THE UNITED REPUBLIC OF TANZANIA

MINISTRY OF HEALTH, COMMUNITY DEVELOPMENT, GENDER, ELDERLY AND CHILDREN

NATIONAL BLOOD TRANSFUSION SERVICE (NBTS)

BLOOD DONOR ASSESSMENT & SELECTION GUIDELINE

Second Edition

November, 2015

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Foreword

Safe blood supply is one of the key elements in strengthening an effective health care system through supporting blood transfusion to patients who are in need and disease prevention through reduction of Transfusion Transmissible Infections (TTIs)'s such as HIV/AIDS, Syphilis, Hepatitis B and Hepatitis C.

However, the availability of safe and adequate blood and blood products for transfusion poses a major challenge to the health delivery system in Tanzania. Collecting blood from safe voluntary non-remunerated blood donors is the foundation of a safe and quality blood transfusion service. This guideline is developed to address the need to provide organizations with information and guidance to reach a goal of recruiting safe voluntary non- remunerated blood donors and contribute to the reduction of transfusion transmissible infections including HIV/AIDS and safeguard blood donor. It is envisaged that the guidelines will assist staff involved in donor selection to carry out their duties as per acceptable standards and recruit safe blood donors in order to distribute safe blood and blood products to the hospitals. This guideline covers every aspect of donor assessment and selection adhering to WHO and AfSBT recommendations. It will serve as an important tool as it covers every aspect of the donor selection programme. This will also be of immense help to all those who are involved with the voluntary blood donation programme in the country, blood establishments such as NBTS, TPDF, LGAs that collect blood and blood components for transfusion or further manufacture conform with National Standards in this guideline, AfSBT and WHO recommendations for assessing and selecting suitable blood donor, defer donor and blood product management.

It will serve as an important tool and be of immense help to all those who are involved with the voluntary blood donation programme in the country. Therefore all blood donor counselors and phlebotomists are required to understand and employ this guideline for proper blood donor assessment and selection.

The Ministry of Health, Community Development, Gender, Elderly and Children wishes to thank all those who contributed in the development of this guideline.

Prof. Muhammad Bakari Kambi
CHIEF MEDICAL OFFICER

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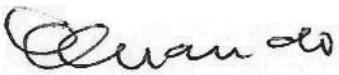
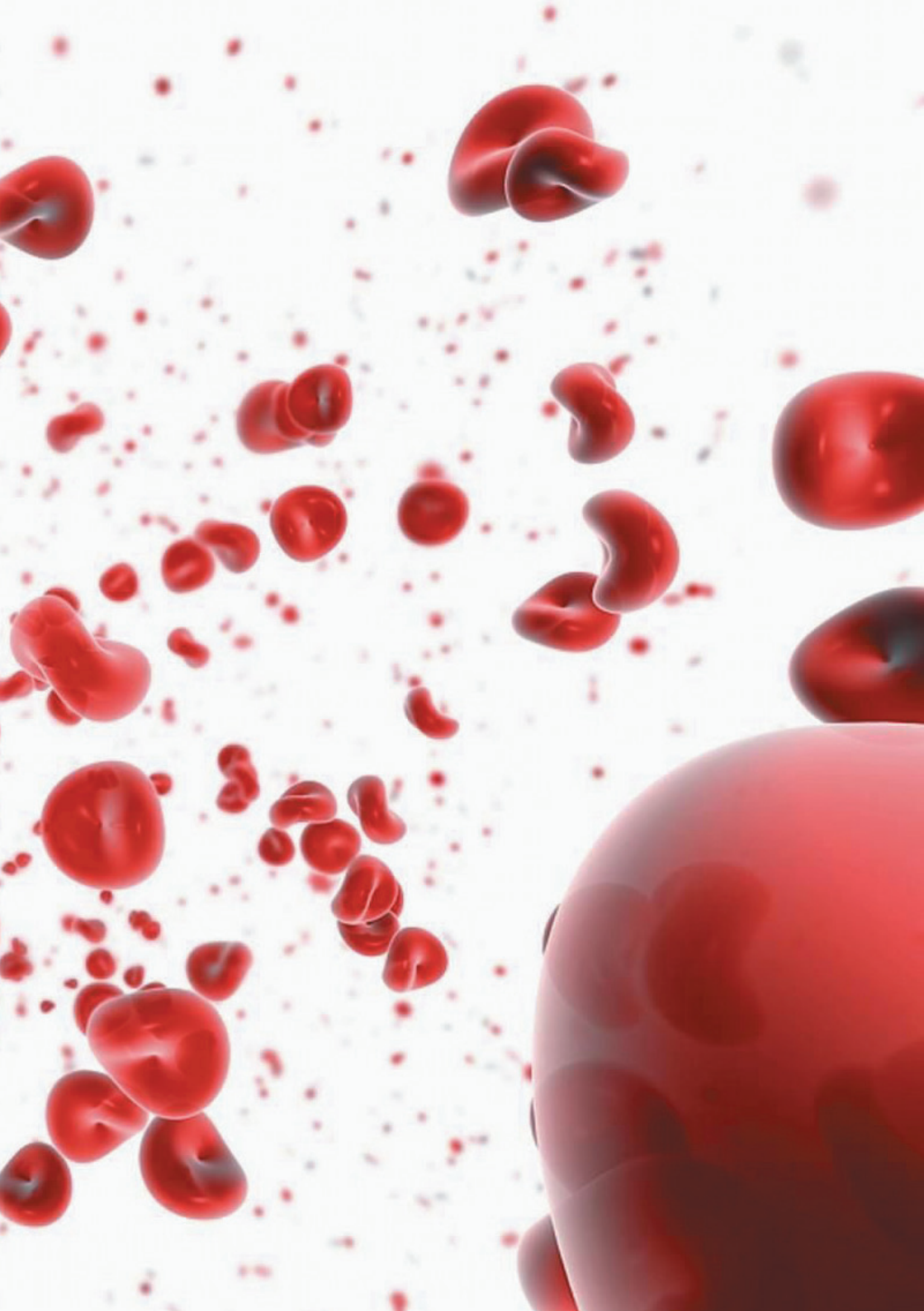


Dr. Margaret E.Mhando
DIRECTOR OF CURATIVE SERVICES

List of Abbreviations

AASLD	American Association for Study of Liver Disease
ALT	Alanine Amino Transferase
Anti HBC	Hepatitis B core antibody
Anti-HBS	Hepatitis B surface antigen antibody
APRI	AST to Platelet Index Ratio
AST	Aspartate Amino Transferase
AIDS	Acquired immunodeficiency syndrome
ARVs	Antiretroviral
HCV	Hepatitis C Virus
HIV	Human Immunodeficiency Virus
HBV	Hepatitis B Virus
HBsAg	Hepatitis B Surface Antigen
Hb	Haemoglobin
NBTS	National Blood Transfusion Service
SOP	Standard Operating Procedure
TTI	Transfusion-transmissible infection
TB	Tuberculosis
WHO	World Health Organization
CHB	Chronic Hepatitis B
DT-CRC	Defer Temporally-counsel .recall
DP	Defer permanently
DP-CRF	Defer permanent -refer
HBcAb	Hepatitis B core antibody
HBcAg	Hepatitis B core antigen
HBeAb	Hepatitis B envelope antibody
HBeAg	Hepatitis B envelope antigen
HBsAb	Hepatitis B surface antibody
HBsAg	Hepatitis B surface antigen
HBcAb	Hepatitis B core antibody
HCC	Hepatocellular Carcinoma
LGAs	Local Government Authority
PCR	Polymerase Chain Reaction
PWID	People who Inject Drugs
MSM	Men who have sex with men



Chapter One

1.0 INTRODUCTION

1.1 Background

National Blood transfusion service (NBTS) has the responsibility to collect blood from donors who are at low risk for any infection that could be transmitted through transfusion and who are unlikely to jeopardize their own health by donating blood.

Blood transfusion though is lifesaving, may cause complications including transmission of infectious diseases if not properly handled. Therefore a rigorous process to assess the suitability of prospective donors is essential to protect the safety of the blood donors , and safeguard the health of recipients of transfusion , while ensuring that suitable donors are not deferred unnecessarily.

This guideline has been developed to assist blood transfusion services in the country to strengthen blood donor's selection process. It is designed for use National Blood Transfusion Services program, blood establishments authorized to collect blood and transfusion facilities

The guideline addresses the requirements for an effective national system blood donor selection based on specific criteria related to general donor assessment, medical history and risk assessment for transfusion-transmissible infections (TTI)

This guideline has been developed in accordance with the WHO and AfSBT guidelines development process which requires systematic review of new evidence for key questions and recommendations, as well as a consideration of programme feasibility and the cost implications of potential new recommendations. Particular efforts were made to identify systematic literature reviews and evidence related specifically to blood donor selection in low- and middle-income countries.

It is anticipated that the recommendations in this document will be valid until when a review will be undertaken based on explored or new evidence, particularly in relation to controversial issues or where changes in practice may be appropriate.

1.2 DEFINITION OF TERMS

1. **Voluntary non-remunerated Blood Donor(VNRBD)**: A person who donates blood (and 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. VNRBDs are safer and play a key role in sustaining blood supply for patient in need of a transfusion. It is highly recommended in Tanzania.
2. **Family Replacement Blood Donor**: Donor who donate blood to replace the blood used by a patient who is family member or friend to him/her. Only recommended where there are no strong base for Voluntary non-remunerated blood donors and during emergency. They are considered to be at a risk of TTIs due to the fact that they donate blood under pressure without stringent selection.
3. **Paid Blood Donor**: A person who donates blood in exchange for money or other form of payment. They carry high risk of TTIs and this type of blood donation is unethical and not recommended in Tanzania.
4. **Autologous Blood Donor:** A donor who donates his/her blood to be stored so that it may be transfused back to him or her during an upcoming surgery for him/her. This type of donation is also recommended in Tanzania
5. **Directed Blood Donors**: Donor who donates blood to be transfused to a specific patient. Directed donors can give whole blood, two units of red blood cells or apheresis platelets. This type of blood donation is unethical and not recommended in Tanzania as it may promote discrimination based on colour, place or religious.
6. **Apheresis Blood Donor:** A donor who donate specific blood component where blood is withdrawn and separated using a blood cell separator (Apheresis machine) from the donor and a portion (such as plasma, leukocytes, or platelets) is separated and retained, and the remainder is re-transfused into the donor. This type of donation is also recommended in Tanzania.
7. **First time Donor:** A voluntary non-remunerated blood donor who donate blood for first time and has never donated blood before.
8. **Regular Voluntary Blood Donor:** A voluntary non-remunerated blood

donor who has donated at least three times, the last donation being within the previous year, and continues to donate regularly without any break for a longer duration between two donations.

9. **Repeat Voluntary Blood Donor:** A voluntary non-remunerated blood donor who donate blood twice a year.
10. **Lapsed Voluntary Blood Donor:** A voluntary non-remunerated blood donor who has donated blood in the past for the period more than one year and does not fulfill the criteria for a regular donor.
11. **Confidential Unit Exclusion:** The removal and disposal of a unit of blood after donation at the request of the donor
12. **Donor Deferral:** The non-acceptance of a potential blood donor to donate blood or blood components, either temporarily or permanently, based on general health or medical condition, or the risk of exposure to pathogens
13. **Donor Haemovigilance:** A set of surveillance procedures for the monitoring, reporting and investigation of adverse donor reactions and events which are designed to prevent their occurrence or recurrence
14. **Donor Assessment:** The process of assessing blood donor to enables the review of the donor's medical history, medications to assess whether the donor is in general good health.
15. **Donor Selection:** The process of assessing the suitability of an individual to donate blood or blood components against defined selection criteria so that blood donation is safe for the donor and the blood products.
16. **Prevalence**: The proportion of a specific population that is infected with an infectious agent at any particular time
17. **Incidence:** The rate of occurrence of new cases of a particular disease in a population being studied
18. **Risk behavior:** Behavior that exposes an individual to the risk of acquiring transfusion-transmissible infection
19. **Self-deferral:** The decision by a potential donor to defer himself/herself from donation of blood or blood components, either temporarily or permanently, based on general health or medical condition, or the risk of exposure to pathogens
20. **Traceability:** The ability to trace each individual unit of blood, or blood

component derived from it, from the donor to its final destination, whether this is a patient, a manufacturer of therapeutic products or disposal, and vice versa.

21. **Transfusion-Transmissible Infection (TTI):** An infection that is potentially capable of being transmitted by blood transfusion.

1.3 DONOR SELECTION GUIDELINE OBJECTIVES

1.3.1 Broad Objective

The aim of this document is to guide and support all blood establishments in establishing effective systems for blood donor selection, including medical assessment, criteria for blood donation and blood donation process in order to ensure the safety of the recipients of blood and blood products and protect donor health and safety.

1.3.2 Specific Objectives

- *Provide guidance on the measures needed to develop and implement effective systems for assessing the suitability of individuals to donate blood.*
- *Review the available evidence base and provide recommendations on criteria for blood donor selection.*

1.4 NATIONAL SYSTEM FOR BLOOD DONOR SELECTION

1.4.1 National Policy and Legislative Framework

Blood donor counselors should comply with National Health Services Act and established Health policies in day to day activities. It is noteworthy that guidelines used must have been reviewed at stipulated interval and updated in response to changes in epidemiology, advances in technology, the latest medical and scientific information and new evidence.

1.4.2 Guideline and Criteria on Blood Donor Selection

The implementation of donor selection process must comply with established National guideline and blood donor criteria. These will protect the health of blood donors and the recipients of transfusion. It will also help to maintain and raise standards of donor management and minimize unnecessary donor deferrals. The blood donor counselors should consider the implementation of the guidelines in

day-to-day routine settings, in both fixed and mobile blood collection sites.

1.4.3 Public Information and Donor Education

Effective public information and donor education are the first steps in the process of donor selection. The dissemination of information on donor suitability through public awareness campaigns and donor information and education materials will help to ensure that individuals who volunteer as blood donors are well-informed and likely to be accepted.

Potential donors must be informed about the health conditions and risky behavior that would make them unsuitable as blood donors and the screening tests that are performed on donated blood. This will enable prospective donors to assess their own suitability and provide an opportunity for them to self-defer. It should be made clear that there is no discrimination in donor selection on the grounds of gender, race or religion, and neither the donor nor the recipient has the right to require that any such discrimination be practiced. Information materials on donor selection process and criteria should be used, including an explanation of their rationale and objectives. These materials should be simple and easy to understand, and written in languages suitable for the donor population.

1.4.4 Infrastructure, Equipment and Facilities

It is essential that suitable infrastructure and facilities are made available in which blood donor selection can be performed in a friendly and conducive environment. Whether it is carried out in a fixed location or mobile setting, the venue for donor selection should provide adequate privacy and confidentiality.

A pleasant atmosphere for blood donation will encourage donors to relax and help to reduce anxiety. Space used for donor selection should be arranged to maximize the opportunities for confidential discussion between BTS staff and donors.

Sufficient, suitable and well-maintained equipment for donor health assessment should be available. This includes equipment for haemoglobin screening, aneroid sphygmomanometers, weighing scales and essential consumables, such as disposable sterile lancets, disinfectants and stationery.

1.4.5 Financial and Human resources

A system of adequate and sustainable finances is imperative for a stable and sufficient supply of safe blood and blood products. The cost of public information programme, donor education and donor selection is an important component of the BTS's operating costs. A dedicated budget will therefore be allocated for training of staff, the development of information, education and communication materials, and the supply of equipment and consumables required for assessing donor suitability. Effective donor education, recruitment and selection contribute to minimizing the collection of blood from unsuitable donors, thus reducing the wastage of blood, consumables, and donor and staff time.

The responsibility for donor selection and care lies with a qualified medical personnel in attendance at the donation session. Staff involved in donor selection shall be appropriately qualified, well-trained and skilled in providing information, advice and counseling in order to assess donor suitability for blood donation.

Staff working in donor selection should have an understanding of the principles and basis for donor selection criteria and have the technical and clinical skills required in performing the health and risk assessment. The key skills, knowledge and competencies required for staff involved in donor selection include:

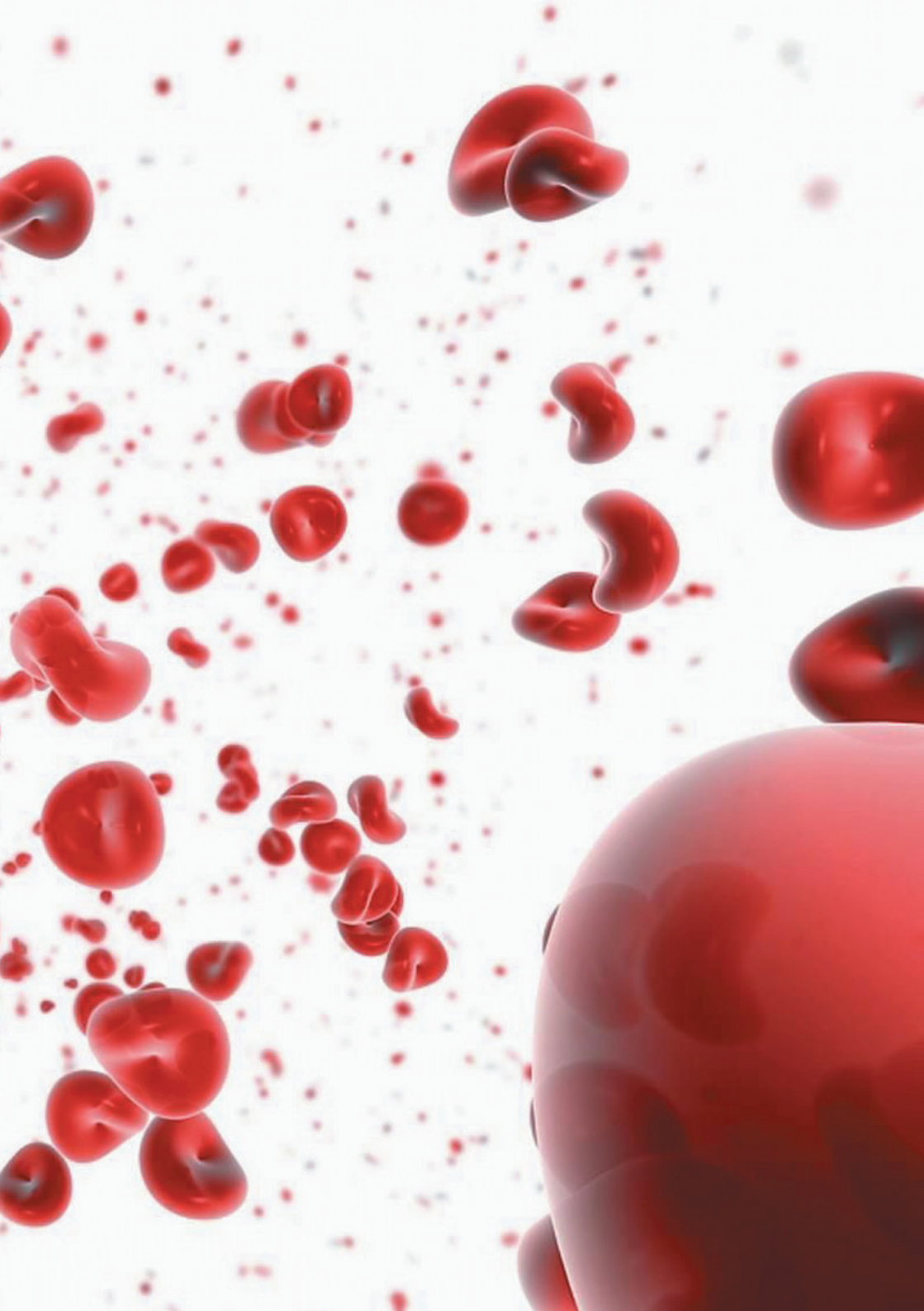
- Understanding of the donor selection criteria
- Pre-donation information and counseling
- Interview and assessment based on a standardized donor questionnaire
- Ability to explain questions in the donor questionnaire, ensure understanding and allay donors' apprehensions
- Basic health check, including haemoglobin screening
- Counseling of deferred donors
- Post-donation advice and care.

1.4.5 Quality Management System

The implementation of a quality management system is a pre-requisite for a consistent approach to donor selection. Essential elements of a quality system

in the donor selection process include:

1. An organizational structure that defines the authority, responsibility and reporting channels of all personnel, including written job specifications.
2. Donor selection criteria, as part of the national guidelines for NBTS, to ensure uniform application in every facility in which blood donations are conducted.
3. Standard operating procedures (SOPs) that guide every process, procedure and task to ensure consistency, accuracy and donor adherence, including information on the necessary staff, facilities, forms, worksheets and references, such as: Donor interview and assessment based on a standardized donor questionnaire.
4. Basic health check, including haemoglobin screening
5. Staff training and competency assessment, including a training curriculum and training records
6. Records system (electronic or manual) that ensures traceability and confidentiality, including:
    - » Donor records associated with each donation, including completed donor questionnaires
    - » Results of basic health check and haemoglobin screening
    - » Donor deferrals and reasons for deferral
    - » Adverse donor reactions
    - » Periodic monitoring and evaluation of the donor selection process.
7. The confidentiality of donor records and the traceability of donations should be assured at all times through the use of unique identification numbers for donors and donations, and a mechanism linking donors to donations.
8. All instruments and equipment used in the donor selection process, such as weighing scale and devices for the measurement of body temperature, blood pressure and haemoglobin, should be maintained and calibrated in accordance with quality requirements. The health and safety of staff must be safeguarded, including protection from sharps injuries during haemoglobin screening. Special attention should be given to the disposal of sharps, effluent copper sulphate and other waste materials.



Chapter Two

2.0 ASSESSING DONOR SUITABILITY

2.1 PRINCIPLES OF DONOR SELECTION

Donors should be in good health at the time of donation and free of infections transmissible by blood. Rigorous donor selection should be consistently applied to all blood donors either donating whole blood or through apheresis, whether first time or repeat donors.

The purpose of donor selection is to assess the suitability of an individual to be a blood donor so that blood donation is safe for the donor and the blood products derived from this donation are safe for the recipients. The donor selection process should be carried out in accordance with the written standard operating procedures.

2.1.1 Principles Guiding Blood Donor Selection

- The NBTS has a duty of care to provide counseling to all deferred donors and referred to health centres for further consultation and management.
- Only individuals in good health should be accepted as donors of whole blood and blood components.
- The selection of blood donors should be based on regularly reviewed selection criteria, without discrimination of any kind including gender, race, nationality or religion.
- A prospective donor's health status and medical history should be evaluated for each donation, on the day of donation prior to blood collection.
- The NBTS should provide appropriate donor information and a simple donor questionnaire for health and risk assessment and obtain the donor's informed consent to blood donation.
- Staff should be suitably qualified and trained in the donor selection process.
- Good communication should be established between the NBTS staff and the donor, and donor confidentiality should be assured.

The following steps are involved in the donor selection process, prior to blood collection

- Pre-donation information
- Donor registration
- Completion of donor questionnaire
- Donor interview and pre-donation counseling
- Informed consent

Compliance with all donor selection criteria is crucial to ensure a safe blood donation process and outcomes. All potential and existing donors should be asked to adhere to the blood donor selection criteria by providing accurate information and answers to all questions asked both for protection of the health and that of patients who receives transfusion.

2.1.2 Pre-Donation Information

Pre-donation information is an important step in the blood donor selection. The process starts even before donors come to give blood through public awareness campaign and donor education. Pre-donation information provides an opportunity for the prospective donors to know about health conditions or high risk behavior that would make them unsuitable to donate blood.

This information assists the donors in deciding whether to self-defer; it may also assist in donor return if they understand the reason why they should not donate blood on this occasion.

The aim of pre-donation information is to increase donor awareness of the donor selection criteria, the process of blood donation and the tests that will be performed on donors' blood, encourage prospective donors to inform the NBTS of any medical conditions or TTI-related risks that may affect their suitability to donate blood and encourage individuals to self-defer from blood donation if they recognize that they are not suitable to donate blood due to general health or medical conditions or risk for TTI's. NBTS Tanzania provides leaflet with pre donation information to prospective donor who read prior registration and donation.

Pre-donation information should cover

- Nature and use of blood and its components; the need for voluntary

non-remunerated blood donors, the importance of maintaining healthy lifestyles.

- The blood donation process, including the donor questionnaire, donor medical history, health and risk assessment, venipuncture, blood collection as whole blood or apheresis procedure, post-donation care and the screening tests performed on donated blood.
- Rationale for the donor questionnaire and pre-donation health assessment and the importance of donor compliance in the donor selection process; and donor's duties, responsibilities and rights.
- Options for the donor to decide about blood donation prior to proceeding further, to withdraw or self-defer at any time during or after the donation process, without any undue embarrassment or questioning.
- Transfusion-transmissible infections, including HIV, HBV, HCV and syphilis, routes of their transmission, natural history and prevention; types of screening tests performed; and window period of infection and alternative testing sites for individuals seeking to ascertain their infection status .
- Possible consequences for donors and the donated blood in the case of abnormal TTI test results; the mechanism for notification about abnormal test results and post-donation counseling, assurance of confidentiality and if necessary referral for further testing, treatment and care on possible adverse donor reactions.

2.1.3 Donor Registration

All prospective donors who meet the general criteria for blood donation such as age and good health should be registered when they attend a blood donation session, even if they are subsequently not accepted for donation. Essential donor registration information includes the individual's full name, date of birth, gender and contact details.

A unique donor number should be assigned at first registration. At each occasion of donation, a unique identity using a numeric or alphanumeric system should be allotted to the donation; this should be attached to the donor questionnaire, primary blood collection bag, its corresponding satellite bags and the blood sample tubes.

During donor registration, prospective donors should be provided

with donor information and education materials and the donor questionnaire, which should be completed on each occasion of donation.

2.1.4 *Pre-Donation Counseling*

Pre-donation counseling is part of the process of donor selection in which each individual's suitability to donate blood is carefully assessed against a set of donor selection criteria at the time of each donation. It also provides donors with the opportunity to ask questions and understand the reasons for donor deferral.

Pre-donation counseling occurs immediately prior to blood donation as part of a confidential interview with a trained member of the BTS staff to ascertain the donor's medical history and assess donor health and TTI risk.

Counseling before donation presents an opportunity to enhance the donor's understanding and compliance with the process of assessing donor suitability for blood donation.

The interviewer should ensure that the prospective donor understands the pre-donation information and donor questionnaire and should create an environment that allows the donor to feel comfortable to ask and answer questions.

The donor's informed consent to blood donation should be obtained at this stage; this signifies that the donor has understood the questionnaire, has provided truthful answers, understands his/her blood will be tested for TTI and blood groups, and is willing to donate blood.

Donors deferred during this stage should be given information about the reason for the deferral and how to maintain healthy lifestyles. They should be given support and care, if necessary, and advised if and when they can return to donate.

