

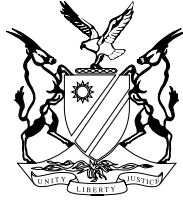


Republic of Namibia

Ministry of Health and Social Services

National Blood Policy

September 2007



Ministry of Health and Social Services

National Blood Policy

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Foreword

Since independence, the Ministry of Health and Social Services has formulated policies to provide guidance to operations in the various departments and units. This policy emphasises the importance Government attaches to the National Blood Programme as an integral part of the health delivery system.

The Government of Namibia as the responsible authority for all health delivery systems in the country recognises the national blood programme as an integral part of the national health delivery system. Therefore, Government, through the MoHSS is committed to support the programme with adequate financial, capital and material resources, and staff training facilities through the provisions of this Policy in order to ensure an adequate and safe supply of blood, products, and transfusion alternatives, ensuring their appropriate use at all health institutions.

Through this policy, the MoHSS therefore seeks to unite all institutions, health professionals and other people involved in blood transfusion into a well organised, nationally coordinated programme for the benefit of all people in the country.

This policy guides all players in the national blood programme on how they should standardise their operations in a nationally coordinated way and ensure accessible and affordable supplies of safe blood and blood products. Voluntary non-remunerated blood donation from low risk populations across the country and adequate screening protocols for transfusion transmissible infections form the foundation of a safe and adequate blood supply.

This is in keeping with the national health principles that are based on equity of services, accessibility, affordability, sustainability, inter-sectoral collaboration and community involvement. It is also in conformity with international obligations to which Namibia is a signatory. To achieve these national aspirations, the policy addresses the organisational structure and the implementation of the policy which entails formulation of a strategic plan, formulation and dissemination of guidelines on appropriate clinical use of blood, implementation of comprehensive quality management systems, resource mobilisation strategies and above all, ensuring national self sufficiency using international best practices under local circumstances.

I trust that the implementation of this policy will strengthen the blood transfusion service in line with the National Health Policy of reaching out to all in Namibia.


Dr Richard Nchabi Kapawi, MP
Minister



Preface

The Ministry of Health and Social Services (MoHSS) recognises the importance of blood transfusion in the health delivery system. It further appreciates the threat to life in the face of insufficient blood stocks and the risk of transfusion transmissible infections (TTI) such as the Human Immunodeficiency Virus (HIV), emphasizing the need for adequate and safe blood supplies to all who may need blood transfusion therapy in the country. The national institutions that share in the delivery of this service across the country need to be coordinated to ensure national quality standards with continual improvement and appropriate use of the blood. Donated blood is a national resource.

The main objectives of the policy are to reiterate Government commitment and support of the National Blood Programme as an essential part of the national health delivery system. The policy strengthens the organisational structure to ensure sustainable and equitable provision of services nationally. It reinforces the principle of voluntary non-remunerated blood donation from low risk populations across the country, supported by appropriate TTI screening, testing and blood processing protocols, quality management systems and the need for guidelines on appropriate clinical use of blood.

The policy took into account the local circumstances, international best practices and recommendations from the World Health Organisation which were all adapted to suit the Namibian situation. Ethical issues and principles are stated as a guide to all in protecting the non-profit nature of the service and to save life by taking precautions to avoid exposing patients to avoidable risk.

The main sections of the policy cover the situation analysis, policy framework, institutional framework for policy implementation, resource implications, monitoring and evaluation and the key implementation phases.

To ensure a consultative and participatory approach from the main players in this field, the MoHSS set up a working group from representatives selected from the major stakeholders to formulate the initial draft. The Working Group then presented the draft to the Ministerial Management Committee and thereafter at a national workshop to a wider representative audience from across the country covering Government, mission, and private hospitals and health institutions. Input received at both fora were incorporated, after

which the draft was again circulated to health institutions country wide for final comments. Various comments were received including from those that had not been able to attend the national workshop on the draft policy.

My appreciation goes to the WHO for providing technical assistance as well as to the Directorate for Tertiary Health Care and Clinical Support Services that coordinated the process of formulating this policy with the consensus and support of all stakeholders.



Dr Kalumbi Shangula
Permanent Secretary



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List of Abbreviations

GACUB	Guidelines for the Appropriate Clinical Use of Blood and Blood Products
GRN	Government of the Republic of Namibia
HBBs	Hospital Blood Banks
HIV	Human Immunodeficiency Virus
HTCs	Hospital Transfusion/Therapeutic Committees
ISBT	International Society of Blood Transfusion
M&E	Monitoring and Evaluation
MIS	Management Information System
MoHSS	Ministry of Health and Social Services
MoU	Memorandum of Understanding
MSBOS	Maximum surgical blood ordering schedule
NAMBTS	Blood Transfusion Service of Namibia
NBA	National Blood Authority
NBP	National Blood Policy
NBPr	National Blood Programme
NGO	Non-Governmental Organization
NIP	Namibia Institute of Pathology
PEPFAR	United States President's Emergency Plan for AIDS Relief
PMDRC	Policy, Management Development and Review Committee
QMS	Quality Management System
SOP	Standard Operating Procedure
Standards	Standards for the Practice of Blood Transfusion
THC & CSS	Directorate for Tertiary Health Care and Clinical Support Services
TTIs	Transfusion Transmissible Infections
WHA	World Health Assembly of Health Ministers
WHO	World Health Organisation

CHAPTER 1: Introduction

1.1 Introduction

The National Blood Policy (NBP) demonstrates the commitment and support by the Government of the Republic of Namibia (GRN) represented by Ministry of Health and Social Services (MoHSS), to establish and maintain a national blood transfusion programme that will ensure the safety and adequacy of the blood supply as an integral part of the national health care system.

Blood transfusion is a vital component of the health care delivery system of every country. Though it is often delegated to a non-governmental organisation, it is the responsibility of government to ensure adequate, safe supplies of blood, blood products and services to meet the needs of all patients in a timely, cost effective and efficient manner.

1.2 Background

In May 1975, the 28th World Health Assembly (WHA) resolution WHA28.72, called on Member States to promote national blood programmes based on voluntary non-remunerated donations, and to promulgate laws to govern their operation. In 1994, the Regional Committee for Africa resolution AFR/RC44/R12 urged Member States of the African Region to take urgent steps to enact blood safety policies and mobilise resources for the development of the infrastructure of blood services in central and district hospitals.

In Namibia, there is a need to strengthen the capacity of the existing national blood programme to provide sufficient blood to meet the national demand using highest possible professional and ethical standards. Formulation and subsequent implementation of this National Blood Policy is the first step towards improving blood supply and safety and ultimately attaining the required national and international ethical, legal and professional standards for proper management and protection of all who need blood transfusion therapy. The National Blood Policy will also drive the formulation of the Blood Transfusion Act and its regulations.

The GRN through the MoHSS has delegated the blood programme to the Blood Transfusion Service of Namibia (NAMBTS), a non-governmental organisation (NGO) run as an association not for gain. However, the legislation and regulations are not complete and there is no national blood policy to empower,

direct and control the national blood programme (NBPr). Completing these will afford the GRN, through the MoHSS, a means of fulfilling its stewardship and regulatory role over all those who contribute to the national blood programme to ensure adequate and safe blood supplies and appropriate clinical use of the national resource. For the national blood programme, it secures authority and ensures support for policy implementation, infrastructure development and resource mobilisation at national and international level.

