PRETRANSFUSION ISSUES AND BEDSIDE PRACTICES

CHAPTER - 6

6.1 Procedure for Collection of Blood Sample of the Patient for Transfusion Testing

1. Blood sample for grouping and cross matching must be drawn by the DOCTOR on duty and not by the trained Nursing Staff or a phlebotomist.
2. Place only one plain / EDTA test-tube /vials / evacuated container, label with patient's name, age / sex, reg. no. ward / bed number.
3. Take the rack with labelled tube to the patient's bed side.

For identification of the patient, follow the following procedure

a) If the patient is conscious at the time of taking the sample, ask him or her to identify themselves by given name, bed number.

b) If the patient is unconscious, ask the relative or second member of the staff to verify the patient's identity.

Also confirm the particulars of the patient from the case file.

a) Draw 5 ml of blood and put in Pre- labelled test tube.

b) Recheck the particulars and sign on the label of test tube and requisition form.

DON'T

1. Draw samples from the patient in an unlabelled tube.
2. Keep more than one tube in the rack.
3. Collect samples from more than one patient at a time.

N.B: The most common reason for mismatch of transfusion is the clerical errors/wrong labeling of the patient's blood samples.

6.2 Procedure for Arranging / Requisitioning of Blood / Component from the BTS

1) Send the completely filled blood requisition form along with properly labelled 5 ml blood sample in plain test tube/EDTA

2) Make sure that the policy for receiving routine and emergency blood requisition is in place

A common cause of transfusion reaction is the transfusion of an incorrect unit of blood that was intended for a different patient. This is often due to mistakes when collecting blood from the blood bank. It is important to follow these instructions.

6.3 Getting Blood / Blood Components Issued from BTS for Emergency / Ward / ICU / OT

1) Send the release form and patient identification slip along with the proper thermo-cool /Ice box for blood issue:

   Full particulars of the patient for whom the blood/blood component is required, should be written in the release form as shown below:

   - **Name of the patient :** **Age/Sex:**
   - **Ward/Bed No. :** **Reg. No.:**
   - **No. of Units required :**
   - **Specify the Blood component i.e.packed RBC, FFP and Platelet Concentrate :**
   - **Date and time :**
   - **Signature of bed side staff filling the patient identification slip.**

2) Blood for routine cases is issued as and when required (It takes about 15 minutes for issue of pre- requisitioned blood).

3) For getting FFP, please inform 45 minutes to 1 hour in advance of exact time of transfusion. For cryoppt inform 30-45 minutes ahead of the exact time of transfusion.

4) For emergencies, blood is issued within 30-45 minutes of receiving requisition.

5) Blood / component units are issued along with a compatibility report (Reaction form) bearing the patient and donor unit details.

6.4 Administration of Blood and Blood Components

Every hospital should have standard operating procedures for each stage of clinical transfusion process. All staff should be trained to follow them. Clear communication and cooperation between clinical and blood bank staff are essential to ensure the safety of blood / component issued for transfusion.

Once the decision to transfuse has been made, everyone involved in the clinical transfusion process has the responsibility to ensure that the right blood gets to the right patient at the right time.

The main steps in this process are as follows

(i) Pre-administration Checks

Appropriate consent is taken before transfusion

Step 1: Check the patient's notes for-

- The component prescribed
- Any special requirements e.g. leucodepletion, warming, irradiation etc.
- Any pre-medication ordered e.g. diuretic

Note: The same process must be repeated for each component administered

Step 2: Ask the patient for –Name, Surname, DOB (Date of Birth)

- Check these details against the details on the patient's wrist band/compatibility label(on blood unit) and report
- Cross check the patients identification against the number on the compatibility report / label by two authorized medical personnel
- Be extra vigilant when checking the identity of the unconscious / seriously ill patient

Note: Do not proceed if there is any discrepancy at any step and contact the blood bank immediately

Step 3: Check the details on the compatibility report against the details on the unit labels (identification and screening on the front side and compatibility label after compatibility testing).

Look for:

- Blood group – Check the blood group of patient in the file, if previously transfused it should be identical. However, in case of non-availability, the next compatible group should be there.
- Unique donation number – the number on the unit must be matched with that on the compatibility report and the label on blood bag.
- Expiry date – Components can be transfused upto midnight of expiry date. Do not use any component beyond the expiry date or time
- Type of component – The label on the unit provides information on type and volume of component
- Signs of deterioration, leaks or clumping
- Any instruction for transfusion from Blood Bank.

Step 4: Checking the unit of blood

- Discoloration or signs of any leakage may be the only warning that the blood has been contaminated by bacteria and could cause a severe or fatal reaction when transfused.

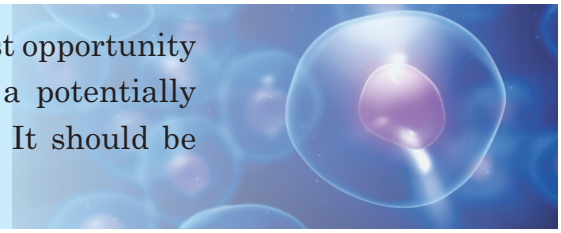
- The final identity check should be undertaken at the patient's bedside immediately before commencing the administration of the blood product. It should be undertaken by two authorized healthcare persons documented in patient's file.
- Check that there are no discrepancies between the ABO and Rh-D group on blood unit, compatibility label and report check that there is no discrepancy between the unique donation number on blood bag compatibility label and report.
- Check that the expiry date on the blood bag has not been crossed.

The blood pack should always be inspected for signs of deterioration (discolouration, gaseous distention, precipitates, clots etc.) on arrival in the ward. However the staff issuing the blood from blood bank should check for any leakage before signing the issue register.

Step 5: Check on patient details before starting blood transfusion

- Check patient's baseline vital signs – temperature, pulse, respiratory rate and BP
- Record the above baseline vitals in the case file
- Document time of starting the transfusion

The final check at the patient's bedside is the last opportunity to detect an identification error and prevent a potentially incompatible transfusion, which may be fatal. It should be preferably done by doctors/nurses.



(ii) Administration of Blood and Blood Component

- Wash hands properly before starting transfusion
- Verify special needs e.g. filtration, pooling, warming blood
- After final patient identity check and baseline medical check at the bedside, start transfusion
- Immediately before transfusion, mix the unit of blood thoroughly by gentle Inversion
- Use standard transfusion set with filters (170 microns) to remove micro aggregates, small clots and other debris
- Observe the patient closely for at least 15-30 minutes
- Only isotonic saline can be used with blood components

- Do not prime the administration set with 5% Dextrose or Ringer Lactate Solutions; (Dextrose may cause haemolysis of the red cells and calcium in Ringer Lactate can lead to clot formation)
- Before administering blood, completely flush all the incompatible IV fluids and drugs with normal saline (0.9%)
- For the first half an hour, patient must be under direct observation
- Rate of transfusion varies with
    - Blood volume /urgency of volume replacement
    - Haemodynamic condition
    - Cardiac status of recipient
    - Initially -1 ml / minute lesser in paediatric patients
        - → 4 ml / minutes after 15 minutes of observation
        - → Paediatric 10-20 ml / kg over 30-60 minutes
- Change blood filter every 4 hours
- Platelet/FFP/Cryoprecipitate – transfuse within 30 – 60 minutes

Roles and responsibilities of nurses:

- Wash hands properly before starting transfusion
- Verify special needs e.g. filtration, pooling, warming blood
- After final patient identity check and baseline medical check at the bedside, start transfusion
- Immediately before transfusion, mix the unit of blood thoroughly by gentle inversion
- Use standard transfusion set with filters (170 microns) to remove blood clots and other debris
- Observe the patient closely for at least 15-30 minutes
- Only isotonic saline is recommended to be used with blood components (DONOT use Dextrose or Ringer lactate)
- Before administering blood completely, flush all the incompatible IV fluids and drugs
- For the first half hour, patient must be under direct observation
- Check the rate of transfusion based on the patient.
- Change blood filter every 4 hours
- Platelet/FFP/Cryoprecipitate – transfuse within 30 – 60 minutes
- Explain the procedure and symptoms of a reaction to the patient.
- Assure the patient, that you are there to care throughout the process

(iii) Monitoring of recipient during transfusion:

- Patients should be transfused in an area where they can be closely observed and have access to a call button
- The procedure and symptoms of an adverse reaction should be explained to the patient
- Encourage the patient to notify the nurse immediately if they begin to feel anxious, or if they experience any of the symptoms
- Monitoring should be done for each and every unit of blood or blood component transfused
- Frequency of observation:-
  - Before the start of the transfusion
  - 15 minutes after starting the transfusion
  - At least every hour during the transfusion
  - On completion of the transfusion
  - 4 hours after completing the transfusion
- Recording the monitoring of the patient
  - Record the patient's vital signs in the patient's case notes/file -Temperature / Pulse / respiratory rate/BP
  - Fluid balance - oral and IV fluid intake, urinary output
  - Any adverse effects
- Post transfusion monitoring – evidence of improved clinical status (HCT. Platelet count, coagulation factors), possibility of DHTR

(iv) Recording the Transfusion

Nurses and other health care providers involved in blood transfusion services should record the following details in the patient's case notes/file

- Type and volume of product transfused
- Donation number and blood group of each product/unit transfused
- Time at which transfusion started and completed
- Change of transfusion set if required
- Signature of responsible person for transfusion

Table 6.1. Time limit for transfusion (Ref: WHO Handbook on Clinical Use of Blood)

	Start transfusion	Complete transfusion
Whole blood/Red Cells	Within 30 minutes	Within 4 hours
Platelet preparations	Immediately	Within 30 minutes
Fresh frozen plasma	As soon as possible	Within 30 minutes

6.5 Disposable Equipment for Administration of Blood

- Cannulas for infusing blood products must be sterile and must never be reused
- Use flexible cannulas if possible as they are safer and preserve the veins Whole blood / Red cells
  - Use a new sterile blood administration set containing an integral 170-200 micron filter
  - Change the set at least 12 hourly during blood component infusion
  - In very warm climate, change the set more frequently, and usually after every four units of blood, if given within a 12 hour period.

6.6 Paediatric Transfusion:

Use a special paediatric set for paediatric patients. These allow the blood or other infusion fluid to flow into a graduated container built into the infusion set. This permits the volume given and the rate of infusion to be controlled simply and accurately.

6.7 Blood Warmers

Blood does not require warming except under limited indications. Red cells should only be warmed using a specifically designed commercial device with a visible thermoindicator and audible warning. Blood components must not be warmed using improvisations such as putting the pack into hot water, in a microwave or on a radiator.

A blood warmer is indicated

1. When blood is transfused
   a) At flow rates of > 50ml/kg/hour in adults
   b) At flow rates of 15ml/kg/hour in children
   c) For exchange transfusion in infants
   d) Transfusion of patients with clinically significant cold agglutinins
   e) Blood and blood components should not be warmed above 37°C
2. Operating temperature of a blood warmer should be recorded on the patient's infusion record when used to warm red cells or blood products.
3. Blood warming devices should undergo a yearly maintenance and calibration.

6.8 Concurrent Fluids and Medications

(i) Concurrent Fluids

The only fluids that can be given concurrently through the same IV line as a red cell transfusion are

- Normal saline
- ABO compatible plasma
- 4-5% albumin

(ii) Incompatible fluids

- Electrolyte and colloid solutions containing calcium (e.g. Haemacel, Gelofusine) should never be given with blood or blood components as they may cause clotting of the infusion line
- 5% Dextrose in water or hypotonic sodium solutions may cause red cells to haemolyse.
- Any other solution shall not be given with red cells unless there is sufficient data to ensure compatibility.

(iii) Medications

Medications should not be added to the blood bag or the transfusion line. If drugs need to be administered via the same IV line, the transfusion should be stopped and the line flushed with normal saline. After administration of the drug, the line needs to be flushed again with normal saline before restarting the transfusion. This procedure should not result in the transfusion of red cells exceeding 4 hours.

6.9 Role of the Hospital Transfusion Committee (HTC)

- A hospital transfusion committee should be established in every hospital.
- HTC monitors the safety, adequacy and reliability of the supply of blood, blood products and IV fluids
- It also monitors the usage of blood and blood products by developing guidelines for appropriate clinical use of blood and blood components and providing appropriate training to the staff.
- Reviews incidences of adverse reactions, errors and taking corrective/preventive action where necessary.
- Plans future needs

(i) Safe Transfusion Practices

- The BTS / blood bank should ensure that the hospital has SOPs in place for all stages of the clinical transfusion process and that all staff are trained to follow them.
- Procedures for the correct identification of the patient, sample and product are essential.
- Morbidity and mortality resulting from the transfusion of incompatible blood components is due to human error. It is entirely preventable if a quality system is in place.
- Safe transfusion depends on:
  - Accurate, unique identification of patient
  - Correct labeling of the blood sample
  - Final check of patient, product and documentation at patient's bedside
  - Correct storage conditions of blood and blood component
  - Utilization within the specified time.
  - Inspection of the unit before transfusion

Pre-transfusion issues and bedside practices- Roles and responsibilities of nurses:

- Nurses have a very important role at every stage of blood transfusion - pre-transfusion, during transfusion and post transfusion.
- Though the medical officer or duty doctor draws the blood for grouping and cross matching, the nurses along with other team members at the blood bank should make sure that the samples are labelled correctly, Only one tube should be in the rack and the sample collected from one patient at a time. The most common reason for mismatch in transfusion is due to clerical errors/wrong labelling of the patient's blood sample. Hence nurses should take special care in checking the labels.
- They should ensure that all the staff in the blood bank follow all the standard operating procedures at all stages of the clinical transfusion process.
- They should train all their subordinate staff on blood safety and SOPs.
- They should be knowledgeable about the procedures for arranging/requisitioning of blood components from the BTS and getting blood/components issued from BTS for emergency / ward / ICU / OT.

Administration of blood and blood components - roles and responsibilities of nurses:

Pre-administration Checks:

- Ensure the right blood gets to the right patient at the right time
- Nurses should check for component prescribed, any special requirements (e.g., warming) and pre medications ordered e.g., diuretics etc.
- Check patient details-Name, surname, Reg. no. etc. extra vigilant care should be taken with unconscious/seriously ill patients.
- Check details on the compatibility label and report against details on blood unit and match patient identification details with patient file. Look for blood group, unique donation number, expiry date of the component, type of component and sign s of deterioration, leakages etc.
- Do not proceed if there is any discrepancy at any stage.
- Check the blood unit before taking the blood from the blood bank before signing the issue register.
- Check for signs of discolouration and leakage.
- Finally, the nurse has to check all the details again at the patient's bedside as this is the last opportunity to detect an error and prevent an incompatible transfusion, which may be fatal.
- Nurses should check patient details, vital signs, record about care and document the time of starting the transfusion.