Temporarily deferred donors are more likely to return if they are told the reason for the deferral and given an appointment for their next donation after the deferral period is over. For example, donors deferred due to suspected acute hepatitis infection, should be asked to seek medical advice, given relevant information such as on how the disease could resolve and advised to return for blood donation following clinical and laboratory recovery.

Objectives Pre-Donation Counseling:

1. To ensure that the donor understands all questions and responds accurately to the donor questionnaire.
2. To inform the donor that his/her blood will be tested for blood group serology and markers of TTI and the provisional test results will be given to the donor.
3. To ensure that the donor is able to give informed consent to donate and recognizes that his/her signature is an affirmation that responses provided to the questionnaire are accurate and the donor is willing to be informed of their test results.
4. To make sure that the donor is aware of all adverse reactions that may occur during donation process. Disclosing history of traveling to a country or region that puts them at high risk for TTI.

2.1.5 Donor Interview and Completion of Donor Questionnaire

Each prospective blood donor should complete a donor questionnaire to provide information in relation to the donor selection criteria established in the national guidelines. In most situations, the donor questionnaire is given to donors at the time of registration for completion before the donor interview and assessment.

The completed donor questionnaire should be reviewed prior to donation in a one-to-one confi-dential interview between the donor and a donor selection staff member so that an assessment can be made of the donor's general health, medical history and any TTI risks. It also provides an opportunity to check whether the donor has understood the questions and has answered them correctly. Many people do not understand medical terms and may be so eager to give blood that they do not recognize the significance of their answers for their own health. Assistance should therefore be provided to anyone who has difficulty in understanding the questions. Assurance about the confidentiality of the donor's medical history is essential. If donors understand why it is in their own interests to give accurate and complete information about their health, it will reassure them that their welfare is important to the BTS and may motivate them to become regular donors. The donor's ability to understand the blood donation process and provide informed consent should be assessed.

2.1.6 Informed Consent

Consent is a voluntary agreement given by the prospective donor to the donation of blood, to the testing of a blood sample for TTI, for the transfusion of the donated blood to patients and if required, for the use of the blood for additional tests, quality assurance or research purposes.

To obtain informed consent, the NBTS should provide the following minimum information to the potential donor;-

- The donation process and potential adverse donor reactions
- The tests that will be performed (TTI and others) on the samples taken from the donated blood and the reasons for these tests
- Confidentiality of all personal information, including test results.

2.1.7 Donor Deferrals

Donors who do not meet the selection criteria should be deferred on a temporary or permanent basis. All deferred donors should be treated with respect and care in a confidential manner and should be given a clear explanation of the reason for deferral and an opportunity to ask questions. They should be informed whether the deferral is to safeguard their own health and/or that of the recipient. It is the responsibility of the BTS to ensure that donors who are deferred due to medical conditions are referred for further investigations and management, as appropriate. .

2.1.8 Donor Records

The record of the donor's general health, medical history and TTI risk assessment as part of the donor questionnaire should always be signed by the donor as being correct. The questionnaire becomes part of the donor's records and documents. Records should be kept for each activity associated with blood donation, ideally in an electronic database capable of generating reports. In addition to donor identification, assessment and selection, records should reflect donor deferrals, adverse reactions or unexpected events and any unsuccessful donations.

2.1.9 Confidential Unit Exclusion (CUE)

The system of confidential unit exclusion (CUE) offers donors the opportunity to inform the NBTS immediately after donation or

subsequently if they consider that their blood may be unsafe for transfusion; this may be particularly useful if donors have been persuaded or coerced to donate. Where CUE is used, donors should be given information to enable them to contact the NBTS and to communicate that their blood should not be used for transfusion. The CUE system is designed to add an additional level of safety to the donor selection and blood screening processes and has been found to be effective in some settings. However, there is some evidence that it may have limited effect on reducing the transmission of infections through window-period donations and may lead to the discard of safe donations.

2.1.10 Adverse Donor Reactions and Post-Donation Care

Donors should be managed in a way that ensures high standards of care and assures them of the importance accorded to their health and well-being by the NBTS. Nevertheless, there are recognized adverse reactions that can occur during blood donation; these can generally be minimized or avoided by appropriate donor selection and care, and appropriately trained staff.

Donors should be provided with oral and written advice on the management of bruises and delayed vasovagal events and should also be given information about how to contact the NBTS for further advice, if necessary.

2.2 PRINCIPLES OF GENERAL COUNSELING

Counselling is defined as a professional relationship of trust that aims at helping the client to make informed choice. There are two types of counselling individual counselling and Group and/or couple counselling.

2.2.1 Counselling Theory

Establishing a theoretical orientation as a counselor is vital in working with clients in the Blood Donation Counseling Department. This is common knowledge in the field because any well-grounded professional needs a basis by which to operate. As a professional counselor, one must know how to respond to various complex individual and family issues, behaviors and emotions. Therefore, being knowledgeable and well-trained in a particular theory have the following advantages as:

- May increase counselor's competence and confidence when

working with clients in need.

- Theories tell us why people do and what they do
- Theories are applied to specific group while other theories are applied to large populations.
- Theories have been advanced to explain human growth and development.
- These counselling theories traditionally have been grouped according to their common underlying principal

This theories includes:

- Psychoanalytic theory
- Behavior theory
- Cognitive theory
- Humanistic theory

The theories provide the justification for Counselling and a basis on which practice is founded. It is important that Counsellors be able to accurately describe what they do rather than rely on the assumption that others know what they do. A Client approach to counsellor is expecting a service, and Counsellors should be able to state exactly what that service is. Counsellors have a responsibility to inform their clients about when they can help and what they cannot help - Counselling is a helping service, but it cannot help in all cases. Counselling is essentially information giving and the information must be accepted and used by the client in order to effect changes in himself/herself.

Psychoanalytic theory

- Psychoanalytical theory was developed from the work of Sigmund Freud; an Australian psychiatrist (1856-1939). His work centred on the unconscious mind and investigates the drives and impulses for behaviour.

Behaviour theory

- This theory deals with behaviour in the here and now. The past is insignificant, it focus on behaviour that is observed and how an individual interacts with his/her environment. It stress the importance of environmental, rather than biological or cognitive factors as determinant of development. (I.P Pavlov (1849 – 1946),

J.B Watson (1878-1958) and B.F Skinner (1904-1990)

- Behavioural theory is based on the premise that preventing HIV transmission requires either reinforcing safe behaviours changing unsafe ones.

Cognitive theory

- Cognitive approaches to personality theory stress the importance of rational thought processes and phenomenological approach. People react individually to situations based on their perceptions rather than objective reality. Piaget (1936/1952) among cognitive theorists, Piaget has had the greatest impact on developmental psychology, concludes that development is a process of adaptation and active seeking to understand the environment.

Humanistic theory

- Carl Rogers (1902-1987) and Abraham Maslow took humanistic approach to personality theory. They believed in the basic goodness of human nature and inherent desire of individuals to achieve higher level of functioning. Humanistic theory emphasizes the essential elements of being human-the genuineness, inherent worth and dignity of human beings and people should explore their potential for growth and achievement.

2.2.2 Basic Communication Skills

- Communication is defined as a means of getting your feeling to reach the other person and it is regarded as a process of passing information and understanding from one person to another. Communication process is the key to counselling and in order to be effective counsellor, good concepts of communication skill are very vital ccommunications involves:

Importance of Effective Communication

- It is communication that ensures the correct message from the sender reaches the receiver.
- It involves the ability to listen, pay attention, perceive and respond non-verbally and/or verbally.
- It also involves seeking for clarification and getting the answers
- Preparation for effective communication requires the following information

- Follow the procedures that require efficiency for effective communication

For effective communication, one should use a number of techniques. The techniques used are:

» Listening skills

» Checking understanding

» Questioning and Answering skills

» Observation skills

» Probing and Summarization skills

2.2.3 Basic Stages in Counselling

The stages in counselling process;

- Relationship building
- Exploration
- Understanding
- Action plan
- The four stages in the counselling process is remembered by the acronym "REUNDA"

Relationship building

- Creation of rapport between the counsellor and the client.
- Very crucial at the beginning of the counselling process.
- It puts the client at ease and makes conditions easy for effective counselling.
- In counselling setting relationship building takes on a more specific meaning.
- Skills used in relationship building are, Social skills such as respect, trust and sense of psychological comfort, cordiality questioning and summarization and nodding.

Exploration

- Collecting and clarifying information related to the client's reason for seeking counselling.

- The counsellor is finding out client's problems, needs, misinterpretations and behaviours.
- It is successfully achieved through the act of asking questions mainly open-ended questions rather closed.
- Skills used in exploration are; Active listening skills, open ended questions, reflecting of feelings, summarizing, cordiality, respect, concreteness, paraphrasing, minimal encourages, imminence and reflection of feelings.
- Having defined the problem the counsellor takes the client to the stage of mutual understanding.

Understanding

- The rapport has to be developed and the client has to air some of the issues so as to reach great understanding.
- The counsellor summarizes what his/her client has been telling to seek client's approval for action plan.
- Skills used in understanding are warmth, trust, respect, genuineness, concreteness, questioning, summarization, self-disclosure, reflection of feelings, minimal encourages and imminence.

Action Plan

- Action plan is last stage where the counsellor and his/her client sum up what has transpired throughout the session.
- At this stage a client can make a decision towards his/her problem.
- The following can be agreed upon:
  - » To make a decision towards the identified problem
  - » To postpone the session to another date
  - » To refer the client to another counsellor
  - » To terminate the process.

2.3 Principles of Blood Donor Counseling

Blood donor counseling is a confidential dialogue between a blood donor and a trained counselor about issues related to the donor's health and the donation process; it may be provided before, during and after blood donation. There are benefits for both the NBTS and the wider health system in implementing blood donor

counseling. It minimizes the unnecessary loss of suitable donors while maximizing the retention of donors, including those who are temporarily deferred.

Counseling provides an opportunity for the NBTS staff to assist donors to provide informed consent for blood donation and to defer unsafe donors; it also aids donors to self-defer if they are aware of having been exposed to any risk of a transfusion-transmissible infection or have a known health condition or have had a treatment that could influence their suitability to donate blood.

Reducing the donation of blood by unsuitable donors that subsequently has to be discarded will decrease the wastage of resources, including donor and staff time, consumables and screening tests, and also avoid needless discomfort to donors. Blood donor counseling contributes to blood safety by reducing the prevalence of TTI in donated blood and assists in maintaining a pool of safe, healthy and reliable voluntary non-remunerated blood donors.

The counseling of blood donors is an important means of promoting healthy lifestyles and makes an important contribution to individual and community health. In addition, counseling contributes to the early diagnosis and treatment of conditions such as anemia, blood disorders and infections.

This offers a crucial early entry point for the treatment and care of donors found to be infected and may contribute to delaying or preventing the development of full-blown disease or complications. This duty of care extends beyond donors themselves to their families and the general population as these individuals may infect others if they are not aware of their infection status. Donor counseling thus contributes to the continuum of care in the health system, plays an important role in preventing the further transmission of infections, contributes to the containment of epidemics and reduces the disease burden on the national health system.

Donor counseling may also reduce adverse donor reactions, improve donor perceptions of the BTS, encourage donors to recommend blood donation to friends and family and, most importantly, increase the likelihood of returning for future donation (5). This is particularly valuable for BTS in the process of transition from a reliance on first-time or family replacement donors to regular voluntary non-remunerated blood donors (VNRBD).

2.3.1 Scope and Content of Blood Donor Counseling.

Pre-donation information and counseling are linked to the process of donor selection in which each individual's suitability to donate is carefully assessed against a set of criteria related to their medical history

and risk for TTI. This is followed by a basic health check to: Ascertain that they are healthy, suitable to give blood and will not be harmed by blood donation; and avoid collecting blood from individuals who may be unsuitable due to the risk of TTI or other health factors that may harm patients.

The effectiveness of the donor selection process is enhanced if relevant information and counseling are provided to prospective donors, enabling them to self-defer if they recognize they are unsuitable to donate blood. Blood donors may be deferred, either on a temporary or permanent basis, on the grounds of their health status, medical or travel history, or TTI risk.

Pre-donation counseling is particularly important for individuals who are temporarily or permanently deferred from blood donation, as it provides them with clear information about the reasons for deferral, maintaining healthy lifestyles, and referral for further testing, treatment, care and support, as appropriate.

Temporarily deferred donors should be encouraged to return after the defined deferral period is over. However, some donors may decide not to return because of what they perceive to be a negative experience and the fear of being rejected again.

Empathetic counseling may lessen a sense of rejection and encourage temporarily deferred donors to return after a suitable interval. Effective counseling may thus minimize an unnecessary loss of blood donors and motivate those who are unable to donate blood to support the BTS as volunteers.

Donor retention or loss is related to how donors feel about the blood center and donors with a positive experience are more likely to encourage their friends to donate blood.

The objective and content of the counseling provided to each donor depends on the conditions and situations that are being addressed. For example, counseling donors with rare blood groups with the intent of enrolling them in a rare donor panel may elicit positive emotions; conversely, revealing information such as positive TTI test results may lead to negative emotions. It is important that staff involved in donor counseling understand the key elements of counseling in different contexts and the most suitable approach to make.

The conditions and situations where blood donor counseling is particularly important are:

- First-time and young donors: To explain the blood donation process and to allay their anxiety and apprehension.
- Temporary or permanent deferral: Individuals who do not meet donor selection criteria based on the assessment of medical history and risk for TTI resulting in temporary or permanent deferral: To explain the reason for deferral (e.g. history of cancer, multiple sexual partners and provide information on further management, as appropriate.
- Temporary or permanent deferral: Individuals whose basic health check reveals a condition indicating temporary or permanent deferral: To explain the reason for deferral (e.g. presence of HBsAg or Anti- HCV positivity) and provide information on further management, as appropriate
- Individuals who may be donating blood to seek testing for infections such as Hepatitis or HIV: To understand their motivation for blood donation and provide information on voluntary counseling and testing services.
- Donors who give post-donation information that warrants temporary or permanent deferral (e.g. significant risky healthy behavior developed shortly after donation): To explain the reason for deferral and provide information on further management, as appropriate. Refer window period of Hepatitis or HIV infection.

2.3.2 Stages of Blood Donor Counseling.

There are four stages during the blood donation process when counseling should be provided to all blood donors, as shown in (Fig 4)

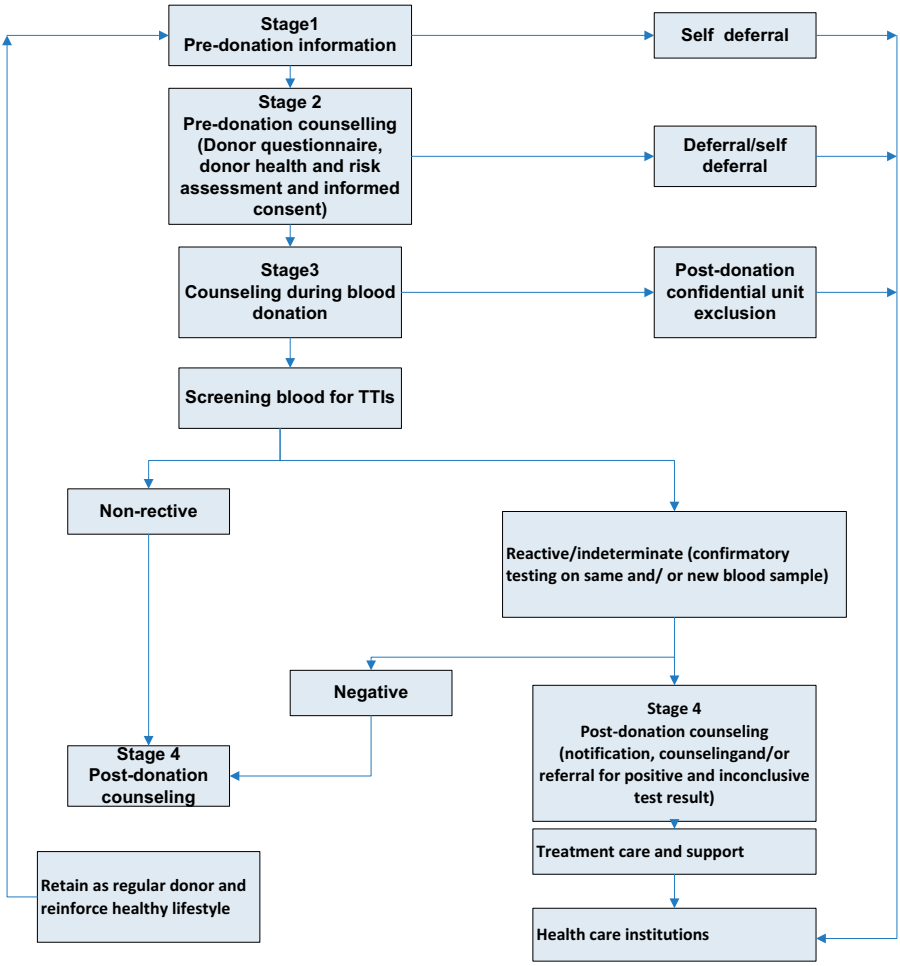
» Pre-donation information before an individual registers for blood donation

» Pre-donation counselling during the confidential interview for medical history, health and TTI risk assessment

» Counselling during blood donation

» Post-donation counselling after blood donation and testing of donated blood for blood group serology and markers of infection.

Figure 1: Stages of Blood Donor Counseling



2.3.3 Elements of Effective Blood Donor Counseling

Stage 1: Pre-donation information

Pre-donation information is an important first step in informing and educating donors about the blood donation process, including donor selection criteria and deferral or self-deferral, blood screening for TTI, blood grouping, counseling and referral. This will enable individuals who may be unsuitable to donate blood to self-defer without going through the blood donation process.

Pre-donation information may be provided orally and through printed, graphic, audio-visual and online materials and should be presented in a simple and clear format. It is usually made available to prospective donors at the same time as the donor questionnaire during the process of registration for blood donation.

Three main objectives of Pre-donation information:

1. To increase donor awareness of:
    - » The NBTS responsibility to ensure donor health and safety, and confidentiality
    - » The steps in the blood donation process and the rationale for each step, and assurance of the safety of the donation process
    - » The paramount importance of the safety of donated blood for transfusion recipients, which can be achieved through honest response and donor adherence to donor selection criteria relating to their health and risk for TTI.
    - » The importance of voluntary non-remunerated blood donation, particularly regular donation, to maintain an adequate supply of safe blood for patients who require transfusion.
    - » The purpose of blood screening for TTI in order to ensure blood safety and not to provide testing for individuals who seek to know their infection status
    - » Mandatory blood screening for TTI, including HIV, HBV, HCV, and syphilis and the limitations of these tests, including the "window period" of infection.
2. To increase donors' trust in the BTS and encourage them to:
    - » To be honest while responding to the donor questionnaire

» Inform the BTS of any recent behaviors that increased the risk of a TTI and medical conditions that may affect their suitability to donate or the safety of the subsequent donations.

3. To encourage individuals to self-defer if they:

» Are suffering from an infection, disease or health condition that may make them unsuitable to donate blood

» Have engaged in behaviors that put them at high risk for TTI

» Are known carriers of infections: e.g. HBV

» Are seeking to know their infection status for HIV or other TTI.

Stage 2: Pre-Donation Counselling

Pre-donation counselling is part of the process of donor selection in which each individual's suitability to donate blood is carefully assessed against a set of donor selection criteria at the time of each donation. It also provides donors with the opportunity to ask questions and understand the reasons for donor deferral.

Pre-donation counselling occurs immediately prior to blood donation as part of a confidential interview with a trained member of the BTS staff to ascertain the donor's medical history and assess donor health and TTI risk. Counselling before donation presents an opportunity to enhance the donor's understanding and compliance with the process of assessing donor suitability for blood donation.

The interviewer should ensure that the prospective donor understands the pre-donation information and donor questionnaire and should create an environment that allows the donor to feel comfortable to ask and answer questions.

The donor's informed consent to blood donation should be obtained at this stage; this signifies that the donor has understood the questionnaire, has provided truthful answers, understands his/her blood will be tested for TTI and blood groups, and is willing to donate blood.

Donors deferred during this stage should be given information about the reason for the deferral and how to maintain healthy lifestyles. They should be given support and care, if necessary, and advised if and when they can return to donate.

Temporarily deferred donors are more likely to return if they are told

the reason for the deferral and given an appointment for their next donation after the deferral period is over. For example, donors deferred due to suspected acute hepatitis infection, should be asked to seek medical advice, given relevant information such as on how the disease could resolve and advised to return for blood donation following clinical and laboratory recovery.

Objectives Pre-donation counseling has the following objectives:

- To ensure that the donor understands all questions and responds accurately to the donor questionnaire.
- To inform the donor that his/her blood will be tested for blood group serology and markers of TTI and the provisional test results will be given to the donor.
- To ensure that the donor is able to give informed consent to donate and recognizes that his/her signature is an affirmation that responses provided to the questionnaire are accurate and the donor is willing to be informed of their test results.
- To make sure that the donor is aware of all adverse reactions that may occur during donation process.
- Disclosing history of traveling to a country or region that puts them at high risk for TTI

Stage 3: Counseling during blood donation

Counseling during blood donation provides an opportunity to explain the venipuncture procedure, show appreciation to donors for their valuable contribution and enhance donor satisfaction with the donation experience and the BTS. Counseling during donation also has an impact on donor motivation and return for future donations.

Counseling during this stage should be provided by donor care staff who have been trained in interpersonal skills as well as skills in performing skin disinfection and venipuncture for blood donation.

Donor care staff with good communication skills and an ability to interpret the nonverbal cues of blood donors, such as the signs of an impending reaction, and interact socially can reduce adverse donor reactions such as pre-syncope. Adverse donor reactions may deter donors from returning to donate in the future and the interpersonal skills of donor care staff have been shown to be inversely related to donor reactions.

Counseling during blood donation may encourage donors who did not reveal potential risks of exposure to TTI during pre-donation counseling to do so, even after donation; this may be particularly important if donors have been persuaded or felt coerced to donate or if they are seeking to ascertain their infection status.

Objectives of Counseling during the blood donation procedure

- To ensure that donors feel comfortable during blood donation process, including the venipuncture.
- To reduce donor anxiety and minimize the risk of any adverse donor reactions, such as fainting.
- To give post-donation advice, including care of the venipuncture site
- To foster donor trust and confidence for donor retention.

Stage 4: Post-donation counseling.

All donated blood should be screened for markers of TTI to ensure the microbial safety of the blood supply and verify that the donation is safe to be used for therapeutic purposes.

In the case of reactive screening results, confirmatory testing should be performed to identify truly infected donors or donors with nonspecific reactivity or inconclusive results; this should be done before the donors are informed, notified and counseled about their infectivity status.

- Donors confirmed to be infected should be notified of their infection status, counselled, deferred from blood donation and referred for treatment, care and support.
- Donors showing repeated reactive results on screening and negative results on confirmatory testing should be informed, reassured, counseled and temporarily deferred until they are non-reactive in a screening assay. Once this becomes negative, they can be accepted again as blood donors.
- Donors with unclear confirmatory testing results, where infection cannot be ruled out at that point in time, should be informed, counselled and deferred temporarily, usually for up to six months. If screen non-reactive and confirmed negative on follow-up, they can be accepted as blood donors in the future.

The donor's record of donations should be updated with the details of the test results, the fate of the donations, the outcomes of counseling and referrals for treatment and care.

Post-donation counseling should be provided as soon as practicable after test results are available. It should be undertaken by a trained health-care professional who is able to explain the results, elicit the donor's medical history and, in the case of a positive TTI test result, counsel the donor with understanding and empathy.

The counselor should allow sufficient time for the donor to comprehend the test results and any health issues that may arise, and provide an opportunity for the donor to ask questions or raise any concerns. Referral to a physician, a specialist or an external agency for further management, treatment and care should be discussed. Any possible risk of further transmission of the infection should be explored and the importance of healthy lifestyles reinforced.

Post-donation counseling should always be conducted privately in a safe and conducive environment that protects the donor's confidentiality. It should be provided in a language with which the donor is familiar and in a culturally sensitive manner. Because of the stigma and discrimination that may arise from having a positive TTI test result, it is vital that BTS staff understand that any sensitive information given by donors must be kept strictly confidential and secure at all times donors should be assured of confidentiality of the information given to the NBTS.

Objectives of Post-donation Counseling:

- To explain and encourage the need for repeat and regular donation for donors found to be non-reactive on blood screening.
- To explain the test results, the need for confirmation of the results, the health implications for the donor and the suitability of the donor for future blood donation.
- To clarify doubts or concerns raised by donors and alleviate donors' anxiety.
- To provide information on precautions for preventing the transmission of infection to others.
- To provide information and refer donors for further investigation, management, treatment and care, if necessary.

» To reinforce the importance of healthy lifestyles for donors found to be non-reactive on blood screening.

Table 1: Examples of essential elements of blood donor counseling in different situations and conditions

S/N	**Situations and conditions**	**Essential elements of counseling**
1.	First-time blood donor and young donor	• Explanation of the entire blood donation process • Reassurance to allay anxiety and apprehension • Promotion of a healthy lifestyle • Encouragement to self-defer if the donor might have been exposed to a TTI, and referral to voluntary counseling and testing services. • Information on the screening of blood for TTI and the test results • Encouragement to return for future blood donations and become a regular blood donor.
2.	Donor deferred temporarily or permanently for not meeting donor selection criteria during the assessment of medical history or basic health check.	• Explanation of the reason for deferral: e.g. for donor and/or patient safety and information about the condition for which the deferral is made • Clarification of the nature of the deferral (permanent or temporary) • Reassurance to allay anxiety and apprehension • Encouragement of temporarily deferred donor to return for future blood donations after the defined deferral period

3.	Donor with risk for TTI: a) Self-deferred b) Deferred temporarily or permanently during pre-donation counselling	• Exploration of motivation for blood donation • Explanation of the reason for deferral and information on the specific risk for TTI • Clarification of the nature of the deferral (permanent or temporary) • Encouragement of temporarily deferred donor to return for future blood donations after the defined deferral period • Information on how to maintain a healthy lifestyle **Examples:** » Donor with specific risk for TTI: refer to a health-care institution for treatment, care and support and provide information on relevant TTI, Including HBV and HCV. » Donor seeking to ascertain infection status: provide information on voluntary counselling and testing services.
4.	Donor who: a) Requests confidential unit exclusion (CUE) b) Gives post-donation information that warrants temporary or permanent deferral	• Exploration of motivation for blood donation • Explanation of the nature of deferral (permanent or temporary), based on the risk for TTI • Encouragement of temporarily deferred donor to return for future blood donations after the defined deferral period • Information on how to maintain a healthy lifestyle.

