

NATIONAL BLOOD POLICY BHUTAN

1st EDITION 2007

**MINISTRY OF HEALTH
BHUTAN**

TABLE OF CONTENTS

Acknowledgement.....	iii
Foreword	iv
Introduction.....	1
Mission statement.....	1
The policy shall address the following major aspects of blood transfusion.....	2
1. Provision of adequate and safe blood supply.....	2
2. Organization and operation of the National Blood Transfusion Service.....	3
3. Promotion of voluntary blood donor recruitment program.....	4
4. Quality assurance in blood transfusion service.....	5
5. Appropriate clinical use of blood.....	6
Annexure I.....	7
Annexure II.....	8
Annexure III.....	9
Annexure IV.....	9

ACKNOWLEDGMENT

The National Blood Policy is an outcome of the efforts of many individuals. The Blood Transfusion Services, Department of Medical Services would like to express deep appreciation and extend sincere thanks to all involved, the Honorable Secretary of Health, Director General of Medical Services, Director of Public Health, Superintendent and the clinicians of the National and Regional Referral Hospitals in sharing their expertise during the drafting and finalizing the policy.

The Blood Transfusion Services would also like to take this opportunity to thank Dr Zarine Bharucha, WHO Short Term Consultant, Dr Rajesh Bhatia, Regional Adviser, Blood Safety and Clinical Technology, WHO, SEARO for their valuable contribution in the formulation of the policy as well as to the World Bank, HIV/STD Prevention and Control Project for the funds provided.

FIRST EDITION -2007



FOREWORD

Access to safe blood transfusion is essential to health and is accorded highest priority all over the world. WHO and World Bank being the main advocates have provided financial and technical support.

Recognizing the importance of safe blood transfusion, the Ministry with technical assistance from WHO, Jigme Dorji Wangchuk, National Referral Hospital is publishing the National Blood Policy with the objective of promoting safe transfusion practice at all levels of health care services. It is also hoped that this policy will create awareness on blood safety among health workers and general population.

I would like to acknowledge the contribution of technical members from WHO, World Bank, JDW, NR Hospital, Thimphu and Ministry of Health who have shown great interest and worked hard in bringing out the National Blood policy document.

(Dr Dorji Wangchuk)
Director General
Department of Medical Services,
Ministry of Health
Thimphu: Bhutan

NATIONAL BLOOD POLICY BHUTAN

Introduction

Blood transfusion is a life-saving intervention, and forms an essential part of modern health care. With the National Blood Policy as an integral part of our health policy, a well organized Blood Transfusion Service (BTS) becomes a vital component of our health care delivery system.

Blood safety is being accorded priority all over the world. World Health Organization has been advocating use of Global Blood Safety Strategy. The WHO strategy emphasizes the critical role of National Blood Policy. With the gradual increase in HIV infections and the risk of transfusion transmitted infections (TTI) through sero-negative transmission, there is an increased concern over the safety of blood and blood components.

It has been also observed that although an adequate donor base exists, blood banks often face a shortage of blood. These two major issues of blood safety and adequacy can be resolved with the help of a well-developed blood donor programme based on voluntary, non-remunerated blood donations and a reduction in the unnecessary use of blood.

Blood Transfusion Service has moved from a cottage industry to being considered as a pharmaceutical industry requiring Good Manufacturing Practices (GMP) categorizing blood as “drug” due to its nature of internal administration, therapeutic and side effects.

Presently, the hospital based blood banking system in the country is faced with a number of challenges. Though nationwide collection of blood demonstrates no absolute shortage, emerged complex disease patterns and their management have led to occasional and seasonal shortages.

Vital resources like trained personnel, adequate infrastructure and a financial base are limited too.

Thus improvement in the blood service in the country necessitates the formulation of a National Blood Policy that defines the organizational, financial and legal structures through a “comprehensive, efficient and a total quality management approach” to ensure easy access to adequate and safe blood supply.

Mission Statement:

- Ensure adequate, timely and easily accessible supply of safe and quality blood and blood products through the establishment of a National Blood Transfusion Service.
- Develop effective legislation and a National Regulatory Body to oversee the operation of the blood service in the country.
- Ensure adequate resources for the operation of a sustainable National Blood Programme.

Blood transfusions shall be advised and carried out under the supervision of a registered medical practitioner or other suitably qualified and authorized health care professional.

The Policy shall address the following major aspects of Blood Transfusion:

1. Provision of safe and adequate blood supply.
2. Organization and operation of the National Blood Transfusion Service
3. Promotion of voluntary blood donor recruitment programme
4. Quality system in National Blood Transfusion Service
5. Appropriate clinical use of blood

1. Provision of Adequate and Safe Blood Supply.

The overall responsibility for the provision of safe blood to the community shall solely lie with the Ministry of Health, under the health care delivery system and the implementation of the activities shall be designated to National Blood Transfusion Service (NBTS).

