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NATIONAL GUIDELINE ON BLOOD DONOR TESTING & COUNSELING SERVICE

Revised Edition, June2017 Addis Ababa, Ethiopia

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FOREWORD

Donor counseling is key strategic activity in blood bank services that enhances safe donor pool by encouraging safe donors to be regular and discouraging those who are not safe depending on their blood test results. It is a key entry point to ensure blood safety among the donor population.

To ensure the safety of blood supply donor counseling is of paramount importance in the blood bank service. Post-blood donation counseling is acknowledged to be a necessary element of donor counseling as an adjunct to informing donors of unusual or abnormal test results.

In the donor counseling process test result notification should be done with the intention of saving donors of unusual test results and their partners and families from farther problems associated with TTIs. Blood donors should be notified of their test results for HIV, HBV, HCV, and Syphilis viruses which can be transmitted through blood transfusion.

These guidelines on blood donor counseling should be used in conjunction with other NBBS resources in particular with the Donors' Medical Assessment Guideline and the quality Manual.

Dr. Habtemariam Demoz A/Director General National Blood Bank Service

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Abraham Zeleke Director, Blood Donor Service Directorate National Blood Bank Service

ACRONYMS

AIDS: Acquired immune-deficiency syndrome CDC = Centers for Disease Control and Prevention (United States) ELISA = Enzyme Linked Immunosorbent Assay HBV = Hepatitis B Virus HCV = Hepatitis C Virus IEC = Information, Education and Communication NBBS = National Blood Bank Service PICT = Provider Initiated Testing and Counseling RBBs = Regional Blood Banks SOP = Standard Operating Procedures VCT = Voluntary Testing and Counseling VNRBD = Voluntary Non-remunerated Regular Blood Donors WHO = World Health Organization

1. INTRODUCTION

The Ethiopian Red Cross Society (ERCS) has been the pioneer organization in developing blood banking services in the country. The first blood transfusion center was established in 1969. The service has been organized as a department under the leadership of the National Red Cross Society with one central and 9 regional blood banks and can only meet part of the country's blood demand. To secure safe blood service the Federal Ministry of Health (FMoH) take over the service from Ethiopian Red Cross Society since 2012 and integrated with the health service under the FMoH and RHBs besides developed a strategic document as to how enhance the service.

In the blood bank service strategic document expansion of the number of blood banks, increasing awareness level of the community towards the need of voluntary blood donation to increase the collection of blood units, strengthening quality control system, enhancing blood transfusion service facilities in place, strengthening the area with research and trainings, equipping blood bank facilities with the latest equipments and materials, opening donor counseling service are some of the initiatives in the blood bank strategic document that helps to bring about radical changes in Blood Transfusion Service.

The revised National HIV Counseling and Testing Guideline (July 2007) provides the legal frame work to do mandatory HIV testing on all voluntary blood, tissue and organ donors, who shall be informed about HIV testing and given opportunity to learn their test results. As per the guideline all other mandatory HIV testing is considered violation of human rights unless ordered by the court of law. However, the guideline doesn't provide clear guidance on what procedures to follow when doing mandatory HIV testing, counseling and test result notification in the setup of blood services, which is the purpose of this guideline to fill the gap. Moreover, the blood bank services (BBS) setup is a unique environment compared to other clinical settings that it needs to deal with all Transfusion Transmissible Infections (TTIs) like Hepatitis B, Hepatitis C and Syphilis;



besides HIV, in order to achieve its goal of providing safe and adequate blood to all in need of it.

However, there is no uniform pre- and post- blood donation counseling and HIV test result notification practice globally, though post blood donation blood sample testing is more or less a universal practice. Most counties provide either pre donation or post donation counseling, notifying test results only if the client requests for.