5.	Donor showing repeated reactive TTI results on screening and negative results on confirmatory testing	• Explanation of the repeated reactive test results, the need for confirmatory testing and the results of confirmatory testing • Information about the donor deferral period: i.e. until screening test is non-reactive on follow-up • Reassurance to allay anxiety and apprehension • Encouragement to return for future blood donations as the confirmatory test results are non-reactive • Information on how to maintain a healthy lifestyle
6.	Donor with indeterminate TTI test results with unclear confirmatory results, where infection cannot be ruled out	• Explanation of the indeterminate test results, the need for confirmatory testing and the results of confirmatory testing • Information about the fate of the blood donation • Exploration of all relevant information, including possible TTI risk • Explanation of the need for temporary deferral and repeat testing • Reassurance to allay anxiety and apprehension • Information on how to maintain a healthy lifestyle
7.	Donor found to have confirmed positive markers for TTI	• Explanation of the positive TTI test results • Information about the health implications of the positive TTI test results for the donor and the donated blood (discard) and the suitability of the donor for future blood donations • Exploration of all relevant information, including the possible TTI risk • Reassurance to allay anxiety and apprehension • Information on how to prevent further transmission • Referral for further investigation, management, treatment and care, if necessary

2.3.4 Skills in Blood Donation Counseling:

Since counselling is a conversation (sharing information), effective communication is essential.

Focus on 4 important skills

1. Attending

Means to pay careful attention, give posture that indicates involvement, face the patient/client, make eye contact, lean forward and be relaxed so you can put your patient/ client at ease.

2. Listening

Show interest to hear the whole message; Watch for non-verbal messages; give feedback to confirm you heard what was actually being said; Put the message in the context of the patient's reality.

3. Empathy

This is to Acknowledges the feelings of the patient "Stepping into their shoes" e.g. Counsellor tries to imagine herself in the place of the patient to understand how it feels. Involves listening to the patient, understanding them, and communicating this understanding back to them. Empathy, offers support, builds trust, encourages the patient to engage in the counselling session and gives an opportunity for more effective intervention.

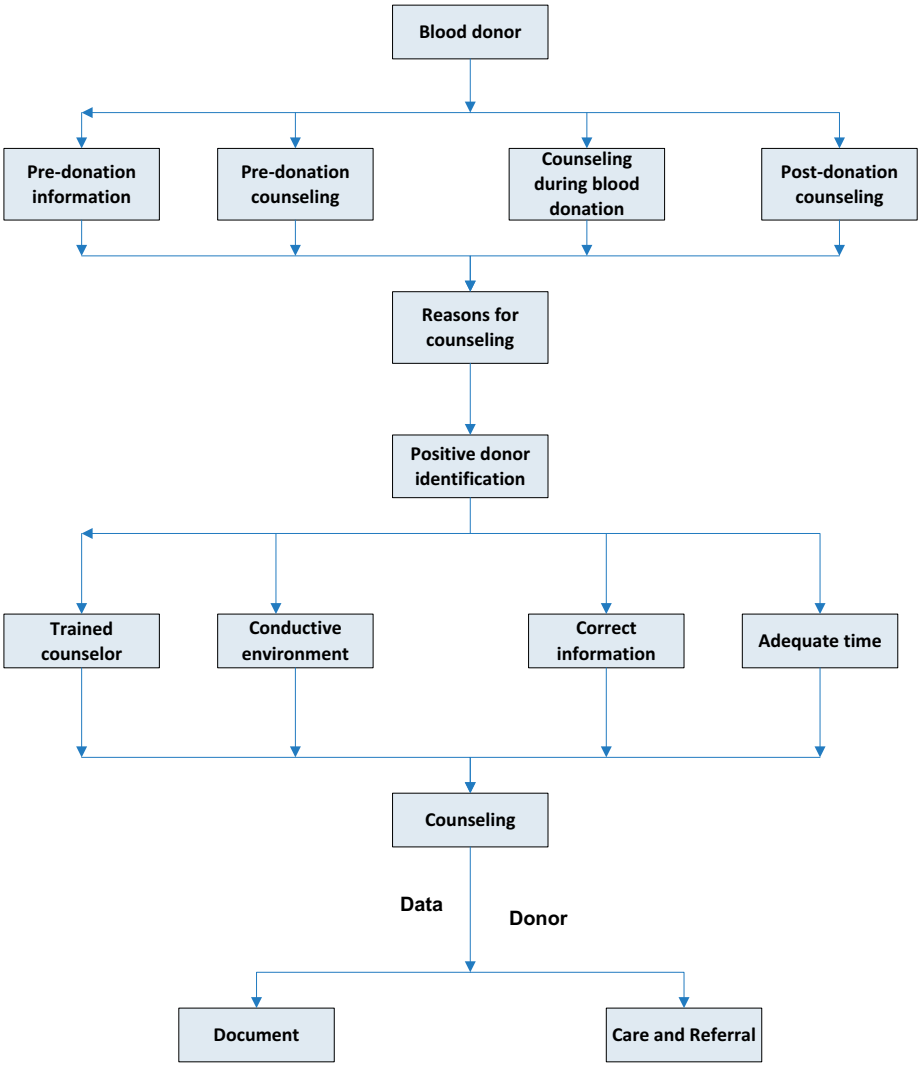
4. Immediacy

Is to step back and noting what is going on "now". What is happening in the counseling relationship as it is happening. By using immediacy the counsellor can help identify a problem and move beyond it.

Immediacy can be used in the following situations:

- When a session is directionless e.g. I feel like we aren't making any progress
- When there is tension e.g. we seem to be getting on each other's nerves. May be we should stop for a moment
- When there is a lack of trust e.g. I sense that you are afraid to talk with me

Figure 2: Elements of Effective Blood Donor Counseling



2.4 POST DONATION COUNSELING IN BLOOD SAFETY

Post donation counseling is a confidential dialogue between a blood donor and a trained counselor about issues related to the results of his/her donated blood. This is counselling done after test results are out regardless of positive or negative test result to enable clients to deal with emotional reactions from the test result and to make informed decisions. It is also acknowledged to be an integral component of donor care for informing the donors of test results hence all donors are encouraged to seek their test results. During post donation counselling donors are informed of their test results and the need for behaviour change or maintenance, depending on the test result.

Post donation counseling is essential for early clinical intervention to minimize their disease and the risk to the partners/close contacts. As per the present protocol each reactive donor is informed about the abnormal test results, counseled and referred for further confirmation and management to the concerned specialty.Reactive donors are intimated by post donation counseling for one-to-one counseling and repeat sampling and to elicit any high-risk behavior. The present policy dictates information and referral of HIV-reactive donors to the CTC for further management and referral of HBV and HCV reactive donors to the gastroenterologist.

Post donation counseling of a blood donor about the abnormal test results is thus a very sensitive and crucial aspect of post-donation counseling as it has its psychological and social impacts. Each donor reacts in a different manner, some people faint, get angry, deny vehemently, start weeping, very calm apparently followed by nervous breakdown and various other emotional disturbances. In Tanzania, post donation counseling involve the following tests

- Blood grouping
- HIV
- HBV
- HCV
- Syphilis

2.4.1 Objectives of Post Donation Counseling (PDC)

- To explain the test results, the need for confirmation of the results, the health implications for the donor and the donated blood (discard) and the suitability of the donor for future blood donation.

- To encourage donors to provide all relevant information, including the possible source of infection.
- To clarify doubts or concerns raised by donors
- To alleviate donors' anxiety.
- To provide information on precautions for preventing the transmission of infection to others.
- To provide information and refer donors for further investigation, management if necessary.
- To reinforce the importance of healthy lifestyles for donors found to be non-reactive on blood screening and encourage regular blood donation.

2.4.2 Importance of Post Donation Counseling (PDC)

- It prevents further transmission of infection.
- It improves donor good perception of BTS
- Increases likelihood of returning for future donation(repeat donors)
- Encourage to recommend blood donations to friends and family.

Definition of test results in Blood Safety

- In blood safety there are two sets of results given in blood safety. The initial test is given for blood sorting and issuing to patients.
- The blood unit with initial positive test results for all TTIs are discarded
- In case of reactive screening results supplementary testing is performed to identify truly infected donors.
- All donors to be notified about infectivity status, counselor should use conclusive supplementary results
- Make any follow-up appointment if necessary.

2.4.4 Principles of Post-Test Counselling: Positive and Negative Result

Prepare yourself for the result-giving by:

- Checking you have the correct result and it is matched to the right client

- Making sure you understand what the results mean before sharing
- Making sure you have the time to spend with the client
- Be sure you are emotionally ready, by being there to empower the client, and if you are not, if available, find another qualified health professional to support the client or receive coaching before you meet with the client by a trained counsellor

Greet and welcome the client and assess if the client is ready for the result.

- Allow the client to lead the session and provide a safe and caring environment.
- Allow the client's issues to be discussed at the client's pace.
- Give the result calmly, professionally and empathically.
- Wait for the client's response. Accept and normalize any of your responses and feelings that have been evoked. Common feelings are shock, disbelief, guilt, blame, loss, sadness, hopelessness, helplessness, fear, anxiety, or agitation.
- At this time the client needs to feel the presence of the counsellor and that she or he is able to disclose feelings. The client may forget or block out this period however will remember you were there for them.
- The client is facing multiple losses: health, future, normality, fitting in, sexuality (such as abstinence), etc. and it may be useful to think of the client as having to grieve and mourn for these losses, there is often a need to over-reassure.
- Discuss disclosing to a supportive person such as an Elder, spiritual healer, or family member that they can trust.
- Ask whether there is a partner involved and how this person will be told.
- If the client cannot tell their partner that they have HIV, discuss how they can negotiate safer sex, or safer practices such as, the dangers of sharing needles or other drug equipment until they have disclosed.
- Explore the client's current relationship, and if there is a relationship then discuss disclosure of HIV status.

- Be prepared to give thorough assistance to the client with the "telling", and being there when it happens for anyone they may want to disclose to. Be prepared to provide culturally appropriate educational and awareness material.
- Explore lifestyle changes that includes: cutting down or abstaining from alcohol or harmful substances, getting sufficient rest and sleep appropriate daily physical activity, managing stress and anxiety, eating nutritious food and a balanced healthy diet, use of supplements and immune boosters safer sexual behaviours and re-infection, safer blood practices and infection control, ways to practice traditional wellness.
- Plan in a clear and concrete manner how the client will manage the next 24hours.
- Give appropriate contact numbers and arrange a follow-up appointment, for the next day if needed. Assess the need for future support and contract for appropriate number of sessions with yourself or another health professional.
- Before the client has left, assess their suicide risk and respond accordingly.

2.4.5 Disclosure of HIV Positive Status

Whether or not to disclose their HIV-positive status is a difficult decision for HIV infected individuals to make because disclosure (or non-disclosure) is often followed by major and life changing consequences. Counsellors should help their clients to carefully consider the benefits as well as the negative consequences disclosure may have for them.

Potential Benefits of Disclosure

- Could help the client to accept their status and reduce the stress of coping on their own.
- Could help the client to access the medical services, care and support that they need.
- Could help the client to protect themselves and others. Openness about HIV status may help women to negotiate safer sex practices.
- It could help to reduce the stigma, discrimination and denial that surround HIV/AIDS.

- Disclosure promotes responsibility-it may encourage the client's loved ones to plan for the future.

Possible Negative Consequences of Disclosure

- Lack of support from family and friends, leaving the client to deal with everything on their own
- Being subjected to angry partners, family or friends, and/or abusive or violent responses
- Placing others at risk of infection, particularly sexual partners and increasing the risk of re-infection for the client.
- Not being able to access appropriate medical care, counselling or support groups.
- People may become suspicious of the clients' actions and behaviours.

2.4.6 Counselling Guidelines for Disclosure

Disclosure is a process, and it is not an event. The counsellor should assist the client in carefully thinking through the pros and cons of disclosing their HIV status and planning ahead before they do. Clients should decide if they want full disclosure i.e. publicly/openly revealing their status, or partial disclosure i.e. only certain people – spouse, relative or friend.

- Allow the client to develop trust in you and feel at ease.
- Discuss the implications of disclosure fully, to help the client consider in advance, the reactions of family, friends, work colleagues and others.
- Help the client to develop a plan. This should include whom they will inform first, how and where they will disclose and the level of disclosure.
- Prepare the client for an emotional, shocked, or a hostile reaction from other people.
- Reassure clients that people close to them will probably learn to accept their HIV status over time.
- Assess the client's ability to cope and establish their sources of support.

- It is important for a client to be strong enough to allow others to express their feelings and concerns after their disclosure. Assist the client to work on these issues over time.
- Provide the client with information and support to 'live positively' and give information on safer sex practices, and reducing risk behaviours.
- Counsellors should protect their clients against undue pressure to disclose.
- The counsellor or someone they feel safe with, such as an Elder, should be willing to mediate the disclosure process and follow up with HIV education and awareness material if the need arises.
- Identify sources of support, such as support groups for people living with HIV/AIDS, and counselling organizations.
- Arrange to see the client again at a time and date agreed by both of you to review this process.
- Provide education and awareness information that the client can share with individuals he or she may disclose to so they may understand HIV better.

If the results are negative:

- Check your patient understands how to protect themselves from HIV (e.g. safe sex, safe injecting practices, other high risk behaviours modified).
- Review the window period and question is there is a need to retest. If the results are positive:
- Provide support and written information about living with HIV, possible treatments, and community resources.
- Provide advice and referrals on where the client can get support for health and mental wellness.
- Discuss contact tracing/partner notification with your client.
- Discuss harm reduction strategies such as safe sex and safe injecting practices.
- Offer appointments for family doctor and specialist follow-up.

2.5 Ethical and Legal Considerations in Blood Donor Counselling

2.5.1 Rights and responsibilities of the NBTS staff and Blood Donors

The primary responsibility of the NBTS staff is to ensure a safe blood supply and to protect the health of blood donors and blood recipients. The right and obligation to defer unsuitable donors is based on a risk assessment of the blood donor physically and using epidemiological data. It is also the responsibility of the NBTS staff to provide appropriate counselling services to individuals who have been deferred.

The NBTS staff should provide a safe and pleasant environment for blood donors, treat them with respect and obtain their informed consent before blood donation. Donors should be given all relevant information and, in particular, provided with TTI test results. The NBTS staff should ensure and assure donors of the confidentiality of all personal information they provide, notably those related to health and exposure to TTI risks. The NBTS staff has an obligation to blood donors to ensure the notification of positive test results and the availability of appropriate counselling and referral.

Prospective Blood donors have rights and responsibilities. These include,

- Right to clear and appropriate information, including the purpose of donor selection, and the consequences of failure to provide the relevant information to the NBTS staff.
- Responsibility to provide the NBTS staff with all relevant information to the best of their knowledge about health conditions that may pose risks for their health and about activities or behaviours that increase their risk for a TTI
- Responsibility to self-defer from blood donation if they believe they are unsuitable to donate; no donor should use blood donation as a means to obtain medical check-ups, to know their HIV status or to be tested for other TTI
- Right to withdraw from blood donation at any time during the procedure for any reason, including doubts as to their suitability as a blood donor, without any need to explain this decision
- Responsibility to inform the NBTS staff after donating blood if they

have any doubts about their suitability or in the event of a change in health status within 28 days after blood donation.

2.5.2 Confidentiality and Privacy

Confidentiality refers to the obligation of health-care professionals and healthcare institutions not to disclose personal and sensitive information about their blood donors to third parties. This duty has long been codified in the Hippocratic Oath and is still one of the core principles of medical ethics.

Strict confidentiality of personal information about donors and their test results should be ensured at all times. A breach of confidentiality may negatively affect the relationship between the NBTS and the community it serves. Confidentiality of donor records should be ensured through the use of unique numbers for donors and donations and the use of codes for infection markers.

Medical data should be shared only with other health-care providers who are, or will be, directly involved in the subsequent care of the donor. Otherwise, no confidential information should be shared without the consent of the donor. In particular, anonymity between blood donors and the recipients of their blood should be ensured. Because of the stigma and discrimination that may be associated with abnormal TTI test results, confidentiality of these results is crucial.

Privacy refers to a person's right to not be asked about matters of a personal nature. Under the ethical principle of respect for a person's autonomy, health workers have an obligation to respect privacy. Therefore, blood donor counselling should be provided in a setting designed to ensure reasonable audio and visual privacy.

In addition to being an ethical obligation, maintaining confidentiality and privacy contributes to a safe blood supply by reinforcing donors' confidence that personal information revealed to NBTS staff will be protected and not shared with any unauthorized person. Potential donors may be more willing to share all relevant, sensitive information if they trust that it will be handled in a confidential manner. The training of NBTS staff and volunteers should include how to ensure privacy of blood donors and confidentiality of donors' personal information and test results

2.5.3 Informed Consent

Informed consent is a voluntary agreement given by the prospective donor to the donation process, including the ***donation of blood***, ***potential adverse reactions***, ***the testing of their donated blood for TTI*** and ***blood group serology, notification of abnormal results*** and, if applicable, ***the use of blood*** for additional tests, quality assurance or research purposes. Informed consent is a process based on the ethical principles of autonomy and respect for the individual. Blood donor must consent that their information may be released to a third party.

Informed consent is obtained during pre-donation counseling when the donor has an opportunity to ask questions. The NBTS staff should provide the following minimum information to the potential donor:

- The blood donation process and potential adverse donor reactions
- The tests that will be performed (TTI, blood group serology and others) on the samples taken from the donated blood and the reasons for these tests
- Confidentiality of all personal information, including test results
- The mode of communication with the donor about unusual or abnormal test results
- If applicable, a sample of the blood or the donated blood unit may be used for additional tests, quality assurance or research purposes, in accordance with the national policies.

Donors should be explicitly informed before blood donation that they will be informed of any abnormal TTI test results. If they are unwilling to receive the TTI test results, they should be counseled and deferred because the NBTS has a duty of care to blood donors. When donors do not wish to know their TTI test results, the NBTS cannot fulfill its duty to provide care through counseling, referral for treatment and support, and in the prevention of further transmission. In the event that a potential donor refuses to provide consent, the blood donation shall not be drawn.

2.6.4 Voluntary partner Notification and Counseling for HIV and other TTIs

In the case of a positive test results for HIV or other TTI, the blood donor has an ethical obligation to inform his/her sexual partner(s),

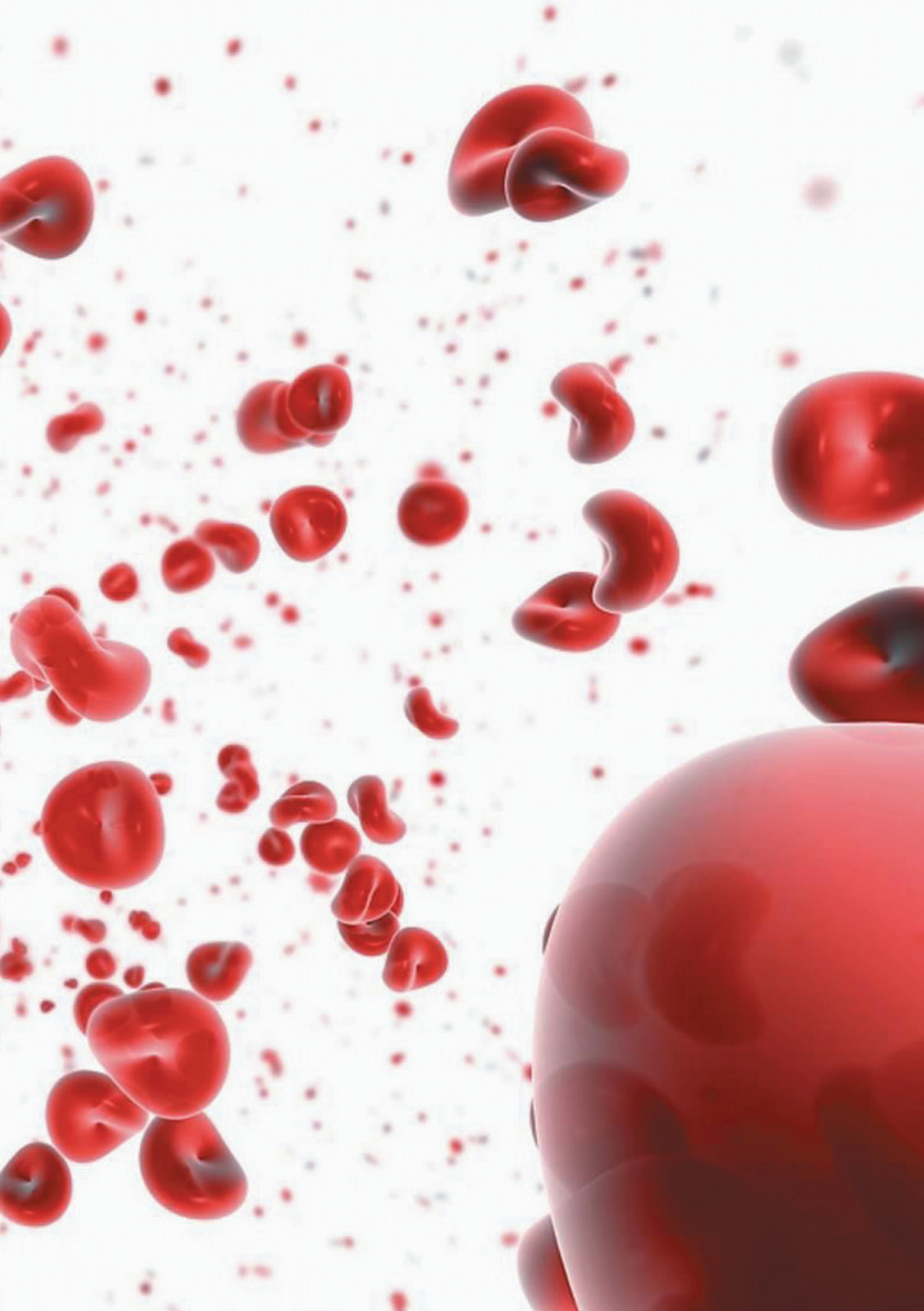
and the NBTS staff should encourage and support the individual in doing so. In particular, a HIV-positive person should be referred to a specialized counseling site that will be able to assist them in partner counseling.

2.5.5 *Stigma and Discrimination*

The social act of voluntary non-remunerated blood donation often provides donors with high self-esteem. If a donor is deferred, disappointment is therefore a natural emotive reaction.

When faced with deferral, or what may be perceived as rejection, the individual's self-esteem may be affected adversely. For an individual who has tested positive for a TTI, stigma, silence, denial and discrimination may undermine prevention, treatment and care efforts and may have a negative effect on the individual, family and community. The NBTS staff should maintain a climate in which there is no stigmatization of deferred donors or discrimination against them.

As part of community education and pre-donation information, the NBTS staff should inform the general public that donor deferral can occur for many different reasons. Counseling sessions should be set up to avoid potential stigmatization. For example, in recruiting donors from schools or other community settings, care should be taken to ensure that deferred donors are not identified or stigmatized, regardless of the reason for deferral. In counseling deferred donors, NBTS staff should carefully explain the reasons for the deferral and attempt to positively reinforce the deferred donor's self-esteem.



Chapter Three

3.0 CRITERIA FOR BLOOD DONOR SELECTION

3.1 General Blood Donor Assessment

Only individuals in good health should be accepted as blood donors. Donors should feel well on the day of donation and be able to perform their routine daily activities. Information about minor illnesses, exposure to communicable diseases, travel to disease endemic areas, pregnancy and lactation and medical and surgical interventions should be elicited so as to determine suitability for blood donation or the need for deferral.

This guideline will provide guidance on what to look for and when to refer a donor to a health-care professional for further medical attention.

Donor Appearance and Inspection

Prospective donors should be accepted only if they appear to be in good health and comply with donor selection criteria

Frequency of Blood Donation

- The minimum interval between donations of whole blood should be three months for males and four months for females
- The minimum interval between donations of platelets should be one month in apheresis
- The minimum interval between donations of plasma should be two weeks in apheresis
- The minimum interval before an apheresis platelet or plasma donation should be one month from the last donation of whole blood, an apheresis red cell donation or a failed return of red cells during apheresis. The main reason for this interval is to allow maturation of newly produced cells and prevent iron depletion

Fluids and Foods before Blood Donation

Before blood donation, the staff should enquire if the donor has eaten in the past four hours. Any donor who has not eaten shall be given a drink and snacks before he/she donate in order to minimize the risk of vasovagal reactions.

3.2 Social Demographic Information

1. **Age limit:** According to this guideline, the age of blood donors in Tanzania ranges between 18 and 65 years. Lower age limit is based on the law of Contract Act of 1961 Cap 433 and The Age of Majority Act(Citizenship Laws) of 1970 which define 18 years age in Tanzania for an individual to give independent consent to participate in blood donation, medical care, including HIV testing, treatment and counseling. Individual aged 17 years or younger in Tanzania are not legally able to consent for blood donation, however blood donor with inability to comprehend with test results may donate blood after a written consent of a parent or recognized guardian.

   The upper age limit of 65 years is based on the fact that older donors have increased incidence of cardiovascular disease, bone marrow degeneration and potential risk of adverse reactions mostly in first-time donors. All prospective blood donors with age above 65 should only be allowed after proper evaluation and endorsement by the blood center physician every year.

2. **Pregnancy, Lactation and Menstruation**

   The average woman need about 350-500mg of additional iron to maintain iron balance during pregnancy. Female donors should be deferred during pregnancy and Lactation, but also should be deferred for 6 months after lactation, abortion or miscarriage to provide sufficient time to allow recovery of iron store.

   Donors who had caesarean section, term delivery or uncomplicated third trimester are deferred for 6 weeks.

   A donor who was pregnant and her delivery required a blood transfusion are deferred for 12 months

   Menstruation is not a reason for deferral, However women who report regular excessive menstrual bleeding and are found to have low Haemoglobin level should not donate blood and should be referred for medical assessment.

3. **Marital Status:** Marital status and some occupations may put one in a group of high risk donors. Blood donor counselor should therefore make a careful assessment on the risks associated with the marital status and occupation of a particular blood donor.

4. **Occupation: A hazardous occupation:** refers to an occupation which may endanger the donor or others if the donor were too faint post donation. People in hazardous occupation e.g. (emergency services & working at

height-pilots, deep sea divers, and extreme mountaineering), (public transport, heavy duty vehicles & working on high scaffolding), not to resume at work after 24hrs and 72hrs respectively after donation.

Health-care workers and workers with animals: These occupations carry an increased risk of exposure to blood-borne infections, while such individuals should have been immunized against relevant diseases. Donors in these occupations questioned and found with possible exposure risk (e.g. needle stick injuries, blood splashes, bites) should be deferred for 6–12 months applied, based on the incubation period of the relevant infection.

Prostitution or **commercial sex workers**: prostitution is a recognized high risk for HIV & Hepatitis B infections. NBTS staff will determine if the prospective donor have engaged in prostitution by receiving money, goods or favor in exchange to sexual activity. If this has been a once off occurrence defer for 12 months from the time of the last sexual activity. If it is a lifestyle choice defer the donor permanently.

