**FOREWORD**

Donating blood is a very humane act. There is no doubt that safe blood transfusions save lives and unsafe blood transfusions may do more harm and can transmit many infections. In Maldives a large percentage of blood transfusions are for children and young adults with thalassaemia. To improve the quality, safety and efficiency of blood transfusion services a modern blood banking system is needed where the blood is donated to the blood bank, where infection screening is done and blood components separated and used according to WHO guidelines.

This policy was spearheaded by Ministry of Health with the objective of ensuring a safe, good quality supply of blood for those who need blood to save life. The success of this policy and strategies therein is dependent upon a large number of people from the community donating blood voluntarily and regularly; and health professionals and public recipients using available blood appropriately and rationally.

I endorse this policy and call upon the voluntary organizations and community’s active participation and ownership of this noble deed. At the same time I call upon health service providers to make appropriate use of this scarce resource and use it frugally. I look forward for development of strong partnerships in the process of implementation of this policy.

May 2007

Minister of Health
Ilyas Ibrahim
**NATIONAL BLOOD POLICY**

**Introduction**

A well organized blood transfusion service is a vital component of any health care delivery system. At present there is no national blood centre in the country. Establishment of a well organized nationally coordinated blood transfusion system is a prerequisite to ensure provision of adequate supply of safe and high quality blood and blood products which is accessible to all patients requiring transfusions. An integrated strategy for blood safety is required to minimize transfusion transmitted infection (TTI). The main components of an integrated strategy include collection of blood from voluntary non-remunerated blood donors, screening for TTI with WHO approved standard tests, and encourage appropriate clinical use of blood and blood products. This would ensure that the same standard of blood transfusion service is received by all patients. This need is great in this community since a large majority of the recipients of blood transfusions are Thalassaemia patients who require repeated and regular transfusions. The burden of finding blood donors when needed has solely been shouldered by the parents of the Thalassaemia patients till now. The current blood transfusion system in place does not allow timely transfusions in emergency situations and render inappropriate ordering of blood by clinicians. This latter factor is partly responsible for the high cross match to transfusion ratio seen in most of our hospitals.

With the present system of hospital based blood banks and mainly directed donations, implementation of a stringent quality assurance programme is difficult. Also it causes great difficulties for those patients requiring blood transfusions outside their place of residence. Thus a need for a change in the blood transfusion service has necessitated formulation of a national blood policy.
Policy Statement

The Government of the Maldives commits to ensure easily accessible and adequate supply of safe and quality blood and blood components collected from a voluntary non-remunerated regular blood donor in well equipped premises and is stored and transported under optimum conditions. Also supervision of blood collection, storage and transfusion under trained personnel through comprehensive, efficient and a quality management approach will be made certain under the policy.

Policy Objective

With the above broad goals in mind, the following objectives are drawn
1. To reiterate firmly the Government commitment to ensure availability of safe blood which is adequate and easily accessible to the population when and where it is needed.
2. To ensure availability of adequate resources for development and organization of the Blood transfusion Services in the country.
3. To make appropriate and updated technology available for operating the Blood transfusion Services.
4. To launch extensive awareness programmes for donor recruitment and retention
5. To promote appropriate and rational clinical use of blood and blood products.
6. To strengthen human resource development.
7. To take adequate regulatory and legislative steps for monitoring and evaluation of Blood transfusion Services and to take steps to eliminate profiteering in blood banks.
Objective 1. To reiterate firmly the Government commitment to ensure availability of safe blood which is adequate and easily accessible to the population when and where it is needed.

Strategies

1.1. The Ministry of health will formulate a National Council (National Blood Council) that is responsible for organizing National Blood Transfusion Services (NBTS) which in turn will organize Regional Blood Transfusion Services (RBTS) where needed. The National Blood Council should be responsible for formulating rules, regulations and standard practice guidelines for donor recruitment, collection, storage and transfusion of blood and blood products in a timely efficient and effective manner.

1.2 A streamlined mechanism for coordination between NBTS and RBTS should be developed by NBTS.

1.3 The development and implementation of a national strategy for the screening of all donated blood for transfusion-transmissible infections as per standard WHO guidelines. It should include usage of the most appropriate and effective assays to test for HIV, hepatitis viruses, syphilis and in relevant cases other infectious agents, such as Malaria.

1.4 The procurement of the necessary and appropriate equipment for blood collection, testing, storage and distribution shall be carried out in a timely fashion. Since reaching the remote areas of the country has been a major hindrance in providing standard health services, a reliable and accessible transport system for the blood samples as well as blood products shall be established and continued in a regular manner.

1.5 Monitor the quality and adequacy of the services through internal / external auditing. This includes adequate monitoring of the facilities and ensuring personnel competency and monitoring of all activities and levels of blood transfusion services. This requires setting up of a regulatory body either under the National Blood Council which is separate from the Service Division (NBTS), or independent of National Blood Council with adequate monitoring and regulating facilities.

1.6 The practice of directed and replacement donors should be gradually phased out to achieve 100% voluntary non-remunerated blood donations to blood banks.

Objective 2. To ensure availability of adequate resources for the development and organization of the BTS in the country.

Strategies

2.1 Blood transfusion service (BTS) shall be financially supported either partly or in full, through government budget non-profit cost recovery and cost subsidized mechanisms.
2.2 Efforts shall be made to develop an appropriate and reliable insurance scheme or other suitable long term financing schemes.

**Objective 3.** To make appropriate and updated technology available for operating the BTS.

*Strategies*

3.1 National standards for testing, processing, component preparation, storage and distribution shall be established and implemented.

3.2 Establish a mechanism for procurement, supply, central storage and distribution of reagents and materials to ensure continuity in testing at all sites.

3.3 Establish a system for the maintenance of an effective blood cold chain for the storage and transportation of blood, blood products and blood samples.

