DEVELOP TOOLKIT
FOR
MONITORING AND QUALITY ASSURANCE
OF SAFE BLOOD TRANSFUSION

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Introduction:

Transfusion of blood and blood components is an established standard way of treating patients who are deficient in one or more blood constituents and is therefore an essential part of health care. A blood transfusion service is a complex organization requiring careful design and management. Essential functions of a blood transfusion service are donor recruitment, blood collection, testing, component preparation, storage and supply of these components to the patients. The organization of a blood transfusion service should receive utmost attention and care for smooth functioning of various components of the service. The goal of blood transfusion service is to provide effective blood and blood components which are as safe as possible and adequate to meet the patients' needs.

Safe blood is blood that does not contain any viruses, parasites, drugs, alcohol, chemical substances, or other extraneous factors that might cause harm, danger or disease to the recipient. People who donate blood should be in good health and should not suffer or have suffered from any serious illnesses. The recipient should not be harmed by receiving blood; the donor should not be put at risk by giving blood. The world relies on safe blood, yet only 20–30% of the world's health systems are able to provide a safe and adequate blood supply. There are a limited number of healthy people donating blood. Every year, over 100 million blood units are collected from blood donors. Many millions more are still needed to fulfill global requirements and ensure availability of blood when and where it is needed.

The emergence of HIV in the 1980s highlighted the importance of ensuring the safety, as well as the adequacy, of national blood supplies. In many countries, even where blood is available, many recipients remain at risk of transfusion-transmissible infections (TTIs) as a result of poor blood donor recruitment and selection practices and the use of untested units of blood. Globally, it is estimated that only 20% of the 100 million units of blood collected annually are collected in the developing world, where 80% of the world's population lives. Shortfalls in the blood supply have a particular impact on women with pregnancy complications, trauma victims and children with severe life-threatening anaemia. Significant number of pregnancy-

related deaths could be avoided each year through access to safe blood. The prerequisite to a safe, secure and ethical supply of blood and blood products is a National blood transfusion service. Because of the public health importance of blood safety, WHO recommends that every country in the Region should establish a national blood transfusion service to ensure a safe and secure supply of blood and blood products and their appropriate and rational use. WHO also recommends that countries should establish national blood policies and also put appropriate legislative frameworks. Blood Transfusion service is an essential part of the health care system. The priority objective of the Blood Transfusion Service is to ensure safety, adequacy, accessibility, and efficiency of blood supply at all level. The infectious agents like HIV, Hepatitis B and C, Syphilis, Malaria and also others are transmitted through blood transfusion.

The growing problem of transfusion associated infection has been acknowledged by the government of Bangladesh. In addition to that Government commitment is also essential for fostering blood safety activities of the country. In many developing countries like Bangladesh, little importance has been given to the subject of transfusion medicine although the demand for blood and blood component is increasing day by day. The requirement of blood and blood product depends upon the population size, health care structure, prevalence of condition requiring regular transfusion, availability of surgical centers and awareness amongst clinician regarding judicious use of blood. There are many ways to estimate the total need of blood but ideally if 2% of the population donates blood it will be sufficient to meet the need of the developing countries. The need for blood varies from 7-15 units depending upon the type of medical care available. The 113 blood centers, established under the safe blood transfusion program are functioning. All the centers were provided basic equipment and furniture which is necessary for running a blood bank. The development of manpower, supply of reagent and mandatory screening of 5 diseases also included under the program.

The basic functions of a blood transfusion centre are -

- Organizing the services
- Recruitment of donors
- Collection, processing, storage and distribution of blood and blood component.
- Laboratory investigation.

- Participation in clinical use of blood and blood component.
- Teaching and training
- Research and development.

The scenario of blood donor and blood screening activities are improving day by day in comparison to the past. The percentage of professional blood donor started to fall significantly in Bangladesh after the intervention of SBT program. But safe blood transfusion still remains an important issue to address especially in terms of their capacity for providing quality service. The perception of quality assurance activities, performance monitoring, use of QA indicators and checklist is not up to satisfactory level. We need to strengthen the said areas with an aim to improve the existing condition of blood bank activities. In this APW the main focus is on the quality assurance of blood safety program.

Background:

Emergence of HIV in the 1980's initiated the importance of ensuring blood safety in Bangladesh. The scenario was not satisfactory at that time in respect of donor selection, screening of five diseases .The country felt need for ensuring safe blood by

- Establishment of a nationally coordinated blood transfusion service.
- Collection of blood from voluntary blood donor from low risk population.
- Testing of all donated blood including screening for TTI.
- Reduction in unnecessary transfusion through the effective clinical use of blood.

There was no quality screening facility available for the blood centre in public, & private sector before the introduction of safe blood transfusion program. Considering the disease scenario and the importance of blood safety one project as a TAPP was approved on 25/5/1998 by the MOH&FW in the name" of Implementation of Safe blood Transfusion ". The total budget of the project was TK 1602.82 lakh. Later activities of the project were included in the HPSP as a Safe blood transfusion program. The main objective of the program was -

1) Establishment of a reference laboratory and building up capacity of 97 blood centre for blood screening (53-District hospital, 13-MCH, 5-Specialist hospital, 13-Combined Military Hospital, other 10- Big Hospital, BDR, Red Crescent and BIRDEM) by providing kit reagents and equipment for detection of HIV, Hepatitis B and C , Syphilis and Malaria.

2) Training of doctor and technologist

3) Enhancement of Voluntary blood donation through motivation program and IEC campaign.

The expected output of the program:

- Mandatory screening of blood for HBsAg, Anti HIV, Anti HCV, Syphilis and Malaria Parasite (MP) in all blood transfusion services in the country.
- Provide support to management and program development for safe use of blood.

- Improvement of the manpower skill in blood transfusion services for maintenance of SOP and quality control of blood screening for HIV and transfusion transmissible disease.
- Development and reinforcement of the capacity of NGO's for the improvement of voluntary blood donation.
- Development of awareness on voluntary blood donation.
- Organize special national days for blood collection on regular basis

Presently under safe blood transfusion program 113 blood centre are running in Bangladesh. The following are the achievement after the intervention:

- The trend of paid donors is declining.
- Skill in respect of SBT developed among the manpower working in the centre.
- Regular monthly blood screening report from all the centers.
- Availability of national data for prevalence of transfusion transmissible infection in different type of blood donors in Bangladesh.
- One law "Safe blood transfusion law-2002" already passed by the parliament and also published in the Gazette for blood safety.
- Quality assurance program for maintaining the quality of blood.

The total number of Safe blood transfusion centre will be increased in phases, especially at upazilla health complex level. Present task of the authority is to strengthen the quality assurance program of blood banks to ensure the safe blood. Side by side performance and quality assurance monitoring is also equally important for the safe blood transfusion program. The authority of SBT program developed a module for the capacity development of the service providers. The module covered some of the areas of quality assurance but not comprehensive in respect of using checklist, monitoring indicators and performance appraisal. So one of the felt need is to develop a separate document on quality assurance and also proper practicing of quality assurance in blood banks.

Justification

The safe blood transfusion centers in Bangladesh are running at the primary, secondary and tertiary level both in the public and private sector and the number is 113. The SBT authority already developed a plan for increasing the number of safe blood transfusion centre in phases especially in the public sector. The entire SBT centre is equipped with necessary equipment and other logistic. Moreover the capacity of the service providers also developed to provide safe blood. In addition to that the authority also designed the system of reporting from the different centre along with a good number of forms and format with an aim to monitor the performance and quality assurance. One training module also developed by the SBT authority for the service providers are the existing basic document supplied to blood centers focusing different aspect of safe blood transfusion. Among the contents one of the content is monitoring performance and quality assurance, but not very much comprehensive in respect of better conceptualization for the said area. Some of the positive result already visible as a result of SBT program intervention like increasing number of Voluntary blood donor, decreasing the number of professional blood donor, quality blood screening and introduction of quality assurance activities. The present challenge of the SBT authority is to develop a structured quality assurance system along with monitoring. The prepared document may provide support in this respect. The quality is an endless journey so we need to address this area very meticulously with an aim to develop better access of safe and quality blood for the patients of Bangladesh. The initiative taken by the DGHS with the support from WHO to prepare this document is very much timely and justified.

Strategy of SBT Quality assurance according to WHO

Strategy: The WHO developed a strategic paper for ensuring quality assurance of Safe blood transfusion program. It is also applicable for Bangladesh. The major focus is

- A well-organized, nationally-coordinated blood transfusion service that can provide adequate and timely supplies of safe blood for all patients in need
- The collection of blood only from voluntary non-remunerated blood donors from low-risk populations
- Testing of all donated blood for transfusion-transmissible infections, blood grouping and compatibility testing
- The appropriate clinical use of blood, including the use of alternatives to transfusion wherever possible, and the safe administration of blood and blood products

The quality and safety of blood provided for patients depends not only on a national quality system for blood transfusion services, but quality in every activity. An effective national quality system requires:

- National quality policy and plan
- Quality officers at national and local levels
- Quality standards
- Documentation system
- Training of all staff
- Assessment of the quality system.

Regular, voluntary non-remunerated blood donors from low-risk populations

are the foundation of a safe blood supply.

Requirements include:

- National blood donor program
- Identification of low-risk donor populations
- National criteria for donor selection
- Safe blood collection procedures
- Donor notification and referral for counseling
- Donor records.

All donated blood should be blood grouped and tested for transfusion transmissible infections (TTI). This requires:

- National strategy for TTI testing and blood grouping
- Evaluation and reliable supply of test kits and reagents.

The preparation of high quality blood components requires:

- Sustainable program that responds to clinical demands
- Application of good manufacturing practice.

