

Division of Blood Transfusion Services

Ministry of Health and Family Welfare



Quality Management (Assurance) in Blood Transfusion Service



Teaching Aim

To introduce the concept of Quality Assurance and Quality Control in Blood Transfusion Service



Introduction

- Quality management is an integrated system of quality assurance covering all matters which individually or collectively influence the components in order to guarantee their quality.
- Good Manufacturing Practice (GMP), quality control and audit programme, all are closely linked together with the management of errors and accidents.
- Internal quality control and proficiency testing are aspects of quality system concerned with examination of material component and the proficiency of the staff



Quality Assurance

This describes all the steps taken both in and outside the Blood Bank to achieve safest possible blood for the recipient.



Requirement of QMS

1. Organization and management
2. Accommodation and environment
3. Personnel
4. Equipment
5. External Services: Supplies & Reagents
6. Process Control
7. Identification of deviations and Adverse Effects
8. Performance Improvement
9. Document Control
10. Records
11. Internal Audit and Management review



Steps of Transfusion (In and Outside Blood Bank)

1. Decision to transfuse the patient with blood/component
2. Sending the requisition form and blood sample of patient to the blood bank
3. Processing the request by the blood bank according to the requisition and in accordance with its own SOP's and standard policies of the hospital transfusion committee

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4. Collection of the component from the blood bank maintaining the cold chain and delivery to the clinical area
5. Storage in the ward/theatre and in blood bank till transfusion is given.
6. Pre-transfusion checks
7. Actual transfusion and monitoring of transfusion
8. Recording the transfusion
9. Audits and
10. Performance improvement



Risks to the Patient from Blood Transfusion

Even with highest level of standards, working sophistication, best of equipments and trained personnel there are inherent risks in blood transfusion. Some are preventable and on some there is no control.



(1) Decision to Transfuse the Patient with Blood Component

- Assess the patient's clinical need for blood and when it is needed.
- A SINGLE UNIT of blood is rarely , if at all is of any benefit to the recipient and carries all the risks associated with blood transfusion.
- Use of WHOLE BLOOD should be discouraged , Administration of components is safer, more effective and is a better utilization of a scarce human resource.



(2) Sample Collection

➤ Request for issue /reservation of blood/ blood component should include:

- 1.Patient (if conscious) confirms his and father's name.
- 2.If unconscious, relative / staff confirms the identity.
- 3.The identity and Reg. number are checked with the medical records and same written on the requisition form.

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4. Requisition form is completely and properly filled.
5. Sample tube carries the patient's name, Reg. No., ward.
6. These should match with the medical records.
7. Phlebotomist should sign the sample tube and checklist.

➤ A “NEW BLOOD SAMPLE” for cross-match is required if the patient has had a recent red cell transfusion that was completed more than 24 hours earlier.





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the hospital that cares

BLOOD BANK

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Quality control-Requisition and Sample

- ☐ Patient (if conscious) confirms to his and father's name.
- ☐ If unconscious Relative(s)/ Staff confirm the identity.
- ☐ The identity, Reg. No. checks with the medical records and same is written on the requisition form.
- ☐ Requisition form is properly and completely filled.
- ☐ Sample tube carries the patient's name, Reg. No., ward.
- ☐ These match with the medical records.
- ☐ Phlebotomist has signed the sample tube.

Signature

Request for issue/Reservation of Blood/Blood Components

Patient's Name		Reg. No.		Age.
Father's Name				
Name of the Hospital & Telephone No.		Ward Bed No.	Date	Sex
Name of Consultant & Telephone No.		Diagnosis		Hb gm%
				Plt. Count.
1. RBC Conc./Packed RBC	Unit	Clinical notes & Reasons for transfusion		
2. Random Donor Platelet Conc.	Unit			
3. Fresh Frozen Plasma	Units	History of Previous transfusion		
4. Cryoprecipitate	Units	Donation Unit No. Blood Group of Patient (if Known)		
5. Whole Blood	Units	Required	On Date	
6. Plasma	Units		At time	
7. Single Donor Platelet (SDP)				

(3) Receiving Sample at Blood Bank Counter

Sample of the patient when received at blood bank counter should be properly checked.