Sporting Activities: Sports men and women preparing for significant sporting events should not donate during the period of preparation. Scholars should not donate on the day of an athletic activity. Donating blood does not have any physically harmful effect on the person – but may well reduce the person's maximum athletic performance.

5. **Weight:** The weight of all blood donors shall be 50kg and above as the volume to be collected shall not exceed 10.5mL / kg of donor weight, including samples proportional to the volume of anticoagulant, with a maximum of ±10% variation. Donors who weigh less than 50kgs are at high risk of donor adverse events. Unexplained recent weight loss of more than 10% of body weight shall be deferred for 6 months and overweight can be a cause of deferral due to inaccessible veins in the antecubital fossa.

6. **Vital signs:** The vital signs shall be checked carefully before a blood donor is deemed eligible for blood donation.

   Blood Pressure: An elevated blood pressure may be an indication of anxiety, if the BP is high, allows the donor to rest for 5 minutes, and then recheck the BP, if the BP remains above the acceptable range advice the donor to see a doctor.

   Acceptable range of BP should be (90/60 – 140/90) that means Systolic BP 90-140mmHg and Diastolic BP 60-90mmHg as per Standard Treatment Guideline and National Essential Medicine list Fourth Edition, for blood

donor with hypertension, whether are on medication or not are deferred permanently to donate blood due to the reason that might have many end organ failure which might lead to donor adverse reaction.

Hypotension is not acceptable if BP is less than 90/60mmHg, There is no fixed deferral period. The donor may return when it is convenient and if the BP is within acceptable range, may be bled.

Pulse rate: acceptable pulse rate shall regular and not <60 or >100 beats/ minute

Body Temperature: The acceptable range should not be more than 37.6 degrees of Celsius

7. **Hemoglobin level:** An accepted hemoglobin level is 12.5 g/dl for female and 13.5 g/dl for males as the threshold, The majority of female donors will have lower Haemoglobin than male donors, however for logistical reasons it is easier to have the same Haemoglobin cut off for both males & females as this is determined by using the copper sulphate method. Therefore both male & females may be allowed to donate if their Haemoglobin is equal or more than 12.5dl/L.

   In Tanzania, Haemoglobin level is determined using copper sulphate (qualitative method) and Haemocue method (quantitative method). Whenever copper sulphate method has been used all blood donors who will be having low Haemoglobin level will be rechecked using Haemocue method to determine their Haemoglobin level using quantitave method before being referred to health facilities for further management.

   Haemoglobin screening safeguards anemic individuals from donating blood. Also good quality blood components, with adequate and consistent Haemoglobin are obtained from individuals with acceptable Haemoglobin level. It is recommended that all individuals who will be discovered in the course of blood donation process to have low Haemoglobin be counseled and assessed for the cause of the low Haemoglobin.

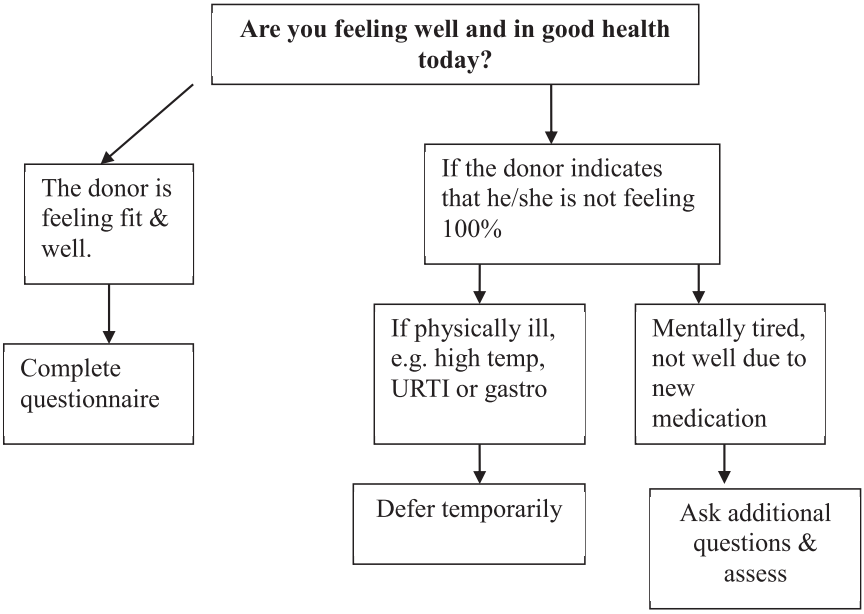
8. **Blood Donation Interval**

   In Tanzania the optimum interval for which it is safe for different donors to give blood is tailored to donors by gender characteristics. **Male:** The normal interval between whole blood donations is after every 12 weeks (three months),so a male can donate 4 times a year. **Female:** The normal interval between whole blood donations is after every 16 weeks (four months), so a female can donate 3 times a year.

This time interval of blood donation in Tanzania is based on the precarious iron status. The micronutrient report of 2010 Tanzania Demographic Health Survey (TDHS) indicate that 30% of women are iron deficient and 41% have anaemia. This interval is intended to ensure iron stores are replenished adequately before next donation.

9. **Illnesses:** Minor non-specific symptoms (e.g. general malaise, pain, fever, headache, cough, and diarrhea) may indicate the presence of an acute infection that may be transmissible by transfusion. Individuals suffering from any kind of illnesses and not feeling well should not donate blood. There is no evidence that minor infections such as common upper respiratory infections can be transmitted by transfusion, but it is nevertheless advisable as a precautionary measure to defer blood donation until any such infection has resolved. Individuals with a history of recent infection should be deferred for 14 days following full recovery and cessation of any therapy, including antibiotics.

Figure 3: Flow Chart for assessing illness of Prospective Blood Donor



3.3 Risk Assessment Guide on Donor Selection

Exposure to HIV

You risk harming a vulnerable patient who needs blood transfusions. With new, advanced tests, the risk of transmitting HIV through a blood transfusion is 1 in 1.5 million. In order to ensure recipient receive as much as safe blood is concern, NBTS staff must ensure that a donor does not display the high risk behaviors associated with certain infectious diseases. Before blood donor donate should asked not give blood if they are at risk for getting and spreading the HIV virus. All prospective blood donor must be assessed risk of having HIV by using this assessment guide. He/she must be asked

- You are a male who has had sex with another male, even once
- You have ever shared a needle, even once, to take any illegal drugs or steroids
- You have taken clotting factor concentrates for a bleeding disorder such as hemophilia
- You have ever had a positive test for AIDS (HIV) or AIDS antibody or antigen
- You have AIDS or one of its symptoms, which include:
  - » Unexplained weight loss (10 pounds or more in less than 2 months)
  - » Night sweats
  - » Blue or purple spots on or under the skin
  - » Long-lasting white spots or unusual sores in your mouth
  - » Mumps in your neck, armpits, or groin that last more than a month
  - » Fever higher than 99 degrees that lasts more than 10 days
  - » Diarrhea lasting over a month
  - » Persistent cough and shortness of breath
- You have had sex with any person with AIDS described above in the last 12 months
- You have been given money or drugs for sex

All prospective blood donors who will suspected to be exposed to HIV through listed questions above, **defer them for 12 months**

All blood donors who will have sexual contact with an individual with HIV infection or at high risk of HIV infection will be **deferred permanently.**

HIV, HBV and HCV Infection

All prospective blood donors with present, past or laboratory evidence of Infection with HIV, HBV and HCV will be deferred permanently.

Sex with a new sex partner

Having sexual activity with a person whose sexual background you do not know or are uncertain of carries a risk of HIV& HBV as well as other sexually transmitted infections (STIs).

The use of a condom will minimize this risk, however if it is a recurrent occurrence the level of risk will increase due to the fact that condoms are seldom used consistently.

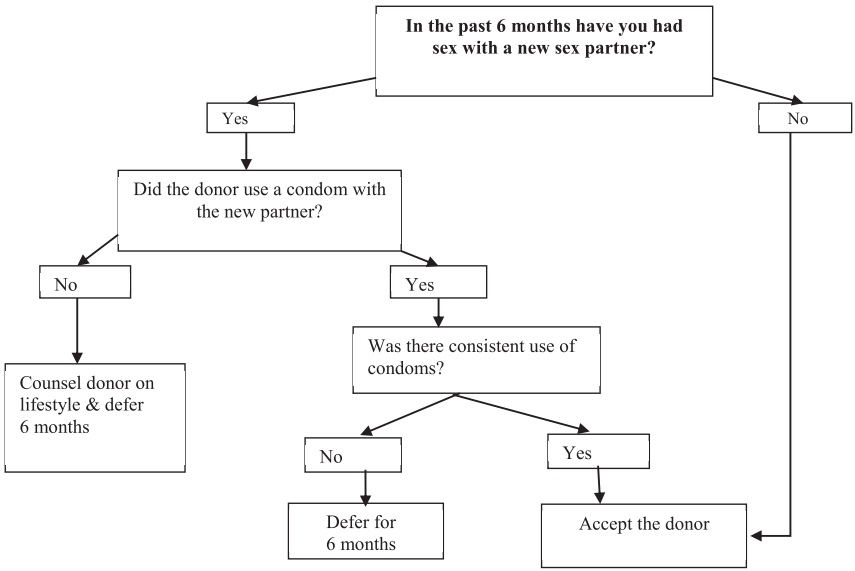
It is therefore safer to defer a donor who is repeatedly having "casual sex" or who has had unprotected sex with a new sex partner in the last 6 months.

Sexual activity is defined as: vaginal sex, oral sex and anal sex

Therefore, all persons in high-risk groups should not donate_

1. Male homosexuals or bisexuals
2. Intravenous drug users
3. Any person with a history of sexually transmitted disease in the past year.
4. Prostitutes
5. Any person who is HIV positive or on ARVs
6. Any sexual contact with the above.

Figure 4: Flow Chart for Assessing Prospective Blood Donor with new sexual partner



Exposure to Sexually Transmitted Disease (STDs)

NBTS staffs are responsible to determine if the prospective donor had sexually transmitted diseases (STDs) in the past 12 months from an infected person during sexual contact. The commonest STD's are gonorrhea, syphilis, non-specified urethritis, & genital herpes.

Persons, who have had STDs such as syphilis, herpes or gonorrhea, will be accepted after 12 months if treated, fully resolved and comply with all other eligibility criteria. Inform donor that if antibodies for syphilis are detected he/she will be permanently deferred. **Defer donor for 12 months** following date of last treatment.

Sexual Contact or Lived with a person who has Hepatitis

1. If the donor's sex partner has been ill i.e. had active acute hepatitis B or hepatitis of unknown origin, defer for 12 months after last contact.
2. If the donor's sex partner has chronic hepatitis, carrier state, HBsAg Positive - defer the 12months.

3. If the donor's sex partner is a Hepatitis B carrier and the donor has been vaccinated against Hepatitis B, the donor will be deferred because of possible viraemia.
4. Sex partner is HCV positive or symptomatic, defer for 12 months from the time of last sexual contact
5. Donor who had a sex partner who was Hepatitis B positive, but who is no longer involved in this relationship defer for 12 months from last sexual contact.
6. If the donor is symptomatic for any other viral hepatitis defer for 12 months

Donor in household contact with someone who has yellow eyes or yellow skin in the past 12 months

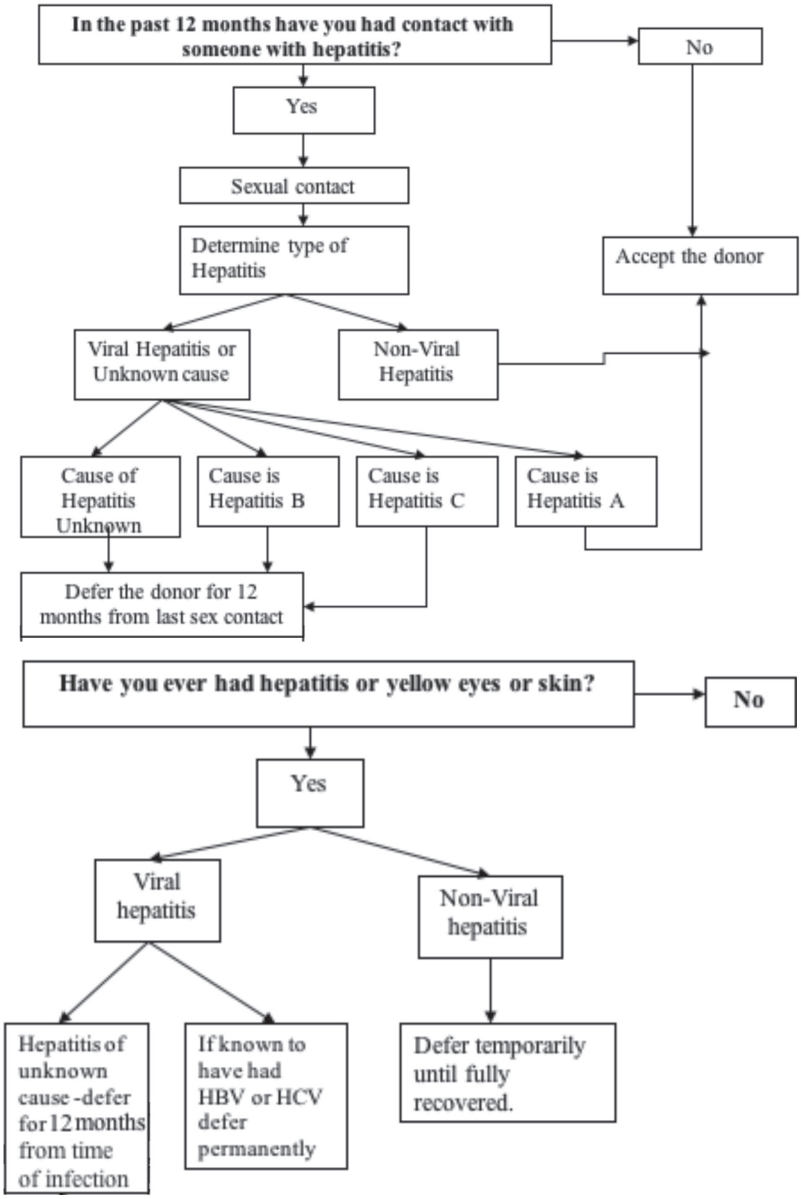
There are many other reasons why people become jaundice and not all will result in deferral of a donor. Non-viral causes of hepatitis/ jaundice are Cholecystitis or problems associated with gall stones, cirrhosis of the liver, jaundice following medication or anesthetic, or jaundice associated with cancer. In certain cases, living with a person with viral hepatitis puts the donor at risk for acquiring viral hepatitis as well. The time of deferral will vary depending on the type of viral hepatitis.

If the donor had had contact with any household member with Hepatitis, NBTS staffs are responsible to determine the type of hepatitis. If the type of Hepatitis was unknown or was HBV/HCV defer the donor for 12 months and if the type of hepatitis was HAV, defer for 8 weeks.

Hepatitis or Yellow eyes or Skin: There are many other reasons why people become jaundice and not all will result in deferral of a donor. An example of this would be a newborn who has neonatal jaundice. NBTS staffs are responsible to determine if the prospective donor has hepatitis or yellowish coloration on skin or mucous membrane of eyes. If you determine that the donor has Hepatitis of unknown cause or of known cause such as HBV/HCV, defers him or her for 12 months from time of infection

Note that non-viral causes of hepatitis/ jaundice are Cholecystitis or problems associated with gall stones, cirrhosis of the liver, jaundice following medication or anaesthetic, or jaundice associated with cancer.

Figure 5: Flow Chart for Assessing Prospective Blood Donor with Exposure to Hepatitis



Potential Risks of Transmitting Malaria

All prospective donor shall be evaluated for potential risks of transmitting malaria. Donor with symptoms of malaria which are flu-like: A high temperature (fever), headache, sweats, chills and vomiting must be **deferred temporary**.

Accidental exposure to blood

NBTS staffs are responsible to identify the risk of accidental exposure to blood or body fluids as a result of a needle stick, mucosal splash or laceration of skin. Non Sterile skin penetration with instruments, equipment's or weapons contaminated with blood or body fluids other than the donor's own, includes tattoos, body piercing and scarification defer them for 12 months. However, you can defer for 3 months if confident of the sterility of the equipment such as single use of the equipment.

The deferral is to protect the recipient against TTIs, especially Hepatitis B. This is regardless of wound assessment or antiretroviral prophylaxis.

The concern about non-sterile instruments lacerating the skin or mucosa is due to the risk of TTIs e.g. Hepatitis B or HIV. A household cut or laceration, where a person cuts himself/ herself with a vegetable knife would not be a reason for temporary deferral but had injected himself or herself or experienced needle injury within a health facility, is a reason for permanent deferral.

Lacerations

Establish the cause of the laceration. If there was possible blood contamination from another source then defer for 12 months. If due to a stab wound, defer for 12 months. If no blood contamination then accept if healed and no infection

Intravenous Drug Use (IVDU)

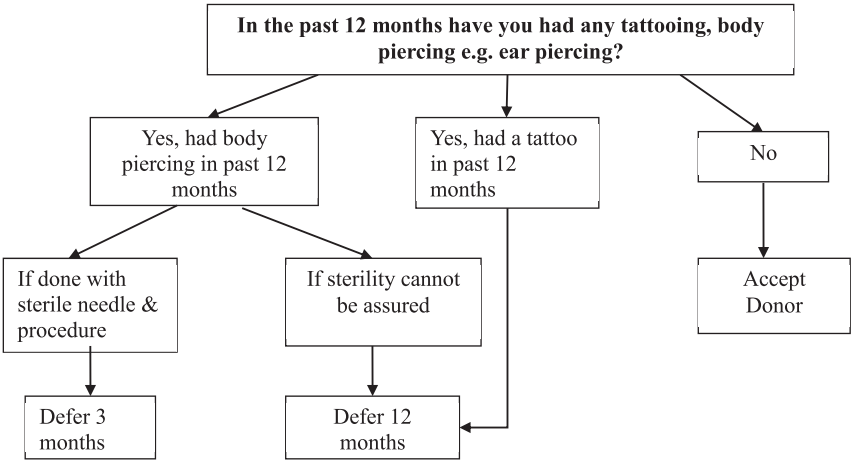
There is a high risk of TTIs due to sharing of needles. This deferral is permanent as a high percentage of IVDU relapse. Hence permanently unfit. Marijuana and other non-medical "recreational drugs" may pose a risk to the safety of the blood supply due to the risky behavior which often occurs whilst high or intoxicated. The deferral period will be 12 months from the last time of non-medical drug use. No donors will be accepted for blood donation if under the influence of alcohol or drugs.

If a donor's sex partner is known to be an IVI drug user then the donor will be deferred due to the potential risk of Infectious diseases.

Tattooing

Persons who have had tattooing or traditional cuts for reason of health or beauty must be deferred for 12 months from the date of the procedure.

Figure 6: Flow Chart for Assessing Prospective Blood Donor with Needle Stick Injury and Body Piercing



Sexual Assault

Sexual assault is regarded as a high risk exposure as the offender is often practicing other high risk behavior. Therefore it is responsibility of NBTS staff to determine if the donor has been a victim of sexual assault e.g. rape, sodomy or engaged in anal sex in the past 12months. The deferral of 12 month is allocated regardless of whether post exposure prophylaxis (PEP) was given or not. As this is a "once off" risk of infection for the donor and not a lifestyle risk a temporary deferral of 12 months is all that is required.

Anal Sex

Anal sex is regarded as high risk behavior due to the association of HBV & HIV infection. The donor Counselor should assess if this was

a once off experience or if this is a lifestyle choice (Men who have sex with men (MSM) or a heterosexual couples). The risk is the same for males or females who are participating in receptive anal sex. Defer men and women who have had anal sex for a period of 12 months since the last anal sex contact. An exception may be made if the donor counselor is satisfied that a married couple man & woman are having anal sex and have no other sex partners.

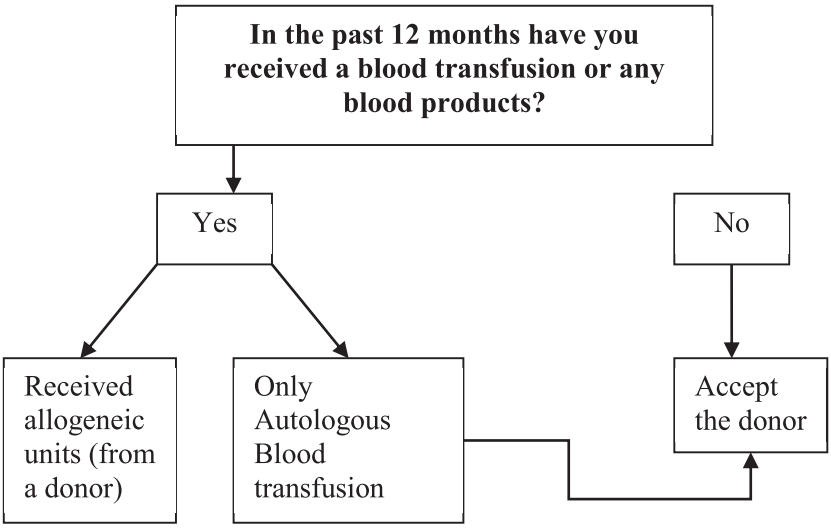
Prisoner

Acceptable, once released, it is felt that prisoners per say do not require a deferral period. The high risk activities which occur in prison are covered in the questionnaire and the prisoner should be deferred accordingly.

Blood Transfusion and Plasma Derived Clotting Factor Concentrates.

If a prospective blood donor has received allogeneic blood transfusion or plasma-derived clotting factor concentrates, should be deferred not donate blood for 12 months. This is due to possible transmission of infectious disease. Although all donated blood is tested, this is a precautionary measure to prevent the transmission of TTIs.

Figure 7: Flow Chart for Assessing Prospective Blood Donor on Blood Transfusion



Alcoholism

Donors should have a sound mental status as they might be at risk of TTIs due to the influence of alcohol. Not acceptable when intoxicated. Only acceptable if the counselor feels comfortable that there is not an undue risk of TTIs

Honesty

NBTS staffs are responsible to test honest of the prospective donor by asking them how they consider their blood to safe for transfusion to patient. The purpose of this question is to allow the donor to reflect on the honesty of his/her answers to all the questions and thus provide the patient with safe blood. It provides a chance for disclosure for donors who have been coerced by colleagues or friends into donating blood when they are unsure of the safety of their blood.

3.4 Medical Assessment Guide

A registered general nurse working within blood center may only accept as a donor, a person who has a negative medical history and appears to be healthy and free of disease. Persons with features indicative of ill health or previous diseases may only be accepted at the discretion of a medical officer of the Blood Transfusion Service.

3.4.1 Donor Selection based on Disease Conditions

Allergy

Body reaction to certain substances, such as pollen, that are present in amounts that do not affect most people. Common indications of allergy include sneezing, skin rashes, itching, and difficulty in breathing and runny nose

- Donors with seasonal allergy type are acceptable only if they are symptom free at time of donation while donors with allergy who present with breathing difficulty at time of blood donation are deferred temporarily.
- In severe allergy including severe reaction to bee sting, donors are deferred permanently, of bee sting with local reaction, defer for 1 week.
- Temporarily defer donors who are on oral steroids as it indicates that their allergic condition is severe. Donors who have had desensitizing injections may donate 48 hours after completion of the course.

Hay Fever

An allergy caused by pollen or dust in which the mucous membranes of the eyes and nose are itchy and inflamed, causing a runny nose and watery eyes.

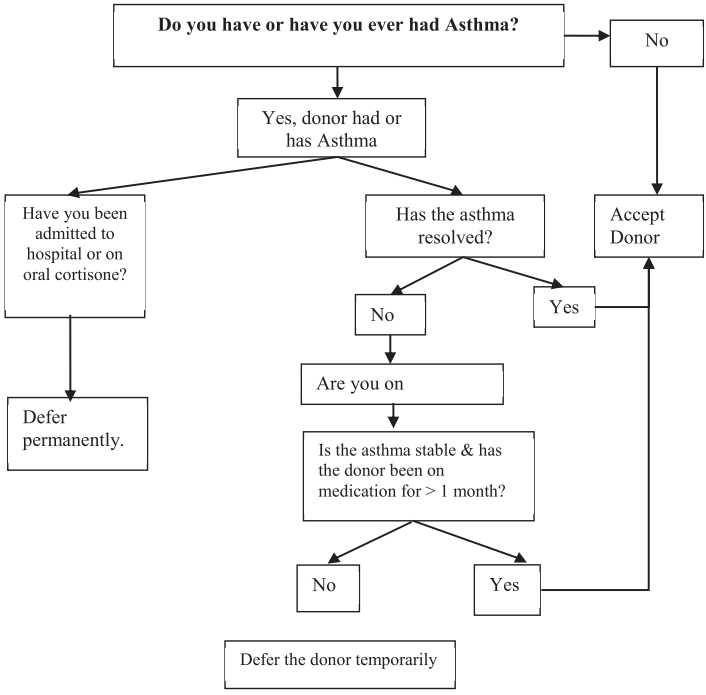
- Blood donors with hay fever are acceptable during symptom free period, seasonal hay fever is acceptable provided there is no secondary infection, but also inquire about medication.

Asthma

A respiratory condition marked by spasms in the airways, resulting from an allergic reaction or other forms of hypersensitivity characterized by recurrent attacks of breathlessness and wheezing causing difficulty in breathing.

- In some setting blood donors with controlled Moderate & Mild asthmatics or when the donor are between attacks and not on a course of oral steroid therapy are acceptable. However, in Tanzania in order to safe guard the blood donor, it recommended that all blood donors diagnosed with asthma whether or attack or stable are deferred permanently.

Figure 8: Flow Chart for Assessing Prospective Donor with Asthma



Severe chronic obstructive Disease

Lung disease is characterized by chronic obstruction of lung airflow that interferes with normal breathing and is not fully reversible.

- Donors who present with symptoms such severe shortness of breath & cyanosis are deferred permanently while donors with mild chronic obstructive disease are accepted if they are on treatment such as a bronchodilator and breathing comfortably.
- Please, ensure at the time of donation that the donor is not on antibiotics for a recent chest infection.

Cancer

It is a group of more than 100 different and distinctive diseases. *Cancer* can involve any tissue of the body and have many different forms in each body area with a malignant and invasive growth or tumor

- Accept prospective donor with cancer only, if the cancer has no recurrence for 5 years from date of diagnosis, surgery or last radiation treatment and if no chemotherapy
- In some skin cancer are acceptable after 3 months provided the lesion is completely excised and healed, however the donor would have to provide a report to the NBTS Medical Officer
- All solid tumors are deferred for 5yrs. If after 5 years there is no evidence of recurrence & the donor is well.
- Defer permanently all Leukemia, Lymphoma, Kaposi Sarcoma and Malignant Melanoma

Polycythemia Rubra Vera

It is a myeloproliferative disorder in which the bone marrow makes too many blood cells with an abnormally high number of red blood cells in your blood.

