood alternatives, such as Dextran, Haemacee, PVP, Ringer's Lactate or saline solution.

As when the condition deteriorated and would have been revertible blood transfusion was given. It is held in this case:

The doctrine of informed consent has developed in the law as the primary means of protecting a patient's right to control his or her medical treatment. Under the doctrine, no medical procedure may be undertaken without the patient's consent obtained after the patient has been provided with sufficient information to evaluate the risks and benefits of the proposed treatment and other available options. The doctrine presupposes the patient's capacity to make a subjective treatment decision based on her understanding of the necessary medical facts provided by the doctor and on her assessment of her own personal circumstances. A doctor who performs a medical procedure without having first furnished the patient with the information needed to obtain an informed consent will have infringed the patient's right to control the course of her medical care, and will be liable in battery even though the procedure was performed with a high degree of skill and actually benefited the patient.

I am of the view that the card had the effect of validly restricting the treatment that could be provided to Mrs. Malette and constituted the doctor's administration of the transfusions a battery. Finally, the appellant appeals the quantum of damages awarded by the trial Judge. In his submission, given the findings as to the competence of the treatment, the favourable results, the doctor's overall exemplary conduct and his good faith in the matter, the battery was technical and the general damages should be no more than nominal. While the submission is not without force, damages of \$ 20,000 cannot be said to be beyond the range of damages appropriate to a tortious interference of this nature. The trial Judge found that Mrs. Malette suffered mentally and

M. Chinnaiyan vs Sri Gokulam Hospital And Anr. on 25 September, 2006

emotionally by reason of the battery.

31. There is a strong force in the argument that the consent should have been taken or there should have been explained to the complainant of the risk of blood transfusion by the attending surgeon.

32. Whether the blood was obtained from R 2? The nurse's clinical note clearly indicates that one bottle of blood was reserved at Queen Mary's Clinical Laboratory. The Exhibit A18 which clearly mentions name of the patient, the IP No., referred by Sri Gokulam Hospital, date and the printed name of the clinic and the address and telephone number. It is difficult to disbelieve this document. Further Shri M Chinnaiyan in his proof affidavit has stated that the complainant's wife was transfused two units of blood after the surgery. The blood was obtained by the first opposite party from the 2nd opposite party's laboratory. At the relevant time Thiru M. Somasundaram was the Assistant in the 2nd opposite party's laboratory and he had delivered the blood to the first opposite party. This has not been controverted by any affidavit of R2.

33. In a counter affidavit filed by Dr. P Chellammal has stated that:

Further it is pertinent to mention a vital fact that during the year 1990's HIV cases were not reported in Salem or for that matter in Tamil Nadu itself and therefore there was no occasion for the first opposite party to have any suspicion of infection of blood b HIV and in this case, the 3rd opposite party is a well established Government approved blood bank and since the blood was certified to be free from any infections, it was administered without any further second test. Therefore, there was no negligence on the part of the first opposite party in administering blood.

34. This statement is not supported by any document and literature. The laboratory was duty-bound as per the Drugs and Cosmetics Rules duly amended on 11.7.1989. Rule 66(A) which clearly stipulates a mandatory condition of conducting HIV antibody test before certifying the purity of blood. This was not complied with by the blood bank and clinical laboratory. Dr. Chellammal merely stated that she relied on the clinical report, blood bank who conducted the test but she did not insist for the blood test certificate. There is no mention about the clinical record maintained by the doctor that the blood was found to be free from infection. This is a clear-cut case of negligence on the part of R1 and R 2.

35. The next issue is to be decided whether, if the blood was transfused in December 1990, whether it can result in full blown HIV AID'S after 3Vi years. In the State Commission's order, dates have been wrongly mentioned that operation was performed in December, 1992 and after VA years of operation the patient was found to be suffering from AIDS. Actually there was a gap of 3Vi years. The medical literature produced by the learned Counsel for the appellant is very clearly mentioned in 'HIV (Pathogenesis and Natural History) by Howard Libman, MD and Harvey J Makadon, MD which reads as under:

Progression to symptomatic HIV Disease-

M. Chinnaiyan vs Sri Gokulam Hospital And Anr. on 25 September, 2006

When the high viral levels associated with acute HIV syndrome are suppressed by the initial immunologic response, an infected person generally moves into an asymptomatic period that may range from several months to more than 10 years. Although symptoms are not present during this period of clinical latency, viral replication is ongoing, leading to a loss of approximately 10% of CD 4 cells per year in most individuals.

