Swaziland National Blood Transfusion Draft Policy

A Draft

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Ministry of Health
P.O. Box 5
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Foreword
Chapter 1

1.0 INTRODUCTION

1.1 National Vision

The Swaziland National Blood Transfusion Service (SNBTS) shall be a semiautonomous service with its own organizational structure, buildings, dedicated staff and adequate budget to provide excellence in donor recruitment, blood collection and the provision of safe blood and blood products according to international standards to meet the needs of the people of Swaziland.

1.2 Current situation

Currently the SNBTS is undergoing a separation process from being a department under the Clinical laboratories to a Semi Autonomous unit with a structure, budget line, centre number and its own personnel within the MOH. A Cabinet paper has been prepared on the establishment of the Semi Autonomous Service, presented to Parliament and has gone through the preliminary stages.

1.3 Purpose

The Swaziland National Blood Transfusion Service (SNBTS) policy shall govern the provision of a service that meets internationally accepted standards of ethics, quality, safety and practice to supply blood and blood products timely, in sufficient quantities and used appropriately and effectively to meet the blood needs of the people of Swaziland.

1.4 Process followed and Key players consulted in the policy making process

The policy development process started in 1996. WHO brought Technical assistance to conduct situational analysis on operations of the SNBTS. The report clearly recommended the separation of SNBTS from the Clinical Laboratories. In 1999, a short term consultant Linda Dots also recommended for the development of a blood policy. Therefore the need to separate these two into two distinct entities in order to enhance efficiency in both of them.

In June 2000, Dr Mngeni developed the first draft of the National Blood Policy. A consultative stakeholders meeting was held on the draft National Blood Policy on the 10 August 2000. Recommendations from the stakeholders stated that the Draft Blood policy could not be implemented as it looked more like guidelines.
In December 2000, Mr David Mvere was invited to prepare a draft National Draft Policy. A plan of action was developed for the stakeholders meeting and the adoption of the Blood Policy. The stakeholders meeting was held on the 1st of July 2001. The draft National Blood policy was presented to MOH on the 31st August 2001. The recommendations from the stakeholders were that the draft could be adopted for further developments to make it a working Blood policy. The consultative meeting was again held at Esibayeni Lodge in 2002. It was recommended that the Draft policy was ready for adoption.

The need for the direction and current development of the SNBTS in 2010 has necessitated the finalization and submission of the draft SNBTS Policy following the template given by the PPCU. A team of Laboratory Supervisors (2010) was assembled with the help of WHO to finalize the draft policies.

1.5 Objectives of the Service

1. Strengthen the organization and management of the SNBTS.
2. Ensure the safety, quality and availability of blood and blood products in sufficient quantities.
3. Ensure the proper, effective, and ethical use of blood and blood products.

1.6 Rationale for policy development

The need for the direction and current development of the SNBTS in 2010 has necessitated the finalization and submission of the draft SNBTS Policy following the template given by the PPCU. A team of Laboratory Supervisors (2010) was assembled with the help of WHO to finalize the draft policies.
Chapter 2.

2.1 Management Of The Service (structure) and Human Resources

Synopsis: Inadequate and unclear organizational structure, no staff allocated specifically for SNBTS no clear plan for staff progression and retention, No focused training programme, inadequate incentives and remuneration to maintain a dedicated staff.

Policy Statements: To establish the SNBTS as a semi-autonomous unit with a budget line, organizational structure and dedicated staff with career progression and adequate remuneration.

Strategies:

2.1.1 The Ministry of Health shall establish the Swaziland National Blood Transfusion Service (SNBTS) herein referred after as the “Service” to administer the national blood programme in accordance with the statutes of the Kingdom of Swaziland. The Service shall be a semiautonomous department with its own identity, structure, building, staff and budget.

2.1.2 The Service shall be directly accountable through the directorate of the Ministry of Health.

2.1.3 The Service shall have sole and direct national responsibility for all activities from blood donor recruitment to transfusion and the importation and distribution of blood components and plasma derivatives.