- Both genetic inherited and secondary type of PRV are unfit for donation but patients with PRV will benefit from venesection, therefore may be accepted for therapeutic bleeding, by NBTS Medical Officer after discussion with the treating doctor who must provide written document to NBTS authority.
- Genetic Inherited PRV is of malignant origin, however it is advised in order to save guide the recipient, all blood donated as therapeutic

management of the Polycythemia Rubra Vera of either inherited or secondary type should be discarded.

Cold, Flu or Sore Throat

- Accept if donor has a simple rhinitis (runny nose)
- Donors with active cold or flu symptoms such as fever, sore throat, productive cough, or general fatigue on day of donation are acceptable 1 week after recovery to avoid the risk of bacterial infection which may enter the bloodstream. .
- If donor was treated with antibiotics defer for 1 week after completion of antibiotics

Dental

- All donors who had dental procedure e.g. filling under local anaesthetic (LA) are deferred for 72 hours while donors who had dental extraction under general anaesthetic are deferred for 1 week. The reason for deferral is due to the fact that tooth extraction and other dental procedures may be followed by a transitory bacteremia (bacteria in the bloodstream).
- A deferral of 3 days is advised. This is probably more than is needed, however it is a precaution to ensure that there is no bacterial contamination of the blood and also it gives the person time to recover before donating blood.
- Accept donors who had teeth cleaning, scaling, root canal and fillings if no infection present

Hyperthyroidism, Hypothyroidism and Thyrotoxicosis

Overactivity of the thyroid gland, resulting in excess production of thyroxine hormone hence increased rate of metabolism causing sudden weight loss, irregular heartbeat, sweating, and nervousness or irritability

- Donors with hyperthyroidism, hypothyroidism or Thyrotoxicosis are permanently unfit to donate blood though there is no published evidence about any adverse effects from blood donation to individuals with a history of thyroid disease, this deferral helps to safeguard donors

Creutzfeldt - Jakob disease (CJD)

CJD is a degenerative neurological disease that is incurable and invariably fatal with loss of intellect and memory.

- All blood donors with a history of CJD diagnosis found at increased risk or if any relatives have been diagnosed with CJD are deferred indefinitely.

Diabetes Mellitus

- All diabetics are permanently deferred from donating blood.
- Women who have gestational diabetes (diabetic during pregnancy) may donate blood. A female who had diabetes during pregnancy may donate provided the diabetes has resolved.

Tuberculosis (TB)

- Potential donors who have active tuberculosis must be deferred. Donors who have had TB may be accepted 2 years after completion of treatment provided no relationship to HIV/AIDS.
- To ensure that the donor has fully recovered or has no reactivation, an assessment of general health, appropriate weight & an Hb screening test must be done on all donors who give a history of having had TB.
- Donors who have been in contact with someone diagnosed with TB should be assessed further. If the donor had contact with the TB patient after he/she has been on TB treatment for 2 weeks then the donor is unlikely to have been exposed to tubercle bacilli.
- If there was contact with a TB patient prior to diagnosis and treatment then donor should be deferred for 3 months.

Heart Disease

Since heart disease lower ability to tolerate hemodynamic changes due to blood donation evaluated individually, must have no restrictions on physical activity, be symptom-free and on no medication for heart disease.

- Donors with heart disease are only accepted to donate blood when they present with musculoskeletal(non-cardiac) chest pain and provided that have no restrictions on physical activity, be symptom-free and on no medication for heart disease

- Donors with coronary Artery Disease or ischaemic heart disease and congestive cardiac failure are permanently unfit, since it lower the ability to tolerate hemodynamic changes during blood donation
- Donors with angina pectoris, a type of ischaemic heart disease are permanently unfit for donation
- Donors with heart disease and had attack are deferred for 6-month after heart attack if have no restrictions on physical activity, symptom-free and on no medication for heart disease.
- Donors with pacemaker and has no restrictions on physical activity, be symptom-free and on no medication for heart disease.

Malaria

- Malaria can be transmitted by blood. Therefore prospective donors who have had malaria should be deferred for two weeks after becoming asymptomatic or from the time of recovery.
- If the donor had malaria more than 2 weeks ago but continues to have symptoms suggestive of malaria e.g. fever, tiredness, it would be better to defer the donor until fully recovered.

Sleeping sickness (Trypanosomiasis)

Sleeping sickness is a vector-borne parasitic disease caused by protozoan parasites Trypanosoma transmitted to humans by tsetse fly. Fever, severe headaches, irritability, extreme fatigue, swollen lymph nodes, and aching muscles and joints are common symptoms.

African Human Trypanosomiasis has re-emerged as one of the major health public importance in Tanzania affecting 43% of the regions (Kigoma, Manyara, Arusha, Tabora, Mara, Lindi, Ruvuma, Kagera and Rukwa)

- Blood donor with sleeping sickness will be deferred pto donate blood permanently are acceptable 3 weeks after recovery

Serious parasitic infection

- Donors who will be evaluated and found to have the following diseases
- Chagas Disease, Babesiosis, Lyme Disease, and Leishmaniasis will be deferred indefinitely

Pregnancy

- Donors who are pregnant are deferred
- Donors who had caesarean section, term delivery or uncomplicated third trimester are deferred for 6 weeks.
- A donor who was pregnant and her delivery required a blood transfusion are deferred for 12 months
- A nursing mother who is breast feeding is not acceptable to donate blood due to the fact that during breast feeding women lose iron through milk

Menstruation

- A female who is menstruating does not need to be deferred unless she is suffering from dysmenorrhea (severe abdominal pain) as long as she pass Haemoglobin check.
- Females who have heavy periods should be advised not to donate on a regular basis because of the concern of making these donors anaemic.

Typhoid

- Donors with typhoid disease are acceptable 6 month after recovery, due to the reason that Salmonella typhi antigens clear slowly after treatment, this help to avoid risk of infection which may enter the bloodstream of the recipient.

Sickle Cell Disease

- Defer indefinitely for sickle cell disease
- Accept for sickle cell trait

Bleeding Disorder

- Donors with hemophilia where the body is unable to synthesize Factor VIII (a clotting factor), this means the patient's blood clots very slowly and patients are usually treated with blood products & should therefore be deferred permanently unfit.

Peptic Ulcer Disease

- Donor with PUD who present with bleeding gastric ulcer at time of donation are deferred until healed. Due to the reason that gastric

ulcers have a tendency to perforate resulting in a large loss of blood.

- Accept donors who have no history of hemorrhage from the ulcer and no current symptoms and are on antacids and/or medication such as Tagamet, Zantac and Losec are acceptable.

Syphilis/Gonorrhea

- Defer if have had or have been treated for in last 12 months
- Defer if positive test for syphilis in past 12 months
- Documentation of treatment may be required

Emphysema

- Donors with emphysema are permanently unfit unless present with a letter from their own doctor and permission granted by NBTS medical officer.
- Although people with emphysema experience some symptomatic relief after a venesection, there are risks of complications.

Gall Stones, Cholecystitis and Pancreatitis

- Because of the risk of transmission of infection to the patient, donors with gallstones are acceptable 4 weeks after recovery.

Cystitis

- Acceptable 1 week after completing antibiotic treatment. Reason for deferral being risk of transmission of infection to the patient

Acute Nephritis

- Because of the risk of bacterial of infection which may enter the bloodstream to the patient, donors with acute nephritis are acceptable 6 months after recovery.

Pyelonephritis

- Because of the risk of bacterial of infection which may enter the bloodstream and then to the patient, donors with Pyelonephritis are acceptable 3 months after recovery.

Chronic Nephritis

- Are permanently unfit for blood donation, this is because of high risk of bacterial infection which may enter the bloodstream.

Renal Colic

- Donors with history of renal stones are acceptable when symptom free, it is for the safety and of the donor

Encephalitis

- Because of high risk infection transmission, acceptable 6 months after recovery.

Migraine

- Assess donor's condition and accept if well.

Brain injury

- Permanent brain injury is permanently unfit. Risky donor as may have impaired memory and may not give accurate information

Blood Donation and Fasting

- For all blood donors who are fasting may be advised to postpone the donation till after iftar during evening, but if he/she need to do so; assess if they meet all blood donation selection criteria and have taken their suhoor (breakfast meal) which is supposed to be taken 30minutes before dawn (fajr) within a recommended time of 4hours. That means the best time to donate individual who are fasting in Tanzania must be not more than 10:00am, or can donate blood once they have broken their fast and replenished their bodies with nutrition and water.

Blood Donation and Alcohol Intake

- You will not be eligible to donate blood if you have consumed alcohol 48 hours before donation this is due to the reason that alcohol metabolism may result dehydration which may put blood donor at a risk of adverse reaction. Moreover an individual who consumed alcohol may have clouded judgment which may lead to partial ability to respond to donor questionnaire or interview and giving informed consent.

Blood Donation and Smoking

- Blood donors will not be considered for donation unless they have been tobacco free (including chewing tobacco) for at least 8 weeks prior to donation. Smoking is strongly discouraged before blood donation to protect long term health of recipients. Research has indicated that recipients of transfused blood are still at a higher risk for the development of cancer, acute cardiovascular symptoms and post-operative morbidity as tobacco use within the last 24 h is related to a higher concentration of vascular endothelial growth factor (VEGF) in the donors' blood. Blood donor can smoke 3 hours after donation

Blood Donation and Psychiatric illness (Schizophrenia, Mania and Depression)

- The acceptance of individuals with current or past mental health problems as blood donors depends on an assessment of their ability to fully answer the donor questionnaire and interview and to give informed consent to the donation process, including the testing of their blood. A history of poor coping or psychiatric illness, a history of not taking good care of their health, or other similar concerns.
- In general, donors with anxiety disorders and mood (affective) disorders, such as depression or bipolar disorder, may be accepted provided they are stable and feel well on the day, regardless of medication. Individuals with psychotic disorders, such as schizophrenia and related conditions, are usually not suitable to donate blood, therefore defer permanently, individuals with psychotic disorders requiring maintenance treatment.
- Dementia and other neurodegenerative disorders
- Individuals with dementia or neurodegenerative disease due to any cause should be permanently deferred due to reasons such as inability to give a reliable medical history and the possibility of vCJD. While there is no evidence of transmission of sporadic or familial CJD through transfusion, individuals with symptoms suggestive of CJD or a family history of CJD should be permanently deferred.

Multiple sclerosis

- Individuals with multiple sclerosis should be permanently deferred because of the progressive nature of the condition and uncertainty regarding the etiology.

Blood Donation and Cerebrovascular disease

- The usual and predictable fall in blood pressure associated with blood donation, especially during sleep the night after donation, may be detrimental to individuals with a history of transient cerebral ischaemic episodes or completed stroke; such individuals should be permanently deferred.

Head Injury

- Acceptable 3 months after recovery, inquire about surgery

Epilepsy

- Accept if seizure-free for 3 months with or without medications, do not donate when present with seizures because of the increased risk of donor adverse reaction.

Convulsions

- Permanently unfit, Risk of adverse reaction

Fainting

- Permanently unfit after 3 consecutive faints or 1 severe faint. This deferral is because of risk of adverse reactions

Gastro-enteritis and Peritonitis

- Because of the risk of bacterial transmission of to the patient through blood, all donors who had gastroenteritis and peritonitis should be accepted 4 weeks after fully recovery

Dysentery

- Acceptable 1 month after a full recovery. This includes amoebic dysentery & bacillary dysentery.

Reynaud's Disease

- Donor with Reynaud's and Thyrotoxicosis disease are permanently unfit for blood donation, it is for the safety of the donor

Scarlet fever

- Donor with scarlet fever and those who had contacts with scarlet fever patient are acceptable after 3 weeks after recovery or contacts

Scabies

- Acceptable provided venesection site is clear and no signs of infection but there are a potential risk to blood collection staff.

Acne

- Donors with acne using local skin lotions are acceptable for blood donation but donor with acne using Roaccutane are deferred for 1 month after completion of the treatment while those who use Tegason will be deferred for 2 years. Reason for deferral is due to the fact that Roaccutane and Tegason are teratogenic i.e. can cause foetal deformities if taken during pregnancy.

Dermatitis (Eczema, Psoriasis)

- Donors with dermatitis (eczema, psoriasis) are acceptable provided the donor has a venipuncture site which is clear, no signs of infection, donor is not on systemic treatment and no indication of HIV/AIDS. Many of the systemic drugs e.g. methotrexate can be harmful to a fetus.

Biopsy

- Accept if benign & healed, a letter from the doctor, indicating that the biopsy was benign, would be required.

Boils

- Acceptable when healed. If antibiotics were used accept 1 week after completion of medicine or injection. The concern is that of infection and not the antibiotic itself.

Glaucoma

- Acceptable once stable and on maintenance treatment, glaucoma is a chronic disease and people are required to use drops to control the pressure in the eye. This treatment is long-term.

Dengue Fever

- Acceptable 1/12 after recovery or contact, Risk of transmission of infection to the patient

Glandular Fever (Infectious Mononucleosis)

- Acceptable 6 months after recovery, for donors who had close contacts with patients with infectious mononucleosis are deferred for 3 months.

Undulant fever (Brucellosis)

- This disease is caused by brucella bacteria. A skin test is of no use as these tests remain positive for years. Accept 2 year after recovery and if blood tests are negative.

Mumps

- Donors with mump infection and those who had close contact with patient of mumps are accepted to donate 3 weeks after recovery. Reason for deferral is because of risk of transmission of infection to the patient

Measles

- Donors who had measles infection or had contact with an infected person are deferred for 3 weeks after recovery or contacts. This deferral is because of risk of transmission of infection to the patient

German measles

- Acceptable 3 weeks after recovery. German measles contact - defer 3 weeks. German measles vaccine – defer for 1 month after given vaccine. This deferral is because of risk of transmission of infection to the patient

Herpes Simplex

- These are fever blister; this lesion can be associated with a depressed immune system. Acceptable after healing and no relation to HIV infection /AIDS. As there is a high association between HIV/AIDS & herpes, the counselor must check for other HIV associated signs, weight loss, nodes etc. & lifestyle. Defer until the cause is treated

Shingles

Shingles is a viral infection (varicella-zoster virus) that causes a painful rash. Although shingles can occur anywhere on your body, it most often appears as a single stripe of blisters that wraps around either the left or the right side of your body trunk or chest.

- Blood donor with shingles is acceptable after healing, as there is a high association between HIV/AIDS & herpes, the counselor must check for other HIV associated signs, weight loss, nodes etc. & lifestyle.

Tick Bite Fever

- Because of high risk of Transmission, acceptable 2 month after recovery

Tetanus

- Acceptable 6 months after recovery Risk of infection which may enter the bloodstream tonsillitis, Acceptable after recovery. Ask about antibiotic use and defer accordingly

Chicken Pox

- Blood donors who had chicken pox or had contact with patient with chicken pox are deferred for 3 weeks after recovery or after contact. This deferral is due to the fact that there is high risk of transmission of infection to the patient

Influenza

- Recovery usually takes 7 – 10 days, therefore acceptable after recovery.

Rheumatic Fever

- Because of high risk of bacterial infection which may enter the bloodstream Acceptable only after consultation with service NBTS Medical Officer.

Rheumatism

- Acceptable, assessment of the suitability of donors depends on the nature and severity of the disorder and the mobility of the donor.

Sarcoidosis

- Permanently unfit, deferral reason is to safeguard the donor

Systemic Lupus Erythromatosis (SLE)

- Permanently unfit for blood donation, this is because, without a full understanding of the cause of SLE we cannot ensure that we are not risking the transmission of harmful chemical or toxin to the patients.

Gout

- Acceptable if quiescent and not on systemic treatment, the donor may donate provided the donor does not have an acute episode

of gout. Medication for gout is not a reason for deferral. If taking aspirin for pain, do not use for platelets production.

Arthritis

- Acceptable unless acute or refer to service medical officer. If the donor has severe rheumatoid arthritis, they may be on drugs such as methotrexate which would be a reason for deferral.

Meniere's Diseases (Vertigo)

- Assess donor's condition and accept if well, acceptable if symptom free.

Snake Bite

- Acceptable 6 month after recovery, because of risk of infection which may enter the bloodstream for some types of snakes and/or envenomation

Septicemia

- Acceptable 6 month after recovery because of the risk of infection which may enter the bloodstream

Ostemyelitis

- Acceptable 6 months after recovery, because of risk of bacterial infection this may enter the bloodstream

Hemochromatosis

- Unfit but may be accepted for therapeutic, hemochromatosis patients benefit from venesection, therefore may be accepted for therapeutic bleed. The NBTS MO after discussion with the treating doctor may provide authority for venesection.

Phlebitis

- Acceptable 1 month after complete recovery, because of risk of bacterial infection this may enter the bloodstream

Thrombophlebitis

- Acceptable 6 month after recovery, because of risk of adverse reactions

Pneumothorax

- Acceptable 6 months after recovery. Because of risk of bacterial

infection which may enter the bloodstream

Whooping Cough

- Acceptable 6 month after recovery, whooping cough contact - acceptable 3 weeks after contact. This is because of high risk of infection.

Bronchitis (Acute)

- Accept one week after full recovery. If antibiotics were taken accept 7 days after completion of antibiotic. Risk of transmission of infection to the patient

Bronchitis (Chronic)

- Acceptable provided there is no infection. Risk of transmission of infection to the patient

Porphyria

- Acceptable with letter from the doctor, Acceptable if asymptomatic. Defer for 3 weeks if the donor has symptoms.

Organ/Tissue Transplants

- Defer 12 months for allogeneic organ or tissue transplants, including dental powder
- Defer if received durra mater transplant
- Accept autologous transplants if only autologous received

Poliomyelitis

- Because of high risk of Transmission, acceptable 6 months after recovery.

Diphtheria

- Acceptable 3 months after recovery, Risk of transmission of infection to the patient

Meningitis

- Acceptable 6 months after recovery, this is because of risk of transmission.

Hematuria

- There are many reasons for Hematuria, the counselor needs to

ask additional questions to establish the cause and defer or accept accordingly. Acceptable after recovery depending on the cause

Bilharzias

- Acceptable 6 month after recovery and completion of successful treatment. These patients suffer from fever and anaemia hence the 6 month deferral period.

Burns (Minor)

- Accept if healed and no sepsis. Risk of transmission of infection to the patient

Burns (Major)

- Accept 6 months after full recovery. Risk of transmission of infection to the patient

Circumcision

- Tribal or traditional circumcision – defer 12 months and circumcision in a health facility – defer 3 months, this is because of TTI risk.

Surgery

- Accept donors with history of recent surgery if underlying illness does not disqualify the donor, stitches dissolved/removed, wound is healed and donor has resumed normal activity and is feeling well
- Accept donors with minor cuts requiring stitches/staples after 48 hours if no signs of infection
- Major surgery defer for 6 months, minor surgery defer for 3 months. Major Surgery: Laparotomy, hysterectomy, cholecystectomy, craniotomy, spinal operations. Thyroidectomy multiple trauma from a motor vehicle accident e.g. fracture femur, hip etc. Minor Surgery: Appendectomy, haemorroidectomy, hernia repair, tonsillectomy, stripping of veins, circumcision in hospital, closed reduction of wrist or ankle fractures.

Colitis (ulcerative)

- Permanently unfit, this includes Crohn's disease and Ulcerative Colitis

Fractures

- Minor fractures acceptable, after 3 month, major fractures or multiple fractures, acceptable after 6 months. Minor fractures are crack fracture, closed reduction of ankle/wrist etc. while major fractures of major bones e.g. femur/pelvis. Check for blood use – defer 12 months

Stab injuries

- Acceptable after 12 months, because of high risk of TTIs

Hepatitis A

- **Infection**: Accept 12 months after recovery, c**ontacts**: Acceptable 8 weeks after contact. Only household contacts need to be deferred. Casual contacts e.g. office workers need not be deferred.

Hepatitis B: Infection

- Permanently unfit, C**ontacts**: Household & sexual partners defer for 1 year. If the donor has a sexual partner who is HBsAg positive i.e. a carrier then the donor will be deferred for the duration of the relationship and for 12 months after the relationship has ended.

Hepatitis C: Infection

- Permanently deferred, c**ontacts:** Sexual partners will be deferred for 12 months. Transmission of hepatitis C from mother to child or by sexual contact is very rare. The deferral of sex partners is a precautionary measure.

3.4.2 Donor Selection based Immunizations/Vaccinations:

Group A Vaccines (Killed and inactivated vaccines)

The term 'killed' is generally used for bacterial vaccines and the term 'inactivated' for viral vaccines. These vaccines are prepared by treating the whole cell or virus with chemicals that cause inactivation. They generate an immune response (to a broad range of antigens) but cannot cause an infection because they are dead and so cannot reproduce. Examples are toxoids vaccines, recombinants vaccines, and polysaccharide and conjugate vaccines.

Therefore, no deferral is required for the killed and inactivated vaccinations provided the donor feels well: Typhoid, capsular

polysaccharide typhoid fever vaccine, Poliomyelitis (injection); Influenza, Diphtheria, Tetanus, Hepatitis A, Tick borne encephalitis, meningococcal and Rabies. Tetanus vaccine-accept individuals who have received toxoids with no history or known exposure and who feel well. Accept hepatitis A vaccine. Accept most other immunizations/ vaccinations, e.g. flu, tetanus, providing donor is symptom-free and fever-free

Group B Vaccines (Live attenuated vaccines)

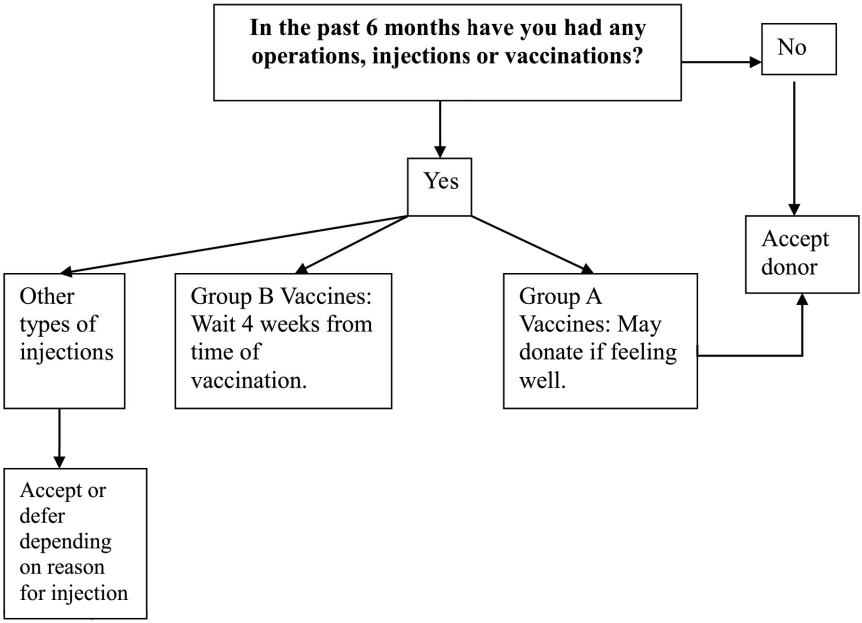
It is a vaccine obtained by weakening a disease-causing virus by repeated culture in the laboratory or by genetic engineering, such as with rotavirus vaccines. The virulence properties of the virus are reduced so that it does not cause disease in healthy individuals. The attenuated vaccine virus multiplies to a limited extent in host tissue and induces an immune response similar to wild virus infection in the majority of subjects. Therefore all live attenuated vaccines are deferred.

Example of Live attenuated and Bacterial Vaccine and deferral duration.

Type of Vaccine	**Duration from the date of vaccination**
BCG (Bacillus Chalmette-Guerin)	**6 weeks**
Herpes Zoster, Varicella zoster	**12 weeks**
Measles, Mumps, Rubella (MMR)	**4 weeks**
Polio (Sabin, oral)	**6 weeks**
Rubella that is German Measles (MMR)	**4 weeks**
Typhoid (Oral)	**4 weeks**
Yellow Fever	**4 weeks**
Botulism Toxin	**4 weeks**
Pertussis Immune Globulin	**24 weeks**
Rabies - Treatment after with Immune Globulin	**52 weeks**
Rh Immune Globulin (RhoGAM)	**6 weeks**
Smallpox	**8 weeks**
Tetanus Antitoxin	**12weeks**
Tetanus Immune Globulin	**24 weeks**
Chickenpox (Varivax & immune globulin,)	**12 weeks**
Hepatitis A and Hepatitis B (Twinrix)	**4 weeks**
Hepatitis B (Engerix B, Recombivax–HB)	**4 weeks**
Hepatitis B Immune Globulin (HBIG)	**4 weeks**

Note: In Tanzania, for logistical purpose and in accordance to AfSBT, blood donors who received all live attenuated and bacterial vaccine listed above are deferred for 4 weeks to donate blood while all other vaccines, including unlicensed vaccines not listed above are deferred to donate blood for 12 months unless otherwise indicated by NBTS Medical Director.

Figure 9: Flow Chart for Assessing Prospective Blood Donor on Immunization



3.4.3 Donor Selection Based on Medications

Anticoagulants

- For blood donors who are on anticoagulants such as Coumadin (Warfarin), defer for the duration of treatment and continue for 2 months after treatment has stopped. Coumadin (Warfarin) is teratogenic therefore a wash out period of 2 months is required after the last tablet.

Anti-epileptic drugs

- Donors on anti-epileptic (anti-convulsant) drugs will be permanently deferred as the condition of epilepsy requires a permanent deferral. The majority of anti-convulsant drugs has

some teratogenic effect and would require deferral. Tegratol, which is sometimes used for phantom pain or severe facial pain, is acceptable as it is not teratogenic.

Antibiotics

- Acceptable 1 week after last dose provided the infection has resolved. The reason for deferral of a donor on an antibiotic is not because of the drug level in the blood but rather because of concern of a bacteremia in the donor's blood. Defer for 2 days from last dose of oral or intramuscular antibiotics or antifungal unless taking for chronic condition

Drugs affecting Platelets Production

- Donors who have had Aspirin containing medication will only be allowed to donate blood after 3days or 72hrs of medication if that blood is intended for platelet production. But donors may donate for whole blood or red blood cells not intended for platelet production.
- Effient (Prasugrel), defer for 14 days after taking this medication before donating blood for platelets production or apheresis
- Feldene (Piroxicam), no waiting period for donating whole blood. However, you must wait 48 hours after taking piroxicam before donating blood for platelet production or apheresis.
- Plavix (Clopidogrel) and Ticlid (ticlopidine), defer for 14 days after taking this medication before donating blood for platelet production or apheresis.

Pituitary Growth Hormone

- If pituitary growth hormone is of human origin, then permanently defer the donor. If growth hormone is of synthetic origin then donor is acceptable.

