

# **National Blood Policy 2050 (1993 AD)**

## **Updated and Revised 2061 (2005 AD)**

### **1. Preamble**

Nepal Red Cross Society (NRCS) began to provide institution based blood services through the transfusion services in department of Pathology in Bir Hospital 2021 BS, and Laxmi Blood Bank was established in 2023 BS.

In recognition of the pioneering and long service of Nepal Red Cross Society, His Majesty's Government of Nepal (HMG/N) mandated Nepal Red Cross Society on Chaitra 24, 2048 BS as a sole agency to organize comprehensive blood collection storage and supply related services in Nepal. In view of blood transfusion services provided by hospitals both in the government and non-government sector, there is a need to develop partnership between supply and demand side in sharing the responsibilities, risks and resources in establishing and maintaining a well-coordinated blood services in Nepal which was hitherto solely entrusted to Nepal Red Cross.

A national policy on blood transfusion related services was developed and approved by HMG/N through a Cabinet decision on Bhadra 10, 2050.

HMG/N recognizes that blood transfusion is an essential part of modern health care, and therefore seeks to organize blood program as an integral part of national health policy and health care infrastructure. Further, it also recognizes that it is the responsibility of the government to ensure adequate supply of safe blood and blood products to meet the transfusion requirements of the patient population.

Thus, HMG/N reiterates its mandate and commits to provide required support to Nepal Red Cross for provision and timely supply of adequate and safe blood to meet clinical needs of all people of Nepal in an equitable and affordable manner.

This Policy is called National Blood Policy 2050 (1993) (updated and revised 2061 BS (2004)).

### **2. Mission Statement of National Blood Policy**

The mission statement of Nepal's blood program is to ensure adequate, safe and timely supply of blood and blood products to meet the transfusion requirements of the people of Nepal in an equitable and affordable manner.

### **3. Objectives**

The main objective of this National Blood Policy is to define the organizational, financial and legal measures that are taken to ensure a safe and adequate blood supply in an equitable manner.

### **4. Guiding Principles of Nepal's Blood Services**

The following guiding principles govern Nepal's blood services:

- (a) The collection of blood is based on voluntary non-remunerated blood donation,
- (b) The provision for blood and blood products must be on non-profit basis,
- (c) No harm should be caused to the blood donor and recipients of blood and blood products
- (d) Every citizen of Nepal or any other country who needs blood and blood products as recommended by the treating physician in any health facilities in Nepal should have equal, prompt and affordable access to blood and blood products,
- (e) Partnership between Ministry of Health and Nepal Red Cross for blood donor recruitment, collection, processing, storage, supply and overall management for provision of safe blood is vital and therefore must be strengthened at all levels central, regional, districts and below by formation of joint committees as guided by regulatory body.
- (f) National blood services standards must ensure that services and products conform to high quality standards,
- (g) Blood transfusion is a medical intervention that should be indicated and prescribed by medical practitioners registered with Nepal Medical Council.
- (h) The rights and duties of blood donors, staffs of the blood program patients and physicians should be observed.
- (i) Minimum wastage of blood should be ensured through effective supply and demand management.

- (j) NBA shall develop appropriate legal framework for enforcement of provisions of the National Blood Policy.