Choose the Best Option:

1. The completely filled blood requisition form along with properly labelled blood sample should contain;
   a. Patient's first & last names
   b. Phlebotomist's signature
   c. Registration number
   d. All of the above

2. Pre- administration check should include all except;
   a. The component prescribed
   b. Any pre- medication ordered
   c. Ask the patient for his personal details
   d. Start transfusion

3. The rate of transfusion varies with
   a. Blood volume
   b. Body weight of the patient
   c. Haemodynamic condition
   d. Cardiac status of recipient
   e. All of the above

4. Safe transfusion depends on the following:
   a. Correct labelling of the blood sample
   b. Correct storage conditions of blood and blood component
   c. Inspection of the unit before transfusion
   d. Use within correct time limits
   e. All of the above

5. Say YES / NO
   a. A hospital transfusion committee should be established in every hospital
   b. Hospital transfusion committee monitors the safety, adequacy and reliability of the supply of blood and blood products
   c. HTC should help the recipient's family through counselling
   d. HTC will supervise the blood bank adequately and will plan the future needs

NOTES:

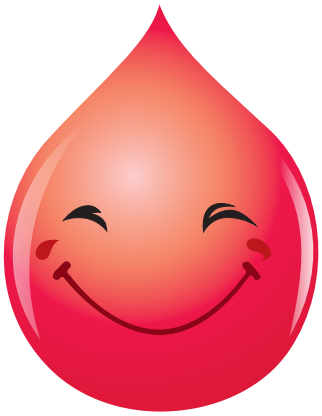
CHAPTER - 7

TRANSFUSION REACTIONS

Learning Objectives

When you have completed this chapter you should be able to:

- List the classification of transfusion reactions
- Recognize the signs and symptoms of transfusion reactions
- Carry out the laboratory investigations for transfusion reactions
- Discuss precautions to avoid transfusion reactions



TRANSFUSION REACTIONS

CHAPTER - 7

Definition:

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

Adverse Reactions

- Transfusion reaction
  - Untoward event
  - Varies from mild to life threatening
  - Majority of transfusion reactions are uneventful
- 10% of transfusion recipients may suffer from untoward effects

Types of Transfusion Reaction:

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

7.1 Immune Transfusion Reaction

It happens due to,

- Patient Abs against donor Ags or vice versa
  - Red cells
  - White cells
  - Platelets
  - Reaction to plasma proteins

Types of Immune Reactions are

1. Haemolytic Transfusion Reactions
   i. Acute
   ii Delayed
2. Febrile Non Haemolytic Transfusion Reactions
3. Allergic / Anaphylactic reactions

4. Allo-immunization
5. TRALI (Transfusion Related Acute Lung Injury)
6. TA-GvHD
7. PTP (Post Transfusion Purpura)
8. Immunomodulation

1. Haemolytic Transfusion reaction

- Increased destruction of donor red cells
  - Acute - Intravascular haemolysis
  - ABO incompatibility – due to activation of Complement cascade
  - Delayed - Extravascular haemolysis
  - Rh / minor group incompatibility- IgG/C3d coated cells removed in RES
- Causes for Acute Haemolysis reaction are;
  - Red cell incompatibility – ABO incompatibility
  - Accidental heating or freezing of RBC
  - Red cells in contact with water or 5% Dextrose
  - Bacterial contamination
  - Administering red cells through small gauge needle

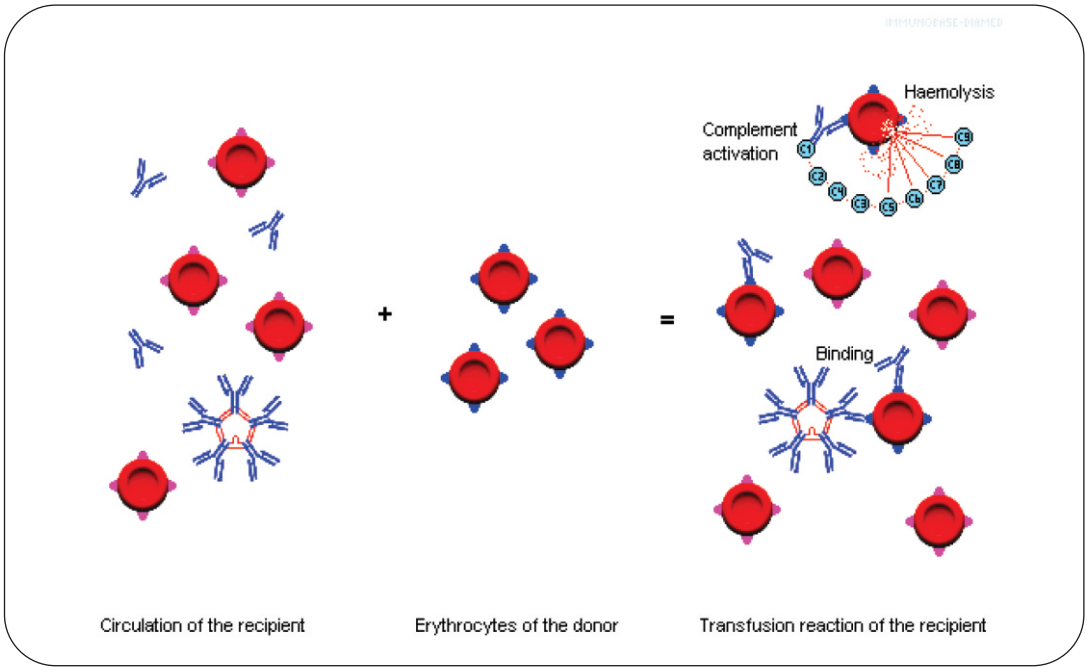


Figure 23: Transfusion Reation

(1). a) ABO incompatible transfusion reaction

Mainly it occurs due to misidentification of the patient.

- Most occur in emergencies, in ICU, Operation Theaters
- In unconscious & anesthetized patients

Causes

- Clerical errors – commonest cause
  - Misidentification of patient / recipient
  - Wrong samples / blood packs
- Technical errors
- In Grouping of patient / donor blood
- In cross matching

Clinical Features

Symptoms	Signs
• **Chills**	• **Fever**
• **Chest / back pain**	• **Rigors**
• **Headache**	• **Flushing**
• **Itching**	• **Restlessness**
• **Palpitation**	• **Hypotension**
• **Dyspnoea**	• **Tachycardia**
• **Nausea**	• **Urticaria**
• **Vomiting**	• **Haemoglobinuria**

- Any febrile transfusion reaction should be considered & managed as AHTR until proved otherwise
- Signs & symptoms may be abolished by drugs
- Patients in coma or under GA - the early alarming sign may be
- Haemoglobinuria
- Hypotension
- Uncontrollable bleeding

Management of Acute Haemolytic Transfusion Reaction

- Stop transfusion immediately
- Maintain an IV line
- Provide cardio respiratory support
- Maintain BP, HR and airway
- Ensure diuresis
- Collect first urine sample for hemoglobinuria
- Check the patient's identification and the blood pack
- Supportive Therapy –O_2, Elevate the foot end.
- Treat DIC –Heparin
- Treat Renal Failure - Dopamine , Diuretics
- Treat hyperkalemia, bicarbonate for acidosis
- Active intervention (hemofiltration, peritoneal dialysis, hemodialysis) *is needed if*

Patient develops

- Uraemic stupor
- Pulmonary oedema
- Hyperkalemia
- Rapidly rising blood urea
- Report the reaction immediately to BTS
- Record
  - Type of reaction
  - Length of time
  - Volume, type & unit number
  - Send post transfusion sample of blood & remaining blood pack with filled reaction form to the Blood bank.
- Monitor blood urea & creatinine level
- Coagulation screen to rule out DIC

(i) b. Delayed HTR

- Days or weeks after the blood transfusion
- Due to secondary immune response

- Rh or minor blood group antibodies
- Extra vascular haemolysis

Clinical Features

- Gradual red cell destruction
- Occurs 5-10 days after transfusion
- Jaundice appears 5-7 days after transfusion
- Fall in Hemoglobin level
- Prevention –screening for alloantibodies & selection of appropriate red cells.

2. Febrile Non Haemolytic Transfusion Reactions

It happens due to;

- Abs in recipient against Ags of donor platelets or WBC
  - HLA Antigens
  - Granulocyte specific Antigens
  - Platelet specific Antigens
- Presence of cytokines in blood components

It is more common in multi-transfused patients

Clinical Features

- Fever
- Chills
- Rigors
- Nausea
- Vomiting
- Hypotension
- Shock

Management of NFHTR

- If mild
  - Slow down the infusion
  - Use Antipyretics

- If severe
  - Stop transfusion
  - Antipyretics and symptomatic treatment
- Usually reactions are self limiting
- Can be prevented by
  - Leucoreduced / Leuco depleted blood components
  - Antipyretic cover /warm patient/ slow transfusion

3. Allergic/Anaphylactic Reaction

- Mainly it occurs due to plasma proteins
- Severity is variable
  - Mild – urticaria
  - Severe – Anaphylactoid reactions
    - Due to IgA deficiency
  - Occurs within minutes of commencing transfusion
- Common in patients with repeated plasma component therapy

Clinical Features

- Mild – urticaria
- Severe / Anaphylactoid
- Cough
- Respiratory distress
- Bronchospasm
- Nausea, vomiting, diarrhea
- Circulatory collapse
- Hypotension & shock

Management mild antihistaminics. Transfusion can be continued

Severe- discountinue transfusion and suppprotive management

4. IgA Deficiency

- Commonest isolated immunodeficiency
- Incidence is 1 : 1000

- Anti IgA – reacting with transfused IgA
- Anaphylactic reaction
- Dramatic reaction with few ml of blood
- Can result in death, unless managed promptly

Management

- Mild – slow down rate of transfusion & administer antihistamine
- Severe - Stop the transfusion
- Adrenaline – 0.5ml IM (1 : 1000)
- Antihistamine
- Treat hypotension
- Steroids – Hydrocortisone
- Prevention
  - Transfuse at slow rate
  - Use Washed blood
  - Blood from IgA deficient donor (1in 600)
  - Autologous blood transfusion

5. Transfusion Related Acute Lung Injury (trali)

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

Clinical Features

- Acute respiratory distress
- Fever with chills
- Non productive cough
- Chest pain
- Bilateral pulmonary oedema

- Chest X-ray – bilateral pulmonary infiltrates in hilar region
- Cyanosis
- Hypotension

Management of TRALI

- No specific treatment
- Largely supportive
- Respiratory support with O_2
- Most cases require mechanical ventilation
- Steroids
- Clinical staff who administer transfusions must be aware to diagnose & manage promptly

6. Transfusion Associated -Graft vs. Host Disease (TA-GVHD)

- Rare & potentially fatal complication-Mortality rate - > 90%
- In severely immuno compromised pts
- Pts with immature immunological system (premature infants)
- Impaired immunological system (thymic alymphoplasia)
- In immuno competent patients, when donor is homozygous for one of the patients' HLA haplotypes (certain communities/ blood relatives
- Due to successful engraftment of allogeneic T lymphocytes & their precursors
- Donor lymphocytes engrafted in recipient & multiply
- Engrafted lymphocytes react with host tissues
- Transfusion Associated GVHD, has not been observed in patients with AIDS.
- Occurs 4-30 days after transfusion

Clinical Features

- Fever
- Diffuse erythematous skin rash
- Maculopapular eruption
- Formation of bullae
- Nausea

- Vomiting
- Watery / bloody diarrhoea
- Hepatitis
- Pancytopenia

Diagnosis

- Detection of donor DNA by PCR

How to prevent?

- Use irradiated blood/blood components (leucodepletion does not prevent TA-GVHD)

7. Post Transfusion Purpura –PTP

- Marked thrombocytopenia 5-10 days after transfusion.
- More common in multiparous women
- Due to platelet specific alloantibodies-HPA 1a,1b3a and 5b
- Antibodies destroy transfused platelets as well as patient's own platelets
- Thrombocytopenia : severe but self-limiting
- Platelet transfusion : not effective
- Therapeutic Plasma Exchange or Intravenous Immunoglobulins are helpful

7.2 Non Immune Transfusion Reactions

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

(i) Transfusion Transmissible Infections

- HIV I & II
- HBV (HAV)
- HCV

- Syphilis
- Malaria
- Cytomegalovirus
- HTLV I & II

Emerging agents

- Nv CJD (new variant Creutzfeldt–Jakob disease)
- Hepatitis F & G
- TTV & Sen V
- West Nile Virus
- SARS
- Bird FLU

ii) Bacterial Contamination & Septic Shock

- Due to contamination of blood components especially platelets at
  - collection
  - processing
  - Storage in blood bank or ward
- Bacteremia in donor
- Endotoxins

Clinical features:

- High grade fever
- Nausea, vomiting
- Abdominal cramps
- Shock
- DIC

Management

- Stop transfusion immediately
- Examine blood pack for any visible change
  - Haemolysis, clots, discoloration

- Start intravenous line
- Broad-spectrum antibiotics
- Dopamine
- Blood cultures from blood pack, tubing, recipient

Prevention

- Aseptic collection, processing
- Proper storage and transportation
- Start transfusion within half an hour after receiving.
- Complete Red cell transfusion within 4 hrs
- Avoid unnecessary blood warming
- Change transfusion set every 24 hrs

Precautions to Avoid Transfusion Reactions

- Avoidance of clerical errors
- Proper identification of patient.
- Correctly labeled samples
- Proper identification of the recipient and the blood pack
- Careful & close observation of the patient while transfusion
- Avoid unnecessary blood transfusion

7.3 Laboratory Investigations

Four essential steps should be done immediately

1. Recheck for clerical errors/Identification errors

a) Details of patient's sample, the blood and blood component issued are to be checked

b) If any discrepancy is found, immediately inform patient's physician, retrieve all the non-transfused units and partially transfused units. This will help to prevent incorrect issue of other blood component which can put other patients at risk.

2. Visual check for haemolysis

a) Serum/plasma: post-transfusion reaction sample is examined for any discolouration and increased yellowish tinge. Intravenous haemolysis as little as 5-10ml of red cells may produce visible haemoglobinemia. Faulty sample collection may give yellowish discolouration as compared to pre-transfusion sample.

b) After 5-7 hrs of acute haemolytic episode, increased unconjugated bilirubin in serum may give a yellowish discolouration as compared to pre-transfusion sample.

c) Fresh post-transfusion urine for Haemoglobinuria

d) Blood sample from the bag should be checked for haemolysis.

e) A satellite tube segment from the blood bag attached to the pre-transfusion sample and kept in the blood bank before issue of blood should be checked to rule out non-immune haemolysis at the time of issue.

3. Serological check for compatibility :Indirect Antiglobulin test (IAT)

- ICT of patient's pre-transfusion sample with donor bag sample to recheck for compatibility.
- In post-reaction EDTA sample, Direct Antiglobulin Test (DAT) is performed.
- In non-immune haemolysis (viz. mechanical, thermal trauma, osmotic lysis of RBCs) Haemoglobinemia is positive but DAT is negative. Also look for any circumstantial evidence for haemolysis.
- In suspected sepsis blood culture from the implicated unit and recipient's blood (collected aseptically in proper culture bottle) is to be sent for bacteriological examination

7.4 Haemovigilance

The primary aim of the Haemovigilance Programme of India is to improve transfusion safety and quality by collecting, collating, analysing and disseminating information on a common set of Serious Adverse Reactions due to the transfusion of Blood and Blood Products.

Haemovigilance is a continuous process of data collection and analysis of Blood Transfusion related Adverse Reactions in order to investigate their causes and outcomes, and prevent their occurrence or recurrence.

It includes the identification, reporting, investigation and analysis of Adverse Reactions and Events in recipients and blood donors as well as incidents in manufacturing process, eventually errors and "near-misses"

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

Transfusion Reactions and Roles and Responsibilities of nurses:

- Avoid unnecessary blood transfusion
- Follow all precautions to AVOID transfusion reactions

- **Roles and responsibilities of nurses before blood/blood products transfusion:**
  - Nurses should have knowledge on blood transfusion related reactions, classification of reactions, should be able to identify signs and symptoms of transfusion reactions.
  - Avoid clerical errors like incorrect labelling, improper identification of patients etc.
  - Avoid technical errors related to transfusion e.g. error in blood grouping of recipient or donor, incompatibility not detected in cross matching etc.
  - Make sure that there are no non-immune mediated haemolysis e.g. bacterial contamination, mechanical trauma associated with infusion, thermal trauma etc.
- **Roles and responsibilities of nurses during blood/blood products transfusion:**
  - Careful and close observation of the patient during transfusion
  - Look for allergic transfusion reactions, anaphylactic and anaphylactoid reactions.
- **Roles and responsibilities of nurses post transfusion of blood/blood products:**
  - Nurses should develop the skills in identifying or evaluating post transfusion reactions like post transfusion purpura, TRALI or Non-Cardiogenic pulmonary edema, transfusion associated GVHD.

Roles and responsibilities of nurses in case of any transfusion reaction:

- Stop transfusion immediately and keep the intravenous line patent by starting a normal saline drip
- Comfort the patient/recipient
- Inform the physician immediately
- Recheck all clerical and identification errors if any, like labels and patient identification
- As per physicians directions, in suspected case of major adverse events, post- reaction blood samples and the transfused bag with its contents is sent to the department of transfusion medicine/blood bank lab for evaluation. Blood is checked for haemolysis (visually) e.g. discolouration and increased yellowish tinge and urine for haemoglobinuria. The blood sample is sent for serological check for compatibility as per physician's directions.

