Blood Donor Counselling

Implementation Guidelines

World Health Organization

In collaboration with:

CDC
Centers for Disease Control and Prevention

International Federation of Red Cross and Red Crescent Societies

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WHO Library Cataloguing-in-Publication Data

Blood donor counselling: implementation guidelines.

1.Blood donors – psychology. 2.Blood donors – education. 3.Blood banks – standards. 4.Counseling – methods. 5.Counseling – ethics. 6.Health policy. 7.Health planning – standards. 8.Infection control – methods. 9.Guideline. I.World Health Organization. II.Centers for Disease Control and Prevention (U.S.). III.International Federation of Red Cross and Red Crescent Societies.

ISBN 978 92 4 154855 7 (NLM classification: WH 460)

The development of this publication was supported by Cooperative Agreement Number PS001426 from the Centers for Disease Control and Prevention (CDC), Atlanta, United States of America. Its contents are solely the responsibility of the authors and do not necessarily represent the official views of CDC.

Contents

Acronyms

AIDS	Acquired immunodeficiency syndrome
BTS	Blood transfusion service(s)
CDC	United States Centers for Disease Control and Prevention
CUE	Confidential unit exclusion
HBV	Hepatitis B virus
HCV	Hepatitis C virus
HIV	Human immunodeficiency virus
IFRC	International Federation of Red Cross and Red Crescent Societies
SOPs	Standard operating procedures
TTI	Transfusion-transmissible infection(s)
VNRBD	Voluntary non-remunerated blood donation
WHO	World Health Organization

Preface

Blood transfusion contributes to saving millions of lives each year and improving the life expectancy and quality of life of patients suffering from life-threatening conditions. The safety and availability of blood and blood products for transfusion requires the recruitment of voluntary non-remunerated blood donors, the selection and care of blood donors[1], the quality-assured testing of donated blood for markers of transfusion-transmissible infections (TTI), blood processing, and the safe and rational use of transfusion.

Individuals who donate their blood provide a unique and precious gift in an act of human solidarity. In order to donate blood, prospective donors should be in good health and free from any infections that can be transmitted through transfusion. Most blood donors perceive themselves to be healthy, but some are unsuitable to donate blood due to the potential risk of compromising or worsening their own health or the risk of transmission of infections to patients.

Blood transfusion services (BTS) have a duty of care towards blood donors as well as to the recipients of transfusion. This duty of care extends to prospective donors who are deferred from donation, whether on a temporary or permanent basis, as well as those who donate blood and are subsequently found to have unusual or abnormal test results. BTS have a responsibility to confirm test results and provide information, counselling and support to enable these individuals to understand and respond to unexpected information about their health or risk status. Counselling is part of the spectrum of care that a BTS should be able to provide to blood donors, including referral to medical practitioners or specialist clinical services.

Historically, blood donor counselling was not widely practised until relatively recently. Some BTS provided information to donors on TTI test results that were indicative of infection, initially with syphilis and later, as tests became available, for the hepatitis B virus. It was not until the HIV/AIDS pandemic of the 1980s and the introduction of screening tests for HIV that BTS began to acknowledge the importance of donor counselling, particularly to ensure the safety of the blood supply.

Pre-donation counselling was recognized as one element of the strategy to reduce and, if possible, prevent the donation of blood by individuals who might be at risk for HIV and other TTI, including hepatitis B and C viruses, as well as to inform donors of the donation process and testing of blood for HIV. Post-donation counselling was acknowledged to be a necessary element of donor management as an adjunct to informing donors of unusual or abnormal test results.

Blood donor counselling by trained specialist staff is now considered to be a key component of the blood system in most countries with a well-developed blood transfusion service. It may be required at a number of stages in the blood donation process or following blood screening and should be available at any point at which the BTS has an interface with donors.

[1] The term “blood donors” includes donors of whole blood, red cells, platelets, plasma and other blood components, donated as whole blood and/or through apheresis.

In many countries, however, blood donor counselling is not yet available in a structured way. The document *Blood donor counselling: implementation guidelines*, has therefore been developed to provide guidance to blood transfusion services that have not yet established donor counselling programmes.

These guidelines on blood donor counselling should be used in conjunction with other WHO resources, in particular *Towards 100% voluntary blood donation: a global framework for action* (*1*), *The Melbourne Declaration on 100% voluntary non-remunerated donation of blood and blood components* (*2*), *Blood donor selection: recommendations on assessing donor suitability for blood donation* (*3*) and *Screening donated blood for transfusion-transmissible infections* (*4*).

Dr Neelam Dhingra
Coordinator
Blood Transfusion Safety
World Health Organization

Dr Christie Reed
Medical Officer
HIV Prevention Branch
Division of Global HIV/AIDS
Centers for Disease Control and Prevention

Dr Lin Che Kit
Chief Executive & Medical Director
Hong Kong Red Cross Blood Transfusion Service

1 Introduction

1.1 BLOOD DONOR COUNSELLING

A blood transfusion service is an essential element of a health-care system and individuals who donate their blood provide a unique contribution to saving lives and improving patient health. To provide a safe and sufficient blood supply, the BTS should build and maintain a pool of safe, voluntary non-remunerated blood donors. Blood donors should be provided with high standards of care and assurance of their health and safety. Counselling is an integral part of the BTS duty of care for all individuals who present themselves for blood donation or are blood donors (*1,5*).

Blood donor counselling is a confidential dialogue between a blood donor and a trained counsellor 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 BTS and the wider health system in implementing blood donor counselling. It minimizes the unnecessary loss of suitable donors while maximizing the retention of donors, including those who are temporarily deferred.

Counselling provides an opportunity for the BTS 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 (*6*). 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 (*7*). Blood donor counselling 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 (*8*).

The counselling of blood donors is an important means of promoting healthy lifestyles and makes an important contribution to individual and community health (*9,10*). In addition, counselling contributes to the early diagnosis and treatment of conditions such as anaemia, 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 (*11,12*). 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 counselling 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.

Counselling may also reduce adverse donor reactions (*13*), 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) (*14*).

Information provided by 164 countries to the WHO Global Database on Blood Safety indicates that, worldwide, more than 92 million blood donations are

collected annually. Of these, an estimated 1.6 million units are discarded due to the presence of markers for TTI, including HIV, hepatitis B (HBV), hepatitis C (HCV) and syphilis. In addition, at least 13 million prospective donors are deferred from donating blood due to anaemia, existing medical conditions or a risk for infections that could be transmitted through transfusion (*15*).

The scale of these discards and deferrals underlines the importance of public health information, donor education and counselling to enable prospective donors who may be unsuitable to donate blood to self-defer at any stage in the donation process. It also highlights the need to establish counselling systems for individuals who are not accepted as blood donors or who are found to have unusual or abnormal test results.

However, many national BTS do not recognize that blood donor counselling is essential for providing quality donor service and care and do not have clear national policies on blood donor counselling or the infrastructure and resources required for counselling.

1.2 AIM AND OBJECTIVES

In 1994, *Guidelines for blood donor counselling on human immunodeficiency virus (HIV)* was published as a collaborative effort of the International Federation of Red Cross and Red Crescent Societies (IFRC), the WHO Global Programme on AIDS, and the United States Centers for Disease Control and Prevention (CDC) (*16*). These guidelines were developed in response to the specific challenges posed by the need to keep blood supplies free from HIV and provide support for blood donors who tested positive for HIV. There were also concerns that, due to the limited availability of HIV testing sites and the potential stigma associated with HIV, some donors might not disclose sensitive information on behaviours that increased their risk of HIV infection or might donate blood for the purpose of ascertaining their HIV status. These concerns are still true today.

In the intervening years, diagnostic technologies and treatment options have advanced for HIV, as well as for HBV, HCV and other infections, such as malaria and Chagas disease. It is now recognized that the scope of donor counselling should not only address HIV but should also encompass other TTI as well as medical conditions that might compromise donor health. The WHO Blood Transfusion Safety programme, in collaboration with CDC and the IFRC, therefore initiated a process to review and update the guidelines and expand their scope beyond HIV to include other TTI and donor health and safety issues.

Aim

The aim of *Blood donor counselling: implementation guidelines* is to support countries in establishing effective national systems for blood donor counselling where they do not yet exist.

Objectives

The specific objectives are to provide:

1 Policy guidance on providing blood donor counselling as an essential component of quality donor service and care and as a requirement for a safe blood supply.

2 Information and technical guidance on the specific measures and actions needed to promote donor care and the safety of blood donors and transfusion recipients through counselling for:

- Prospective donors who have been deferred from blood donation to protect their own health or that of patients receiving transfusion
- Blood donors with unusual red cell serology or rare blood groups
- Blood donors with abnormal test results for HIV, HBV, HCV, syphilis, Chagas disease or other TTI.

1.3 INTENDED AUDIENCE FOR GUIDELINES

The intended audience for these guidelines includes the following organizations and institutions:

- National blood programmes in ministries of health
- National advisory bodies responsible for policy making on blood safety including counselling, such as national blood commissions or councils
- BTS and hospital blood banks, including directors, medical officers, blood donor managers, quality managers, staff responsible for blood donor selection, donor care and donor counselling, laboratory managers, and other staff
- Reference laboratories for confirmatory testing for TTI
- Public health institutions
- Blood donor organizations and other nongovernmental organizations involved in blood donor education and recruitment
- Professional societies and patient associations.

These guidelines may also be useful for other relevant stakeholders such as education and training institutions, transplantation services, plasma collection facilities and disease prevention programmes focusing on infections such as HIV, hepatitis, malaria and Chagas disease.

1.4 METHODOLOGY

In 2008, the WHO Blood Transfusion Safety programme convened an Expert Consultation on Blood Donor Counselling. The specific objectives of the consultation were to review *Guidelines for blood donor counselling on human immunodeficiency virus (HIV)* and to define the scope for updating and expanding these guidelines in the context of blood safety and overall public health.

The consultation was convened as a technical working group comprising international experts in the field of blood donation and donor counselling from both developing and developed countries in all WHO regions (see *Acknowledgements*). The technical working group recommended that updated guidelines should not be confined to counselling on HIV, but should address pre-donation and post-donation counselling on major TTI, including HBV, HCV and syphilis, as well as medical conditions requiring deferral, and donor care. The scope of the revised document was agreed and its structure and content were planned. The technical working group met to prepare, review and revise drafts of the guidelines.

The WHO Blood Transfusion Safety programme established an external review group comprised of members of the WHO Expert Advisory Panel on Blood Transfusion Medicine, experts from WHO Collaborating Centres in Blood Transfusion Medicine, directors of national blood transfusion services and blood programme managers in each WHO region (see *Acknowledgements*). The composition of the external review group was designed to ensure a wide range of specialist expertise and experience from BTS in all regions at different stages of development. The role

of this group was to review the draft guidelines and advise WHO on the relevance and applicability of these guidelines in their countries. An editorial team edited the various document drafts.

In 2011, an external review of an advanced draft to assess the feasibility of the implementation of these guidelines was undertaken by participants in an inter-regional workshop on blood donor selection and donor counselling for priority countries in the African and Eastern Mediterranean regions (*17*) (see *Acknowledgements*).

Literature search

Members of the technical working group searched the literature using PubMed, MedLine, the WHO Library Database (WHOLIS) and regional databases. Particular efforts were made to identify systematic literature reviews and publications related to blood donor counselling in developing countries. Some elements of counselling are not unique to blood donation; thus, general principles of psychosocial and HIV counselling and the evolving methodologies, literature and guidelines on training and the supervision of health care counsellors have been applied to blood donor counselling.

Review and updating of the guidelines

It is anticipated that these guidelines will be reviewed in 2017 in terms of any new developments or feedback on their implementation. The WHO Blood Transfusion Safety programme will be responsible for initiating the review to assess the need for updating.

2 Scope and stages of blood donor counselling

2.1 SCOPE AND CONTENT OF BLOOD DONOR COUNSELLING

Pre-donation information and counselling are linked to the process of donor selection in which each individual's suitability to donate is carefully assessed against a set of criteria (*2,18*) 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 counselling 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 counselling 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 counselling may lessen a sense of rejection and encourage temporarily deferred donors to return after a suitable interval. Effective counselling may thus minimize an unnecessary loss of blood donors and motivate those who are unable to donate blood to support the BTS as volunteers (*19,20,21,22,23,24*). Donor retention or loss is related to how donors feel about the blood centre and donors with a positive experience are more likely to encourage their friends to donate blood (*25*).

Following the laboratory testing of donated blood for blood group serology and markers of infection, unusual red cell serology, rare blood groups or reactive TTI test results may be found in some donations. The BTS has the responsibility to ensure the confirmation of reactive test results, the notification and counselling of the respective donors, and their referral to other health-care institutions, as appropriate (*4*). Counselling should be provided promptly, accurately, confidentially and in a manner that alleviates anxiety and promotes understanding. Donors with positive or indeterminate TTI test results should be referred to appropriate health-care institutions for further evaluation, treatment and care.

The objective and content of the counselling provided to each donor depends on the conditions and situations that are being addressed. For example, counselling 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 therefore very important that staff involved in donor counselling understand the key elements of counselling in different contexts and the most suitable approach to make

each counselling session successful and beneficial to both the donor and the BTS (*26,27*). A poorly handled counselling session may lead to unnecessary psychological distress for the donor and damage to the reputation of the BTS and may affect future donor recruitment.

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

- First-time and young donors: to explain the blood donation process and to allay their anxiety and apprehension (*28*)
- 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 (*29*)) and provide information on further management, as appropriate
- Individuals whose basic health check reveals a condition indicating temporary or permanent deferral: to explain the reason for deferral (e.g. low haemoglobin level) (*30*) and provide information on further management, as appropriate
- Individuals who may be donating blood to seek testing for infections such as HIV: to understand their motivation for blood donation and provide information on voluntary counselling and testing services (*31*)
- Donors who had experienced adverse reactions during or after donation in the past: to allay their anxiety and apprehension (*32*)
- Donors who, after a previous donation, had asked for confidential unit exclusion (CUE) or informed the BTS that their blood should not be transfused: to be aware of the reason for CUE and refer for further management (*33,34*)
- Donors who give post-donation information that warrants temporary or permanent deferral (e.g. significant health problem developed shortly after donation): to explain the reason for deferral and provide information on further management, as appropriate (*35,36*)
- Donors with unusual red cell serology, rare blood groups or abnormal TTI test results: to explain the importance of these results for the donor and provide information on further management (*37,38*).

2.2 STAGES OF BLOOD DONOR COUNSELLING

There are four stages during the blood donation process when counselling should be provided to all blood donors, as shown in Figure 1.

1 Pre-donation information before an individual registers for blood donation.

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

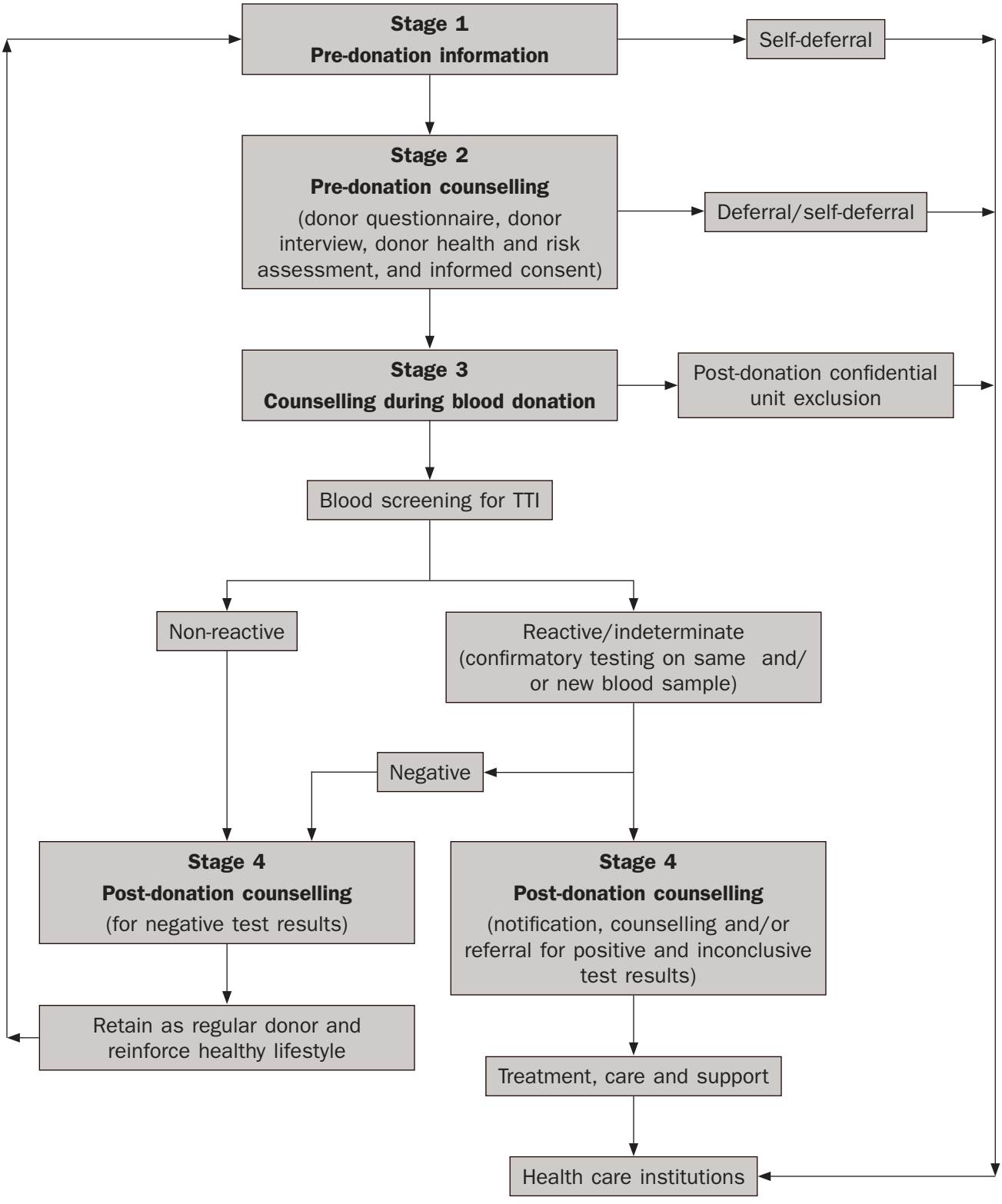
3 Counselling during blood donation.