2.1.4 The Minister of Health shall appoint an Advisory Council in terms of an Act of Parliament to give opinion and advice in the best interest of the country on ethical, technical, clinical and administrative issues of the National Blood Transfusion Service.

2.1.5 The Service shall be fully funded by the Ministry through a budget allocation provided to the Ministry of Health and may also receive grants directly or indirectly to support its activities.

2.1.6 The Service will have the following major divisions:
- Donor Recruitment Department
- Donor Blood Collection Department
- Blood Transfusion Laboratory Department
- Quality Assurance, Training and Safety Department
- Administration
- Component Production

2.1.7 The head of the Service shall be a Technical Director.
2.1.8 The Service shall collaborate with government departments and non-government organizations in pursuit of fulfilling its goals and objectives and those of the Ministry of Health.

2.1.9 Hospital blood banks shall fall under the professional and administrative control of the Service. However, the administrative authorities of the hospital shall, on behalf of the management of the Service, monitor and report on the performance of the hospital blood bank.

2.1.10 The Service is responsible for pre and post donation counseling of all donors and may refer donors to other counseling organizations as deemed necessary and in the best interest of the donor.

2.1.11 Blood donation and transfusion practice shall not entail discrimination of any kind including gender, race, nationality or religion. Neither donor nor potential recipient has the right to demand that any such discrimination be practiced.

2.1.12 The Service has professional responsibility to donors that may be harmed as a direct result of the donation process (in consultation with relevant hospitals).

2.1.13 All staff shall strictly observe confidentiality on all matters relating to donors and or test results. No information shall be disclosed to third parties without the approval of the donor.

2.1.14 The Service shall provide for an “after hours” emergency service.

2.2 Quality Management, Lab tests and cold chain

Synopsis: The Service is not adequately conforming to the ISO 17025 Standards.

Policy statement: To raise and maintain standards at acceptable level and ensure provision of quality blood, products and derivatives through effective monitoring, evaluation and intervention.

Strategies:

2.2.1 A Quality Policy Manual (QPM) for procedures to be undertaken by the Service shall be developed and this shall form the basis of Standard Operating Procedures (SOPs) to be used from blood donor recruitment to transfusion.

2.2.2 There shall be a QA manager to monitor, evaluate and assess the overall QA performance of the Service and reports the Service performances to the service Technical Director.
2.2.3 All personnel shall be trained on the use and application of the quality manual and all referenced procedures.

2.2.4 Blood cold chain equipment (plasma freezers and refrigerator) shall be wired to standby generators in order to maintain required temperatures in the event of power failure on the national electricity supply.

2.2.5 A record of the temperature of the freezer, refrigerator or cold room with blood shall be maintained for 3 years. The recording apparatus shall have a battery backup power source.

2.2.6 Temperature alarm devices shall be mandatory for all refrigeration or freezer units. The alarm devices shall have a battery backup power source.

2.2.7 The "cold chain" shall be maintained during the transportation of blood and blood products. Blood provided to the hospital ward for transfusion shall not be kept at room temperature for more than 30 minutes prior to commencement of transfusion.

2.2.8 Approved Standard Operating Procedures shall be used in the laboratory. All blood donations and samples thereof shall be processed and tested by Blood Transfusion Service Laboratory.

2.2.9 Blood components shall be prepared from each and every donation whenever possible in order to make maximal and ethical use of each donation.

2.2.10 The Service shall have the final responsibility to select reagents and consumables for use in the laboratory and donor clinic. The reagents and test kits shall meet the minimum internationally acceptable standards.

2.2.11 All unit collected shall be tested prior to transfusion for Human Immunodeficiency Virus (HIV I & II), Hepatitis B, Hepatitis C and Syphilis and any other transfusion transmissible microbial diseases that may be thought to be relevant by the blood transfusion service, using approved well controlled techniques and procedures according to WHO.