- 1.Name and registration No. of patient on the requisition form and on the sample should tally.
- 2.Name of patient and hospital should be confirmed by the relatives.
- 3.Appearance of sample
- 4.Entries in request register made
- 5.Registration number put on sample (s)
- 6.Sample is sent to the red cell serology lab.



(4) Blood Bank Procedure

Donor Selection

➤ Donors should be asked for any history of following in the past 6 months

Jaundice	Malaria	Heart disease
Repeated diarrhea	Lung disease	Cancer
Vaccination including rabies	Epilepsy	Tuberculosis
Acute infection	Typhoid	Tattooing
Dental extraction	Swollen gland	Ear piercing
Unexplained weight loss	Anemia	Leprosy
Low grade fever	Kidney disease	Diabetes
Surgery Major/ Minor in last one year		



Donor should be screened for RISK BEHAVIOUR

1. Did you ever have sexual contact with a person of same sex?
2. Did you ever have sex with a commercial sex worker?
3. Did you ever use IV drugs?
4. Have you or your partner ever been tested and found positive for HIV, Hepatitis C and B?



Pre donation Counseling

The donor should be counseled and consent should be taken for testing of blood for HIV and informing the test results.



Quality Control - TTI



Quality control- activities including steps of verification and testing which are used to assure the materials and processes meet their intended specifications.

Proficiency testing – an aspect of Quality Assurance which monitors the ability to perform laboratory procedures within established limits of accuracy through the analysis of unknown specimens distributed by an external source.

The line between QC and PT in some cases is ill defined. The performance of QC procedures on component and reagent will be in itself a measure of the proficiency of the staff preparing these components.



EXTERNAL QUALITY ASSURANCE



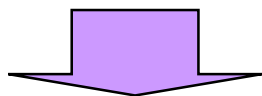
External Quality Assurance

- The internal QC should be complemented by regular external quality assurance eg : participation in a proficiency testing programme
- Proficiency programme test, coded “normal” and “problem” blood samples are distributed from national or regional reference laboratory to the participants usually twice to four times in a year.

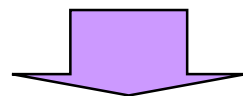
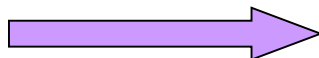
EQAS- responsibilities

Organizing Lab

Participating Lab



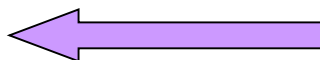
Prepare QA
Specimen



Examine
specimen



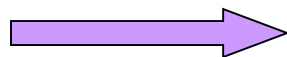
Report results



Analyze results



Prepare report



Evaluate



EQAS- Benefits to participating Labs

- Comparison with performance of other participating labs.
- Identification of problems relating to laboratory processes, techniques and reagents
- Provision of information & education to improve performance
- Encouragement of best practice
- Enhanced credibility of the laboratory
- Access to a network of labs for exchange of information.



EQAS in Transfusion Medicine

- Method by which entire testing process including quality of results generated by a lab is assessed
- Assess laboratory's performance using samples of known but undisclosed content

EQAS in Transfusion Medicine

Monitors

- Whether samples are handled correctly
- Assays are performed accurately & efficiently
- Results are recorded appropriately

(5) Transportation

Collection of the component to and from the blood bank, maintaining the cold chain and delivering to the ward/theatre involves following steps:-

- the patient's relative accompanied by ward attendant collect the blood

Following care is to be taken before issuing:

- Check the patients name, age and registration number with the details on the cross-match tag.
- Check that blood group and unit number on the cross match tag tallies with those on the blood unit.
- Check the expiry date.
- Check for any leakage, discoloration or haemolysis.
- Deliver the blood unit only in insulated containers.
- Deliver it to ward nurse/ doctor who shall be responsible for proper storage till transfused.