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

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

Figure 1: Stages of blood donor counselling



deferral or self-deferral, blood screening for TTI, blood grouping, counselling 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.

Objectives

Pre-donation information has three main objectives:

1 To increase donor awareness of:
- The BTS 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 donor adherence to donor selection criteria relating to their health and risk for TTI (*39*)
- 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, syphilis and other relevant TTI and the limitations of these tests, including the "window period" of infection.

2 To increase donors' trust in the BTS and encourage them to:
- Adhere to donor selection criteria while responding to the donor questionnaire
- Inform the BTS of any recent behaviours 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 behaviours that put them at high risk for TTI
- Have travelled to a country or region that puts 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.

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To achieve the above objectives, pre-donation information should include (*40*):

- Nature and use of blood and its components; the need for voluntary non-remunerated blood donors; and the importance of maintaining healthy lifestyles

- Rationale for the donor questionnaire and pre-donation health assessment; the importance of donor compliance in the donor selection process; and the donor's duties, responsibilities and rights (*41*)
- Options for the donor to withdraw or self-defer at any time before, during or after donation, without any undue embarrassment or questioning
- Blood donation process and potential adverse donor reactions, such as fainting or haematoma
- Availability of qualified and trained medical staff throughout the process
- Common TTI, including HIV, HBV, HCV and syphilis, routes of their transmission, natural history and prevention; types of screening tests performed; window period of infection; and voluntary counselling and testing services for individuals seeking to ascertain their infection status
- Basic information about blood group serology and tests performed on donated blood
- Possible consequences for donors and the donated blood in the event that the test results show unusual red cell serology or rare blood groups
- Possible consequences for donors and the donated blood in the case of abnormal TTI test results; the mechanisms for confirmatory testing, information and notification of TTI test results; assurance of confidentiality; and referral for further investigation, counselling, treatment and care.

Information for blood donors on haemoglobin and iron, and bruising is provided in Annexes 1 and 2.

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 (*2,42,43,44,45*). 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 (*46*).

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. Studies have shown that temporary deferrals (e.g. convalescence, medication, travel history or risk factors for infections) may influence blood donor return rates and subsequent blood donations, particularly among first-time donors (*2,21,22,24*). 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 (*47,48*). For example, donors deferred due to low haemoglobin level should be asked to seek medical advice, given relevant information such as on nutrition and advised to return for blood donation after

the haemoglobin level becomes normal. The frequency of future donations should be reviewed to avoid depleting their iron stores (*47*).

Objectives

Pre-donation counselling has the following objectives:

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 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.

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To achieve the above objectives, pre-donation counselling should include:

- Reviewing the donor's responses to the donor questionnaire
- Explaining the processes of donor selection, blood donation and blood screening
- Encouraging self-deferral if the donor may have been exposed to a TTI and referring to voluntary testing and counselling services, if further testing is warranted
- Explaining post-donation counselling procedures, including the modes of notification and the availability of TTI test results
- Obtaining the donor's informed consent to donate blood
- Providing suitable counselling to deferred blood donors, including referral for treatment and care, as appropriate
- Advising temporarily deferred donors when they can return to give blood.

Stage 3: Counselling during blood donation

Counselling during blood donation provides an opportunity to explain the venepuncture procedure, show appreciation to donors for their valuable contribution and enhance donor satisfaction with the donation experience and the BTS. Counselling during donation also has an impact on donor motivation and return for future donations (*49*).

Counselling 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 venepuncture for blood donation (*50*). 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 (*51*). 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 (*13,23*).

Any adverse donor reactions, whether generalized or local, including failed venepuncture, haematoma, arterial puncture, thrombophlebitis nerve injury and fainting, should be managed immediately. Once the donor has recovered, counselling specific to the event should be provided to ensure that the donor

understands the cause of the adverse event and any treatment or care given (*52*). Further explanation may be necessary if the reaction is delayed and happens outside the blood centre or the donor is referred for further treatment and deferred temporarily or permanently (*53,54*).

Counselling during blood donation may encourage donors who did not reveal potential risks of exposure to TTI during pre-donation counselling 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. Donors should be able to indicate at any time during and after the donation if their donated blood should not be used for transfusion. Confidential unit exclusion (CUE) allows donors to inform the BTS, in a confidential manner, whether to use their blood for transfusion or not. The donor should be informed of the process of CUE, if this system is in place in the BTS (*33,34,55*).

Donors should be advised of the need to contact the BTS and provide post-donation information if they become unwell, particularly with an illness that they might have been incubating at the time of donation (usually within 28 days of donation), or remember important information about a past illness or their risk for a TTI that should have been declared before donation.

All donors should be provided with information on post-donation care to reduce the risk of adverse donor reactions and be advised to provide the BTS with any additional information that may affect the safety of the blood for transfusion (*56*). An example of post-donation advice to blood donors is given in Annex 3.

Objectives

Counselling during the blood donation procedure has the following objectives:

1 To ensure that donors feel comfortable during blood donation process, including the venepuncture.

2 To reduce donor anxiety and minimize the risk of any adverse donor reactions, such as fainting (*57*).

3 To give post-donation advice, including care of the venepuncture site.

4 To secure donors' cooperation in the confidential unit exclusion or post-donation information process.

5 To foster donor trust and confidence for donor retention.

Contents

To achieve the above objectives, information and counselling provided during blood donation should include:

- The venepuncture procedure and the need to properly disinfect the skin and find a suitable vein
- The volume of blood to be collected and the time needed for the procedure
- Personal care after the donation, including care of the venepuncture site and how to prevent and manage acute and delayed donor reactions
- The confidential unit exclusion system and the importance of informing the BTS if there is any reason why the donated blood may not be safe for transfusion
- The need for the donor to provide information to the BTS as soon as possible about any acute infection or reaction within 28 days of blood donation.

Stage 4: Post-donation counselling

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. The assays used for blood screening usually have high sensitivity; however, there are some trade-offs on their specificity and false-reactive results sometimes occur (*4*). In the case of reactive screening results, confirmatory testing should be performed to identify truly infected donors or donors with non-specific reactivity or inconclusive results; this should be done before the donors are informed, notified and counselled about their infectivity status. Effective confirmation requires appropriate and well-designed confirmatory testing strategies for each TTI, including the selection of assays and algorithms for the analysis and interpretation of results (*58*). Every BTS should have access to a reference laboratory that is able to perform accurate, reliable and appropriate confirmatory testing (*37*).

Counselling donors who have unusual red cell serology, rare blood groups or abnormal TTI test results is an essential part of quality donor service and care.

- Donors confirmed to be infected should be notified of their infection status, counselled, deferred from blood donation and referred for treatment, care and support (*59*).
- Donors showing repeated reactive results on screening and negative results on confirmatory testing should be informed, reassured, counselled 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.
- Donors with unusual red cell serology or rare blood groups should be given an explanation of the significance of the results and their implications for them.

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

Post-donation counselling 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 counsellor 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 (*60*). Referral to a physician, a specialist or an external agency for further management, treatment and care should be discussed (*12*). Any possible risk of further transmission of the infection should be explored and the importance of healthy lifestyles reinforced (*61*).

Post-donation counselling 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 (*16,22,26,59,60,62,63,64,65*) and donors should be assured of confidentiality of the information given to the BTS.

Post-donation counselling enables the BTS to collect demographic and risk-exposure information about TTI positive donors as part of its haemovigilance programme. This information can be valuable in making future decisions about donor selection criteria and assessing the usefulness of questions in the donor questionnaire (*66*).

Objectives

Post-donation counselling has the following objectives:

1 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.

2 To encourage donors to provide all relevant information, including the possible source of infection.

3 To clarify doubts or concerns raised by donors.

4 To alleviate donors' anxiety.

5 To provide information on precautions for preventing the transmission of infection to others.

6 To provide information and refer donors for further investigation, management, treatment and care, if necessary.

7 To reinforce the importance of healthy lifestyles for donors found to be non-reactive on blood screening and encourage regular blood donation.

Contents

To achieve the above objectives, post-donation counselling should provide accurate information about the significance of the test results.

- Donors with reactive or inconclusive TTI test results should be informed and counselled about the need to give a new blood sample to confirm their test results, in accordance with the confirmatory testing strategy.
- Donors who have confirmed positive TTI test results should be provided with information about the infection:
  - How it is transmitted
  - The possible implications for the donor's health
  - Treatment opportunities
  - The prevention of further transmission
  - The need to inform contacts who might be at risk of infection so that they can be tested and treated as early as possible.
- Arrangements should be made for referral to an external agency such as an HIV treatment and care service (*12,26,60*).
- Donors should also be informed that their donated blood has been discarded and that they are deferred from further blood donation, either permanently or temporarily for a defined period of time, depending on the infection.
- Donors who have unusual red cell serology or rare blood groups should be given information about:
  - The antibodies or blood group
  - The implications for future blood donations

— The importance of carrying this information personally at all times in case they ever need a blood transfusion

— Opportunities for enrolling on the rare blood donor panel.

Annex 4 outlines the steps in post-donation counselling of blood donors with confirmed TTI. Examples of information sheets for blood donors with confirmed HIV infection, hepatitis B and C virus infections, syphilis, malaria and Chagas disease is also included in Annexes 5–10.

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

Situations and conditions	Essential elements of counselling
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 counselling 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
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 ■ Information on how to maintain a healthy lifestyle Example: Donor with low haemoglobin: refer to a health-care institution for haematological investigation and further management, and provide information on nutrition
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, such as HIV, HBV, HCV, syphilis, malaria and Chagas disease ■ Donor seeking to ascertain infection status: provide information on voluntary counselling and testing services
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
Donor who has experienced an adverse reaction during or after donation or has previously had a reaction to donation	■ Explanation of the reasons for the adverse donor reaction and the treatment given ■ Information and advice on preventive steps to reduce the risk of adverse reactions, such as adequate fluid intake before donation, in the case of fainting during a previous donation ■ Assurance of care for donor well-being ■ Reassurance to allay anxiety and apprehension ■ Encouragement to return for future donations Example: Donor with post-donation bruising or haematoma: explain why and how bruising occurred and the actions that the donor can take to reduce the bruising and pain. Discuss possible preventive measures against bruising during future donation.
Donor whose donation resulted in a serious adverse transfusion reaction in the transfused patient	■ Explanation of the reasons for an adverse transfusion reaction in the patient ■ Reassurance to allay donor anxiety and apprehension Example: Donor whose donations caused transfusion-associated lung injury (TRALI): evaluate suitability for future donation.
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

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
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
Donor with unusual red cell serology or rare blood group	■ Information and explanation of the nature and importance of the unusual red cell serology, such as an atypical red cell antibody, or a rare blood group ■ Advice to carry this information personally at all times in case the donor ever needs a blood transfusion ■ Encouragement to return for future blood donations and enrolment in the rare blood donor panel

3 Establishing a national system for blood donor counselling

3.1 NATIONAL POLICY AND GUIDELINES ON BLOOD DONOR COUNSELLING

The management and counselling of blood donors is an essential part of the blood donation process. Donors are the source of blood and blood components that are processed and released for clinical use or for fractionation. A positive donation experience has also been noted as a major determinant of donor return behaviour (*35,67*). Accordingly, donors should be managed in a way that ensures high standards of care and assures them of the concern of the BTS for their health and well-being (*23,54,68*).

Counselling should be provided to all prospective donors. National health authorities and BTS are responsible for ensuring that relevant policies, legislative frameworks, guidelines and infrastructure are in place, and adequate resources are made available, to ensure a consistent and reliable system for the counselling of all blood donors. The scope of the system will depend on the level of development of the health-care system, the capacity and infrastructure of the BTS, and available resources.

Every country should have a national blood policy which defines the principles and strategies for blood donor recruitment, selection and deferral, blood screening, confirmatory testing, notification, counselling and referral. The policy should define the requirements for the screening of all blood donations for markers for TTI and the confirmatory testing of reactive screening test results. Screening and confirmatory testing for TTI are crucial for determining the suitability of donated blood for therapeutic use, notifying donors of positive TTI test results and also for providing post-donation counselling. The national blood policy should be supported and enforced by a legislative and regulatory framework, and its implementation should be in accordance with national guidelines (*69*).

A coherent national blood policy that addresses blood donor counselling will help to:

- Provide a uniform application of national guidelines and standardized procedures across the country
- Raise and maintain the quality of donor services and care
- Identify and support the provision of the necessary resources to support counselling activities
- Integrate services and the processes of information management, confidentiality, notification of test results and referrals to relevant health-care institutions and facilities
- Define the roles and links between the BTS and other health-care services, including reference laboratories, health-care facilities and counselling services, and non-governmental organizations.

National guidelines on blood donor counselling should be developed through a full consultative process. The BTS should involve all key stakeholders, including blood

donors, in developing the counselling guidelines and ensure that these guidelines correspond to the national donor selection criteria (*2*). The counselling guidelines should be based on evidence or international best practice and reflect the structure of the health-care system and the socio-cultural environment in the country.

Each country that does not currently have a system of donor counselling should conduct an assessment of the existing mechanisms and practices of blood donor selection and counselling (*23*). This assessment may include a survey of the knowledge, attitudes and practice of prospective and registered blood donors as well as of health-service providers. The survey should be representative of the whole country, taking into account social and cultural differences.

Strategies for the provision of counselling, notification and referral should be based on the assessment and clearly defined in the guidelines. These should include how to inform donors of their TTI test results, especially donors who are below the national legal age of majority. Referral procedures should also be piloted and any necessary adjustments made before they are formally adopted and publicized.

3.2 INFRASTRUCTURE AND FACILITIES

Counselling should be conducted in a friendly and conducive environment with suitable infrastructure and facilities (*70*). Whether it is provided in a fixed location or mobile setting, the venue for donor counselling should provide adequate audio and visual privacy, and confidentiality. A variety of options can be considered to create counselling space in existing fixed or mobile locations, such as utilizing existing offices or reconfiguring the space using permanent or transportable room dividers or screens.

3.3 HUMAN AND FINANCIAL RESOURCES

Counselling should be provided by trained and qualified personnel. The BTS should have adequate numbers of trained staff who are assigned to provide blood donor counselling. The staff should allocate sufficient time for each stage of the counselling process. In the absence of personnel with a specific background and training in counselling, existing staff with suitable attributes, personal qualities and abilities may be trained and designated as counsellors (*71*) (see also Section 5.3). Many other BTS staff, including volunteers, may interact with blood donors and it is important that they also receive some basic training, including training on developing communication skills (*72*).

The provision of adequate and sustainable financial resources is required for an effective blood donor counselling programme, including a dedicated budget for staff training in counselling and the development of information, education and communication materials.

3.4 QUALITY SYSTEM

All elements of a quality system apply to the donor counselling process as with other technical aspects of the BTS (*73*), including:

- An organizational structure that defines the authority, responsibility and reporting relationships of all personnel, including written job specifications
- A documented quality policy and guidelines that ensure a consistent approach to quality during blood donor counselling

- Standard operating procedures (SOPs) that guide every process, procedure and task for consistency, traceability and accuracy, including information on the necessary staff, facilities, forms and references; there should be SOPs and documentation for all stages of counselling, including the following:
  - Confidential interview during pre-donation counselling
  - Counselling during blood donation
  - Invitation to donor for post-donation counselling
  - Notification and post-donation counselling
  - Referral to health care services
  - Counselling process and outcomes
  - Monitoring and evaluation of counselling
  - Other necessary follow-up: e.g. product recall or donor and recipient look-back
- Staff training based on a structured training curriculum, including competency assessment and training records (see also Section 5)
- Records system (electronic or manual) that ensures traceability, confidentiality and easy retrieval for counselling of the right donor at the right time, including:
  - Donor records associated with each donation, including donor identification, reasons for deferral, any adverse reactions, TTI test results, counselling and outcomes, such as referrals
  - A donor deferral registry, which is a confidential list of donors who are permanently deferred
  - Confidentiality of donor records assured at all times through the use of unique numbers for donors and donations and the use of codes for infection markers
- Systems of monitoring and continual improvement on donor recruitment, donor questionnaire, pre- and post-donation counselling, notification and the referral mechanism, including an internal audit programme that is conducted regularly by the BTS and referral services, as appropriate (*2,74*).

3.5 REFERENCE LABORATORIES

The purpose of screening donated blood is to ensure the microbial safety of the blood supply. Confirmatory testing is performed to confirm the infectious status of donors who were deferred from donating on the basis of reactive screening test results, allowing referral for appropriate treatment and care. Effective confirmation requires appropriate and well-designed confirmatory testing strategies for each TTI, 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 reference laboratories unless considerable expertise and resources are available within the BTS itself (*4,37*).

3.6 DONOR INFORMATION AND EDUCATION MATERIALS

Donor information materials should be developed on the donor selection criteria and donation process. These should include information on blood and its components, the need for blood donation, the importance of maintaining healthy lifestyles and the rationale for the donor selection process. These materials

should be written in simple language that is easy to understand and available in sufficient quantities (*42*). Full contact details of the BTS and relevant health-care institutions and services should be included in the materials.

3.7 MEDIA AND PUBLIC RELATIONS

The print, broadcast and electronic media are among the most powerful allies of the blood donor programme. Their ability to reach large numbers of people is unique and their support should be nurtured and valued. Thus, the media can play a vital role in raising public awareness on blood donation and donor recruitment, assessment of donor suitability and counselling, thereby assisting the BTS to achieve its goal of providing a safe and adequate blood supply (*1*). All media should be provided with accurate information on the duties, responsibilities and rights of blood donors. Proactive involvement and good relationships with the media help to ensure that journalists are well-informed and do not unwittingly fuel negative attitudes to blood donation by reporting stories inaccurately or in a negative way.

Considering the public interest and involvement in blood donation, people are often keen to take note of any event, incident or situation related to blood donation and transfusion. In the absence of blood donor counselling services or if counselling is not provided in a professional manner, any donor incident or complaint may escalate and result in negative media coverage. The BTS should therefore maintain an open and transparent policy at all times, while respecting and honouring its commitment to donor confidentiality and privacy. Well-provided and effective counselling may generate a positive image of the BTS in the community and attract public appreciation.

