

REPUBLIC OF RWANDA



**MINISTRY OF HEALTH
NATIONAL CENTRE FOR
BLOOD TRANSFUSION
P.O.BOX 4719 KIGALI**

**DOCUMENT OF THE NATIONAL
POLICY FOR BLOOD TRANSFUSION**

KIGALI, May 2006

FOREWORD

Blood Transfusion is a therapeutics based on the use of human blood and its derivatives. Without transfusion Medecine, a lot of deaths would be registered in the Maternities because of obtetrical haemorrages, in Paediatrics because of aenemias from malaria and other parasites, and in Surgery because of accidents. In developped countries, progresses in cardiac surgery and chimiotherapy would be very limited without the large quantities of blood used in those areas of Modern Medecine.

If Blood Transfusion is essential for Medecine, this therapeutics cannot be without risk. Indeed, in some circumstances, it can be the cause of immunological and infectious accidents, susceptible to put the patient's life in danger.

In Rwanda, at least 23.000 patients are transfused each year, from who 50% are children under five years. The most important causes of transfusion are : malaria in children under five years, haemorrhagic obstetrical complications, surgical problems and chronical diseases. In order to meet all transfusion needs, some 38.000 blood units must be collected every year. The quantity may increase due to constant improving of the quality and accessibility of health care.

Then, it is necessary to collect enough blood for transfusion, because the patient's life in need would be in danger if shortages occur. Blood to be collected must be in best quality: it should not be at risk for contamination and all attention should be paid to prevent all immunological incidents occuring from administration of incompatible or bacteria contaminated blood.

To reach optimal blood safety, strategies are defined and implemented in order to : recruit blood donors from infectious low risk groups, to make blood donors regular donors, organize blood collection, to preverve, screen and process blood, to distribute it and to use it rationnally.

A programme of quality assurance is also set up and quality norms defined. This will allow that blood destined to transfusion has all blood safety requirements.

Activities linked to blood transfusion are carried out in an autonomous structure, the National Centre for Blood Transfusion/Centre National de Transfusion Sanguine (NCBT/CNTS), a public institution to which enough resources (human, fiancial and material) must be provided to achieve its mission.

Essential strategies and norms for a suitable blood safety are defined in the present document of the national blood transfusion policy. The document is a guidelines which will help health professionals to provide and administrate enough and safe blood for transfusion to all the patients in need.

Those professionals are encouraged to follow and respect faithfully all the instructions of this national blood transfusion policy. A system of monitoring and evaluation will be set up to ensure that everything is made to supply safe blood and that every patient in need is properly served.

At the hospital level, the staffs are requested to respect all the instructions related to the rational use of blood, based on the principle that blood is used only when nothing else can be done to save a life.

Hospital transfusion committees will be set up to manage blood use in hospitals and all incidents related to blood administration.

I'm convinced that if this document of blood transfusion policy is quickly used and all instructions correctly applied, activities will be facilitated, and the results will be an improved quality of blood used for transfusion.

Then, I urge all the concerned persons to start immediately to use this important tool, so that blood safety will be as best as possible.

Done at Kigali,

The Minister of Health

Dr Jean Damascène NTAWUKULIRYAYO

INTRODUCTION

1. BLOOD FOR TRANSFUSION IS ESSENTIAL FOR MEDECINE

Blood Transfusion is a therapeutics based on the use of human blood and its derivatives. Within the African context, blood transfusion is very important since many women continue to die from haemorrhagic complications, and children are subject to serious deficiency or parasitic anaemia.

However, this therapeutics cannot be without risk. Indeed, in some circumstances, it can be the cause of immunological and infectious accidents, susceptible to put the patient's life in danger.

When HIV/AIDS occurred, the pressure on blood transfusion centres has become serious, in order to ensure the maximum safety to patients. It is now required to all States to put in place a policy as well as regulation texts that allow health professionals to carry out blood transfusion within the best conditions of safety.