Choose the Best Option:

1. Acute haemolytic transfusion reactions may occur due to all of the following reasons except:
    a. All antibodies
    b. Improper storage of blood
    c. Bacterial contamination of blood
    d. Volume overload

2. Which of the following is a delayed transfusion reaction:
    a. Urticaria
    b. Febrile non-hemolytic transfusion reaction
    c. Anaphylaxis
    d. Iron overload

3. Development of jaundice within 48-72 hours of transfusion indicates:
    a. Transfusion transmitted hepatitis
    b. Transfusion transmitted bacterial sepsis
    c. Delayed hemolytic transfusion reaction
    d. Citrate toxicity

4. The major advantage of red cell additive solution are all EXCEPT:
    a. Improved haematocrit of packed red cells
    b. Decrease in transfusion transmissible diseases
    c. Prolonged shelf life of red cells
    d. Improved viability over whole blood

NOTES:

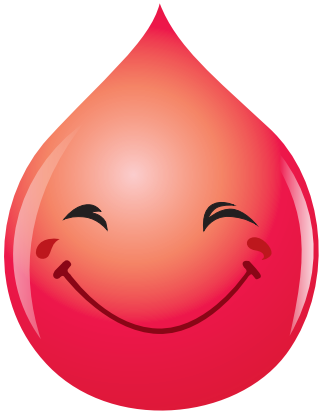
CHAPTER - 8

QUALITY MANAGEMENT IN BLOOD TRANSFUSION SERVICES

Learning Objectives

When you have completed this chapter you should be able to:

- Define and list the different types of quality management system.
- Describe in detail about the organization and management of a blood bank
- Discuss the standards and rules of blood bank in Drugs and Cosmetics Act
- Explain the selection, procurement and installation of equipment in the blood bank
- Discuss the policy and procedure for lab supplies
- Describe performance improvement in the blood bank
- Explain the documentation and document control, records and test reports



QUALITY MANAGEMENT IN BLOOD TRANSFUSION SERVICES

CHAPTER - 8

The aim of quality assurance in blood transfusion service is to ensure the provision of safe transfusion of blood and its components.

Need for Quality in Blood Transfusion Services

Blood bank is the only laboratory which is directly responsible for the patients with no intervening physician interpretation. So any mistake in blood transfusion service can be disastrous. In order to prevent mistakes, it is essential to have adequate quality assurance in blood transfusion services.

QMS in BTS is needed to achieve

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

8.1 Terms and Definitions in Quality Management System

(i) Quality Control

Quality Control is the monitoring system that checks the effectiveness of quality assurance by testing the quality of the final products by checking the quality fulfillment (conformity with the specified standard) of a product, process or a service.

Example: Checking a platelet concentrate for volume, platelet count and pH etc. and comparing the results with the standard given by the Drugs and Cosmetics act (DCA), Government of India.

(ii) Quality Assurance

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

Example: To get a quality platelet concentrate we have to ensure SOP is followed at all critical steps of process flow, starting from donor screening, phlebotomy site cleaning, and phlebotomy, temperature maintenance during blood transport, calibrated centrifuge and trained technical staff in the component lab.

(iii) Quality Management

Co-ordinated activities to direct and control an organization in regard to quality and includes: quality control, quality assurance to be achieved by application of Good Manufacturing Practices(GMP)/Good Lab Practices (GLP)/Good Clinical Practices(GCP), planning (quality policy) and improving.

(iv) Total Quality Management

Management approach centred upon quality based upon the participation of all the staff and aiming at long term success through customer satisfaction and benefits to all staff and society.

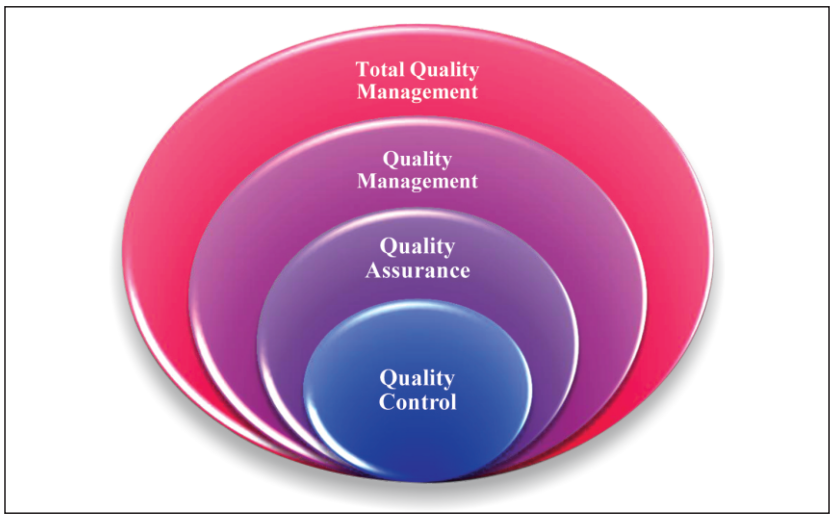


Figure 24: Concept of Quality Management

(v) Standards on Blood Banks / Blood Centres and Transfusion Services:

As per "Standards on Blood Banks/Blood Centres and Transfusion services" issued by National Accreditation Board for Hospitals and Healthcare Providers, Quality Council of India, quality management system is divided into eleven quality essentials:

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

Details of two of the above mentioned standards (Equipment, External services and supplies) are explained below. Complete details can be accessed from NABH website.

➲ Equipment

The blood bank should have an equipment management system in place. It should have a policy for the selection, procurement and installation of equipment: This includes:

a) Design qualification

Specifications of equipment according to users need. Designing specification is very a crucial step in getting quality equipment. Example: Specifications of refrigerated centrifuge for centrifugation of blood bags can have few special specifications according to user needs like capacity of 6 or 12 blood bags/spin according to work load, blood bag buckets with hook adapters for centrifugation of buffy coat bags for preparation of buffy coat derived platelet concentrate.

b) Installation qualification

This includes electrical power requirements of equipment, physically checking of equipment for any damages during transport and proper positioning of equipment.

Example: Installation Qualification of refrigerated centrifuge will include ensuring proper electrical supply and checking of availability of uninterrupted power supply (UPS), balancing of equipment, checking ambient temperature of room for proper functioning of compressor, adequate space from the wall and on all sides of equipment and interference to other equipments.

c) Operational qualification

Check the functioning of the equipment after installation usually under ideal conditions. Training of the staff on equipment is done during this phase.

Example: Operational qualification of refrigerated centrifuge includes; checking the internal temperature of centrifuge with digital thermometer and checking the accuracy of rotor speed with tachometer, checking the centrifuge by mock runs at different temperature, speed, acceleration and deceleration and noting down the run time with each variable. Train the staff for operating and maintaining a clean centrifuge.

d) Performance qualification

Checking the functioning of equipment in day to day work and whether it is fulfilling the function it is intended for.

Example: Performance qualification for refrigerated centrifuge includes; after successful operational qualification, the equipment will be subjected to test runs for routine work using previously standardized centrifugation speeds and time. Products prepared using this equipment should be subjected to various parameters of quality control to check whether the equipment is yielding quality blood products or not. During this period the equipment is checked for any errors or shutdowns during run or any unusual noise... It is recalibrated if it is not yielding quality blood components.

e) Labelling

All equipments should have a unique identification number and an equipment label indicating the calibration date and calibration due date. Instructions for use and for daily maintenance should be available.

f) Log book maintenance

A log book of all critical equipment should be available and it should include the following details: installation report, AMC/CMC status, service engineer's contact number, and specimen signature of all staff that uses the equipment, details of all maintenance and repair and day to day functioning.

g) Calibration of equipments

- **Calibration:** A set of operations which establish under special conditions the relationship between values indicated by measuring instruments and known standards.

  For quality assurance it is essential to calibrate the equipments used in blood bank by taking measures to ensure the accuracy and reliability of equipment and instruments used in the collection, testing and storage of blood products.

  It is the responsibility of the supervisor of the section to

  (i) Plan, schedule, organize and maintain records of the calibration programmes for various equipment under them

  (ii) Ensure that equipment and instruments are continuously calibrated or are removed from use.

  (iii) The staff should be trained for performing calibration/performance checks.

- **Performance checks:** The routine checking of the performance of an instrument to verify that it has remained within the specified range of accuracy and precision.

- **Accuracy:** The closeness of agreement between the result of a measure and the true value of measurement. Calibration is used to determine the accuracy of an instrument.)

- **Precision:** The closeness of agreement between the results of successive measurement of a defined procedure several times under prescribed conditions.

- **Measurement standard:** A instrument or material which physically defines a unit of measurement or value of a quantity. Measurement standards used for calibration should be traceable to the SI units of standard measurements.

h) Calibration Schedules

- Place new equipment on stock register prior to use.
- Ask the supplier prior to delivery or after installation to calibrate the new equipment and provide a certificate of calibration.
- Maintain calibration / maintenance schedules for all equipment.

Table 8.1: Schedules and procedures for equipment maintenance and calibration

Equipment	Performance check
Blood collection monitor	Observe weight/volume of the first blood bag filled
Copper sulfate solution	Check specific gravity for each lot number mentioned.
Emergency power supply	Check at least once monthly
Freezers, refrigerators and platelet incubators	Monitored by temperature recording device, digital recorder or by thermometers daily. Thermographs to be reviewed weekly. Alarm system to be checked monthly.
Digital temperature recorder	Compare with thermometers daily.
Refrigerated centrifuge	Observe and record temperature and machines speed each day of use.
General lab centrifuge	Check speed by tachometer every 6 months of use
Micro hematocrit centrifuge	Standardize before initial use, after repair or adjustments and annually
pH meter	Check pH on the day of use
Resuscitation equipment	Test flow meter and pressure gauge of O_2 tank on day of use
Laboratory water baths	Read and record temperature daily before test.
Water baths for thawing Fresh Frozen Plasma	Read and record temperature daily before thawing
Shakers or rotators	Calibrate oscillations per minute daily before use.

➲ External Services and Supply

Inventory: is the listing of items which are available and used in the workplace.

Stock: is the record of quantity of items procured and their status.

Inventory / Stock management is to maintain adequate supplies to ensure uninterrupted service.

Stock management ensures availability of material and kits, avoids the use of expired kits and minimizes wastage. Steps in Inventory / Stock management are as follows.

1. **Performing a 'Stock count':** It involves physically counting each item in the stock. Stock count is to be done each time an item is issued and at regular intervals. It is to be done by a designated staff member. All items must be accounted for and everything that comes in and goes out must be recorded.

2. **Maintaining inventory records:** Stock book contains listing of all items in the store. It must be updated regularly after physical count.

3. **Determining when to re-order:** Re-ordering is to be done when stock reaches minimum level.

   Minimum stock is defined as the amount of stock required to support the operations until additional supplies are received.

   Lead time is defined as the time between placing an order and receiving it.

   Maximum usage is the number of articles used in a given time period.

   Minimum stock level = Maximum lead time X Maximum stock usage.

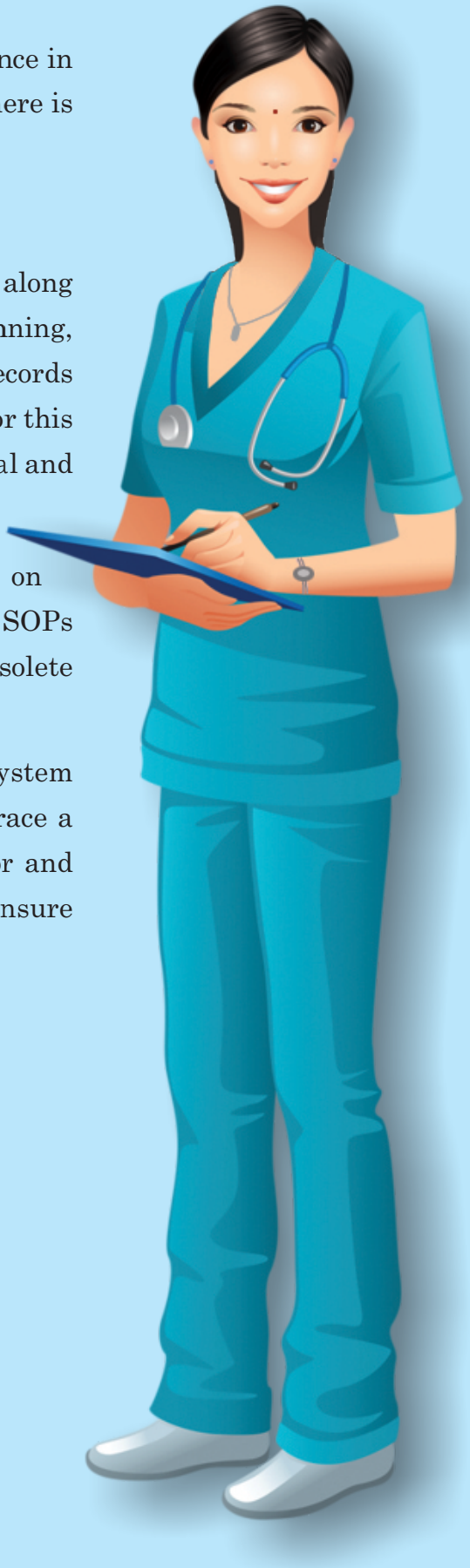
4. **Determining how much to re-order :** Establish the full stock level. Re-order to reach that level. Never order more than the storage space can hold. Never order more supplies than what can be used before the material expires. Also, the cost of shipping needs to be considered.

5. **Placing orders:** Follow the local system to place order for supplies. Maintain the record of the order i.e. what, how much, when and to whom the order has been placed.

6. **Inspecting delivery of new orders:** The following should be done upon receipt of the material :

   a. Verify and tally the contents of the order received with requisition.
   b. Check integrity of received supplies.
   c. Date each item received.

Quality Management in the Blood Transfusion Services and Roles and Responsibilities of nurses



- Nurses should have knowledge of quality assurance in blood transfusion services and make sure that there is safe and adequate blood available in the lab.
- Use blood appropriately and effectively
- As part of quality management systems, nurses along with the other staff should ensure effective planning, operation and control of its processes and records according to international/national standards. For this to take place, the lab should have a quality manual and documents.
- Make sure that all relevant SOPs are available on work bench and used by all. One copy of all the SOPs should be maintained in a master file and the obsolete versions archived.
- The nurse should be able to maintain the record system along with other staff and make it possible to trace a unit of blood / component from the source (donor and collecting facility) to the final destination and ensure confidentiality of donor and patient records.

Choose the Best Option:

1) QMS in BTS is needed to achieve

   a) Safe and adequate blood supply

   b) Appropriate and effective use of blood

   c) Prevention of errors and risks

   d) All of the above

2) As per "Standards on Blood Banks/Blood Centres and Transfusion services" issued by National Accreditation Board for Hospitals and Healthcare Providers, Quality Council of India, quality management system is divided into how many quality essential.

   a) 10 b) 11 c) 12 d) 14

3) Freezers, refrigerators and platelet incubators should be monitored by temperature recording device, digital recorder or by thermometers

   a) Daily b) Weekly c) Monthly d) Yearly

4) Records help in traceability of any unit from its collection from the donor to transfusion in the recipient in cases of :

   a) Clerical errors

   b) Technical errors

   c) Adverse reaction related to donor or the recipient

   d) All of the above

5) Donor deferral register shows the following except

   a) Details of donor b) ABO & Rh typing

   c) Permanent or temporary deferral d) Reason for deferral

NOTES:

FURTHER READINGS

1. Drugs and Cosmetics Act and Rules 1940 (along with Amendments), Sections XB and XIIB, Ministry of Health and Family Welfare Govt. of India.

2. Standards for Blood Banks Accreditation, NABH.

3. AABB Technical Manual, 17th edition (2010), AABB Press, USA.

4. Clinical Use of Blood. World Health Organization, Blood Transfusion Safety, Geneva, 2001

5. Screening donated blood for transfusion transmissible infections – recommendations. World Health Organization, Geneva, 2010.