All blood and blood products must be stored and transported correctly to

prevent bacterial contamination and maintain viability. This requires:

- Specialized storage and transportation equipment
- Regular monitoring and maintenance of equipment.

The provision of safe blood and blood products requires an appropriate infrastructure and an adequate and reliable supply of reagents and test kits. Trained staff and continuing professional development are a prerequisite. Provision should be made for a rapid response to emerging infections, emergency situations and post-disaster reconstruction.

.The appropriate clinical use of blood requires:

- National policy and guidelines on transfusion
- Training of all staff involved in transfusion
- Availability of alternatives to transfusion
- Hospital transfusion committees
- Blood request form
- Blood ordering schedule
- System for monitoring transfusion practice.

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- Regular monitoring and maintenance of equipment.

Concept of quality

- Quality is a relative term not absolute / ideal.
- Quality means different things to different people.
- We should have a common understanding of the concept of quality.

Definitions of quality of care

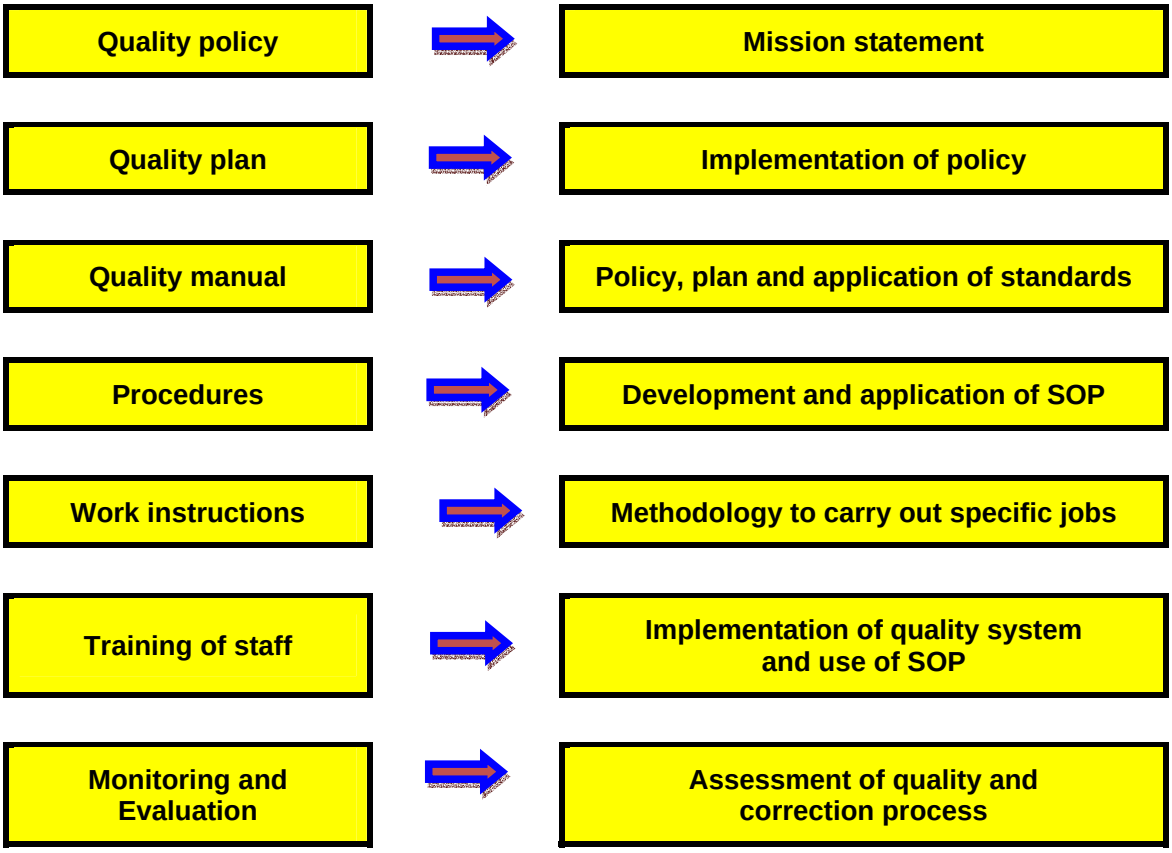
- The application of medical science and technology in a way that maximizes its benefits to health without correspondingly increasing its risks. The degree of quality is, therefore, the extent to which the care provided is expected to achieve the most favorable balance of risks and benefits.
- Proper performance (according to standards) of interventions that are known to be safe, that are affordable to the society in question, and that have the ability to produce an impact on mortality, morbidity, disability, and malnutrition. (- M.I. **Roemer and C. Montoya Aguilar, WHO, 1983)**

Dimension of quality

- Effectiveness
- Technical competence
- Efficiency
- Safety
- Access to services
- Continuity
- Interpersonal Relations
- Amenities

Development of a Quality system

The Development of a quality system can be done in a step-wise approach as shown in figure below:



Definition of Quality assurance

1) All the arrangements and activities that are meant to safeguard, maintain, and promote the quality of care'' (- Dr. Donabedian.)

2) A process of measuring quality, analyzing the deficiencies discovered, and taking action to improve performance followed by measuring quality again to determine whether improvement has been achieved. It is a systematic, cyclic activity using standards of measurement." (Dr. Heather Palmer, a QA expert in U.S. ambulatory care)

Focus on Quality assurance

- Focus on the client: Services should be designed so as to meet the needs and expectations of clients and communities.
- **Focus on systems and processes: Providers** must understand the service delivery system and its key service processes in order to improve them.
- **Focus on measurement: D**ata are needed to analyze processes, identify problems, and measure performance.
- **Focus on teamwork: Q**uality is best achieved through a team approach to problem solving and quality improvement.

Steps of quality assurance planning

- Planning for quality assurance
- Developing guidelines and setting standards
- Communicating standards and specifications
- Monitoring quality
- Identifying problems and selecting opportunities for improvement
- Defining the problem operationally
- Choosing a team
- Analyzing and studying the problem to identify its root causes
- Developing solutions and actions for improvement
- Implementing and evaluating quality improvement efforts

Component of QA

- Personnel with adequate training and experience
- Proper specimen collection
- Employment of techniques with precision and accuracy
- Proper performance of tests
- Efficiency processing of results
- Reagents and equipment of good quality
- Methods for detecting errors
- Correctives steps when analyses go out of control
- Preventive maintenance of equipment
- Continuous training of staff, coordination and timely feedback

Total quality

- Focus on professional quality
- Focus on client satisfaction
- Focus on system effectiveness
- Focus on interconnections
- Organizational and societal unification

The role of consumer, service provider and manager in relation to quality assurance is different but always directed towards quality from their own perspectives.

Role of consumer

- Definers of Quality
- Evaluators of Quality
- Informants of Care
- Co-producers of care
- Targets of Quality Assurance
- Controllers of Practitioner Behavior
- Reformers of Health Services

Role of service providers

- To be accountable
- To provide quality care(plan, implement)
- To safeguard the quality of care services
- To be evaluated by colleagues
- To evaluate his colleagues
- To continue learning
- To collaborate with colleagues and management

Role of manager

- Do their job(Quality Management)
- Exert leadership
- Participate in Quality Management
- Communicate on Quality matters
- Be accountable for quality
- Evaluation of Quality Management
- Provide resources

Quality Assurance in Blood Transfusion Service

A simple definition of quality is 'fitness for a purpose'. In blood transfusion service, the primary goal of quality is 'transfusion of safe unit of blood.' The objective 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.

To achieve quality in a defined procedure, a laboratory may encounter constraints e.g.

a. Organizational constraints in terms of staffing patterns, finances available, training of staff, and/or
b. Technical constraints e.g. ability of laboratory to perform a specific test.

Need for Quality

A failure in the quality of blood collected or screening of donated blood unit can be very serious and may result in fatal consequences. If appropriate quality systems are designed, implemented and monitored, the issue of an improperly tested unit can be avoided.

Besides laboratory testing, a failure in the quality system can lead to numerous situations which may be potentially dangerous to the patient, i.e.

- failure to identify the patient correctly
- wrong sample labeling
- mix-up of results amongst different patients
- failure to detect presence of antibody in the patient's sample.
- issue of unscreened blood due to faulty laboratory procedures

Therefore, it is very important to recognize the need for quality and implementation of quality assurance scheme in all laboratory procedures.

Quality Assurance and Quality Control

The difference between these two terms may be unclear to many people and the terms cannot be used interchangeably.

Quality Assurance

Quality assurance deals with the maintenance of a system to ensure that the performance in a laboratory is of the required quality. In a blood transfusion centre, it means that a management system should exist to look into provision of a safe unit of blood and, if any errors are identified, these should be corrected.

Quality Control

Quality control is the inspection system which involves specific actions performed to monitor the effectiveness of the system and checks that the mistakes have not occurred.

Quality System & Total Quality Management (TQM)

In a blood transfusion service, the quality system deals with all aspects to ensure that the product or the tested and 'safe unit of blood' is as safe as possible.

Quality system must be applied to all laboratories, whether small or more advance. It should include the implementation, maintenance and monitoring of the quality assurance system.

The introduction of a quality system in blood transfusion centre starts with:

- in-depth vision and knowledge of all the aspects of blood transfusion.
- planning required for effective donor selection, donor screening, laboratory work, issue of safe blood and transfusion of blood to the recipient.
- formulating the mechanism for monitoring to ensure that quality is maintained.