(6) Pre Transfusion Checks

Before administering blood component, FINAL IDENTITY check of the patient, blood unit compatibility tag and the complete documentation should be done.

1. This is the last chance to detect an identification error and to prevent a potentially incompatible transfusion.
2. Ask the patient, if conscious, to identify himself/ herself by name, parentage, age or any other identification.
3. If unconscious ,ask relatives or any other staff to verify the patient's identity.

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4. Check that details on the compatibility tag exactly match with the documentation.
5. Check that there is no discrepancy between the unique donation number, blood group between the blood unit and the compatibility tag.
6. Check that expiry date on the unit has not already passed.
7. Check the blood unit for any leakage and for any visible discoloration.



Quality Control Pre-transfusion

	Please use the checklist. It is for your' and patient's protection.	
1	Patient if conscious, has confirmed his and his father's name.	Yes
2	If unconscious, relatives have confirmed the identity.	Yes
3	The identity, registration number on the tag, tally with those in medical records.	Yes
4	Unit number, blood group on the tag tally with those on blood bag.	Yes
5	There is no leakage in the blood bag.	Yes
6	There are no visible blood clots in the bag.	Yes
7	No sign of deterioration of the blood/ component.	Yes
8	The bag is within expiry period.	Yes
	Signature of Transfusionist:..... Date:.....	



(7) Storage in Ward/Operation Theatre

- Proper storage of blood and blood components both in the blood bank and in the clinical area is important to preserve the function and prevent bacterial contamination.
- Red cells are to be stored in refrigerator at 2-6°C ,Platelets are to be kept at room temperature of 20-24°C till transfused.
- In case a domestic refrigerator is being used, do not keep the component on the shelves of the door or chill tray.
(former will have a higher temperature and the latter have a lower temperature than desired.)



Time Limits of Transfusion

Product	start infusion	complete transfusion
Whole blood/ Red Cell Concentrate	Within 30 min after removal from refrigerator	within 4 hours or less if temperature is high
Platelet concentrate	Immediately	Within 20 mts
FFP	within 30 mts	within 40 minutes

Platelet concentrate –Fresh blood transfusion set primed with saline should be used

Monitoring the transfused patients.

1. Encourage the patient to notify any discomfort during transfusion.
2. Acute reaction generally occurs within 15 minutes.



(8) Recording the Transfusion

The following information should be recorded .

Pre-transfusion checks carried out and found satisfactory.

Condition of blood unit and the identity of the recipient are found satisfactory.

1. Time the transfusion is started
2. Time the transfusion is completed.
3. Volume and type of all the components transfused.
4. Unique donation number of all components transfused.
5. Any adverse effects.
6. Signature of the person giving transfusion.



(9) Audits

Internal audits

- to ensure that all procedures and associated quality control are performed according to the principles of Good Manufacturing Practices.(GMP)
- should be carried out according to an established programme by responsible person.

External audits

- should also be performed by a designated approved authority.

Personnel and organization

- adequate number of qualified and trained personnel.
- presence of organization chart showing the hierarchical structure of the blood transfusion service.



(10) Performance improvement

Complaints and component recall-

- Investigate as soon as possible the complaint and information that may suggest the defective blood components.

Investigation of errors and accidents-

- To identify system problems.
- “Near- miss” events as well as actual events with benign outcomes should be addressed as part of the quality system review related to errors and accidents.
- Document the corrective actions.

Corrective and Preventive action



Types of Errors

- Pre-analytical: Blood/component request, patient and sample identification, sample collection, transport.
- Analytical: sample testing
- Post-analytical: reporting test results, interpretation, storage, retesting if needed.



Learning Outcome

The participant is enabled to:

1. Establish Quality Assurance in Blood Transfusion Service.
2. Implement Internal Quality Control and understand the need to participate in the External Quality Assurance Programme.