6. Barbara John. Viruses. VoxSanguinis 2004, 87 (supplement 1), S91 – S94.

7. Busch M, Kleinman HH, Nemo GJ. Current and emerging infectious risks of blood transfusions. JAMA 2003, 289:959-962.

8. Manual on HIV testing in laboratories. NACO, 2007.

9. Transfusion Medicine – Technical Manual. 2nd Ed. New Delhi, India: Directorate General of Health Services (DGHS), Ministry of Health and Family Welfare, Government of India; 2003.

10. Voluntary Blood Donation Program An Operational Guidelines - NACO,2007.

11. An Action Plan for Blood Safety - NACO, 2007.

12. Standards for Blood Banks and Blood Transfusion Services - NACO, 2007.

ANNEXURES

SAMPLE OF BLOOD DONOR QUESTIONNAIRE

XYZ Blood Bank

Thank you for coming forward to donate blood

To ensure your safety as a blood donor and the safety of the patients who will receive your blood, please read the information leaflet provided and answer this questionnaire correctly. If you have any difficulty in filling this form please ask for help from the Blood Centre Staff. Al details given by you will be kept confidential.

Donor's Name: _____

Date of Birth: _____

Address (Resi.):_____		Sex:
_____		Age:

Address (Office) _____

_____

Contact Nos :.(Resi.) _____(Office)_____(Mobile)_____

E-Mail _____

1. Have you donated Blood previously? Yes No
   - 1.1. If yes how many times
   - 1.2 Date of last donation:
   - 1.3. Did you experience any ailment, difficulty or discomfort during previous donations?
   - 1.4. What was the difficulty?
   - 1.5. Have you ever been advised not to donate blood? Yes No
- 2.1. Are you feeling well today?
- 2.2. Have you eaten anything in the last 4 hours?
- 2.3. After donating blood do you have to engage in heavy work, driving heavy vehicle or work at heights today Yes No

3. Have you had / have any of the following? If yes, discuss with the doctor present:

• Allergy • Cancer • Fainting attacks • Heart disease • Lung disease • Asthma	• Kidney disease • Mental illness • Amoebiasis • Cold / cough • Liver disease • Fever	• Endocrine disease • Diabetes • Syphilis • Gonorrhoea • Skin disease • High / Low Blood Pressure	• Leprosy • Epilepsy • Blood / Bleeding disorder • Tuberculosis • Polycythemia • G – 6 PD deficiency

4. During past 12 months have you had any of the following?

4.1.	Received blood or blood components?	Yes	No
4.2.	Any accidents or operations	Yes	No
4.3.	Received any vaccinations	Yes	No
4.4.	Bitten by any animal, which can result in rabies?	Yes	No
4.5.	Had tattooing / ear piercing or acupuncture treatment?	Yes	No
4.6.	Have you been imprisoned for any reason?	Yes	No

5.	Have you had jaundice in the last 1 year?	Yes	No
5.1.	Has your blood ever tested positive for hepatitis B or C?	Yes	No
5.2	Have you had close contact with anyone (family / others) suffering from jaundice in the last 1 year?	Yes	No

6.	Have you had tuberculosis or typhoid during the last year?	Yes	No
7.	Have you had malaria or taken antimalarial drugs in the last 3 years?	Yes	No

8. Have you had any of the following in the last 6 months?

Dental Procedure	Yes	No
Measles	Yes	No
Mumps	Yes	No
Chicken Pox	Yes	No
Dengue	Yes	No

9.	Have you taken any medicine in the last 7 days especially aspirin or antibiotic	Yes	No
10.	Do you know that you should not give blood in following conditions?	Yes	No

Please Remember

- If you were found to be positive for HIV, Hepatitis B, C or Syphilis infections
- If you are having multiple sex partners or have engaged in male to male sexual activity
- If you have ever worked as a sex worker or had sex with a sex worker
- If you have ever injected any drug (esp. Narcotics) not prescribed by a qualified doctor
- If you suspect that you or your partner may have HIV or any other sexually transmitted disease

11. Do you or your sexual partner belong to one of the above categories? Yes No

11.1. Do you have any reason to believe that you have been infected by the virus that causes AIDS? Yes No

11.2. In the last 6 months have you had:

Night sweats Yes No
Persistent diarrhea Yes No
Persistent fever Yes No
Unexplained Weight Loss Yes No
Swollen Glands Yes No

12. In case you are a woman:

a. Are you pregnant or have you had an abortion in the last 6 months? Yes No
b. Have you a child less than 1 year of age? Are you breast feeding? Yes No

Consent

I understand that

(a) Blood donation is a totally voluntary act and no inducement or remuneration has been offered

(b) Donation of blood/components is a medical procedure and that by donating Voluntarily, I accept the risk associated with this procedure.

(c) My donated blood, blood and plasma recovered from my donated blood may be sent for plasma fractionation for preparation of plasma derived medicinal products, all of which may be used for larger patient population and not just this blood bank.

(d) My blood will be tested for Hepatitis B, Hepatitis C, Malaria parasite, HIV/AIDS and syphilis diseases in addition to any other screening tests required ensuring blood safety.

(e) I would like to be informed about any abnormal test results done on my donated blood: Yes/No

Donor's Signature: Signature of Medical Officer:

XYZ Blood Bank

MEDICAL ASSESSMENT	Name of Medical Officer:	Sign:
Donor's Name:_____ **Weight:** _____ **kgs Hb Level: ≥ 12.5g/dl** **<12.5g/dl**		
History Check list:	Feeling well / Adequate sleep (>5hrs) / Last meal within 4 hrs Ever hospitalized Current illnesses or medications:	
Examination Check List:	Unhealthy look / pallor / icterus / alcohol smell Infected wounds / Venepuncture site lesions Pulse:.....beats/min BP:.....mmHg Heart:..... Lungs:.....	
Counseling Points:	Post donation instructions / making a regular donor Need for follow up for TTI purposes. How to contact for follow up purposes: By a letter / By phone / By e-mail	
Outcome:	Donor accepted/ Temporary deferral/ Permanent deferral	
Remarks / Reasons for Deferral:		

REGISTRATION	Name of Medical Officer:	Date
Donor I.D. No.	**Blood Unit No.**	**Segment No:**
Type of Bag: Single:	Double: Triple:	Quadruple:

BLOOD COLLECTION	Name of Phlebotomist:	Sign:
Check: Donor's Name **Check Donation No:** On Donation record / Blood Bags / Specimen Tubes **Start time:**..... a.m. / p.m. Time Taken:.....mins. **Volume:**.....ml		
Complications: Faint: Fits: Double Prick: Haematoma: Others (please specify):		
Management:		

S.F. No.: **Version No.:**

(I): QC of $CuSO_4$

XYZ Blood Bank QC of Working $CuSO_4$ Solution

Date	Specific gravity of DW	Specific gravity of working $CuSO_4$ Solution	Result Pass Fail	Known Controls <12.5 P/ F >12.5 P/F	Sign

Specific gravity of distilled water (DW) 1.00

Specific gravity of copper sulphate ($CuSO_4$) 1.053 (12.5gm / dL Hb)

Known controls to be obtained very week from laboratory of hematology QC to be performed once a week.

Corrective measures if taken:

Signature of technologist / MO

(II): Donor Reactions

XYZ Blood Bank

Donor Reactions Report

Donation date & time:_____ **Name:** _____

Age / Gender:_____**Weight:** _____ **Unit ID:**_____

Type of Donation: Replacement / Voluntary/ WB / Apheresis Donation Status: First time/ report/ repeat (no)

Volume Collected:

Donor Reaction Details: (Circle all that apply)

- **Location:** Examination room / Phlebotomy room / Refreshment room / Others _____
- **Time:** Before donation / During donation / After Donation
- **Symptoms:** Dizziness / Light headedness / Nausea / Weakness / Difficulty in breathing / tingling / numbness in lips / others _____
- **Signs:** Pallor / Diaphoreses / Nervousness / Vomiting / Incontinence / Hypotension / Muscle twitching / hyper ventilation / bradycardia / tachycardia / LOG _____ sec / min. Others _____
- **Action Taken:** Donation discontinued / Feet elevated / Encouraged fluid intake/ Donor chair reclined / assisted to floor / cool compress / Ammonia inhalation / Others _____

Vital Monitoring

Time	Pre- donation	Donation	Post - Donation
BP (mm of Hg)			
Pulse (Beats/ min)			

H/O previous reaction: Yes / No. If yes ⟶ Level mild / moderate / severe

Reaction Level: 1 / 2 / 3 Advise for future donation: Yes / No / Others _____

Other donor complications

Hematoma Size: _____Ice applied / Pressure bandage applied / Others :_____

Arterial puncture:_____ Arm pain: _____

Others :_____ Bandage allergy:_____

Recovery period: _____ **min Discharge time:**_____

Corrective measures if taken:

Sign of personnel attending doctor **In charge signature**

(i) SAMPLE OF BLOOD & BLOOD COMPONENTS REQUEST FORM

Department of Transfusion Medicine / Blood Center:

- The sample in EDTA via (preferably vaccutainer) for blood grouping and the vial must be labelled
- Requisition form and sample with discrepancy are UNACCEPTABLE
- This form will not be accepted if it is not signed or any relevant section is left blank.

Patient's Name.....ID No.....Age..... Sex..... Ward.....

Diagnosis..... Clinician In charge.....

Blood group.....Rh.....(Send fresh 2ml sample in EDTA vial for blood grouping If the patient has received transfusions check blood group from records as its correct information is responsibility of the doctor filling this requisition form).

Indication for Transfusion:

Pre-transfusion values:

Platelet count: _____ x 10^5/µL APTT: _____ sec. PT: _____sec.

PTI: _____ % Serum albumin: _____ g/dL

Quantity of unit(s) required: _____

☐ Whole blood_____ ☐ Packed cells: _____ ☐ Apheresis Platelets:____

☐ Platelets _____ ☐ FFP / Plasma:_____ ☐ Cryoprecipitate:_____

☐ Special products

Previous Transfusion	Yes ☐	No ☐
H/O Pregnancy / Abortion	Yes ☐	No ☐
Adverse Reaction, if any	Yes ☐	No ☐

Certify that I have personally collected the blood sample after identification of patient's ID No. and name. I have explained the necessity of component transfusion and the risks associated with it to patient / relatives and have taken informed consent.

Time _____ AM/PM Signature of MO _____

Date _____ Name _____

(ii): SAMPLE - CONSENT FORM FOR TRANSFUSION

Name of the Hospital.....

CONSENT FOR THE TRANSFUSION OF BLOOD / BLOOD COMPONENNTS

Patient's Name.....Registration No.....Ward / Bed No.....

Blood transfusion is a lifesaving medical procedure. Blood can be given as 'whole blood' or as components such as: Red cells, platelets, Plasma and Cryoprecipitate.

1. I/My patient have/have been informed of the transfusion options available and expected benefits of transfusion of blood and / or components.

2. I/My patient understand/s that blood / blood components in the interest of proper medical care.

3. I / My patient understand/s that blood / blood components to be administered have been prepared ad tested in accordance with rules established by National Regulation. However, there is still a very small chance that an adverse reaction can occur such as: fever with or without chills and rigor, itching and hives, which are treatable. Rarely an unpredictable life threatening event can also occur.

4. I/My patient have/has been informed that despite mandatory screening for blood borne infections such as HIV, Hepatitis B, Hepatitis C, Syphilis and Malaria, the risk of acquiring these infections is not totally eliminated.

5. I/My patient have/has had the opportunity to ask questions about transfusions, alternatives to transfusion, risk of not transfusing, the procedures to be used and the relative risks and hazards involved

6. I/My patient believe/s that I/My patient have /has been sufficiently informed to make a decision to give consent for transfusion of blood / blood components.

7. I/My patient have/have been informed and explained the above in a language that I/My patient understand/s.

AUTHORIZATION BY PATIENT

Name of the Patient	
Signature / Thumb Impression	
Name of Witness	
Signature / thumb Impression	

Date ---------- Doctor ---------- Designation: ----------

PATIENT'S ATTENDANT / NEXT TO KIN

The patient is unable to give consent because ----------

And I ---------- (name / relationship to the patient), therefore consent for the patient. I acknowledge that I have had an opportunity to discuss this procedure, as stated above, with my physician, physician designee and hereby consent to this procedure.

If consent is not taken please mention reason for it.

Signature of Medical Officer

(4.1) WHOLE BLOOD / BLOOD COMPONENT / BLOOD PRODUCT FORM

(COMPATIBILITY REPORT)

(Form no. 1 Annexure II of Guidance document for Reporting Serious Adverse Reactions in Blood Transfusion Services, National Institute of Biologicals)

(Name of hospital .....)

(To be retained in patient's file)

1.0 PATIENT DETAILS

S. No. _____ Date _____

Name of Pt. _____

Age / Sex _____

Reg. No. _____

Blood Group _____ Rh _____

Hosp. _____ Wd _____Bed _____

2.0 PRODUCT DETAILS:

2.1 Blood / Components

1. WB
2. PRBC
3. LPRBC
4. PC
5. PRP
6. FFP
7. Cryo Poor Plasma
8. Cryo Precipitate
9. Blood Product (Name) .....

Batch No. .....Manufacturer.....

..... Expiry .....

Bag No (s)	Date	Blood Bank
1.		
2.		
3.		
4.		
5.		

Signature of Medical Officer

(4.2) WHOLE BLOOD / BLOOD COMPONENT /BLOOD PRODUCT TRANSFUSION REACTION FORM

(Form no. 2 Annexure III of Guidance document for Reporting Serious Adverse Reactions in Blood Transfusion Services, National Institute of Biologicals)

(Name of hospital .....)

(To be sent to Department of Transfusion Medicine / Blood Bank after transfusion)

S. No. _____ Date _____

Name of Pt. _____

Reg. No. _____ Group _____ Rh ____

Blood Group _____ Rh _____

Hosp. _____Wd _____Bed _____

Donor Units

Blood Bag No(s).

1.

2.

BLOOD / COMPONENTS / PRODUCTS

1. WB
2. PRBC
3. LPRBC
4. PC
5. PRP
6. FFP
7. Cryo Poor Plasma
8. Cryo Precipitate
9. Blood Product (Name) .....

Batch No. .....Manufacturer.....

..... Expiry .....

Transfusion started at _____ completed at __ _____ Rate to Transfusion _____ drops per minute Actual quantity of blood transfused _____(ml)

CLINICAL OBSERVATION:

General condition	Pre Transfusion	During Transfusion	Post Transfusion
Pulse			
Resp.			
Temp.			
B.P.			
Rigor			
Chills			
Myalgia			
Urticaria			
Other Observation			

Doctor / Nurse

Note: In any case of transfusion reaction, inform the blood bank staff immediately. Send blood bag, transfusion set, Post – transfusion sample (EDTA)

Signature of Medical Officer / Nurse

(4.3) PROTOCOL FOR THE INVESTIGATION OF ACUTE TRANSFUSION REACTION

(Annexure IV of Guidance document for Reporting Serious Adverse Reactions in Blood Transfusion Services, National Institute of Biologicals)

Investigation of Acute Transfusion Reactions

- Take immediate note and inform blood bank
- Seek help immediately from skilled anaesthetist or emergency team
- Complete the transfusion reaction form and appropriately record the following:-
  - Type of Transfusion Reaction
  - Time after the start of transfusion to the occurrence of reaction
  - Unit No. of component transfused
  - Volume of the component transfused

Send the following for lab investigations:

1. Repeat ABO & Rh (D) Grouping
2. Repeat Antibody Screen and Cross Match
3. Direct Antiglobulin Test

Send EDTA and citrated blood sample and urine sample to Hematology for:

4. Complete Blood Count (CBC)
5. Plasma Hemoglobin
6. Urine Hemoglobin
7. Coagulation Screen

Send clotted Blood sample to Biochemistry Lab for:

8. Renal function test (urea, creatinine and electrolytes)
9. Liver function tests (bilirubin, ALT and AST)

Send Blood culture in special blood culture bottles to Microbiology Lab.

(4.4) IMPUTABILITY LEVELS

(Sub Annexure V of Guidance document for Reporting Serious Adverse Reactions in Blood Transfusion Services, National Institute of Biologicals)

Term	Assessment Scale
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 favour of attributing the adverse event to the transfusion or an alternate cause.
Unlikely (Doubtful)	When the evidence is clearly in favour 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.