The GRN identified the needs of the NBPr and mobilised resources for the strengthening of the programme including the technical support from the World Health Organisation (WHO).

The NBP will strengthen the delegated responsibility and autonomy of the NAMBTS as a non-governmental organisation, registered with the Registrar of Companies as an Incorporated Association not for gain under the Companies Ordinance No. 19 of 1928.

1.3 Rationale for Policy Methodology Followed during Policy Development.

The objective of the NBP is to define the organizational, financial and legal measures relating to the establishment of an efficient, cost-effective and sustainable National Blood Programme. It will also define the measures that will be taken to meet the transfusion requirements of the Namibian population through the provision of safe blood and related products and their appropriate use.

The MoHSS set up a Core Working Group from key stakeholders in the national blood programme. The group ensured process awareness creation, consensus building, and ownership through regular meetings and reviews and input to the draft. To widen ownership, the MoHSS then invited all the major stakeholders to attend a workshop for consultation and participation in the whole process.

After several meetings, the first draft was presented to the Under Secretary: Department for Health and Social Welfare Policy to ensure that the group was on course. Thereafter the Working Group presented the draft to the Ministerial Management Committee and the top management of the institutions represented by the Working Group. Additional input and emphases on issues of concern in the policy were received and incorporated into the draft. This was followed by a presentation at a national workshop with representatives from all institutions and organisations involved in the NBPr. Having incorporated the input from the workshop, the final

draft was circulated for further comments before it was presented to the Policy, Management Development and Review Committee (PMDRC) of the MoHSS for the approval and adoption process.

1.4 Scope of the policy

The NBP addresses the establishment of a NBPr with a sustainable financial structure, based on the recruitment and retention of voluntary non-remunerated blood donors from low risk populations; the testing of all donations for Transfusion Transmissible Infections (TTIs); appropriate blood grouping and compatibility testing and the promotion of the appropriate clinical use of blood and blood products.

CHAPTER 2: Situation Analysis

2.1 Historical background of NAMBTS

The blood donor services was handled by the Red Cross Society until 1963 when NAMBTS was incorporated, as a non-profit organization with the aim of providing blood for hospitals throughout Namibia. Donor testing was, however, performed by the South African Institute for Medical Research (SAIMR) which was later transformed into the Medical Laboratory Services (MLS), a division in the Ministry of Health and Social Services. This was subsequently commercialised through an Act of Parliament, Act 15 of 1999 and became the Namibia Institute of Pathology (NIP) Ltd. In 1987, a testing laboratory was opened at the centre after which NAMBTS took over its own blood testing until today. The Blood Transfusion Service of Namibia (NAMBTS) with its Headquarters situated in the old State Hospital grounds in Windhoek and its satellite centres in Oshakati and Swakopmund, is the sole organization responsible for the provision of blood transfusion services in Namibia.

2.2 Organisation

In Namibia, NAMBTS runs the NBPr. NAMBTS has Articles of Association which state that membership to the Council / Executive Committee, includes blood donors, honorary members including hospital representatives, medical practitioners and other representatives. However, the current position is that the Council is comprised of blood donors only. There is no specific mention of official Government or MoHSS representation on the Council. MoHSS is therefore not represented on the Council. There are no advisory committees for the major NAMBTS departments. On the part of management, the Medical Director is in charge. Below him is a Medical Officer who supervises the clinic and laboratory managers. The administration and quality managers report to the Medical Director. There is no formal working agreement between the major stakeholders, (NAMBTS, NIP, and MoHSS) in the NBPr.

NAMBTS has crossmatch laboratories serving all the hospitals in Windhoek and 2 other laboratories in Oshakati and Swakopmund. Of the 25 hospitals/ laboratories that were interviewed during the blood safety data collection, 19 are under NIP while 6 are under the hospital administration. Of these 25, 11 have Hospital Blood Banks (HBBs) and 14 have blood storage facilities only. One private hospital has its own hospital blood bank. A memorandum

of understanding / performance agreement exists between NIP and MoHSS. There is no written bilateral or tripartite undertaking between MoHSS, NAMBTS and NIP.

2.3 Legislation and Regulation

NAMBTS is a non-governmental organisation, registered with the Registrar of Companies as an Incorporated Association not for gain under the Companies Ordinance No. 19 of 1928. The Articles of Association stipulate the membership of the organisation, constitution and terms of reference of the Council and the role of the Medical Director.

The main regulations are No. R. 1950 of November 30 1962, No. R.66 of 17 January 1969, No. R. 2060 of November 1972, No. R. 278 of 26 February 1971, No. R 2354 of 12 December 1975 and No. R. 87 of 15 April 1980. Current legislation requires that the medical director be the licensee of NAMBTS.

Namibia drafted its own Human Tissue Transplantation and Blood Transfusion Bill in 1996. It has not been promulgated as yet. The draft blood transfusion legislation is now separated from the Human Tissue Transplantation aspect.

Section 31 of the Hospital and Health Facilities Act of 1994 provides a regulatory instrument that allows for annual inspections and licensing of health facilities per se but in the Documentation Required for: NAMBTS Licenses (Donor Society / Processing Laboratory) and Hospital and Health Facilities Act License of November 1999, the MoHSS licenses NAMBTS, through its Medical Director as the only organisation in the country to collect, test, and process and issue blood for transfusion purposes. The Schedule of Health Facilities however, does not specifically mention blood transfusion service or blood collection.

There are no regulatory inspections being conducted at the hospital blood banks at present (National Blood Safety Data Report November 2005).

2.4 Human Resources

There has been a great improvement from the situation in late 2004 into 2005. By January 2006, in the 3 NAMBTS centres in Windhoek, Oshakati and Swakopmund, there were three qualified medical technologists, six qualified blood transfusion technicians and another six trainee technicians who were also going to write their standard examinations.

Financial constraints had also limited the recruitment of adequate nursing staff for the establishment. By February 2006 there were three donor recruitment staff that had in house training and had also attended WHO regional training workshops again signifying an improvement from the single untrained individual who was assisted by nursing staff in donor recruitment activities at the beginning of the United States President's Emergency Plan for AIDS Relief (PEPFAR) supported programme in 2004/5. Blood donor counsellors have not had any formal training. There is however, a referral blood donor counselling system in place. Medical laboratory technologists are trained in South Africa where training facilities are available while technicians are trained at NAMBTS and also write the South African examinations. Due to financial constraints, there is one part time Medical Director and a part time Medical Officer. National training facilities for the requisite blood bank professionals and other health care workers are inadequate.

2.5 Funding

There is a cost recovery policy in place but NAMBTS is reportedly financially constrained due to under funding. Cash flow problems are further exacerbated when debtors delay payments due for services provided.