4 Ethical and legal considerations in blood donor counselling

4.1 RIGHTS AND RESPONSIBILITIES OF THE BTS AND BLOOD DONORS

The primary responsibility of the BTS 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 epidemiological data (*75*). It is also the responsibility of the BTS to provide appropriate counselling services to individuals who have been deferred (*2*).

The BTS 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 BTS 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 BTS has an obligation to blood donors to ensure the notification of positive test results and the availability of appropriate counselling and referral; this may be provided using different counselling models (see also Section 6.3).

Individuals have rights and responsibilities as blood donors. 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 BTS
- Responsibility to provide the BTS 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 BTS 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.

4.2 CONFIDENTIALITY AND PRIVACY

Many countries have laws and regulations on confidentiality and privacy. The issue of confidentiality may be handled under the broad label of “privacy rules” or “privacy laws”.

Confidentiality

Confidentiality refers to the obligation of health-care professionals and health-care institutions not to disclose personal and sensitive information about their patients or 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 BTS 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

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 BTS 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 BTS staff and volunteers should include how to ensure privacy of blood donors and confidentiality of donors' personal information and test results (*76*).

4.3 INFORMED CONSENT

Informed consent is a voluntary agreement given by the prospective donor to the donation process, including the donation of blood, the testing of blood for TTI and blood group serology and, if applicable, the use of blood for additional tests, quality assurance or research purposes (*77,78,79*). Informed consent is a process based on the ethical principles of autonomy and respect for the individual.

Informed consent is obtained during pre-donation counselling when the donor has an opportunity to ask questions. The BTS 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 counselled and deferred because the BTS has a duty of care to blood donors. When donors do not wish to know their TTI test results, the BTS cannot fulfil its duty to provide care through counselling, referral for treatment and support, and in the prevention of further transmission.

In countries in which young people under the legal age of majority may be accepted as blood donors, written consent to donate blood may be obtained from a parent or guardian, prior to donation, in accordance with national requirements.

Annex 11 provides an overview of steps in obtaining informed consent for blood donation.

4.4 VOLUNTARY PARTNER NOTIFICATION AND COUNSELLING FOR HIV AND OTHER TTI

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 BTS should encourage and support the individual in doing so.

In particular, a HIV-positive person should be referred to a specialized counselling site that will be able to assist them in partner counselling. The issue of partner notification and counselling should also be addressed in the national blood policy and legislative framework (*80, 81*).

4.5 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 BTS 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 BTS should inform the general public that donor deferral can occur for many different reasons. Counselling 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 counselling deferred donors, BTS staff should carefully explain the reasons for the deferral and attempt to positively reinforce the deferred donor's self-esteem.

4.6 SPECIAL CONSIDERATIONS FOR ADOLESCENT BLOOD DONORS

Special consideration should be given to adolescent donors in terms of informed consent, disclosure to parents or guardians, and donor notification. National laws vary as to the legal age for consent to blood donation. If the donor selection criteria in a country permit blood donation by minors, the national blood policy

and legislative framework should address the matter of confidential notification and counselling of these donors. During the process of pre-donation counselling and obtaining informed consent, adolescent blood donors should be informed if it is standard practice to report test results to parents or guardians.

WHO and UNAIDS encourage countries to provide adolescents with independent access to HIV prevention, treatment, care and support (*64*). The BTS should make efforts to ensure that TTI-positive adolescent donors receive adequate counselling and referral services.

5 Training requirements for blood donor counselling

5.1 OBJECTIVES OF TRAINING

Training in blood donor counselling should be provided for all staff who interact with prospective and current blood donors. These include nurses, phlebotomists, doctors, donor recruitment staff, laboratory technicians and volunteers. The purpose of training in blood donor counselling is to provide staff with the necessary knowledge and skills to conduct counselling effectively (*82*).

Depending on their prior qualifications, BTS staff may have had little or no training in health communication and counselling to enable them to handle confidential interviews on sexual history or risk behaviour. Some may have conducted donor counselling sessions based on their own trial and error or from following the practices of senior staff. It is, therefore, necessary to provide specific training on communication and counselling skills for all staff involved in any stage of blood donor counselling (*83*). The provision of training may also present an opportunity for the BTS to consider task-shifting in donor counselling sessions, for example, from physicians to nurses (*71*).

The objectives of training are to ensure that all staff and volunteers involved:

- Understand the rationale for various stages of blood donor counselling and the importance of confidentiality
- Acquire knowledge and skills in the donor counselling process
- Follow established procedures at all times.

5.2 TRAINING METHODOLOGY

The approach to training on blood donor counselling should be systematic and participatory with emphasis on good communication skills. The involvement of participants in small and large group discussions facilitates motivation, and provides an opportunity for them to ask and answer questions, make presentations and act as facilitators. Exercises may be conducted through role playing, case studies and demonstrations (*72,84,85*). Audio-visual aids should also be used during training (*86*). Training should be continually updated and periodically refreshed, as appropriate, to maintain high levels of quality of service over time (*87*). An example of donor counselling training modules is included as Annex 12.

5.3 STAFF PROFILES

Effective counselling requires that the BTS counsellor has a combination of specific personal attributes and abilities, including:

- Self-awareness: has knowledge of their own personal beliefs and values that can affect the donor–counsellor relationship
- Empathy: has the capacity to understand the feelings, thoughts and experiences of another person, even when these are not explicitly conveyed, and relate to blood donors
- Interpersonal communication skills: has the ability to build rapport and develop trust with the donor

- Critical and analytical thinking: has the ability to process information and make rapid decisions: e.g. on donor suitability and deferral
- Non-judgemental: is objective and neutral.

Given that the role of a BTS counsellor goes beyond simply providing information and educating donors, counsellors should have the ability to:

- Facilitate a session which may involve discussion of unexpected news, such as positive TTI test results, and elicit information about the donor's health status or TTI risk
- Listen and respond to the donor's concerns
- Identify, address and appropriately manage any situations or problems identified during the course of the counselling process.

5.4 RESPONSIBILITIES OF BTS COUNSELLORS

Individuals designated to be BTS counsellors should be responsible for the following activities, in accordance with written standard operating procedures (SOPs):

- Explaining blood donors' responsibility to respond accurately to the donor questionnaire
- Assessing the risk and severity of the conditions for which donors are being counselled
- Providing relevant information
- Informing, notifying and disclosing test results (both negative and positive) and counselling donors on how to protect their health and prevent the transmission of infection
- Encouraging healthy lifestyles for donors who are not infected
- Ensuring proper management and referral of donors who have:
  - Positive TTI test results
  - Negative TTI test results but who are at risk of acquiring TTI
  - Other health conditions requiring deferral
- Correctly documenting interventions and services using standard protocols
- Ensuring that all documentation and records are kept for the defined time period, while maintaining confidentiality

5.5 COUNSELLING KNOWLEDGE AND SKILLS

All BTS staff involved in donor care should have a basic understanding of the donor selection criteria and the necessary skills to interact with donors to make every blood donation a safe and pleasant experience. Communication and counselling skills are particularly important for staff in blood donor counselling settings who should understand the role they play in interacting with the community and blood donors in building rapport, alleviating fears and reassuring anxious donors.

Knowledge necessary for providing counselling

BTS counsellors should have in-depth knowledge of blood donation and blood safety to enable them to answer donor questions at all stages of counselling and provide information, particularly on infection risks and prevention. This should include:

- Key health requirements for safe blood donors
- Infections that may be transmitted through blood transfusion
- Behaviours and activities that increase the risk of TTI

- Blood donor selection and deferral process
- Blood donation process and adverse donor reactions
- Components that may be derived from donated blood for clinical transfusion
- Tests that are performed on donated blood
- Information, notification and assurance of confidentiality of test results
- Availability of donor counselling and care, including referral to other health-care institutions.

BTS counsellors involved in post-donation counselling should also be trained in disclosing TTI test results and referrals to other facilities for confirmatory testing, post-donation counselling and for treatment and care, as appropriate.

Counselling skills and techniques

BTS counsellors need to be empathetic and should not convey any emotional or moral judgements. They should aim to develop rapport with donors and put donors at ease to build their confidence in counselling and encourage open discussion. The following skills and techniques can be developed through practice:

- **Careful listening**: this is central to successful counselling. It encourages donors to share their feelings and concerns. This enables the counsellor to gather the information needed to determine whether they should be accepted or deferred as blood donors, counsel on risk prevention and make appropriate referrals.
- **Attentive behaviours**: the counsellor should use culturally appropriate body language, eye contact and tone of voice to show that he or she is paying attention and to convey sincere concern and support. Examples of attentive behaviours include:
  - — Engaging with the donor through culturally appropriate gestures, such as making eye contact or nodding the head
  - — Using encouraging words such as “Yes”, “I see” and “Go on” while the donor is speaking to encourage him/her to continue.
- **Reflective listening**: this is a way of showing that the counsellor is focused on the donor and understands what he or she is saying. In reflective listening, the counsellor identifies the central message that the donor is conveying and “reflects” it back to the donor using one of the following techniques:
  - — Rephrasing or paraphrasing, repeating, in different words, what the donor has said, using introductory phrases such as “So you are saying that...?”, “In other words...”.
  - — Identifying emotion, acknowledging a feeling, whether expressed or implied, using an introductory phrase such as “So you feel...”.
- **Open-ended questioning**: the counsellor should question the donor strategically using open-ended questions in order to obtain relevant information. Open-ended questioning allows the donor to give detailed responses rather than simple “Yes” or “No” answers. Open-ended questions often start with the words “Who?” “What?” “When?” “Where?” or “How”. Open-ended questions are generally preferable to close-ended questions in the counselling setting. Examples:
  - — Open-ended question: “How do you plan to disclose your HIV status to your family?”
  - — Close-ended question: “Will you disclose your HIV status to your family?”

- **Giving feedback**: the counsellor should give constructive feedback by acknowledging positive donor behaviour, such as keeping appointments, and giving feedback that expresses concern in helpful, specific, and non-accusatory ways when needed.
- **Maintaining focus**: the counsellor should bring the conversation back to the main point at hand if the donor becomes distracted or diverted.

5.6 STAFF COMPETENCY AND SUPERVISION

Staff competency should be assessed to determine if they have acquired both the knowledge and skills to be able to counsel donors independently. Tests of knowledge may be oral or paper-based and can be incorporated into the training sessions (e.g. pre- and post-tests) at the time of final competency evaluation and as part of supervision. On-going and refresher training should emphasize any updates to the content of the knowledge base.

Evaluating the individual's counselling skills involves observation, initially during training sessions and subsequently during sessions with donors. *UNAIDS Tools for evaluating HIV voluntary counselling and testing* (*88*) addresses many issues in common with blood donor counselling, particularly regarding disclosing results. It deals with issues of confidentiality and unfounded fears that the observation may be intrusive, noting that many counsellors and clients mention that they are unaware of the observer soon after the session has started. The key element is to clarify that the purpose of the observation is to assist the counsellors to improve their counselling skills. Many of the tools can be adapted to suit the content and structure of training on blood donor counselling.

The method of observation used will depend on the stage of training and the resources available. Each method has its advantages and disadvantages in terms of cost and feasibility for the assessment of competency during training or routine, on-going supervision and monitoring. These methods include:

- Role play
- Dummy patients or trained volunteers
- One-way mirrors
- Direct observation
- Audio recording of counselling sessions
- Video recording of counselling sessions.

Use of a checklist helps to assure consistency and objectivity across methods of observation. The contents of the checklist should align with required competencies and skills for a blood donor counsellor. This will often have to be completed after the observation is over so as not to interfere with the process.

Periodic observation should be part of routine supervision. The supervisor should then debrief the counsellor in private to discuss the findings of the observation and mentor the counsellor by providing support and guidance. The role of the mentor is to discuss cases with the counsellor, observe the counsellor during practical counselling sessions and assist in resolving problems. This can be undertaken on an individual basis or in a group. Mentoring should not involve evaluation or assessment of the individual's performance.

Regular staff meetings and case discussion can assist counsellors to discuss difficult cases and improve the overall quality of counselling (*26*). These meetings can also be important for counsellors in dealing with stress, and their own anxieties and vulnerabilities. Staff may find it helpful to meet with counsellors in other fields (e.g. HIV counsellors) for guidance and to discuss complex cases.

6 Providing counselling services to blood donors

6.1 ESSENTIAL FEATURES IN THE PROVISION OF BLOOD DONOR COUNSELLING

All blood donors should receive counselling. Good counselling can enhance the image of the BTS, especially when it is provided in a pleasant and considerate manner, and contributes to a positive donation experience and donor retention (*49*). Donors' perceptions of their treatment by BTS staff before, during and after donation and their physical wellbeing are the strongest predictors for the retention of safe donors (*7,25*). Blood donor counselling shares features that are essential in all counselling activities (*27,64*):

- Counselling sites should be easily accessible to blood donors and provide a suitable and conducive environment
- Counselling should focus on the matters that concern the donor most and provide an opportunity for the donor to ask questions
- Counselling should deliver a consistent and accurate message that should be repeatable by the donor, meaning that when given twice, it should still have the same meaning
- Counselling should be objective and empathetic, focusing on the donor's situation and feelings
- Counselling should not be affected by the counsellor's subjective feelings about the donor or the donor's needs
- Counselling should fit within the cultural setting
- Counselling should ensure confidentiality at all times
- Counselling should be provided at times convenient to the donor
- Adequate time should be allowed for counselling so that trust can be developed and information given is more likely to be understood and valued by the donor.

Elements of effective blood donor counselling are outlined in Figure 2.

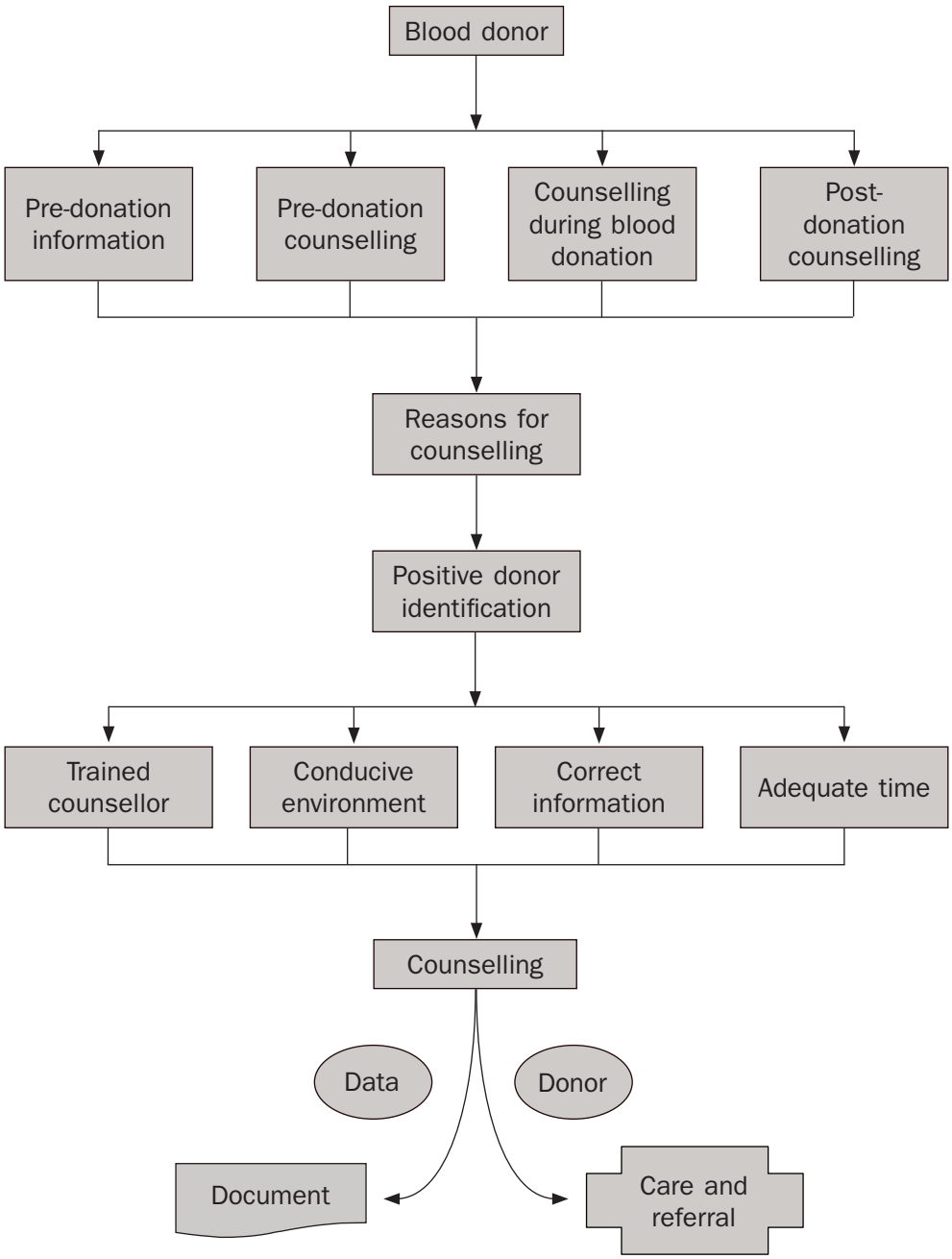
6.2 BTS RESPONSIBILITIES IN THE PROVISION OF BLOOD DONOR COUNSELLING

In carrying out its essential functions in blood donor counselling, the BTS has the following responsibilities.

1 Obtain written informed consent from donors prior to blood donation by (*77*):
   - Providing donor information materials that are factual, culturally appropriate and in a language and form that is easy to understand by all donors (*42,78*)
   - Training staff to deliver the appropriate information to donors and assess their understanding.

2 Manage donors who are deferred temporarily or permanently for health reasons, high risk for infection or positive test results consistent with infection by:

Figure 2: Elements of effective blood donor counselling



- Providing information on the reasons for deferral and where to seek medical advice, if necessary
- Providing counselling to donors who have been deferred for health reasons or risk for infection
- Confirming the screening test results for donors whose screening tests are reactive for infection
- Notifying donors when their reactive screening test results are confirmed
- Providing post-donation counselling to all donors deferred for infection.