(4.5) TRANSFUSION REACTION WORK-UP FORM

(Annexure VI of Guidance document for Reporting Serious Adverse Reactions in Blood Transfusion Services, National Institute of Biologicals)

(Name of the Hospital .....)

S. No.

Name: .....Hospital .....

Registration No.....Ward/Bed No.....

Age/Sex.....Unit In charge.....

Diagnosis.....

Indication for Transfusion.....

Clinical Status of Patient:

Respiratory system:	Renal:
CVS:	GIT:
CNS:	Liver:

H/o Previous Transfusion, Pregnancy, Transplantation:

.....

H/o Drug intake:.....

Any other infusion through B.T. set:.....

Reaction details:.....

Received:

Reaction form (duly filled):.....

Blood Bag/Bags along with transfusion set:.....

Post transfusion sample:.....

Date/time at which blood / Blood component was transfused:.....

Date/time at which reaction occurred:.....

Date/time at which sample/reaction form were sent to blood bank.....

TRANSFUSION REACTION WORK-UP FORM (Contd.)

(Name of the Hospital .....)

S. No.

Blood/Blood Component unit No. .....

Amount of Blood/Blood Component Transfused: .....

Investigation:
Identification of Patient:

Rechecking of Records:

Cross match file .....

Issue Register .....

Blood Grouping Register .....

Visual Examination of Bag/Transfusion set .....

Supernatant of Sample:
Pre Tx Sample:

Post Tx Sample.....

Bag Sample.....

Blood Group:
Pre Tx Sample.....

Post Tx Sample.....

Bag Sample.....

Direct Coombs Test (DCT):
Post Tx Sample:.....

Pre Tx Sample.....

Repeat cross match of Blood Bag Sample with:

Major (RT)	Major (370) AHG Phase	Minor (RT)
Pre Tx Sample		
Post Tx Sample		

TRANSFUSION REACTION WORK-UP FORM (Contd.)

(Name of the Hospital .....)

S. No.

Evidence of Haemolysis:

Plasma Haemoglobin.....Haemoglobin: Pre Tx.....

Serum Bilirubin:..... Post Tx:.....

Urine Haemoglobin:.....

Urine Hemosiderin:.....

Coagulation status:

PTI:.....

Platelet count:.....

Blood Culture (Date/time at which culture was sent):

Blood Bag:.....

Patient:.....

Peripheral Blood smear (Patient sample / Blood Bag sample):

Leishman stain.....

Gram stain:.....

Unstained smear:.....

Blood Bag Details:

Type of Blood Bag:.....

Lot No.....Date of collection:.....

Tube No.....Date of Expiry.....

Cross match details:

Date of Cx-match:.....

Emergency / Routine.....

Name of Technical staff who cross matched the unit.....

Date/time of Issue:.....

Interval between issue and transfusion.....

Where was blood kept during that interval:.....

Was the blood warmed before transfusion, if yes , by what method:.....

TRANSFUSION REACTION WORK-UP FORM (Contd.)

(Name of the Hospital .....)

S. No.

If Blood bag has been previously Cx-matched/issued:

Date of Cx Match	Date/time of Issue	Date of Receive Back

Donor Details

Name:.....Age/Sex.....

Address:.....

Phone.....

Date of Collection:.....Place of Collection.....

Name of Phlebotomist / Assistant:.....

Type of Donor VD / RD.....

Any special Investigation.....

.....

Inference:

.....

.....

.....

Signature of Consultant / Senior Resident/ Junior Resident / Medical Officer

(4.6) TR – TD (TRANSFUSION REACTION – TRANSFUSION DOCUMENT)

RECORD TO BE MAINTAINED BY

THE DEPARTMENT OF TRANSFUSION MEDICINE / BLOOD BANK

(Annexure VII of Guidance document for Reporting Serious Adverse Reactions in Blood Transfusion Services, National Institute of Biologicals)

Sl. No.	TRRF No.	Patient Reg No. of Hospital	Adverse Reaction	Blood / Blood component / Blood product transfused	Batch No/ Bag No. Mfg. date/ Expiry date	Indications for transfusion	Date & time of observed adverse reaction	Clinical features of the adverse reaction observed	Laboratory findings	Imputability Level	Final outcome of the transfusion reaction

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

(Annexure VIII of Guidance document for Reporting Serious Adverse Reactions in Blood Transfusion Services, National Institute of Biologicals)

National Institute of Biologicals – Indian Pharmacopoeia Commission
Ministry of Health & Family Welfare Govt. of India
HAEMOVIGILANCE PROGRAMME OF INDIA, NATIONAL INSTITUTE OF BIOLOGICALS
(National Coordinating Centre)

For reporting of Transfusion Reactions by Healthcare Professionals

A) PATIENT INFORMATION

Patient initials *.....DOB / Age in years*.....Blood Group*.....Diagnosis.....

Hospital Code No.....Hospital Admission No*.....Sex* F M

Date * & Time of Transfusion .....Date * & Time of reaction ..... Date & Time of recovery .....

B) TRANSFUSION PRODUCT DETAILS*

Components	Select Components	Unit Number (Transfused)	Expiry Date of the Blood Component	Manufacturer of the Blood Bag	Batch Number	Indications	1st time / Repeat Transfusion (No. of Repeats)
Whole Blood							
Red Blood Cells							
Platelets Apheresis							
Platelets Pooled / RDP							
Solvent detergent (SD) Plasma							
FFP							
Cryoprecipitate							
Any other							
Plasma Products (Please Specify)	**Manufacturer of the Plasma Product**		**Batch Number**	**Expiry Date of the Plasma Product**			

C) NATURE OF ADVERSE REACTIONS*

	Reactions	Please Tick (✓)
1	Immunological Haemolysis due to ABO Incompatibility	
2	Immunological Haemolysis due to other allo – antibodies	
3	Non Immunological Haemolysis	
4	Transfusion Transmitted Bacterial Infection	
5	Anaphylaxis / Hypersensitivity	
6	Transfusion Related Acute Lung Injury **(TRALI)**	
7	Transfusion Transmitted Viral Infection **(HBV)**	
8	Transfusion Transmitted Viral Infection **(HCV)**	
9	Transfusion Transmitted Viral Infection **(HIV - 1/2)**	
10	Transfusion Transmitted Viral Infection, other **(Specify)**	
11	Post Transfusion Purpura	

12	Transfusion Transmitted Parasitic Infection - **Malaria**				
13	Transfusion Transmitted Parasitic Infections **(Others specify)**				
14	Transfusion Associated Graft versus Host Disease **(TAGvHD)**				
15	Febrile Non Haemolytic Reactions **(FNHTR)**				
16	Transfusion Associated Dyspnea **(TAD)**				
17	Transfusion Associated Circulatory Overload **(TACO)**				
18	Other Reaction(s)				
D)	**OUTCOME OF THE ADVERSE REACTION (s)***		**E)**	**REPORTER**	
	Death following the adverse reactions			Name and professional Address: ---------- Pin Code:---------- Email---------- Tel. No. (with STD code) ----------	
	Recovered				
	Recovered with sequelae				
	Permanently disabled				
	Unknown				
Any other Information ……..			**F)**	**CASUALTY ASSESSMENT***	Date of this report (DD/MM/YYYY)

(4.8) TRANSFUSION REACTION REPORTING FORM (TRRF)

(Annexure VIII of Guidance document for Reporting Serious Adverse Reactions in Blood Transfusion Services, National Institute of Biologicals)

ADVICE ABOUT REPORTING

- Report adverse experience with Blood Transfusion or Blood Products Administration
- Who Can Report?
  - Any health care professional (Doctors including Dentists, Nurses and Pharmacists)
- Where to Report?
  - Please send the completed form to the nearest Medical Colleges / Hospitals / Blood Banks / Institutes under Haemovigilance Programme of India or to National Coordinating Center – Haemovigilance Programme of India. NIB
  - A list of nationwide Medical Colleges / Hospitals / Blood Banks / Institutes under Haemovigilance Programme of India is available at: http://www.nib.gov.in
- What happens to the submitted information
  - The causality assessment is carried out at Medical Colleges / Hospitals / Blood Banks / Institutes under Haemovigilance Programme of India
  - The information collected in Transfusion Reaction Reporting Form (TRRF) will be forwarded to National Coordinating Centre – Haemovigilance Programme of India NIB, through a software (Haemo-Vigil) developed in house by NIB's IT division. This data will be collated & analysed to identify trends, recommend best practices and interventions required to improve patient care & safety
  - These recommendations will be forwarded to IPC National Coordinating Centre, PvPI for onward transmission to Drugs Controller General (India). Central Drugs Standard Control Organization.
  - These recommendations will be used to formulate safety related regulatory decisions on Blood & Blood Products Transfusion which will be communicated to various stakeholders.
  - The information will be submitted to the advisory Committee of Haemovigllance Programme of India constituted by the Ministry of Health and family welfare. The Committee is entrusted with the responsibility to review the data and suggest any interventions that may be required.

TRANSFUSION REACTION REPORTING FORM (TRRF)

For VOLUNTARY reporting of Transfusion Reactions by health care professionals.

National Institute of Biologicals

National Coordinating Centre-Haemovigilance Programme of India
Directorate General of Health Services
Ministry of Health & Family Welfare, Government of India
A-32, Sector- 62. NOIDA
http://www.nib.gov.in

Confidentiality

The patient's identify is held in strict confidence and protected to the fullest extent. Programme staff is not expected to and will not disclose the reporter's identity in response to a request from the public, ***Submission of a report d oes not constitute an admission that medical personnel or manufacturer or the product caused or contributed to the reactions.***

TRRF can be downloaded from the websites:
www.nib.gov.in. www.ipc.gov.in. www.cdsco.nic.in

(4.9) FLOW CHART FOR REPORTING SERIOUS ADVERSE REACTIONS ASSOCIATED WITH BLOOD TRANSFUSION

(Annexure IX of Guidance document for Reporting Serious Adverse Reactions in Blood Transfusion Services, National Institute of Biologicals)

Medical Ward: Adverse Reaction noted by the Physician / Nurse.

↓

Medical Ward: Documentation in Form No.1 (Annexure II of NIB document)

↓

Medical Ward: Fill up Form No.2 (Annexure III of NIB document). Along with form No.2 send Blood Bag, Transfusion Set, and Post-transfusion Sample to Department of Transfusion Medicine / Blood Bank for further investigation including Repeat ABO & Rh (D) Grouping, Repeat Antibody Screen and Cross Match, Direct Antiglobulin Test.

↓

Medical ward: Send Post Transfusion Blood in special Blood Culture Bottles to Microbiology Lab.

↓

Medical Ward: Send EDTA and Citrated Blood Sample and Urine Sample of the patient to Hematology Lab for Complete blood count (CBC), Plasma hemoglobin, Urine hemoglobin, Coagulation screen.

↓

Medical Ward: Send clotted Blood Sample to Biochemistry Lab. For Renal Function Test (Urea, Creatinine and Electrolytes), Liver Function Test (Bilirubin, ALT and AST).

↓

Department of Transfusion Medicine / Blood Bank: to further investigate the Transfusion Reaction as per the Reaction Work up Form, document the findings, compilation of the reports from other departments and reporting results and inferences to the respective departments.

↓

Department of Transfusion Medicine / Blood Bank: Assess the Imputability Level of the Transfusion Reaction in coordination with the attending Physician of the respective medical departments.

↓

Department of Transfusion Medicine / Blood Bank: Enter the details in the Transfusion Reaction – Traceability Document (TR –TD). (Annexure VII of NIB document)

↓

Haemo – Vigil Software: Enter the information as per the Transfusion Reaction Reporting Form for Blood & Products for onwards transmission of data to NCC, NIB.

(4.10) ISBT TABLE OF REPORTABLE SERIOUS ADVERSE REACTIONS (SARS)

Serious Adverse Reactions	Clinical Features	Laboratory features
Immunological: Haemolysis due to ABO incompatibility	Fever, Chills/rigors, facial flushing, chest pain, abdominal pain, back/flank pain, nausea/vomiting, diarrhoea, hypotension, pallor, jaundice, oligoanuria, diffuse bleeding, dark urine, decreased haemoglobin levels. Reactions may occur within 24 hours (acute) or may not main fest for up to 28 days.	Haemoglobinuria, decreased serum haptoglobin, unconjugated hyperbilirubinaemia, increased LDH and AST levels. Blood group serology shows ABO incompatible mismatch between recipient and donor.
Immunological: Haemolysis due to other allo-antibody	As above	As above but blood group serology shows either allo-antibodies to donor red cells or auto-antibodies in the recipient
Non-immunological: haemolysis	As above	As above but due to non-immunological, possibly mechanical factors such as malfunction of a pump or blood warmer, or the use of hypotonic solutions etc.
Transfusion – transmitted bacterial infection. Note – MUST be reported	Fever, rigors and joint pain with no evidence of symptoms pre-transfusion or alternative source of infection.	Positive blood cultures from recipient and donor pack (matching organisms) or at least one component received by the infected recipient shown to contain the agent of infection
Transfusion-transmitted viral infection (HCV)		As above
Transfusion-transmitted viral infection HIV 1 &2		As above
Transfusion-transmitted viral infection – other		As above
Post transfusion purpura	Bruising, severe haemorrhage, oozing wounds. Usually occurs 5 -12 days post transfusion.	Thrombocytopenia (5-12 days post transfusion) and anti-HPA antibodies present
Graft versus host disease	Fever, rash, liver dysfunction, diarrhea. Usually occurs 1-6 weeks after transfusion. E.g. Febrile non haemolytic transfusion reactions	Pancytopenia, characteristic histological appearances on bone marrow biopsy, bone marrow hypoplasia, chimerism

	(FNHTR) where fever > = 39^{0}C oral or equivalent and a change of > = 2^{0}C from pretransfusion value, chills, rigors, headache, nausea. Usually occurs within 4 hours of transfusion and without any evidence of hemolysis, bacterial contamination or underlying condition. E.g. Transfusion associated circulatory overload (TACO) acute respiratory distress, tachycardia, increased blood pressure, acute or worsening pulmonary oedema on frontal chest x-ray, evidence of positive fluid balance. Usually occurs within 6 hours of completion of transfusion. E.g. Transfusion associated dyspnea (TAD) – respiratory distress occurring within 24 hours of transfusion but without the symptoms of TRALI, TACO or allergic reactions and not explained by any underlying condition	

INDUCTION TRAINING SCHEDULE FOR BLOOD BANK NURSES

DAY 1					
Time	**Session**	**Activity**	**Methodology**	**Duration**	**Resource Person**
9.00am - 9.30am		Registration	Group activity	30 minutes	Training Coordinator
9.30am - 10.10am	**Session 1** Introduction	**Activity 1:** Participant introduction	Ice breaker	15 minutes	Senior Staff Nurse
		Activity 2: Expectation of the participants	Individual Activity	5 minutes	
		Activity 3: Pre training assessment	Individual Activity	20 minutes	
10.10am - 10.45am	**Session 2:** Introduction to National blood safety program & National Blood Policy	**Activity 1:** Over view of National blood safety program	Video	15 minutes	SACS Quality Manager
		Activity 2: National Blood policy	Power point presentation	20 minutes	
10.45am - 11.00am	**TEA BREAK**				
11.00am - 1.00pm	**Session 3 :** Blood donor selection	**Activity 1**:Donor recruitment and retention	Power point presentation	30 minutes	Senior Counsellor, Senior Staff Nurse, Senior Doctor/MO Blood bank
		Activity 2: Donor room procedure & Adverse Donor Reaction	Power point presentation & Trigger video	60 minutes (Video- 20 minutes , PPT- 40 minutes)	
		Activity 3: Organization of blood donation camp	Group activity	30 minutes	
1.00pm - 1.45pm	**LUNCH**				