Anaesthetic

- Local Anaesthetic (LA): Provided the donor is well and not in pain, the use of the local anaesthetic is not a reason for deferral. Defer or accept depending on the type of procedure that has been done. General Anaesthetic (GA): Defer for 1 week post GA

Anti-Cancer Drugs

- Accutane, Amnesteem, Claravis, Isotretinoin Proscar, Propecia and Gold therapy, defer for 4 weeks from the last dose
- Avodart or Jalyn (dutasteride), defer for 6 month from the last dose from the last dose
- Soriatane (acitretin), defer for 3 years from the last dose
- Tegison (etretinate) at any time are not eligible to donate blood

Injections of radioactive material

- Defer for 8 weeks for

Insulin dose

- Defer for 2 weeks

Antiviral drugs

- But not for ARVs defer for 2 days from last dose of

3.5 Donor Deferral Criteria for the Emerging Infectious Diseases

Definition: An emerging disease is defined as a disease appearing for the first time in Tanzania or that disease may have existed previously but whose incidence rises sharply in incidence or geographic range.

Emerging infectious diseases can affect a geographical area greater or lesser extent as they can also spread rapidly around the world, depending on the contamination routes. Many factors influence their occurrence, increasing their impact and velocity. As some of these pathogens are transmissible by transfusion, measures must be taken to limit the risk of transfusion.

There are few laboratory tests for the diagnosis of these emerging infections, or they are very sophisticated tests (such as those of molecular biology), very expensive and therefore inaccessible to the countries of Africa.

Every discovery of a new infectious agents in humans leads to considerations of potential blood safety implications often resulting in expanded deferral or screening recommendations. Once Epidemiology and Infectious Disease Unit at the Ministry of Health, Community Development, Gender, Elderly and Children confirm on the outbreak of one of the emerging infectious disease through an official Minister press release, NBTS Tanzania will ensure all blood donors at risk are excluded to safeguard recipient.

1. Chikungunya Virus (CHIKV)

Chikungunya Virus (CHIKV) is an Arbovirus belonging to the Alphavirus genus, Chikungunya virus is most often spread to people by *Aedes aegypti* and *Aedes albopictus* mosquitoes. They bite mostly during the daytime mosquitoes either via cycle involving primates, or by a direct human-mosquito-human cycle. The virus is endemic to Africa, India, Southeast Asia and the Philippines. Recently, it has been notable for causing explosive outbreaks, particularly in islands in the Indian Ocean.

Mode of Transmission of CHIKV

» Often spread to people by mosquito bite

» From mother to newborn around the time of birth

» To date no reports of spread through a blood transfusion.

Symptoms of Chikungunya Virus Infection

» High fever with headache, myalgia, and joint pain

» Pruritic maculopapular rash

» Persistent incapacitating arthralgia.

» Meningoencephalitis

Donor Screening and Deferral criteria for Chikungunya Virus (CHIKV)

- NBTS Tanzania recommend a *temporary deferral period* for donors who have traveled to nonmalarious areas experiencing a CHIKV outbreak.
- The deferral period for clinical chikungunya will be several weeks (6-8 weeks) after the resolution of symptoms.

2. Yellow Fever Virus (YF)

Yellow fever is an acute viral hemorrhagic disease transmitted by infected mosquitoes. The "yellow" in the name refers to the jaundice that affects some patients.

A small proportion of patients who contract the virus develop severe symptoms and approximately half of those die within 7 to 10 days.

Mode of Transmission of Yellow Fever Virus

» The yellow fever virus is an Arbovirus of the Flavivirus genus and is transmitted by mosquitoes, belonging to the Aedes and

Haemogogus species

» Transmission through Blood Transfusion: transmission of YF 17D vaccine virus from recently immunized donors to recipients and through breast milk has been reported.

Symptoms

Yellow fever develops quickly, with symptoms occurring three to six days after exposure. The initial symptoms of the infection are similar to those of the influenza virus. They include:

» Headaches

» Muscle aches

» Joint aches

» Chills

» Fever

Donor screening and Deferral criteria for Yellow Fever Virus (YFV)

NBTS Donor Questionnaire is designed to prevent donor with flue like symptoms or malaria to donate blood, hence in this way we will be able to prevent and interdict Yellow Fever.

Our donor questionnaire is also designed when appropriately applied and responded to, should prevent transmission of the 17D vaccine virus. In the past 8 weeks have you had any vaccination, an affirmative answer for Yellow Fever vaccine require 2 weeks deferral.

3. Dengue Virus (DV)

From the family of Flaviviridae and Genus of Flavivirus causes dengue fever, dengue hemorrhagic fever (DHF) or dengue shock syndrome; this is a serious disease especially in immunocompromised. At risk Populations are tropical areas of Asia, Oceania, Africa, Australia, and the Americas usually in the monsoon or rainy season, especially among persons residing in substandard living conditions.

Mode of Transmission of Dengue Virus

» Spread by mosquito of the Aedes type, A. aegypti

» Through contaminated Blood Transfusion

Symptoms

Begin 3-14 days after infection. Therefore, travelers returning from endemic areas are unlikely to have dengue if fever or other symptoms start more than 14 days after arriving home.

Present with sudden-onset fever, headache (typically located behind the eyes), vomiting, muscle and joint pains, and a characteristic skin rash

Donor screening and Deferral criteria for Dengue Virus

- NBTS Tanzania recommends blood donors with clinical dengue to donate 120 days after resolution of symptoms.

4. West Nile Virus (WNV):

WNV from the family of Flaviviridae and Flavivirus genus can cause neurological disease and death in people, is commonly found in Africa, Europe, the Middle East, North America and West Asia. WNV is transmitted between birds and mosquitoes. Humans, horses and other mammals can be infected. Many cases of transfusion transmission have been described not only the US but also in Greece and Italy.

Symptoms

» No symptoms in most people (70-80%) who become infected with WNV

» About 1 in 5 people who are infected will develop a fever with headache, body aches, joint pains, vomiting, diarrhea, or rash.

» Less than 1% of people who are infected will develop neurologic illness

Mode of Transmission

» West Nile Virus is most commonly transmitted to humans by mosquitoes

» Blood Transfusions

» Organ Transplants

» Exposure in a laboratory setting

» From mother to baby during pregnancy, delivery, or breastfeeding

Donor screening and Deferral criteria for West Nile Virus (WNV)

- Any prospective blood donor who has been diagnosed with West Nile virus will be deferred to donate blood for 120 days

5. Zika Virus (ZIKV)

The Zika virus belongs to the *Flaviviridae* family and the *Flavivirus* genus, and is thus related to the *Dengue, Yellow fever, and West Nile Viruses.* The vertebrate hosts of the virus is primarily monkeys (monkey-mosquito cycle) with only occasional transmission to humans. The outbreak began in early 2015 in Brazil, then spread to other parts of South and North America; it is also affecting several islands in the Pacific

Mode of Transmission

- Zika is primarily spread by the female Aedes aegypti mosquito, which is active mostly in the daytime
- Zika can be transmitted from a man to his sex partners
- The Zika virus can spread from an infected mother to her fetus during pregnancy or at delivery
- Zika can be transmitted through blood transfusions

Symptoms may include

- Fever,
- Red Eyes,
- Joint pain,
- Headache
- Maculopapular rash.

Symptoms generally last less than seven days. It has not caused any reported deaths during the initial infection. Infection during pregnancy causes microcephaly and other brain malformations in some babies. Infections in adults has been linked to Guillain–Barré syndrome (GBS). It also cause microcephaly in newborns

Donor screening and Deferral criteria for Zika Virus (ZIKV)

In areas without active transmission of ZIKV, NBTS Tanzania recommend blood donor deferral for 4 weeks if

- Donor present with history of Zika Virus infection
- Donor report symptoms such as (fever, arthralgia, maculopapular rash, and conjunctivitis) consistent with Zika within 2 weeks of leaving an area with active transmission of Zika Virus
- Donor had sexual contact with a man who has been diagnosed with Zika or travelled to or lived in an area with active transmission of Zika virus in the past 3 months
- Donor has lived in or travelled to an area with active transmission of Zika Virus during the past four weeks

When Tanzania becomes an area with active transmission of Zika Virus like Cape Verde, Mexico, Caribbean countries, Central America, Pacific islands, and South America

- NBTS will only collect blood from donors once Zika virus infected units can be identified and prevented from entering the blood supply.
- NBTS will make arrangement to import blood units for use from an area without active transmission.
- NBTS will authorize the use of blood in area with active transmission only if the prescribing physician identifies an urgent need for blood transfusion that outweighs the risk.
- NBTS will collect and use blood only if they are able to test blood units donated in that active transmission by NAT

6. Ebola Virus (EV):

Ebola Virus Disease (EVD), also known as Ebola hemorrhagic fever (EHF) or simply Ebola, is a viral hemorrhagic fever of humans and other primates (monkeys, gorillas, and chimpanzees) caused by infection with a virus of the family Filoviridae, genus Ebolavirus. It is a rare and deadly disease

Mode of Transmission

» Direct contact (through broken skin or mucous membranes in, for example, the eyes, nose, or mouth) with blood or body fluids (including but not limited to urine, saliva, sweat, feces, vomit, breast milk, and semen) of a person who is sick with or has died from Ebola,

» Needles and syringes injury that have been contaminated with body fluids from a person who is sick with Ebola or the body of a person who has died from Ebola.

» Infected fruit bats or primates (apes and monkeys)

» Contact with semen from a man who has recovered from Ebola (for example, by having oral, vaginal, or anal sex)

» Transmission through blood transfusion has never been reported probably due to the fact that the infected patients deteriorate faster and shorter persistence of the virus in the event of survival

» Recently some Western African countries (Guinea, Liberia and Sierra Leone) have been seriously affected by the Ebola virus. Many factors can cause the emergence of these diseases, such as climate change, human behavior changes, travel, mosquito resistance, variability of the virus, etc.

Symptoms

» Abrupt onset of fever and chills with myalgia, malaise, and headache

» Nausea, vomiting, abdominal pain, diarrhea and pancreatitis; chest pain, cough, and pharyngitis; vascular and neurologic manifestations

» Bleeding manifestations, such as petechial and hemorrhages, occur in half or more of the patients.

Donor screening and Deferral criteria for Ebola (EVD)

- NBTS Tanzania will defer all blood donor from the area with the event of a repetition of the outbreak, if had contact with the blood of imported primates or an association with sick primate handlers.

7. Hepatitis E Virus Infection (HEV):

Hepatitis E Virus from the family of Hepeviridae and genus of Hepevirus cause a liver disease. Usually the infection is self-limiting and resolves within 2-6 weeks. Occasionally a serious disease, known as fulminant hepatitis (acute liver failure) develops, and a proportion of people with this disease can die.

The disease is common in resource-limited countries with limited access to essential water, sanitation, hygiene and health services. In these areas, the

disease occurs both as outbreaks and as sporadic cases. The outbreaks usually follow periods of faecal contamination of drinking water supplies and may affect several hundred to several thousand persons. Some of these outbreaks have occurred in areas of conflict and humanitarian emergencies, such as war zones, and in camps for refugees.

Endemic and epidemic in residents of Southeast and Central Asia plus Japan, Middle East, North and West Africa, Mexico, Brazil and Sporadic cases occur in developed Nations.

Mode of Transmission

- » It is transmitted mainly through contaminated drinking water. The virus is shed in the stools of infected persons, and enters the human body through the intestine.
- » Zoonotic spread may occur from swine or other domestic animals to humans through consumption of uncooked meat products or close environmental contact.
- » Transmission by Blood Transfusion has been documented in endemic areas (e.g. Saudi Arabia and Hokkaido in Japan)
- » Vertical transmission from a pregnant woman to her fetus

Donor screening and Deferral criteria for Hepatitis E Virus (HEV)

- » Individuals with active HEV infection are deferred for 12 months after full recovery for blood donation
- » All prospective donors who had Sexual contacts, household and other close contacts of individuals with HEV infection will be deferred for 12 months since last contact

3.6 Special Consideration of donor selection for Apheresis

Apheresis is the process by which the required blood component of whole blood is separated and collected from the donor using an automated blood cell separation devices known as apheresis machine. Components that can be donated by apheresis include platelets (plateletpheresis), plasma (plasmapheresis), leucocytes (leucapheresis) and red blood cells (erythrocytapheresis). Medical criteria for accepting blood donors in respect to the donors' health should be the same as whole blood.

For apheresis platelet donation, the donors' platelet count should be above $150x10^9$ while for the plasma apheresis donation, the donors total protein level

should be greater than 60g/L and for double red cell apheresis, donors of either gender require a minimum haemoglobin level of 14g/dl.

3.7 Special Consideration of donor selection for Autologous Blood Donors

Candidates for pre-operative blood collection are stable patients scheduled for procedures in which blood transfusion is likely to undergo major orthopedic procedures, most commonly total joint replacement, and vascular surgery, cardiac or thoracic surgery.

The candidate must meet the routine requirements for allogeneic donation and should donate one unit per week and no more than one unit every three days. For orders of four units or less, donation should start three to four weeks prior to surgery. If more than four units are requested, donation should occur over several months.

The documentation used to refer a patient for autologous blood collection should be signed by a medical practitioner and be accompanied by a signed patient consent form.

There some contraindications to participation in autologous blood donation program. Donor-patients considered not to be candidates are those with:

- Evidence of infection and risk of bacteremia
- Scheduled surgery to correct aortic stenosis
- Unstable angina
- Uncontrolled seizure disorder
- Myocardial infarction or cerebrovascular accident within 6 months of donation
- Significant cardiac or pulmonary disease who have not yet been cleared for surgery by their treating physician
- High-grade left main coronary artery disease
- Cyanotic heart disease
- Uncontrolled hypertension.

3.8 Special Consideration of donors Selection for Donors with Disability

NBTS is committed to the promotion of disability equality and this includes;

- Access to donor care and services
- Ease of use of facilities
- Providing information in accessible formats where it is possible to do so

The aim of this section of the document is to ensure that wherever possible all donors and potential donors are given the opportunity to attend a donation session, regardless of whether they have a disability. This information is provided in order to clarify the potential for disabled donors to donate blood. The sections provide information, resources, standard screening processes that involve donor selection process assisting donor with various disabilities and create conducive environment for them to donate in order to improve their donation experience.

Facilities

Disabled facilities vary, by location, for blood donation sessions in public venues, such as Church Halls and Community Centers. However, all our static donor sites are designed to accommodate donors with walking disabilities

Hearing

Due to the Blood Safety Quality Regulations, signers and translators are currently not permitted to be utilized on session during our screening process

Sight

It is recommended that all blood donors with visual impairment are verbally taken through the donor health check questionnaire and screening process by a member of NBTS staff. However, NBTS does not have Braille and audio versions for blood donation session.

Learning Difficulties and Social Communication disorders

NBTS printed materials may not be best suited to those with colour blindness or dyslexia, however, all of our blood donation session welcome desks have a range of coloured overlays to be used by donors who require them. It is imperative for donor and recipient safeties that NBTS staffs are satisfied that potential donors fully understand the consequences of the screening process

and the blood donation process it. Should NBTS staff be in any doubt as to the level of understanding by the potential donor, then the donor in question will not be allowed to undertake the donation process.

Reduced Mobility and wheelchair users

It is essential for your own health and safety that you are able to get yourself from your wheelchair to the donation beds or chairs and back again. NBTS staffs are trained on customer as professional career to assist blood donors on and off the donation beds or chairs.

3.9 Monitoring and Evaluation on implementation of donor selection guideline

The process of donor selection requires on-going monitoring and evaluation to ensure that it achieves its objectives of ensuring donor and patient health and safety and a sufficient supply of safe blood and blood products. The main parameters to be monitored include:

- Donor demographics and characteristics
- Donor deferrals
- Donor adverse reactions
- Confidentiality, including facilities, procedures and documentation
- Complaints
- Blood screening results
- Transfusion reactions in recipients of blood and blood products
- Errors and untoward events
- Staff competency assessment and training needs.

The following indicators may be used to monitor and evaluate the system of donor selection:

- Total number of individuals presenting to donate blood
- Number and percentage of deferrals from donation, by types of deferral: Permanent deferral and Temporary deferral
- Number and percentage of deferrals from donation, by reasons for deferral: Low haemoglobin, other medical conditions, high-risk behavior, travel and other reasons

- Number and percentage of deferrals from donation, by age and gender of donors
- Percentage of donors who self-deferred following donor assessment and counseling
- Percentage of incomplete donor questionnaires
- Rate of adverse donor reactions, by types of reaction
- Prevalence of markers of transfusion-transmissible infection in screened donations: HIV, HBV, HCV, Syphilis and others
- Number and percentage of confirmed positive donors, by age, gender and types of donor.
- Number of repeat, regular and lapsed blood donors

In order to maintain a balance between sufficiency, safety and emerging risks, donor selection criteria and the reasons for donor deferrals should be regularly evaluated to identify whether any criteria need to be removed, modified or extended to provide improved protection of donors and recipients, and to minimize the deferral of suitable donors.

Epidemiological monitoring of infection rates in blood donors, including age and gender-specific prevalence rates in new and repeat donors, contributes to a better understanding of donor behavior and assessment of risk. Knowing and understanding confirmed infection rates in blood donors helps to ensure that donor selection, donor deferral and blood screening strategies are up-to-date and effective.

While the donor questionnaire and interview process is intended to elicit relevant information on which to assess donor suitability for blood donation, the process sometimes may not be effective and operational research may be required to identify mechanisms for improving the process of donor selection and to address issues such as:

- How to improve donor selection criteria
- How to improve the effectiveness of donor education
- How to assess the sensitivity and specificity of certain questions in the donor questionnaire
- How to ask donors culturally-sensitive questions
- Whether donors understand the donor questionnaire

- How to increase donor adherence to selection criteria
- How to reduce blood discard rates

4.0 Summary on overall Process Flow on Blood Donor Assessment and Selection

Recruitment

Identification of low risk donor population, who are associated with low window period

Education and information on risk factors

Self-deferral – not presenting self for donation after self-assessment based on education information.

Donor Registration and Eligibility Assessment

Demographic registration

Eligibility assessment; Age, weight, Previous donation history if is repeat blood donor.

Physical Assessment

Check for General Appearance, skin coloration, lesions, gaiety, lymph nodes and disability needs assistance.

Information and education "Psychological Priming"

Perform Health Check

- Blood Pressure
- Pulse rate
- Haemoglobin estimation

Medical Assessment

Information and education "Psychological Priming", assess for diseases conditions that put both recipient and donor at risk and use of donor questionnaire

Risk Behavior Assessment

Information and education "Psychological Priming", assess social behavior that put recipient at risk and use of donor questionnaire

Deferral and referral

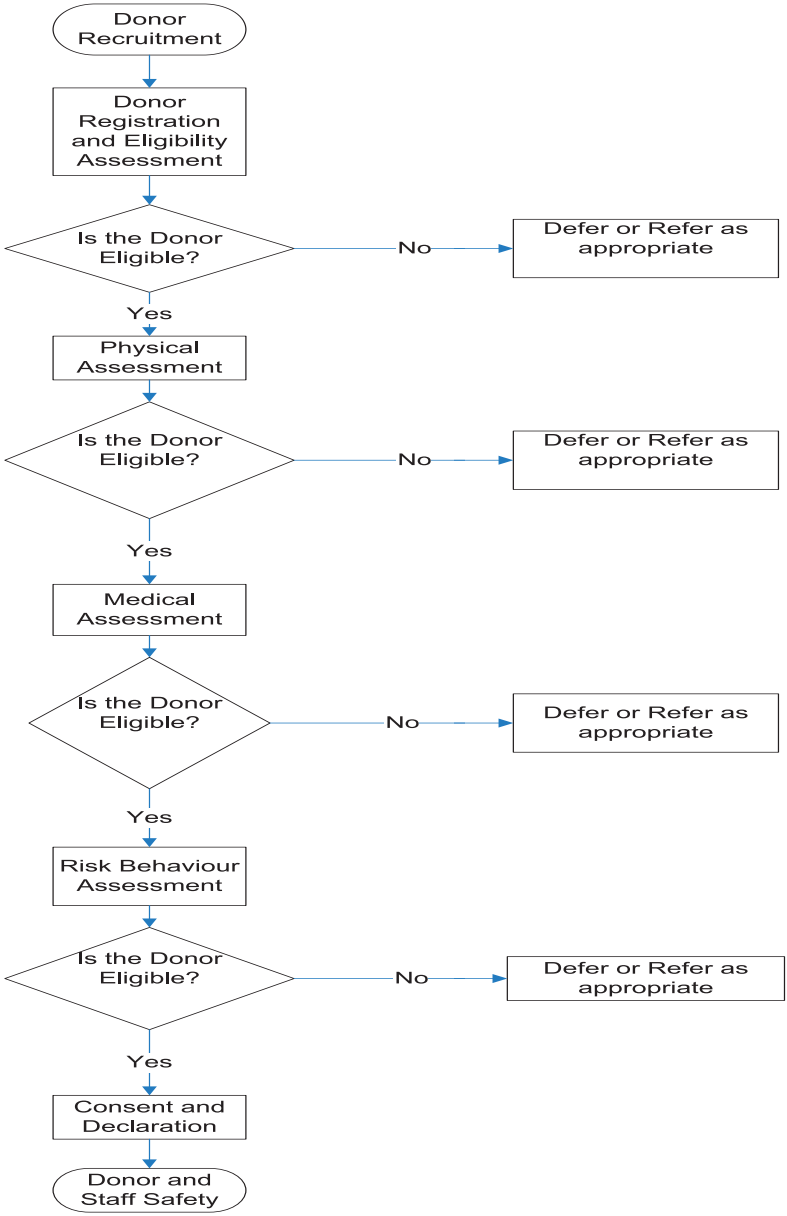
After gathering information from the blood donor

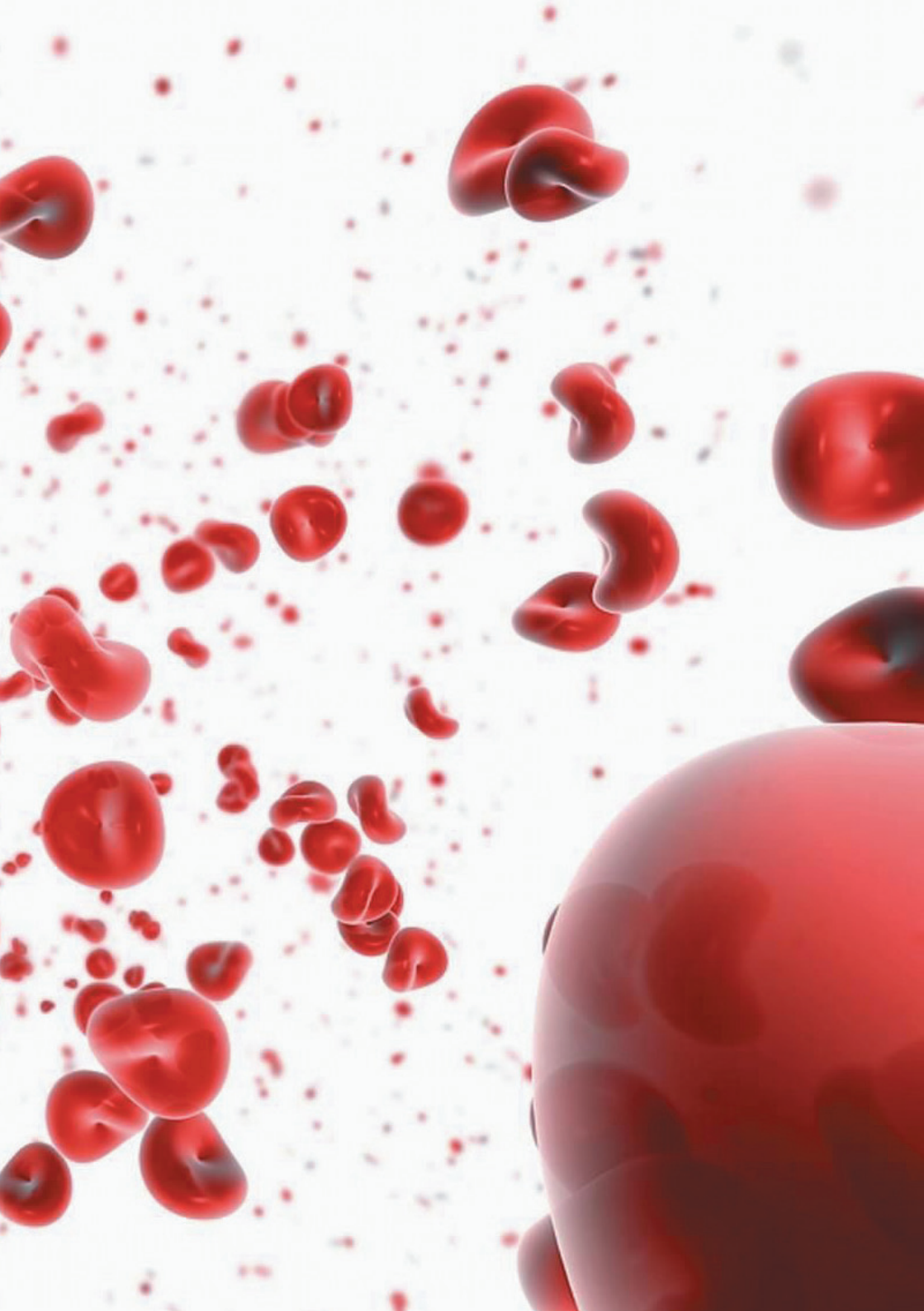
- Refer donors as appropriate
- Defer donor as appropriate
- Encourage self-deferral (Self exclusion)
- Encourage confidential exclusion of blood unit

Consent and Declaration

Once blood donor has passed all behavior and medical assessment, before donor sign consent and declaration inform the donor about donation adverse reaction the test to be done on the unit, results notification and on further communication.

Figure 10: Summary of Process Flow on Blood Donor Assessment and Selection





Chapter Four

4.0 VIRAL HEPATITIS SCREENING AND MANAGEMENT AMONG BLOOD DONORS

4.1 BACKGROUND OF VIRAL HEPATITIS B & C

4.1.1 Hepatitis B Viruses (HBV)

Epidemiology of HBV

Hepatitis B infection is caused by the hepatitis B virus (HBV), an enveloped DNA virus that infects the liver and causes hepatocellular necrosis and inflammation. HBV infection can be either acute or chronic, and may range from asymptomatic infection or mild disease to severe or rarely fulminant hepatitis.

Acute hepatitis B is usually a self-limiting disease marked by acute inflammation and hepatocellular necrosis, with a case fatality rate of 0.5-1%. Chronic hepatitis B (CHB) infection encompasses a spectrum of disease, and is defined as persistent HBV infection (the presence of detectable hepatitis B surface antigen [HBsAg] in the blood or serum for longer than six months), with or without associated active viral replication and evidence of hepatocellular injury and inflammation .