2.6 Quality Management

At NAMBTS, the quality policy and documented quality system and several standard operating procedures are now in place. A Quality Manager appointed in 2005 is responsible for the implementation of the quality system. The quality gaps in equipment procurement and maintenance, and also in quality systems as reported in the WHO September 2004 report and in the situation analysis conducted in April 2005 are all being addressed. The quality programme however needs to be extended to all hospitals and hospital blood banks beyond the NAMBTS institutions to raise the blood transfusion standards of practice at all levels.

Only 3 out of the twenty six blood storage refrigerators are validated. Ten of the fridges are maintained while 15 are not. There is a limited number of outdated blood group serology standard operating procedures (SOPs) at 5 hospital blood banks and 8 hospital blood banks do not have SOPs, while 12 other hospitals do not do these tests. Cross matching SOPs are available at 3, under development at one, not available at 8 and not applicable at 13 laboratories / hospitals. SOPs for distribution and storage of blood are available at 3 blood banks and not available at 22 institutions (National Blood Safety Data Report November 2005).

NAMBTS uses the Standards for the Practice of Blood Transfusion in South Africa published by assent of the Minister of Health in terms of section 37 of the Human Tissue Act 1983 (No 65 of 1983) and the relevant regulations under it. (Relating to Blood and Blood Products No R. 1935 of 17 August 1990 3rd edition of 1999) The Standards for the Practice of Blood Transfusion in Namibia (Standards) are being formulated.

2.7 Blood Donation

There is only one donor motivator for the whole country and there are no specific activities for donor education, recruitment and retention. Donor clinic nurses assist in donor education and recruitment. Donor education material is very limited.

Three teams operate a mobile out reach programme from Windhoek, collecting blood from Khomas, Omaheke, Hardap, Erongo, Otjozondjupa, Oshikoto, Kunene and Karas regions. About 19 164 donations were collected from 10 018 donors in 2004 (NAMBTS data base 1st April 2004 to 31st March 2005). Approximately 20% more blood is required to meet the demand. There are 2 fixed blood donor centres in Windhoek and a prospective one in Swakopmund that will also issue blood to hospitals in the region. The Windhoek centre currently issues blood to all the hospitals country wide.

2.8 Blood Supply, Storage and Transport

Government and mission hospitals use about 80% of the total blood supplies. Blood shortages occur at most of the hospitals during the Malaria season because of the increased demand. Shortages also occur during holidays, festivals and education term breaks when blood collections are limited. Blood shortages are worsened by the increased use of group O blood due to cross matches not being done at some of the hospitals.

Twenty two hospitals outside of Windhoek administer blood transfusions. The frequency of blood orders ranges from weekly for 6 hospitals, every 2 weeks for 10 hospitals and monthly for 6 hospitals. Eight of the hospitals stock group O blood only.

There are adequate cold chain facilities at the blood centre in Windhoek. Eleven hospitals have blood bank refrigerators, while 6 have commercial refrigerators, and 8 are using domestic refrigerators. Seven hospitals have deep freezers while 18 do not have. None of the hospitals have quarantine/

expired blood storage facilities. Eight hospitals have temperature monitoring devices while 16 have maximum minimum thermometers and 3 have other types of thermometers (National Blood Safety Data Report November 2005).

Temperature monitoring is in place at all blood storage facilities in NAMBTS and NIP. Transport for blood between hospitals is sometimes not readily available especially to NIP that handles most of the stock at Government and mission hospitals in the regions.

Four hospitals are more than 1000 km from Windhoek, the blood supply centre while 7 are between 501 and 1 000km, 8 are between 101 and 500km while seven are between 1 and 100km. For deliveries, 4 of the hospitals get their blood after 72 hours, while one gets the blood between 25 and 72 hours, the rest are overnight deliveries. Thirteen hospitals experience transport problems while 3 have no problems. (National Blood Safety Data Report November 2005)

2.9 Blood Screening for TTIs, Component Production, Blood Grouping and Compatibility Testing

Currently, the South Africa National Blood Service Inland Region is doing all the screening for TTIs for the blood programme in Namibia because of the lower costs and added advantage of automated systems and improved blood safety using nucleic acid testing. During the 2005/6 financial year, it was at least N\$45 per test cheaper to send the tests to South Africa than to do them locally. This also saved especially the MoHSS on tariff increase for blood products and services. This however is not without its own problems as there are delays in the turn around time and other concerns with the arrangement for the TTI screening. Blood grouping is done at NAMBTS.

The 2004 calendar year HIV sero-prevalence was 0.35%, down from 0.52% the previous year. Hepatitis B was 0.78%, Hepatitis C 0.02%, and Syphilis 0.77% (NAMBTS Data Base). For HIV, this is in comparison to a range of 0-1.4% in regular blood donors in 18 countries in the African Regional. For HBV this compares with a range of 0-3.8%, HCV compares with 0 to 2.4% while Syphilis ranges from 0 to 1.1% amongst the same countries. The percentages in new blood donors in the same countries range from 0-11% for HIV, 0.53-18.9% for HBV, 0.16-7.2%, 0-10% for Syphilis. (WHO Global Data Base for Blood Safety 2004).

About 50% of the blood is processed into components. The rest is used as whole blood. Plasma exports have also ceased. NAMBTS is endeavouring to meet the required standards in order to resume plasma exports.

Compatibility testing is performed at all the 3 NAMBTS centres; in Windhoek from 7h00 to 22h00, and in Oshakati and Swakopmund from 7h30 till 17h00. Thereafter, hospitals have access to emergency stock usually kept at the Intensive Care Units. Compatibility testing is also offered at 8 of the 34 district hospitals which have NIP laboratories and that administer blood transfusions. Fourteen of the hospitals issue uncrossmatched blood.

2.10 National Guidelines for Clinical Use of Blood

The national referral hospital has partial guidelines on clinical use of blood, while only one private hospital uses guidelines from South Africa. There are no national guidelines on appropriate clinical use of blood and blood products. There are also no hospital transfusion committees, and no maximum surgical blood ordering schedules (MSBOS) at any of the hospitals. There is no specific training of doctors and nurses in the clinical use of blood. There are 2 crossmatch request forms from MoHSS and NAMBTS with only very slight differences between them that are used by all the hospitals except for one private hospital that uses its own form. Only 2 hospitals that do cross matches practise the system for group and save. The majority of the district hospitals do not do compatibility tests.

Of the 25 hospitals that reported in the blood safety data collection all reported that, the doctors are responsible for prescribing blood transfusion and completing the request form while the nurses collect the crossmatch samples and administer and monitor the transfusion. Eight hospitals had blood warmers, while 17 warmed the blood against the patient and another seven used tap water which has risks of overheating the blood and contaminating the transfusion ports.

Baseline observations of the patients before, during and after the transfusion varied from hospital to hospital. The procedures in dealing with and investigating transfusion reactions also differ from hospital to hospital, with only 12 out of the 25 hospitals submitting blood samples for the investigation and only 2 to NAMBTS. Only one hospital reported urine collection for the investigation of a transfusion reaction (National Blood Safety Data Report November 2005).

Information management and record keeping is inadequate at most of the hospitals to the extent that it was not possible to obtain blood usage patterns at any of them.

2.11 Haemovigilance

Only one private hospital has laid down surveillance procedures covering the whole transfusion chain in order to report, investigate, correct and prevent

incidents and serious hazards of transfusion. The National Referral Hospital has partial guidelines in place for the same.