1.45pm - 3.30 pm	**Session 4:** Immunohematology	**Activity1:** Basic red cell serology	Power point presentation	30 minutes	Senior Doctor/MO blood bank
		Activity 2: ABO and Rh grouping & Typing	Power point presentation & Trigger video	60 minutes (Video- 20 minutes , PPT- 40 minutes)	
		Activity 3 : Basics of ABO grouping discrepancies	Power point presentation	15 minutes	
3.30pm - 3.45pm	**TEA BREAK**				
3.45pm - 4.45pm	**Session 4 :** Immunohematology – Continuation	**Activity 4 :** Lab demonstration - HB estimation, ABO , RH Grouping & typing)	Lab demo	60 minutes	Senior lab technician
DAY 2					
Time	**Session**	**Activity**	**Methodology**	**Duration**	**Resource Person**
9.00am - 9.30am	Warming Up	**Recap of DAY 1 Session**	Presentation	30 minutes	Rapporteur & time keeper
9.30am - 10.30am	**Session 1:** Transfusion transmissible infections	**Activity 1:** Basics of TTI	Power point presentation	30 minutes	Senior staff nurse
		Activity 2: Screening of TTI	Lab demo	30 minutes	Senior Lab technician
10.30am – 11.30am	**Session 2:** Bio safety & Waste management	**Activity 1:** Bio safety	Power point presentation & video	60 minutes (Video- 20 minutes , PPT- 40 minutes)	Senior Doctor/MO blood bank & Staff nurse
11.30am – 11.45am	**TEA BREAK**				
11.45am – 12.Noon	**Session 2:** Bio safety & Waste management (contd.)	**Activity 2: "**Bin it in a minute" Game	Individual Activity	15 minutes	Participants
12Noon – 1.00pm		**Activity 3:** Bio medical waste management	Power point presentation	60 minutes	Senior Doctor/MO blood bank
1.00pm – 1.45pm	**LUNCH**				

1.45pm – 2.15pm	**Session 3:** Equipment management & calibration	**Activity 1:** Equipment management & calibration	Power point presentation	30 minutes	Senior staff nurse & Senior Lab technician
2.15pm – 3.15pm	**Session 4:** Blood Components	**Activity 1:** Blood components	Trigger video & power point presentation	60 minutes (Trigger video – 20 minutes, PPT – 40 minutes)	Senior Doctor/MO blood bank
3.15pm – 3.30pm	**TEA BREAK**				
3.30pm – 3.45pm	**Session 4:** Blood Components (contd.)	**Activity 2:** Storage & Transportation	Power point presentation	15 minutes	Senior blood bank Staff Nurse
3.45pm – 4.15pm		**Activity 3:** Administration of blood components	Power point presentation	30 minutes	Senior blood bank Staff Nurse
Day 3					
Time	**Session**	**Activity**	**Methodology**	**Duration**	**Resource Person**
9.00am-9.30am	Warming Up	**Recap of DAY 2 Session**	Presentation	30 minutes	Rapporteur & time keeper
9.30 am-11.00 am	**Session 1:** Pre transfusion issues & Bed side practices & Transfusion reaction	**Activity 1 :** Pre transfusion issues	Power point presentation	30 minutes	Senior Staff Nurse
		Activity 2: Bed side practices	Power point presentation	30 minutes	
		Activity 3 : Transfusion reaction	Power point presentation	30 minutes	
11.00am - 11.15am	**TEA BREAK**				
11.15am - 12.15pm	**Session 2 :** Roles & responsibilities of Staff Nurse	**Activity 1:** Roles & responsibilities of Staff Nurse	Power point presentation	60 minutes	Senior Staff Nurse

12.15pm - 1.00 pm	**Session 3:** QMS in BTS	**Activity 1:**"Simon Says" Game	Group activity	15 minutes	By Participants
		Activity 2: Quality Management & Haemovigilance	Power point presentation	30 minutes	Senior Doctor/MO blood bank & Senior staff nurse
1.00pm-1.45pm	**LUNCH**				
1.45pm - 3.15pm	**Session 4:** Record keeping, documentation & legal aspects	**Activity 1**: Record keeping & documentation	Power point presentation	45 minutes	Senior Doctor/MO blood bank & Senior staff nurse
		Activity 2: Legal aspects of Blood bank	Power point presentation	45 minutes	
3.15pm-3.30pm	**TEA BREAK**				
3.30pm-4.00pm	**Session 5 :** Licensing and Regulation, Drugs and Cosmetic Act	**Activity 1:** Licensing and Regulation, Drugs and Cosmetic Act	Power point presentation	30 minutes	Senior Doctor/MO blood bank & Senior staff nurse
4.00pm-4.30pm	**Session 6:** Data analysis, computer use and reporting	**Activity 1:** Data analysis, computer use and reporting	Power point presentation	30 minutes	
4.30pm - 5.30pm	**Session 6:** Post training assessment & wrap up	**Activity 1**:Post training assessment & feedback on quality of training	Pre Structured questionnaire	30 minutes	Training Coordinator
		Activity 2: Valedictory & certificate distribution		30 minutes	Training Coordinator

LABORATORY DEMONSTRATION

Day 1: Hb estimation, ABO , RH Grouping & Typing

Day 2: Screening of TTI

ROLES AND RESPONSIBILITIES OF BLOOD BANK MEDICAL OFFICERS

1) Administration, Oversight and Coordination

a) Overall supervision

b) Inventory management

c) Fulfilling regulatory requirements

d) Recording & reporting

e) Convening hospital transfusion committee meetings

f) Fulfilling program requirements

g) Undergo appropriate training programs

h) Provide consultation to supervisory and technical personnel on maintaining adequate inventory of all blood components.

i) In times of limited inventory, provide interface to attending physician and resident staffs on requests for those components in short supply

j) Evaluate function of blood bank periodically

2) Donor Management

a) Perform routine donor evaluation and monitoring, including physical examinations and phlebotomy site examination and review of periodic laboratory testing.

b) Provide consultation to Blood Bank technical and clerical personnel concerning donor selection and acceptability.

c) Evaluate and manage blood donor reactions.

d) Evaluate and follow-up donors with abnormal test results, including infectious disease testing.

e) Evaluation and approval of requests for specific components from specific donors

f) Selection of donors for specific patients

g) Evaluation of donor acceptability

h) Donor monitoring.

3) Camp Management

a) Medical officer should check the following :

b) Exact venue ,number of donors, time or the camp, refreshment for donors, furniture, space, mobile vans, appliances for collection and transportation of blood, and emergency box

c) Record and report the details about the blood camp to the Blood transfusion committee.

4) Testing (IH/ TTI)

a) Provide consultation and support to technical and clinical staff concerning specimen and requisition acceptability.

b) Review and interpret:

i) Blood typing discrepancies

ii) Positive antibody screens

iii) Antibody panels; prenatal titers

iv) Positive direct/ indirect anti-globulin tests

c) Provide consultation to technical staff concerning additional evaluation of patients with complex serologic problems.

d) Review clinical significance of serologic findings and decide on additional testing required prior to transfusion.

5) Component Management

a) Provide consultation to apheresis nursing and technical staff concerning donor selection and acceptability.

b) Evaluate and manage apheresis donor reactions.

c) Provide medical direction of component collection via cell separator.

d) Evaluate and approve requests for selected and specialized blood components, including washed red cells and apheresis derived platelet

6) QMS/QA

a) Assists with developing, implementing, and maintaining the quality assurance with respect to

i) Organisation

ii) Personnel

iii) Technical

iv) Document control

v) Infrastructure management

vi) Equipment

vii) QA

viii) Audits

b) Perform the initial review of the Quality Control records with the quality manager

c) Ensure staff and departmental compliance with all regulatory, safety, and institution policies and procedures.

d) Ensure that all work is done according to the required standards

e) Ensure the SOP is followed at all critical steps of process flow like donor screening , phlebotomy site cleaning, phlebotomy, temperature maintenance during blood transport, calibrated centrifuge and trained technical staff in component lab

f) Ensure the application of Good Manufacturing Practices (GMP), / Good lab practices(GLP)/Good Clinical Practices(GCP).

g) Co ordinate with respective training institute for continuous improvement

7) Training

a) Cross training of different levels of staff

b) Competency management

c) Plans and Helps in Conduction of the refresher and regular training program of the staff in the blood bank

d) Helps in evaluating the knowledge of the new staff and arrange for the training programs.

8) Clinical Services

a) Provide consultation to clinical staff concerning selection and acceptability of donors for autologous transfusion.

b) Consult with the attending physician and resident staffs as necessary.

c) Determine risks of transfusion in: patients with complex serologic problems and patients who require transfusion before routine serologic testing can be completed. Provide consultation to attending physician and resident staffs as indicated

d) Review initial workup of all transfusion reactions reported to the Blood Bank.

e) Determine additional evaluation required and prepare a written interpretation for review and discussion with the in-charge blood bank and provide consultation to attending physician and resident staffs as indicated.

f) Provide initial evaluation of patients who are candidates for therapeutic apheresis. This includes: review of patient problem; prepare initial draft of consultation report and review with the Consultant Transfusion Medicine to select appropriate patients for therapeutic apheresis; determine the apheresis protocol to be used; determine methods to be used for evaluating patient response to therapeutic apheresis.

g) Obtain informed consent for therapeutic apheresis from patients.

h) Schedule therapeutic apheresis procedures with apheresis personnel.

i) Complete apheresis worksheets and write the detailed orders for the apheresis procedure.

j) Write therapeutic apheresis orders.

k) Evaluate patient pre-procedure and document procedure/"SOP" note.

l) Evaluate and manage patient reactions during therapeutic apheresis.

m) Monitor and evaluate patient response to therapeutic apheresis.

n) Haemo vigilance

o) Actively conduct HTC quarterly.

9) Biosafety & Infection Control

a) Ensuring BMW management

b) Infection control practices

c) Ensure universal precautions should be used consistently by all the staff of blood bank

ROLES AND RESPONSIBILITIES OF BLOOD BANK NURSES

1) Donor Management

a) Assist with donor room preparations, prepare and distribute supplies and equipment, maintain drugs & consumables and equipment management.

b) Assist MO in preparing the patient for phlebotomy procedure.

c) Assist MO in donor selection.

d) Provide information related to donor screening & post donation instructions to donors

e) Perform phlebotomy& manage post donation care

f) Collect samples in pilot tubes, supervise transportation of pilot tubes & collected blood bags to the respective labs

g) Maintain documentation related to donor records

h) Assist in apheresis procedure, donor eligibility and donor care.

i) Perform duties assigned by the BB MO in charge

j) Assist in Donor motivation activities

2) Camp Management

a) Ensure that all the documents and records are made ready before the camp.

b) Ensure that all the equipment's and furniture's are made available.

c) Arranges all the apparatus and equipment's required for the mobile blood collection unit.

d) Assist in storage and transportation of collected blood.

e) Records the concerns about the blood donation camp

3) Administrative/ Programme management/ Regulatory Aspects

a) Coordinate activities in blood collection unit, including work flow and work assignments

b) Coordinate with technician preparation of monthly report for related to donor area to be sent to SACS/SBTC/Drug Control Departments

c) Prepare and keep ready with the monthly/ quarterly/ annual reports

4) QMS/QA

a) Perform quality control of donor related equipment, and maintain records as per D& C act

5) Training

a) Assist in training new staff.

b) Instruct new nursing staff in specific tasks and job techniques as required

c) Training of other clinical department nurses on bedside transfusion practices

6) Clinical Services

a) Obtain informed consent for apheresis from patients.

b) Help MO in scheduling apheresis procedures with apheresis personnel.

c) Help MO in Completing apheresis worksheets

d) Maintain the records of daily apheresis orders, pre-procedure records and document procedure / "SOP" note.

e) Periodically take vitals of patients / donors during apheresis procedure.

f) Maintenance of first aid kit / emergency medical drugs.

g) Maintain the records related to management of patient reactions during therapeutic apheresis.

h) Maintain records and reports with patient response to therapeutic apheresis

i) Haemovigilance

7) Biosafety & Infection Control

a) Ensure Universal precautions are followed strictly

b) Ensuring BMW management

c) Infection control practices

ROLES AND RESPONSIBILITIES FOR BLOOD BANK LAB TECHNICIANS

1) Donor Management

a) Assist in Donor motivation activities

b) Assist in donor room activities including assisting in apheresis procedures

c) Identifies and communicates abnormal test reports by alerting supervisory personnel& safe disposal of TTI reactive units as per BMW regulation.

2) Testing

a) Understands blood bank methods, demonstrates knowledge of testing processes which includes donor screening, blood grouping, cross matching, IH testing, TTI screening.

b) Organize work by matching blood requests with test tube labelling; sorting samples; checking labelling; logging samples; cross matching and reserving units ready for issue, keeping work surfaces clean and orderly.

3) Component management

a) Performs blood component separation, labelling, quality control of blood components produced.

4) Administrative/ Programme management/ Regulatory Aspects

a) Perform duties as assigned by the BB MO

b) All activities & records to be maintained as per relevant SOP & D&C act.

c) Document all the necessary information in the required blood bank records in the respective work area

d) Prepare periodic reports to be sent to SACS / SBTC & Drugs control department.

e) Maintains donor/patient confidence by keeping laboratory information confidential.

f) Sign on all respective documents related to their work area.

5) QMS/QA

a) Assist in preparation of SOPs

b) Maintains quality results by running standards and controls, verifying equipment function through routine equipment maintenance and advanced trouble shooting; calibrating equipment utilizing approved testing procedures; monitoring quality control measures and protocols.

c) Perform & maintain records of QC procedures related to reagent, kits & equipment's.

6) Training

a) Responsible for in house staff training.

7) Clinical Services

a) Ensures the issue of blood components / units for patient care.

8) Biosafety & Infection Control

a) Ensure Universal precautions are followed strictly

b) Ensure Infection control practices

ROLES & RESPONSIBILITIES OF COUNSELLORS

1. Donor Education

a. To explain the blood donor of the entire blood donation process.

b. To ensure that the donor understands all questions and responds accurately to the donor questionnaire.

c. To inform the donor that his/her blood will be tested for blood group serology and markers of TTI and the test results will be given to the donor.

d. To ensure that the donor is able to give informed consent to donate and recognizes that his/her signature is an affirmation that responses provided to the questionnaire are accurate and the donor is willing to be informed of their test results.

2. Donor Education regarding Blood Donation Process

a. To ensure that donors feel comfortable during blood donation process, including the venepuncture.

b. To reduce donor anxiety and minimize the risk of any adverse donor reactions, such as fainting

c. To give post-donation advice, including care of the venepuncture site.

d. To secure donors' cooperation in the confidential unit exclusion or post-donation information process.

e. To clarify doubts or concerns raised by donors.

f. To alleviate donors' anxiety.

3. Donor Education regarding TTI Reactivity

a. To keep the donor informed about the health implications of the positive TTI test results for the donor and the donated blood (discard) and the suitability of the donor for future blood donations

b. To guide and help the blood donor with positive screening results in further investigation, management, treatment and care, if necessary

c. To encourage donors to provide all relevant information, including the possible source of infection.

d. To explain the test results, the need for confirmation of the results, the health implications for the donor and the donated blood (discard) and the suitability of the donor for future blood donation.

e. To provide information on precautions for preventing the transmission of infection to others.

4. Donor Deferral and Preventive Health Education

a. To explain and clarify of the nature of the deferral (permanent or temporary) Example: Donor with low hemoglobin: refer to a health- care institution for hematological investigation and further management, and provide information on nutrition

b. To encourage temporarily deferred donor to return for future blood donations after the defined deferral period

c. To keep the donor informed about the donor deferral period: i.e. until screening test is non-reactive on follow-up

d. To encourage individuals to self-defer if they are suffering from an infection, disease or health condition that may make them unsuitable to donate blood

5. Referral and Linkages

a. To provide information and refer donors for further investigation, management, treatment and care, if necessary.

b. To organise and scheduling Blood Donation Camps

c. To mobilize communities for blood donation.

d. To organize and lead mobile blood donations in colleges, workplaces, etc.

e. To give blood donation lectures at workplaces, schools and voluntary organisations

f. To prepare donor cards and certificates to voluntary blood donors

g. To maintain effective communication and working relationship with team members, other health workers and clients

h. To develop list of prospective donor groups by using organizational, professional, and industrial listings and directories.

i. To contact prospective donor groups to explain requirements and benefits of participation in blood donor program.

j. To visit prospective or participating blood donor group to discuss blood program.

k. To distribute promotional material and uses audio-visual aids to motivate groups to participate in blood-donor program.

l. To arrange specific date of blood collection for blood-donor group and confirms appointment in writing.