As per the information reported to WHO global data base by 173 countries on blood safety, 61 countries provide only pre donation counseling; 55 countries provide post donation counseling in all blood bank centers while only 48 countries reported to provide both pre and post donation counseling in all blood bank centers. In South Africa, for instance pre donation counseling and donor education are provided as part of general pre donation donor risk assessment and screening procedure which may lead to self or permanent deferral. Positive results are however notified some other time as part of the proactive donor follow-up procedure when results are notified with proper counseling and confirmatory tests by the medical department of the Blood Bank Service and clients are linked to proper care and treatment facilities and an insurance system pays the fees. In Ethiopia, there is a pre donation counseling and donor education service as part of donor risk assessment and screening with no proactive post donation and positive test notification, referral and linkage mechanism in place. Positive TTIs test results are notified by blood bank centers in Ethiopia only when the client/donor has requested for test results of their interest with proper counseling and referral services to the proper governmental health facilities. However, it is up to the clients themselves to seek and utilize further care and treatment services.

The BBS has the duty of protecting the health of blood donors and recipients of blood by ensuring safety of procedures and products, setting and complying with policies, standards and procedures. It also needs to play a leadership role and contribute to the national effort of averting new HIV infection and other TTIs which might be transmitted through





known TTIs positive donors and contaminated units of blood. In order to discharge this responsibility the BBS should establish and implement a system of proper pre and post blood donation counseling and test result notification and referral system, at all levels. Proper implementation of this strategy will enable the BBS to expand and retain pool of healthy voluntary donors, through counseling and education on pursuing healthy lifestyle, besides gaining the benefit of preventing new HIV and other TTIs infection through referral linkage of positive clients/donors to appropriate HIV/ TTIs prevention care and support facilities. It also directly contributes to cost effectiveness and efficiency of the system through self and permanent deferral as it reduces the cost of unnecessary blood collection and processing

Post donation counseling service has a vital role in encouraging self-deferral and encouraging non-reactive donors to become regular non-remunerated blood donors thereby discard rate due to TTIs will dramatically decreases among blood donors.

2. Definitions of Technical Terms

AIDS: A disease that can affect the immune and central nervous systems and can result in neurological problems, infections, or cancers. It is caused by human immunodeficiency virus (HIV).

Blood donor: Person whose blood is collected for transfusion. This term is most commonly used for donors of whole blood but may also be used for donors of plasma, platelets, etc.

Confidential unit exclusion: The removal and disposal of a unit of blood after donation at the request of the donor.

Confidentiality: the obligation of health-care professionals and healthcare institutions not to disclose personal and sensitive information about their clients or blood donors to third parties.

Donor deferral: Term referring to the non-acceptance of a prospective blood donor. Deferral may be temporary (for a specific time) or indefinite (no specific time can be assigned) or even permanent.

ELISA Test: Enzyme-Linked-Immuno-Sorbent-Assay, a quantitative assay which utilizes the affinity of antibodies for their antigens and an



enzyme which serves as a part of the detection method.

False negative: A negative test result for a person who is actually infected. **False positive:** A positive test result for a person who is actually not infected.

Hepatitis: Inflammation of the liver. In the context of blood transfusion, hepatitis refers to the various forms of viral hepatitis which can be transmitted by blood transfusion, of which hepatitis B and hepatitis C are of the most serious concern.

HIV: Human immunodeficiency virus, which causes AIDS. Several types of HIV exist, with

HIV-1 & HIV-2 being the most common.

Informed consent: The legally effective permission of a donor/client or legally authorized representative(e.g., parent or legal guardian of a minor child) to undergo a medical test or procedure or to donate blood for those who are minors.

Rapid test: A test to detect antibodies to TTIs that can be collected and processed within a short interval of time (e.g., approximately 10-60 minutes).

Risk behavior: Behavior that exposes a person to the risk of acquiring transfusion transmissible infections.

Self-deferral: The decision by a potential donor to wait until a condition that makes him/her unsuitable has resolved.

Self-exclusion: The decision by a potential donor not to give blood because he/she has engaged in risk behavior or because of the state of his/her own health condition.

Sensitivity: The probability that a test will be positive when infection or condition is present.