All these challenges justify the need for a NBP with adequate support and commitment from GRN in order to ensure a sustainable and effective national blood programme involving all the stakeholders. In general, an ideal blood programme should have GRN support and commitment, be nationally and centrally coordinated, have a robust organisational structure, be based on voluntary non-remunerated blood donation, have quality management systems, have appropriate Human Immunodeficiency Virus and other TTI screening, and should also have appropriate guidelines on clinical use of the blood and blood products.

2.12 Development strategy

In view of the findings of the situation analysis, the MoHSS assumed the responsibility of upgrading the organization of blood transfusion activities all over the country in order to meet the needs for blood and related products.

In 2004 the Project for the Rapid Strengthening of the National Blood Programme was initiated. The Project's target is to establish a safe, effective and efficient blood transfusion programme that covers all of Namibia and the development of the NBP and the legislative framework that govern blood practices. The implementation of the Project will last until 2010.

CHAPTER 3: Policy Framework

3.1 Mission Statement

The National Blood Programme, under the Ministry of Health and Social Services, unites all health institutions and professionals into a nationally coordinated programme using appropriate technology to provide the patients of Namibia with adequate, safe and effective blood products and transfusion alternatives in an equitable and sustainable manner.

3.2 Goal

The goal of the NBP is the provision of a regulatory framework that will ensure an adequate supply of safe and effective blood products and related medical services that are used appropriately for the benefit of all patients in Namibia. This will be achieved through the establishment of suitable organisational structures and through ongoing monitoring and evaluation of services and products.

3.3 Principles

This policy is in accordance with the National Health Policy Framework that subscribes to the Constitution of Namibia and the laws thereof.

The NBP, under the stewardship of the MoHSS, upholds the following principles:

- 3.3.1 All representatives in the NBPr are autonomous at the operations level.
- 3.3.2 All blood must be obtained from voluntary, non-remunerated blood donors.
- 3.3.3 Blood products are a national resource and must at all times be obtained and utilised in the national interest.
- 3.3.4 The safety of recipients, blood donors and health care workers shall be given the utmost consideration at all times.
- 3.3.5 The appropriate screening of blood for HIV and other TTIs and good laboratory practices.
- 3.3.6 The appropriate clinical use of blood and blood products at all health institutions.
- 3.3.7 Fees levied for blood products and related services shall be determined on a cost recovery basis only.

- 3.3.8 Patients will not be denied access to blood products because of an inability to pay for those products.
- 3.3.9 The principles noted in “A Code of Ethics for Blood Donation and Transfusion” of the International Society of Blood Transfusion (ISBT) as adopted in July 2000.

3.4 Objectives and Strategies

3.4.1 Objective :

To strengthen the organisation, management and coordination of all the stakeholders in order to ensure a sustainable NBPr

Strategies

- 3.4.1.1 Establish and strengthen the organisational structures as defined in this policy.
- 3.4.1.2 Formalise the working relationship between all stakeholders through contracts, memoranda of understanding or performance agreements where appropriate.
- 3.4.1.3 Implement the NBPr in accordance with this policy.
- 3.4.1.4 Strengthen the budgeting and finance systems of the major stakeholders through effective cost recovery and/or GRN grants and external resource partner support in order to ensure sustainability.
- 3.4.1.5 Develop and implement national quality systems embracing the entire NBPr, including, but not limited, to blood donation, TTI screening, component production, blood grouping and compatibility testing, thus ensuring equitable service delivery throughout Namibia.
- 3.4.1.6 Develop and strengthen the information management systems within the NBPr.
- 3.4.1.7 Institute relevant training programmes for health personnel involved in blood transfusion.
- 3.4.1.8 Develop and harmonise relevant legislation for the NBPr.
- 3.4.1.9 Define criteria for the import and export of blood products
- 3.4.1.10 Develop and implement a monitoring and evaluation plan to ensure that the objectives of the policy are achieved.

3.4.2 Objective:

To develop a national contingency plan to ensure adequate continuity of services in the event of regional or national disasters.

Strategies:

- 3.4.2.1 The NAMBTS in consultation with the National Health Emergency Management Committee, shall ensure that each blood transfusion

- centre or hospital blood banks has named responsible individuals who are fully trained and authorized to act if the situation arises
- 3.4.2.2 The NAMBTS shall test the contingency plan at least annually.

3.4.3 **Objective:**

To ensure appropriate clinical use of blood, products and transfusion alternatives

Strategies:

- 3.4.3.1 Formulate and disseminate national guidelines on appropriate clinical use of blood and blood products.
- 3.4.3.2 Establish and implement a haemovigilance system.
- 3.4.3.3 Monitor and evaluate the clinical use of blood and blood products.

3.4.4 **Objective:**

To promote the observance of internationally acceptable ethical values and principles

Strategies:

- 3.4.4.1 Ensure informed consent for both blood donors and transfusion recipients.
- 3.4.4.2 Transfuse only when the benefit to the patient outweighs the risks of transfusion.
- 3.4.4.3 Uphold the non-profit nature of blood transfusion chain.

3.5 Policy Expected Results / Outcomes

3.5.1 Organisational Infrastructure

- 3.5.1.1 Completed and consolidated legal framework.
- 3.5.1.2 Representation of all key stakeholders on the National Blood Authority.
- 3.5.1.3 A centrally coordinated organisational structure.
- 3.5.1.4 Suitable training facilities for transfusion medicine personnel
- 3.5.1.5 Adequate blood transfusion centres and hospital blood banks.
- 3.5.1.6 Sufficient qualified / trained staff in all key institutions.
- 3.5.1.7 Adequate supplies of essential resources.
- 3.5.1.8 Financially viable and sustainable operations at all institutions.

3.5.2 Service Utilisation

The NBP will improve:

- 3.5.2.1 Clinical use of blood and component therapy.
- 3.5.2.2 Availability and use of crystalloids, colloids and haematinics to minimise the inappropriate use of blood.

- 3.5.2.3 Service delivery through appropriate facilities serving all hospitals.

3.5.3 Service Availability / Accessibility

The NBP will provide for:

- 3.5.3.1 Regular donor panels and adequate blood donation centres in strategic regions.
- 3.5.3.2 Availability of counselling facilities for all donors that test positive for any of the TTI markers.
- 3.5.3.3 Sufficient blood stocks and cross-match services at as many hospitals as possible.
- 3.5.3.4 Blood and blood products to meet at least 95% of requirements throughout Namibia at all times.