2.2.12 The Service shall not be involved in testing routine patients’ samples for clinical management except in special circumstances. However, the Service may enter into contractual agreement with a third party to conduct testing for HIV, Hepatitis B & C and other viral infections for which it has the equipment in the interest of research and health delivery. All serum samples of donated blood including autologous or directed donations shall be stored for at least five (5) years and frozen individually to enable repeat or new tests to be done.
2.3 THE BLOOD DONOR RECRUITMENT, SELECTION AND BLOOD COLLECTION

Synopsis: Inadequate pool of regular voluntary non remunerated blood donors

Policy Statements: To promote pool of voluntary non remunerated blood donation and develop donor selection criteria and retention.

Strategies:

2.3.1 Blood donation including hematopoietic tissues for transplantation shall, in all circumstances, be voluntary and non-remunerated; no pressure of any kind shall be brought to bear upon the donor. The donor shall provide informed consent to blood donation.

2.3.2 The Quality Policy Manual of the Service shall define the minimum standards of medical fitness and other criteria a potential donor must meet before a donation is acceptable. These standards shall be reviewed from time to time in accordance with national and international best practice. Standard Operating Procedures to be used in donor selection and the donor clinic shall be strictly followed.

2.3.3 Any healthy person between 16 and 60 years of age, both included, may become a blood donor. Regular donors may continue to donate up to 65 years. Donors between 65-70 years may only donate upon the approval of a medical doctor by form of a written consultation.

2.3.4 The donor shall acknowledge that he/she has been made aware of socio-behavioral risk factors associated with increased risk of transfusion transmissible infections.

2.3.5 Pre-donation individual counseling shall be used to identify donors at risk. A donor with an identified risk will be temporarily or permanently deferred from donating blood.

2.3.6 Only donors who accept to be informed of their serostatus shall be accepted for donation, notwithstanding the fact that the public shall not identify the Service or use it as a voluntary test center for such infections as HIV.

2.3.7 Blood shall be collected under the responsibility of a qualified medical personnel.

2.3.8 Pre-donation testing for HIV infection shall be discouraged or referred to a voluntary counseling and testing center.

2.3.9 Post-donation counseling shall be provided to all donors where there is a temporary or permanent deferral of a donor.
2.3.10 Post donation counseling of persons below 18 years of age who are sero-positive for transfusion associated infections shall be handled in their best interests.

2.3.11 Anonymity between donor and recipient must be respected except in special cases such as directed donations.

2.3.12 Direct donations shall be discouraged. However in special conditions subject to the approval of the Medical Director it can be considered.

2.3.13 Autologous blood donations shall be promoted for certain clinical conditions following international acceptable standards.

2.3.14 Patients requiring therapeutic haemapheresis may be referred to a medical doctor who will bleed the patient and harvest for disposal the unwanted component(s).

2.3.15 In an event of adverse reaction due to blood donation, the donor shall be exempted from hospital fees.

2.3.16 All blood, blood products and derivatives imported shall comply with nationally and internationally accepted standards.

2.4 SAFE ETHICAL and RATIONAL USE of BLOOD

Synopsis: Inappropriate transfusions are performed. Unavailability of clinical guidelines on Blood transfusion practice.

Policy Statements: To ensure appropriate transfusion of blood and blood products in accordance with Clinical guidelines.

Strategies:

2.4.1 Clinical guidelines on appropriate and rational use of blood components and products shall be made available to all hospitals and clinics that carry out blood transfusion.

2.4.2 Every hospital that carries out blood transfusion shall establish a “Hospital Transfusion Committee” that monitors compliance to the clinical transfusion guidelines. The committee shall report all adverse reactions reactive or infective in accordance with the “Haemovigilance protocol”.
2.4.3 All necessary steps shall be taken to ensure that blood and blood products for transfusion are as safe as possible.

2.4.4 All involved in the process of blood transfusion shall accept the impossibility of any absolute guarantee of inadvertent risk from blood transfusion whether reactive or infective. Blood and blood products shall not be given unless a genuine therapeutic benefit will be realized.

