

# **Division of Blood Transfusion Service**

**Ministry of Health and Family Welfare**



# Quality Control of Blood Components

# Teaching Aims

- This presentation aims to familiarize participants with
  1. essential quality elements that govern quality control of blood components including sampling and the criteria for quality control for different components
  2. maintenance and calibration of equipment used in preparation of blood components
- Participants will also understand the factors that affect quality of blood components

# Blood Components

- Packed Red Blood Cells (PRBCs)
- Platelet Concentrates (PCs)
  - Platelet Rich Plasma (PRP-PC)
  - Buffy Coat (BC-PC)
  - Apheresis (AP-PC)
- Fresh Frozen Plasma (FFP)
- Cryoprecipitate

Quality Blood Components can be made available only if all aspects of blood collection, component preparation, testing, storage and transport are monitored

Procedures  
Personnel



Equipments  
Reagents

Indicated in the contents of the final products

# Quality Control of Blood Components (1)

- **Definition:**

**Testing** of random components to ensure they achieve reliably certain specific standards

- **It includes analysis** of test results and **detection of irregularities** to identify deficiencies in production of Blood & Blood Components

# Quality Control of Blood Components (2)

## Indian standards

- Drugs and Cosmetics Act 1940, Rules 1945 (Sch F, Part XII-B), Govt of India
- Transfusion Medicine Technical Manual DGHS, Ministry of Health And Family Welfare, Govt of India, 2<sup>nd</sup> edition 2003
- Blood Bank Standards of NACO, Ministry of Health and Family Welfare, Govt of India
- NABH Accreditation Standards for Blood Banks

# Quality Control of Blood Components (3)

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



# Quality Control of Blood Components

## Volume

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

Specific gravity

- Packed RBC = 1.093
- Platelets = 1.035
- Plasma = 1.030
- Whole blood = 1.050

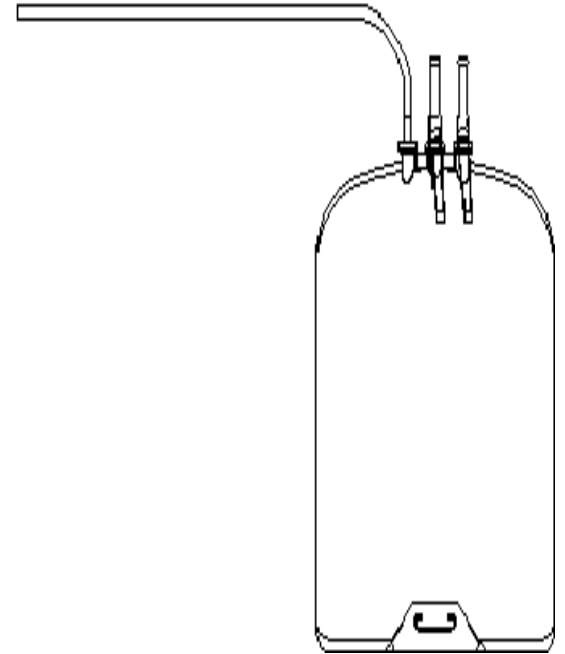
- Volume should be recorded on all units
- Appropriate labels should be put

# SAMPLING (1)

- **stripping** of tubes to get a representative sample of the concerned blood component for sampling
- **Sampling methods must be validated and as per SOPs** to ensure that they produce consistent samples, regardless of the operator
- **For platelet count** samples should be taken into a dry EDTA tube, to induce disaggregation

## SAMPLING (2)

- NOT to be taken from the last part of the tube
- This section is difficult to strip properly and the last 2 cm should be cut off after stripping the rest of the line



# QC of Blood and Blood Components Whole Blood

Parameter	Quality requirement	Frequency of control
Volume	350/450 ml $\pm$ 10%	1% of all units
Anticoagulants	49/63 ml	All units
PCV (Hct)	30-40%	4 units / month
Serology (HIV1+2, HBsAg, HCV, MP, Syphilis)	Negative	All units
Sterility	By culture	Periodically (1% of all units)