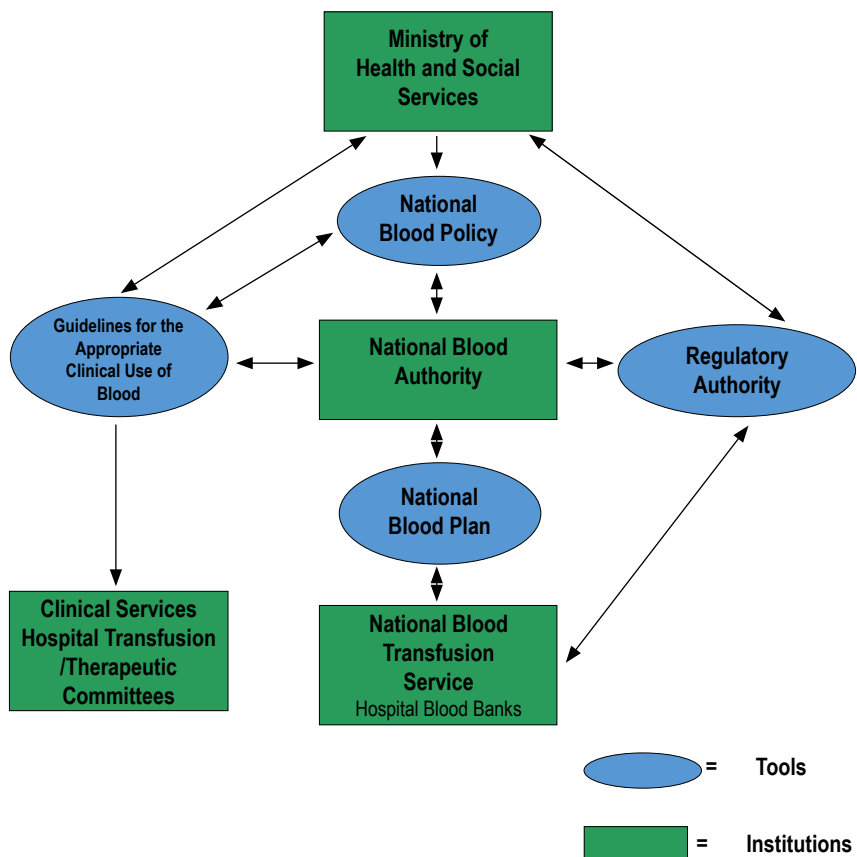
3.5.4 Quality

- 3.5.4.1 Effective and efficient organisation, processes and procedures at all institutions, resulting in adequate and safe blood supplies.
- 3.5.4.2 Enhanced donor retention through improved donor management.
- 3.5.4.3 An efficient blood cold chain covering all aspects of storage and transportation.
- 3.5.4.4 An effective haemovigilance system.
- 3.5.4.5 Adequate trained staff involved with blood transfusion.
- 3.5.4.6 Local TTI screening of donated blood when deemed appropriate by the NBA.
- 3.5.4.7 Reduced “window period” risk of HIV and other TTIs.

CHAPTER 4: The Institutional Framework For Policy Implementation

The NBPr shall have organisational structures that will cater for the blood transfusion needs at all levels of the health delivery system in order to ensure efficient and effective supply of blood, blood products and related services to all those in need.

Figure 1: National Blood Programme



The principal authorities in the NBPr are as follows:

4.1 Ministry of Health and Social Services (MoHSS)

The Ministry is the official body responsible for the centrally coordinated NBPr. The NBPr falls under the Directorate Tertiary Health Care and Clinical Support Services (THC / CSS) in the MoHSS.

The roles and responsibilities of the Ministry are:

Administration

- 4.1.1 To establish the appropriate legal framework for the NBPr to protect donors and recipients and to ensure the quality of blood transfusion services, i.e. the Blood Transfusion Act.
- 4.1.2 To establish an NBA whose role would be to advise the Minister of Health and Social Services regarding the overall strategy, policy, direction and organization of the NBPr.
- 4.1.3 To register the institution and issue the licenses for the collection and processing of blood in terms of the relevant legislation.
- 4.1.4 To oversee the appropriate formation of the NAMBTS, which shall have the responsibility and authority to collect, process, screen and supply blood and blood products in Namibia
- 4.1.5 To ensure that the NAMBTS fulfils its responsibility to provide sufficient safe blood and blood products.
- 4.1.6 To facilitate the working relationships within the NBPr through contracts / memoranda of understanding / performance agreements where appropriate.
- 4.1.7 To work with NAMBTS in the initial development, implementation of comprehensive management information systems covering all of the relevant activities of the NBPr.
- 4.1.8 To produce, update and promote the Guidelines for the Appropriate Clinical Use of Blood and Blood Products in Namibia (GACUB)
- 4.1.9 To ensure that any critical issues affecting patient safety that are identified through the haemovigilance system, but lie outside the direct responsibility of the NAMBTS, are investigated and resolved.
- 4.1.10 To ensure appropriate bio-safety and waste management for the NBPr
- 4.1.11 To adopt the ISBT Code of Ethics for Blood Transfusion Services and the Principles for the Clinical Use of Blood as defined in GACUB.

Quality

- 4.1.12 To regulate all blood transfusion activities within Namibia through monitoring, evaluation and oversight of the delivery, access to and quality of the blood transfusion service.

- 4.1.13 To facilitate the incorporation of transfusion medicine/science into the curricula of institutions offering education programmes relevant to the NBPr.
- 4.1.14 To ensure that appropriate national Standards for the Practice of Blood Transfusion (the Standards) are developed, formally adopted, implemented and periodically reviewed as required.
- 4.1.15 To plan, develop and implement procedures to ensure adequate continuity of service to all users in times of emergency
- 4.1.16 To annually review the attainment of the objectives of the NBP.

Finance

- 4.1.17 To ensure adequate financial resources for the NBPr through budgetary allocation and coordination of external support in order to ensure sustainability.
- 4.1.18 To jointly with NAMBTS, determine a sustainable cost recovery system
- 4.1.19 To define criteria for the import and export of blood and blood products

4.2 The National Blood Authority (NBA)

The NBA is accountable to the Minister of Health and Social Services.

Membership

Members of this NBA shall include representatives from MoHSS, NAMBTS and other institutions and organisations appointed by the Minister of Health and Social Services. This Committee shall be chaired by the Permanent Secretary or his/her delegatee.

The roles and responsibilities of the NBA:

Will be as defined in the Blood Transfusion Act

4.3 The Blood Transfusion Service of Namibia (NAMBTS)

A licence to collect and process blood for transfusion purposes will only be issued by the MoHSS to the NAMBTS if the NAMBTS conforms to the following requirements: The NAMBTS shall be:

- 4.3.1 Registered as a (Section 21 Company, Association not for Gain)
- 4.3.2 Controlled by a Council which shall have the following powers:
 - 4.3.2.1 To determine the Policy of the NAMBTS and to ensure that such policy is in the best interest of the NBPr and of the public.