**Objective 4.** To launch extensive awareness programmes for donor recruitment and retention.

*Strategies*

4.1 NGO’s shall be encouraged to participate in increasing public awareness and motivation of potential blood donors, especially among youth.

4.2 Directed donations should be discouraged and phased out and voluntary blood donations encouraged.

4.3 Develop and maintain a national network of donor data base with a unique donor number. This database shall be used to minimize the chances of transfusion of blood from first degree relatives to Thalassaemia patients.

4.4 Develop a pre and post donation counseling programme.

**Objective 5.** To promote appropriate and rational clinical use of blood and blood products.

*Strategies*

5.1 National guidelines on clinical use of blood and blood products shall be developed, users trained and followed.

5.2 Hospital transfusion committees shall be established in each transfusion center to monitor and audit the use of blood and blood products including haemovigilance.

5.3 Appropriate alternative strategies to minimize the need for transfusion shall be promoted.

**Objective 6.** To strengthen human resource development.
Strategies

6.1 In service training programmes shall be organized for all categories of personnel in BTS and clinical staff. This would include doctors, nurses, phlebotomists, laboratory technologists, blood transfusion service staff (BTS staff) and counselors.

6.2 Intra country and international training shall be organized for all aforementioned categories of personnel to improve quality of BTS.

6.3 Training of trainers in order to disseminate knowledge and skills in BTS throughout the country.

Objective 7. To take adequate regulatory and legislative steps for monitoring and evaluation of BTS and to take steps to eliminate profiteering in blood banks.

Strategies

7.1 The NBTS shall be regularly monitored by the National Blood Council or any other regulatory body it delegates the task to. In cases where a new facility is set up which requires GMP, approval and license should be obtained from the licensing authority.

7.2 Remuneration for donation of blood shall be declared illegal. No material incentive or benefits should be offered to those donating blood.

7.3 Trading of blood and blood products shall be prohibited and steps taken to prevent undue profiteering in BTS.

7.4 In cases of need, blood and blood products may be imported or exported between two authorized blood centres with all the due precautions.

7.5 The mandatory testing of the blood for screening purposes should be preceded by adequate pre-test counseling and the mere signing of the consent papers does not negate the necessity of this.

7.6 Confidentiality should be maintained in accordance with medical ethics and in cases of breach of this confidentiality the actions to be taken should be well known and visibly implemented.

7.7 The legislative mechanisms necessary for the implementation of the BTSs shall be developed and enforced by Ministry of Health.
Appendix 1

Responsibilities

Ministry of Health

- Ministry of health has ultimate responsibility to implement and revise the blood policy when needed.
- To ensure this it will set up a National Blood Authority with mandate and adequate infrastructural and human resource capability to implement the National Blood Policy.

The National Blood Council

- National Blood Transfusion Services shall be set up by the NBA to organize the blood transfusion services in the country.
- NBA shall also collaborate with the Food and Drug Agency (FDA) to monitor and assess the quality of services by the NBTS.
- National Blood Authority should also assist in formulation of legislations that aid in implementing its objectives.
- NBA has the overall responsibility for the planning, implementation and monitoring of all activities related to blood transfusion throughout the country.
- NBTS is responsible for the collection, testing, processing and distribution of blood and blood products for transfusion.
- The National Blood Transfusion Services has the responsibility to oversee, develop and implement the policies and procedures related to blood transfusion. It is also responsible for identifying and managing risks associated with transfusion. It reports regularly to the National Blood Authority.
- Ensuring the provision of adequate supply of safe blood and blood products.
- NBTS has responsibility of ensuring that staff who are involved in the blood transfusion process are competent through training to follow procedures which ensure optimal use of blood.
- Ensuring that policies on patient identification are in place, implemented and monitored throughout the blood transfusion process from prescription, sampling, laboratory testing and issue of blood to collection and administration of blood transfusion.
• Ensuring that written information is made available to patients about blood transfusion and potential alternatives.

• Ensuring adequate blood stores via blood camps and other recruitment procedures.

The blood transfusion laboratories (blood banks) are responsible for:-

• Cross matching and compatibility testing

• Adequate storage and issuing of blood after proper identification procedures have been carried out

• Carrying out internal quality assessment.

• Maintaining a good inventory system for the blood, reagents and equipment.

• Monitoring, calibrating and maintenance of all critical equipments.

• Maintaining and ensuring blood cold chain.

• Maintain an adequate supply of blood.

Staff Responsibilities:-

Medical and Nursing staff are responsible for:-

• Maintaining and updating there knowledge and practice.

• Ensuring rational use of blood and blood products and requesting blood using appropriate forms (follow local guidelines) providing full information on transfusion request forms as defined by procedures.

• Following standard approved procedures in ordering, procuring and administration blood as well as carrying out proper identification.

• Reporting and documentation of transfusion reactions or other incidents

• Documentation of indication for transfusion, number of units administered and observations recorded in patients medical notes.

• Ensuring that the patient is positively identified through verbal interrogation and by looking at the patient identity papers where necessary prior to taking a blood sample for cross match or administrating a blood or component transfusion.
• Medical staff is responsible for prescribing blood, blood components or blood products.

The Head of Blood Banking facilities:

• Responsible for the ensuring that health care professionals are informed of and follow the MBTS policies and guidelines where appropriate
• Responsible for ensuring that all the staff follows the standard guidelines and procedures when collecting blood samples in all steps of transfusion services.

Phlebotomists and others taking blood samples are responsible for:-

• Checking the identity of a patient before taking any blood samples
• Checking and verification of information written on the request form is complete.
• Using safe techniques for obtaining blood.
• Correct labeling of blood sample tubes in accordance with procedures.
• Reporting incidents.

MAY 2007
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