As an essential component of the health care delivery system, this service shall be made available wherever and whenever required in an efficient and co-ordinated manner.

Strategies:

- A. Constitute a National Blood Transfusion Committee, (NBTC) as the ultimate decision making body for all matters related to the blood transfusion service
- B. Secure annual fund for blood transfusion service.
- C. Develop an effective legislative framework, within which the Blood Transfusion Service is organized, managed and regulated.

(Please refer to **Annexure I**)

2. Organization and Operation of the National Blood Transfusion Service

A Blood Transfusion Service that is developed within the existing framework of the health care delivery system shall be more suitable than creating another parallel one. For smooth functioning of the service, all activities shall be planned and implemented according to the allocated funds. The NBTS shall be responsible for the provision of safe blood and blood products and liaison with clinical services for appropriate clinical use of blood.

It shall also address the emergency requirements of blood and blood products during crisis through contingency fund reserves.

Strategies:

- A. Introduce “National Blood Transfusion Service” as a programme under the division of “Health Care and Diagnostic Services”, Department of Medical Services with a well defined organizational and reporting structure.

National blood bank at JDW/National Referral Hospital shall act as the focal center for all co-ordination and technical backstopping.

(Please refer to **Annexure II**)

- B. Monitor and supervise the blood transfusion service at regional, dzongkhag and BHU grade I levels
- C. Expansion of the service to other levels of health care facilities in future.
- D. Develop database for the costing of the activities in the Action Plan.

(Please refer to **Annexure III**)

- E. Ensure training opportunities for different categories of relevant healthcare professionals.

3. Promotion of voluntary blood donor recruitment programme

With the objective to achieve 100% voluntary blood donation, collection of blood from voluntary donors shall be encouraged. With blood donor recruitment and counseling system in place and information kits available on certain medical conditions, self-deferral by unsuitable donors shall be ensured.

Trading of blood i.e. sales and purchase of blood shall be strictly prohibited.

Strategies: Adequate and safe blood to be collected through:

- A. Establishment of effective blood donor recruitment programme
- B. Following stringent selection criteria for blood donor suitability
- C. Safe blood collection procedures
- D. Effective counseling and referral system

4. Quality system in the Blood Transfusion Service

In order to ensure quality, all processes of procuring, collecting, testing, preparing and administering blood and blood products shall pass through an established quality system in the blood transfusion service.

The Quality system shall be reviewed at regular intervals and accredited by an external agency for example an Accredited Laboratory or a Blood Bank.

Strategies:

- A. Set national standards and guidelines
- B. Provide a framework for Quality Assurance System
- C. Standardize the procurement of equipment and consumable supplies
- D. Establish information network to enable adherence to quality
- E. Introduce an accreditation process

5. Appropriate Clinical Use of Blood

Appropriate clinical use of blood and blood component therapy shall remain the guiding principle for prescribing blood and blood products to needy patients.

Strategies:

- A. Utilization of blood, a scarce resource in the most efficient manner.
- B. Encourage the use of available, effective alternatives to blood therapy.

ANNEXURE I:

Under the Medicines Act of The Kingdom of Bhutan 2003, section 5.14, the Bhutan Medicines Board has the power to declare any article as medicinal product. This Act and the Rules thereof provide the legal framework.