2.4.5 All patients shall benefit from the administration of human blood or blood products if clinically indicated irrespective of race, gender, religion, and financial status.

2.4.6 Wherever clinically feasible, patients shall be informed of the benefits, possible ill effects, and alternative treatment regimes so that they may make an informed consent to transfusion. In the case of minors, parental or the guardian’s informed consent shall be obtained. The outcome of the dialogue shall be documented.

2.4.7 In the case of adults unable to make an informed choice, or parents and guardians who deny such treatment to a minor the clinician shall make a decision in the best interest of the patient as according to existing laws.

2.4.8 Plasma expanders (crystalloid and colloids) and haematinics shall be considered for restoring blood volume before resorting to blood transfusion, except when oxygen carrying capacity is compromised.

2.4.9 As far as possible the patient shall receive only that component of blood (cells, plasma or plasma derivatives) that is clinically appropriate and afford optimal safety.

2.4.10 Before any transfusion of blood or a blood product a written request signed by a doctor or issued under his responsibility must be made, which specifies the identity of the recipient, the clinical diagnosis and the nature and quantity of the blood or product to be administered.

2.4.11 In cases of extreme emergency, The Medical Practitioner shall prescribe for use of group "O" Rhesus negative blood or red cells. Otherwise all red cell transfusion shall necessitates preliminary blood grouping tests on the recipient and compatibility tests between the donor and the recipient. The tests shall be in accordance with nationally approved SOPs.

2.4.12 In the absence of group "O" Rhesus negative blood, the Doctors discretion shall suffice.

2.4.13 Before dispatch and administration, it must be verified that the blood or blood product is correctly identified and appears normal on inspection, and that the expiry date has not passed.
2.4.14 The recipient's identity must be verified, using a 4 point identity, i.e. any 4 of the following:

- Full names
- Personal Identity Number (PIN)
- Date of Birth
- Ward
- Hospital number
- Blood pack number

2.4.15 The actual transfusion process shall be given under the responsibility of a doctor.

2.4.16 Patients on blood transfusion shall be under continuous observation for the first 15 minutes, and thereafter they shall be observed at half-hour intervals until the end of the unit being transfused and finally 24 hours after the last transfusion.

2.4.17 Any observation of abnormal signs or symptoms shall lead to immediate stoppage of the transfusion. The doctor in charge of the patient and the officer in charge of the blood bank shall be informed immediately for necessary intervention and investigation. Immediate or delayed transfusion reactions shall be reported to the laboratory providing the blood.

2.4.18 Pulse Rate (PR), Blood Pressure (BP), Temperature (T) and Respiratory Rate (RR) shall be recorded before, during and after transfusion according to the Transfusion Monitoring Chart. The beginning and end of each transfusion must be recorded in the Chart. The Transfusion Monitoring Chart should be carefully kept in the patient’s case file.

2.5 Data Management System, Document and Records Management

Synopsis: There is no Blood Bank Data Management System in place.

Policy statement: To establish and implement an appropriate Blood Bank Data Management System.

Strategies:

2.5.1 All Service documents shall be controlled and kept within the Blood Bank.

2.5.2 Appropriate authority shall review Service documents before they are approved for use.
2.5.3 Laboratory records of all blood grouping and compatibility tests done on the patient and donor blood shall be maintained for at least 10 years.

2.5.4 All records pertaining to donor recruitment, blood collection, screening and distribution shall be confidentially kept for 10 years within the Service.

2.5.5 Documents shall be reviewed by appropriate authority periodically for relevancy and for any changes.

2.5.6 Records shall be legible, identifiable, and retrievable for at least ten years from the date of creation or in compliance with national regulation accreditation and information systems.

2.5.7 There shall be written guidelines for the management of paper-based Service information.

2.5.8 There shall be an electronic data management system to manage the increasing volume of donors to reduce clerical errors within the service.

2.5.9 Before purchasing DMS, the Service shall evaluate the system to verify and validate that it meets the Service specific needs such as identifying functional requirements for each instrument interfaced or if the Service has the resources to maintain the system.