Sero-status: Blood test report of an individual who has been tested for a certain transfusion transmissible infection in which the result is specified as positive or negative.

Specificity: The probability that a test will be negative when the infection or condition is not present.

Standard Operating Procedure: A prescribed procedure adopted under controlled conditions to be followed in the performance of a task.





Transfusion-Transmissible Infection (TTIs): An infection that is potentially capable of being transmitted by blood transfusion such as HIV, Hepatitis B, Hepatitis C, and Syphilis.

True Positive: A positive result on both the initial test and the confirmatory test.

Window period: The period between infection and the development of detectable antigen or antibodies.

3. Objectives

The primary objective of this guideline is to provide health providers and counsellors working in the National Blood Bank Service (NBBS) and Regional Blood Banks (RBBs)with policy and proper technical guidance, so that they can provide and promote quality assured pre and post blood donation counselling, test results notification and referral services to all blood donors accessing the BBS, within in the context of the National HIV Testing and Counselling Guideline and National Guideline for Prevention and Control of Viral Hepatitis in Ethiopia when applicable.

3.1. Specific objectives are to provide counselling and referral services:

- for individuals who are deferred from blood donation for health conditions such as anaemia and hypertension etc.
- for blood donors with reactive blood test results for transfusion-transmissible infections (TTIs), including HIV, hepatitis B, hepatitis C, and syphilis and for unusual blood cell serology.
- for healthy regular blood donors to promote good health, care and safety .

4. Blood Donor Counseling & Its Types

4.1. Blood Donor Counseling

Blood donor counseling is a confidential dialogue between a blood donor and a counselor about issues related to the donor's health and the donation process in an environment that ensures voluntarism, privacy





and confidentiality of information. The counseling can be provided before an individual successfully registers for blood donation, i.e. pre-donation counseling, or after blood donation if there is a blood test result the BBS needs to inform him or her, i.e. post-donation counseling. For the latter, the counseling process includes an evaluation of the personal risk of transmitting or acquiring TTIs, the facilitation of preventive behavior and referral to care and treatment services.

4.2. Types of Blood Donor Counseling

4.2.1. Pre-donation Information

At this stage donors should be aware about voluntary blood donation and all the procedures to be followed thereafter.

It is an important first step informing and educating the blood donors about the blood donation process before donation. It provides orally or through printed materials, audio-visual and online materials. It is usually made available to prospective donors at the same time as the donor questionnaire is administered during the process of registration for blood donation.

Donors should be assisted to make an informed decision to donate or self-defer. Thus, the information to be provided for the prospective donors should include:-

- + Donor's rights and responsibilities
- Nature ,use blood and its component and the importance of maintaining healthy life styles
- + Rational for the donors questionnaire and pre-donation health assessment
- + Blood donation process(donor selection criteria and deferral)
- Potential donation related reactions(fainting or hematoma)
- ✤ Tests performed on donated blood(screening TT Is and ABO
- + Importance of regular donations
- + Donation intervals
- Transfusion-transmissible infections, including window period and transmission and prevention of common TTIs(HIV,HBV,HCV and syphilis)



- Information and notification of TTIs results; assurance of confidentiality and referral for further investigation, counseling, treatment and care
- + High-risk behavior and how to avoid infection risk

4.2.2. Pre-donation counseling

One of the most important activities of the BBS is to ensure that donors are free from any possible infections that could be transmitted through their blood and are in a good state of health. Pre-donation counselling is closely linked with the process of donor selection in which each individual's suitability to donate blood is carefully assessed against a set of standard criteria through:

- a basic health check and medical history to ensure that the donor is healthy and it is appropriate and safe for the donor to donate
- a health and behavioural assessment of the risk of transfusion-transmissible infections or other health factors that may harm the recipient of donated blood.