## 5. Legal Framework

### 5.1 Regulating Body

- (a) National Blood Authority consisting of the following officials and representatives of different Ministries and non-governmental organizations is formed:
- |   |                  |
|---|------------------|
| 1. Secretary, Ministry of Health  | Chair            |
| 2. Secretary General, Nepal Red Cross   | Co-Chair         |
| 3. Director General, Department of Health Services  | Member           |
| 4. Representative Member of Ministry of Health  | Member           |
| 5. Senior Surgeon, Sir Hospital   | Member           |
| 6. Chief, Central Blood Transfusion Services, Nepal Red Cross                             | Member           |
| 7. Representative, one of the Teaching Hospital   | Member           |
| 8. Representative, Private Health Institution of Nepal<br>(Private hospitals association) | Member           |
| 9. Representative, Blood Donors Associations of Nepal                                     | Member           |
| 10. Representative, Consumers Forums  | Member           |
| 11. Representative, Pathologist Body nominated by the NBA                                 | Member           |
| 12. Director, Maternity Hospital  | Member           |
| 13. Director, p ruc Administrative Department   | Member           |
| 14. Director, National Center for AID and STD Control (NCASC)                             | Member           |
| 15. Director, National Public Health Laboratory   | Member-Secretary |
- (a) In case of representatives, the Committee will agree on the qualifications and skills and request the concerned organization to designate the members meeting such qualifications criteria.
- (b) The National Blood Authority (NBA) shall be the apex policy making and regulating body for all blood collection, processing, storage and transfusion related services, import export and overall management for provision of safe blood and blood products to patient population in a timely manner.
- (c) National Public Health Laboratory, DoHS shall be the Secretariat for the NBA.
- (d) The Terms of Reference of the NBA will be as follows:
- (i) Advise Ministry of Health (MOH) on National health policies and relevant technical and medical developments in relation comprehensive to blood services.
  - (ii) Develop a national blood plan for the implementation of the national blood policy.
  - (iii) Contribute to development of legislation and regulation as required.
  - (iv) Take overall responsibility for the management guidance of national blood program in accordance with the national standards.
  - (v) Monitor the implementation of national standards.
  - (vi) Regularly review and where necessary update and revise the national blood policy and standards.
  - (vii) Act as a forum for discussion on national issues relating to blood services.
  - (viii) Provide technical inputs through expert groups on various issues on blood services.
  - (ix) Develop and issue national standards and guidelines on blood services.
  - (x) Regular monitoring and auditing of national standards.
  - (xi) Facilitate appropriate funding for blood services.
  - (xii) Adaptation of international standards in to Nepal Standards as recommended by WHO.
- (e) NBA may form different sub-committees and task forces for assisting it in developing national standards and operating policies and procedures and ensuring their compliance by all units of blood collection, processing, storage and transfusion related services across the country.
- (f) NBA shall define its working procedures by itself.

## **5.2 Other Legal principles**

- (a) The collection, buy and sale of blood on commercial considerations is prohibited.
- (b) Donation of blood and blood products on replacement basis that consist of an element of coercion and pressure is also unethical and liable for legal action.
- (c) The organizations involved in blood service should ensure adequate health of the service providers and donors.
- (d) The autonomy, physical integrity and privacy of the blood donors should be maintained. Should the donated blood found non-transfusable due to existence of HIV, Hepatitis C, and syphilis or alike, the identity of the blood donor should not be disclosed publicly without his/her concurrence.

## **6. Operation of Blood Services**

Nepal Red Cross Society, as an auxiliary to government, through its regional, districts and peripheral institutional network or through the public hospitals shall organize and manage blood services within the mandate and the national standards approved by NBA.

## **7. Blood Donor Recruitment and Blood Collection**

### **7.1. Promotion of voluntary non -remunerated blood donation**

- (a) Every unit of blood should be collected based on the principle of voluntary non-remunerated blood donation.
- (b) Replacement of blood from the relatives of the patients or any other third party is discouraged, and shall be phased out gradually.
- (c) The blood donation shall be made through individual, groups or institutional donors

### **7.2 Blood Donation Campaigns, Selection and Recruitment of Donors.**

- (a) NRCS shall mobilize the local government, class organizations of the political parties, social organizations, colleges/schools etc. for blood donation campaigns.
- (b) NRCS, in cooperation with other organizations as mentioned in (a) above shall identify the population at low risk for transfusion-transmissible infections who can be selected as blood donors.
- (c) Standard information and education materials on blood donation, including guidance on confidential self-deferral and self-exclusion will be developed and disseminated.
- (d) The organizations supporting NRCS for blood collection shall help to recruit donors; counsel, and retain them as blood donors.
- (e) Suitable blood donors shall be selected for blood donation for protecting the recipient from any effect through transmission of disease or drug by blood transfusion, and protecting volunteer donor from any harm,
- (f) The potential donor's medical history should be evaluated on the day of donation by a suitably qualified person. This will include physical health check up and hemoglobin testing.
- (g) A checklist will be developed clearly mentioning the criteria who is and is not eligible to donate blood. Blood donations from persons with some infectious diseases shall result into permanent exclusion.
- (h) NRCS Offices and Blood Service Centers (BSCs) at all levels shall maintain the list of donors of all groups of bloods and to prepare, in case of emergency, sources of blood donation particularly for rare blood group. All essential data on the blood donors should be correctly maintained.
- (i) The individual and institutional donors will be provided social recognition and other forms of appreciation.