Total quality management includes:

- Quality in procurement (donor, material, reagent)
- Quality in preparation (efficient and effective blood component preparation)
- Quality in design and development (improved techniques and procedures)
- Quality in preservation;
- Quality in supply (transportation and service)

Laboratory Quality Assurance Scheme

Laboratory quality assurance scheme includes:

- Proper identification of all samples
- Validation of the sensitivity, specificity and reproducibility of new batch of test kits and reagents
- Strict adherence to the recommended procedure
- Use of the appropriate test and internal controls
- Regular proficiency testing exercise
- Adherence to safety guidelines and safe disposal.

Internal quality Assurance (IQA)

Internal quality assurance is meant to allow laboratory technicians to check their performance by themselves and help them to monitor the reliability of their technique. In other words, it deals with the measures taken by a local laboratory to maintain laboratory standards. IQA includes procedures designed for continuous evaluation of the work of the laboratory concerned and it aims at achieving high level of safety and efficiency.

External quality assurance (EQA)

External quality assurance involves a central reference laboratory which monitors the standards of local laboratories. EQA is a system whereby a set of reagents and techniques are assessed by an external source and the results of testing laboratory being compared with those of an approved

reference laboratory. EQA is an effective way of identifying process problems within the laboratory and provides the laboratory with an objective view of its performance relative to other laboratories. Participation in EQA involves testing sets of samples of known, but undisclosed, content that are sent to participating centers by the EQA scheme. Each participating laboratory receives an identical set of samples which should be processed in the same way as routine clinical samples to ensure that its performance in EQA accurately reflects its usual performance. Following the collation and analysis of results, each centre receives its own results, together with the anonymized results for all other participating centers, which enables it to compare its performance with other centers. The measurement of performance through EQA enables the identification of any problems and deficiencies. As a result, the required corrective and preventive measures can be implemented. Thus, information generated by the scheme helps to improve the overall quality of the blood transfusion laboratory and the safety of the blood and blood products it issues for transfusion. Even if a formal quality system is not in place, EQA can still be introduced into laboratory practice as part of a process of continuous quality improvement.

Different Quality Assurance Aspect

Blood Bank Premises Design

In planning the design of a blood transfusion service, the activities and flow of operation should be considered for adequate utilization of space. The functional plan of a blood transfusion service is thus based on the paths taken by the donors, the blood unit, blood samples and material.

1. Donor Complex

The donor complex consists of a donor waiting area, donor registration, and medical examination room with preliminary testing, blood collection area, apheresis area, donor rest room, refreshment and toilet. The flow of donors should be uniform and clearly defined to avoid unnecessary traffic in the corridors .The donor complex should be pleasant and comfortable. Donor educational material can be made available to prospective donors in the reception or waiting room. The donor organizers should be associated with donor complex for donor motivation, recruitment and retention.

2. Blood storage (Primary)

Initial storage of blood should be in the vicinity of the place where donor blood is collected; this is called as the primary storage. After all the tests are performed, blood should be stored in vicinity of the issue area.

3. Component preparation

The area for blood component should be close to quarantine storage. The component laboratory should be clean, dust-free and well lit.

4. Serology laboratory

This laboratory is basically meant for red cell serology testing and donor and patient samples. A separate laboratory may be designated for antenatal and specialized serology.

5. Laboratory for transfusion transmitted disease

A separate laboratory should be designated for screening of all donor units for transfusion-transmitted infections.

6. Issue counter

Outside the serology laboratory a small counter should be designed for accepting blood samples and issue of blood, to avoid unnecessary and unauthorized entry of personnel in the laboratory. Besides the essential donor and laboratory complexes, the premises should have provision for quality assurance laboratory, washing room, disposal facilities, distillation room, day care/therapeutic area, conference room, departmental library, administrative office, store and staff room.

Blood Collection

Medical care of donors and collection of blood are important functions of a transfusion centre. A pleasant experience during collection ensures regular donation. Proper venepuncture has an important role in ensuring safety of blood. Medical or paramedical staff that perform and supervise the venepuncture must be skilled so as to minimize the discomfort to the donor. An imperfect technique may discourage the donor from becoming a regular donor.

Donor Room

The phlebotomy room should be separate, clean, well-aerated and air-conditioned.

The height of the donor beds should be 3 feet. Beds should be covered with a soft mattress and a clean sheet.

Equipment and Chemicals

1. Blood collection bags with anticoagulant
2. Weighing scale to weigh the blood bag during collection (mixture, monitor)
3. Sphygmomanometer

4. Weighing machine, thermometer, artery forceps, gloves, masks, gown, scissor, hand gripper etc.
5. Sterile cotton swabs, savlon and methylated spirit (Each of these must be placed in clean lapelled containers.)
6. Tube sealer with clips
7. Medicated dressing (Band-aid)
8. Emergency kit: Intravenous fluids, ampoules of adrenaline, dexamethasone, calcium gluconate, mephentamine, oxygen cylinder with regulator and mask, smelling salt.
9. Test tube with rack.

Identification of Donor

Before starting the phlebotomy, identify the donor by a donor name & number. After collection, attach the donor number to the blood bag and pilot tubes. The date of collection and expiry; and the blood group of donor if tested, should be written on the blood bag label.

Inspection of the bag

All blood bags must be inspected before starting the blood collection procedure. The anticoagulant must be clear. Look for any leaks, breaks, turbidity or any change in colour of the anticoagulant, fungal growth over the bag, or under the label or an abnormally large air bubble. Check the intact ports and a sealed needle.

Volume of blood

The volume of blood collected is proportionate (1:7) to the anticoagulant

Procedure of Venepuncture

1. Make the donor lie down comfortably.
2. Selecting the vein
    a. Inspect both arms in the antecubital fossa to select a suitable vein. The selected vein should be large and firm, but not very superficial, slippery or mobile.
    b. Apply a sphygmomanometer cuff and inflate to systolic BP to select a vein. Ask the donor to make a first which will help in

selecting the vein. Release the cuff pressure and ask the donor to loosen the tight first, after selecting the vein.

3. Cleaning the Venepuncture site: Clean 4-5 cm of area around the selected vein in a concentric centrifugal (spiral) pattern starting from the venepuncture site as the centre.

   a. Apply 15% Chlorhexidine (Savlon) as the antiseptic and detergent solution to remove the dirt from the donor arm.
   b. Remove the savlon with methylated spirit.
   c. Do not touch the cleaned area after preparation.

4. Put a loose knot just near the needle end of the tubing, which enables the needle to be easily disconnected from the tubing after blood collection.

5. Raise the cuff pressure to mid diastolic level, break the seal and insert the needle held at an angle of 45degree with bevel upwards into the skin and then to vein. Push a little way into the vessel lumen to avoid displacement. Anchor the needle hub with adhesive tape on the donor arm.

6. Never leave the donor unattended during the process of blood collection.

7. Mix the blood and anticoagulant gently and periodically during collection of blood either manually or using automated mixing equipment.

8. Monitor the volume of blood being drawn

9. When the appropriate amount has been collected, clamp the tubing with artery forceps and deflate the cuff. Place a sterile, dry swab at puncture site and withdraw the needle.

Care of the donor

1. The donor should be under constant observation. After the phlebotomy he should remain on the couch for a short while.

2. Ask the donor to keep the arm raised. Apply firm pressure on the venepuncture site with 2-3 fingers of the other hand, till the bleeding

stops. Never ask the donor to fold the arm over the swab, as it may give him a false sense of security and blood may keep oozing from the venepuncture site causing a haematoma.

3. When the oozing stops, apply a medicated dressing such as band-aid.

Instructions to donors

1. Drink more fluids than usual in the next 24 hours.
2. Do not smoke for half an hour and do not consume alcohol for next 24 hours.
3. Avoid strenuous exercise for 24 hours.
4. If feeling faint or dizzy, lie down or sit with the head between the knees. If the symptoms persist the donor should report to the blood bank or consult a doctor immediately.
5. Drivers or pilots may not report for duty for next 24 hours. (to avoid any fatalities due to delayed faint)
6. If the phlebotomy site bleeds, special measures.

The basic requirements for blood donation are:

1. Education, Motivation and Retention of blood donors.
2. Options of blood donations, at the mobile camps or at the premises of the blood bank. The minimum requirements for an ideal blood collection programme.
3. Conclusive questionnaire on the health history of the blood donor.
4. Physical examination of the donor.
5. Details procedure followed in blood collection.
6. Post donation care of the donor.
7. Management of adverse reactions of the donor.
8. Ideal follow up program of the blood donors to build and sustain effective donor registry.
9. Proper steps of operations for transport of blood and shipment to the blood bank from the blood donation camps.

10. Proper methods followed for the disposal of non-reusable materials used in the blood collection site.

Procedure followed in blood group serology laboratory:

1. Proper care of the glassware used in the blood bank and the cleaning methods.
2. Preparation of normal saline used in the blood bank laboratory.
3. Procedure of washing the red cells before the regular tests.
4. ABO grouping (a) Slide Method. (b) Tube method forward and reverse.
5. Subgroup identification if needed.
6. Rh Typing technique, slide or tube methods.
7. Antiglobulin tests (coombs') both Indirect and Direct.
8. Rh antibody detection and titration methods.
9. Compatibility test procedure.
10. Storage and proper care of all reagents, blood samples and stock control sera.
11. In screening lab: MICRO ELISA Procedure for the detection of antibodies to HIV1&2 HCV and HBsAg.
12. RPR test for Syphilis.
13. PBF for the detection of MP.

