

**MONITORING
OF
SAFE BLOOD TRANSFUSION ACTIVITIES**

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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 monitor safe blood transfusion activity for ensuring quality. The quality is an endless journey so we need to monitor 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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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

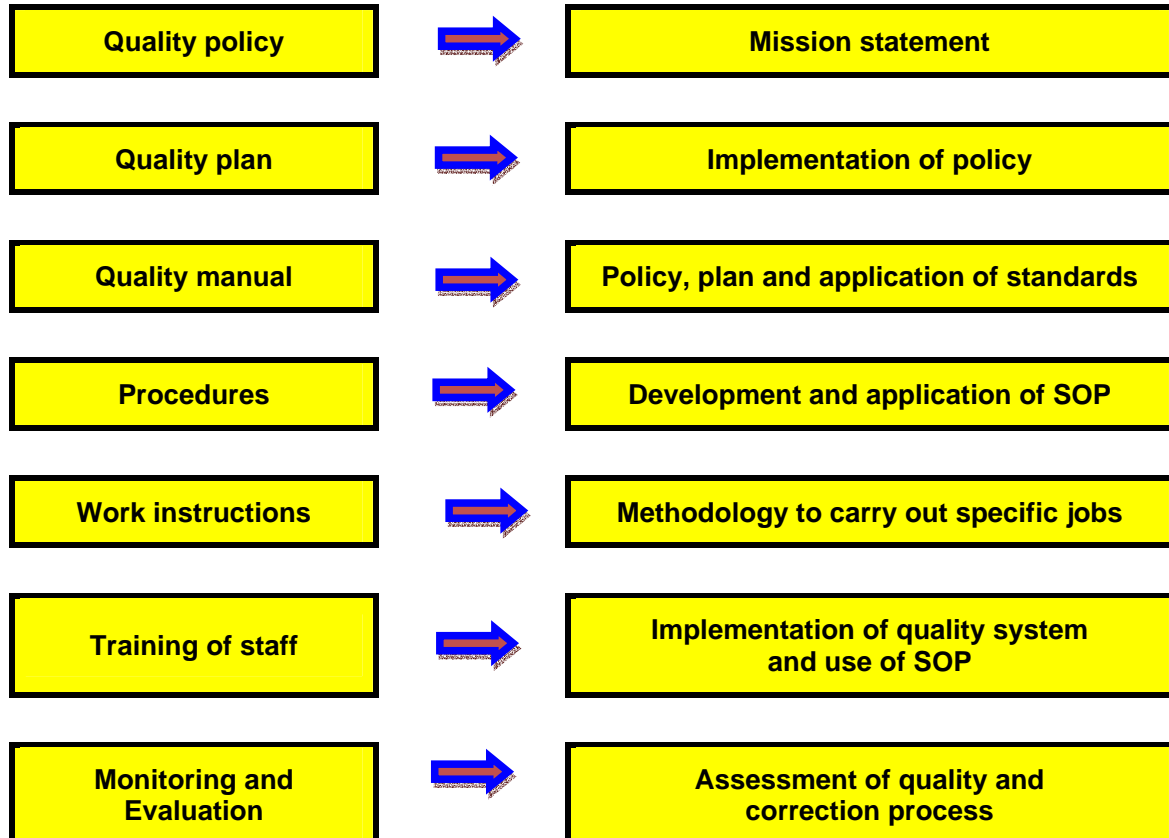
- The application of medical science and technology in a way that maximizes its benefits to health without correspondingly increasing its risks. The degree of quality is, therefore, the extent to which the care provided is expected to achieve the most favorable balance of risks and benefits.
- Proper 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:



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:	

<ul style="list-style-type: none"> a) Serum grouping: b) Cell grouping: c) Cross matching done by: <ul style="list-style-type: none"> i) Saline agglutination method: ii) 37°C incubation method: iii) Indirect coombs' test: 	
<p>3. Any quality control system for blood grouping, cross matching, ICT & DCT and others?</p> <ul style="list-style-type: none"> 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. 	
<p>4. Service providing from this centre</p> <ul style="list-style-type: none"> a) Routine ABO/RH blood grouping and cross matching b) Component preparation: c) Antibody detection / titration: d) DCT / ICT: e) Others (specify): 	
<p>D. Donor Selection:</p>	
<p>1. Donor selection criteria: are followed or not:</p> <ul style="list-style-type: none"> a) Form (supplied from SBTP) used or not: b) Who assess the donor: 	

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

<ul style="list-style-type: none"> b) ELISA method c) Routine Testing – Rapid/ELISA 	
<p>5. How quality control is maintained for –</p> <ul style="list-style-type: none"> a) Storing of kits / reagents /sample – whether in freeze, in separate freezes. 	
<p>6. Who does monitor the temperature of the refrigerators?</p>	
<p>7. How monitored?</p> <ul style="list-style-type: none"> a) 6 hourly / daily b) Temp. Chart is hanged : c) Temperature chart is inside- 	
<p>8. Do the lab personnel follow the standard safety precaution-</p> <ul style="list-style-type: none"> a) Gloves b) Apron : c) Hand wash d) Sterilization during phlebotomy e) Any food in laboratory 	
<p>9. Blood Component practiced or not?</p>	
<p>10. What are the types of component supplied from the centers?</p>	
<p>11. Waste management system of this centre infected bag:</p> <ul style="list-style-type: none"> a) Bags b) Reactive samples: c) Syringe/needle : d) Others (specify): 	
<p>12. Documents maintained:</p> <ul style="list-style-type: none"> 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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