- 4.3.2.2 To make, alter and repeal regulations for the management of the NAMBTS and its Branches, Divisions and Depots; for the duties of any officers or servants of the NAMBTS; for the admission of members of all classes and the termination of membership etc.
- 4.3.2.3 To appoint any subcommittee and delegate powers thereto.
- 4.3.2.4 To create Branches or Divisions or Depots and to include such Divisions or Depots in any Branch it may deem fit.
- 4.3.2.5 To control the funds of the NAMBTS and to lay down the system of the Administration of the NAMBTS and of its Branches, Divisions and Depot.
- 4.3.2.6 To provide for the insurance of the recipients of blood or blood products from the NAMBTS
- 4.3.2.7 To frame a tariff of charges for services rendered by the Association
- 4.3.2.8 To regulate and control fees of medical practitioners or other bodies or institutions utilizing the services of NAMBTS.
- 4.3.3 The Council shall:
 - 4.3.3.1 Appoint a Medical Director who shall have the responsibility for all medical matters relating to the NAMBTS.
 - 4.3.3.2 Appoint a full-time Chief Executive Officer who will be responsible for the day to day management of the Organisation
 - 4.3.3.3 Appoint a full-time competent management team with the responsibility and authority for day-to-day operations of the NAMBTS.
- 4.3.4 Membership of the Council
 - 4.3.4.1 Blood Donors, elected from amongst their ranks, and who at all times must make up at least 50% + 1 of the Council
 - 4.3.4.2 Honorary members appointed to represent a hospital, voluntary association, or any other body nominated by the Council.
 - 4.3.4.3 Honorary Life Members, who shall be members or other persons who have been admitted as such by the Council by reason of outstanding services rendered to the NAMBTS.
 - 4.3.4.4 A maximum of two members appointed by the MoHSS.
- 4.3.5 The roles and responsibilities of the NAMBTS
The NAMBTS shall:

Quality

- 4.3.5.1 Ensure that all blood collection and transfusion processes are done under the oversight of a medical doctor registered with the relevant Namibian authority.
- 4.3.5.2 Collaborate with national and international partners to improve the quality and distribution of transfusion services.

- 4.3.5.3 Create a suitable network of appropriately managed, equipped and staffed transfusion centres in the country.
- 4.3.5.4 Ensure that the NBA is advised of any appropriate technologies and developments in transfusion medicine
- 4.3.5.5 Appoint a quality manager who will have the responsibility and authority, in consultation with relevant stakeholders, for ensuring the overall functioning and effectiveness of the Quality Management System (QMS).
- 4.3.5.6 The NAMBTS shall have the duty of developing, implementing and co-ordinating the following:
 - 4.3.5.6.1 A national QMS to cover all aspects of the NBPr from donor selection to hospital bedside practices.
 - 4.3.5.6.2 A central procurement programme for all reagents, consumables and equipment needed for the NBPr.
 - 4.3.5.6.3 Good manufacturing practice and good laboratory practice in all areas of its activities.
 - 4.3.5.6.4 The cold chain for the storage and transportation of blood and blood products from the NAMBTS to all users.
 - 4.3.5.6.5 Research and development related to transfusion medicine and blood safety.
 - 4.3.5.6.7 Reference facilities and services to support the NBPr.
 - 4.3.5.6.8 Regular reporting of activities and performance to MoHSS.

Access to Blood and Blood Products

- 4.3.5.14 Ensure that Namibia is self sufficient in blood and blood products collected and processed locally.
- 4.3.5.15 Establish branches as required to improve quality of service, blood stock handling and distribution.
- 4.3.5.16 Collect, prepare and screen blood products in sufficient quantity and quality to meet the requirements of the medical community

Testing and Processing

- 4.3.5.17 Determine the ABO and Rh for all blood donations together with any additional and appropriate serological testing as defined in the Standards.
- 4.3.5.18 Screen all blood donations for TTIs as defined in the Standards.
- 4.3.5.19 Prepare blood components as required according to the Standards.
- 4.3.5.20 Ensure that compatibility testing is carried out before transfusion as defined in the Standards. NIP & other hospital blood banks shall carry out compatibility testing in some hospitals.
- 4.3.5.21 Ensure the final and proper disposal of all bio-hazardous waste according to the appropriate regulatory requirements.

Equipment

- 4.3.5.22 Procure and properly maintain, calibrate and validate all laboratory equipment, reagents and consumables as defined in the Standards.
- 4.3.5.23 Make available the equipment needed to ensure that all blood and blood products are stored and transported at the correct temperatures.

Haemovigilance

- 4.3.5.24 Establish and implement a national haemovigilance system covering all transfusion activities, from the collection of blood and its components to the follow-up of its recipients.
- 4.3.5.25 Report any critical issues affecting donor and patient safety, to the MoHSS within 3 working days.
- 4.3.5.26 Ensure that any critical issues affecting donor or patient safety that are identified through the haemovigilance system, within the responsibility of the NAMBTS, are investigated and resolved.
- 4.3.5.27 Compile an annual haemovigilance report and submit this report to the MoHSS within three months of the end of the NAMBTS financial year.

Hospital Blood Banks (HBBs)

- 4.3.5.28 Be responsible for the management (methods, reagents, equipment, training and transportation of blood and blood products) of all NIP & other hospital blood banks, both government and non-government. The terms of this management shall be defined in Memoranda of Understanding (MoUs) between NAMBTS, NIP & other hospital blood banks and the MoHSS.
- 4.3.5.29 Ensure that there are procedures in place at each HBB.

General

- 4.3.5.30 Ensure that it is appropriately licensed and accredited to function as the responsible body for blood transfusion within Namibia
- 4.3.5.31 Be responsible, together with the Ministry, for the continuing education and training of all personnel working in the field of transfusion medicine.
- 4.3.5.32 Be responsible for ensuring that all personnel who will be tasked to carry out laboratory tests for transfusion purposes be certified competent.
- 4.3.5.33 Prepare an annual report on the NBPr as defined in the Standards and submit the report to MoHSS through the NBA within three months of the end of the NAMBTS financial year.
- 4.3.5.34 In consultation with the National Health Emergency Committee, ensure that each blood transfusion centre or HBB has named

responsible individuals who are fully trained and authorized to act if an emergency situation arises. The NAMBTS shall test the mechanism at least annually.

- 4.3.5.35 Retain all relevant documentation as stipulated in the Standards.
- 4.3.5.36 Carry out any other NBPr activities in collaboration with other stakeholders as delegated by MoHSS.
- 4.3.5.37 Create and establish facilities for stem cell collection and cord blood banking when required.
- 4.3.5.38 Establish a national registry for HLA typed stem cell donors in co-operation with all relevant health institutions when required.
- 4.3.5.39 Monitor the TTIs in the donor population.
- 4.3.5.40 Develop and implement a mechanism of donor deferral, counselling and notification, including referral to other agencies when indicated.
- 4.3.5.41 Collect blood only from voluntary non-remunerated blood donor. Replacement donation is prohibited.
- 4.3.5.42 Give due recognition and appreciation to regular blood donors for their humanitarian act. No payment or other gifts for services shall be given to blood donors as a reward for their blood donations, with the exception of token gifts such as promotional materials and milestone awards that may be made at the discretion of the NAMBTS
- 4.3.5.43 Archive donor samples at below -20°C for at least 3 years.

4.4 NIP & other HBBs Public and private HBBs are located in government and non-government health facilities that undertake procedures that may require transfusion support.

- 4.4.1 The roles and responsibilities of the HBBs

The HBBs shall:

- 4.4.1.1 Order and properly store blood, blood products and reagents.
- 4.4.1.2 Group, antibody screen and cross-match blood, where possible
- 4.4.1.3 Support the national haemovigilance programme.
- 4.4.1.4 Not provide blood and blood products to other hospitals except with the permission of HTC's

4.5 Hospital Transfusion Committees (HTCs)

All hospitals or other healthcare institutions that undertake the transfusion of blood or blood products shall establish an HTC, or extend the functions of an existing Therapeutic Committee, to monitor the appropriate use of blood and blood products, and to provide a forum to meet with the NAMBTS to discuss any issues relating to transfusion activities.