36. Apart from the duty of the clinical laboratory and the blood bank to ensure that the blood is free from infection and it is the duty of attending physician to ensure that the blood is free from infection. The decision to transfuse blood or blood products must be based on a careful assessment which indicates that they are necessary for saving life or for preventing major morbidity. Responsibility for the decision to transfuse must rest ultimately with the attending physician, although this will often be made in consultation when a specialist transfusion advice is available.

37. Considering the age and profession of the complainant and the report that they have been leading a clean life, it is clear from the records that the blood transfused resulted in contracting HIV infection which ultimately after gestation period became full blown AIDS and the patient succumbed to her terminal illness.

Now the issue to be decided is the quantum of compensation to be awarded:

38. Complainant has stated that his wife was 51 years old at the time of her death and her last basic pay drawn was Rs. 1,850 per month with six years service left. She had incurred more than Rs. 1.5 lakh for her medical treatment, travel cost to and fro Salem and Chennai. She would have drawn Rs. 3.00 lakh salary for six years. Further the agony suffered by her and the family is untold and a conservative amount of Rs. 2.00 lakh is claimed as damages for mental agony and anguish. Hence the complainant is entitled for Rs. 6.5 lakh. Complainant has also stated that she had two unmarried daughters and a son who is unemployed. It is quite likely that daughters may not be able to get married due to the stigma attached by society to the infection.

39. Considering the trauma caused to the family and untimely death of the wife of the complainant due to AIDS we award a consolidated sum of Rs. 4.00 lakh as compensation with interest @ 6% p.a. from the date of filing the complaint which is to be paid jointly and severally by the respondents. The respondents are also directed to pay Rs. 10,000 as cost.

40. Accordingly, the impugned order of the State Commission is set aside, the complaint is allowed and the appeal is disposed of with the above directions.

Annexure 2

Paste/ write patient registration
details here

CONSENT FOR RECEIVING TRANSFUSION OF BLOOD /BLOOD COMPONENTS

I, _____, (the Patient) or representative of
patient

_____, have (please tick the correct option above and below)

- ☐ Read
- ☐ Been explained this consent form in _____ (name of language) which I fully understand.

That I need to receive blood/blood component transfusion. The nature, purpose, risks, expected benefits and possible alternatives alternative to transfusion have been explained to me.

I understand that blood/blood component transfusion is a lifesaving medical procedure prescribed by a doctor. Blood may be given 'whole' but more often a component or combination of components or apheresis component is transfused.

I have been explained that despite careful screening by mandatory tests prescribed by the Drug Control Department of Government of India (and as amended from time to time) there are rare instances of life threatening infections such as HIV, Hepatitis and /or other infections as yet unknown. I understand that there is no practical way of eliminating all such risks. I also understand that unpredictable reactions may occur, which include but are not limited to, fever, rash, shortness of breath, shock and in rare instances death.

Expected benefits of transfusion include minimization of shock, minimizing damage to tissues (like brain, lungs etc.), hastening recovery, and replacement of lost blood. However I do understand that the beneficial response (s) may vary between individuals and I declare that no guarantees have been made to me.

I have been explained that I have the right to refuse acceptance of transfusion. I have understood the implications of not being transfused with blood/components.

I have been provided with an opportunity to ask questions about transfusion, alternate forms of treatment, procedure of transfusion and also the risks involved.

I understand that in case of any immediate or life threatening event during the procedure, the doctor will treat me to the best of his/her judgement.

I am now aware of the procedure details, benefits, risks and possible alternatives to blood/component transfusion.

Initials of Patient / Patient's representative (only if Patient is a minor or unable to give consent)

I declare that I have received & fully understood the information provided in this consent form, that I have been given an opportunity to ask questions to relating to blood /component transfusion including procedure details benefit, risks and possible alternatives, and that all my questions have been answered to my entire satisfaction insertion or completion were filled in my mind. I further declare that all fields (of this form) requiring insertion or completion were filled in my presence at the time of my signing this form.

I, the above named Patient /named patient's representative, do further hereby declare that I am above 18 years of age as on the date of signing this form, mentally sound and am giving consent without any fear, threat or false misconception

	Signature / Thumb Impression	Name
Patient		
Surrogate/Guardian (if applicable*)		(Write name & relationship with patient)
Reason for surrogate consent	Patient is unable to give consent because	

Witness		
Interpreter (if applicable)		

*Right hand for Males & Left Hand for Female

#only if patient is a minor or unable to give consent

Signed by the above on ----- at ----- AM/PM

I the undersigned doctor, have explained the details, benefits, risks and possible alternatives to blood/component transfusion to the patient/patient representative. I am confident that he/she has understood the information fully as described in this document.