2.6 Equipment, Reagents, procurement supplies and inventory management

Synopsis: There is no policy on management system outlining procurement of equipment, reagent and service contracts procedures and there is an evident need for a technically competent laboratory scientist in the stores department.

Policy statement: To provide necessary procurement, storage, distribution and inventory management system.

Strategies:

2.6.1 The Service shall have adequate equipment and reagent supplies to perform testing for each level of care.
2.6.2 The Service shall be responsible for the verification and validation of the equipment/reagent to ensure that they perform to specifications.

2.6.3 The Service shall have policies and procedures that require regular monitoring of calibration and preventive maintenance of the equipment.

2.6.4 There shall be adequate funding to sustain service growth in keeping with the mission of the Service.

2.6.5 There shall be a revolving fund to facilitate the timely disbursement of funds to the Service to minimize interruption of services.

2.6.6 There shall be representation of Service personnel on the MOH national and regional technical and tender committees to ensure laboratory participation in the procurement process.

2.6.7 The Service shall develop a procurement plan for the reagent or rental/outright purchase of equipment in conformity to the guidelines of the Public Procurement Regulations 2008.

2.6.8 There shall be a central storage and supplies manager who is a qualified medical laboratory scientist trained in procurement management and responsible for procurement and disposition of reagents and supplies.

2.6.9 The Service shall be responsible for inventory control to ensure adequate reagent and supplies to support continued services and to minimize wastage.

2.6.10 All purchased equipment shall be given an inventory number when received into the Service.

2.6.11 Disposition of old equipment must follow the Stores Regulation Guidelines and other national guidelines.

2.7 Design, infrastructure and environmental conditions

Synopsis: There is inappropriate design and infrastructure as according to internationally acceptable standards.

Policy statement: To ensure a conducive environment for blood donation with ample space, uninterrupted power, climate control, water, access control and transport access.

Strategies:
2.7.1 The Screening laboratory and donor blood collection shall have adequate space and safe environment to perform the activities.

2.7.2 The Service management trained in blood transfusion shall approve the design and the structure of the facility before construction begins according to WHO approved designs for Blood transfusion Services.

2.7.3 All constructions shall conform to National Public Works guidelines and other national agencies.

2.7.4 The Service shall have adequate access control, electrical outlets, back-up generator and UPS system in place, lighting, ventilation, temperature control, clean water supply and refuse holding area.

2.7.5 There shall be adequate storage space for reagents and supplies with appropriate shelving and temperature control.

The service shall have restricted access to non Service Personnel

2.8 **Personnel Safety**

**Synopsis:** Safety procedures are not in place.

**Policy statement:** To develop and implement guidelines for Service safety and waste management.

**Strategies:**

2.8.1 The Service shall develop a Safety Manual to promote safe Service practices and in compliance with national guidelines.

2.8.2 The Service shall develop a Service Medical Waste management and Disposal Plan in accordance with the National Environmental Health Policy and Infection Prevention and Control guidelines.

2.8.3 The Service shall establish a Safety Committee to address general safety and infection control issues.

2.8.4 Service personnel shall be trained and instructed to follow safety, infection control and medical waste disposal policy guidelines.

2.8.5 The Service shall have guidelines for the treatment of Service personnel accidentally exposed to infectious agents while at work.
2.8.6  The safety of the donor shall be a responsibility of the Service as long as they are within the Building.

2.9 **Haemovigilance**

**Synopsis:**  Inadequate/inefficient system of haemovigilance

**Problem statement:**  To develop and adhere to guidelines for monitoring haemovigilance.

**Strategies:**

2.9.1  The Service shall develop and distribute Haemovigilance guidelines to all facilities it serves.

2.9.2  The Hospital Blood Transfusion Committees shall monitor adherence to the haemovigilance guidelines.

2.9.3  All hospitals providing blood transfusion therapy shall provide information on all adverse reactions experienced by the patients to Hospital Blood bank, Service and heads of relevant Hospitals.
Chapter 3
Draft Blood Transfusion Act

1. (1) This Act may be cited as the Blood Transfusion (Regulation) Act, ..... 