3 Coordinate and integrate functions with existing health-care services by establishing:

- Linkages with other services that have the capacity for confirmatory testing, notification, counselling, treatment and care of blood donors
- Mechanisms for regular communication among different partners to ensure that all blood donors are counselled and followed up
- Mechanisms for referring and documenting:
  - Individuals deferred from donating due to health reasons (e.g. because of low haemoglobin) and who are referred to a health centre for further tests and medical attention
  - Individuals who are perceived to be at risk for infection and who are referred to another health service for counselling and follow-up or treatment
  - Individuals who seek to donate blood for the purpose of testing for infections and who are referred to a voluntary testing and counselling service or another health-care service

Individuals who are confirmed positive for TTI and who are referred to another health-care service for further investigation, counselling, treatment and care

6.3 MODELS FOR THE PROVISION OF POST-DONATION COUNSELLING

It is the responsibility of the BTS to establish a system with adequate capacity and resources to counsel blood donors. The delivery of blood donor counselling services, especially post-donation counselling, however, is still a challenge for blood transfusion services and health-care systems in many countries.

Different models can be used to provide post-donation counselling services, based on the level of development and infrastructure of the health-care system and the organizational structure of the BTS. In broad terms, there are two different models: a) where the BTS is directly provides post-donation counselling and b), where the BTS links to other institutions within the health-care system to provide these services. Different approaches may be used for different infections or for different parts of the country.

Decisions on how best to provide counselling services for blood donors require an assessment of the situation in the country, including the local epidemiology; available infrastructure and financial and human resources; available HIV prevention, treatment, care and support services; and the existing social, policy and legal frameworks. The strategic choice and implementation of a model of counselling should be based on an analysis of the epidemiological, social and programmatic context in order to maximize impact and equity (*89,90*).

To develop post-donation counselling as a core activity, the BTS should have sufficient trained personnel as well as suitable infrastructure and facilities to ensure that counselling can be provided effectively. When the BTS has limited capacity or when other organizations within the health-care system have sufficient capacity, the BTS should consider delegating counselling services to these organizations. These arrangements would require the development of formal agreements or memoranda of understanding with the identified organizations to clearly define the roles and responsibilities and the mechanisms for the protection of donor confidentiality.

Standard protocols should be developed for the referral of blood donors to other institutions for counselling or for further investigations, treatment and care. Referrals and their outcomes should be documented.

6.4 MODE OF COMMUNICATION WITH BLOOD DONORS

As part of the national counselling guidelines, each country should define a standard mode of notification of blood donors who test positive for infection. The BTS may adopt different channels to inform and/or notify donors of the test results for different infections. In some countries, for example, test results for infections such as HIV are given only in a face-to-face meeting in a safe and conducive environment with proper counselling facilities. In contrast, for many other infections, such as Chagas disease, the results may be given in a standard letter. Whichever mode of communication is used, there should be a mechanism to protect the confidentiality and privacy of the notified donors.

At the time of donor registration, BTS staff should ask for the donor's preferred mode of communication, obtain the necessary contact details and tell blood donors how they will be informed about their blood test results.

6.5 DONOR COUNSELLING IN SMALL AND MOBILE FACILITIES

Small, remote and under-resourced facilities and settings, including mobile blood donation sessions, may have difficulty in achieving the level and quality of blood donor counselling that is possible in large, central facilities. This may be due to a lack of sufficient time at blood donation sessions, a limited number of staff, a lack of suitable facilities to assure privacy and confidentiality, or other reasons.

However, even in small and mobile facilities, the essential features of blood donor counselling should be consistently followed. Small blood donation facilities have the same responsibilities as large facilities regarding confidentiality and giving information to donors. Some elements of counselling, such as the reasons for deferral, should be given at the site of donation to ensure the donor understands their importance and the implications for blood safety or the donor's health. The staff in-charge at these settings has the responsibility to assess the available resources and determine the feasibility of providing information and counselling.

Staff should receive in-service training to enable them to fulfil their multiple functions, including providing counselling in small and mobile facilities and the ability to make appropriate referrals at the post-donation stage.

7 Monitoring and evaluation of blood donor counselling

7.1 OBJECTIVES OF MONITORING AND EVALUATION

Monitoring is the routine assessment of on-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 (*91*). 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.

BTS counselling activities require regular monitoring and evaluation to ensure compliance with SOPs as part of a quality system, to assess the BTS 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.

7.2 METHODS OF MONITORING AND EVALUATION

Monitoring and evaluation may be undertaken using qualitative and/or quantitative methods. Donor satisfaction surveys are frequently used. Periodic observation by a supervisor to assess the quality of counselling, the session content, and the problem-solving capacity of the counsellor, helps to identify any improvements that can be made in the procedures and staff training. Measuring the average length of various types of counselling sessions (e.g. pre-donation or post-donation counselling, with or without deferral) is an example of quantitative monitoring. These data can be used as a baseline and to follow-up on the indicators by which counselling can be assessed so that measures can be taken to improve practices.

7.3 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 deferred and counselled and the number of donations discarded due to reactive screening test results. 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.
- **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 and location of donation.
- **Tally sheets**: This may include the number of prospective donors who enter the BTS who receive information and leave without proceeding further or who request an HIV test but are deferred. This might be undertaken on a regular basis (e.g. annually) or before and after a new communication campaign or new information materials are introduced to measure their impact.

- **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.. This may reveal whether particular questions are ambiguous and enable the BTS to clarify and improve the quality and sensitivity of the questions and eliminate those that are not useful to reduce the number of questions to the minimum necessary to capture essential information.

7.4 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 analysed with the intent of improving the performance and effectiveness of blood donor counselling (*92*).

Well-designed systems of data collection and analysis are central to monitoring and evaluation. Indicator data can be collected from many sources including population surveys such as Demographic and Health Surveys, population census, vital records, facility surveys, surveys of donors and staff, and counselling service statistics. The linkages and data flow between existing institutional structures created for the coordination of counselling services at various levels should also be clarified (*93,94*).

Indicators for the monitoring and evaluation of blood donor counselling should include:

- **Inputs**: the resources invested in blood donor counselling, including financial, technical and human resources.
- **Processes**: the activities carried out to achieve the objectives of blood donor counselling; monitoring these activities will show what has been done as well as how well and timely it has been done.
- **Outputs**: the results achieved at the programme level (programmatic products) such as:
  - Number of activities conducted: e.g. counsellor training sessions, information, education and communication materials developed
  - Service outputs that measure the accessibility and quality of counselling.
- **Outcomes**: the changes observed in blood donors as a result of donor counselling, such as:
  - **Effects**: short to medium range changes in behaviour promoted by donor counselling: e.g. donor return rate following temporary deferral
  - **Impacts**: changes that occur over the long term: e.g. reduction in the prevalence of infection among donors.

7.5 MONITORING AND EVALUATION PARAMETERS

Monitoring and evaluation of the performance of BTS blood donor counselling should be implemented through a system of regular audits of the following parameters.

Prerequisites

Audits should assess whether the prerequisites for effective donor counselling services are available, including a national policy and guidelines on blood donor selection, deferral and pre-donation counselling, blood screening, confirmatory testing of reactive blood donations, donor notification, post-donation counselling and referral.

Effectiveness of the service delivery model

Audits should include an assessment of whether the available facilities and adopted service delivery model result in effective counselling that meets the BTS requirements.

Number of counselling staff

Staffing requirements will depend on the adopted service delivery model. However, even if counselling services are delegated to another organization outside the BTS, staff adequacy should be monitored to assess the coverage and quality of service provision.

Number of volunteers involved

In situations of staff shortage, the services of volunteers can be particularly helpful in augmenting service provision. Audits should include an assessment of the number and effectiveness of volunteers involved in blood donor counselling.

Staff and volunteer training

Audits should provide information on whether staff providing counselling services have been trained in the required specialized skills. All staff and volunteers involved in counselling should also be properly trained in carrying out their assigned tasks. Volunteers require careful supervision and close management to ensure adherence to appropriate standards of practice and confidentiality. Refresher training and periodic updates in training for staff and volunteers should be included in the audit.

Staff competency assessment

Audits should identify whether the competency of the staff and volunteers providing counselling to blood donors is regularly reviewed and assessed. Regular staff meetings and case discussions can also help to monitor and improve the quality of counselling.

Availability of donor information and education materials

Audits should assess whether donor information and education materials on donor suitability, personal health, infection risks, and frequently asked questions (FAQs) (refer to Annex 13 for an example of FAQs) are available in appropriate languages to promote donor education and self-assessment about suitability for blood donation.

Availability and use of standard operating procedures

Audits should assess whether written standard operating procedures are available and being used by staff at all stages of the counselling process in order to provide consistent and quality services.

Donor satisfaction

Audits should include an assessment of mechanisms for monitoring donor satisfaction through donor surveys, suggestion boxes and other feedback mechanisms to improve the quality of service provision.

Donor confidentiality

The performance monitoring and evaluation system should include criteria to assess whether donor confidentiality is being maintained under all circumstances and throughout all stages in donor counselling. This is vital in maintaining public confidence and trust, presenting a positive image of the BTS and avoiding any donor stigmatization.

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 deferred donors provided with counselling (pre-donation and post-donation)
- Prevalence of TTI among donors who are accepted as donors: first-time and regular/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 an annual basis and compared with those from previous years in order to identify trends over time or in response to interventions undertaken by the BTS 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. For example, differences in infection prevalence rates among donors may be explained by the introduction of a new test with a different sensitivity or specificity; donor mobilization may have expanded blood donations from a new area or community with a different prevalence of TTI; or the communications team may have revised the donor information and education materials. The exchange of information can assist with the interpretation of data, and also aid in identifying solutions and implementing required corrective actions for the improvement of services.

7.6 DONOR SURVEYS

The use of regular donor satisfaction surveys is fundamental to monitoring a well-established donor counselling system. The results of surveys should be collated and analysed using qualitative and quantitative statistical methods and should be reviewed by senior managers. Targets for donor satisfaction should be set and corrective actions implemented where results do not meet target specifications.

Frequency

Donor surveys are usually undertaken on an annual basis or whenever there are significant changes to the selection or counselling processes.

Sample size

Sufficient numbers of donors should be surveyed at all sites where counselling is performed in order to ensure that the sample is representative of the counselled donor population. In some circumstances, such as when there are only a small number of donors who are positive for an infection, it may be appropriate to survey all donors in this category to obtain a sufficient sample size.

Survey method

The most appropriate survey method will depend on the types of counselling provided (i.e. pre- and/or post-donation) and the counselling system in place.

Adequate time should be allowed to elapse between the counselling process and the donor survey so that donors have sufficient time to reflect on the process. Donor surveys can be used to monitor both pre-donation and post-donation counselling and may be conducted remotely by letter, telephone or may be web–based. However, where the use of these methods is not possible, face-to-face interviews at the completion of the counselling process by staff or volunteers who were not involved in the provision of counselling may be used as an alternative. The survey method used should allow information to be collected anonymously in order to maintain donor confidentiality.

Survey content

The survey should consist of a series of non-leading questions to ascertain donors' attitudes about the counselling and deferral process. Questions should be in plain language and reviewed by experts skilled in survey applications. Questions should elicit opinions on the relevance of the information given by the counsellor, the clarity of the oral and written information provided, the skill, attitudes and manner of the counsellor, the adequacy of the referral process when relevant, and information about the availability of follow-up and support. Donors' understanding of the deferral process and the duration of the deferral should specifically be assessed. For temporarily deferred donors, the willingness to return should also be ascertained.

Examples of survey questions may include:

- Do you have particular beliefs or values about blood donation and reasons for giving or not giving blood?
- How do you feel about having your blood tested for HIV, hepatitis viruses and other infections?
- Do you want to be informed of your blood test results?
- Do you come to give blood because it is a good way of getting tested for HIV?
- What sort of information and counselling would you like to have about HIV and AIDS, and the HIV test, and what is the best way to make such information available?
- What worries do you have about receiving information and counselling from the BTS?
- Are you satisfied with the information and counselling that you received?
- What do you think is the impact of information and counselling on blood donors' knowledge, risk behaviour and intentions to donate?
- Are the available pre-donation deferral and post-donation referral processes acceptable to you?

- How should donors be told that they have HIV or another infection that can be transmitted through their blood?
- What are the main problems faced by donors and others with positive test results for HIV, hepatitis viruses and other infections?
- In your view, why do people not keep appointments for counselling and discussion about their test results?
- Where and to whom do donors and others with HIV and hepatitis virus infections go when they need support?

Annex 14 provides an example of a blood donor survey.

Glossary

Apheresis
Any procedure in which blood is withdrawn from a donor, a portion (such as plasma, leukocytes or platelets) is separated and retained, and the remainder is re-transfused into the donor

Audit
Systematic, independent and documented examination to determine whether activities comply with a planned and agreed quality system

Blood bank/hospital transfusion laboratory
A laboratory or part of a laboratory within a hospital which receives and stores TTI screened blood and blood components from a blood centre, performs compatibility testing and issues blood and blood components for clinical use within the hospital

Blood centre
A facility (stand-alone or hospital-based) which carries out all or part of the activities for donor recruitment, blood collection (whole blood and, in some cases, apheresis), testing for TTI and blood groups, processing into blood components, storage, distribution to hospital blood banks within a defined region, and liaison with clinical services

The following should not be categorized as blood centres:

- Mobile or fixed blood collection sites/rooms which are operated as part of a blood centre
- Hospital blood banks which only store, perform compatibility testing and issue screened blood

Blood donor counselling
A confidential dialogue between a blood donor and a counsellor about issues related to the donor's health and the donation process, provided before, during and after blood donation

Blood donors

- **Voluntary non-remunerated blood donor**: 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
- **Family/replacement blood donor**: A person who gives a replacement unit of blood only when a family member or friend requires transfusion
- **Paid "donor"**: A "donor" who gives blood for money or other form of payment
- **Autologous donor**: A patient who donates his/her blood to be stored and reinfused to him/her, if needed, during surgery

Blood transfusion service (BTS)
A generic term to describe an organization(s) that is involved in the provision of blood for transfusion; its activities may be carried out by a single blood centre or through a network of blood centres and hospital blood banks

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

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

Donor selection
The process of assessing the suitability of an individual to donate blood against defined selection criteria

Haemovigilance
A set of surveillance procedures for the identification, reporting, investigation and analysis of adverse reactions and events (including incidents, errors and near-misses), designed to prevent their occurrence or recurrence, covering the entire transfusion chain from blood donors to the recipients of transfusion, including the epidemiological follow-up of donors

Incidence
The rate of occurrence of new cases of a particular disease in a population being studied

National blood policy
A formal statement of intent by the ministry of health that defines the key organizational, financial, technical and legal measures that will be undertaken to develop a national blood system for ensuring the quality, safety, availability, accessibility and rational use of blood and blood products within the country

National blood programme
A programme under the ministry of health with overall responsibility for the planning, implementation and monitoring of all activities related to blood transfusion throughout the country

Precautionary principle
The concept that a precautionary action may be justified to mitigate a perceived risk to the safety or supply of blood if the best available evidence shows that there are reasonable grounds to support this action, even if the probability of that risk occurring is small

Prevalence
The proportion of a specific population that is infected with an infectious agent at any particular time

Quality system
The organizational structure, process, procedures and resources needed to implement quality requirements

Risk behaviour
Behaviour that exposes a person to the risk of acquiring a transfusion-transmissible infection

Self-deferral
The decision by a potential donor to defer himself/herself from the donation of blood or blood components, either temporarily or permanently, based on general health or medical condition, or the risk of exposure to pathogens

Standard operating procedures (SOPs)
Written instructions for the performance of a specific procedure in a standardized manner

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 recipient, a manufacturer of medicinal products or disposal, and vice versa

Transfusion-transmissible infection(s) (TTI)
An infection that is potentially capable of being transmitted by blood transfusion

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Acknowledgements

The WHO Blood Transfusion Safety team wishes to express its thanks to the following experts in the field of transfusion medicine and science, public health, epidemiology and ethics for their contribution to the development of these implementation guidelines.

These guidelines were developed in collaboration with the US Centers for Disease Control and Prevention (CDC), Atlanta, and the International Federation of Red Cross and Red Crescent Societies (IFRC).