Maintenance of cold chain and mechanical equipments

All the cold chain equipment should be regularly inspected, recorded of the performance including the alarms. Calibrate, if required and temperature to be recorded at periodic intervals. The important equipment are -

1. Blood Bank Refrigerators.
2. Deep Freezers -40 & -80 deg C.
3. Refrigerated Centrifuge
4. Weighing Balance.
5. Electronic Sealers
6. Thawing Bath

7. Desk Centrifuges & Cell Washers.
8. Cell Separators.

Requirement and maintenance of records - record keeping

The Following Registers should be maintained

1. ABO Grouping and Rh Typing Register.
2. Blood Collection Register.
3. Preparation of stock of Various Components Register.
4. Issue Register for various components supplied.
5. Screening tests of Blood donors for TTD Register.
6. Compatibility Register.
7. Stock Register for all Materials purchased, stocked and issued.
8. Transfusion Requests received from Clinicians - File
9. Inspection Record Register for all Instruments.
10. Register for Error Detection and Rectification.
11. Register on the Details of the Blood Donation camps held.

Laboratory Record Documentation and Maintenance

Blood transfusion service should develop and maintain documents that demonstrate the achievement of specified quality standards. Documentation provides' ability to trace prospectively and retrospectively all the steps in all procedures which are necessary far monitoring the techniques, component preparation, laboratory testing, etc.

Quality Monitoring

A regular quality monitoring is essential to ensure that a full quality assurance system has been implemented and is effective. The purpose of a quality monitoring is to check the integrity of the QA programme. For example, during screening for viral markers, data other than just the final screening results must be recorded:

1. Temperature monitoring record for the laboratory equipments i.e. incubator, refrigerators used for storing kits, reagents, water baths, etc.,
2. Records of maintenance of equipment e.g. centrifuges, incubators, refrigerators, ELISA reader, etc.
3. The results obtained should be reviewed in light of the test run validity and the control values.
4. Records of disposal of any positive donation.

If during quality monitoring, problems are identified they must be resolved as soon as possible. A follow-up audit is required later to ensure that changes have actually been incorporated.

A sequence of events can be followed from collection of a unit, passing through all the processes till it is issued, by checking all the necessary documentation.

Quality monitoring

- Monitoring of the results obtained
- Monitoring of the control values
- Monitoring of operation of the equipment
- Routine monitoring
- Calibrations (incubator, pipettes, etc.)

Adverse donor reactions

Adverse reactions due to donation of blood are rare but sometimes the donor may develop reactions during or after donation of blood. Each transfusion centre must have medical and paramedical staff trained to handle and manage adverse reactions.

Recruiting Safe Donors

All efforts must be made to motivate voluntary donors to become regular donors.

Donor Identification/Registration

It should be possible to trace every unit of blood donated by the donor. The following information pertaining to each donor must be recorded.

1. Date of donation
2. Name, age (date of birth) and sex of donor
3. Father's and mother's name including national ID number
4. Address and telephone no - office -residence
5. Blood group, if known
6. Type of donor, voluntary, replacement, professional or autologous.
7. Date of last donation
8. Donor adverse reaction, if any during last donation
9. Previous rejection from donation and its reason
10. Consent in writing

Criteria for Donor Selection

Stringent and critical donor selection is a very important approach for the ultimate objective of blood safety. Recruitment of healthy blood donors is important both for the safety of donor and the recipient.

The suitability of a donor for blood donation is determined by medical history, physical examination and few preliminary laboratory tests. These guidelines ensure that the donor is in good health and protects the recipient from any ill effects of disease transmission.

Medical History

A brief medical history should be recorded for all prospective donors. The donor must be explained the need to give accurate information about his health status and any medication or drugs that he may be taking. Donor must be assured that confidentiality will be maintained under all circumstances. A medical officer/trained nurse should take the history.

It is preferable to record the medical history on the day of donation. Each time a donor comes to donate blood a standard history questionnaire should be filled. This ensures a systematic collection of the information. It also provides a permanent record of the health status of the donor. In donors who donate blood regularly it provides base line data regarding their health.

All donors must be treated courteously and any doubts/apprehensions must be cleared. This will encourage them to become regular donors. Careful donor selection plays a major role in determining donor and recipient safety.

Physical Assessment of Donors

A brief clinical examination of the blood donor should be done by a medical officer to ascertain his fitness to donate blood.

1. **General appearance**: Only persons in good health should be accepted as donors.
2. **Age:** Donors should be between the ages of 18-60 years.
3. **Haemoglobln :** The haemoglobin should be > 11 gm/dl in both males and females.
4. **Haematocrlt :** The haematocrit should be > 38%
5. **Weight of donors:** Donors weighing 45 kg.
6. **Blood pressure**: The systolic blood pressure should be between 100-180 mm Hg and the diastolic pressure between 60-100 mm Hg.
7. **Oral temperature**: This must not exceed 99°F. This is important to rule out a low grade fever which may be the presenting feature of several infectious diseases.
8. **Pulse:** Pulse should be between 60-100 beats per minute, good volume and regular.
9. **Skin:** The skin at the venepuncture site must be clear. Check for multiple needle marks to rule out an intravenous drug addict or a professional blood donor.
10. **Lymph nodes:** A through examination should be done to detect presence of lymphadenopathy. This may be indicative of any underlying infection/malignancy.
11. **Systemic examination:** The cardiovascular system, the respiratory system and the abdominal examination should be within normal limits.

The donor must have had light meals before donation and adequate hydration helps in smooth collection of blood and plasma. The record of physical examination and medical history must be signed by the medical officer. If the donor is deferred / rejected the reason must also be recorded.

The donor selection programme must be monitored continuously to ensure that it is working smoothly. This will help in achieving a safe and adequate blood supply in your transfusion centre.

Donor Records

Complete information about the donor should be recorded, sufficient enough for calling back a donor and tracing of any donated blood unit. The following records should be maintained by each transfusion centre.

- Donor records
- Medical history and examination record
- Donor deferral record
- Donor adverse reaction record
- Donor blood collection record
- Donor laboratory test-serology & markers of infection record.
- Quality control records of donor selection and blood collection
- Regular and rare donor panel record
- The records should be maintained for a period of 5 years.

Documentation & Record Maintenance

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.

An effective record system helps to judge the performance of the blood transfusion service traces any donated unit of blood from its source to the final fate and also helps in legal or investigational purposes. Various aspects which need proper documentation are:

1. Donor records including details of donor information, rare donor panels, donor deferrals and adverse donor reactions.
2. Record of results and interpretation of all laboratory tests.
3. Patient's record (for all patients and specifically important in patients with multiple transfusions, previous transfusion reactions, presence of unexpected antibodies or cross-match problems).
4. Record of component preparation.
5. Inventory of blood, blood components, reagents and consumables, etc.

6. Record of compatibility testing.
7. Record of discarded blood units.
8. Record of issue of blood.
9. Quality control record (which helps in taking corrective actions to improve the performance of any procedure or working of any equipment and reagents).

Record and documents also help to identify possible sources of error in any technique.

The results of manually performed tests should be recorded carefully in a clean and easily understandable way i.e. as the laboratory worksheet. Laboratory worksheets should be preserved as permanent record of the test performed and the readings obtained. Records of the reagents and kits used for a particular test with their batch no., lot no. and expiry dates should be maintained so that in case of any problem, it is easier to find the source of error. All records must include the date and signature of the laboratory staff performing the test. Records should be retained for at least 5 years and kept confidential.

Computers are being widely employed in maintaining the records. With the growing demand for improving the efficiency, accuracy and effectiveness it has become imperative to introduce computers in the blood transfusion service.

Computers can help the functions of a blood transfusion service in-

- Donor identification / registration
- Donor blood collection
- Processing of blood
- Maintenance of records of laboratory testing
- Inventory management
- Issue & labeling of blood

Donor Recruitment and Motivation Program

Hospital-based blood transfusion services may either initiate their own donor recruitment drive. The coordination may be in terms of sending a team of medical officer, laboratory technologist and donor attendant for

outdoor mobile blood donation camps to participate in collection of blood organized by voluntary agencies. This program required to develop a voluntary donor base in the regional community by donor appeals, community or personal-based approach. It is of utmost importance to retain the motivated and once recruited blood donors. Success of any donor recruitment program can be assessed by the number of regular donors donating blood. Repeated donor appeals before conducting an outdoor voluntary donation camp help in effective donor motivation and recruitment. Donor's recruiters or trained social workers can play a significant role in developing voluntary donor registry, encouraging healthy family members to become voluntary donors and allaying apprehensions of prospective donors. Very strict environmental cleanliness, donor screening and procedure of blood collection should be maintained while conducting outdoor voluntary donation camps.

Laboratory Techniques

Serology techniques

The laboratory has multifold activities

- Processing of donor blood
- Pretransfusion testing of recipient
- Preparation of components
- Quality control procedures
- Histo-compatibility testing (optional)

All laboratory samples must be preserved for at least 7 days after the test. Any transfusion reactions reported to the blood transfusion service must be properly worked-up with tailed repeat laboratory testing on donated unit and recipient's samples (pre-and post-transfusion). A complete record of the type of transfusion reaction and results of the investigation must be kept. Adequate controls must be set up with each technique to avoid false reactions.

Screening for transfusion transmitted diseases

It is mandatory in Bangladesh, to screen all donated blood units far Hepatitis B viral infection (HBsAg), HIV infection (anti-HIV-1 and anti-HIV-2), syphilis (anti-treponemal antibodies by VDRL/TPHA test) and malaria (peripheral blood smear examination), and HCV. To achieve the goal of transfusion safety and prevent transfusion - transmitted infections it is imperative to use highly sensitive and specific test assay systems to detect weak reactions. The test assay system or test kits should be revalidated. Procedures should be strictly adhered to and appropriate test and internal control (positive and negative) must be put with each batch of test. A test run validity and proper calculations are also important to avoid any false-negative or positive results. The donated units with a positive marker of infection must be isolated soon after completion of the test and discarded after proper disinfection or incinerated if facility is available. A continuous supply of validated test kits is essential for successful screening of all donated units. Adequate storage of kits at recommended temperature must be maintained for proper functioning of the test kits and reagents.