Rwanda, whose the 1st blood transfusion service started in 1976, is not yet provided with a policy as well as regulation texts that allow organisation of this key sector of any performing health system. Thus, it is urgent to provide the country with an institutional and framework that fits to a good running of transfusion structures.

2. CURRENT SITUATION CONCERNING TRANSFUSION SAFETY IN RWANDA

2.1 Organisation and legislation

Even though the first blood transfusion structures have been established in Rwanda in 1976, no policy document and/or regulations texts have been elaborated by the Ministry of Health. However, already, the Cabinet Ministers has recognized Blood Transfusion as a public institution

2.2 Infrastructures

Currently, the blood transfusion program comprises 3 blood transfusion centres in Kigali (centre), Butare (south) and Ruhengeri (north). Two (2) transfusion posts are located in Rwamagana and Cyangugu.

The Kigali blood transfusion centre is located in a new building, but its rooms need to be reorganized and repaired so that it can be more operational.

The Butare blood transfusion centre has no facility. Works for building a new facility have started. The Ruhengeri blood transfusion centre has its own facility, sufficiently spacious. Its rehabilitation is going on.

2.3 Equipments

The equipments for the Kigali National Transfusion Centre allow maintaining the current level of its activities. However, to reach properly the future mission of a national centre for blood transfusion, additional equipments are being purchased. The equipments for the two other centres are incomplete and many of them are timeworn. Because of lack of performing maintenance service, many devices among others centrifuges are no longer functional. They are in phase of replacement.

2.4 Staff

The body of blood transfusion establishments employs currently 65 persons. These are: 2 doctors, 1 manager, 1 accountant, 3 senior technologists, 1 blood donor officer, 44 paramedical staffs, and 13 other support staff. The total staffs planed in the organic framework is 79 persons.

These employees are not sufficient, and only some of them were appropriately trained. The program has suffered from the departure of experienced staff that resigned blood transfusion in order to join more profitable services. The lack of a training program and plan hampers seriously the sector that is not yet attractive, subject to difficult working conditions and lack of career profile for those who wish to stay.

2.5 Transport

In Rwanda, transport plays a key role in the success of blood transfusion program. Indeed, 90% of all blood collections are done by mobile teams, and difficulties of recruitment encountered in Kigali city, are directly related to transport problems for blood donors. While it is now possible to acquire all needed vehicles, the new regulation concerning transport in public services don't allow Blood transfusion to solve the problem.

2.6 Financial resources

Up to 2004, the funding source of the national program for blood transfusion came exclusively from the ordinary budget of the GVT, which is only 25% of what is needed. From this year of 2005, the Centers for Disease Control and Prevention grant has so far solved the problem. This project of "Strengthening of National Program for Blood Transfusion" will continue until 2010.

A reflection on the cost recovery is in process, but the implementation of modalities of this collection will be preceded by an explanation campaign to avoid compromising program of voluntary blood donor recruitment.

2.7 Procurement system for consumables and reagents

The current procedures of procurement are not adequate and were responsible for frequent shortages, hampering blood collections, screening, and other related activities. However, there is an improvement in those procedures and when procedures are started early problems are alleviated. The Government has exonerated most of supplies and reagents.

2.8 Blood donation

For a population corresponding to 8.200.000 inhabitants, the yearly blood collection all around the country, corresponds to 37.800 blood units, all of them taken from voluntary, non remunerated blood donors. This is the only blood donation system applied in Rwanda.

The current blood collection covers most of the hospital needs. The remaining problem is the production of the platelets, and the negative rhesus blood units.

Blood donors are recruited in rural area (55%), in schools (40%), and in the urban cities (5%). However, the cities represent an important potential that is not yet exploited. Blood donors are mainly recruited among the youth under 25 years old (75%), the majority being male (88%). The percentage of regular donors is estimated to 55%. They provide an average of 2 blood donations a year.

2.9 Biological qualification

Since 1985, all blood collected for transfusion is tested to detect HIV, Hepatitis B and Syphilis. The screening for Hepatitis C was introduced in 1999. Serological tests are carried out using ELISA methods.