6. Donor Identification and Motivation

a. To identify donors with rare-type blood from blood-bank records, and telephone donors to solicit and arrange blood donation.

b. To increase donors trust in the BTS and encourage them to adhere to donor selection criteria while responding to the donor questionnaire

c. To foster donor trust and confidence for donor retention.

d. To reinforce the importance of healthy lifestyles for donors found to be non-reactive on blood screening and encourage regular blood donation.

7. Reporting and Record Keeping

a. To keep records of organizations participating in program.

b. To record information for mobile blood-collection unit, such as space available, staffing required, and number of donors anticipated.

c. To consult blood bank records to answer questions, monitor activity, or resolve problems of blood donor groups.

d. To prepare reports of blood-donor program and recruitment activities.

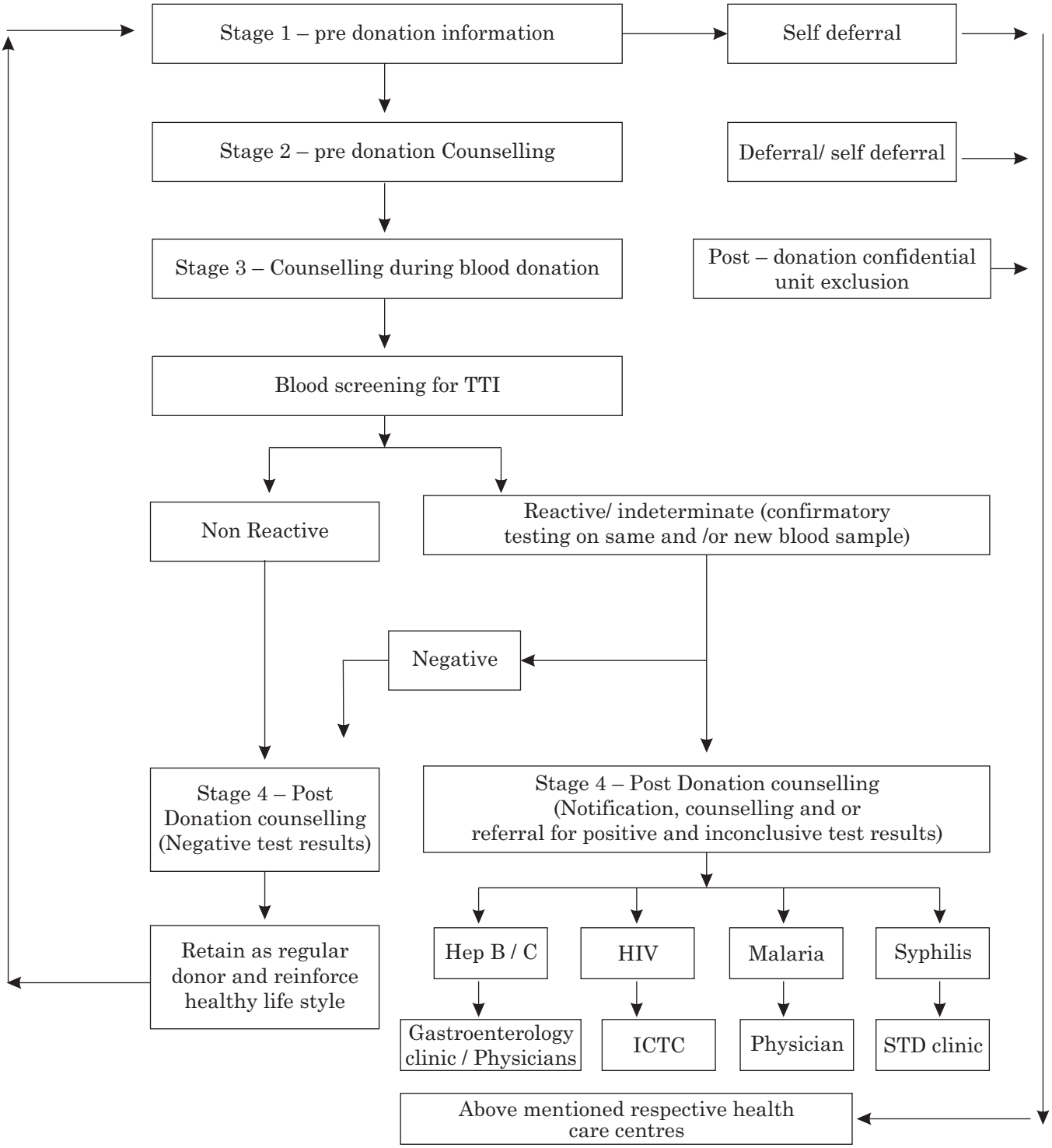
8. Self Motivation and Monitoring

a. Develop and maintain continuing personal and professional development to meet the changing demands in the area of blood donor services

b. Monitor own performance against objectives and standards

c. Keep up-to-date on job-related issues as appropriate and keep log of own performance and in-service training log for purposes of appraisal

STAGES OF BLOOD DONOR COUNSELLING



PRESENTATIONS AVAILABLE IN DVD

DVD-1

Resource Materials

1. Training program agenda – Medical Officers, Lab Technicians & Nurses.
2. Training Module for Blood Bank Medical Officers & Lab Technicians
3. Training Module for Blood Bank Nurses
4. Facilitators Guide for Blood Bank Lab Technicians & BCSU Medical Officers
5. Facilitators Guide for Blood Bank Medical Officers (Non-BCSU)
6. Facilitators Guide for Blood Bank Nurses
7. Hand book on component preparation and Apheresis for BCSU
8. Training program power point presentations – Medical Officers, Lab Technicians & Nurses

DVD-2

Videos

- Documentary
  a) National Blood Safety Program

- Trigger Videos
  a) Phlebotomy
  b) ABO Grouping and Typing
  c) Component Preparation
  d) Screening of TTI

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ANNEXURE 12

ANSWERS TO MULTIPLE CHOICES

Chapter 1	
Q.No	**Answer**
1	a
2	b
3	b
4	c
5	b
6	a
7	d
8	a
9	c
10	a

Chapter 2	
Q.No	**Answer**
1	c
2	a
3	c
4	c
5	b
6	a
7	b
8	b
9	d

Chapter 3	
Q.No	**Answer**
1.a	True
1.b	True
1.c	False
1.d	False
1.e	True
1.f	True
1.g	True
1.h	True
2	b
3	a
4	c
5	a
6	b

Chapter 4	
Q.No	**Answer**
1	a
2	a
3	b
4	d
5	d

Chapter 5	
Q.No	Answer
1	d
2	d
3	a
4	e
5	d
6	d

Chapter 7	
Q.No	Answer
1	d
2	d
3	c
4	b

Chapter 6	
Q.No	Answer
1	d
2	d
3	e
4	e
5.a	Yes
5.b	Yes
5.c	No
5.d	Yes

Chapter 8	
Q.No	Answer
1	d
2	a
3	a
4	d
5	b

NATIONAL BLOOD POLICY
NACO,2007

Introduction

A well organised Blood Transfusion Service (BTS) is a vital component of any health care delivery system. An integrated strategy for Blood Safety is required for elimination of transfusion transmitted infections and for provision of safe and adequate blood transfusion services to the people. The main component of an integrated strategy include collection of blood only from voluntary, non-remunerated blood donors, screening for all transfusion transmitted infections and reduction of unnecessary transfusion.

The Blood Transfusion Service in the country is highly decentralised and lacks many vital resources like manpower, adequate infrastructure and financial base. The main issue, which plagues blood banking system in the country, is fragmented management. The standards vary from State to State, cities to cities and centre to centre in the same city. In spite of hospital based system, many large hospitals and nursing homes do not have their own blood banks and this has led to proliferation of stand-alone private blood banks.

The blood component production/availability and utilisation is extremely limited. There is shortage of trained health-care professionals in the field of transfusion medicine.

For quality, safety and efficacy of blood and blood products, wellequipped blood centres with adequate infrastructure and trained manpower is an essential requirement. For effective clinical use of blood, it is necessary to train clinical staff. To attain maximum safety,the requirements of good manufacturing practices and implementation of quality system moving towards total quality management, have posed a challenge to the organisation and management of blood transfusion service.

Thus, a need for modification and change in the blood transfusion service has necessitated formulation of a National Blood Policy and development of a National Blood Programme which will also ensure implementation of the directives of Supreme Court of India - 1996.

Mission statement

The policy aims to ensure easily accessible and adequate supply of safe and quality blood and blood components collected / procured from a voluntary non-remunerated regular blood donor in well equipped premises, which is free from transfusion transmitted infections, and is stored and transported under optimum conditions. Transfusion under supervision of trained personnel for all who need it irrespective of their economic or social status through comprehensive, efficient and a total quality management approach will be ensured under the policy.

Objectives of the policy:

To achieve the above aim, the following objectives are drawn:

1. To reiterate firmly the Govt. commitment to provide safe and adequate quantity of blood, blood components and blood products.
2. To make available adequate resources to develop and reorganise the blood transfusion services in the entire country.
3. To make latest technology available for operating the blood transfusion services and ensure its functioning in an updated manner.
4. To launch extensive awareness programmes for donor information, education, motivation, recruitment and retention in order to ensure adequate availability of safe blood.
5. To encourage appropriate clinical use of blood and blood products.
6. To strengthen the manpower through human resource development.
7. To encourage Research & Development in the field of Transfusion Medicine and related technology.
8. To take adequate regulatory and legislative steps for monitoring and evaluation of blood transfusion services

OBJECTIVE – 1

To reiterate firmly the Govt. commitment to provide safe and adequate quantity of blood, blood components and blood products.

STRATEGY:

1.1 A national blood transfusion Programme shall be developed to ensure establishment of non-profit integrated National and State Blood Transfusion Services in the country.

1.1.1 National Blood Transfusion Council (NBTC) shall be the policy formulating apex body in relation to all matters pertaining to operation of blood centres. National AIDS Control Organisation (NACO) shall allocate a budget to NBTC for strengthening Blood Transfusion Service.

1.1.2 State/UT Blood Transfusion Councils shall be responsible for implementation of the Blood Programme at State/ UT level, as per the recommendations of the National Blood Transfusion Council.

1.1.3 Mechanisms for better co-ordination between NBTC and SBTCs shall be developed by the NBTC.

1.1.4 Mechanisms shall be developed to monitor and periodically evaluate the implementation of the National Blood Programme in the country.

1.1.5 The enforcement of the blood and blood products standards shall be the responsibility of Drugs Controller General (India) as per Drugs and Cosmetics Act/Rules, with assistance from identified experts.

1.1.6 NBTC shall ensure involvement of other Ministries and other health programmes for various activities related to Blood transfusion services.

1.2. Trading in blood i.e. Sale & purchase of blood shall be prohibited.

1.2.1 The practice of replacement donors shall be gradually phased out in a time bound programme to achieve 100% voluntary non-remunerated blood donation programme.

1.2.1.1 State/UT Blood Transfusion Councils shall develop an action plan to ensure phasing out of replacement donors.

1.3 The following chain of Transfusion Services shall be promoted for making available of safe blood to the people.

1.3.1 State Blood Transfusion Councils shall organise the blood transfusion service through the network of Regional Blood Centres and Satellite Centres and other Government, Indian Red Cross Society & NGO run blood centres and monitor their functioning. All Regional Centres shall be assigned an area around in which the other blood banks and hospitals which are linked to the regional centre will be assisted for any requirement and shall be audited by the Regional Centre. It will also help the State Blood Transfusion Council in collecting the data from this region.

1.3.2 The Regional Centres shall be autonomous for their day to day functioning and shall be guided by recommendations of the State/UT Blood Transfusion Councils. The Regional Centre shall act as a referral centre for the region assigned to it.

1.3.3 NBTC shall develop the guidelines to define NGO run blood centres so as to avoid profiteering in blood banking.

1.4 Due to the special requirement of Armed Forces in remote border areas, necessary amendments shall be made in the Drugs & Cosmetics Act/Rules to provide special licenses to small garrison units. These units shall also be responsible for the civilian blood needs of the region.

OBJECTIVE – 2

To make available adequate resources to develop and reorganise he blood transfusion services in the entire country.

STRATEGY:

2.1 National & State/UT Blood Transfusion Councils shall be supported/strengthened financially by pooling resources from various existing programmes and if possible by raising funds from international/bilateral agencies.

2.2 Efforts shall be directed to make the blood transfusion service viable through non-profit recovery system.

2.2.1 National Blood Transfusion Council shall provide guidelines for ensuring non-profit cost recovery as well as subsidised system.

2.2.2 Efforts shall be made to raise funds for the blood transfusion service for making it self-sufficient.

2.2.3 The mechanism shall be introduced in government sector to route the amounts received through cost recovery of blood/blood components to the blood banks for improving their services.

OBJECTIVE – 3

To make latest technology available for operating the blood transfusion services and ensure its functioning in an updated manner.

STRATEGY:

3.1 Minimum standards for testing, processing and storage shall be set and ensured.

3.1.1. Standards, Drugs & Cosmetics Act/Rules and Indian Pharmacopoeia shall be updated as and when necessary.

3.1.2. All mandatory tests as laid down under provisions of Drugs & Cosmetics Act/Rules shall be enforced.

3.1.3. Inspectorate of Drugs Controller of India and State FDA shall be strengthened to ensure effective monitoring.

3.1.4. A vigilance cell shall be created under Central/State Licensing Authorities.

3.2 A Quality System Scheme shall be introduced in all blood centres.

3.2.1 Quality Assurance Manager shall be designated at each Regional Blood Centre/any blood centre collecting more than 15,000 units per year to ensure quality control of Blood & its components in the region assigned. He shall be exclusively responsible for quality assurance only.

3.2.2 Every blood centre shall introduce an internal audit system to be followed by corrective actions to reduce variations in Standard Operating Procedures (SOPs) as a part of continuous improvement programme.

3.2.3 Regular workshops on the subject of quality assurance shall be conducted to update the personnel working in blood centres.

3.2.4 Regular proficiency testing of personnel shall be introduced in all the blood centres.

3.3 An External Quality Assessment Scheme (EQAS) through the referral laboratories approved by the National Blood Transfusion Council shall be introduced to assist participating centres in achieving higher standards and uniformity.

3.3.1 Reference centres shall be identified in each State/UT for implementation of EQAS. All blood centres shall be linked to these reference centres for EQAS.

3.3.2 NBTC shall identify a centre of national repute for quality control of indigenous as well as imported consumables, reagents and plasma products.

3.4 Efforts shall be made towards indigenisation of kits, equipment and consumables used in blood banks.

3.5 Use of automation shall be encouraged to manage higher workload with increased efficiency.

3.6 A mechanism for transfer of technology shall be developed to ensure the availability of state-of-the-art technology from out side India.

3.7 Each blood centre shall develop its own Standard Operating Procedures on various aspects of Blood Banking.

3.7.1 Generic Standard Operating Procedures shall be developed by the National Blood Transfusion Council as guidelines for the blood centres.

3.8 All blood centres shall adhere to bio-safety guidelines as provided in the Ministry of Health & Family Welfare manual 'Hospitalacquired Infections : Guidelines for Control' and disposal of biohazardous waste as per the provisions of the existing Biomedical Wastes (Management & Handling) Rules - 1996 under the Environmental Protection Act - 1986.

OBJECTIVE – 4

To launch extensive awareness programmes for donor information, education, motivation, recruitment and retention in order to ensure adequate availability of safe blood.

STRATEGY:

4.1 Efforts shall be directed towards recruitment and retention of voluntary, non-remunerated blood donors through education and awareness programmes.

4.1.1 There shall not be any coercion in enrolling replacement blood donors.

4.1.2 The replacement donors shall be encouraged to become regular voluntary blood donors.

4.1.3 Activities of NGOs shall be encouraged to increase awareness about blood donation amongst masses.

4.1.4 All blood banks shall have donor recruitment officer/ donor organiser.

4.1.5 Each blood centre shall create and update a blood donor's directory which shall be kept confidential.

4.1.6 In order to increase the donor base specific IEC campaigns shall be launched to involve youth in blood donation activities.