TECHNICAL WORKING GROUP

Dr Neelam Dhingra, Coordinator, Blood Transfusion Safety, Health Systems Policies and Workforce, WHO-HQ, Geneva, Switzerland	**Dr Lin Che Kit**, Chief Executive and Medical Director, Hong Kong Red Cross Blood Transfusion Service, Hong Kong SAR, P.R. China
Dr Christie M Reed, Medical Officer, HIV Prevention Branch, Division of Global HIV/AIDS, CDC, Atlanta (now CDC Resident Advisor, President's Malaria Initiative, Division of Parasitic Diseases & Malaria, Monrovia, Liberia)	**Dr Noryati Abu Amin**, Medical Officer, Blood Transfusion Safety, Health Systems Policies and Workforce, WHO-HQ, Geneva, Switzerland
Ms Jan Fordham, formerly Technical Officer, Blood Transfusion Safety, Health Systems Policies and Workforce, WHO-HQ, Geneva, Switzerland	**Mr Peter Carolan**, formerly Senior Officer, Health and Care (Blood), IFRC, Geneva, Switzerland
Dr Rana Al-Abdulrazzak, Director, Medical and Donor Affairs, Kuwait Central Blood Bank, Kuwait	**Ms Terhi Aaltonen**, Programme Officer, Prevention, Care and Support Unit, UNAIDS, Geneva, Switzerland
Ms Stephanie Behel, Epidemiologist, HIV Testing and Counseling, HIV Prevention Branch, Division of Global HIV/AIDS, CDC, Atlanta, United States of America	**Mr James Chitsva**, Technical Officer Blood Transfusion Safety, Health Systems Policies and Workforce, WHO-HQ, Geneva, Switzerland
Dr Malhi Cho Samaniego, Medical Officer, Pan American Health Organization, WHO Regional Office for the Americas, Washington DC, United States of America	**Dr Gayatri Ghadiok**, formerly Blood Safety Specialist, WHO Regional Office for the Western Pacific, Manila, Philippines
Dr Donna Higgins, Medical Officer, HIV Prevention in Health Sector, WHO-HQ, Geneva, Switzerland	**Ms Alicia S Hunter**, Senior Public Health Analyst, Division of Nutrition, CDC, Atlanta, United States of America

Dr Anthony Keller, Australian Red Cross Blood Service, Melbourne, Australia	**Mr Wim de Kort**, Division Director and Coordinating Manager of Donor Research, Sanquin Blood Bank Southeast, Nijmegen, The Netherlands
Dr Matthew J Kuehnert, Director, Office of Blood, Organ, and other Tissue Safety, Division of Healthcare Quality Promotion,, CDC, Atlanta, United States of America	**Dr Shirish Kumar**, formerly Medical Officer, Blood Transfusion Safety, Health System Policies and Workforce, WHO-HQ, Geneva, Switzerland
Dr Dorothy Kyeyune, Director, Uganda Blood Transfusion Service, Ministry of Health, Kampala, Uganda	**Dr June Lee**, Medical Officer, Australian Red Cross Blood Service, Melbourne, Australia
Dr Guy Levy, formerly Medical Director, Swiss Red Cross Blood Transfusion Service, Bern, Switzerland	**Dr Lawrence H Marum**, formerly Team Lead, Medical Transmission, HIV Prevention Branch, Division of Global HIV/AIDS, CDC, Atlanta, now Country Director, CDC, Lusaka, Zambia
Dr Champa Manchanayake, formerly Senior Medical Officer, National Blood Transfusion Service, Colombo, Sri Lanka	**Mr David Mvere**, Chief Executive Officer, Zimbabwe National Blood Service, Harare, Zimbabwe
Dr Ana del Pozo, Chief of Hemotherapy Service, Hospital Garrahan, Buenos Aires, Argentina	**Dr Andreas Reis**, Technical Officer, Ethics and Human Rights, WHO-HQ, Geneva, Switzerland
Dr Chhorn Samnang, Head, Blood Donor Programme, National Blood Transfusion Center, Phnom Penh, Cambodia	

EXTERNAL REVIEW GROUP

Dr Yasmin Ayob, Consultant, National Blood Center, Kuala Lumpur, Malaysia	**Dr Zarin Bharucha**, Consultant in Transfusion Medicine, Mumbai, India
Dr Frank E Boulton, Emeritus Consultant, NHS Blood and Transplant, Southampton, United Kingdom	**Professor Kamel Boukef**, Consultant in Transfusion Medicine, Tunis, Tunisia
Professor Dr Ashley J Duits, Medical Director, Red Cross Blood Bank Foundation, Curaçao, Netherlands Antilles	**Dr Anthony E Fiore**, Associate Director for Science, Division of Parasitic Diseases and Malaria, CDC, Atlanta
Dr Marcela Garcia Gutierrez, Consultora Servicios de Sangre, Bogota, Colombia	**Dr Patricia Hewitt**, Consultant Specialist in Transfusion Microbiology, NHS Blood and Transplant, North London, United Kingdom

Dr Anthony A Marfin, Team Leader, Medical Transmission Prevention, HIV Prevention Branch, Division of Global HIV/AIDS, Center for Global Health, CDC, Atlanta	**Mr Emmanuel Masvikeni**, formerly Blood Procurement & Public Relations Manager, National Blood Service, Harare, Zimbabwe
Dr Faten M Moftah, formerly Director General, National Blood Transfusion Service, Ministry of Health and Population, Cairo, Egypt	**Dr Susan P Montgomery**, Epidemiologist, Division of Parasitic Diseases and Malaria, CDC, Atlanta
Dr Koji Nabae, formerly Deputy Director, Division of Blood and Blood Products, now Deputy Director, Division of Infectious Diseases, Ministry of Health, Labour and Welfare, Tokyo, Japan	**Dr Soisaang Phikulsod**, Director, National Blood Center, Thai Red Cross Society, Bangkok, Thailand
Mr Paul Rogers, Technical Officer, Health Technology, WHO Western Pacific Regional Office, Manila, Philippines	**Dr Dorothy Stainsby**, Emeritus Consultant in Transfusion Medicine, NHS Blood and Transplant, Newcastle upon Tyne, United Kingdom
Mr Sini Subrayen, Public Relations Practitioner, South African National Blood Service, Johannesburg, South Africa	**Dr Elizabeth Vinelli**, Medical Director, National Blood Programme, Honduras Red Cross, Comayagüela, Honduras
Professor Zhu Yong Ming, President, Shanghai (Red Cross) Blood Center, Shanghai, P.R. China	

EXTERNAL EVALUATION

Inter-regional workshop on blood donor selection and donor counselling for priority countries in the African and Eastern Mediterranean regions, 27–30 June 2011, Nairobi, Kenya

The final draft of these guidelines, *Blood donor counselling: implementation guidelines*, was evaluated in an inter-regional workshop on blood donor selection and donor counselling for priority countries in the African and Eastern Mediterranean Regions, June 2011, Nairobi, Kenya. The objective of the workshop was to identify the major challenges and constraints faced by participating countries, to define appropriate strategies to improve donor selection, notification, pre- and post-donation counselling, and to assess the feasibility of the implementation of these guidelines.

The countries selected included both those with successful donor selection and counselling programmes and those without national systems for blood donor selection and counselling or with high rates of donor deferral due to transfusion-transmissible infections.

Participants

Dr Lucy Asamoah-Akuoko, Senior Medical Officer, National Blood Transfusion Service, Accra Area Blood Centre, Accra, Ghana	**Dr Samuel Baker**, Programme Manager, National Safe Blood Transfusion Services Programme, Ministry of Health and Sanitation, Freetown, Sierra Leone
Mr Alemayehu Belete, Officer, Federal Ministry of Health, Medical Services Directorate, Addis Ababa, Ethiopia	**Mrs Lwopu M Bruce**, Program Manager, Ministry of Health & Social Welfare, National Blood Safety Program, Ministry of Health & Social Welfare, Monrovia, Liberia
Mrs Judith Charle, Head, Blood Donation Department, National Blood Transfusion Service, Dar Es Salaam, Tanzania	**Dr Girma Tesfaye Debella**, Director, National Blood Bank Service, Ethiopian Red Cross Society, Addis Ababa, Ethiopia
Professor Raziq Fazle, Professor of Hematology and Focal Person Safe Blood Transfusion Project, Province of Khyber Pakhtunkhwa, Peshawar, Post-Graduate Medical Institute, Hayatabad, Peshawar, Pakistan	**Dr Debasish Gupta**, Project Director, Blood Safety, CHF International Kenya, Nairobi, Kenya
Dr Enayatullah Hashemi, General Manager, Diagnostics, Ministry of Public Health, Senama Pamir Central Blood Bank, Kabul, Afghanistan	**Mrs Senet Awolker Ibrahim**, Quality Manager, National Blood Transfusion Service, Medical Services Division, Asmara, Eritrea
Mr Musa Kabba, Regional Donor Recruitment Officer – East, National Safe Blood Transfusion Services Programme, Ministry of Health and Sanitation, Kenema, Sierra Leone	**Mr Mulbah J Kerkula**, Field Coordinator, National Blood Safety Program, Ministry of Health & Social Welfare, Monrovia, Liberia
Ms Mercy Kokha, Chief Clinic Nurse, Malawi Blood Transfusion Service, Blantyre, Malawi	**Dr Dorothy Kyeyune Byabazaire**, National Programme Manager/ Director, Uganda Blood Transfusion Services, Nakasero, Kampala, Uganda
Mrs Helen Hatia Mahama, Head, Donor Care, National Blood Transfusion Service, Accra Area Blood Centre, Accra, Ghana	**Dr Bridon M'Baya**, Medical Director, Malawi Blood Transfusion Service, Blantyre, Malawi
Dr Faten M Moftah, Director-General, National Blood Transfusion Service, Ministry of Health and Population, Cairo, Egypt	**Dr Nehad Mohamed Mosad**, Deputy, National Blood Transfusion Service, Ministry of Health and Population, Cairo, Egypt
Mr Stanley Mtemeri, Quality Assurance Manager, Laboratory, Swaziland National Blood Transfusion Service, Ministry of Health, Manzini, Swaziland	**Dr Maingi Sylvester Mulli**, Medical Director, Regional Blood Transfusion Centre, Embu, Kenya

Ms Lerato Mamakhelelise Ncheke, Blood Donor Counsellor, Lesotho Blood Transfusion Service, Ministry of Health and Social Welfare, Maseru, Lesotho	**Dr Maxwell Solomuzi Ngcobo**, Medical Officer, South African National Blood Service, Pinetown, Durban, South Africa
Dr Titus Ngulungu, Director, Regional Blood Transfusion Centre, Ministry of Medical Services, Nakuru, Kenya	**Dr Efesper Nkya**, Programme Manager, Tanzania National Blood Transfusion Service, Ministry of Health and Social Welfare, Dar Es Salaam, Tanzania
Ms Maleqhoa Grace Nyopa, Manager, Lesotho Blood Transfusion Service, Ministry of Health and Social Welfare, Maseru, Lesotho	**Ms Halima Saad**, Head of Blood Donation Department, Ministry of Public Health, Senama Pamir Central Blood Bank, Kabul, Afghanistan
Mrs Aminatta Sarr-Bojang, Programme Manager, National Blood Transfusion Service, Ministry of Health and Social Welfare, Banjul, The Gambia	**Mrs Cynthia Sims**, Haemovigilance Professional Nurse Medical (Transfusion Transmitted Infection Donor Counselling), Western Province Blood Transfusion Service, Cape Town, South Africa
Mrs Mamjarra Nyabally Sonko, Senior Blood Donor Recruiter, National Public Health Laboratories, National Blood Transfusion Service, Ministry of Health and Social Welfare, Banjul, The Gambia	**Professor Hosea Sukati**, Technical Director, Swaziland National Blood Transfusion Service, Manzini, Swaziland
Dr Yifde-Amlak Tesfamariam Baraki, Director, National Blood Transfusion Service, Medical Services Division, Asmara, Eritrea	**Professor Mahfooz-Ur-Rahman**, Director, Institute of Blood Transfusion Services, Punjab, Lahore, Pakistan
Mr Mugisha William, National Blood Donor Programme Officer, Uganda Blood Transfusion Services, Nakasero, Kampala, Uganda	

International facilitators

Dr Lin Che Kit, Chief Executive & Medical Director, Hong Kong Red Cross Blood Transfusion Service, Hong Kong SAR, P.R. China	**Dr Neo Moleli**, Lead Consultant, Donor Services, South African National Blood Service, Roodepoort, South Africa

World Health Organization

Dr Neelam Dhingra, Coordinator, Blood Transfusion Safety, Health Systems Policies and Workforce, WHO-HQ, Geneva, Switzerland	**Dr Nabila Metwalli**, Regional Adviser, Blood Transfusion Safety, Laboratory Imaging & Clinical Technologies, WHO Office for the Eastern Mediterranean, Cairo, Egypt

Dr Jean-Baptiste Tapko, formerly Regional Adviser, Blood Safety, WHO Regional Office for Africa, Brazzaville, Congo	**Dr Rex Gadama Mpazanje**, Project Manager, WHO Country Office, Nairobi, Kenya
Dr Mohammed Zahran, National Programme Officer, Blood Transfusion Safety, World Health Organization, Khartoum, Sudan	

US Centers for Disease Control and Prevention

Dr Christie M Reed, Medical Officer, HIV Prevention Branch, Division of Global HIV/AIDS, CDC, Atlanta (now CDC Resident Advisor, President's Malaria Initiative, Division of Parasitic Diseases & Malaria, Monrovia, Liberia)	**Dr Jane Mwangi**, Branch Chief, Division of Global HIV/AIDS Laboratory Branch, CDC, Nairobi, Kenya
	Dr Daniel Kimani, Technical Advisor, Blood and Injection Safety, Division of Global HIV/AIDS Laboratory Branch, CDC, Nairobi, Kenya

Kenya National Blood Transfusion Service

Dr Margaret Oduor, Medical Director, National Blood Transfusion Service, Nairobi, Kenya	**Mr Charles Rombo**, Quality Manager, National Blood Transfusion Service, Nairobi, Kenya
Mr Benard Kassam, In-charge, Donor Notification Program, National Blood Transfusion Service, Nairobi, Kenya	**Mrs Seline Ooku**, In-charge, Donor Clinics, National Blood Transfusion Service, Nairobi, Kenya

DECLARATION OF INTERESTS

Declaration of interest statements were collected from all members of the technical working group, external reviewers, and participants in the inter-regional workshop. No conflict of interest was declared by any contributors to the guidelines.

ANNEXES

The WHO Blood Transfusion Safety programme acknowledges with thanks the Hong Kong Red Cross Blood Transfusion Service, Kenya National Blood Transfusion Service, South African National Blood Service, United Kingdom NHS Blood and Transplant and Zimbabwe National Blood Service for providing the examples for the annexes.

Annex 1

Haemoglobin and iron: information for blood donors

Every time you come to give blood or platelets we check your haemoglobin level. Haemoglobin (Hb) is a protein found in the red blood cells that carries oxygen in your body and gives blood its red colour. Haemoglobin levels vary from person to person. Men usually have higher levels than women. A haemoglobin "cut-off" level is set for blood donation to ensure that your haemoglobin will not drop below normal after you have donated blood. Normal ranges for haemoglobin differ between ethnic populations, and males and females, and are also affected by age, especially in women. Individuals with haemoglobin levels below the normal range are, by definition, anaemic. There are many causes of anaemia and anaemia due to iron deficiency is common.

What happens next?

If your haemoglobin level is less than the cut-off value, you will not be able to donate blood until the time you have further tests to know the reason for your low haemoglobin, receive treatment for the condition and have a normal haemoglobin value above the cut-off level. We want you to come back as soon as possible to donate blood, but your health comes first. So it's important to wait a while to allow your haemoglobin to reach the normal level. We hope that next time you come to give blood your haemoglobin will be above the cut-off level and that you will not be disappointed again.

More about iron

Iron is very important because it helps your body to make haemoglobin. You give away iron when you donate blood and so it is even more necessary for blood donors to eat plenty of iron-containing foods.

Where does iron come from?

As iron is found in a variety of foods, you can usually get enough from a balanced diet. The major sources of iron are meat and meat-based foods, cereals and cereal products, and vegetables.

What can I do to boost my iron levels?

Iron is not easily absorbed by the body so we all need a regular supply of it. Try to eat a well-balanced diet. Also, every day, try to eat three portions of food that are good sources of iron. Reducing the amount of snacks and sugary foods which contain very little iron will also help.

These foods are good sources of iron:

- Pulses and beans
- Eggs
- Breakfast cereals – some cereals are fortified with iron
- Lean red meat, turkey and chicken

- Fish – including frozen and canned fish such as mackerel, sardines, salmon and pilchards
- Nuts
- Brown rice
- Tofu
- Bread – especially whole meal or brown breads
- Leafy green vegetables – especially spinach curly kale, watercress and broccoli
- Dried fruit – in particular apricots, raisins and prunes.

The amount of animal fat in your diet should be kept low. So when eating meat, try to choose lean meat. It is also better to grill, steam, roast or microwave food rather than fry it. A note about tea: tea may reduce the absorption of iron from foods. Avoid drinking tea just before, after or with meals.

Vitamin C

Vitamin C (ascorbic acid) helps you to absorb more iron. So to get the most from the food you eat, have vitamin C rich foods with meals: for example, fresh fruits and vegetables or drinks such as fresh orange juice.

What if I am a vegetarian or vegan?

Although iron from non-meat sources is more difficult for the body to absorb, people following a well-balanced diet should be able to get enough iron in their diet.

Do I need to take iron tablets?

Most people should be able to get all the iron they need by eating a varied and balanced diet and should not need to take iron supplements or tablets. Iron tablets should only be taken if your doctor has advised you to take them.

Annex 2

Bruising: information for blood donors

Although it is hoped that no donor will have any ill-effects from giving blood, occasionally bruising of the arm may develop at the venepuncture site. The bruise can look dramatic and some people may find this worrying, but it is usually harmless and recovers within a few days.

Bruising is caused by bleeding under the skin, which occurs due to injury to blood vessels. These injured blood vessels leak a small amount of blood, which collects in the area as a bruise. If a bruise occurs during blood donation, the process may be discontinued to prevent it from worsening. With time, the familiar blue-black discolouration changes to green, then yellow and eventually fades and disappears. This may take two to three weeks if the bruise is large. It is normal for bruises to spread out before fading.

During or after blood donation, the following may happen:

- The vein is pierced during blood donation, causing some blood to leak into the surrounding tissue. The donor is more likely to develop a bruise if the venepuncture procedure was more difficult than usual.
- There are tiny fragile blood vessels running just under the skin, as well as the larger veins from which the blood donation is obtained. When the donation needle is inserted into the arm, one of these small vessels may be injured and bleeding occurs.
- Inadequate pressure placed on the venepuncture site after removal of the needle may allow blood to leak in the surrounding tissues.
- Lifting heavy objects after blood donation could put pressure on the venepuncture site and dislodge the clot formed.

Prevention and management of bruising following blood donation

- Wear clothes with loose fitting sleeves when donating blood. A tight sleeve can act as a tourniquet and cause congestion in the vein, increasing the chance of bruising.
- Apply firm pressure to the venepuncture site after donation, as advised by the BTS staff member, until the bleeding has stopped. A plaster will be applied to cover the venepuncture site; this should be kept on for a minimum of six hours.
- Avoid lifting heavy objects for a few days as this could aggravate the bruising. However, gentle movements are recommended whilst the bruise is healing.
- If bruising has developed, applying cold compresses to the area can also help to relieve any pain or discomfort.
- If you require more pain relief, it is recommended to take paracetamol (according to the manufacturer's instructions); avoid taking aspirin or ibuprofen for the first 24 hours.

- If you experience any of the following, seek further help or call the BTS for advice:
  - Severe pain
  - Numbness or persistent ”pins and needles” in the arm, hand or fingers
  - Swelling which is large or increasing in size
  - Painful redness and inflammation.

Annex 3

Post-donation advice to blood donors

Blood Transfusion Service

Dear Blood Donor,

Thank you for donating blood today. Your valued donation is a vital contribution to our community, and we sincerely hope that you have found it a worthwhile experience. We would like to advise you to read carefully the following points for care after blood donation. If you have any enquiry regarding post-donation matters, please call (insert the telephone number and time when this service is available).

Over the next 48 hours:

- Drink plenty of fluids to replenish the volume lost during donation.
- Avoid lifting heavy weights with the donation arm or participating in strenuous physical activities or sports after donation to prevent bruising of the venepuncture site and dizziness.