In 2005, HIV prevailing among blood donors varied between 0, 70% to 1, 40% according to the centres. The national average is 1,0%. The average of HBs rate is 2, 76%. HCV rate is 1, 4%. For syphilis, the rate is 0,7%. The immuno-haematological qualification is essentially concerned with ABO Rhesus grouping. The haemoglobin determination on all blood donors will start very soon.

2.10 Quality assurance

The national program for quality assurance has not yet started. The quality assurance is currently understood as negative and positive controls during screening tests. All centres are not provided with written procedures. Thus, it is urgent to elaborate a national policy of quality management and train all employees in fundamental notions of quality assurance.

2.11 Distribution of blood and blood derivatives

All the blood transfused to all the patients in public and private hospitals and clinics is provided by the National program for blood transfusion. The hospital can receive, according to its availability, blood will allow covering the needs for 7 to 15 days.

2.12. The use of blood

The blood that is transfused to patients is free of charge for all. A guide of rational use has been elaborated in 1966 and has been distributed to all practitioners. Nevertheless, no training was provided to nurse staffs that have a heavy duty of transfusing blood and look after those transfused patients. There are no hospital committees of blood transfusion.

Almost 23.000 patients are transfused each year. Some 50% are children under 5 years old. The whole blood is the most used, especially in the Maternities, surgery and resuscitation services. In Paediatrics, however, packed cells are more frequently prescribed.

2.13 Haemovigilance

The program of haemo-vigilance doesn't exist. It should be quickly put in place in order to allow a better follow up of transfused patients and a good management of the use of blood provided by the blood transfusion centres.

3. OBJECTIVES

3.1 Main objective:

To cover 100% of the national needs in blood for transfusion and its derivatives, of a good quality.

3.2 *Specific objectives*

- *Ensure the availability of blood and blood derivatives in all hospitals*
- *To care about its availability by those in need, without any financial or geographical consideration*
- *To provide a safety guarantee and promote the rational use of the blood and blood derivatives*

4. STRATEGIES

To reach these objectives, the main strategies to put in place are:

- 4.1 Organization and the control of blood transfusion services
- 4.2 building material, and human capacities for blood transfusion establishments
- 4.3 Putting in place effective mechanisms of resource generation for the perpetuation of the system
- 4.4 Reinforcement of the blood collection structures and systems
- 4.5 Development and implementation of a national policy of quality management
- 4.6 Promotion of a rational use of blood and blood derivatives in relation with the national program of anaemia prevention
- 4.7 Putting in place a performing system of collection and diffusion of information relating to blood transfusion
- 4.8 Putting in place a performing procurement system
- 4.9 Research promotion.

5. LINKAGES

5.1 MDG goals in Health

- Eradicate extreme poverty
- Reduce child mortality
- Improve maternal health
- Combat HIV/AIDS, Malaria and other Diseases

5.2 2020 Vision in the Health context

- To combat the spread of endemic diseases : HIV/AIDS, malaria, TB, etc
- To reduce child mortality
- To improve maternal health

5.3 Health policy objectives

Blood transfusion is linked with the Programme 5 of the Health policy which is itself linked to 2020 vision and MDG health goals:

- To strengthen the measures to prevent HIV transmission by providing enough safe blood for transfusion
- To improve the care of patients with malaria, by providing blood for patients with anaemia coming from Malaria
- To reduce maternal mortality by providing enough blood for transfusion to all women suffering from acute haemorrhages as complication related to pregnancy, labour, and delivery
- To reduce infant mortality by providing enough blood for all young patients suffering from malaria anaemia and other kind of deficiencies (malnutrition, parasites)

5.4 Linkage with WHO Blood safety strategy

A well organized blood transfusion service is a prerequisite for the safe and effective use of blood and blood products. The WHO integrated strategy for blood safety adopted by the 2005 General Assembly includes :

- Establishment of a blood transfusion service as a separate unit with responsibility and authority, having enough means and a secure government commitment and support.
- Blood collection only from voluntary non remunerated blood donors from low risk populations
- Screening of all donated blood for transfusion transmissible infections, including HIV, hepatitis viruses, syphilis and other infectious agents
- Reduction of unnecessary transfusion through the effective use of blood, including the use of alternatives to transfusion (crystalloids and colloids) wherever possible