Consent obtained by:

Dr. _____ Designation&

Dept. _____

Signature: _____ Date: _____

(Being person performing the procedure or member of his/her team)

REFUSAL OF TRANSFUSION

I declare that in spite of having received & fully understood the information provided in the consent form. I do not wish to undergo blood/component transfusion for myself/my patient. I am aware of the risk to my health on account of my refusal and take full responsibility for my actions.

	Signature / Thumb Impression*	Name	Date & Time
Patient			
Surrogate/Guardian (if applicable #)		(Write name & relationship with patient)	
Reason for surrogate consent	Patient is unable to give consent because		

Witness		
Interpreter (if applicable)		

**Right Hand for Males* * *Left Hand for Female*
consent

#only if patient is a minor or unable to give

ANNEXURE 3



CODE OF ETHICS RELATING TO TRANSFUSION MEDICINE

Purpose

This Code defines the ethical and professional principles that the International Society of Blood Transfusion (hereinafter the Society) as a body of transfusion medicine professionals believes should underpin the establishment and activities of a Blood Service and identifies ethical and professional standards for practitioners active in the field.

Introduction

The availability of a safe, effective and sufficient supply of blood and blood products (hereafter defined as 'blood') as well as their optimal use for patients, underpins the practice of modern medicine. *Blood* is a medical product of human origin and its availability is dependent on the contribution of the *donor* who gives *blood* for the benefit of others with no physical benefit to her/himself. It is therefore important that the contribution of the *donors* and their donation is respected and that all reasonable steps are taken to protect their health and safety and that appropriate safeguards are in place to ensure that the products derived from the donation are used appropriately and equitably for the patients.

The Society endorses the principles contained in the *Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine: Convention on Human Rights and Biomedicine* (Oviedo Convention 1997)¹ and also the recommendations contained in the *World Health Assembly Resolution on the Utilization and supply of human blood and blood products (WHA28.72)*². Consistent with this we affirm the importance of the principle of voluntary non-remunerated donation as the basis for the establishment and development of Blood Services.

Blood Services provide *blood* for patients and information and advice to clinicians to support the appropriate use of *blood*. The rights and responsibilities of *donors* and patients are of equal importance and the health, safety and well-being of the *donor* should not be compromised in order to meet the needs of patients.

This Code of Ethics outlines the responsibilities of *Professionals* involved in the field of transfusion medicine to *donors* and to patients. These responsibilities are aligned to the well acknowledged four principles of biomedical ethics: autonomy, non-maleficence, beneficence, and justice. A specific aspect of another principle, dignity, covering all four principles, specifically applies to *donors* (all five key ethical principles are shown in the table below).

The Code also includes a series of statements directed to health authorities that relate to the stewardship of the blood supply. The Society expects that Professionals involved in the field will, to the extent within their control, also adhere to the principles contained in this section of the document.

¹ Council of Europe CETS No 164 Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine: Convention on Human Rights and Biomedicine <http://www.coe.int/en/web/bioethics/oviedo-convention>

² World Health Organisation: Resolution 28.72 on the utilization and supply of human blood and blood products 1975. <http://www.who.int/bloodsafety/en/WHA28.72.pdf>

<i>Ethics - ‘the branch of knowledge that deals with moral principles’³</i>	
<i>Dignity</i>	A human being has an innate right to be valued and receive ethical treatment.
<i>Autonomy</i>	The capacity of a rational individual to make an informed, un-coerced decision.
<i>Beneficence</i>	Beneficence is action that is done for the benefit of others. Beneficent actions can be taken to help prevent or remove harms or to simply improve the situation of others
<i>Non maleficence</i>	To “do no unnecessary or unreasonable harm.”
<i>Justice</i>	Concerned with the equitable distribution of benefits and burdens to individuals in social institutions, and how the rights of various individuals are realised.

1. Definitions

1.1 “*Blood*” means human blood that is collected, including whole blood and blood components collected by apheresis and hematopoietic stem cells, either for direct transfusion or for use in the preparation of a medicinal product for human use.