Preservation, Storage & Transportation of blood

Introduction

The primary objective of preservation, storage and transportation of blood and blood components is to preserve the viability and function of each relevant constituent, prevent any physical changes of the blood constituent during storage and minimize bacterial growth.

Various anticoagulant-preservative mixtures have been formulated with the ultimate goal of preventing clotting and to provide proper nutrition for cell metabolism during storage. This ensures that blood and blood components are kept therapeutically viable for a stipulated time.

Aim

Aim of this section is to acquaint the medical officers with the various anticoagulants available for preservation of blood and blood components, their mechanism of action and stipulated shelf life for the constituent. In addition, to emphasize the role of adequate ‘and proper storage and transportation of blood to maintain the therapeutic effectiveness of the blood components till the time it is transfused to the recipient.

Processing of donor blood

The processing of blood is based on the way the bag is going to be handled. If the blood unit has to be processed for platelet preparation, store it in a 22°C incubator or in an air-conditioned room till processed. The separation into components should be done within 6 hours of blood collection. However, if the blood unit has to be processed for red cell concentrate, fresh frozen plasma or to be stored as whole blood, store at 4°C for 6 hours till processed.

The following tests are done on the blood samples collected in the pilot tubes.

1. **Serology testing**
    a. ABO grouping: A technique using both cell and serum grouping should be employed.

b. Rh (D) grouping: The Rh (D) group is determined using anti-D reagent preferably from two different (mono & poly).

c. Donor blood may be tested for unexpected antibodies by saline, enzyme and antiglobulin techniques using a panel of red cells.

After the ABO & Rh (D) groping of the donor pilot sample, the blood group must be mentioned as the blood unit label clearly and boldly.

2. Screening for transfusion transmitted diseases

a. Hepatitis B surface antigen (HBsAg): All units of blood must be screened for HBsAg prior to issue. The unit is issued only if found non-reactive. Testing is done usually by ELISA or RPHA techniques.

b. Human Immunodeficiency Virus (HIV) infection: It is essential to screen all units of blood for antibodies to HIV-l+2 by ELISA technique or rapid tests available.

c. Syphilis: It is mandatory to screen all blood units for serologic test of syphilis by TPHA/VDRL technique.

d. Malaria: A stained peripheral smear may be examined for presence of malarial parasites.

e. HCV – Anti HCV (Rapid of ELISA).

The label on blood bag should contain following information:

1. Blood unit number
2. Date of collection
3. Date of expiry
4. ABO & Rh(D) blood group
5. Tested negative for HBsAg, syphilis and HIV 1+2 along with the date of testing for these markets.

3. Component preparation:

The collected blood unit must be processed immediately or within 6 hours of collection. All components made from a blood unit must carry all the information as on the primary blood bag.

Quality Control of Blood Storage

All efforts must be made to store and transport blood, blood components and plasma in as safe a way as possible. Important element of maintenance of temperature is:

1) Equipment to store and transport
2) Organization of staff responsible for maintenance of safe temperature controlled storage.

In some of the hospitals, operation theatre maintains a separate storage space for blood and blood components. The staff of blood transfusion centre should maintain the storage conditions in distant storage places also.

Temperature monitoring

In all blood storage equipment, regular monitoring of temperature using good thermometers is essential. A daily temperature recording chart may be affixed on the front door of the refrigerator and an 8 - hourly temperature recording should be done by responsible laboratory staff member. Maximum and minimum thermometers can also be used to detect how low or high the temperature had been. The temperature should be recorded in different shelves on different occasions to check for uniformity of temperature.

If blood has to be stored in domestic refrigerator it should never be kept close to the freezer compartment or in the door of the refrigerator due to wide variation in temperature in these parts of the refrigerator. The temperature recording is a must in a domestic refrigerator whether storing blood units or reagents and test kits. If wide variation in temperature is noted, the temperature may be adjusted using the adjustment knob and storage may be done according to the temperatures in different shelves of the refrigerator.

The outdated blood bags may be sent for bacterial culture, which can also act as a quality control for sterility of blood collection and storage condition.

Table 1. Storage and transport conditions for whole blood and red cells

Condition	Temperature range	Storage time
Transport of pre-processed blood	+20 °C to +24 °C	Less than 6 hours
Storage of pre-processed or processed blood	+2 °C to +6 °C	According to anticoagulant used
Transport of processed blood	+2 °C to +10 °C	Less than 24 hours

Table 2. Permitted storage time according to temperature used to store fresh frozen plasma and cryoprecipitate

FFP	Storage temperature	Maximum storage time
FFP or Cryoprecipitate	–65 °C or below	7 years
FFP or Cryoprecipitate	–40 °C to –64 °C	24 months
FFP or Cryoprecipitate	–30 °C to –39 °C	12 months
FFP or Cryoprecipitate	–25 °C to –29 °C	6 months
FFP or Cryoprecipitate	–20 °C to –24 °C	3 months

Table 3. Length of time permitted for the storage and transportation of platelet Concentrates within the temperature range +20 °C to +24 °C

Process	Maximum Storage Time
Storage	5 days
Transport	24 hours
After issue, before transfusion	30 minutes
Open system and/or pooled	04 hours

Summary

- Whole blood and packed red cells must always be stored at +2 °C to +6 °C and transported between +2 °C and +10 °C.
- Blood components and plasma derivatives should never be stored in unmonitored equipment.
- Red cells, platelets or whole blood must never be allowed to freeze.
- The optimal storage temperature for conditions for fresh frozen plasma and cryoprecipitate is <30°C, and they must always be frozen solid.

STORAGE AND TRANSPORTATION OF BLOOD AND BLOOD COMPONENTS MAINTENANCE AND USE OF BLOOD COLD CHAIN EQUIPMENT

They can be stored at lower temperatures, but must never be warmer than –20 °C.

- Platelets must be stored at +20 °C to +24 °C with constant agitation and transported at temperatures within this range.
- During transportation, frozen components must be maintained at a temperature that ensures they will remain frozen.
- It is important to use a temperature monitor during transportation in order to check temperature ranges on receipt of the shipment.
- To assist the maintenance of temperatures for blood components, it is often useful for hospital wards to possess a refrigerator for short-term storage of issued blood from the blood bank.

The key elements of the Guidelines for Clinical Use of Blood

(According to WHO)

The key elements of the Guidelines for Clinical Use of Blood are -

- Guidelines for the clinicians to support urgent decision-making on whether or not to transfuse a patient should be practical, comprehensive and relevant to local circumstances.
- Standard blood request form. Ideally it should be developed by the blood transfusion service and reviewed by the National committee and be used throughout the country. The form will aid monitoring and evaluations of clinical use of blood and promote clinical transfusion practice.
- Indications for the use of blood/blood products and alternatives to blood transfusion.
- Information should cover indications, dosage, and contraindications for blood and blood products and replacement fluids.
- Blood ordering schedules. The blood ordering schedule should reflect the clinical team's usage of blood for common procedures. It should give guidance to screen and group policy. A blood-ordering schedule saves time and expense by making it easier to analyze usage of blood.
- Standard operating procedures for:

  – ordering blood for routine and emergency procedures

  – issue of blood and blood products

  – transportation, storage and administration of blood

  – recording of all transfusions in patient records

  – monitoring patient before, during and after the transfusion

  – management, investigation and recording of transfusion reactions.
- Indications for transfusion. Indications should include both the clinical and laboratory indications.

The appropriate clinical use of blood must take into consideration the following points.

- Transfusion is only one element of management.
- Prescribing decisions should be based on guidelines and the condition of the patient.
- Blood loss should be minimized.
- Effective resuscitation by IV fluids/oxygen should be used while assessing the need for blood in acute blood loss.
- The decision to transfuse is based on clinical condition and laboratory results.
- Awareness on the local risks of transfusion and weighing up the risk/benefit ratio.
- Recording the reasons for transfusion.
- A trained person should be available to monitor the blood transfusion.

CHECKLIST
FOR
PERFORMANCE MONITORING
AND QUALITY ASSURANCE
OF
SAFE BLOOD TRANSFUSION

Checklist for reviewing Quality system

Sl no	Quality system area	Yes	No
1.	Is the organizational structure within your institution defined and documented?		
2.	Are job descriptions written for all category of staff		
3.	Is there a system for assessing the training needs of the staff: e.g. at appraisal?		
4.	Is there a staff training policy?		
5.	Is competency assessment undertaken for all laboratory staff?		
6.	Are written standard operating procedures in place?		
7.	Is there a system for equipment validation and calibration?		
8.	Is there a record of equipment maintenance and repair?		
9.	Is there a system for the evaluation of test kits and reagents?		
10.	Are all reagents used according to the manufacturers' instructions?		
11.	Are all reagents validated in-house?		
12.	Are all reagents used within their expiry date?		
13.	Is there a maximum blood ordering schedule in operation for surgical and medical cases?		
14.	Is there a mechanism for reporting and investigating errors?		

Person responsible for filling check list: The checklist will be filled up by the In-charge of blood bank or any doctor assigned by In-charge and cross checking will be done by institutional head on the filled up checklist

Frequency of filling checklist: The total number of checklist will be once in a month.

Checklist on Quality Control System

Activities to maintain Quality	Done properly	Not done properly	Not done at all	Reason
Identification of blood sample with documentation				
Recording of Blood sample collection with date				
Recording of blood sample exam with date				
Recording of reagent in respect of product no, batch no, and date of expiry				
Recording of supervision with date				
Temperature monitoring of incubator , water bath and refrigerator				
Safe disposal of infected blood with recording – as well as other waste.				
Proper exam of the used calibration				

Person responsible for filling check list: The checklist will be filled up by the In-charge of blood bank or any doctor assigned by In-charge and cross checking will be done by institutional head on the filled up checklist.