## **8. Blood Transportation, Processing, Storage and Pre-transfusion**

### **8.1. Estimation of Blood Requirement**

- (a) The central regional/district hospitals requiring blood and blood products of different groups should estimate the annual and periodic requirement and submit to concerned NRCS blood transfusion centers.

- (b) NRCS will make a donor recruitment and blood collection plan based on the estimation submitted by the hospitals.

## **8.2. Blood Collection and Transportation**

- (a) Only trained person shall do blood collection.
- (b) Disposable needles and syringes shall be used in blood collection.
- (c) Blood collected and transported from mobile units should be kept in clean and closed containers with a temperature maintained not above 22 degree Celsius and transported within 8 hours to the blood bank.
- (d) There should be a team of trained personnel and emergency life saving equipments in every blood donation camps.
- (e) Every unit of blood transported will be properly labeled.

## **8.3. Blood Processing**

- (a) The minimum testing standards for every unit of donated blood shall be as follows:
  - Blood Grouping-both cell and serum grouping test should be performed
  - Rh typing
  - HBsAg
  - HCV
  - VDRL
  - HIV (according to WHO/UNAIDS strategy)
  - Malaria and other similar diseases (according to the residential area of the donor/s)
  - Other antibody screening tests (as advised NBA)
- (b) Every unit of blood will be labeled with: donor's identification number, blood groups, type of blood components, type and quantity of anticoagulant, test results as mentioned in (a) above, blood collection and expiry date, and storing temperature.

## **8.4. Blood Storage**

- (a) No other items except blood/blood components shall be Kept in the refrigerator.
- (b) National Standards for Storage and its Duration shall be as issued by NBA, and these will be strictly complied with by all blood banks and hospitals receiving and storing blood and blood products temporarily.
- (c) Blood components shall be returned to the Blood Services Centers immediately if they are not used.

## **8.5. Waste Disposal and Infection Prevention**

- (a) Blood not used shall be disposed off according to standard waste disposal and infection prevention practice norms.

## **8.6. Pre-transfusion testing**

- (a) The following minimum standards are set for pre-transfusion testing:
  - patients blood sample rechecked for identity
  - blood grouping-both cell and serum grouping
  - Rh typing
  - cross matching by standard method
- (b) Transfusion will be done only on the prescription of a qualified physician.

## **9. Preparation and Service of Blood Components**

- (a) NRCS with the cooperation of the concerned hospitals should help to prepare adequate and ready-to-use blood components.
- (b) Central, regional and district hospitals physicians should have knowledge on appropriate use of blood components.
- (c) The blood services centers should possess following blood components,
  - packed red cell
  - plasma-fresh frozen, cryo-removed (CRP)
  - cryoprecipitate and other factor components
  - platelet concentrate
  - WBC concentrate

## **10. Rationale Use of Blood**

### **10.1. Clinical Use of Blood**

- (a) Blood should be used in case of absolute necessity only. It is the primary responsibility of the physician to ensure appropriate use of blood.
- (b) Indications and guidelines regarding use of blood in various conditions should be prescribed. These conditions, inter alia are:
  - (i) Acute loss of blood by the patient: if lost more than or equal to 20% of blood volume as indicated by clinical and vital signs,
  - (ii) Chronic anemia: blood transfusion should be avoided if the cause can be detected and treated by alternate method. The anemic level for transfusion shall be determined by NBTC through the Standard Operating Procedures and Guidelines (SOP).
  - (iii) Blood transfusion needs in case of chemotherapy, prior to surgical procedures and other conditions shall be elaborate<sup>9</sup> in the SOP.
- (c) Detailed Guidelines will be issued by NBA on the conditions and indications for blood transfusion.

### **10.2. Blood Request Forms and Formats**

- (a) The Central Blood Service Center (CBSC) should assist Blood Services Centers (BSe s) at all levels and concerned hospitals to develop standard blood request form.
- (b) Standard operating procedures for each stage of clinical transfusion process for adaptation by hospitals at all levels of the health care system shall be developed and implemented. These will include, procedures for monitoring transfused patients and investigations and management of transfusion reactions.