If you feel dizzy, unwell or have cold sweats:

- Take a seat or lie down immediately, preferably with your feet raised, until the feeling passes.
- Loosen any restrictive garments and keep breathing smoothly.
- Keep calm and take slow and long deep breaths.
- Seek assistance from any passer-by or people near you.
- If the condition does not improve or for any reason something doesn't feel right, call the number provided above.

Care for the venepuncture site:

- In uncommon situations where fresh bleeding occurs after the plaster is removed, put gentle pressure on the venepuncture site, raise your arm for 3–5 minutes and apply a bandage to the site. The bandage or the dressing can be removed after 5 hours.
- If you notice bruising around the venepuncture site, it is usually caused by bleeding into the tissue underneath the skin. It will usually resolve in a week's time. If you feel pain or discomfort, applying a cold compress to the area may help.
- If the venepuncture site becomes swollen or blue or you experience pain or numbness in the donation arm, please call (insert telephone number) for advice or consult a doctor.

Important information for the BTS

If any of the following situations occur, please inform the BTS immediately by calling (insert telephone number and time when this service is available):

- You believe that the blood you have donated might not be suitable for transfusion to a patient
- You would like to make any revisions to the information you provided in the donor questionnaire
- You develop an acute infection such as fever, a cough or cold within 4 weeks of blood donation
- You develop jaundice, hepatitis, tuberculosis or malaria within 3 months of blood donation.

When you call, the BTS will ask you to confirm your name and other personal data and will request you to provide information on the date and place where you donated blood to enable us to locate the donated blood unit. All information that you have provided will be kept strictly CONFIDENTIAL. Your cooperation is of the utmost importance to your health as well as to the safety of the recipient of blood.

Blood Transfusion Service
Street address
Postal address
Post code
Telephone number (office hours)
Telephone number (outside office hours or 24-hours)
Fax number
E-mail address
Website address

Annex 4

Steps in post-donation counselling of blood donors with confirmed TTI

In the case of blood donors whose TTI test result is confirmed positive, the staff providing post-donation counselling should:

1 Inform the donor of the result simply and clearly.

2 Give the donor time to consider the information.

3 Ensure that the donor understands the result.

4 Allow the donor to ask questions.

5 Help the donor cope with emotions arising from the test result.

6 Discuss any immediate concerns and assist the donor to suggest a person among their close family and friends who may be available and acceptable to offer immediate support.

6 Describe follow-up services that are available in the health facility and in the community, with special attention to available services for treatment, care and support.

8 Provide information on how to prevent the further transmission of infection.

9 Provide information on other relevant preventive health measures, such as healthy lifestyles and good nutrition.

10 Discuss possible disclosure of the result, including when and how this may happen and to whom.

11 Encourage and offer referral for the testing and counselling of partners and children

12 Arrange a specific date and time for a follow-up visit or referral for treatment, care, counselling, support and other services, as appropriate.

Annex 5

HIV infection: information for blood donors

The human immunodeficiency virus (HIV) is one of the world's leading infectious diseases, claiming more than 25 million lives over the last 30 years. In 2010, there were approximately 34 million people living with HIV.

Once someone is infected with HIV, it is present in the body permanently. HIV invades white blood cells, called T-lymphocytes, which have an important role to play in the body's defences against infection and cancer. HIV destroys these cells and, if unchecked, causes the body's defence mechanism – or immune system – to fail. This is known as "immune deficiency". Failure of the immune system allows infections which are usually kept under control to cause illness, and makes the person more likely to develop certain cancers. The most advanced stage of HIV infection is acquired immunodeficiency syndrome (AIDS), which can take 10–15 years to develop. This stage is defined by the development of certain cancers, infections or other severe clinical manifestations.

Transmission

HIV is a sexually-transmitted disease and can be transmitted via unprotected sex and close contact with a variety of body fluids of infected individuals, such as blood, breast milk, semen and vaginal secretions. HIV can also be passed from mother to baby during pregnancy and through breastfeeding. Although primarily transmitted through person-to-person sexual contact, HIV can also be transmitted by blood transfusion from an infected blood donor.

Examples of HIV transmission routes include:

- Unprotected anal or vaginal sex with an HIV-infected partner
- Mother-to-child transmission during pregnancy, childbirth, or breastfeeding
- Transfusion with HIV-infected blood or blood products
- Sharing of contaminated injection equipment, tattooing, skin-piercing tools and surgical equipment.

HIV infection cannot be spread through ordinary day-to-day contact such as shaking hands or sharing personal objects, food or water. Activities such as eating and drinking with friends or family, sharing washing or toilet facilities, and hugs and kisses are all safe. There is no risk of infection from shared cooking and eating utensils, or baths, showers or swimming pools. HIV cannot be passed on by tears, sweat, coughs, sneezes or insect bites.

Signs and symptoms

The symptoms of HIV vary depending on the stage of infection. Although people living with HIV tend to be most infectious in the first few months, many are unaware of their status until later stages. In the first few weeks after initial infection, individuals may experience no symptoms or a flu-like illness including fever, headache, rash or sore throat.

As the infection progressively weakens the person's immune system, the individual can develop other signs and symptoms such as swollen lymph nodes, weight loss, fever, diarrhoea and cough. Without treatment, they could also develop severe illnesses such as tuberculosis, cryptococcal meningitis, and cancers such as lymphomas and Kaposi's sarcoma, among others.

Important information about your test results

The tests performed on your donation have given positive results for the antibodies and the virus particles in your blood, which means that you are infected with HIV. Antibodies are the body's reaction to infection, but unlike antibodies to other infections, HIV antibody is unable to overcome the virus and eliminate it from the body. Because the virus is also in the blood, it can be passed on to the recipient of blood transfusion. The tests do not give any information about when or how you became infected, or the state of your immune system. The positive test result does not mean that you have AIDS. Other tests must be performed which will give much more information about your health.

Your test results are regarded as strictly confidential and will not be disclosed to anyone without your consent. However, we could refer you to a hospital or an HIV/AIDS centre for further medical care and treatment. Furthermore, you are infectious to your sexual partner and should seek treatment for both yourself and your partner. If you do not want to, or are unable to inform your partner, the HIV/AIDS centre may be able to help you with that.

We advise you to think very carefully before telling anyone, particularly in the first few days after hearing the news, when the initial reaction may be to take others into your confidence without thinking of the possible consequences.

You should tell those with whom you recently or regularly had sexual contact. You should also tell your doctor and any other doctor who may look after you, particularly if it may help in diagnosing an illness. Your dentist should be informed about the HIV-positive status so that he/she can take the necessary precautions in the surgery to prevent the spread of infection.

If you are a health care worker, you will need to inform your occupational health adviser. If you are engaged in exposure-prone procedures with patients, you should not work until this has been done. For most people there are no occupational health issues and other people do not need to know.

Having someone to talk to may help, especially in the first few days after you hear the news. You can contact the doctor or nurse at the BTS again. The specialist centre that we refer you to will also have people who can help you. There are helplines which offer counselling and support as well as information leaflets on a wide range of topics. You may also look up "AIDS" or "HIV helplines" on the internet for access to other organizations. If you would like to get in contact with someone who also has HIV infection, one of these organizations may be able to put you in touch with a local support group.

Medical care and treatment

It is very important that you have a full medical check-up. This should be arranged at a specialist centre or voluntary counselling and testing centre for the care of people with HIV infection. The centre will arrange a full medical assessment which will give much more information about your health. You will also have access to support for other problems which may arise as a result of the infection, such as informing partners and family.

There is no cure for HIV infection, but modern treatments aim to keep people with HIV healthy for as long as possible. HIV can be suppressed by combination antiretroviral therapy (ART) consisting of three or more antiretroviral (ARV) drugs. ART does not cure HIV infection but controls viral replication within a person's body and allows an individual's immune system to strengthen and regain the power to fight off infections. With ART, HIV-infected individuals can live healthy and productive lives.

How to prevent the virus from being transmitted to others

Blood donation: Unfortunately, you will no longer be able to give blood. Any current sexual partner cannot be a donor either.

Sexual contact: Understanding and practicing "safer sex" can reduce the risk of passing on the virus. For sex to be "unsafe", infected body fluids from one person need to get inside the body of another person, enabling the virus to get into the bloodstream. The body fluids most likely to transmit the virus are semen, vaginal fluids and blood.

This means that the sexual activities most likely to pass on the virus are:

- Unprotected anal intercourse (that is, without a condom). This activity carries a particularly high risk and, even with a condom, is still "high-risk" because of the high failure rate of condoms in these circumstances. This is why the infection is transmitted so easily from an infected man to another man.
- Unprotected vaginal intercourse (that is, without a condom).
- Any activity which draws blood – this would include sexual intercourse during the menstrual period.

The infection is passed more readily from a man to a woman than from a woman to a man, but it is recommended that condoms are used with all partners, and consideration is given to other forms of sexual activity which do not allow exchange of infected body fluids. Vaccines against HIV are under development and are being tested in clinical trials, but are not yet available for general use. Immunization of a partner is not currently possible.

Pregnancy and breastfeeding: The virus can be passed on to the baby during pregnancy. Treating the mother reduces this risk, but it is advisable to seek expert advice before planning pregnancy. Any existing children can be tested at the specialist centre. Breastfeeding should be avoided.

Accidents which involve blood spillage could expose other people to risk, so it is recommended that you:

- Wipe up spillages yourself, using disposable paper towels and then swab the area with household bleach or detergent
- Cover cuts or open wounds
- Dispose carefully of soiled dressings and used sanitary towels or tampons, by flushing them down the toilet, or by packing them carefully in waterproof wrapping (plastic) before disposal
- Wash blood-stained linen or clothing in the usual way using a domestic washing machine
- Do not share razors, toothbrushes or nail scissors since traces of blood may be left on them after use
- Do not play contact sports if you have a cut or other injury which is likely to bleed.

Annex 6

Hepatitis B virus infection: information for blood donors

Hepatitis B is a very common virus. Worldwide, an estimated two billion people have been infected with hepatitis B virus (HBV), and more than 350 million are chronic carriers of the virus, mostly in Asia, Africa and China. HBV infects the liver and can cause hepatitis. Hepatitis simply means "inflammation of the liver".

Transmission

HBV is transmitted between people by contact with the blood or other body fluids (i.e. semen or vaginal fluid) of an infected person. Common modes of transmission in developing countries are:

- Perinatal (from mother to baby at birth)
- Early childhood infections (unapparent infection through close interpersonal contact with infected household contacts)
- Sexual contact
- Unsafe injection practices
- Blood transfusions.

In many developed countries (e.g. those in Western Europe and North America), patterns of transmission are different from those mentioned above. Today, the majority of infections in these countries are transmitted during young adulthood by sexual activity and injecting drug use.

HBV infection cannot be spread through ordinary day-to-day activities such as eating and drinking with friends or family; sharing washing or toilet facilities and hugs and kisses are all safe. There is no risk of infection from shared cooking and eating utensils, or baths, showers or swimming pools. HBV cannot be passed on by tears, sweat, coughs, sneezes or insect bites. HBV is not spread by contaminated food or water, and cannot be spread casually in the workplace.

Signs and symptoms

There are usually no symptoms from hepatitis B virus infection unless there is liver damage, but even then the symptoms may be vague. Persistent tiredness is a common symptom and there may be a short flu-like illness, feeling generally unwell and loss of appetite. There may also be jaundice, which might make the whites of the eyes look yellow and the urine become darker than usual. Severe liver damage can cause bleeding, usually from the gut, fluid retention in the abdomen and even jaundice. Having hepatitis B virus infection does not necessarily mean that the liver will be permanently damaged, but it is very important that the person has a full medical check-up, including liver function tests.

Most (95%) adults who become infected with hepatitis B virus recover completely from the infection and develop antibodies which make them immune to further infection. Babies or small children, or people whose immune system is depressed

for some other reason, may not be able to overcome the virus and get rid of it. They may become persistently infected with hepatitis B virus, and will have the virus in their liver for most of their lives. Persistent infection with hepatitis B virus can lead to inflammation of the liver in the long term. This may result in liver damage and cirrhosis of the liver. People who develop cirrhosis have an increased risk of developing liver cancer.

Important information about your test results

The tests performed on your donation have given positive results for HBV. This means that you are infected with HBV and that the virus is in your bloodstream. Because the virus is also in the blood, it can be passed on to the recipient of blood transfusion. The tests do not give any information about when or how you became infected, or whether your liver is inflamed or not. Other tests should be performed which will give much more information about your health.

Your test results are regarded as strictly confidential and will not be disclosed to anyone without your consent. Being infected with HBV does not necessarily mean that your liver is inflamed or that you will become ill in the future. However, we could refer you to a specialist in liver disease for further medical care and treatment. Furthermore, you are infectious to your sexual partner and should seek treatment for both yourself and your partner. If you do not want to, or are unable to inform your partner, the specialist centre may be able to help you with that.

We advise you to think very carefully before sharing your result with others. Most people do not need to know. You should tell those with whom you recently or regularly had sexual contact. You should also tell your doctor (GP) and any other doctor who may look after you, particularly for females who are planning a pregnancy. You should also inform your dentist of the possible infection risk.

If you are a health care worker, you will need to inform your occupational health adviser. If you are engaged in exposure-prone procedures with patients, you should not work until you have taken advice. For most people there are no occupational health issues and other people do not need to know.

Having someone to talk to may help, especially in the first few days after you hear the news. You can contact the doctor or nurse at the BTS again. The specialist centre that we refer you to will also have people who can help you. There are helplines which offer counselling and support as well as information leaflets on a wide range of topics.

Medical care and treatment

It is very important to have a full medical check-up. This should be arranged with a specialist in liver disease. The specialist will arrange a full medical assessment of your liver which will give much more information about your health. You will also be advised if any treatment is necessary.

There is no cure for hepatitis B virus infection, but medications are available which can reduce the harmful effects of the virus. Whether or not you need treatment will depend on how the virus is affecting your liver. There is no special diet that should be followed, but it is important to avoid alcohol as this also causes hepatitis and liver damage.

How to prevent HBV from being transmitted to others

Blood donation: Unfortunately, you will no longer be able to give blood. Any current sexual partner cannot be a donor either.

Sexual contact: Any sexual contact, where infected body fluids enter the body of another person, carries the risk of infection. The degree of risk varies with the activity. The sexual activities most likely to pass on the virus are:

- Unprotected anal intercourse (that is, without a condom)
- Unprotected vaginal intercourse (that is, without a condom)
- Any activity which draws blood – this would include sexual intercourse during the menstrual period.

The infection is passed more easily from a man to a woman than from a woman to a man, but it is recommended that:

- A regular partner is immunized against hepatitis B virus to protect against the risk of transmission; this can be arranged by your doctor
- Condoms are used with other partners to reduce both the risk of passing on HBV and the risk of acquiring some other infection.

Pregnancy and breastfeeding: There is a risk of the virus being passed from mother to baby at the time of birth. Throughout the world this is probably the most common way for the infection to be passed on, but it can be prevented if the baby is given protective injections at birth. There is also a risk from breastfeeding, but this is prevented if the baby has been protected.

Accidents which involve blood spillage could expose other people to risk, so it is recommended that you:

- Wipe up spillages yourself, using disposable paper towels and then swab the area with household bleach or detergent
- Cover cuts or open wounds
- Dispose carefully of soiled dressings and used sanitary towels or tampons, by flushing them down the toilet, or by packing them carefully in waterproof wrapping (plastic) before disposal
- Wash blood-stained linen or clothing in the usual way using a domestic washing machine
- Do not share razors, toothbrushes or nail scissors since traces of blood may be left on them after use
- Do not play contact sports if you have a cut or other injury which is likely to bleed.

Annex 7

Hepatitis C virus infection: information for blood donors

Hepatitis C virus (HCV) is found worldwide. It is estimated that 3–4 million people are infected with HCV each year and that 130–170 million people are chronically infected with the virus. HCV is among the most common viruses that infect the liver and can cause hepatitis. Hepatitis simply means "inflammation of the liver".

Transmission

HCV can be passed on in body fluids, particularly blood. It is usually spread when blood from a person infected with the virus enters the body of someone who is not infected. It is most commonly transmitted through exposure to infected blood, such as through injecting drug use; injections given with contaminated syringes and needles; needle-stick injuries in health-care settings; receipt of contaminated blood transfusions, blood products or organ transplants; and being born to an HCV-infected mother. It is less commonly transmitted through sex with an infected person.

HCV infection cannot be spread through ordinary day-to-day contact such as shaking hands, or sharing personal objects, food or water. Activities such as eating and drinking with friends or family, sharing washing or toilet facilities, and hugs and kisses are all safe. There is no risk of infection from shared cooking and eating utensils, or baths, showers or swimming pools. HCV cannot be passed on by tears, sweat, coughs or sneezes.

Signs and symptoms

Following initial infection, approximately 80% of people do not exhibit any symptoms unless there is liver damage, but even then the symptoms may be vague. Those people who are acutely symptomatic may exhibit fever, fatigue, a short flu-like illness, decreased appetite, nausea, vomiting, abdominal pain, dark urine, grey-coloured faeces, joint pain and jaundice (yellowing of skin and the whites of the eyes). About one in four people is able to overcome the virus and get rid of it, but they will still have detectable antibodies in their blood.

Most people who become infected with HCV remain persistently infected and became chronic carriers of HCV. This can cause long-term inflammation of the liver and may lead to liver damage and cirrhosis of the liver after many years of infection. People with cirrhosis have an increased risk of liver cancer.

Important information about your test results

The tests performed on your donation have given positive results for HCV. This means that you are infected with the hepatitis C virus. Unlike antibodies to other infections, the HCV antibody does not always overcome the virus and eliminate it from your body. It does not provide immunity to hepatitis C virus infection.

About 70% of people who have been infected with hepatitis C virus become persistently infected and will have the virus in their liver for most of their lives.

There is a blood test for the virus itself which will also have been done on your blood sample. If this test is positive then you are still infected with hepatitis C virus. If the test is negative, you may have overcome the virus, but still have the antibodies. It is important to repeat the virus test before assuming that the infection has gone.

Because the virus is also in the blood, it can be passed on to the recipient of blood transfusion. The tests do not give any information about when or how you became infected, or whether your liver is inflamed or not. Other tests should be performed which will give much more information about your health.