6. ORGANISATION

The National Program for Blood Transfusion has been accepted as a public institution named “Centre National de Transfusion Sanguine/National Centre for Blood Transfusion: CNTS/NCBT”

6.1 The executive organs of the CNTS/NCBT are:

- National Centre for Blood Transfusion with headquarters in Kigali
- Two Regional Centres for Blood Transfusion, located in Butare and Ruhengeri
- 3 Transfusion posts located in Rwamagana, Kibuye, Cyangugu

6.1.1. The Mission of the CNTS/NCBT

- Organise, monitor, and coordinate all the blood transfusion activities all over the country
- Provide with the MOH, proposals concerning national standards relating to transfusion safety
- Acquire and distribute materials, reagents and consumables that are necessary for blood transfusion
- Validate all reagents intended to blood transfusion before their use
- Promote voluntary non remunerated blood donation

- Process and distribute and blood derivatives to all health institutions
- Put in place and regularly upraise the national program for quality assurance
- Train and upgrade the level of employees of centres and posts of blood transfusion, as well as the use of blood and blood products.
- Promote research in the field of immuno haematology and infections transmitted through blood transfusion.

6.1.2. The mission of RCBT

The Regional Centre for Blood Transfusion is technical and decentralized unit of the CNTS/NCBT. Their mission is:

- Assure the collection, preparation and storage of blood and blood products
- Distribute blood and blood products for transfusion to all hospitals located in the sphere of action
- Coordinate blood collection activities in the transfusion posts
- Ensure technical control of the transfusion posts located in the sphere of action
- Train and upgrade the level of employees of RCBT, Transfusion posts and the blood users.

6. 1.3. The Mission of the Transfusion Posts

The Transfusion posts are put under the supervision of RCBT. Their mission is:

- To contribute to the promotion of the voluntary, non remunerated blood donation
- To organize and carry out blood collections in collaboration with the RCBT
- Store and distribute blood and blood products that are processed and tested by NCBT and RCBT

6.2. Advisory organs

The Consultancy organs are constituted of a National Advisory Committee for Blood Transfusion and the Hospital Committee for Blood Transfusion

6.2.1. The National Advisory Committee for Blood Transfusion (NCCBT) is the national advisory organ that will tackle all difficulties relating to blood safety.

It gives technical and scientific view on the management of the CNTS/NCBT services. Its constitution and working will be defined by a ministerial order from the Minister of Health

6.2.2 The Hospital Committee for Blood Transfusion provides advice to directors of Hospitals and watch over the respect of blood transfusion procedures in those hospitals. They meet whenever it is necessary, in order to examine and provide technical advice on difficulties relating to transfusion practices in the hospitals.

7. MANAGEMENT OF THE CNTS/NCBT

7.1 It is assured by :

- The Board of Directors
- The Directorate

7.2. The Members of the Board of Directors are appointed by the Cabinet of the Ministers. The attributions of the Board of Directors is to determine the general organisation activities and the internal rules and régulations of the CNTS/NCBT, to take decisions on recruitment and

dismissal of the personnel, to vote annual budget and to control its utilization, to establish an investment plan, to approve the plan of action and the book of the accounts

7.3 The Directorate is placed under the supervision of a director, medical doctor, state officer, trained in the domain of blood transfusion or related field, having experience in transfusion practices and being registered in the Medical Council. He is appointed by an order of the Prime Minister. He is assisted by the directors of the following units : Administrative and Financial unit, the directors of the 3 blood transfusion centres. His attributions are : to ensure the daily management of the CNTS/NCBT, to put in practice the national policy of blood transfusion. He executes the decisions the Board of Directors, and prepare different reports.

7.4 Each Regional Centre for Blood Transfusion is supervised by a director, medical doctor, trained in the domain of the transfusion or related field, and registered in the Medical Council.