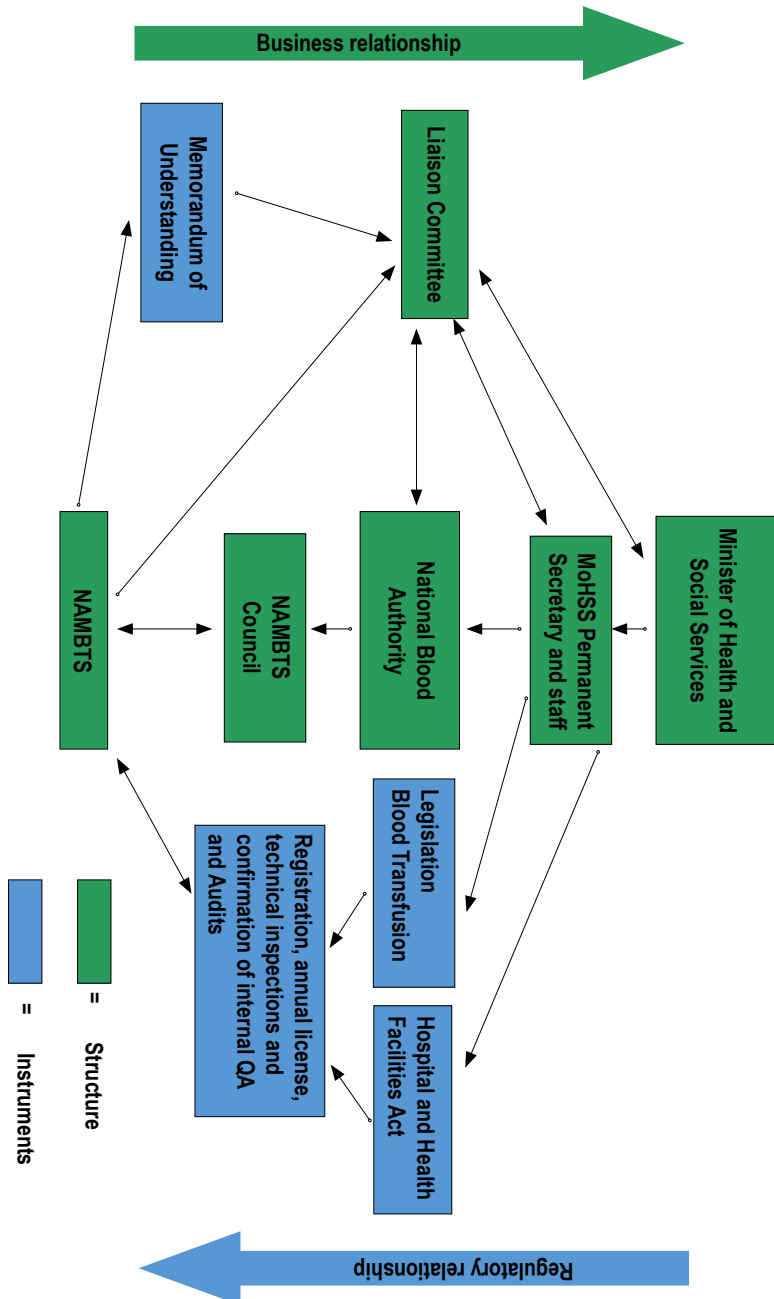
The Head of the hospital shall determine the membership of the HTC, but should always nominate members of the HBBs to serve on this committee.

4.5.1 The roles and responsibilities of the HTCs

The HTCs shall:

- 4.5.1.1 Develop a maximum surgical blood ordering schedule and other procedures as defined in GACUB.
- 4.5.1.2 Monitor the availability, safety, adequacy and reliability of the supply of blood, blood products and alternatives to transfusion (e.g. crystalloids, colloids and haematinics).
- 4.5.1.3 Promote the effective implementation of GACUB, including monitoring the usage of blood and blood products.
- 4.5.1.4 Review incidents of severe adverse effects or errors associated with transfusion and identify any corrective action required.

Figure 2: Relationship Between MoHSS and NAMBTS



CHAPTER 5: Resource Implications

5.1 Financial Resources

To ensure sustainability and appropriate development of the national blood programme, fees will be levied for all blood products and services provided by the partners in the national blood programme on cost recovery basis. This will be the main source for funds for recurrent expenditure and sustainable development. Private patients will pay the full cost of products and related services. Cost recovery on all administration and handling cost by HBBs, such as NIP, while preparing blood for transfusion purposes should be recovered from NAMBTS.

The Ministry will mobilise adequate financial resources for the implementation of the National Blood Policy.

5.2 Human Resources

- 5.2.1 The NAMBTS shall ensure sustainability with regard to human resource requirements by carrying out recruitment, training and development as well as retention programmes for health professionals.
- 5.2.2 The Ministry will collaborate with other ministries to achieve a sustainable human resource base.

5.3 Infrastructural Resources

The Ministry:

5.3.1 Buildings

- 5.3.1.1 Will make provision for financial and technical support for the development of appropriate infrastructure.

5.3.2 Equipment

- 5.3.2.1 Will facilitate the importation of relevant technology as appropriate.
- 5.3.2.2 Will ensure that all role players must include allowances for capital replacement and maintenance in their annual budgets.

5.3.3 Information Resources

- 5.3.3.1 Will ensure that other role players shall make available all documents necessary for the implementation of the NBP.
- 5.3.3.2 In collaboration with NAMBTS and other role players shall develop a comprehensive MIS for the NBPr.

5.3.4 Logistic resources

- 5.3.4.1 Shall facilitate the provision of other logistical requirements such as transport, energy and water as required.

CHAPTER 6: Monitoring and Evaluation

6. Monitoring and Evaluation

In order to ensure that the NBPr is meeting its objectives and fulfilling the requirements as stipulated in this policy on an ongoing basis, it is necessary that an effective M&E plan be developed.

The M&E plan shall include, amongst other key indicators, organisational structures, blood collection, blood testing and processing, transfusion and blood utilisation, training and sustainability.

The MoHSS, through the NBA, shall be responsible for establishing and implementing the M&E programme and produce an annual report for submission to the MoHSS.