(2) This Act shall come into operation on a date to be fixed by the King by Statutory instrument.

2. In this Act:
"approved service" means the Swaziland National Blood Transfusion Service, a department within the Ministry of Health and Social Welfare, approved by the Minister to take charge of all matters relating to the procurement, processing testing and distribution of blood and blood products.

"blood product" means plasma, platelets, red cells and plasma derived products.

"Council" means the Advisory Council on Blood Transfusion established by subsection.... ;

"Minister" means the Minister of Health and Social Welfare or any other Minister to whom the King may, from time to time, assign the administration of this Act;

3. (1) It shall be the responsibility of the Minister to ensure that there is safe and adequate supply of blood products for all persons in Swaziland who are in need thereof;

(2) In order to meet his responsibility in terms of subsection (1), the Minister shall ensure that the approved service performs its duties as laid down in this Act;

(3) The approved service shall:
(a) have in place a quality management policy and procedures approved by the Minister on the advice of the Council
(b) collect blood and blood products from voluntary, non-remunerated donors only;

(c) take all measures possible to ensure that blood and blood products will be taken only from low risk donors;
(d) take all measures possible to enable donated blood and blood
products to be adequately screened and tested before transfusion;

(e) ensure that, so far as is practicable, safe blood products are available for transfusion to all members of the public who require blood or blood products;

(f) take all steps possible to ensure the appropriate use of blood products

4. The approved Service shall, within four months of the end of each financial year, submit to the Minister a report concerning the operations of the service during the financial year concerned.

5. The Minister may at any time call for such returns or information as he/she may require to satisfy himself that the approved Service is complying with the requirements set out in subsection ...........

(1) There is hereby established the Advisory Council on Blood Transfusion to advise the Minister and the approved Service on the policy and other matters for ensuring:

(a) a safe and adequate supply of blood products for all those in need thereof in Swaziland; and

(b) the appropriate use of blood products in Swaziland.

(2) Subject to subsection ...., the Council shall consist of not less than five and not more than ten members appointed by the Minister of whom:

(a) one shall be a hospital senior medical officer or his representative;

(b) one shall be a member representing the medical association of Swaziland or similar body;

(c) one shall be a representative of BSRCS;

(d) one shall be a pharmacist;

(e) one shall be an anaesthetist;

(f) one shall be a registered general nurse;

(g) one shall be a laboratory scientist

(h) two shall be blood donors.

(i) One shall be a member of the legal profession.

(3) The Minister may if he/she thinks fit, appoint a person to be a member of the Council.

(4) The Minister shall appoint from among members of the Council a Chairman and a Vice-Chairman.

(5) The Minister shall, by statutory instrument provide for:

(a) the term of office and other conditions of service of members of the Council;

(b) the procedures to be followed at meetings of the Council;
(c) the powers of the Council:
(j) to call for information and reports from medical personnel and health service providers in Swaziland and the penalty, not exceeding a fine of one thousand Emalangeni, for those who fail to provide any information or reports required;
(k) to appoint committees for specific purposes.

(6) Any statutory instrument made in terms of subsection (5) shall be subject to the approval of the Minister.

7. No person, other than the approved Service shall:

(a) collect blood or blood products or hold itself out to be willing to collect blood or blood products from members of the public or any section of the public for transfusion purposes; or
(b) manufacture or produce blood products; or
(c) use for transfusion purposes a blood product which has not been supplied by the approved Service:
   Provided that this paragraph shall not apply to blood products which have been approved for sale by the Medicines Control Authority of Swaziland.

Any person who contravenes the provisions of subsection (1) shall be guilty of an offence and liable to a fine not exceeding fifty thousand Emalangeni or to imprisonment for a period not exceeding two years or both such fine and such imprisonment.
Annex- SNBTS Structure