Frequency of filling checklist: The total number of checklist will be once in every 15 days interval.

Checklist for monitoring basic facilities

Sl no	Facility	Status		Remarks
		Yes	No	
1.	Separate reception room			
2.	Separate blood collection room with air conditioning system.			
3.	Separate office room			
4.	Donor Selection Room			
5.	Donor Counseling Room			
6.	Duty doctors Room			
7.	Expert Room			
8.	Medical Technologist Room			
9.	Day Care Service Room			
10.	Lab facility for examination with preservation of blood bag			
11.	Donor waiting room with sitting arrangement			
12.	Proper ventilation			
13.	Proper light			
14.	Air condition of the lab.			
15.	Water supply with wash basin			
16.	Patient toilet			
17.	Safe water for client			
18.	Privacy for female client			

Person responsible for filling check list: The checklist will be filled up by the In-charge of blood bank or any doctor assigned by In-charge and cross checking will be done by institutional head on the filled up checklist.

Frequency of filling checklist: The total number of checklist will be once in a month.

Checklist for checking use of the different checklist to assess laboratory performance on Blood transfusion

Sl. No.	checklist name	Use of Checklists		Status		Accuracy			Remarks
		Yes	No	Complete	Partial	Good	Average	Poor	
01	ABO grouping checklist								
02	Rhesus “D”typing								
03	Cross match								
04	Agglutination								
05	Haemolysis								
06	Signs of deterioration of blood or plasma								
07	Issue of blood or plasma								
08	Giving blood or plasma to a patient								
09	Daily Qc of reagents								
10	Safety in the laboratory								
11	ELISA test								
12	Lab. Equipment								
13.	Screening								
14.	Other Serological Tests								

Person responsible for filling check list: The checklist will be filled up by the In-charge of blood bank or any doctor assigned by In-charge and cross checking will be done by institutional head on the filled up checklist.

Frequency of filling checklist: The total number of checklist will be once in a month.

Sampling checklist for ensuring ideal donor screening

Sl no	Donor selection criteria	Screening practice		Remarks
		Yes	No	
1.	Whether using prescribed donor selection norms.			
2.	The donor shall be in the age group of 18 to 60 years			
3.	The donor shall not be less than 45 kilograms			
4.	Temperature and pulse of the donor shall be normal			
5.	The systolic and diastolic blood pressures are within normal limits without medication			
6.	Haemoglobin shall not be less than 12.5 g/dL			
7.	The donor shall be free from acute respiratory diseases			
8.	The donor shall be free from skin diseases			
9.	The donor shall be free from any disease transmissible by blood transfusion, in so far as can be determined by history and examination			
10.	Defer the donor permanently if suffering from any of the listed diseases			
11.	Temporary deferral for specific diseases			
12.	Private interview for excluding sexual disease			
13.	Taking of informed consent from the client			
14.	Proper documentation in relation to donor screening			

Person responsible for filling check list: The checklist will be filled up by the in charge of blood bank as a sampling basis and cross checking will be done by institutional head on the filled up checklist

Frequency of filling checklist: The total number of sampling checklist will be one in a week.

Checklist for checking records on Blood transfusion activities

Sl. No.	Name of the register /document	Register /Document maintained		Status of record keeping		Accuracy			Remarks
		Yes	No	Complete	Partial	Good	Average	Poor	
01.	Patient register								
02.	Patient grouping register								
03.	Donor grouping register								
04.	screening register								
05.	cross matching register								
06.	Blood supply register								
07.	Blood stock register								
08.	Monthly performance report								
09.	Blood requisition form								
10.	Medical assessment of blood donor form								
11.	Cross match report form								
12.	Request for investigation								
13.	Serological report form								
14.	Donor Deferral register								
15.	Blood Discard Register								
16.	Component preparation register								
17.	Component stock register								
18.	Monthly screening report form								
19.	Monthly component report form								
20.	Special serological investigation register								

Person responsible for filling check list: The checklist will be filled up by the In-charge of blood bank or any doctor assigned by In-charge and cross checking will be done by institutional head on the filled up checklist.

Frequency of filling checklist: The total number of checklist will be twice in a month (15day interval).

Checklist for checking donor records

Sl. No.	Name of the document/area	Document maintained		Status of record keeping		Accuracy			Remarks
		Yes	No	Complete	Partial	Good	Average	Poor	
01	Pre donation history								
02	Physical examination result								
03	Informed consent								
04	Interpretation of infectious disease marker								
05	Confirmatory testing result								
06	Notification of donors who are permanently deferred (Confidentiality should be maintained)								
07	Temporary and permanent donor deferral list with reason								

Person responsible for filling check list: The checklist will be filled up by the In-charge of blood bank or any doctor assigned by In-charge and cross checking will be done by institutional head on the filled up checklist.

Frequency of filling checklist: The total number of checklist will be once in a month.

Safety measure maintenance checklist in the blood transfusion unit

Name of the activities	Done properly	Not done properly	Not done at all	Remarks
a. Wearing apron, Cap & Mask				
b. Use of gloves				
c. Needle recapping				
d. Daily cleaning with disinfectant of lab and equipment				
e. Hand washing				
f. Visitor control				
g. Restriction of food, smoking etc. in lab				
h. Disposal of lab waste				
i) General waste				
ii) Sharp waste				
iii) Infected clinical waste				
iv) Liquid waste				

Person responsible for filling check list: The checklist will be filled up by the In-charge of blood bank or any doctor assigned by In-charge and cross checking will be done by institutional head on the filled up checklist.

Frequency of filling checklist: The total number of checklist will be once in a month.

Performance monitoring of blood bank service delivery

Category of test	Available		Target (Monthly)	Achievement			
	Yes	No		1st Qtr.	2nd Qtr.	3rd Qtr.	4th Qtr.
ABO grouping and Rh typing							
Cross Matching							
Direct Coombs test							
Indirect Coombs' test							
Antibody detection							
Antibody titre							
Rhesus factor C/c/ D / E/ e							
Rhesus Genotype and phenotype							
Haemolysin test							
ABH Secretor Status							
VDRL / RPR (Screening)							
HBs Ag (Screening)							
HCV(Screening)							
HIV(Screening)							
Malaria(Screening)							

Person responsible for filling check list: The checklist will be filled up by the MT(Lab) of blood bank on quarterly basis (Jan to March-1st quarter, April to June-2nd quarter, July to Sept.-3rd quarter , Oct. to December-4th quarter) and performance need to evaluate on quarterly basis by the blood bank committee

Frequency of filling checklist: Quarterly once.

* The target of individual category of test should be fixed up by the local authority on the basis of previous performance and also service growth.

Monitoring of Procedural practice

Name of the test/ Screening activities	Done properly	Not done properly	Not available	Remarks
Preparation of normal saline				
Collection of blood sample				
Cell washing and preparation of cell suspension.				
Haemoglobin Estimation				
ABO grouping				
Rhesus typing				
Cross match				
Emergency cross match				
Coombs test				
Preparation of the red cell concentrate and other components				
HIV screening				
HBV				
HCV				
Syphilis				
Malaria				

Person responsible for filling check list: The checklist will be filled up by the In-charge of blood bank or any doctor assigned by In-charge and cross checking will be done by institutional head on the filled up checklist.

Frequency of filling checklist: The total number of checklist will be once in a week.

Monitoring of Blood grouping and screening reagent utilization

Sl no	Name of the reagent	Utilization of reagent against performance							
		1st Qtr.		2nd Qtr.		3rd Qtr.		4th Qtr.	
		Quantity utilized	# of test done	Quantity utilized	# of test done	Quantity utilized	# of test done	Quantity utilized	# of test done
1.	HBsAg								
2	HIV								
3	HCV								
4	VDRL/RPR								
5	M.P.								
6	Anti-A								
7	Anti-B								
8	Anti- D								
9	Anti-AB								
10	Anti-Ai								
11	Anti-H								
12	AHG (Anti human globulin)								
13	22% Bovine Albumin								
14	Enzyme								
15	Anti C, $\overline{c}$, E, $\overline{e}$								

Person responsible for filling check list: The checklist will be filled up by the MT(Lab) of blood bank on quarterly basis (Jan to March-1st quarter, April to June-2nd quarter, July to Sept.-3rd quarter , Oct. to December-4th quarter) and performance need to evaluate on quarterly basis by the blood bank committee.

Frequency of filling checklist: Quarterly once

Monitoring of Blood Transfusion management activities

Activities	Done properly	Not done properly	Not done at all	Reason for not done properly/Not at all
a) Blood donor selection				
• Visual assessment				
• History taking				
• Medical examination				
Lab examination				
b) Preservation of blood bag				
• Daily Stock-ledger verification				
• Blood bag preservation				
• Monitoring of temperature				
• Cold chain for blood bag				

Person responsible for filling check list: The checklist will be filled up by the In-charge of blood bank or any doctor assigned by In-charge and cross checking will be done by institutional head on the filled up checklist.

Frequency of filling checklist: The total number of checklist will be once in a week.

Monitoring of procurement plan

Sl no	Name of the reagent / material	Monitoring of logistics against developed plan							
		IstQR		2ndQR		3rdQR		4thQR	
		Quantity planned	Procured quantity	Quantity planned	Procured quantity	Quantity planned	Procured quantity	Quantity planned	Procured quantity

Person responsible for filling check list: The checklist will be filled up by the MT(Lab) of blood bank on quarterly basis (Jan to March-1st quarter, April to June-2nd quarter, July to Sept.-3rd quarter , Oct. to December-4th quarter) and performance need to evaluate on quarterly basis by the blood bank committee.