1.2 “*Donor*” means any person who voluntarily gives blood or blood components

1.3 “*Blood Service*” means any structure or body that is responsible for any aspect of the recruitment of *donors*, collection and testing of *blood*, whatever their intended purpose, and their processing, storage, and distribution when intended for transfusion.

1.4 “*Professional*” means any professional involved in either the activities of a Blood Service or in the clinical use of *blood*.

The use of the terms ‘must’ and ‘should’ have been carefully controlled within this document. The term ‘must’ identifies something as mandatory. A *professional* will have the ability to control if this can be achieved. In contrast ‘should’ identifies a term where either the principle is outside of the control of the *professional* (i.e. a stewardship statement) or where the ability of the professional to make a decision might, in individual cases, be constrained by external factors such as public health or legal requirements and resourcing decisions.

³ Definitions derived from *Human Bodies: Donation for medicine and research*. Nuffield Council on Bioethics http://nuffieldbioethics.org/wp-content/uploads/2014/07/Donation_full_report.pdf

2. Ethical Principles Relating to Patients

In addition to equitable access to treatment, the patient has a right to expect that her/his autonomy is respected, and that a decision to transfuse is made for her/his benefit and avoids the risk of unnecessary or unreasonable harm to her/him.

2.1 *Autonomy*

- 2.1.1 Specific consent must, where feasible, be obtained prior to the transfusion. The consent should be informed and in order to achieve this, information must be provided on the known risks and benefits of blood transfusion and any possible alternative therapies in order to enable a decision whether to accept or refuse the procedure. The information must be provided in a way that is comprehensible to the potential recipient.
- 2.1.2 In the event that specific consent cannot be obtained the basis for treatment by transfusion must be in the best interests of the patient.
- 2.1.3 Any valid advance directive should be respected.

2.2 *Beneficence and non-maleficence*

- 2.2.1 The patient has a right to be treated with dignity and therefore decisions on the need for transfusion should be based on genuine clinical need.
- 2.2.2 Transfusion therapy must be given under the overall responsibility of a registered healthcare Professional who is competent to do so.
- 2.2.3 Patients should be informed if information becomes available following a transfusion that indicates they have, or may have been, harmed by the transfusion.
- 2.2.4 Information concerning the patient and the treatment that they receive should be managed in a confidential manner.

2.3 *Justice*

- 2.3.1 Patients should be treated equitably for the same healthcare condition. This implies that medical decisions relating to transfusion of *blood* should be based on the best available evidence and treatments for patients (adapted to the local healthcare situation).
- 2.3.2 The patient should, within the constraints of the local health system, receive the most appropriate blood product(s) that is (are) available. As far as possible the patient should receive only those particular products (whole blood, cells, plasma, or plasma derivatives) that are clinically appropriate and afford optimal safety.
- 2.3.3 There should be no financial incentive to prescribe *blood*.

3. Ethical Principles Relating to Donors

The autonomy and dignity of the *donor*, including potential *donors*, must be respected at all times. The *donor* does not physically benefit from the donation, thus the *donor* should be exposed to as little harm as possible, in compliance with the principle of non-maleficence.

3.1 *Autonomy*

- 3.1.1 The *donor* must expressly provide consent to the donation of *blood*. The consent must be informed. Informed consent should include: knowledge of all known risks associated with the donation, of the subsequent legitimate use of the donation and of how information pertaining to the *donor* and donation will be treated confidentially. The consent should, where appropriate, include information on possible commercialisation of the products derived from the donation and whether the donation might be used for research, quality control or any other purpose.
- 3.1.2 Information provided by the *donor* and generated about the *donor* (i.e. test results) *must* be treated confidentially. The *donor* should be informed in advance of the release of any such information.

3.2 *Dignity and non-maleficence*

- 3.2.1 Donor selection criteria must be applied to protect the health of recipients and *donors*. *Donors* must be made aware of their responsibility not to harm the recipient
- 3.2.2 *Donors* must be informed if they have, or may have been harmed or in the event that any results or information regarding their donation may have an impact on their health.
- 3.2.3 The decision to administer any substance or medicine to a *donor* for the purpose of increasing the concentration of specific components of the blood or for any other reason should take into account that there is no benefit to the *donor*. This should only be considered when there is good evidence of specific benefits to the recipient, or in the context of research approved by an Ethics Committee and when the *donor* has been informed of all known risks and these have been reduced as far as is possible.
- 3.2.4 Anonymity between *donor* and recipient should be ensured except when both *donor* and recipient freely and expressly consent otherwise.