4.2 Enrolment of safe donors shall be ensured.

4.2.1 Rigid adherence to donor screening guidelines shall be enforced.

4.2.2 At blood donation camps, appropriate attention shall be paid on donor enrolment and screening in accordance with national standards instead of number of units collected.

4.2.3 A Counsellor in each blood centre shall be appointed for pre and post donation counselling.

4.2.4 Result seeking donors shall be referred to a Blood Testing Centre (BTC) for post donation information and counselling.

4.3 State/UT Blood Transfusion Councils shall recognise the services of regular voluntary non-remunerated blood donors and donor organisers appropriately.

4.4 National/State/UT Blood Transfusion Councils shall develop and launch an IEC campaign using all channels of communication including mass-media for promotion of voluntary blood donation and generation of awareness regarding dangers of blood from paid donors and procurement of blood from unauthorised blood banks/laboratories.

4.5 National / State / UT blood transfusion councils shall involve other departments / sectors for promoting voluntary blood donations.

OBJECTIVE – 5

To encourage appropriate clinical use of blood and blood products.

STRATEGY:

5.1 Blood shall be used only when necessary. Blood and blood products shall be transfused only to treat conditions leading to significant morbidity and mortality that cannot be prevented or treated effectively by other means.

5.2 National Guidelines on 'Clinical use of Blood' shall be made available and updated as required from time to time.

5.3 Effective and efficient clinical use of blood shall be promoted in accordance with guidelines.

5.3.1 State/UT Governments shall ensure that the Hospital Transfusion Committees are established in all hospitals to guide, monitor and audit clinical use of blood.

5.3.2 Wherever appropriate, use of plasma expanders shall be promoted to minimise the use of blood.

5.3.3 Alternative strategies to minimise the need for transfusion shall be promoted.

5.4 Education and training in effective clinical use of blood shall be organised.

5.4.1 Medical Council of India shall be requested to take following initiatives:

5.4.1.1 To introduce Transfusion Medicine as a subject at undergraduate and all post graduate medical courses.

5.4.1.2 To introduce posting for at least 15 days in the department of transfusion medicine during internship.

5.4.1.3 To include Transfusion Medicine as one of the subjects in calculating credit hours for the renewal of medical registration by Medical Council of India, if it is introduced.

5.4.2 CME and workshops shall be organised by State Blood Transfusion Councils in collaboration with professional bodies at regular intervals for all clinicians working in private as well public sector in their States.

5.5 Blood and its components shall be prescribed only by a medical practitioner registered as per the provisions of Medical Council Act - 1956.

5.6 Availability of blood components shall be ensured through the network of regional centres, satellite centres and other blood centres by creating adequate number of blood component separation units.

5.7 Appropriate steps shall be taken to increase the availability of plasma fractions as per the need of the country through expanding the capacity of existing centre and establishing new centres in the country.

5.8 Adequate facilities for transporting blood and blood products including proper cold-chain maintenance shall be made available to ensure appropriate management of blood supply.

5.9 Guidelines for management of blood supply during natural and man made disasters shall be made available.

OBJECTIVE – 6

To strengthen the manpower through Human Resource Development.

STRATEGY:

6.1 Transfusion Medicine shall be treated as a speciality.

6.1.1 A separate Department of Transfusion Medicine shall be established in Medical Colleges.

6.1.2 Medical Colleges/Universities in all States shall be encouraged to start PG degree (MD in transfusion medicine) and diploma courses in Transfusion Medicine.

6.1.3 PG courses for technical training in transfusion medicine (PhD / MSc) shall also be encouraged.

6.2 In all the existing courses for nurses, technicians and pharmacists, Transfusion Medicine shall be incorporated as one of the subjects.

6.3 In-service training programmes shall be organised for all categories of personnel working in blood centres as well as drug inspectors and other officers from regulatory agencies.

6.4 Appropriate modules for training of Donor Organisers/Donor Recruitment Officers shall be developed to facilitate regular and uniform training programmes to be conducted in all States.

6.4.1 Persons appointed as Donor Organisers/Donor Recruitment Officers shall undergo training for Donor Motivation and Recruitment organised by State Blood Transfusion Councils.

6.5 Short orientation training cum advocacy programmes on donor motivation and recruitment shall be organised for Community Based Organisations(CBOs) and NGOs who wish to participate in Voluntary Blood Donor Recruitment Programme.

6.6 Inter-country and intra-country exchange for training and experience of personnel associated with blood centres shall be encouraged to improve quality of Blood Transfusion Service.

6.7 States/UTs shall create a separate cadre and opportunities for promotions for suitably trained medical and para medical personnel working in blood transfusion services.

OBJECTIVE – 7

To encourage Research & Development in the field of Transfusion Medicine and related technology.

STRATEGY:

7.1 A corpus of funds shall be made available to NBTC/SBTCs to facilitate research in transfusion medicine and technology related to blood banking.

7.2 A technical resource core group at national level shall be created to co-ordinate research and development in the country. This group shall be responsible for recommending implementation of new technologies and procedures in coordination with DC(I).

7.3 Multi-centric research initiatives on issues related to Blood Transfusion shall be encouraged.

7.4 To take appropriate decisions and/or introduction of policy initiatives on the basis of factual information, operational research on various aspects such as various aspects of Transfusion Transmissible Diseases, Knowledge, Attitude and Practices (KAP) among donors, clinical use of blood, need assessment etc shall be promoted.

7.5 Computer based information and management systems shall be developed which can be used by all the centres regularly to facilitate networking.

OBJECTIVE – 8

To take adequate regulatory and legislative steps for monitoring and evaluation of blood transfusion services and to take steps to eliminate profiteering in blood banks.

STRATEGY:

8.1 For grant/renewal of blood bank licenses including plan of a blood bank, a committee, comprising of members from State/UT Blood Transfusion Councils including Transfusion Medicine expert, Central & State/UT FDAs shall be constituted which will scrutinise all applications as per the guidelines provided by Drugs Controller General (India).

8.2 Fresh licenses to stand-alone blood banks in private sector shall not be granted. Renewal of such blood banks shall be subjected to thorough scrutiny and shall not be renewed in case of noncompliance of any condition of license.

8.3 All State/UT Blood Transfusion Councils shall develop a State Action Plan for the State/UT Blood Transfusion Service where in Regional Blood Transfusion Centres shall be identified. These centres shall be from Government, Indian Red Cross Society or other NGO run blood banks of repute. Approved regional blood centres / government blood centres/Indian red cross blood centres shall be permitted to supply blood and blood products to satellite centres which are approved by the committee as described in para 8.1. The Regional Centre shall be responsible for transportation, storage, cross-matching and distribution of blood and blood products through satellite centres.

8.4 A separate blood bank cell shall be created under a senior officer not below the rank of DDC(I) in the office of the DC(I) at the headquarter. State/UT Drugs Control Department shall create such similar cells with the trained officers including inspectors for proper inspection and enforcement.

8.5 As a deterrent to paid blood donors who operate in the disguise of replacement donors, institutions who prescribe blood for transfusion shall be made responsible for procurement of blood for their patients through their affiliation with licensed blood centres.

8.6 States/UTs shall enact rules for registration of nursing homes wherein provisions for affiliation with a licensed blood bank for procurement of blood for their patients shall be incorporated.

8.7 The existing provisions of drugs & Cosmetics Rules will be periodically reviewed to introduce stringent penalties for unauthorised / irregular practices in blood banking system.

ANNEXURE 14

NATIONAL POLICY FOR ACCESS TO PLASMA DERIVED MEDICINAL PRODUCTS FROM HUMAN PLASMA FOR CLINICAL/THERAPEUTIC USE, NACO NBTC, 2014

Introduction

Athe Plasma Policy aims at making available, easily accessible and adequate supply of high quality of human plasma derived proteins for clinical/ therapeutic use. The plasma is prepared as part of safe and quality blood and blood components collected/procured from a voluntary non-remunerated regular blood donor in well-equipped premises, which is free from transfusion transmitted infections, and is stored and transported under optimum conditions. Plasma has limited utility in its raw form for various coagulopathies, plasma exchange, etc, but is one such important blood component is the raw material for the manufacture of many more lifesaving proteins of immense clinical significance. Such proteins are known as Plasma Derived Medical Products (PDMPs). Examples of PDMPs include Albumin, coagulant proteins such as FVIII, immunoglobulin's such as IVIG and hyperimmunes products from specialized source plasma HBIg, Tetanus Ig etc.

Plasma forms the raw material for the manufacture of Plasma Derived Proteins (PDMPs). Currently plasma derived proteins are manufactured within the country in limited quantity by existing Plasma Fractionation Centres. These centres fractionate the unused plasma recovered from whole blood at various licensed blood component separation units of the country but since the plasma availability in the country is limited, a. significant quantity of PDMPs, plasma or its intermediates are obtained through import from other countries.

At present, all the recovered plasma is not being used clinically or for plasma fractionation. The policy aims at enabling the mobilization of this excess plasma stocks at the blood banks for fractionation to make some more high value products, which hitherto are not often available in adequate quantities to meet the increasing clinical requirements.

The process of collecting standard plasma and transporting them under optimum conditions for fractionation, identifying critical parameters for safety, ensuring compliance with regulatory requirements, training for the appropriate usage of these products will be covered under this policy. The policy reiterates the endeavor of the government to facilitate supply of affordable products to the needy, regardless of their economic status. The policy will result in a comprehensive way to optimize usage of plasma for the manufacture of high quality blood components, and make our country self-reliant and standardize their availability and utilization through comprehensive, efficient and a total quality management approach.

OBJECTIVES OF THE POLICY

To achieve the aim of facilitating national access to Plasma Derived Medical Products (PDMPs) for clinical/therapeutic use, the following objectives are drawn:

1. To reiterate that Government will facilitate availability and utilization of safe and adequate quantity of plasma derived products for clinical/ therapeutic use.
2. To make available adequate resources to develop and organize the plasma/ PDMPs mobilization throughout the country.
3. To take adequate Regulatory and Legislative steps for monitoring of activities related to plasma derived products.
4. To encourage Research & Development in the field of blood components, plasma fractionation and plasma derived products.
5. To strengthen Quality Systems in Blood Transfusion Services for plasma collection, transportation, processing, production and distribution of PDMPs.

OBJECTIVE – 1

To reiterate that Government will facilitate availability of safe and adequate quantity of plasma derived products for clinical / therapeutic use.

STRATEGY:

1.1 To augment set up & functioning of Blood Component Separation Units (BCSU), including plasmapheresis, with the help of national and state blood transfusion services in the country in order to optimize recovery and utilization of surplus plasma as raw material for plasma fractionation and manufacturing of PDMPs.

1.2 To establish guidelines for plasmaphresis, to collect source plasma for fractionation.

1.3 To establish a mechanism in place for appropriate transfer of plasma from BCSU to warehouses / Plasma Fractionation Centers (PFC).

1.4 To standardize screening of plasma for infections prior to further processing for fractionation.

1.5 To put in place mechanisms to improve coordination and interaction between various BCSU and plasma warehouses/PFCs in order to achieve desired end product quality.

1.6 To advocate for effective and judicious clinical use of human plasma and PDMPs to minimize unwarranted use of whole blood/ plasma/PDMPs.

1.7 To formulate national guidelines on 'Clinical use of plasma derived products' and update as required from time to time.

1.8 To review plasma (raw material for fractionation)/PDMPs (finished products for clinical use) utilization by various facilities acting as an end user individuals / organizations.

1.9 To promote interdepartmental activities with all concerned including other Ministries, stakeholders and health programs that would help optimize production & utilization of PDMPS.

1.10 To facilitate access and availability of PDMPs to cater to special requirement including remote locations will be done with closed coordination with DGAFMS.

1.11 To establish evidence based latest technology and time to time upgradation to bring about self-sufficiency for PDMPs.

1.12 To participate in public private partnership / collaborations to improve production and improve availability of PDMPs.

1.13 To evolve mechanisms for periodical review and evaluate the implementation of the policy across the country.

OBJECTIVE – 2

To make available adequate resources to develop and organize the plasma mobilization throughout the country.

STRATEGY:

2.1 To support/ strengthen the existing network of Blood Transfusion Services (BTS) so as to consolidate and improve blood and plasma donor base, blood componentization and recovery of safe and good quality of plasma.

2.1.1 To allocate resources and funds in existing public health programs as well as advocate for resource allocation by corporate sectors, bilateral/international agencies for plasma mobilization.

2.1.2 To additionally strengthen source plasma collection through licensed plasma collection centers across country existing BCSU/ Apheresis/ Blood banks with capacity of conducting plasmapheresis

2.2 To ensure engagement of trained manpower at all levels to facilitate plasma mobilization

2.3 To ensure proper infrastructure, equipment and transportation facilities to have high quality of plasma.

2.4 To direct efforts towards recruitment and retention of voluntary, non-remunerated blood donors, through education and awareness programs also incorporating IEC strategies, NGO involvement, special donor registries for hyperimmune products etc. as an integral part of voluntary blood donation programs

2.5 To standardize pricing, with the help of existing policies/ resources, to ensure not for profit but techno-financial viable and selfsustaining mechanisms of various types plasma, used as raw material, and PDMPs.

OBJECTIVE – 3

To take adequate Regulatory and Legislative steps for monitoring of activities related to plasma derived products.

STRATEGY:

3.1 Formulate regulations to ensure 80 % componentization of whole blood and mandatory channelization of excess unutilized plasma for fractionation.

3.2 Legislative steps to legalize the collection of source plasma for fractionation and licensing mechanism for establishment of plasma collection centers to collect source plasma.

3.2 To facilitate the regulatory approval of updated methodology with the purpose of increasing plasma recovery from donated blood

3.3 To review the regulatory framework with respect to availability/ manufacturing and distribution of acceptable quality of PDMPs for clinical use.

3.4 To review and update Standards, Drugs & Cosmetics Act / Rules and Indian Pharmacopoeia, with respect to national blood policy, from time to time.

3.5 To periodically review the existing provisions of prevailing regulatory frameworks as well as introduce stringent penalties for unauthorized/irregular practices in plasma processing and delivery of PDMPs.

OBJECTIVE – 4

To encourage Research & Development in the field of blood components, plasma fractionation and plasma derived products.

STRATEGY:

4.1 To organize capacity building/exposure visit & hands on training of personnel dealing with plasma fractionation, related to all process and quality aspects.

4.2 To facilitate research in blood components, plasma fractionation and PDMPs in association with recognized national and international bodies including ICMR, DST and DCGI.

4.3 To make available financial support for the conduct of R&D in processing of plasma & PDMPs through various channels.

4.4 To collaborate with industry and academia to launch blood products faster and promote Inter-country and intra-country exchange for training and experience of personnel associated with plasma fractionation.

4.5 To direct efforts towards development of indigenous of kits/ processes and technology, to make them cost competitive.

4.6 To facilitate evidence based practices in research involving utilization of human plasma/ blood, from units unused/ discarded from blood banks due to any reason and evolve a regulatory framework thereof.

OBJECTIVE – 5

To strengthen Quality Systems in Blood Transfusion Services for plasma collection, transportation, processing, production and distribution of PDMPs.

STRATEGY:

5.1 To set national quality standards covering all aspects in manpower, equipment, processes, procedures, products and quality systems.

5.2 To articulate a continuous all round improvement program in plasma fractionation as part of quality systems as an endeavor to work towards gold standards.

5.3 To mandate that Plasma Fractionating Centres allocate resources for improving the quality of plasma as a raw material to linked BCSU in form of manpower, equipment, logistics etc.

5.4 To encourage training programs to ensure proficiency, accreditation and other changing quality parameters from time to time.

5.5 To encourage higher standards and uniformity, External Quality Assurance Scheme (EQAS) shall be introduced, through the referral laboratories approved by the National Blood Transfusion Council.

5.6 To ensure complete process control with sound documentation system, to inculcate data sharing and create opportunities to promote learning and growth.

5.7 To collate and analyze the data and share with all stakeholders, regularly as a part of the larger quality management initiative in the area of plasma fractionation.