Frequency of filling checklist: Quarterly once

Monitoring of the Status of the supplied major equipment and instrument:

Name of the equipment and logistic	Available			Not available
	Number	Service-able	Non-serviceable	
Bench top centrifuge				
Refrigerator for storing reagent, ABO cell and sample				
Blood banking refrigerator $+2^0C$ - $+6^0C$				
Ultra Deep Freezer -20^0C - -80^0C				
Refrigerated Centrifuge Machine				
Cell Separator				
Haematology Auto-Analyzer for donor selection and quality assurance				
Blood Collection equipment / Bio-mixer				
Blood Sealer				
Plasma Expresser				
Plasma Throwing machine				
Platelet Agitator and Incubator				
Deep freezer for storing serum sample				
Water bath at 37 degree centigrade on incubator				
Thermometer				
Pasteur pipette (Different size)				
Micropipette (Different size)				
Glass tube for indirect anti-globulin test (75x12 mm) - (Different size)				
Waterproof marker for glass and plastic tube				
Hand Lens				
Microscope				
Weight machine				

Name of the equipment and logistic	Available			Not available
	Number	Service-able	Non-serviceable	
Hot Air Oven				
Distilled Water Plant				
VDRL Shaker				
BP Machine				
ELISA				
Haemoglobin Skella/$CuSO_4$				
Blood Warmer				
Stethoscope				
Autoclave Machine				
Donor Coach / Bed				
Ambo Bag & Oxygen Cylinder				
Sterilizer				
Test Tube holder				
Cell Washer				
Generator and Air Cooler				
Hospital Bed				
Saline Stand				
Beaker & Petri-dish				
Micro-Typing				
Lucodeplated filter				

Person responsible for filling check list: The checklist will be filled up by the MT (Lab).

Frequency of filling checklist: The frequency will be once in a month

Checklist for installation of equipment

Sl no	Area	yes	No
01	Is the equipment placed so that it is never in direct sunlight or near other sources of heat?		
02	Is there good air circulation between the equipment and the walls and ceiling?		
03	Is the cabinet raised off the floor to protect it from damp and dirt		
04.	Is the voltage correct for the local power supply? How do you know?		
05	Is the supply cable plugged in?		
06	If there is an On/Off switch, is the refrigerator switched on?		
07	Are the materials used to clean suitable or not ?		
08	Has the alarm system been checked?		
09	Does the indicator light show that the equipment is connected to the power supply?		
10	Does the cabinet door or lid seal properly? How has this been checked?		
11	Does the temperature record for the refrigerator cabinet indicate a temperature of more than +2 °C and less than +6 °C?		

Person responsible for filling check list: The checklist will be filled up by the MT (Lab) and cross checked by the In-charge blood bank

Frequency of filling checklist: The frequency will be once in a month

Comprehensive performance monitoring checklist for a Blood bank

Sl. No	Description	Yes	No	N/A
1.	***PROFICIENCY TESTING*** Are records of all proficiency testing results, including interpretations, maintained?			
2.	Is proficiency testing results periodically reviewed and evaluated by the blood transfusion medicine authority?			
3.	***PERSONNEL/ TRAINING*** Is the blood bank authority responsible and have authority blood bank SOPs?			
4.	Does the authority delegate responsibilities for administering the blood bank to a properly qualified and trained designee and are the designee's duties outlined in the SOPs?			
5.	Does the blood bank have one or more qualified supervisors who supervise all blood banking functions			
6.	Does the blood Transfusion medicine authority have a responsible individual on the premises who is qualified to provide emergency care during the collection or transfusion of blood			
7.	Does the blood bank have an adequate number of personnel?			
8.	Are personnel associated with donor or transfusion related functions suitably trained through a documented formal training program and supervised in the performance of their prescribed tasks?			
9.	Are personnel's job descriptions current and are job qualifications defined for each job position/title?			
10.	Does the blood Transfusion medicine authority have a process for identifying and monitoring the training needs of personnel who are performing activities which affect the quality of blood and blood components?			
11.	Does the blood Transfusion medicine authority evaluate the competency of personnel at specified intervals? Is there a process for initial and ongoing competence assessment of personnel?			

Sl. No	Description	Yes	No	N/A
12.	***FACILITIES, EQUIPMENT AND CONTAMINATED MATERIAL*** Does the blood Transfusion medicine authority have adequate environment, and equipment to maintain safe and acceptable standards for handling of human blood and blood components?			
13.	Does the blood transfusion medicine authority uniquely identify all equipment +critical to the provision of blood and blood components? Is there a schedule for monitoring and maintaining the equipment			
14.	Does the blood transfusion medicine have quality control and quality assurance programs to ensure blood and blood components, reagents and equipment perform as expected?			
15.	Do the SOP manuals contain all policies and procedures developed for use?			
16.	Is there evidence of validation of all methods used by the blood transfusion medicine authority?			
17.	Are new or changed SOPs validated before implementation?			
18.	Is there evidence of periodic evaluation of reagents and equipment including the date of performance?			
19.	Are QC results for reagents and equipment reviewed and documented?			
20.	Are equipment problems documented, investigated and resolved?			
21.	Does the blood transfusion medicine authority have a process for scheduled monitoring and preventive maintenance for equipment which includes: frequency of checks, check methods, acceptance criteria, and actions to be taken for unsatisfactory results?			
22.	Is there evidence of periodic evaluation to determine that policies and procedures are appropriate and are followed?			

Sl. No	Description	Yes	No	N/A
23.	Does the blood transfusion medicine authority use only current SOPs, forms and valid documents?			
24.	Is there evidence that the blood transfusion medicine authority supervisor perform a daily review of error correction records?			
25.	Is there evidence of adequate and timely corrective action for malfunctions, failures or adverse events?			
26.	Is there evidence of a QA & QC review by the supervisor or the director?			
27.	Are all materials, containers and reagents for collection, preservation, storage and testing of blood and components used in accordance with the manufacturer's written instructions and meet specified requirements?			
28.	Are significant changes to procedures reviewed, dated and signed by the Chairman / Head of Dept. blood transfusion medicine department?			
29.	When blood or blood components a re collected and/or prepared, does a key individual in the operation of the blood transfusion medicine authority conduct a documented review prior to the release and final labeling of blood and blood components to ensure that blood from unsuitable donors is not distributed for transfusion?			
30.	Are the sequence of the numbers of the blood and blood components drawn verified?			
31.	Are required tests performed correctly and properly interpreted			
32.	Are all blood and blood components from donations that have positive or questionable test results quarantined until their final disposition is determined?			
33.	Are final disposition/destruction records completed at the time of disposition/ destruction and are there documented reviews to verify that records accurately reflect that disposition/destruction?			
34.	Does the blood transfusion medicine authority have a policy which addresses the confidentiality of donor and recipient records?			

Sl. No	Description	Yes	No	N/A
35.	Are corrections to errors made in this manner: 1. Not conceal the original entry; 2. Document the reason for the correction; and 3. Include the date the change was made and the initials of the person making the change?			
36.	Does the blood transfusion medicine authority validation include review of confidentiality of donor information, security of data and system documentation?			
37.	Are records maintained in the computer in compliance with all requirements?			
38.	Do records include all data secured and developed by blood transfusion medicine authority concerning donor and/or recipient testing, donor identification, medical qualifications, registration as well as the processing, storage, distribution and final disposition of blood and blood components?			
39.	Do records make it possible to trace a unit of blood or component by a sequential numeric or alphanumeric identifier from source to final disposition?			
40.	Are records readily available for review?			
41.	Are actual results of each test observed recorded immediately and is the final interpretation recorded upon completion of testing?			
42.	Do records include all the significant steps of the process and who performed them?			
43.	**Do donor records include at least the following:** **i.** An annual record of each unit of blood and blood component, listed by sequential numeric or alphanumeric identifier, as to its source bank and final disposition?			
	ii. Donor history, examination, consent, deferral, reactions and also the result of required laboratory tests performed on all blood donors?			
	iii. An annual alphabetical file of donor registration cards (manual or computerized) or a cross index system?			

Sl. No	Description	Yes	No	N/A
	iv. Storage temperatures of components, including dated and initialed temperature recording charts?			
	v Results of visual inspection of blood?			
	vi Results of blood processing, including test results and interpretation of all tests and retests?			
	vii. A system that relates a donor with each previous donation?			
44.	Do recipient records include at least the following: i. An alphabetical file of the recipient and all units administered?			
	ii. Transfusion request records?			
	iii. Test results, interpretations and release or issue date for compatibility testing?			
	iv. Transfusion adverse reaction & Its management			
45.	A data sheet for each cytapheresis procedure with records of: volume of blood processed; anticoagulants given; duration of procedure; volume of product; drugs given; identity of the donor; any reactions that occurred and how they were treated and any other information necessary to ensure the proper preparation of the component and the safety of the donor?			
46.	Quality control and quality assurance records, including, but not limited to: periodic evaluation of personnel, blood and blood components, reagents, equipment, including dates of performance; tests performed; observed results; interpretations; identification of personnel performing the tests; any appropriate corrective action taken; and review by the supervisor?			
47.	Reports of suspected adverse reactions to transfusions and laboratory investigations?			
48.	Are lot numbers of supplies and reagents documented?			
49.	Is there a method to identify persons performing each significant step in collecting, processing, compatibility testing and distributing blood or blood components?			