Your test results are regarded as strictly confidential and will not be disclosed to anyone without your consent. Being infected with HCV does not necessarily mean that your health is affected or that you will become ill in the future. However, we could refer you to a specialist in liver disease for further medical care and treatment. Furthermore, you are infectious to your sexual partner and should seek treatment for both yourself and your partner. If you do not want to, or are unable to inform your partner, the specialist centre may be able to help you with that.

We advise you to think very carefully before sharing your result with others. Most people do not need to know. You should tell your doctor (GP) and any other doctor who may look after you. You should also inform your dentist of the possible infection risk. You should tell those with whom you recently or regularly had sexual contact, or those you may have put at risk in some other way.

If you are a health care worker and have a positive HCV test result, you should contact your occupational health adviser, particularly if you perform exposure-prone procedures. For most people there are no occupational health issues and other people do not need to know.

Having someone to talk to may help, especially in the first few days after you hear the news. You can contact the doctor or nurse at the BTS again. The specialist centre that we refer you to will also have people who can help you. There are helplines which offer counselling and support as well as information leaflets on a wide range of topics.

Medical care and treatment

It is very important that you have a full medical check-up. This should be arranged with a specialist in liver disease. The specialist will arrange a full medical assessment of your liver which will give much more information about your health. You will also be advised if any treatment is necessary.

Considerable progress in treatment for hepatitis C virus infection has been made in recent years. There are drugs which are effective in reducing the harmful effects of the virus, and many patients can now be cured of hepatitis C virus infection. There is no special diet that should be followed, but it is important to avoid alcohol as this also causes hepatitis and liver damage.

How to prevent HCV from being passed to others

Blood donation: Unfortunately, you will no longer be able to give blood. Any current sexual partner cannot be a donor either, unless it is shown that you no longer have the virus.

Sexual contact: Hepatitis C virus is not passed on easily by sexual contact, but any activity where infected body fluids enter the body of another person carries the risk of infection. The degree of risk varies with the activity.

The sexual activities most likely to pass on the virus are:

- Unprotected anal intercourse (that is, without a condom)
- Unprotected vaginal intercourse (that is, without a condom)
- Any activity which draws blood – this would include sexual intercourse during the menstrual period.

The infection is passed more easily from a man to a woman than from a woman to a man. It is recommended that the use of condoms with a regular partner is considered, in particular if that partner is known to be uninfected. The partner can arrange to be tested by asking his/her own doctor. Condoms should be used with other partners to reduce both the small risk of passing on the hepatitis C virus and the potentially greater risk of acquiring some other infections.

Pregnancy and breastfeeding: The risk of the virus being passed from mother to baby at the time of birth is very low, but it is advisable to have a specialist medical assessment before planning pregnancy. Pregnancy can have a detrimental effect on the health of a mother with hepatitis C virus infection. Breastfeeding is most unlikely to pass on hepatitis C virus.

Accidents which involve blood spillage could expose other people to risk, so it is recommended that you:

- Wipe up spillages yourself, using disposable paper towels and then swab the area with household bleach or detergent
- Cover cuts or open wounds
- Dispose carefully of soiled dressings and used sanitary towels or tampons, by flushing them down the toilet, or by packing them carefully in waterproof wrapping (plastic) before disposal
- Wash blood-stained linen or clothing in the usual way using a domestic washing machine
- Do not share razors, toothbrushes or nail scissors since traces of blood may be left on them after use
- Do not play contact sports if you have a cut or other injury which is likely to bleed.

Annex 8

Syphilis: information for blood donors

Syphilis is a sexually-transmitted infection caused by the bacterium *Treponema pallidum*. Syphilis is spread from person to person through direct contact with a syphilis sore during vaginal, anal or oral sex. Although primarily transmitted through person-to-person sexual contact, syphilis may be transmitted by the transfusion of blood and blood components donated by asymptomatic donors harbouring the infection. Syphilis can also be passed from mother to baby during pregnancy and childbirth; this is known as congenital syphilis. Syphilis cannot be spread through contact with toilet seats, doorknobs, swimming pools, hot tubs and bathtubs, shared clothing or eating utensils.

Signs and symptoms

In adults, in the acute phase, syphilis causes sores, usually on the genitals, within the first three months of becoming infected. These sores are small ulcers which then heal, often leading the person to believe the problem has gone away. Shortly after the ulcers have gone, the person may notice enlarged glands and a skin rash, often on the palms of the hands, soles of the feet and the trunk, and perhaps a sore throat. These symptoms also disappear. If untreated, the infection can go on to a chronic phase and cause severe health problems involving the heart and the brain. Shortly after infection occurs, the body produces syphilis antibodies that can be detected by a blood test. Even after full treatment, antibodies to syphilis remain in the blood and may be detectable for many years after the infection has gone.

An infected baby can be severely ill, but some babies will show no signs of syphilis. In many countries, a test for syphilis is a routine part of medical care during pregnancy. If you have had congenital syphilis, you may have antibodies for life.

Other human diseases caused by related bacteria include yaws and pinta which are found in Central and South America, the Caribbean, parts of Africa, South-East Asia and parts of the South Pacific. They are spread by close contact, but are not sexually transmitted diseases. Yaws causes skin rashes and swollen bones and, if untreated, can recur and go on to produce ulcerated and scarred skin, swollen tissues and bone deformities. Pinta causes health problems similar to syphilis, but the early scaly skin rash is not usually on the genitals. As with treated syphilis, the antibodies to yaws and pinta may be detectable in the blood for many years after the infection has gone.

Important information about your test results

The tests performed on your donation have given positive results for antibodies to a treponema bacterial infection. Antibodies are your body's reaction to infection, and often mean that you have had a particular infection, but no longer have it. In general, the tests used to identify the presence of syphilis in donated blood in the BTS are not able to distinguish between infection by syphilis or by yaws or pinta. These three diseases are quite separate, but the bacteria which cause

them are so closely related that we cannot distinguish the antibodies from each other and know which disease they relate to from the results alone.

From the pattern of the test results it is usually possible to decide whether or not your infection is recent. This will have to be discussed with you by one of our doctors or nurses.

- If you have already had full treatment for one of these diseases and your test results are consistent with past infection, then the results are of no significance for your future health; you are not infectious to anyone else, and you do not need to do anything
- If your test results indicate infection in the past, but you are not aware of it and consequently have not had full treatment for it, we would advise you to inform your doctor so that you could get further treatment from the health service

If your test results indicate a recent infection this is most probably acute. You may have had symptoms which you did not think were important, or may not have noticed anything at all. However, you are infectious to a sexual partner and should seek treatment, both for yourself and your partner. If you do not want to, or are unable to inform your partner, your doctor may be able to help you with that.

Your test results are regarded as strictly confidential and will not be disclosed to anyone without your consent.

Blood donation

Unfortunately, you will no longer be able to give blood. Even after full treatment our blood test will continue to show a positive result for antibodies. Although your blood is no longer infectious, regulations in many countries do not allow the use of blood that gives a positive test result for these antibodies.

Treatment

All these diseases are fully treatable with antibiotics, usually penicillin. If you are allergic to penicillin you will be given an alternative antibiotic. Treatment is usually by injection, so if you have been treated in the past and given oral antibiotics it would probably be best for you to speak to your doctor for advice.

Annex 9a

Malaria: information for blood donors (if sensitive and multi-specific antibody screening tests are available in non-endemic countries)

Malaria is caused by parasites called plasmodium, which are transmitted via the bite of infected mosquitoes. Malaria in humans is caused by four different species of plasmodium: *P. falciparum*, *P. malariae*, *P. ovale* and *P. vivax*. Malaria infection is a risk in tropical and subtropical areas of over 100 countries. It is estimated that 500 million people worldwide are infected. Of these, more than 600 000 die each year and the majority of these are children. In the human body, the parasites multiply in the liver and then infect red blood cells. Although malaria is a concern in endemic countries, it is increasingly also a matter of concern to blood transfusion services in non-endemic countries. Significant numbers of blood donors from non-endemic countries travel regularly in malaria endemic areas and there is wide migration from endemic areas to non-endemic areas where migrants may then become blood donors. An estimated 30 000 international travellers suffer from malaria annually. Fever occurring in a traveller one week or more after entering a malaria endemic area, and up to one year after return, is a medical emergency that should be investigated urgently. Prompt diagnosis and correct treatment of malaria can mean the difference between life and death.

Transmission

The malaria parasite is transmitted to humans through the bite of infected female Anopheles mosquitoes, which bite mainly between dusk and dawn. Malaria can also be transmitted by blood transfusion from an infected blood donor or by unsafe injection practices.

The risk of contracting malaria when travelling is reduced by using measures to avoid mosquito bites such as insect repellent and mosquito nets, and by taking anti-malaria medication (as advised by your doctor). Despite taking all sensible precautions, visitors to many tropical areas remain at some risk from malaria. This is why blood donors are always asked about travel to malaria endemic areas of the world before they donate blood.

Signs and symptoms

Malaria is an acute febrile illness. In an individual who has never been exposed to malaria (a non-immune individual), symptoms appear seven days or more (usually 10–15 days) after the infective mosquito bite. The first symptoms – fever, headache, chills and vomiting – may be mild and difficult to recognize as malaria. If not treated, malaria can quickly become a life-threatening condition by disrupting the blood supply to vital organs. Children with severe malaria

Annex 9b

Malaria: information for blood donors (in endemic countries)

Malaria is caused by parasites called plasmodium, which are transmitted via the bite of infected mosquitoes. Malaria in humans is caused by four different species of plasmodium: *P. falciparum*, *P. malariae*, *P. ovale* and *P. vivax*. Malaria infection is a risk in tropical and subtropical areas of over 100 countries. It is estimated that 500 million people worldwide are infected. Of these, more than 600 000 die each year and the majority of these are children. In the human body, the parasites multiply in the liver and then infect red blood cells. Prompt diagnosis and correct treatment of malaria can mean the difference between life and death.

Transmission

The malaria parasite is transmitted to humans through the bite of infected female Anopheles mosquitoes, which bite mainly between dusk and dawn. Malaria can also be transmitted by blood transfusion from an infected blood donor or by unsafe injection practices.

Taking personal protection against mosquito bites represents the first line of defence for malaria prevention. Vector control through the use of insecticide-treated mosquito nets and indoor spraying with residual insecticides are also effective way to prevent malaria transmission at the community level. Antimalarial medicines can also be used to prevent malaria.

Signs and symptoms

Malaria is an acute febrile illness. In an individual who has never been exposed to malaria (a non-immune individual), symptoms appear seven days or more (usually 10–15 days) after the infective mosquito bite. The first symptoms – fever, headache, chills and vomiting – may be mild and difficult to recognize as malaria. If not treated, malaria can quickly become a life-threatening condition by disrupting the blood supply to vital organs. Children with severe malaria frequently develop one or more of the following symptoms: severe anaemia, respiratory distress in relation to metabolic acidosis, or cerebral malaria. In adults, multi-organ involvement is also frequent.

People in endemic areas may develop partial immunity to malaria infection, allowing asymptomatic infections to occur. Furthermore, clinical relapses may occur weeks to months after the first infection with *P. vivax* and *P. ovale*.

Important information about your test results

The tests performed on your donation have given positive results. This means that there are malaria parasites circulating in your blood and that we cannot use the blood that you have donated. Furthermore, with your test results, you will be deferred from blood donation for six months following completion of treatment and full recovery.

Medical care and treatment

Early diagnosis and treatment of malaria is effective in achieving clinical cure and clearing the malarial parasite. With this finding, we would advise you to inform your doctor so that you can get further advice and treatment from the health service.

Annex 10

Chagas disease: information for blood donors

Chagas disease, also known as American trypanosomiasis, is a potentially life-threatening illness caused by the protozoan parasite *Trypanosoma cruzi* (*T. cruzi*). It is found mainly in Latin America, where it is mostly transmitted to humans by exposure to the faeces of triatomine bugs, known as "Reduviid bugs" or "kissing bugs" among other names, depending on the geographical area. An estimated 8 million people are infected worldwide, mostly in Latin America where Chagas disease is endemic. More than 25 million people are at risk of the disease. Chagas disease is named after Carlos Ribeiro Justiniano Chagas, a Brazilian doctor who first discovered the disease in 1909.

Distribution

While Chagas disease occurs mainly in Latin America, in the past few decades it has been increasingly detected in the United States of America, Canada, many European and some Western Pacific countries. This is due mainly to population mobility between Latin America and the rest of the world.

Transmission

In Latin America, *T. cruzi* is mainly transmitted by exposure to faeces of infected blood-sucking triatomine bugs. These bugs typically live in the cracks of poorly-constructed homes in rural or suburban areas. Normally they hide during the day and become active at night when they feed on human blood. They usually bite an exposed area of skin such as the face, and the bug defecates close to the bite. The parasites enter the body when the person instinctively smears the bug faeces into the bite, the eyes, the mouth, or into any skin break.

Although primarily transmitted by an insect vector, Chagas disease is readily transmitted by the transfusion of blood donated by asymptomatic infected donors. The parasite is released into the bloodstream during its lifecycle and will therefore be present in donated blood from infected individuals.

Chagas disease can also be transmitted through food contaminated with triatomine bug faeces that carry *T. cruzi*, through congenital transmission from an infected mother to her newborn child during pregnancy or childbirth, through organ transplantation and less frequently through laboratory accidents.

Signs and symptoms

Chagas disease presents itself in two phases. The initial acute phase lasts for about two months after infection. During the acute phase, a high number of parasites circulate in the blood. In most cases, symptoms are absent or mild, but can include fever, headache, enlarged lymph glands, pallor, muscle pain, difficulty in breathing, swelling and abdominal or chest pain. In less than 50% of people with the acute infection characteristic first visible signs can be a skin lesion or a purplish swelling of the lids of one eye.

During the chronic phase, the parasites are hidden mainly in the heart and digestive muscle and in most cases infected individuals are asymptomatic. However, over time, up to 30% of patients suffer from cardiac disorders and up to 10% suffer from digestive (typically enlargement of the oesophagus or colon), neurological or mixed alterations. In later years, the infection can lead to sudden death or heart failure caused by progressive destruction of the heart muscle.

Important information about your test results

Option 1: confirmatory testing not available to the BTS, screening results not confirmed before contacting the donor

The screening tests performed on your donation were positive for antibodies to *T. cruzi*. This test is performed to identify persons who may have been infected with *T. cruzi* at some time. However, because our test was only an initial screening test, it needs to be confirmed in another laboratory. If an infection is confirmed, the tests do not tell us when or how you became infected. Therefore, we would need to refer you to a medical specialist to talk to you and examine you. If they confirm that you are infected, they will provide you with the appropriate clinical advice and care. In the meantime, until it is more clear if you are infected or not, please do not donate blood.

Option 2: screening results confirmed before contacting the donor

The screening tests performed on your donation have given positive results for antibodies to *T. cruzi*. Additional confirmatory testing was performed and was also positive. This tells us that you were infected with *T. cruzi* at some time. We need to refer you to an appropriate specialist clinic to review the test results, to determine when and how you became infected, and to provide you with the appropriate clinical advice and care. In the meantime, please do not donate blood.

Treatment

Chagas disease can be treated with either benznidazole or nifurtimox. Both medicines are almost 100% effective in curing the disease if given soon after infection at the onset of the acute phase. However, the efficacy of both drugs diminishes the longer a person has been infected. Treatment is also indicated for those in whom the infection has been reactivated (for example, due to immunosuppression), for infants with congenital infection and for patients during the early chronic phase. Infected adults, especially those with no symptoms, should also be offered treatment.

Annex 11

Steps in obtaining informed consent for blood donation

1 Ensure audio and visual privacy and explain that confidentiality is always respected in your facility.

2 Follow your facility's policy in obtaining informed consent.

3 Use your established protocol to conduct the counselling while maintaining good communication, listening carefully and addressing the donor's concerns, giving time for them to understand the messages you plan to communicate, and allowing them to make their own decisions.

4 Counter-check with the prospective donor if they would like to consult with another person, such as a family member, before making a decision. Do not pressure them to make a decision before they are ready.

5 Give all the necessary information on the donation process and the related tests that will be performed, including:

- The donation process and potential adverse donor reactions
- The laboratory tests to be performed (TTI, blood group serology and other) on the donated blood
- Information on confidential unit exclusion
- The reasons why these tests will be performed
- The clinical and prevention benefits of testing for TTI and the potential risks of a positive test result
- The referral services that are available in the case of abnormal test results, including whether treatment is available or not
- The fact that the test results will be treated confidentially and will not be shared with anyone other than health-care providers directly involved in providing services to the person concerned (in case a notifiable diseases is involved, it should also be communicated beforehand)
- The importance of disclosure of the TTI result to other persons who may be at risk of exposure to prevent further spread and to ensure early treatment
- If applicable, the information that a sample of the blood might be used for the purposes of quality assurance, additional tests or research. Approval from a research ethics committee should be sought for any research on the blood donation or part of it.

6 Ask the donor if they have any questions, and answer them.

7 Counter-check whether the donor has understood the consent by asking them to repeat the points that may be difficult or important, or by using other words to reiterate the most important issues.

8 Correct any misunderstandings.

9 Document the informed consent, either on a consent form or, if the consent was oral, add a note in the donor file.

Annex 12

Donor counselling training modules

Introduction: (time allotted: 6 hours)

Session 1: Course objectives, overview of the learning programme, learner expectations, how to use the training manuals, assessment criteria, and introduction to group work and role plays.

Session 2: Pre-course assessment test.

Group activity

Review of previous knowledge and understanding, based on questions that have been asked by peers, friends, and family and community members.

Module 1: Self-awareness (time allotted: 5 hours)

Module objectives

1 To provide an opportunity for the counsellor to interact with "self".

2 To enable the counsellor to appreciate other people's beliefs, values and traditions different from theirs.

Session 1: Introduction to systems theory.

Session 2: Developing a comprehensive understanding of self and others.

Session 3: Developing insight into personal perceptions or misperceptions, values and beliefs, cultures and traditions, and subsequent behaviours.

Module 2: Counselling principles, skills, characteristics and attitudes (time allotted: 12 hours)

Module objectives

1 To define the qualities of a good counsellor.

2 To acquire knowledge on the ethics, principles and legal issues affecting counselling.

Session 1: Principles of counselling, what is counselling, benefits of counselling, models, confidentiality versus secrets, ethics and ethical principles and legal issues, setting boundaries with clients, why is counselling necessary, and who should provide counselling.