7.5 The director of the RCBT is responsible before the Director of the CNTS/NCBT and the provincial director in charge of Health in the zone on which he depends.

8. BLOOD DONATION

8.1 Blood donation, should be in any circumstance, voluntary and non remunerated. No pressure of any kind can be made to a blood donor.

8.2 The blood donor should be informed about the risk related to blood taking. His health and his safety should be a constant concern.

8.3 The financial profit should not be a motivation for either blood donors, or the persons in charge of blood collection

8.4 Blood transfusion should remain anonymous between blood donor and blood recipient, except in particular cases

8.5 Blood donation should not be subject to any racial, national, or religious discrimination

8.6 Blood should be taken under the supervision of a medical doctor

8.7 Any person aged between 17 and 60 years can be a blood donor

8.8 The quantity of blood to be taken by one donation will be 7 ml/Kg maximum

8.9 Before any blood donation, the blood donor should answer the questionnaire relating to his identity, his health status, and his previous history

8.10 Blood transfusion should be encouraged at any time the state of the patient requires it

8.11 Before any blood donation, the donor will be subject to a clinical examination. This includes the measure of arterial pressure, the pulse, and the heart examination. The measure of haemoglobin rate will also be determined. Any low or high blood pressure is a contraindication for blood donation. The haemoglobin rate lower than 12,5 for a woman and 13,5 for a man constitutes also a contraindication.

8.12 The interval between 2 donations should be at least 3 months. However, it can be reduced to 2 months in case of rare group.

8.13 Blood collection will be carried out using disposal materials, and with respect of strict rules of asepsis

8.14 Light refreshments and meals will be offered to the blood donors after each donation

8.15 A blood donor's card will be delivered to the blood donor after 3 consecutive donations

8.16 The motivation and fidelity encouragement of blood donors will be given in the form of a letter of acknowledgement and encouragement, diplomas, and medals to voluntary donors that will be characterised by their assiduity and seriousness.

9. BIOLOGICAL QUALIFICATION

The following exams should be systematically carried out for all blood units intended for transfusion:

- 9.1 ABO and Rhesus blood grouping, using antiserum reagents and test red cells. This should be done by 2 separate technicians, using 2 different reagents
- 9.2 Determination of the standard Rhesus factor and Weak D antigen (D^u antigen) with the phenotyping of all negative Rhesus persons
- 9.3 Screening for HIV, HBs antigen, HCV antibody and Syphilis, by appropriate techniques
- 9.4 Test of any diseases that can be transmitted through blood transfusion, in accordance with the national regulations into force and by considering new progresses
- 9.5 Research of irregular antibodies, if necessary.

10. STORAGE OF BLOOD AND BLOOD PRODUCTS

- 10.1 The whole blood units and the packed red cells will be stored in a constant T° of +4°C (between +2 and +6°C). The duration for whole blood and red cell concentrates varies between 21, 35 and 42 days depending on the composition of the preservative solution
 - 10.2 The Fresh Frozen Plasma (FFP) and the Cryoprecipitate will be stored under 30°C during two years
 - 10.3 The platelet concentrates will be stored between 20 and 24°C during 3 to 5 days, under a constant T° and agitation
- The mentioned T° must be respected all along the blood or blood products transport.