## **11. Standard Equipment, Reagents and Kits**

- (a) The standard list of equipment for use in Blood Service Centers of different types and capacities shall be as elaborated in the Standard Operating Procedures and approved by NSA.
- (b) Blood Services Centers at all levels shall use manufacturing and processing standards, reagents and kits, and technical and ethical standards approved by NBA as recommended by WHO and International Society of Blood Transfusion (ISBn).

## **12. Organization and Management of Blood Service Centers**

### **12.1. Mandate**

- (a) HMG/Nepal. Ministry of Health mandates NRGs to coordinate and conduct all programs related to information and dissemination, blood donor recruitment and all other programs related to voluntary non-remunerated blood donation, storage and supply of adequate and safe blood at all times.
- (b) Though authorities and responsibilities pertaining to comprehensive blood programs is entrusted to NRCS, an effective partnership will be developed between Ministry of Health and NRCS at different levels and maintaining a nationally well-coordinated effective blood service in Nepal.

## **13. Management of Blood Transfusion**

Nepal Red Cross will form Management Committees with the representation of Ministry of Health, civil society, local government, and NGOs for the management of Blood Services Centers at all levels.

The Management Committee shall take all necessary actions for effective management of the case that includes establishing technical standards, and monitoring the compliance with national standards and standard operating procedures. The Committee shall establish efficient systems for the management, costing and financial control of the blood services and the cost effective use of resources. Further, it will have additional responsibility of granting licenses and accreditations to the Blood Services Centers (SSGs) and providing technical and other support to SSGs. The detailed terms of reference (TOR) of the Committee shall be elaborated in the SOP.

## **14. Human Resources**

- (a) The human resources requirement, and the qualification of the technicians required for operating blood services shall be prescribed in the SOP
- (b) Appropriate human resources for managing the blood services shall be developed in coordination with academic institutions.

## **15. Financial and Logistics Provision for Operating Blood Services**

- (a) Financial Resources: The resources for operations of blood services shall be raised from the following sources:
  - (i) HMG Grants
  - (ii) Nepal Red Cross Contribution
  - (iii) Service Charges from the Patients.
  - (iv) Contribution from national and international organizations
  - (v) Contribution from generous individual donors
  - (vi) Resources generated through fund raising activities
- (b) The cost of capital, fixed and other operating costs of the blood services shall be estimated annually. HMG/N, Ministry of Health shall earmark the annual cost through annual budget for blood services. Ministry of Health shall facilitate to mobilize resources for blood services.
- (c) Blood services shall be operated on cost-recovery basis. Strict measures shall be applied to curtail the operating expenses, so that the people do not pay for inefficiency related costs. No profit margin is allowed to be levied on the service charges.
- (d) Appropriate mechanisms shall be established and maintained for provision of blood to the poor patients (as determined by concerned management committees) free of service charges.

## **16. Legislations, Regulations, Standards and Guidelines**

### **16.1. Regulations and Guidelines**

NBA shall, along with expertise of National Public Health Laboratory, develop and approve the regulations and national standards on:

- (i) Licensing and accreditation for managing blood .banks of different nature and capacities and terms and conditions under which licenses and accreditation will be suspended revoked or cancelled
- (ii) Physical infrastructure, equipment, human resources and other minimum standards for operating blood transfusion centers of different nature and capacities,
- (iii) Transfusion and clinical use of blood
- (iv) Norms, standards and specifications necessary for ensuring the safety, efficacy and quality of blood and blood products and
- (v) Administrative and legal measures that will be applied when the national standards are not complied with.

### **16.2. Standard Operating Procedures and Guidelines**

Standards and Guidelines for organization and management of national blood program and blood transfusion services shall be developed approved and implemented.

### **16.3 Authority and Accountability**

The authority and accountability for developing the regulations and standards, and ensuring the compliance shall vest on the National Blood Authority.

## **17. Monitoring and Audit**

The NBA shall form different sub-committees and task forces to facilitate its work for monitoring and audit of blood services. Two permanent sub-committees will be in place. i) monitoring, technical audit and compliance sub-committee ii) accreditation and licensing recommendations sub-committee. The CBSCs Management Committee shall provide license to the health institutions for blood services on the recommendation of this sub-committee.