These checks or assessments will not be effective without the provision of relevant information and counselling to prospective donors. This is because some donors may choose to self-defer if they realize that they do not meet the criteria for blood donation. Others will need to be deferred, either on a temporary or on a permanent basis, on the grounds of their health status or risk behaviour. Counselling is particularly important for deferred donors as it provides an opportunity to offer advice on health and behavioural issues and to refer them to other healthcare services for further management and care. Empathetic counselling may also serve to lessen a sense of rejection and encourage temporarily deferred donors to return again after a suitable time interval. Counselling of healthy and self-deferred donors enables reinforcement to be given about healthy lifestyles and behaviour as part of the care of blood donors to ensure a safe, healthy and reliable pool of voluntary non-remunerated blood donors (VNRBDs).

At this stage stringent screening of donors should be done to the level enabling them to make an informed decision as per the blood donor assessment medical guideline; and donors should also be properly informed to use the post donation counselling service. Pre-donation counseling is a strategy to reduce and prevent the donation of blood by individual who might be at risk for TTIs. It is part of the process of donor selection and assessment of donor suitability for blood donation based on donor selection criteria before donation, as a routine step in a confidential interview of donor's medical history; assess donor health and TTIs risk for every donor at each donation.

It includes:-

- Reviewing the Donor's responses to the donor questioner
- Explaining the processes of donor selection, blood donation and test of blood for TTIs
- Encouraging self-deferral if any exposed to TTIs
- Explaining post-donation procedure
- Obtaining the Donor's informed consent to donate blood
- Providing suitable counselling to deferred blood donor
- Refer the donor, if necessary, for further investigations, diagnosis, treatment and care
- Advising temporarily deferred donors when they return at a suitable time to give blood

4.2.3. Counselling During Donation

At this stage there has to be a follow up of the blood donor and encourage him/her to complete the donation process. It provides an opportunity:-

- ♦ To explain the vein puncture procedure, the need to properly disinfect the skin and find a suitable vein.
- ♦ To show appreciation to donors for their valuable contribution and enhance donor satisfaction with the donation experience.
- \diamondsuit It also has a positive impact on donor motivation and return for future donation

The professional should be skilled:-

- ♦ In interpersonal communication
- Know the procedure of disinfecting the skin and making suitable the vein for donation
- \diamond The volume of blood to be collected and the time needed for the procedure



- ♦ Personal care after; vienpuncture site and how to prevent and manage acute and delayed donor reaction
- Explain about the confidential unit exclusion system.

4.2.4. Post-donation Counselling

Following donation, a proportion of donors will be found to be reactive in screening tests for TTIs or to have unusual blood cell serology test results. Counselling donors who have reactive test results is an essential adjunct to blood screening and is an important part of donor care as the implications may be very serious, especially for those whose test results are confirmed and their true infectious status established.

The service should be rendered for all blood donors who seek it. However; BBS especially should ensure that all donors whose test results are confirmed positive are given information and counseling promptly, accurately, confidentially and in a manner that alleviates anxiety and promotes understanding. However, since BBS do not usually have the expertise to provide the proper clinical care for such donors, they should be referred to their own physicians or appropriate specialist clinical services for further investigations, diagnosis, treatment and care. Donor counseling is thus part of a continuum of care that involves both the blood service and the wider healthcare system.

5. Target Audience/ Blood Donors for Counseling

5.1. Categories of Blood Donors for Counseling

Three categories of blood donors are identified based on their health status, information and counseling needs. These are healthy blood donors, temporarily and permanently deferred blood donors.

- I. Healthy blood donors need to be counseled on maintaining their good health through encouraging and giving them information and support to adopt and maintain healthy lifestyle.
- II. Donors may also be deferred temporarily for temporary health reasons (such as anemia, low weight, malaria infection, etc). They are prospective donors whom the BBS needs to support to regain and maintain their good health through counseling and providing the right information.



III. The third category of blood donors are the permanently deferred blood donors who are known positives to one, some or all of TTIs and who can pose danger of transmitting such infections because of their irresponsible actions. So this group of donors needs to be carefully counseled and educated on coping mechanisms, consequences and implications of their positive status and linked to appropriate health facility to get the proper HIV and other TTIs prevention, care and treatment services and support them to pursue positive and responsible way of life.