11. BLOOD AND BLOOD PRODUCTS UTILIZATION

- 11.1 The purpose of blood transfusion is to ensure an efficient therapeutics so that the recipient will benefit from it with a maximum safety.
- 11.2 Before any blood or blood product transfusion, a written prescription delivered and signed by a medical doctor, or produced under his responsibility, must specify the identity of the recipient, the nature and quantity of the product to be transfused
- 11.3 Before any transfusion, it is necessary to check the expiry date of the blood product, the identity of the recipient, and the state of the blood unit
- 11.4 Any blood transfusion should be done under the responsibility of a medical doctor
- 11.5 Blood transfusion should be done only if there is a real therapeutic reason. It will never be done with a financial motivation, either for the one who delivers prescription, or for the health institution where the patient is treated.
- 11.6 Whatever his/her financial resource, every patient in need is supposed to have a blood or blood product transfusion whenever they are available.
- 11.7 As far as possible, it is recommended that the patient receives only the blood product (cells, plasma, or plasma component) which he is in need of.
- 11.8 Except when it is urgent to use the O blood group or the group O red cells, no blood transfusion will take place before a cross-match between recipient and donor blood is done.
- 11.9 A patient will receive blood transfusion only when there is nothing else to do. As far as possible, the clinician will use blood substitutes for the patient resuscitation.
- 11.10 While under transfusion, the patient will remain strictly under surveillance. During the first 15 minutes, he will not stay alone. Afterwards, he will be visited every 30 minutes until the transfusion operations take the end. The patient will be observed during 24 hours later if necessary.

11.11 When an incident related to transfusion occurs, the transfusion should be stopped immediately. The clinician and the blood bank will be informed as quickly as possible, and investigations started to identify the cause, and make corrections if any.

11.12 The nurse will take the patient's pulse, blood pressure, T°, and the respiratory rhythm before, during and after each transfusion. The starting and the end time of transfusion must be written down, and the same report registered in the patient's file.

12. QUALITY ASSURANCE

The National Centre for Blood Transfusion will prepare and carry out the national program for quality management, which must refer to every step of the transfusion chain, from blood collection until the blood is transfused to the patient.

13. HAEMOVIGILANCE

13.1 Hemovigilance consists in the setting up of an accurate system of the follow up of the blood unit since it is collected until it is transfused, and even after the transfusion period.

13.2 This system is essential and allow the detection, collection and the analysis of informations related to the negative and unexpected effets of blood transfusion

13.3 Haemovigilance will work well only if all datas concerning the blood donor and the recipient are well recorded

13.4 The NCBT is responsible for the elaboration and the implementation of the program of haemovigilance.

14. TRAINING

A training programme will be defined and adapted to the various categories of the personal, according to the needs and the quality requirements:

- * Technical staff for blood transfusion centres
- * Technical staff for hospitals
- * Blood donor staff
- * Administrative staff
- * Staff in charge of maintenance,
- * Etc.

The training program will be carried out as an initial training of a continuous training

15. FUNDING

16.1 The perpetuation of every blood transfusion system needs an adequate financial contribution. This will be possible when the GVT establishes a system of fund generation to covers the needs of the CNTS/NCBT

16.2 A policy of partnership and fund mobilisation should be encouraged and supported

16.3 Donations and legacies of all kinds will be managed according to current national rules and regulations.

16. RESEARCH

Research will be encouraged and supported. It will be directed to 2 aspects: fundamental and operational

The main axes of research will include among others:

- Mobilization and motivation of voluntary blood donors
- Infections transmitted by blood transfusion

17. SUCCESS FACTORS

To achieve the defined objectives, the following factors will play a key role:

- Commitment of the national authorities. The MOH will commit itself to provide necessary means to the good running of the CNTS/NCBT activities
- Adaptation and implementation of the transfusion policy
- Releasing and transparent management of funds allocated to CNTS/NCBT
- Putting in place a plan of capacity building and to improve the conditions of work for the staffs
- Mobilisation of the population as regard to the blood donor recruitment
- Elaborate and implement the blood donor recruitment and fidelization program
- Monitoring and regular evaluation of the implementation of the national policy for blood transfusion

18. CONCLUSION

Transfusion safety is one of the main aspects of our health system.

Analysis of the current situation shows that, despite the reached progress since 1976, the percentage of regular donor remains low and the prevalence of transfusion transmitted diseases remains high.

Moreover, the current funding means does not allow the perpetuation of the system for the long term

To improve this situation, today's policy suggests nine (9) strategic axes intended to make the blood transfusion service more performing, in order to improve its quality, increase the number of blood donors and ensure the system perpetuation.

It is important for the GVT to find enough material, financial and human resources for implementing this policy, in order to ensure maximum safety to patients whose recovery and survival require a blood transfusion.

Done at Kigali,