# QC of RED CELL CONCENTRATE

## (from 450 ml blood)

Parameter	Quality requirement	Frequency of control
Volume	280 ml $\pm$ 40 ml	1% of all units
PCV (Hct)	70% $\pm$ 5%	Periodically
Sterility	By culture	Periodically (1% of all units)

# QC of RED CELL CONCENTRATE in preservative solution (Adsol/SAGM)



Parameter	Quality requirement	Frequency of control
Volume	350 ml $\pm$ 20 ml	1% of all units
PCV (Hct)	60% $\pm$ 5%	Periodically
Sterility	By culture	Periodically (1% of all units)

# QC of Fresh Frozen Plasma (FFP)

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

\* Not mandatory



# QC of Cryoprecipitate

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

\* Not mandatory

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



# QC of Platelet concentrate

(RDP from 450 ml whole blood)

Parameter	Quality requirement	Frequency of control
Volume	50-70 ml	All units
Platelet count	$\geq 4.5 \times 10^{10}$	4 units / month
pH	$> 6.0$	4 units / month
RBC contamination	$< 0.5 \text{ ml}$ ( $5.5 \times 10^9 \text{ RBCs}$ )	4 units / month
WBC contamination	$< 5.5 \times 10^7 - 5 \times 10^8$	4 units / month



*No pink/red discoloration on visual inspection  
= insufficient red cells to cause immunization*

# QC of Platelet concentrate

(RDP from 450 ml whole blood)

Platelet count	$\geq 4.5 \times 10^{10}$ per bag	4 units / month
----------------	--------------------------------------	-----------------

Platelet Count in bag = Concentration x Volume

Concentration =  $1100 \times 10^9 / L$   
 =  $1100 \times 10^9 / 1000 \text{ ml}$

1000 ml =  $1100 \times 10^9$   
 50 ml = ?

=  $\frac{50 \times 1100}{1000} \times 10^9$

=  $\frac{50 \times 110}{1000} \times 10^{10} = \frac{5500}{1000} \times 10^{10}$

=  $5.5 \times 10^{10}$  per bag

# QC of Platelet concentrate

(RDP from 450 ml whole blood)

<b>RBC contamination</b>	<b>&lt; 0.5 ml</b>  <i>(5.5 x 10<sup>9</sup> RBCs)</i>	<b>4 units / month</b>
--------------------------	--	------------------------

No pink/red discoloration on visual inspection  
= insufficient red cells to cause immunization

$$\text{MCV of RBC} = 90 \mu^3 \sim 100 \mu^3 = 10^2 \mu^3$$

$$\begin{aligned} 1 \text{ ml} &= 1 \text{ cc} = 1 \text{ cm}^3 = 1 \times (10 \text{ mm})^3 \\ &= 1 \times 10^{12} \mu^3 \end{aligned}$$

$$\begin{aligned} 0.5 \text{ ml} &= 0.5 \times 10^{12} \mu^3 \\ &= 0.5 \times 10^{10} \times 10^2 \mu^3 \\ &= 0.5 \times 10^{10} \text{ RBCs} \\ &= 5 \times 10^9 \text{ RBCs} \end{aligned}$$



## QC of Platelet concentrate (prepared from buffy coat)

Parameter	Quality requirement	Frequency of control
Volume	70-90 ml	4 units / month
Platelet count	$\geq 6-9 \times 10^{10}$	4 units / month
pH	$> 6.0$	4 units / month
RBC contamination	Traces to 0.5 ml	4 units / month
WBC contamination	$10^7$ to $10^8$	4 units / month

