

Quality management system

The main Objectives of quality in blood bank

1. Is to ensure availability of a sufficient supply of blood, blood components of high quality with maximum efficacy and minimum risk to both donors and patients.
2. To ensure maximum efficacy and safety of blood
3. To determine problems in the whole transfusion chain and solved it .

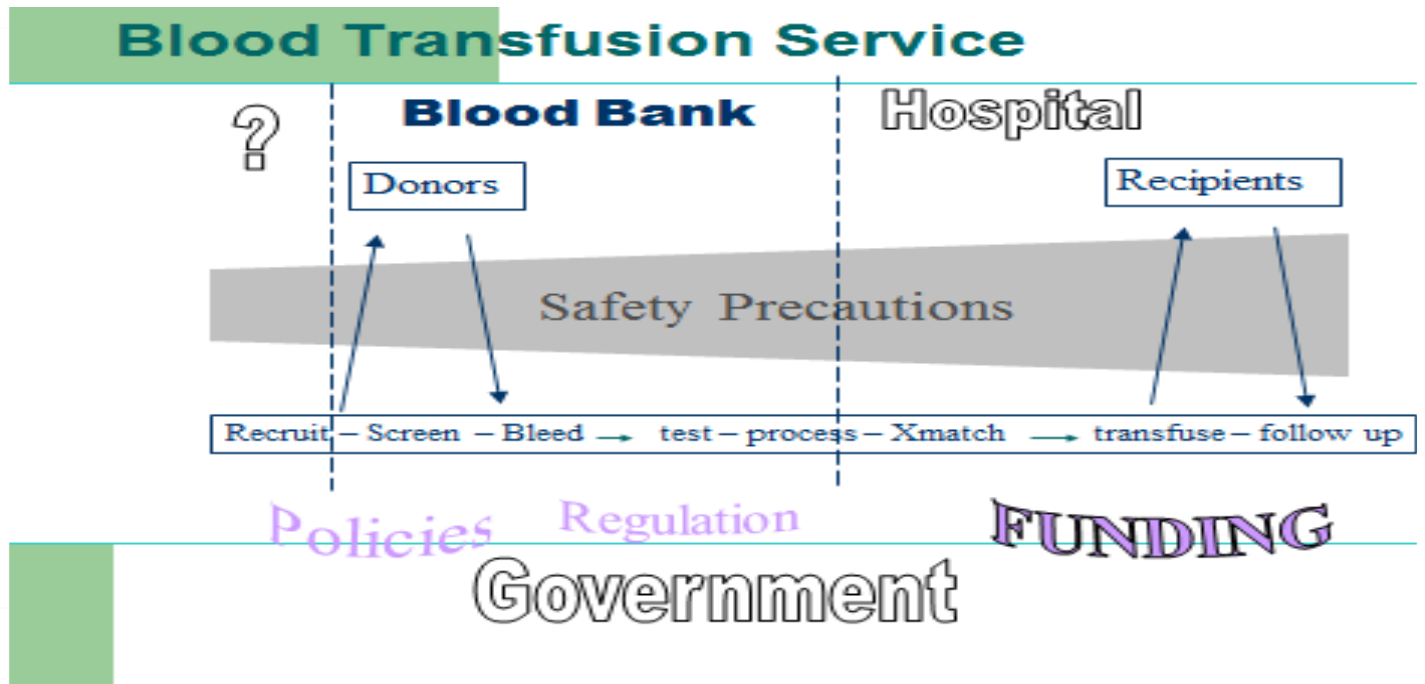
The quality requirements involve : -

1. Quality control and proficiency testing
2. Internal and external audits
3. Personnel and organization
4. Premises, equipment and materials
5. Documentation
6. Blood processing

QC in Blood Bank Technology

1. Donor services and Blood collection
2. Blood grouping
3. Crossmatch & antibody screening
4. Transfusion
5. Component preparation
6. Storage , issue and transportation .

7. Positive and negative controls on all tests
8. Reverse grouping
9. Good documentation, SOPs etc
10. Equipment monitoring, calibration, maintenance



1. Personnel and organisation

The Blood Service must ensure that adequate resources are provided to implement and operate the quality management system, These include : -

1. All personnel shall have up-to-date job descriptions that clearly set out their task and responsibilities. Organisations shall assign the responsibility for processing, management and quality assurance to different individuals who function independently.

2. All personnel shall receive initial and continued training appropriate to their specific tasks. Training records shall be maintained. Training programmes shall be in place and shall include good practice.
3. The contents of training programmes shall be periodically assessed and the competence of personnel evaluated regularly.

2. Premises

a. General

Premises including mobile sites shall be adapted and maintained to suit the activities to be carried out. They shall enable the work to proceed in a logical sequence so as to minimise the risk of errors, and shall allow for effective cleaning and maintenance in order to minimise the risk of contamination.

A. Donation area

There shall be an area for confidential personal interviews and assessment of individuals to determine their eligibility to donate. This area shall be separated from all processing areas.

B. Collection area

Collection shall be carried out in an area intended for safe donation, appropriately equipped for the initial treatment of donors experiencing adverse reactions, and organised in such a way as to ensure the safety of both donors and personnel as well as to avoid errors in the collection procedure.

C. Testing and processing areas

There shall be a dedicated laboratory area for testing that is separate from the processing area with access restricted to authorised personnel.

D. Storage areas

Storage areas shall provide for properly secure and segregated storage of different categories of blood, blood components, tissues and materials including quarantine and released materials .

E. Waste disposal area

An area shall be designated for the safe disposal of waste, disposable items used during the collection, testing and processing , and for rejected blood or blood components.

3. Equipment and materials

A. Equipment checks and record keeping

All equipment shall be validated, calibrated and maintained to suit its intended purpose. Operating instructions shall be available and appropriate records kept.

A. Selection of equipment

Equipment shall be selected to minimise any hazard to donors, personnel or blood components.

B. Computerised systems

When computerised systems are used, software, hardware and back-up procedures must be checked regularly to ensure reliability, be validated before use, and be maintained in a validated state.

4. Documentation

Documentation provides the ability to trace prospectively and retrospectively all steps in all procedures, dating from collection of the blood to monitoring techniques, component preparation, laboratory testing, issue and transfusion of blood.