5.2. Age and Informed Consent

As per the National Blood Bank Standards those who are under 18 years of age are considered as minors and are not allowed to donate blood unless consents are obtained from their parents or guardians. From this we can understand that persons only 18 years old and above can give informed consent for post donation counseling and test result notification service. Counselors should carefully consider and confirm to whom they disclose test results.

6. Approaches to Blood Donor Counseling

The National HIV Counseling and Testing Guideline of July 2007 identifies three HIV counseling and testing approaches; provider initiated HIV testing and counseling (PICT), Client initiated counseling and testing (VCT) and mandatory and compulsory HIV testing. Though the last approach seems applicable to blood bank services settings and allow donor information of test results of blood, fluids and tissues, it doesn't properly address the need for proper counseling before or after blood or tissue donation and doesn't give guidance on the HIV test and result notification timing and procedures to be used for testing.

In order to fill the gap the BBS has to implement the following approaches:

- Blood donors have to be counseled pre and post donation of blood, before notifying test results and any time the donor asks for within one month period after donation.
- The NBBS/RBBs has to use both approaches i.e. the proactive or provider initiated (PICT) and client initiated approach (VCT).

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- Blood tests have to be done on samples collected post-donation, not pre-donation.
- Blood tests should be done using the most sensitive and specific test methods like ELISA, NAT, etc. as technology allows – releasing the product and Rapid test kits to counsel the donor.
- Repeat/Confirmatory tests have to be done at the blood bank centers or at any HIV counseling and testing centers after referral and linkage as appropriate.
- Positive HIV or TTIs test results should not be notified in the same day of blood donation and test; sessions should be arranged prospectively and clients invited to attend, usually between 5 30 days after donation.
- The HIV and other TTIs test result notification and post donation counseling service should be done only at the blood bank centers and mobile blood collection sites as appropriate.
- No post donation counseling and test result notification using telephone, emails, etc.
- All HIV and other TTIs positive clients should be referred and linked to appropriate care and treatment facilities for further counseling, testing, care and treatment. Blood banks should follow-up and seek feedback from the referral facilities.

7. Standard Operating Procedures (SOPs) for Counseling

Counseling services at blood banks begin with the recruitment and registration of the donor, followed by pre-donation information, pre-donation counselling and counselling at donation.

After donation donors have to be provided with a friendly and reassuring advise; besides they have to be invited for post donation counselling service before their next donation as per the procedure mentioned under no.6.

Test results are notified for donors in post-donation counseling sessions. Clients (donors/counselee) may then be referred for follow-up support, at public VCT site in another facility, or to community services for care and support as appropriate for the client to be referred. A user-friendly Standard Operating Procedure (SOP) guide, quick reference manual or pre





& post donation, test result notification and referral algorithm, referral and feedback formats, appropriate for use in blood services setting should be adopted or developed to guide staff and clients (donor)concerning HIV and other TTIs counseling, test result notification and referral services. The NBBS/RBBs should rather adopt an approach of proactive post donation counseling and test result notification procedure that involves arrangement of sessions and inviting the client for counseling and test result notification. The BBS therefore need to keep and update complete records of all blood donors in a data base including clients' (donors') full address and relevant information and needs to have complete list of public health facilities and community based organizations providing HIV prevention, care and treatment services, to facilitate referral and linkage services. The process of pre and post donation counseling, test result notification and referral should be carried out in an environment that promotes the following:

- Voluntarism: the client/donor or counselee should give his/her full consent to be counseled, tested, referred and share test results to the referral facilities.
- Privacy: the counseling process should be done in places that ensure both visual and auditory privacy.
- Confidentiality: all clients' information should not be shared without knowledge and consent of the client and be kept secret in locked boxes.

8. Requirements for Pre and Post Donation Counseling Test Result Notification and Referral

All BBS based pre and post donation donor counseling, test result notification and referral sites should fulfill minimum requirements regarding staff, space, equipment and supplies in order to provide quality services as described by this guideline.