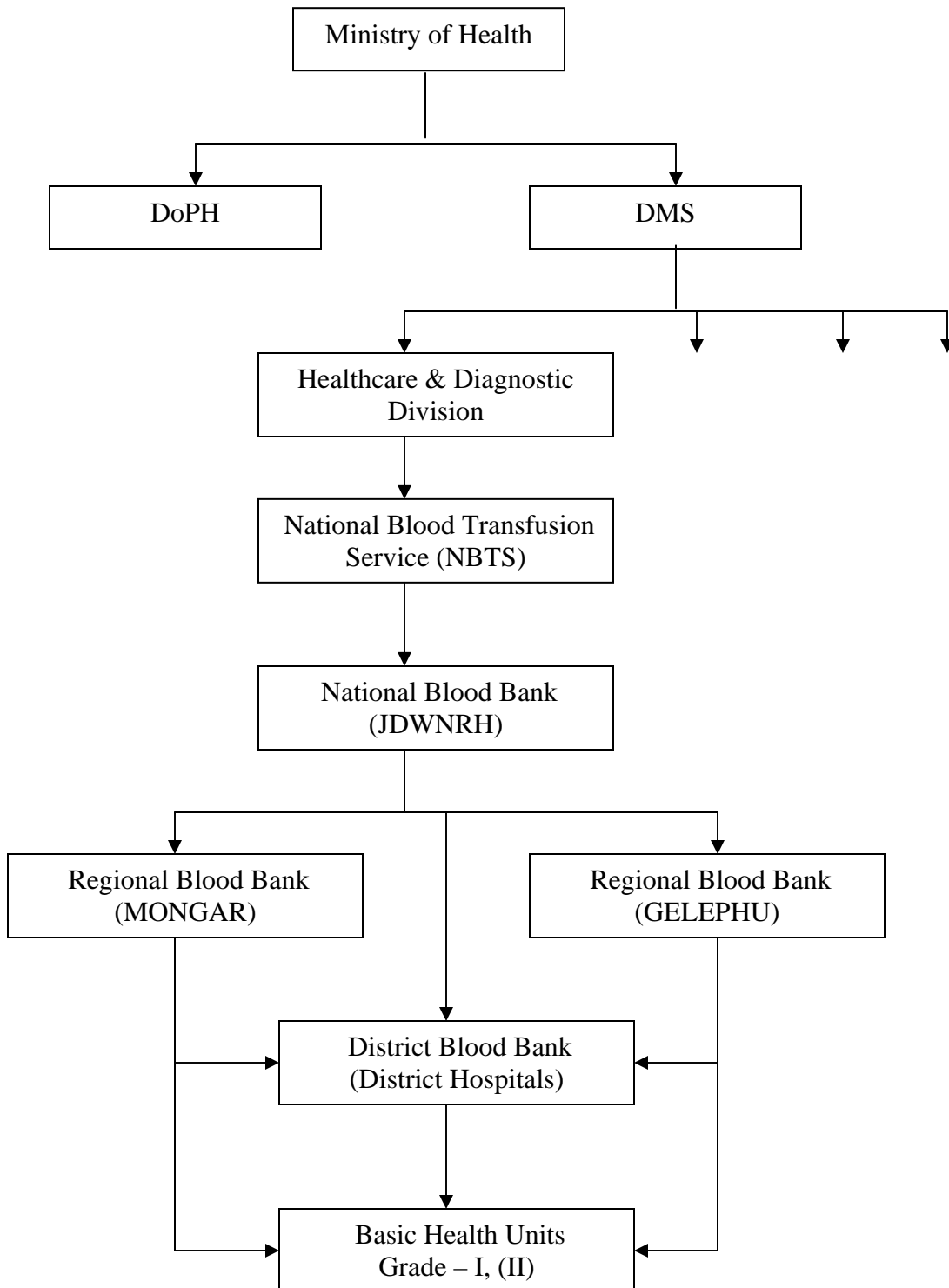
Human blood and blood components due to their therapeutic nature shall be declared as medicinal products and shall be regulated and controlled.

The regulation shall necessitate the fulfillment of following criteria:

1. Premises: Requirement of basic infrastructure suitable to blood banking.
2. Equipment: Basic minimum requirement of equipment.
3. Manpower: Minimum qualification and experience of the staff to run a blood bank.
4. National Guidelines and Standards:
5. Confirming to these standards:
 - a. Donor Selection criteria
 - b. Test protocols
 - c. Blood Screening criteria
 - d. Appropriate clinical use of blood
6. Storage and transport facilities.
7. Issue and supply policy.
8. Replacement / banking procedure.

Annexure II:

Organizational Structure of National Blood Transfusion Service



Annexure III:

The activities that need to be included in the costing for an annual budget requirement:

- Campaigns for motivation, education, recruitment and retention of blood donors.
- Organizing blood donation camps.
- Informative, educative and counseling material development, its printing and distribution to general public.
- Procurement of necessary equipment and consumables for collection, storage, processing, testing and transporting blood and blood products.
- Participation in National and International External Quality Assurance Programme
- In-country and ex-country training of the concerned health care professional.
- Participation in Continued Medical Education
- Cost of office supplies and equipment like computers, printers etc.

Annexure IV:

Activities to be included in the Implementation Plan:

- Appoint National Blood Transfusion Committee members and define their roles and responsibilities
- Develop National Standards, Guidelines, Standard Operating Procedures and other documents on donor recruitment, blood testing, processing, storage and transport
- Define low risk donor population to direct recruitment activities
- Appoint Donor Recruitment Personnel.
- Conduct national motivation and education campaigns
- Develop and disseminate IEC materials.
- Standardize manpower requirement at different levels of blood banks
- Develop a standard list of necessary consumables and equipment
- Training the health professionals on the use of National Standards, Guidelines and Standard Operating Procedures
- Train laboratory technicians in diploma courses in blood banking.
- Develop National Guidelines on “Appropriate Clinical Use of Blood
- Organize training programme with CME on various aspects of blood banking and Transfusion Medicine
- Train Medical Officers in blood banking to manage the services in the regional and district blood banks
- Introduce documentation and database management system
- Conduct periodic supervision, monitoring and evaluation of the blood banks.
- Participate in National and International External Quality Assurance Schemes