Age is a key factor in determining the risk of chronic infection. Chronicity is common following acute infection in neonates. 90% of neonates born to hepatitis B e antigen [HBeAg]-positive mothers and in young children under the age of 5 years (20–60%), but occurs rarely (<5%) when infection is acquired in adulthood. Worldwide, the majority of persons with CHB were infected at birth or in early childhood.

The spectrum of disease and natural history of chronic HBV infection are diverse. In some people, CHB is inactive and does not lead to significant liver disease. In others, it may cause progressive liver fibrosis, leading to cirrhosis with end-stage liver disease, and a markedly increased risk of hepatocellular carcinoma (HCC), independent of the presence of cirrhosis, usually many years after initial infection. Longitudinal studies of untreated persons with CHB show an 8-20% cumulative risk of developing cirrhosis over

five years. In those with cirrhosis, there is an approximately 20% annual risk of hepatic decompensation and the annual incidence of hepatitis B-related HCC is high, ranging from <1% to 5%. Untreated patients with decompensated cirrhosis have a poor prognosis, with 15-40% survival at five years. Several host and viral factors, especially co infections with HIV, HCV and hepatitis D virus (HDV), together with other cofactors such as alcohol use, may increase the rate of disease progression and risk of developing HCC.

It is estimated that worldwide, 2 billion people have evidence of past or present infection with HBV, and 240 million are chronic carriers of HBV surface antigen (HBsAg). Age-specific HBsAg seroprevalence varies markedly by geographical region, with the highest prevalence (>5%) in sub-Saharan Africa, while in Tanzania is reported to be about 8%.

Virology of Hepatitis B (HBV):

HBV is one of the smallest viruses known to infect humans, and belongs to the hepadnavirus family. It is a hepatotropic virus, and liver injury occurs through immune-mediated killing of infected liver cells. HBV is also a recognized oncogenic virus that confers a higher risk of developing HCC.

The virus circulates in serum as a 42-nm, double-shelled particle, with an outer envelope component of HBsAg and an inner nucleocapsid component of hepatitis B core antigen (HBcAg). HBV DNA can be detected in serum and is used to monitor viral replication. HBeAg, unlike HBsAg and HBcAg, is not particulate, but rather is detectable as a soluble protein in serum.

Worldwide, at least nine genotypes of HBV (A through I) have been identified on the basis of more than 8% difference in their genome sequences. Higher rates of HCC have been found in persons infected with genotypes C and F compared to other genotypes. Antiviral therapy is equally effective, and the HBV vaccine is protective against all HBV genotypes.

Transmission of HBV:

HBV is spread predominantly by percutaneous or mucosal exposure to infected blood and various body fluids, including saliva, menstrual,

vaginal, and seminal fluids, which have all been implicated as vehicles of human transmission. Sexual transmission of hepatitis B may occur, particularly in unvaccinated men who have sex with men and heterosexual persons with multiple sex partners or contact with sex workers.

Infection in adulthood leads to chronic hepatitis in less than 5% of cases. Transmission of the virus may also result from accidental inoculation of minute amounts of blood or fluid during medical, surgical and dental procedures, or from razors and similar objects contaminated with infected blood; use of inadequately sterilized syringes and needles; intravenous and percutaneous drug abuse; tattooing; body piercing; and acupuncture.

Perinatal transmission is notably the major route of HBV transmission. In the absence of prophylaxis, a large proportion of viraemic mothers, especially those who are seropositive for HBeAg, transmit the infection to their infants at the time of, or shortly after birth.

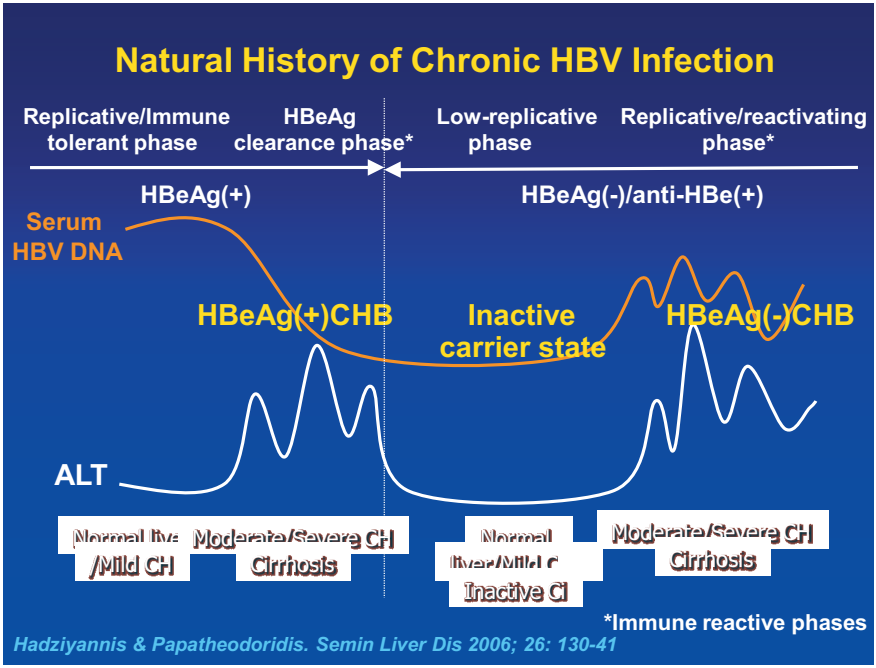
The risk of perinatal infection is also increased if the mother has acute hepatitis B in the second or third trimester of pregnancy or within two months of delivery. Although HBV can infect the fetus in utero, this appears to be uncommon and is generally associated with antepartum hemorrhage and placental tears. The risk of developing chronic infection is 90% following perinatal infection (up to 6 months of age) but decreases to 20–60% between the ages of 6 months and 5 years.

Horizontal transmission, including household, intra familial and especially child to-child, is also important. At least 50% of infections in children cannot be accounted for by mother-to-infant transmission and, in many endemic regions, prior to the introduction of neonatal vaccination, the prevalence peaked in children 7–14 years of age.

Natural history of HBV.

The natural history of Hepatitis B is dynamic and complex, and progresses nonlinearly through several recognizable four phases namely – *Immune tolerant*, *Immune clearance*, *Inactive carrier state*, *Reactivation Phases*. (Figure 1)

Figure 11: Showing Natural History of Chronic Hepatitis B. (CHB)



However, not every patient goes through all phases; for example, the immune tolerance phase is short or absent in patients with childhood or adult acquired HBV infection that becomes chronic and many patients may never progress to the reactivation phase. Importantly the sequence does not always relate directly to criteria and indications for antiviral therapy.

Diagnosis and staging of HBV

Routine assessment of HBsAg-positive persons is needed to guide management and indicate the need for treatment. This generally includes assessment of additional serological markers of HBV infection (HBeAg); measuring aminotransferase levels to help determine liver inflammation; quantification of HBV DNA levels; and stage of liver fibrosis by non-invasive tests (NITs) such as aspartate aminotransferase (AST)-to-platelet ratio index (APRI), transient elastography (Fibro Scan) or (Fibro Test).

a) HBV serological markers

Previous HBV infection is characterized by the presence of antibodies (anti-HBs and anti-HBc). Immunity to HBV infection after vaccination is characterized by the presence of only anti-HBs. CHB is defined as the persistence of HBsAg for more than 6 months. Recently, quantitative HBsAg level determination has been proposed to differentiate inactive HBsAg carriers from persons with active disease.

It also needs to be established whether the person is in the HBeAg positive or HBeAg-negative phase of infection, though both states require lifelong monitoring, as the condition may change over time. In persons with CHB, a positive HBeAg result usually indicates the presence of active HBV replication and high infectivity.

Spontaneous improvement may occur following HBeAg-positive seroconversion (anti-HBe), with a decline in HBV replication, and normalization of ALT levels. This confers a good prognosis and does not require treatment.

HBeAg can also be used to monitor treatment response, as HBeAg (anti-HBe) seroconversion in HBeAg-positive persons with a sustained undetectable HBV DNA viral load may be considered a potential stopping point of treatment. However, this is infrequent even with potent Nucleotide analogue therapy. Some HBeAg negative persons have active HBV replication but are positive for anti-HBe and do not produce HBeAg due to the presence of HBV variants or pre-core mutants.

Virological evaluation of HBV infection Serum HBV DNA concentrations quantified by real-time polymerase chain reaction (PCR), correlate with disease progression and are used to differentiate active HBeAg-negative disease from inactive chronic infection, and for decisions to treat and subsequent monitoring.

Serial measures over a few months or longer are preferable, but there remains a lack of consensus regarding the level below which HBV DNA concentrations are indicative of "inactive" disease, or the threshold above which treatment should be initiated. HBV DNA concentrations are also used for optimal monitoring of response to antiviral therapy, and a rise may indicate the emergence of resistant variants.

WHO standards are now available for expression of HBV DNA concentrations. Serum HBV DNA levels should be expressed in IU/mL to ensure comparability; values given as copies/mL can be converted to IU/mL by dividing by a factor of 5 to approximate the conversion used in the most commonly used assays (i.e. 10 000 copies/mL = 2000 IU/mL; 100 000 copies/mL = 20 000 IU/mL; 1 million copies/mL = 200 000 IU/mL). The same assay should be used in the same patient to evaluate the efficacy of antiviral therapy. Access to HBV DNA testing remains very poor in resource-limited settings.

b) Assessment of the severity of liver disease

A full assessment includes clinical evaluation for features of cirrhosis and evidence of decompensation, and measurement of serum bilirubin, albumin, ALT, AST, alkaline phosphatase (ALP), and prothrombin time; as well as full blood count, including platelet count. Other routine investigations include ultrasonography and alpha-fetoprotein (AFP) measurement for periodic surveillance for HCC, and endoscopy for varicose vein in persons with cirrhosis.

4.1.2 Hepatitis C Viruses (HCV)

Epidemiology of HCV

According to recent estimates, more than 185 million people around the world have been infected with HCV, of whom 350 000 die each year. The prevalence of hepatitis C in Tanzania is estimated at 2% and infection varies substantially around Africa, highest being in Egypt at 25%.

Most people infected with the virus are unaware of their infection and, for many who have been diagnosed, treatment remains unavailable to majority, One third of those who become chronically infected are predicted to develop liver cirrhosis or hepatocellular carcinoma. However, Treatment is successful in the majority of persons who get treated. Groups are at higher risk of HCV infection includes,

- People with sexual partners who are HCV-infected.
- People with HIV infection including men who have sex with men (MSM).

» People who have used/shared intranasal drugs.

» People who have had tattoos or piercings.

» People who have been exposed to unsafe injection practices and unscreened or inadequately screened blood transfusion occurring in health care settings.

» People who inject drugs (PWID).

» Babies borne to mother infected with HCV. The risk of transmission of HCV from a Mother to her child occurs in 4–8% of births to women with, HCV infection and in 17–25% of births to women with HIV and HCV coinfection.

Virology of Hepatitis C

The hepatitis C virus is a small, positive-stranded RNA-enveloped virus belonging from Hepacivirus genus within the Flaviviridae family. It has a highly variable genome and multiple genotypes and sub genotypes.

The distribution of HCV genotypes and sub genotypes varies substantially in different parts of the world. Some genotypes are easier to treat and, thus, the duration of and recommended medicines for therapy vary by genotype. For this reason, determining a patient's genotype is important to appropriately tailor therapy. It is possible that this advice may change when antiviral agents that are active against all genotypes (referred to as pangenotypic) are licensed for use.

Natural history of HCV

Hepatitis C virus causes both acute and chronic infection. Acute HCV infection is defined as the presence of HCV within six months of exposure to and infection with HCV. It is usually clinically silent, and is only very rarely associated with life-threatening disease.

Spontaneous clearance of acute HCV infection occurs within six months of infection in 15–45% of infected individuals in the absence of treatment. Almost all the remaining 55–85% of persons will harbor HCV for the rest of their lives (if not treated) and are considered to have chronic HCV infection.

Anti-HCV antibodies develop as part of acute infection and persist

throughout life. In persons who have anti-HCV antibodies, a nucleic acid test (NAT) for HCV RNA, which detects the presence of virus, is needed to confirm the diagnosis of chronic HCV infection. Left untreated, chronic HCV infection can cause liver cirrhosis, liver failure and hepatocellular carcinoma (HCC). Of those with chronic HCV infection, the risk of cirrhosis of the liver is 15-30% within 20 years. The risk of HCC in persons with cirrhosis is approximately 2-4% per year.

The risk of cirrhosis and HCC varies depending upon certain patient characteristics or behaviors. For example, persons who consume excess alcohol, persons with hepatitis B or HIV coinfection and immunosuppressed individuals are all at higher risk of developing cirrhosis or HCC.

Disease associated with HCV is not only confined to the liver. Extra hepatic manifestations of HCV include cryoglobulinaemia, glomerulonephritis, thyroiditis and Sjögren syndrome, insulin resistance, type-2 diabetes mellitus, and skin disorders such as porphyria cutanea tarda and lichen planus. Persons with chronic HCV infection are more likely to develop cognitive dysfunction, fatigue and depression.

4.2 VIRAL HEPATITIS SCREENING AMONG BLOOD DONORS

4.2.1 Clinical Evaluation and Risk Assessment to Viral Hepatitis before Blood Donation

General Considerations prior to ordering tests for hepatitis, consider the patient's history, age, risk factors hepatitis vaccination status, and any available previous hepatitis test results.

Assess the risk factors which should critically be captured in structured questionnaire tool.

With HBV Screening most international guidelines recommend that several high-risk groups be screened for HBsAg, and that those at risk and not immune should be offered hepatitis B vaccination.

HCV Screening for HCV infection screening for HCV infection is done using HCV serological testing. If positive, a NAT for HCV RNA assay is needed to confirm chronic HCV infection.

It is important to consider the possibility of infection with other blood borne viruses in persons with HCV, and to offer screening for HBV and HIV in addition to HCV.

Major risk factors that should be captured from the Questionnaire tool (Appendix 1) in relation to viral hepatitis should include but not limited to:

- Substance use includes sharing drug snorting, smoking or injection equipment
- High risk sexual activity or sexual partner with viral hepatitis
- Travel to or from high risk hepatitis endemic areas of exposure during a local outbreak
- Immigration from hepatitis B&C endemic countries
- Contacts to household with an infected person especially if personal items e.g. razors, toothbrushes, nails clippers) are shared.
- Recipient of unscreened blood products
- Needle stick injury or other occupation exposure e.g. health care workers
- Children born to mothers with chronic hepatitis B or C
- Attendance at day care
- Tattoos and body piercing
- History of incarceration
- HIV or other sexually transmitted infection
- Hemodialysis screening of donated blood products for hepatitis C (anti-HCV).

4.2.2 Donor health status Survey or Screening for Hepatitis:

Demographics:

Name, Age, Sex, Place of birth, Occupation, Marital Status, Contact details place address & cell number; Donor Status Number of donations, place of donation, Any history of deferral previously?

Table 2: Questionnaire for Donor health status Survey or Screening for Hepatitis

S/N	Questionnaire	Answer	Intervention
1.	Have you ever tested for Hepatitis before? Status?	Yes	DP-CRF
2.	Have you received blood transfusion before? How many times before? When was the last BT given? (User guide)	Yes	DT-CRC (12months?)
3.	Have you ever injected **any** drug by yourself or being assisted of? (See user guide)	Yes	DT- CRC /DP -CRF
4.	Have you ever had a stab wound OR needle or pricked accidentally in the past? Or spilled of blood/body fluids (user guide)	Yes	DT –CRC (3months?)
5.	Do you wear a tattoo or been involved in body piercing practices? (User guide)? Place and tools used	Yes	DT –CRC (12months?)
6	Have you ever been a victim of sexual assault/ rape?	Yes	DT –CRC (3months?)
6	Do you practice anal sex?	Yes	DP-CRF
6	Do you practice oral sex?	Yes	DT- CRC
6.	Do you have more than one sexual partner? Does your partner have more sexual partners? Within 6months? (user guide)	Yes	DT –CRC
7.	When was your last sexual encounter with new partner	Yes	DT –CRC 3months
7	Polygamous? Number of spouse? User guide	Yes	DT-CRC/AD
8.	Have you ever been in contact with a person with Hepatitis or with history of jaundice? User guide: What kind of relation/ activities you had with such a person in on number	Yes	DT -CRC
10.	Do you have a relative/sexual partner with history of Hepatitis/jaundice (user guide) expand on relativity. User guide: What kind of relation/ activities you had with such a person.	Yes	DT CRC

12.	Have you ever been vaccinated for Hepatitis? Sate reason for receiving vaccination?	Yes	AD
13.	Have you ever been hospitalized Guide: for what and where?	Yes	AD/DT -CRC
14	Safe delivery?	Yes	
14.	Do you have any other chronic medical problem? State if yes,	Yes	DP-CRF
15.	Are you currently taking any long term medications? State if yes,	Yes	DP- CRF
16.	Have you ever been told by a doctor that you have abnormal blood tests /AUS for your liver? Sequence?	Yes	DP-CRF
17.	Do you share razor blades, tooth brushes, shaving blades or other sharp accessories within 6months? User guide:	Yes	DT-CRC/AD
18.	Medical or surgical procedure? Probe: Dental extraction, circumcision, genital mutilation,	Yes	DT-CRC
19	Have you ever of recent within 6months experienced fevers, associated right upper abdominal pains, nausea or vomiting?	Yes	DT CRC
20.	Have you ever had history of jaundice or yellowing of your eyes or dark yellow urine?	Yes	DT-CRC
21.	Have you ever or currently experiencing one of the following: -Persistent right upper quadrant abdominal pains? -Anorexia, -Generalized body fatigue? Weight loss?	Yes	DT CRC

4.3 Management of Blood Donor with Positive HBV&HCV

4.3.1 Blood Unit Screening and Donor Results Disclosure for HBV&HCV

The purpose of screening donated blood is to ensure the microbial safety of the blood supply. Microbiological screening of blood is performed on donations from apparently healthy, asymptomatic donors to rule out the presence of infections and assure safe blood for transfusion. Blood screening involves a single test with the resultant action, such as the release or discard of the donated blood. An initially reactive result is followed by repeat testing.

Screening vs. Diagnostic Testing

Diagnostic testing is performed as part of a clinical investigation to pursue a diagnosis of infection either as a result of signs and symptoms in an individual or a specific or identifiable risk of infection.

Diagnostic testing often involves additional testing over a period of time either to pursue the diagnosis in early infections or to follow-up or monitor infection.

Screening vs. Confirmatory Testing

Confirmatory testing is performed to confirm the infectious status of donors deferred on the basis of repeat reactive screening tests, allowing the appropriate action then to be taken. It is also used to obtain accurate epidemiological data on infections in the blood donor population.

Effective confirmation requires appropriate and well-designed confirmatory strategies for disease, including the selection of assays and algorithms for the analysis and interpretation of results. Special equipment and advanced training are also required.

Confirmatory testing should be performed by a reference laboratory unless considerable expertise and resources are available within the NBTS itself.

Confirmatory testing is primarily concerned with the status of the donor and the subsequent action to be taken. Donations that are

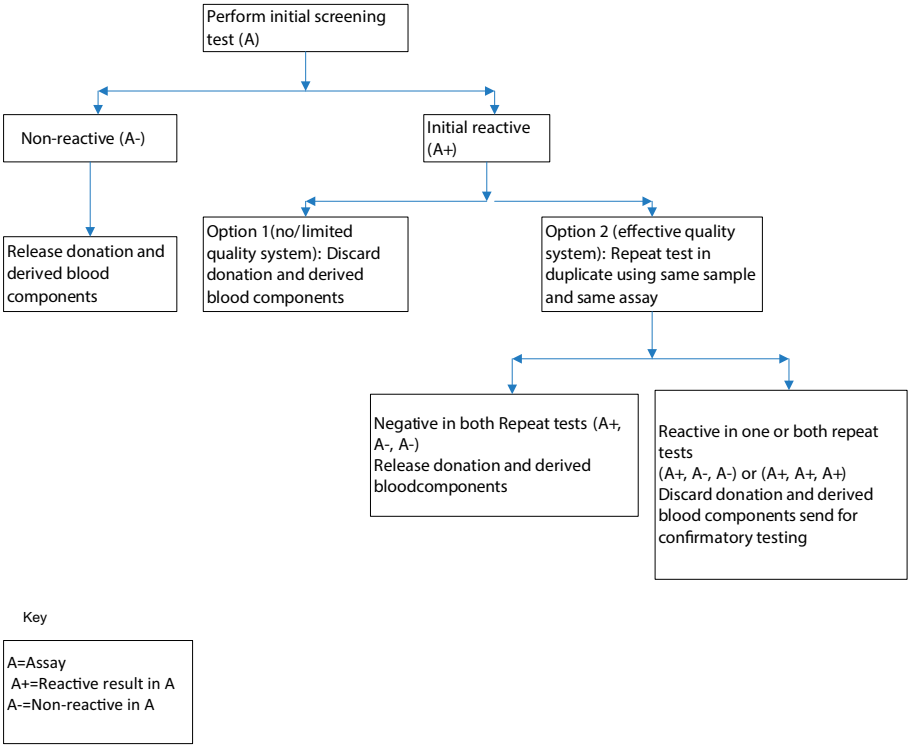
repeat reactive may be confirmed as being of negative, inconclusive or positive status:

- A negative conclusion on confirmatory testing indicates that the donor is not infected with the specific infection. However, a donor showing repeat reactive results on screening and negative results on confirmatory testing should be counseled and temporarily deferred until screen non-reactive on follow-up. The donor can then be accepted for future donations.
- An inconclusive outcome is usually due to non-specific reactivity not related to the presence of the infectious agent. The donor should be counseled, deferred for blood donation and followed-up for further investigations.
- A positive conclusion confirms that the donor is infected and should be deferred from future blood donation, counseled and referred for appropriate medical care
- The appropriate confirmatory testing strategy for blood donor management should be applied before notifying donors of their infectivity status. The results of all tests performed for infection markers for TTIs and blood group serology should be evaluated when making final decisions on the release of blood units for therapeutic use.

Selection of Screening and Confirmatory Test

- In low incidence or prevalence disease such as HCV in the country, a significant proportion of blood donors whose donations give reactive screening results are not truly infected. A considerable number of donors may be lost due to deferral resulting from non-specific reactivity, especially if a test is not highly specific.
- The assay selected for blood screening should be highly sensitive and specific. The aim is to detect all possibly infected donations while minimizing wastage due to false positive results. Donations that yield reactive or indeterminate test results should be discarded using methods in accordance with standard safety precautions (Fig.3)

Figure 12: Model algorithm for blood screening:



4.3.2 Hepatitis Post Test Counseling Checklist for Exposed Blood Donors

The proposed format below is for Hepatitis post-test counseling and communication skills checklist. Note that, Hepatitis Post-test counseling should always be conducted in an individual setting, ensuring the client's privacy and confidentiality.

1. Welcome client, record her /his name and file number
2. Provide test results and give client time to react, give emotional support
3. Discuss any concerns the client has about his/her own about the newly confirmed disease
4. **Discuss Hepatitis infection basics**

- » What is hepatitis; how is it acquired; the course and complication of disease
- » Treatment and prevention aspects
- » Other STI screening, prevention, signs, and treatment.

5. **Counsel on staying healthy and protective to the community**
   - » Follow all appointments at the referral center.
   - » Importance of emotional support from family and friends
   - » Adherence to further evaluation at specialized referral centers
   - » Adherence to management plan provided at specialized referral center if eligible or non-eligible.
6. **Disclosure - who will he/she share the results with? (Special cases)**
   - » Partner testing, testing other children. Encourage partner testing and couples counseling.
   - » Partner testing, testing other children. Encourage partner testing and couples counseling.
   - » Safer sex (e.g., mutual faithfulness, always using condoms, abstinence)
   - » Avoid Nutrition and Toxic drugs which would exacerbate liver damage. Nutrition (reduce alcohol intake and protein food), use the following drugs under close follow of physician acetaminophen, Isoniazid, chlorpromazine and Halothane.
   - » Hygiene
7. Counsel on safe delivery and at birth dose of the born child for infected women anticipating pregnancy (special cases)
8. Ask if she has any questions or concerns he/she wants to discuss now
9. Provide appropriate referrals and take-home information
10. Summarize the session and next steps, including the next clinic appointment/referral
11. Record counselor name, signature and date of counseling

Disclosures specifically for Hepatitis Blood Donors

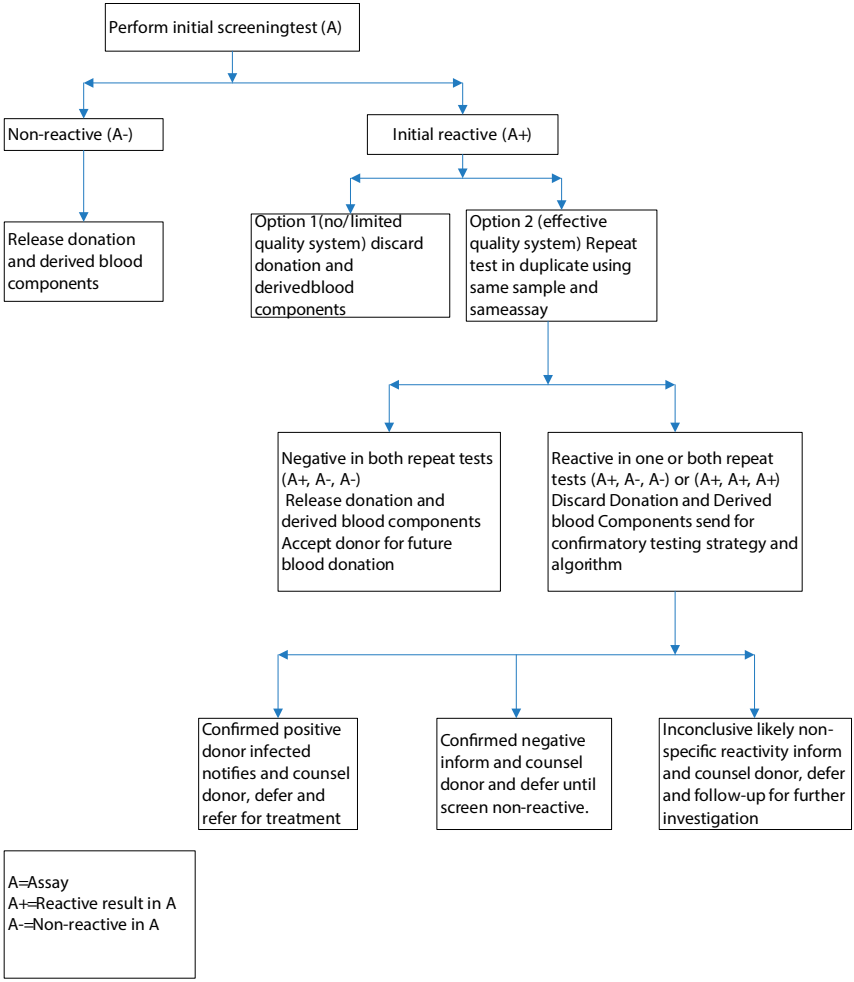
Negative Test Results

- Results should be given in person
- Where antibody test results are negative, patients should be counselled that any continued risky behavior may lead to infection in the future.
- Repeat testing is advised if the patient is believed to have been recently exposed to the virus, since HCV antibodies can take up to six months to develop.).