4. Stewardship

Health authorities have a responsibility to ensure that *Blood Services* are established and progressively developed so as to assure the needs of the patients using an ethical framework encompassing the care of both *donors* and patients.

The Society endorses the principles contained in the *Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine: Convention on Human Rights and Biomedicine* (Oviedo Convention 1997)¹ and also the recommendations contained in the *World Health Assembly Resolution on the Utilization and supply of human blood and blood products* (WHA28.72)². Consistent with this we affirm the importance of the principle of voluntary non-remunerated donation as the basis for the establishment and development of Blood Services.

The Society therefore urges Health Authorities to ensure that the activities of *Blood Services* are undertaken in a manner consistent with the contents of this Code of Ethics and that in addition the following key principles should underpin their governance and delivery.

4.1 Dignity and Beneficence

- 4.1.1 Donated *blood* should be seen as a 'community good' in order to assure the dignity of the *donor* and of their donation and not as a commodity to meet others' ends. Therefore, the establishment and running of a *Blood Service* should be based upon not-for-profit principles.
- 4.1.2 Blood donation should be voluntary and non-remunerated². A donation is considered voluntary and non- remunerated if the person gives *blood*, of his/her own free will and receives no payment for it, either in the form of cash, or in kind which could be considered a substitute for money. This would include time off work other than that reasonably needed for the donation and travel. Small tokens, refreshments and reimbursements of direct travel costs are compatible with voluntary, non-remunerated donation⁴.
- 4.1.3 Any form of incentive⁵ that might influence the underlying reason to donate *blood* should be actively discouraged and must be prohibited if this will either impact on the safety of the *blood*, result in exploitation of the *donor* or lead to inequity of access for recipients
- 4.1.4 Donation is a civic act for the benefit of others and contributes to social cohesion. There is no right to donate.
- 4.1.5 Blood donor selection should be based on current, accepted and regularly reviewed scientific data. The ability to donate should not be unnecessarily restricted and blood donation criteria should not be justified on the basis of gender, race, nationality, religion, sexual orientation or social class.

¹ Council of Europe CETS No 164 Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine: Convention on Human Rights and Biomedicine <http://www.coe.int/en/web/bioethics/oviedo-convention>

² World Health Organisation: Resolution 28.72 on the utilization and supply of human blood and blood products 1975. <http://www.who.int/bloodsafety/en/WHA28.72.pdf>

⁴ Council of Europe Definition contained in Article 2 of Recommendation No R (95)14

⁵ Based on the *Intervention Ladder* contained in *Human Bodies: Donation for medicine and research*. Nuffield Council on Bioethics http://nuffieldbioethics.org/wp-content/uploads/2014/07/Donation_full_report.pdf

4.1.6 Neither *donor* nor potential recipient has the right to require that any such discrimination be practiced.

4.1.7 No coercion should be made on the *donor* to give blood

4.2 Justice

4.2.1 *Blood* and blood products should be considered as a public resource. Access to the products should be based on clinical need taking into account the overall capacity of the local health system. Discrimination based on factors such as patients' resources should be avoided.

4.2.2 Wastage of *blood* should be avoided in order to safeguard the interests of all potential recipients and the *donor*.

4.3 Non-maleficence

4.3.1 All matters related to donation of *blood* and its clinical use should be in compliance with appropriately defined and internationally accepted standards.

The original Code was adopted by the General Assembly of ISBT, July 12, 2000.

It was amended by the General Assembly of ISBT, September 5, 2006.

This revision was adopted by the General Assembly of ISBT, June 20, 2017.

Annexure 4

Name of Department

Name of Hospital

Requisition Form for red cell components

Patient's Name _____ Hospital Admission Number. No. _____ Age _____ Sex _____

Diagnosis.....Clinician In-charge _____ Ward _____ Bed No. _____

Blood group (if known) _____

Indication for transfusion:

- ☐ Anemia ☐ Exchange transfusion ☐ Trauma
☐ Bleeding ☐ Surgery ☐ IUT

Pre-transfusion Hb: _____ gm/dL

Quantity of blood unit(s) required: Packed Red Blood Cells (PRBCs)/Whole Blood: Previous Transfusion ☐ Yes ☐ No PRBC unit nos. _____Adverse Reaction, if any ☐ Yes ☐ No Any alloantibody identified earlier _____

Any other significant medical or surgical history _____

Previous pregnancy ☐ Yes ☐ No

Certified that I have personally collected the blood sample after identification of the Patient's Name and Hospital identification Number etc. I have taken the informed consent and explained the necessity of blood transfusion with the risks associated with it to patient/relatives.