Sl. No	Description	Yes	No	N/A
50.	Is any hemolytic or delayed hemolytic and other known or suspected life-threatening transfusion reaction reported to the Department on required forms within 10 days of occurrence?			
51.	Is any known or suspected fatal transfusion reaction reported by telephone by the next working day and a written follow-up sent using the form provided by the Department within 10 days of occurrence? Is any known or presumed case of transfusion associated AIDS reported to the Department within 10 days on forms provided for this purpose?			
52.	Are errors that result in the wrong blood or blood component being transfused, regardless of harm to the recipient, reported on forms provided by the Department within 15 working days of the recognition of the error?			
53.	Are blood donors identified by an identification card or another form of authorized identification?			
54.	Is the type of identification used written on the donor registration card at the time of each blood donation?			
	MEDICAL HISTORY; PHYSICAL EXAMINATIONS, BLEEDING LIMITATIONS			
55.	Are procedures used for performing donor medical history, physical examinations?			
56.	Is the prospective donor's history evaluated on the day of the donation and the donor examined by trained and qualified blood transfusion medicine personnel?			
57.	Is donor consent obtained in writing and is the procedure adequately explained to the prospective donor and gives the donor an opportunity to ask questions and refuse consent?			
58.	Is the donor instructed in post phlebotomy care and cautioned as to possible adverse reactions?			
59.	Is the blood transfusion medicine authority responsible for notifying the donors of the cause of rejection?			

Sl. No	Description	Yes	No	N/A
60.	Is educational material given to the blood donors to allow donors to determine whether or not they have engaged in high risk behavior prior to the collection of blood?			
61.	Are blood and blood components that are positive to serologic tests for HIV or collected from a donor known to be HIV positive discarded? / And also inform to proper authority.			
62.	Does the blood transfusion medicine authority maintain records pertaining to all HIV requirements and test results in a confidential manner?			
63.	Does the procedure for the collection, processing, storage, and distribution of blood and blood components meet the requirements of standard?			
64.	Is the donor adequately prepared prior to phlebotomy to protect donor and recipient from infection?			
65.	Is all equipment used in the collection of blood, such as syringes, needles, lancets or other blood letting devices sterile and pyrogen free?			
66.	Are all personnel concerned with the collection of blood instructed in appropriate first aid procedures in the event of donor reaction?			
67.	Is the method employed for the removal of blood from the donor conforming to accepted standards of asepsis?			
68.	Are blood containers and donor sets sterile and pyrogen-free?			
69.	Are the anticoagulant solution and the blood thoroughly mixed during bleeding?			
70.	Does the blood transfusion centers and transfusion service have a system for detecting and evaluating suspected adverse reactions to transfusion?			
71.	Are suspected transfusion reactions evaluated promptly once physician determines them as possible transfusion reaction?			

Sl. No	Description	Yes	No	N/A
72.	**In the event of a suspected transfusion reaction, does the staff attending the patient** 1. Notify the blood bank and the responsible clinical practitioner immediately and document all instructions for the evaluation of the suspected reaction? 2. Note the reaction in the patient's medical record and on the blood transfusion documentation?			
73.	**If an acute hemolytic transfusion reaction is suspected, is the transfusion discontinued and does the blood bank staff:** 1. Check labels on the blood container and all other records associated with the transfusion to detect clerical errors in identification; 2. Retype the post transfusion reaction sample for ABO group and Rh typing and compare the results to the pretransfusion results; 3. Inspect the post reaction plasma or serum for evidence of hemolysis 4. Perform Direct Antiglobulin Test (DAT); 5. Notify the blood transfusion medicine authority immediately if discrepancies or adverse results are identified.			
74.	Does the blood transfusion medicine authority have a written procedure that specifies the additional tests that need to be performed when discrepancies or adverse results exist?			
75.	Does the blood transfusion medicine authority ensure that blood is not released for transfusion while the suspected transfusion reaction investigation is in progress unless documented approval is received from the blood bank authority?			
76.	Are required tests completed promptly?			
77.	Are the issue and administration of blood and blood components performed at the request of a clinical practitioner?			
78.	Before the blood container is released from the blood bank for transfusion, does it contain an attached label or tag to positively identify the unit with the intended recipient?			

Sl. No	Description	Yes	No	N/A
79.	Does the person receiving the blood present a written request with sufficient information for the positive identification of the recipient at the time the blood or blood component is released from the blood transfusion authority for transfusion?			
80.	Does the technologist who issues the blood perform an active identification check along with the person picking up the blood which includes the recipient's full name, as it appears on the identification band, traceable identification number, the type and quantity of component and the date of the transfusion? Do the blood transfusion department staff records the unit number and the type of component issued on the issue slip or claim form?			
81.	Is blood or blood components for transfusion prescribed by a clinical practitioner?			
82.	Is the procedure for warming of blood consistent with Standards?			
83.	Is the unit of blood or blood components not issued for transfusion purposes if the color or physical appearance is abnormal or if there is any indication or suspicion of Contamination?			
	TEMPERATURE MONITORING SYSTEM			
84.	Are blood samples retained and stored at +2 to +6 degree C for at least three days after transfusion?			
85.	Are there written procedures containing directions on how to maintain blood and blood components within permissible temperatures and instructions to be followed in the event of power failure or other disruption of refrigeration available?			
86.	Are refrigerators used for the storage of blood and blood components capable or maintaining the blood at a temperature between 2 to 6 degree Centigrade?			
87.	Does the equipment used to store blood and blood components have a system to record temperature continuously? In the event of equipment failure, are the storage temperatures recorded at least every four hours?			

Sl. No	Description	Yes	No	N/A
88.	Is the temperature recording device calibrated periodically, inspected at least daily and are written records of the temperatures kept on file?			
89.	Is there a written procedure posted prominently for staff to follow in case of electrical or equipment failure?			
90.	Are stored blood and/or blood components inspected daily and are records maintained during the entire period of storage and immediately prior to issue or use?			

The checklist can be used by the blood transfusion medicine authority or by the external party. The frequency of filling this checklist should be after 03 month interval.

SAFE BLOOD TRANSFUSION PROGRAMME

Questionnaire/check list for centre visit

Date of visit:

A. Manpower and Infrastructure:	
1. Name of the in-charge of the dept.: 2. Total no. of beds in the hospital: 3. How many sections in blood transfusion department?	
4. Total number of staff and their position? a) Experts: b) Medical officer: c) Medical Technologist: d) Nurses e) Number of Vacant post: f) Manpower requirement:	
5. No. of trained and untrained staff? a) Medical officer: b) Medical Technologist:	
6. Who is maintaining the logistics?	
7. Type of renovation work immediately needed? a) Laboratory: b) Donor Room: c) Reception / Enquiry :	

8. Equipment needs repair immediately? Mention the name:	
B. Functional Status of Equipments:	
1. Number of Blood Bank Refrigerator: a) Working condition: b) Out of order: c) Required:	
2. Refrigerator centrifuge machine: a) Working condition: b) Out of order: c) Required:	
3. A. Condition of ELISA Machine i) Working condition: ii) Out of order:	
B. Others equipment (Specify):	
4. Mention the types of equipment supplied recently from WHO? Enumerate the uses of the machine.	
C. Immuno Hematology / Serology:	
1. Do the centre have SOP for grouping, cross matching, Coombs' Test, Rh- Phnotyping and investigation of adverse Selection, donor selection with hematology, auto analyzer?	
2. Methods used for group: a) Serum grouping: b) Cell grouping:	

c) Cross matching done by: i) Saline agglutination method: ii) 37^0C incubation method: iii) Indirect coombs' test:	
3. Any quality control system for blood grouping, cross matching, ICT & DCT and others? a) ABO cell suspension prepared daily / or not : b) Reagents control checked daily / or not : c) Major and minor cross matching done / not: d) Any record keeping system available for grouping, cross-matching, ICT & DCT? e) Quality control of component preparation. f) Quality control of AHG technique.	
4. Service providing from this centre a) Routine ABO/RH blood grouping and cross matching b) Component preparation: c) Antibody detection / titration: d) DCT / ICT: e) Others (specify):	
D. Donor Selection:	
1. Donor selection criteria: are followed or not: a) Form (supplied from SBTP) used or not: b) Who assess the donor: c) Procedure of donor selection:	

2. What are the facilities for Donor available? a) Donor entertainment: b) Refreshment system for donors maintained or not : c) Donor care / counseling maintained or not?	
3. Donor card issued or not?	
4. Who does bleed the donor?	
E. Screening Section:	
1. Donor sample is tested for: a) HIV: b) HCV: c) HBV: d) MP e) Syphilis:	
2. Screening Test: a) Done by: b) Supervised by:	
3. Screening Test modality: a) Pre-donation screening, if 'Yes' Why? b) Post donation screening: c) SOP available or not?	
4. What is the method of screening test? a) Rapid Testing b) ELISA method c) Routine Testing – Rapid/ ELISA	

5. How quality control is maintained for – a) Storing of kits / reagents /sample – whether in freeze, in separate freezes.	
6. Who does monitor the temperature of the refrigerators?	
7. How monitored? a) 6 hourly / daily b) Temp. Chart is hanged : c) Temperature chart is inside-	
8. Do the lab personnel follow the standard safety precaution- a) Gloves b) Apron : c) Hand wash d) Sterilization during phlebotomy e) Any food in laboratory	
9. Blood Component practiced or not?	
10. What are the types of component supplied from the centers?	
11. Waste management system of this centre infected bag: a) Bags b) Reactive samples: c) Syringe/needle : d) Others (specify):	
12. Documents maintained: a) Donor/Patient's register: b) Screening register : c) Cross matching register: d) Blood supply register: e) Blood stock register: f) Blood discard register:	

g) Adverse Reaction register h) Blood return register:	
Information Collected by: *(Please put the reference of assignment)* Assisted by:	
Salient feature of the Centre: Signature:	

Reference:

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