8.1. Staff

BB Sites providing counseling, test result notification and referral services should ensure adequate staffing in accordance with demand for services and resources available. The staff must have received training as required



by the FMoH (need to be trained for at least 3 weeks as per the national HIV counseling and testing guideline).Minimum requirement at blood bank level should be: three professionals (one counselor- who also be a focal person for the service, one assistant counselor and one data clerk). A counselor may need to have a qualification of Bsc Nursing or a Health Officer or health professionals with a background of psychology or social work are more suitable counselors at Blood Bank Services. However, the BBS may exercise task shifting approach and use lower level professionals or even community counselors with appropriate training in cases of man power shortage. The counselor may serve as supervisor in the mobile sites and accountable to the Blood Bank Director.

8.2. Infrastructure

The BBS must ensure and secure adequate space and an environment that guarantees privacy, confidentiality, and access to all types of donors including those with some disabilities.

8.3. Equipment

BBS providing pre and post blood donation counseling, test result notification and referral services should have the equipment like full office furniture, computers and file cabinets with lockers and supplies necessary for the services.

8.4. Donor Education

IEC materials and Audio visual should be available at all sites to provide education to waiting donors. It is a cost effective intervention for providing information on TTIS prevention, treatment and services available.

8.5. Data Management

All pre and post donation donor counseling, test result notification and referral sites should adopt the standardized data collection and reporting tools developed by the Ministry of Health so that consistent and standardized data is obtained at all levels of the NBBS and BBS facility should have staff assigned to compile and submit in a timely manner all data required by the reporting system.





8.6. Referral linkage and Deferral

The BBS need to keep and update complete records of all blood donors in a data base including donors' full address and relevant information and needs to have complete list of public health facilities and community based organizations providing TTIS prevention, care and treatment services, to facilitate referral and linkage. The BBS also needs to adopt appropriate referral & feedback formats necessary to facilitate linkage and follow-up. Records of those donors who are referred to other health facilities and permanently deferred from voluntary blood donation should be managed properly. We have to clearly mark on their enrollment card according to SOP-BDS-14, Procedure7.14.

8.7. Language

Blood is a national resource and it is mandatory to follow the same procedures at levels and regions to have the same quality product and build a trustworthy service across the nation. However, language barrier should not be considered as a trespass of the cardinal rules. Hence Regional Blood Banks can translate the donor questionnaire and other relevant documents to their local languages; however they have to consult the NBBS.

8.8. Counseling Staff Donors

Counselors should be accountable to their professional ethics and keep in mind the oath they promised to obey in maintaining confidentiality. However; in some situations the challenge may not be as such easy. One of the scenarios where the challenge becomes a dilemma is counseling a work colleague/a staff donor. In such a situation the counselor should look for other options such as bringing a counselor from a nearby RBB or sending/ referring the donor to his/her private doctor.

9. Management and Coordination

9.1. Coordination of Pre &Post Blood Donation Counseling and Referral Services

In order to ensure optimal use of limited resources and maximum impact of services, coordination should start at NBBS level. The NBBS needs to





organize a system of program planning, implementation management and coordination at all levels to maintain the standard and quality of services and ensure efficiency. Key elements of coordination may include setting standards, guidelines and protocols for counseling, test results notification and referral. Important management and coordination tools may include;

- > Developing and standardization of training materials for counselors
- Set minimum requirements to conduct pre & post blood donation counseling, test result notification and referral at the BBS and set up regulations
- > Determining the qualification, salaries and benefits of counselors.
- Developing and standardizing counselors guidelines, SOPs and aid tools
- Selection of common indicators for uniform monitoring and evaluation which can be integrated into the national Health Management Information System
- Preparation of standardized referral, feedback and reporting forms for a centralized data collection and analysis system.
- Developing a system of program supervision, reporting, review and learning platform

At region, zone and site/ blood bank Counselors and supervisors are expected to work as one team responsible for all activity or issues related to counseling, TTIs test result notification and referral and the management need to closely monitor adherence to the procedures and protocol developed by the NBBS and improve performance.