CHAPTER 7: Key Implementation Phases

Table 1: Organisation and Resources

Major Activities	Responsible Office	Collaborating Partner	Time Frame in Years		
			07/08	08/09	09/10
Organisation- National Blood Authority (NBA)	MoHSS	NAMBTS	√		
Organisation – Key Management positions (MoHSS representation, CEO)	NAMBTS		√		
HR- recruitment for immediate needs	NAMBTS	NIP & other hospital blood banks	√		
HR-training for long term needs (sustainability)	NAMBTS	NIP & other hospital blood banks	√	√	√
Finances – costing exercise (sustainability)	NAMBTS	NIP & other hospital blood banks	√		
Finances – for capital expenditure and development (sustainability)	NAMBTS MoHSS Hospitals	NIP & other hospital blood banks		√	√

Table 2: Voluntary Non-remunerated Blood Donation

Major Activities	Responsible Office	Collaborating Partner	Time Frame in Years		
			07/08	08/09	09/10
Mapping- blood transfusion centres (regional NAMBTS distribution centres and HBBs)	MoHSS, NAMBTS, WHO	NIP & other hospital blood banks		✓	
- Development of blood donor base	NAMBTS		✓	✓	✓
- Development of infrastructure	MoHSS NAMBTS,	NIP & other hospital blood banks	✓	✓	✓
- Procurement of equipment	NAMBTS,	NIP & other hospital blood banks	✓	✓	✓
KAP study-IEC material development and use	NAMBTS, WHO		✓	✓	✓
Donor Recruitment Dept – establishment and training	NAMBTS		✓	✓	✓
Clinic- staff recruitment and training	NAMBTS		✓	✓	✓

Table 3: Transfusion Transmitted Infection Screening of Donated Blood

Major Activities	Responsible Office	Time Frame in Years		
		07/08	08/09	09/10
Protocols for TTI screening	NAMBTS MoHSS	✓		
Technology and assays	NAMBTS MoHSS		✓	✓

Table 4: National Guidelines for the Appropriate Clinical Use of Blood

Major Activities	Responsible Office	Collaborating Partner	Time Frame in Years		
			07/08	08/09	09/10
National Blood Policy	MoHSS, NAMBTS, WHO		✓		
Dissemination and training on guidelines	MoHSS, NAMBTS, WHO		✓	✓	
Monitoring and evaluation	MoHSS, NAMBTS,	NIP & other hospital blood banks	✓	✓	✓

GLOSSARY

Autologous transfusion - transfusion of blood or products donated by the recipient

Blood and blood products - these terms include all therapeutic substances derived from whole blood i.e. cellular components (red cells, platelets, white blood cells) and plasma derivatives (e.g. albumin, immunoglobulin, factor V111 etc.)

Blood bank – a facility within a hospital or blood transfusion centre in which screened and tested blood is stored, crossmatched and issued for transfusion purposes.

Blood substitutes - any substance that can replace or partially replace the functions of blood or blood products

Cold Chain - the name given to the continuous uninterrupted storage of blood or blood products at the temperature that will best preserve the viability of the product

Compatibility testing - a series of laboratory tests which aim to make sure that the transfused red blood cells will survive and function normally in the recipient

Directed donations - blood donated specifically for a named recipient

Emergency blood storage facility – a facility within a hospital that stores group O blood for emergency use only.

Family replacement blood donors - donors who give blood only when it is required by a member of his/her family

Major / Key stakeholders - MoHSS, NAMBTS, HTC's, medical professionals, NIP & other hospital blood banks, patient associations e.g. haemophiliacs etc

Maximum surgical blood ordering schedule (MSBOS) - A guide to expected normal blood usage for elective surgical procedures which lists the number of units of blood to be routinely crossmatched or grouped, screened and held for each procedure

National Blood Programme - the programme with overall responsibility for planning, implementation and monitoring of all activities related to blood transfusion throughout the country.

National Blood Authority - The highest policy formulation and decision-making body under the MoHSS for issues pertaining to blood transfusion activities in the country. All major stakeholders in the blood transfusion process are represented on this Committee.

National Blood Policy - Policy formulated by MoHSS that defines the organisational, financial and legal measures that will be taken to ensure the safety, availability and accessibility of blood transfusion within the country

The Blood Transfusion Service of Namibia (NAMBTS) - The organisation with statutory national responsibility for the provision of blood for transfusion.

Paid or commercial blood donor - One who donates blood in return for money or some other form of payment

Plasma - Liquid portion of whole blood composed of water, salts, and proteins

TTI Screening - Screening for carriers of specific diseases by means of serological tests

Transfusion transmissible infections - These are infections such as HIV, Hepatitis, Syphilis and, Chagas Disease / Trypanosomiasis that are transmissible through blood transfusion

Voluntary non-remunerated blood donors - Persons who give blood, plasma or other blood components of their own free will and receive no payment for it, either in the form of cash, or in kind. This includes time off work, other than that reasonably needed for the donation and travel. Small tokens of acknowledgement or recognition, refreshments and reimbursements of direct travel costs are compatible with voluntary, non-remunerated blood donation

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ANNEX 1



A CODE OF ETHICS FOR BLOOD DONATION AND TRANSFUSION

The objective of this code is to define the ethical principles and rules to be observed in the field of Transfusion Medicine.

Blood Centers: donors and donation

1. Blood donation including haematopoietic tissues for transplantation shall, in all circumstances, be voluntary and non-remunerated; no coercion should be brought to bear upon the donor. A donation is considered voluntary and non-remunerated if the person gives blood, plasma or cellular components of his/her own free will and receives no payment for it, either in the form of cash, or in kind which could be considered a substitute for money. This would include time off work other than that reasonable needed for the donation and travel. Small tokens, refreshments and reimbursements of direct travel costs are compatible with voluntary, non-remunerated donation.
The donor should provide informed consent to the donation of blood or blood components and to the subsequent (legitimate) use of the blood by the transfusion service.
2. A profit motive should not be the basis for the establishment and running of a blood service.
3. The donor should be advised of the risks connected with the procedure; the donor's health and safety must be protected. Any procedures relating to the administration to a donor of any substance for increasing the concentration of specific blood components should be in compliance with internationally accepted standards.
4. Anonymity between donor and recipient must be ensured except in special situations and the confidentiality of donor information assured.
5. The donor should understand the risks to others of donating infected blood and his or her ethical responsibility to the recipient.
6. Blood donation must be based on regularly reviewed medical selection criteria and not entail discrimination of any kind, including gender, race, nationality or religion. Neither donor nor potential recipient has the right to require that any such discrimination be practiced.

7. Blood must be collected under the overall responsibility of a suitably qualified, registered medical practitioner.
8. All matters related to whole blood donation and haemapheresis should be in compliance with appropriately defined and internationally accepted standards.
9. Donors and recipients should be informed if they have been harmed.
10. Blood is a public resource and access should not be restricted.
11. Wastage should be avoided in order to safeguard the interests of all potential recipients and the donor.

Hospitals: patients

12. Patients should be informed of the known risks and benefits of blood transfusion and/or alternative therapies and have the right to accept or refuse the procedure. Any valid advance directive should be respected.
13. In the event that the patient is unable to give prior informed consent, the basis for treatment by transfusion must be in the best interests of the patient.
14. Transfusion therapy must be given under the overall responsibility of a registered medical practitioner.
15. Genuine clinical need should be the only basis for transfusion therapy.
16. There should be no financial incentive to prescribe a blood transfusion.
17. As far as possible the patient should receive only those particular components (cells, plasma, or plasma derivatives) that are clinically appropriate and afford optimal safety.
18. Blood transfusion practices established by national or international health bodies and other agencies competent and authorised to do so should be in compliance with this code of ethics.

The Code has been elaborated with the technical support and adopted by the WHO.

Adopted by General Assembly of ISBT, July 12, 2000

Amended by the General Assembly of ISBT, September 5, 2006