Positive Test Results:

- It is important that the patient clearly understands the result and what to do next. Acute HBV positive results may need to be retested after six months to confirm chronic progression.
- The patient may need support to come to terms with a positive test result and potential future implications.

Figure 13: Model algorithm for blood donor management based on screening and confirmatory testing *for Hepatitis B*



The model algorithm shown in Figure 2 Represents the minimum processes recommended for blood donor management and epidemiological monitoring based on initial screening and confirmatory testing.

It relates to blood screening option 2 for facilities where effective quality systems are in place. The model algorithm shows the decision points on whether the donor should be accepted, counseled, deferred or referred, based on the results of confirmatory testing.

Confirmatory testing is an essential component of look-back for ascertaining the true infectious status of the donor and recipients of previous donations. It also provides further benefit to the NBTS in the epidemiological monitoring of infection rates in blood donors, thus contributing to a better understanding of donor behavior and assessment of risk.

Knowing and understanding confirmed infection rates in blood donors helps to ensure that donor selection, donor deferral and blood screening strategies are up-to-date and effective.

Figure 14. Testing and Management algorithm guide for HBV

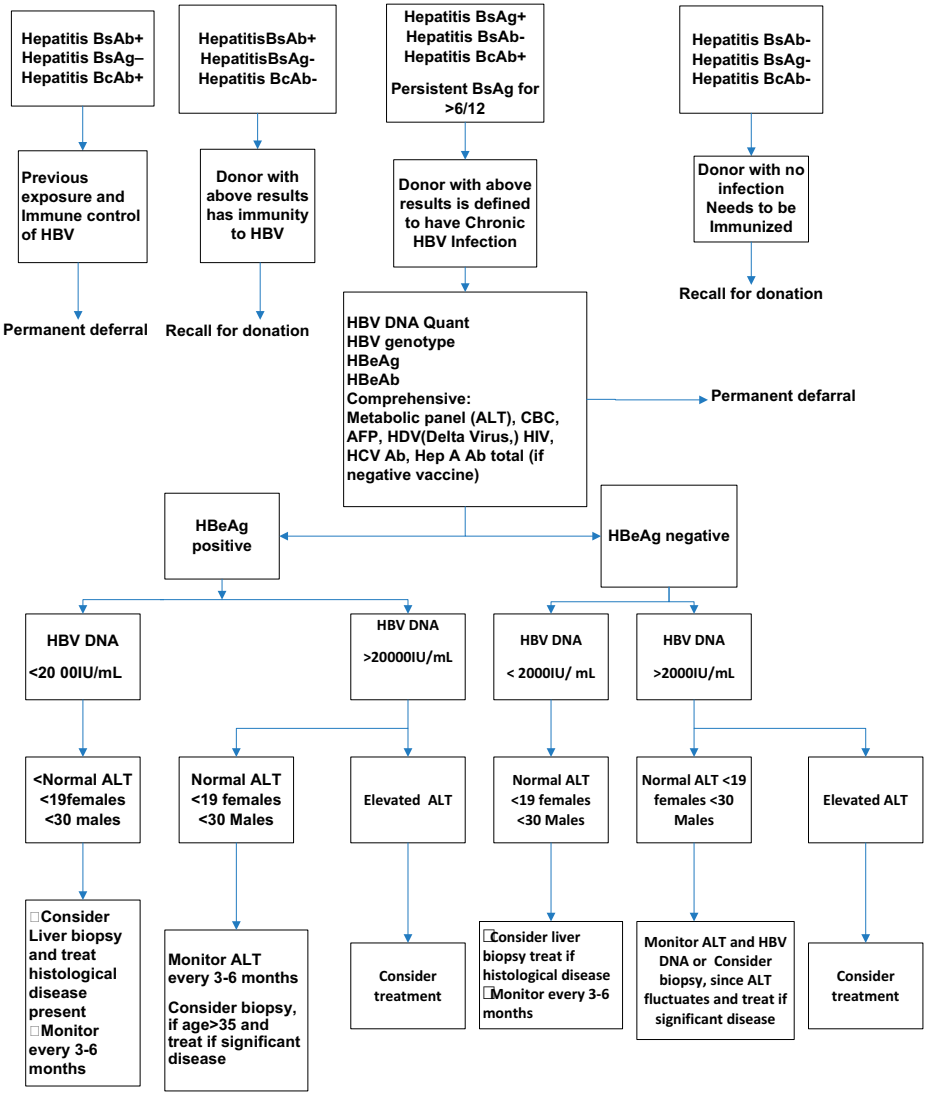
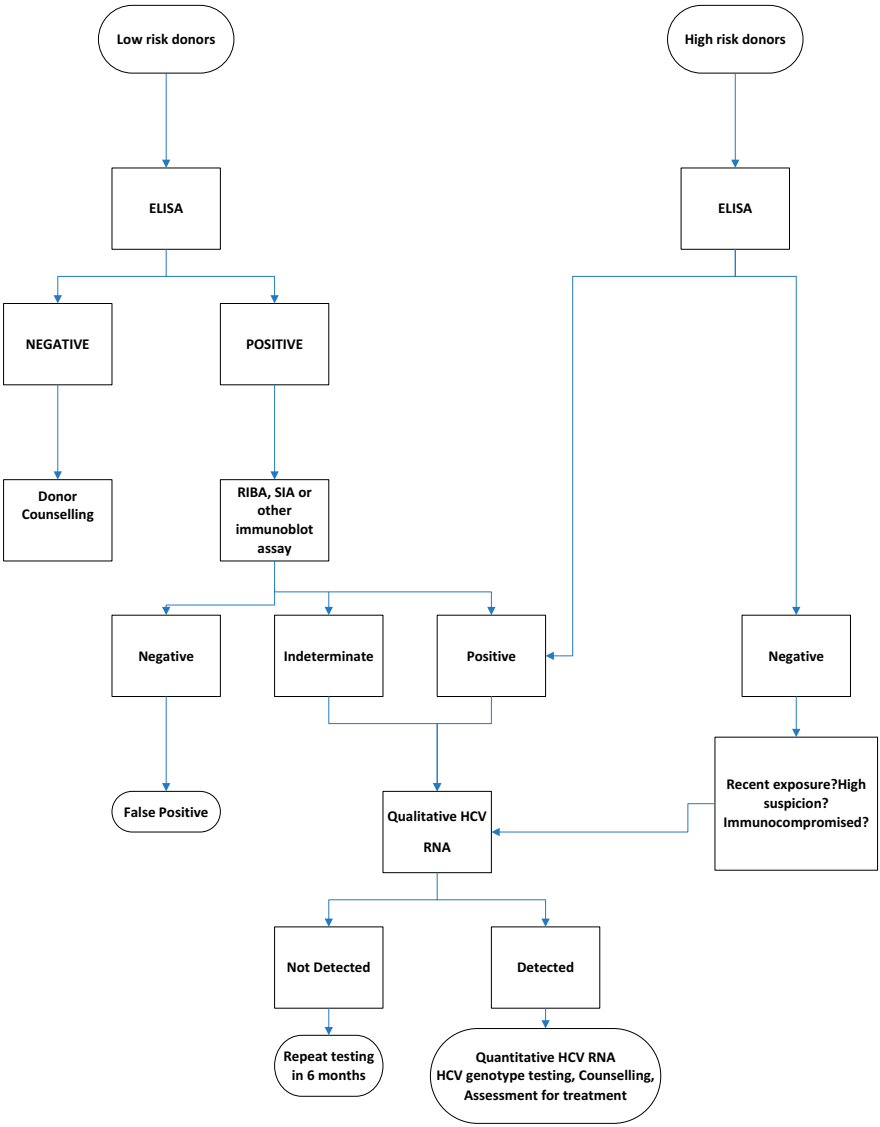


Figure 15. Testing and Management algorithm guide for HCV



4.3.2 Referral and Networking for Blood Donor with Positive Results of HBV&HCV

NBTS should identify and establish referral centers within the hierarchy of National referral system in Tanzania. The centers should have adequate clinical and diagnostic expertise in management of acute and chronic hepatitis including follow up managements of clients.

Muhimbili National Hospital has got a designated Hepatology Centre Clinic which evaluates and manages most referred cases of Hepatitis in the country. Zone Referral Hospitals should be integrated within the Hepatitis Referral Network to maximize care and treatment strategy of referrals from NBTS centers in the country.

A consolidated network involving the Districts Hospitals, Regional Hospitals, Zone centers, MNH, and NBTS should be strengthened to improve the referral process, care and treatment; and assist on national surveillance efforts on Hepatitis.

NBTS center will refer cases to specific district, and from district to regional centers in department of medicine. The Regional Hospital will refer to hepatology clinic at zonal level .In this level key persons will be identified to care and manage these clients. All client will be confirmed at National level for Hepatitis B infection.

Figure 17: Showing referral system for Blood Donors with Positive results of HBV&HCV Identified through NBTS Centers, Regional and District teams

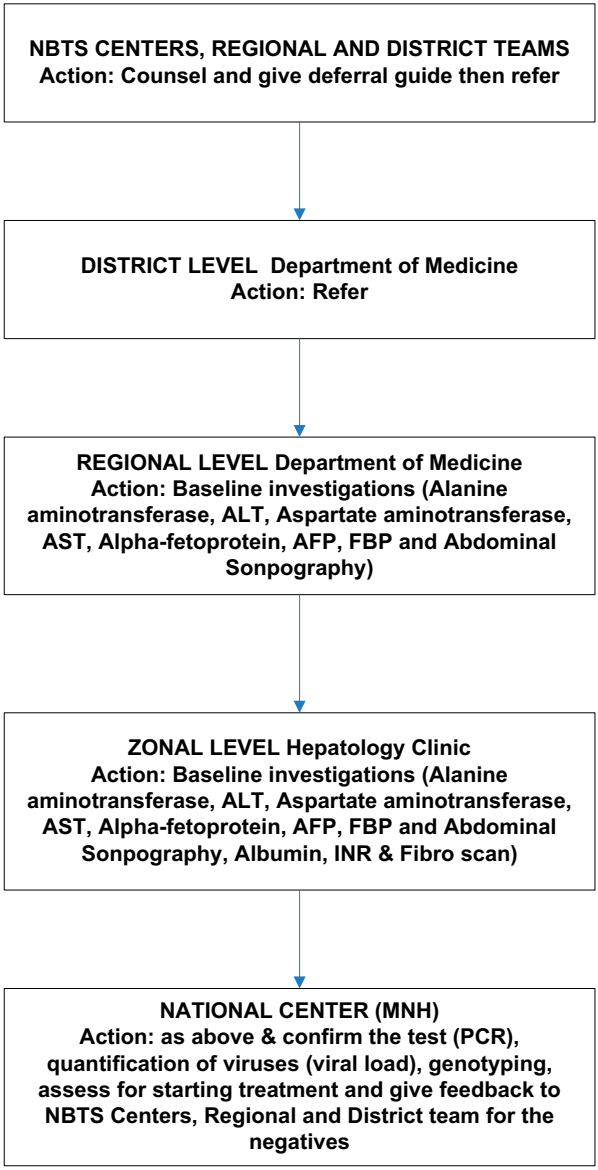
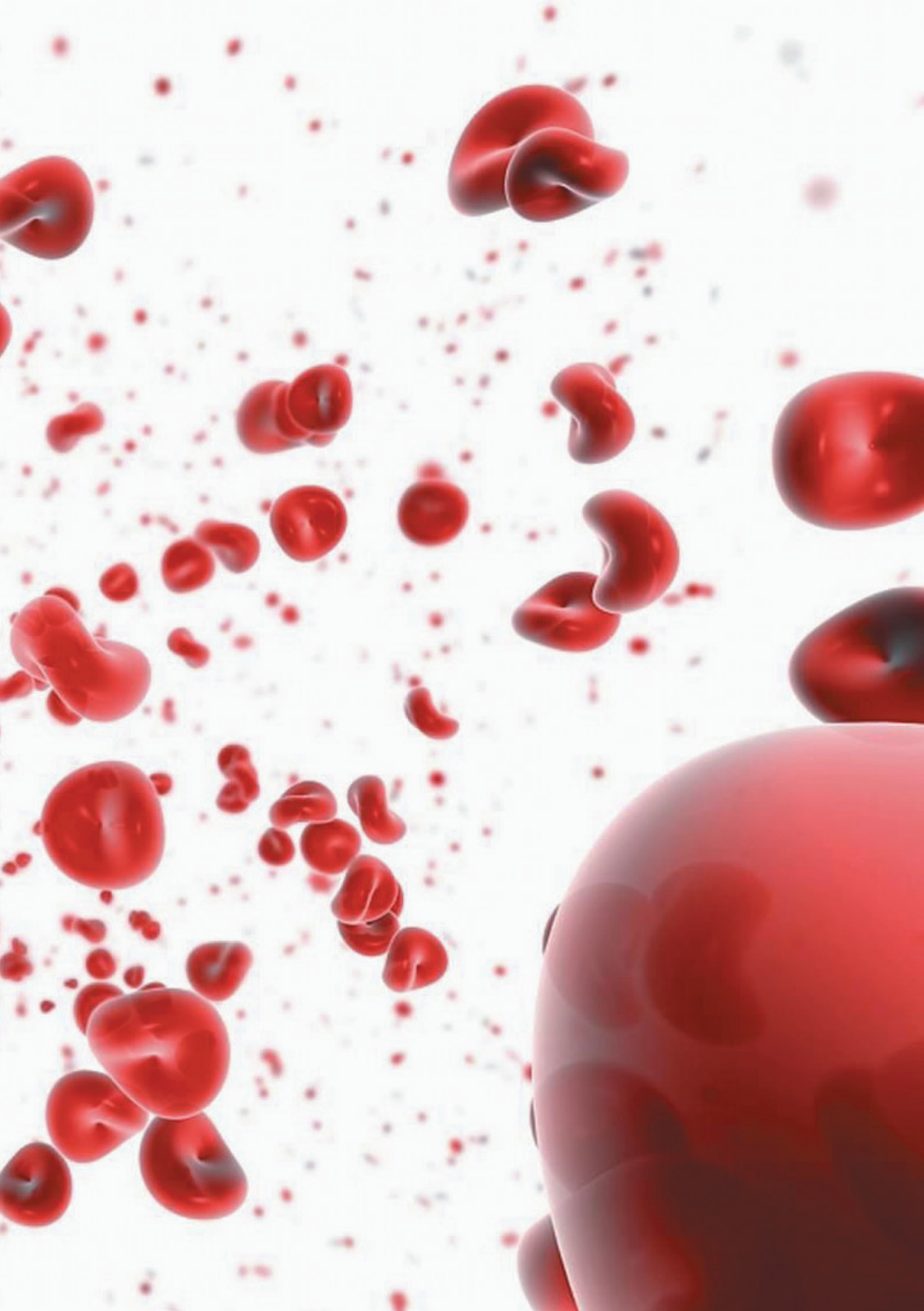


Table 3: Current Treatment Options for Hepatitis B&C

S/N	Genotype	Regimens	Route& Duration
HEPATITIS B			
1.	**A to I**	*Inj Pegyated Interferon 180mcg*	SC ,weekly for 48 weeks
2.		*Tab. Tenofovir (Viread) 300mg*	PO, daily 48 -72 weeks
3.		*Tab. Entecavir (Barclude) 1mg*	PO, daily 48 – 72 weeks
HEPATITIS C (for Non-Cirrhotic Patients Only).			
4.	**1,4,6**	*Ledipasvir 90 mg/ Sofosbuvir 400mg (Harvoni)*	PO, daily, 12 Weeks –naïve patients OR 24 weeks treatment experienced.
5.	**2**	*Sofosbuvir 400mg/ Ribavirin 600 -1000mg*	PO, daily, 12 weeks – naïve patients OR 16 weeks – treatment experienced.
	3		PO, daily, 24 weeks – naïve and treatment experienced patients.
	4		PO, daily, 24weeks –naïve and treatment experienced patients.
	5		PO, daily, 12 weeks – naïve and treatment experienced



Chapter Five

5.0 Monitoring and Evaluation on Implementation of Donor Selection Guideline

5.1 Monitoring and Evaluation of Blood Donor Counseling

5.1.1 Objectives of Monitoring and Evaluation

Monitoring is the routine assessment of o n-going activities and progress to provide an overview of what has been done. Evaluation is the episodic assessment of overall achievements to measure what impact has been made. The effectiveness of blood donor counselling should be monitored to assess whether activities are being carried out properly and evaluated to ascertain whether programme strategies and activities have the desired impact.

NBTS counselling activities require regular monitoring and evaluation to ensure compliance with SOPs as part of a quality system, to assess the NBTS capacity to provide counselling, and determine their impact on building a pool of regular voluntary non-remunerated blood donors. Information obtained from monitoring and evaluation can be used for reporting to stakeholders and improving the quality and relevance of counselling activities, as well as refining the training of counsellors. As part of the quality management process, these data should be regularly monitored by supervisors and quality managers at an interval specified in an SOP. Appropriate corrective and preventive action should be taken, where needed.

5.1.2 Data for Monitoring and Evaluation

Data for monitoring and evaluation can be obtained from many sources including:

- **Routine functions:** This may include the
  - » Number of donors counselled
  - » Number of donors deferred
  - » Number of units discarded due to reactive screening test results.

- **Reviews of records:** Logs and incident reports: This may include
  - » Infection rates in first-time and regular/repeat donors
  - » Donor demographics (e.g. gender and age)
  - » Donor deferral rates
  - » Location of donation.
- **Periodic surveys:** This involves measuring the amount of time taken for different stages of counselling and can be useful in determining staffing patterns and work flow. These surveys may also be used as indirect measures of quality (e.g. if a particular counsellor takes more or less time than others) and could also be combined with other data such as donor return rates, donor satisfaction surveys and feedback.
- **Interviews:** Completed donor questionnaires can be reviewed with donors with abnormal infection test results to determine whether there was any significant history of infection risk at the donor's pre-donation counselling.

5.1.3 Monitoring and Evaluation Indicators

It is essential to identify and monitor critical indicators in blood donor counselling (including the required numerators and denominators) and to evaluate these indicators to ensure compliance. This will allow modification of strategies, assessment of the quality of blood donor counselling and identification of areas for improvement. Appropriate indicators should be selected and collected data should be analyzed with the intent of improving the performance and effectiveness of blood donor counselling.

From the performance audit, data on the following indicators should be available for assessing the effectiveness of blood donor counselling. Some of these indicators are interrelated and should be interpreted in conjunction with other relevant indicators to ensure that the assessment is meaningful:

- » Number of donors deferred, by reason for deferral
- » Number of Repeat/Regular donors
- » Number of deferred donors provided with counselling (pre-donation and post-donation)

- » Prevalence of TTI among first-time, regular and repeat donors
- » Discard rate due to: Confidential unit exclusion or post-donation information by donors-Reactive test results for TTI
- » Return rate of temporarily deferred donors
- » Number of referrals of deferred donors for medical attention, by reason for deferral
- » Number of adverse donor reactions, by type
- » Return of suitable donors who experienced adverse donor reactions in the past.

All data should be examined on quarterly and annual basis and compared with those from previous years in order to identify trends over time or in response to interventions undertaken by the NBTS or other agencies. It is important to include all relevant parties in the monitoring and evaluation system, as changes undertaken in one part of the organization may influence outcomes in other parts.

5.2 References

Donor Number: _____ Unit Number:_____

Place of Session: _____

District:_____ Date:_____

Surname: _____

Other names: _____

Date of Birth -----/----/------	Age:	Sex: Male /Female	Occupation:	
Marital Status	Not married	Married	Divorced/ Separated	Widowed

Contact Details:

Postal Address: _____

Physical Address: _____

_____

_____

Cell phone number: _____Email: _____

Donor Status	First time	Repeat	Regular	Donor club member	Donor Association
Donor Types	Voluntary non-remunerated blood donors		Family Replacement	Conversion from Family replacement to voluntary non-remunerated blood donor	
Information	Media	Received sms	Received call	Meetings	Social media

Number of donations: _____When was your last donation? _____

Where _____

Donor Number: _____ Unit Number:_____

Place of Session: _____

District:_____ Date:_____

Surname: _____

Other names: _____

Date of Birth -----/----/------	Age:	Sex: Male /Female	Occupation:	
Marital Status	Not married	Married	Divorced/ Separated	Widowed

Contact Details:

Postal Address: _____

Physical Address: _____

_____

_____

Cell phone number: _____Email: _____

Donor Status	First time	Repeat	Regular	Donor club member	Donor Association
Donor Types	Voluntary non-remunerated blood donors		Family Replacement	Conversion from Family replacement to voluntary non-remunerated blood donor	
Information	Media	Received sms	Received call	Meetings	Social media

Number of donations: _____When was your last donation? _____

Where _____

Donor Questionnaire: _____

#	Health Check		#	In the past 12 months have you:	
1	Are you feeling well and in good health today?	Yes/No	22	Ever had a stab wound or accidentally needle stick injury?	Yes/No
2	Have you eaten in the last 4 hours?	Yes/No			
3	Have you had malaria in the past 2 weeks?	Yes/No	23	Had any tattooing or body piercing e.g. ear piercing?	Yes/No
	In the past 6 months have you:	Yes/No			
4	Been ill, received any treatment/medication?	Yes/No	24	Injected yourself or been injected, besides in a health facility?	Yes/No
5	Had any operations, injections or vaccinations?	Yes/No			
6	Had typhoid fever?	Yes/No	25	Had a sexually transmitted disease (STD)?	Yes/No
7	Experienced fever associated with right upper abdominal pains, nausea or vomiting?	Yes/No	26	Been a victim of sexual assault e.g. rape or sodomy?	Yes/No
8	Been pregnant or breast feeding? *(females only)*	Yes/No	27	Received money goods or favors in exchange for sex?	Yes/No
	Do you have or have you ever had:	Yes/No			
9	Any problems with your heart or blood pressure?	Yes/No	28	Received a blood transfusion or blood products?	Yes/No
10	TB or Asthma?	Yes/No	29	Ever contacted relative or sex partner with history of hepatitis/Jaundice?	Yes/No
11	Severe bleeding or a blood disease?	Yes/No			
12	Sugar sickness in the blood (Diabetes)?	Yes/No	30	Had yellow eyes or yellow skin?	Yes/No
13	Any type of cancer including blood cancer?	Yes/No	31	Ever tested for hepatitis before? Status?	Yes/No

14	Any other long term illness, such as epilepsy?	Yes/No	32	Ever been in contact with a person with hepatitis or Jaundice?	Yes/No
	Risk Assessment				
	In the past 6 months have you		33	Had spilled of blood or any other body fluids?	Yes/No
15	Had a new sex partner?	Yes/No	34	Ever been vaccinated for hepatitis?	Yes/No
16	Had more than one sex partner?	Yes/No	35	Had contact with someone with yellow eyes or yellow skin?	Yes/No
17	Has your sex partner had sex partner more than you in the past 6 months?	Yes/No			
18	Do you practice oral sex?	Yes/No	36	Ever had history of jaundice or yellow eyes or pass dark yellow urine?	Yes/No
19	Do you practice anal sex?	Yes/No			
20	In the past 6 months have/do you share sharps accessories e.g. razor/shaving blades?	Yes/No	37	Ever been on long distance travelling away from your domicile?	Yes/No
21	Ever been hospitalized? Received medical	Yes/No	38	Do you consider your blood safe?	Yes/No

Donor consent:

I confirm that the information I have given above is true and correct. I understand and consent to any potential adverse reaction might occur during the donation process. I understand and consent to my blood been tested for HIV, Hepatitis B & C, and syphilis and I am willing to receive the results of my tests from the National Blood Transfusion Centers/satellites and may be released to the third part.

I consent to further communication by the BTS regarding future blood donor clinics and campaigns.

Donor's Signature: _____ Date: _____

For Official Use:

Observation

Weight:	Weighing scale used:					Checked by (Name: Sign:
Hb	<12.5dl/L>	12.5dl/L	Checked by (Name): Sign:			
BP & Pulse	BP: mmHg	Pulse: /min	BP machine used:	Name: Sign:		

Final Donor Assessment	Donor Accepted	Temporally deferred	Permanently deferred

Reason for Deferral	Medical	Social	Age	Weight	Hb	BP

Polygamy	Yes	No	If Yes number of spouses:

Comments: _____

Counselor's name: _____

Signature:

Time needle in *(Insert)*	Time needle out *(Insert)*	Successful venipuncture *(Tick)*	Unsuccessful venipuncture *(Tick)*	Low volume *(Tick and insert vol)*

Donation weighing scale	Weighing scale used:

Donor Adverse Event	Hematoma	Faint			Others (Specify)
		Mild	Moderate	Severe	

Comments: **Phlebotomist: _____Signature: _____**

BLOOD DONOR REFEERAL FORM

ADDRESS OF THE BLOOD CENTER, REGIONAL OR DISTRCT TEAM
From……
P.O.Box……..
Telephone number……..……
Fax number……
Date……
BLOOD DONOR REFERRED TO (Please tick √ appropriate)
1. CTC 2. MEDICAL CLINIC 3. OTHER SPECIFY
GENERAL INFORMATION OF THE CLIENT

Name……..

Age…….

Sex……..

ID Number……..…

Address……..…

REFERRAL DATE

Date……...

MEDICAL INFORMATION

The above mentioned client is a voluntary/replacement blood donor who donated blood at our center. After testing the blood unit donated by this donor we found that he/she has a positive screening test results on……

This was based on the following tests performed at NBTS blood centers. Mention tests

1st assay……..

2nd Assay…….

Others…….....

REASON FOR REFERRAL (Please tick √ appropriate)

1. For Medical Services

2. Other Supportive Services

3. Sexual Transmitted disease (STD) Services

REFERRED BY (Please tick √ appropriate)

BLOOD CENTER MEDICAL OFFICER/COUNSELOR

Name……

Signature…….

Date……

Thank you for your cooperation in the matter. Should you require any further information please do not hesitate to contact us NBTS Zonal Centre using above address.

References

1. *Blood donor selection. Guidelines on assessing donor suitability for blood donation.World Health Organization, 2012*
2. *Specific Blood Transfusion Practice Guidelines. Ministry of Health and Social Welfare, 2006.*
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Notes

Notes


NATIONAL BLOOD TRANSFUSION SERVICE-TANZANIA
Donate Blood. Save Lives.