10. Monitoring and Evaluation

In order to monitor the efficiency and effectiveness of planned pre & post test counseling, test result notification and referral activities and assess the impact of the program in reducing spread of new TTIS infections, having an inbuilt monitoring and evaluation system should be a key component of the interventions. Monitoring and evaluation takes place at multiple levels and stages of program where different information is gathered, compiled



and analyzed to demonstrate how services are being delivered and their outcomes. The program should also focus on program implementation, quality assurance, ethical issues and confidentiality. The following are key tools for monitoring and evaluation of the program:

- > Set of agreed upon indicators on which data are collected and reported
- Data capturing/ collection and reporting tools on daily, monthly or quarterly basis
- Data flow system
- > Data processing, analyzing, dissemination and utilization mechanism.
- Data clerks, managers and supervisors

11. Challenges of Blood Donor Counseling

Many countries are unable to provide effective blood donor counseling services due to variety of constraints and barriers. At the policy level, particular challenges include a failure to recognize donor counseling as a core function of the BBS, resulting in a lack of political commitment and support and the absence of a clear national policy and guidance on blood donor counseling. Organizational barriers to the provision of donor counseling include the lack of adequate human and financial resources, training, suitable infrastructure for confidentiality, appropriate strategies and facilities for screening and confirmatory testing and medical referral services. Uncoordinated blood transfusion services with blood being collected in multiple small centers or hospital blood banks pose particular challenges since suitable staff and facilities are less likely to be available in small centers as compared to those in coordinated blood transfusion services. Similarly, opportunities to follow-up donors may be particularly limited in rural areas.

12. Provisional Note

Upon the implementation of the Blood Safety Information System (BSIS) at the national level (in all the blood banks), this guideline should undergo another revision to complement the system.





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ANNEX I



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PRE AND POST BLOOD DONATION COUNSELING AND TEST RESULT NOTIFICATION GUIDELINE

			Reviewed by		Approved by	
Revision No Revision date		Summary of Changes	Name	Sign	Name	sign
01		New prepared				
						+

*If no changes required, enter comments 'reviewed - no changes required

*If changes of significant nature are required, please submit the revised copy with changes highlighted to director/designee for authorization.

*If there is no change in document, revision number and effective date will remain the same.

**Annual SOP (technical) review is done by the BDS & laboratory department. Review of quality

documents by quality department and management/administrative policies by the director/manager.

Authorized by Dr.Habtemariam Demoze Director General

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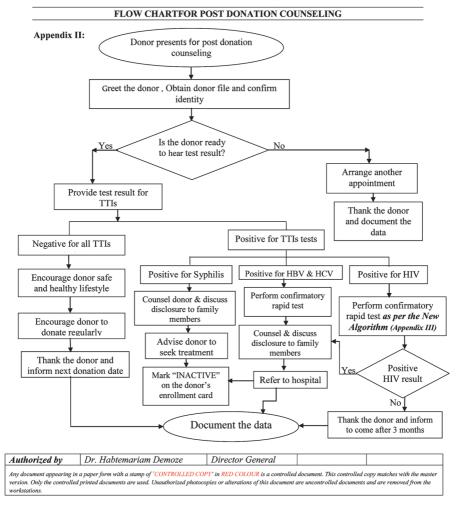




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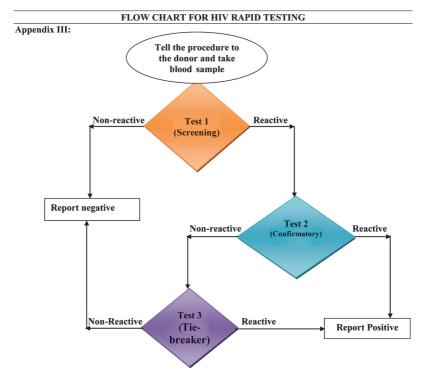
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