☐ **Urgent** (Emergency cross match technique)☐ **Routine** (AHG cross match technique)

Time.....AM/PM

Doctor 's Signature.....

Date.....

Name.....Contact Number.....

(Space to be used by the Laboratory)

Time of receiving the requisition _____ Signature of Staff receiving the sample _____

CROSS MATCH RECORD

Cell grouping				Serum grouping			Blood group	
Anti-A	Anti-B	Anti-AB	Anti-D	A cells	B cells	O cells	ABO	Rh(D)

Auto control: ☐ Positive☐ Negative

S. No.	Blood component and unit no.	Blood group (ABO & RhD)	Technique of crossmatch (tube/gel)	Volume (ml)	Immediate Spin Saline crossmatch (room temperature): Major	AHG crossmatch (37°C): Major	Compatible	
							Yes	No

Signature.....

Date.....Time.....AM/PM

Annexure 5 Hospital Transfusion Committee

Proposed frequency of meeting: Every 3 months.

Proposed composition:

Convener: Head of blood centre/ Transfusion Medicine Department or any designated senior person from the department.

Members of the committee (Chairperson to be elected from amongst the members but the convener should not be the chairperson) – some or all of these can be the members:

1. Head of Cardiothoracic & Vascular surgery department
2. Head of Obstetrics and Gynecology department
3. Head of General surgery department
4. Head of Pediatrics department
5. Head of nursing department- mandatory member
6. Head of Anesthesiology and Critical care department
7. Head of laboratory department
8. Representative from the administration – mandatory member
9. Head of Internal Medicine department
10. Head of other medical and surgical departments
11. Representative of patient feedback/ Medical social worker department.

Model agenda of the HTC:

1. Develop policies for effective functioning of the blood centre/ transfusion medicine department.
2. Enforce rationale use of blood and blood components.
3. Monitor safety of blood transfusion from safe donors, appropriate and cost effective testing strategies, safe storage, transport and proper identification and transfusion to the patient.
4. Reviewing data for infectious marker percentage in blood donors.
5. Reviewing number and type of transfusion reactions with appropriate investigation and reporting at local as well as national level.
6. Identifying educational opportunities for the stakeholders.
7. Quality management system of the blood transfusion chain.
8. Enhancing voluntary blood donations

(D) Investigations									
<input type="checkbox"/> Clerical Checks		Specify Error Found if any:							
Investigation		Pre-transfusion sample				Post-transfusion sample			
<input type="checkbox"/> Visual Check									
<input type="checkbox"/> Repeat Blood Grouping		O+ /A+ /B+ /AB+ /O- /A- /B- /AB-				O+ /A+ /B+ /AB+ /O- /A- /B- /AB-			
<input type="checkbox"/> Repeat Crossmatch		<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 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"/> 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"/> Labeling 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"/> 3. Recovered with Sequelae		
<input type="checkbox"/>	Hypotensive Transfusion Reaction								
<input type="checkbox"/>	Transfusion Related Acute Lung Injury (TRALI)								
<input type="checkbox"/>	Definite <input type="checkbox"/>								
<input type="checkbox"/>	Possible <input type="checkbox"/>								
<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								
IMPUTABILITY ASSESSMENT									
(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) Saline Washed Red Cells									
2) COVID-19 Convalescent Plasma									
3) Fresh Frozen Plasma									
4) Whole Blood									
5) Packed Red Blood Cells (PRBC)									
6) Buffy Coat Depleted PRBC									
7) Leucofiltered PRBC									
8) Random Donor Platelets/ Pooled									
9) Apheresis Platelets									
10) Cryoprecipitate									
11) Any Other									



National Institute of Biologicals- National Coordinating Centre-HvPI

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Ministry of Health and Family Welfare,
Government of India

A-32, Sector-62, Near NH-24,
Noida - 201309, Uttar Pradesh

NIB website: <http://nib.gov.in/>

Email: haemovigilance@nib.gov.in

Tel: 0120-2400072, 0120-2593612 Fax: 0120-2403014,

Toll free No. 1800-180-2588 [Mon to Fri (9:00 a.m. to 5:30 p.m.)] query related to
Haemovigilance Programme of India