# QC of Platelet Concentrate (by Apheresis)

Parameter	Quality requirement	Frequency of control
Volume	200-300 ml	4 units / month
Platelet count	$\geq 3.0-7.0 \times 10^{11}$	4 units / month
pH	$> 6.0$	4 units / month
RBC contamination	Traces to 0.5 ml	4 units / month
Residual leucocytes	$< 5.0 \times 10^6$	4 units / month

# Quality Check for Platelet Concentrates

**All units should show ‘swirling’ effect**

‘Absence of swirling in platelet concentrates is highly predictive of poor post-transfusion platelet count increments and increased risk of bacterial contamination’

# When to Perform Quality Control

- For platelet products it should be done on expiry date (end of storage period) of the component.
- On installation and after repair of equipments (refrigerator, centrifuges, deep freezers etc.)
- Modification in procedure for components preparation.
- Recruitment of new personnel.

# Factors Affecting the Quality of Blood Components (1)

1. Selection of donor
  - Antiplatelet drug therapy, defer for 72 hours
2. Quality of blood bag and anticoagulant preservative solution used
3. Techniques of phlebotomy
  - Clean venipuncture
  - Minimal tissue trauma
  - Flow-continuous and uninterrupted and should be completed in 8-10 min
  - Frequent gentle mixing.



## Factors Affecting the Quality of Blood Components (2)

4. Time period: separation should be done within 6 hrs of collection
5. Transit temperature: 20-24<sup>0</sup>C for not more than 6 hours (for Platelet components)
6. Refrigerated centrifuge calibration for maximum yield in minimum time
  - Critical variables – speed, temp, duration, rotor size
  - Accurate balancing – dry weight preferred
  - Bag position
  - Swinging cups better than fixed angle cups

# Factors Affecting the Quality of Blood Components (3)

## 7. Storage temperature

- $4\pm 2^{\circ}\text{C}$  = WB, PRBC
- $20^{\circ}\text{C}$ - $24^{\circ}\text{C}$  = PRP-PC, BC-PC, AP-PC
- $\leq -30^{\circ}\text{C}$  = FFP, Cryoppt

## 8. Uninterrupted, gentle flat bedded platelet incubator/agitator

- 60-70 cycles /min
- $1\frac{1}{2}$ " inch movement on either side.

# QC OF EQUIPMENTS

## REFRIGERATED CENTRIFUGE

- Buckets & centrifuge bowls – clean with
  - warm water and mild detergent
  - 1% Na hypochlorite after each spill/breakage
- Calibrated upon receipt, repairs or if low platelet yields
- Preventive Maintenance
  - calibration of speed with a tachometer (twice a year)
  - cleaning and lubrication of motor
  - regular change of worn out carbon brushes



# QC OF EQUIPMENTS (contd...)

## CRYOPRECIPITATE BATH/WATER BATH

- Temperature - checked and recorded daily
- Change water once a week or if leakage
- Recalibration of temperature controller if
  - temp. probe/ circuit board replaced
  - difference in digital display & certified thermometer



# QC OF EQUIPMENTS (contd...)

## Platelet Agitator

- No. of strokes – 60-70/min
- Periodic cleaning & lubrication



# QC OF EQUIPMENT FOR COMPONENT STORAGE

- Daily temp check of REFRIGERATORS, FREEZERS & PLATELET INCUBATOR
- Visual and audio alarms – check regularly
- Monitoring device - THERMOGRAPH (continuous temperature recorder)
- Temperature check
  - different locations in large equipment
- Actual temperature checked with calibrated thermometer in glycerol
- Alarm test - sensor dipped in a beaker with tap water / ice slush



# Documentation

## Registers

- Component preparation
- Quality control of packed red cells
- Quality control of platelets (PRP-PC & BC-PC)
- Quality control of AP-PC
- Quality control of FFP and cryoprecipitate

# Learning Outcome

At the end of this presentation, for ensuring good quality of blood components, participants must be familiar with

1. Criteria for quality control for different components
2. Maintenance and calibration of equipment used in preparation of blood components
3. Factors that affect quality of blood components