Session 2: Skills including attentive listening, questioning, probing and exploring, summarizing and paraphrasing, reflecting and understanding, creating an environment conducive to counselling and setting personal boundaries; and also common counselling errors, nonverbal communication techniques, and discussing sensitive topics.

Session 3: Attitudes including respect, genuineness or congruence, empathy, acceptance and non-judgementalism; and the qualities of a good counsellor.

Session 4: The counselling process and enabling clients to reach a point where they can make decisions, solve their problems or cope better with their problems or environment.

Group activities

1 Demonstrate the attitudes and skills required in counselling to assist clients with their presenting problems.
2 Counselling role plays to demonstrate proficiency in dealing with various problems that clients present with.
3 How to do a self-assessment and a peer assessment of the counselling role plays.

Module 3: Managing counselling outcomes (time allotted: 12 hours)

Module objectives

1 To define the rights of stakeholders in the counselling process.
2 To acquire knowledge on how to deal with the different types of psychosocial responses in counselling.

Session 1: Client rights, human rights, medical rights, and discrimination/ non-discrimination.

Session 2: Anxiety, depression, stress and recognizing suicidal tendencies.

Session 3: Stress and crisis management, and skills of the counsellors to cope emotionally with situations.

Session 4: Accessing relevant resources and referring clients to such resources; setting up and facilitating a support group for counselling.

Module 4: Introduction to blood transfusion processes (time allotted: 12 hours)

Module objectives

1 To understand the overall procedures applied in donor health and risk assessment.
2 To acquire knowledge on blood bank processes and procedures.

Session 1: Donor health assessment, including purpose of the assessment, SOPs, audits, settings and tools required, types of deferrals on health grounds: e.g. low haemoglobin level, unacceptable blood pressure or pulse, low body weight, age or medical conditions specified in the donor selection criteria; handling of deferrals.

Session 2: Donor risk assessment, including purpose of the assessment, SOPs, audits, settings and tools for pre-donation counselling, donor or partner-related risks for HIV, hepatitis viruses or other TTI, as specified in the national guidelines on donor selection; handling of deferrals.

Session 3: Overview of blood groups and allo-antibodies, TTI in a blood transfusion setting including HIV, hepatitis B and C viruses, syphilis and other TTI, testing algorithms for each infection, SOPs, audits, quality management in the BTS, and documentation of test results.

Session 4: Donor records management including SOPs, manual and electronic records of donor data and test results, staff and equipment requirements, and donor recall system.

Group activities

1 Donor health and risk assessment using role plays.
2 Visit to a BTS laboratory to view blood grouping and TTI testing.
3 Visit to a donor records department to understand systems for filing and recall.

Module 5: Introduction to blood donor counselling (time allocated: 10 hours)

Module objectives

1 To understand why blood donor counselling is necessary.
2 To understand the stages of blood donor counselling.

Session 1: Aims of blood donor counselling, what is blood donor counselling, the essential features of blood donor counselling, and information for potential blood donors and its importance in pre-donation counselling.

Session 2: Stages of blood donor counselling and their impact on blood safety and donor care.

Session 3: Pre-donation counselling, including why pre-donation counselling is necessary, how it contributes to blood safety, key conditions for an effective pre-donation one-on-one counselling session, when and how to apply a group counselling session, administering the donor health and risk assessment questionnaire or reviewing a self-administered questionnaire, health promotion counselling, pre-donation counselling of new and repeat donors, and obtaining informed consent to donate.

Session 4: Post-donation counselling, including why post-donation counselling is necessary, how it contributes to blood safety, key conditions for an effective post-donation one-on-one counselling session, post-donation counselling for a negative result, post-donation counselling for a positive result, and information materials to be provided to the donor.

Module 6: Information on transfusion-transmissible infections for use in blood donor counselling (time allocated: 6 hours)

Module o bjectives

1 To acquire knowledge of TTI for use in counselling donors.

Session 1: HIV/AIDS infection, including global and national epidemiology of the infection, the nature of the disease and its modes of transmission, progression of the infection, prevention and treatment options, and partner notification issues.

Session 2: Hepatitis B virus infection, including global and national epidemiology of the infection, the nature of the disease and its modes of transmission, progression of the infection, conducting hepatitis B profile testing, prevention with vaccines and treatment options, and partner notification issues.

Session 3: Hepatitis C virus infection, including global and national epidemiology of the infection, the nature of the disease and its modes of transmission, progression of the infection, prevention and treatment options, and partner notification issues.

Session 4: Syphilis infection, including global and national epidemiology of the infection, the nature of the disease and its modes of transmission,

progression of the infection, prevention and treatment options, and partner notification issues.

Session 5: Other transfusion-transmissible infections, such as HTLV I/II, malaria, Chagas disease and emerging infections such as variant Creutzfeldt-Jakob disease (vCJD); national requirements for implementing routine testing for other TTI in the BTS.

Group activity

Participants conduct post-donation counselling for different types of persons: e.g. young people below the age of 18, positive and negative donors for different markers of TTI including HIV, hepatitis B and C viruses, and syphilis.

Module 7: Information on critical factors in the health assessment of a blood donor (time allocated: 4 hours)

Module objectives

1 To acquire knowledge on the critical factors leading to donor deferral on health grounds.

2 To acquire skills on how and when to refer a donor for further evaluation.

Information materials on various health factors and symptoms observed or reported by the donor that may put the donor at risk if blood is donated should be standardized so that counsellors provide consistent information to blood donors deferred on health grounds. In particular the following are pertinent.

Session 1: Low haemoglobin level for blood donation, and the need to relate to nutritional status, frequency of donation and other potential causes, and referral to a health care institution or doctor for further tests.

Session 2: Cardiovascular problems such as high or erratic pulse rate, low or high blood pressure, and the need to determine whether the donor is on treatment or not; appropriate referral procedures and how to explain why the donor is not accepted for blood donation.

Session 3: Other medical conditions or recent illnesses, such as malaria or a history of epilepsy, reported by the donor or observed by the counsellor that may put the donor at risk if accepted for blood donation.

Group activity

Carry out a short study on how to establish systems for the referral of donors who have been deferred from blood donation on health grounds.

Module 8: Management of blood donor counselling (time allocated: 12 hours)

Module objectives

1 To acquire knowledge on how to establish a blood donor counselling programme.

2 To acquire knowledge on how to manage various activities for ensuring a successful blood donor counselling programme.

Session 1: Donor notification systems, including what is donor notification, statutory requirements and the responsibilities of the BTS in donor notification; review of various options and their advantages, disadvantages and cost-effectiveness; and the need for a national policy on donor notification.

Session 2: Strategies for a successful donor counselling programme, including training of all donor session staff on donor counselling, continual review of the training needs of counselling staff in order to strengthen their capacity, ways to improve access to counselling services, and providing evidence-based pre-donation information on health and risk factors, deferral and referral procedures to all donors.

Session 3: Essential documentation for donor deferral, donor notification, counselling registers and donor referral; and record-keeping and reporting.

Session 4: Essential data for analysis of the performance of donor counselling systems, and how to use the data to strengthen pre-donation information and pre-donation counselling.

Group activity

Review of donor health and risk questionnaire, counselling registers and other related documentation.

Module 9: Monitoring and evaluation of donor counselling (time allocated: 6 hours)

Module objectives

1 To recognize the need for monitoring and evaluation of the donor counselling programme.

2 To identify the key tools for effective monitoring of the donor counselling programme.

Tools for monitoring and evaluating should be built into the donor counselling programme.

Session 1: Need for monitoring, data capture tools for monitoring and data analysis of the following:

- Number of donors given pre-donation information vs. numbers presenting for pre-donation counselling
- Numbers of donors deferred, the reasons for deferral and their frequency
- Number of donors accessing post-donation counselling facilities.

Session 2: Evaluation aims at determining the impact of the donor counselling programme on blood donors, blood safety and on the process as a whole. For example:

- Is there a reduction in the prevalence of TTI in donated blood?
- Are the behaviours of donors and their attitudes towards donation and repeat donation changing in a positive way for the BTS?

This session would also include when and who should conduct the evaluation.

Module 10: Evaluating the quality and effectiveness of the training programme (time allocated: 4 hours)

Module objective

1 To identify important factors in evaluating the quality and effectiveness of the donor counselling training programme.

The training imparted needs to be evaluated in terms of its appropriateness and effectiveness in capacity building and in developing the appropriate attitudes and skills of staff in donor counselling.

The evaluation will include the following elements:

- Number of staff that have undergone the training
- Faculty assessment reports
- Pre- and post-course assessments and performance of staff in the field
- Review of training needs of those who moved to the field
- Audits of counselling procedures
- Records and outcomes.

Group activity

Groups discuss pre- and post-course assessment forms.

Annex 13

Example of frequently asked questions

Why should I donate blood?

The need for blood affects us all. Eight out of ten people need blood or blood products at some time in our lives. One out of every ten patients in hospital requires blood transfusion. The number of blood donations that patients receive depends on their medical condition. Although an average of three donations is transfused to a patient, some patients require many more.

Blood is in constant demand for the treatment of patients involved in accidents, patients with anaemia, malaria, cancer or a bleeding disorder such as haemophilia. Many surgical operations would not be possible without the availability of blood. Blood may be needed during or following childbirth or for an exchange transfusion in newborn babies.

The need for blood never stops. Blood donors save lives. Every blood donation gives the person who receives it a new chance at life.

Who may donate blood?

Donors should be between the ages of 18 and 65, weigh at least 50 kg and not have donated blood within the previous 12 weeks (for males). The criteria, which are applied before a person can be accepted as a blood donor, are very strict. Not everyone can be a blood donor. This is designed to protect the health of the donor as well as the health of the patient who receives the blood.

For example, people who have certain medical conditions or who are taking certain types of medication are not permitted to donate blood. People whose sexual behaviour places them at increased risk of transmitting infections through transfusion are also not permitted to donate. If any of the deferral criteria apply to you, or if for any reason you think that your blood may be unsafe to transfuse to a patient, you are advised not to donate.

The mission of the blood transfusion service is to provide all patients with sufficient, safe, quality blood and blood products. If you are in any doubt about whether you should donate blood, please discuss it with a staff member. We know it can be disappointing if you are not able to give blood. However, we hope you will understand that our overriding responsibility is to ensure the safety of donors and the safety of the blood for patients.

What do I get in return for my blood donation?

Blood is donated voluntarily, freely and without payment or reward of any kind. Blood must only be donated in the spirit of altruism for patients who need blood or blood products as part of their medical treatment. Blood is donated as an act of goodwill towards a fellow human being and nothing should be expected in return for giving this gift of life.

What you do get in return is a physical and emotional sense of well-being and the knowledge that you have helped to save someone's life. We all hope that someone will do the same for us when we need a blood transfusion.

Is there a substitute for blood?

Blood is made up of different components and each component has its own important function. The main function of red blood cells is to carry oxygen to the tissues and remove carbon dioxide.

The main function of platelets and the coagulation factors is to prevent and stop bleeding. Each one of these blood components has an important role, and any one of these components may be used in the treatment of patients with certain medical conditions.

Substances designed to carry oxygen, such as a haemoglobin solution prepared from cattle's blood, are currently being evaluated. This is available in very limited quantities internationally. These oxygen carriers circulate in the bloodstream for a short period and are usually used only as an interim measure.

In cases of trauma or during surgical operations, the volume of blood which is lost by the patient may initially be replaced with synthetic solutions (crystalloid or colloid solutions) such as normal saline. These solutions are not recognized as "blood substitutes" but are blood volume expanders. They do not carry oxygen. They are frequently used in the initial treatment of patients, for example in the ambulance or in the operating theatre, while blood is being obtained from the blood bank.

There is no substitute for blood. When the patient's haemoglobin level, platelet level or coagulation factor level falls below a critical point, blood transfusion is the only option. Patients rely on voluntary blood donors to provide red blood cells, platelets and coagulation factors, to meet their medical needs.

What does it mean to have a rare blood type?

Every person has an ABO and rhesus blood group: i.e. group A, B, AB, or O and RhD negative or RhD positive. In addition to these ABO blood groups, people's red blood cells consist of many other antigens as part of their red cell structure.

Occasionally, people have an unusual, specific red cell antigen. Alternatively, some individual's red cells lack an antigen which is common to most people. This would be recognised as a "rare" blood type. Some patients have antibodies against a specific blood type and in these circumstances it may be difficult to find blood from a regular blood donor which is compatible with that of the rare type of the patient.

Before every blood transfusion, compatibility tests are performed on the blood of the patient and on the blood of the donor, to ensure that the transfused blood will not cause any untoward reaction in the recipient.

First-time blood donors are notified by mail of their ABO blood group and RhD type, after the blood has been tested in the BTS laboratory.

How does the BTS meet the need for rare blood types?

If a patient who needs a blood transfusion is identified by the BTS as having an unusual blood type, blood that is compatible with that of the patient will be identified from the panel of regular blood donors.

A panel of blood donors who have rare blood types has been compiled. This is the so-called "rare blood donor file". Blood from donors on this panel can be obtained whenever needed.

In exceptional cases, where compatible blood cannot be obtained in this country, blood is obtained from another country through the international rare blood

donor file. Similarly, on rare occasions, blood from a donor with a rare blood group from one country may be sent to another country to be transfused to a specific patient.

Is there anything special I need to do before donating?

Eat at your regular mealtimes and drink plenty of fluid before you donate blood. Have a snack at least four hours before you donate, but do not eat too much right before the donation.

Before you leave the blood donor clinic after your blood donation, have some tea, coffee or a soft drink to help replace the blood volume (approximately 450 ml) which has been reduced as a result of your donation.

Avoid taking aspirin or aspirin-like anti-inflammatory medication in the 72 hours prior to your donation, because aspirin inhibits the function of blood platelets. If you have taken aspirin within this period, your blood platelet component cannot be transfused to a patient.

What is the procedure when I donate blood?

Firstly, you will be asked to provide personal details such as your name, address, age, weight, ID number and/or date of birth. A medical history is taken by means of a written questionnaire.

These questions are designed to ascertain that it is medically safe for you to donate blood and that the recipient of your blood will not be harmed in any way. In addition, very personal questions relating to your mode of life and sexual behaviour are asked to ascertain that you are not at increased risk of potentially transmitting infection through transfusion. People are asked to exclude themselves from blood donation if any of the deferral criteria apply to them.

A finger prick test is performed in order to ascertain if your haemoglobin level is within a safe range for donation purposes. Potential donors will be permitted to donate only if this measurement is within the defined, acceptable range. If everything is in order you will proceed to donate your blood.

How long does the donation take?

The procedure, which is performed by a trained, skilled health-care professional, takes approximately 30 minutes. You will give about 450 ml of blood, after which you will be advised to remain on the donor bed for a few minutes longer and then to take some refreshments. Plan to spend about half an hour to an hour at the blood donor centre for the entire process, depending on the size of the centre and the number of donors.

Does the needle hurt the entire time?

No. There may be a little sting when the needle is inserted, but there should be no pain whatsoever during the rest of the donation.

How long will it take my body to replenish the donated blood?

Your body replaces the blood volume (plasma) within 24 hours. Red blood cells are replaced by the bone marrow into the circulatory system within about three to four weeks, while the lost iron is replaced over approximately six to eight weeks.

How will I feel after the donation?

Most people feel great! Donors who know what to expect and have eaten regular meals, or have had a snack and fluids before donating, are usually fine. Most

people who donate blood have no after-effects. You should drink extra fluids for four hours following your donation. A small number of people feel light-headed and others occasionally faint after donating.

In the unlikely event that you feel faint, be sure to quickly lie completely flat. Lying flat, even if on the floor, with your legs elevated, will usually resolve any feelings of dizziness or light-headedness quite quickly and may prevent fainting.

In the event that you do not feel well after a blood donation, please contact the staff at your nearest blood donor centre.

Can I donate during my menstrual period?

Yes, if you are feeling well.

How soon after donating can I participate in sport?

After donation, it's best to have a snack and drink plenty of fluids over the next four hours. You can then resume routine sporting or training activity. It is advisable not to donate blood three to four weeks before participating in a major sporting event such as a marathon, or a competitive rugby or football match, where you intend to push yourself to the limit of your ability.

In the unlikely event that you do feel faint, light-headed or unwell during any sporting activities, you should immediately stop the activity and rest. Many active sports people are regular blood donors.

People who frequently push themselves to their limit during their sporting activities should consider donating only platelets. In this situation the red blood cells are returned to the donor after the donation and the individual's oxygen-carrying capacity and performance are not compromised.

What is a "unit" of blood?

A unit is about 450 ml of donated blood. The average adult has between four and five litres of blood in his or her body, and can easily spare one unit.

How often can I donate blood?

You may donate either whole blood or a specific blood component such as blood platelets. Each type of donation requires a certain waiting period before you can give again. After a whole blood donation, a person must wait at least 56 days before donating again.

The minimum interval between whole blood donations is 12 weeks for men and 16 weeks for women. Platelet and plasma donors are able to donate more frequently.

Is it possible to get HIV/AIDS from donating blood?

No. You cannot get AIDS or any other infectious disease by giving blood. The materials used for your blood donation, including the needle, blood collection bag, tubes and finger prick needle are new, sterile and disposable. These are used only once for your blood donation and then destroyed after use.

What tests are performed on my blood after donation?

A sample of your blood will be tested to determine your ABO blood group and RhD type. Other tests will be performed to detect certain transfusion-transmissible infections such as hepatitis B and C viruses, HIV and syphilis. Not every infection

in a person's blood can be detected by these blood tests. It is therefore vitally important that people who may have been infected with a transfusion-transmissible infection do not, under any circumstances donate blood.

After the tests have been performed, your blood will be used either as whole blood (transfused to one patient) or, after separation into its various components such as the red blood cells, platelets and plasma components, to help several patients.

If you test the blood that is donated, why do you have such a lengthy donor selection process?

Our duty is to provide a safe blood supply and the BTS needs your help to maintain these standards. Although all blood donations are tested for viruses, including hepatitis B, hepatitis C, HIV and syphilis, there is a period of time after a person first becomes infected with a virus during which the infection may not be detectable (this is often referred to as the "window period"). So, the person's blood could still transmit a disease if transfused to a patient, even though their tests were negative and there was no sign of infection at the time of donation. Also, tests are not available for infections such as variant Creutzfeldt-Jakob disease (vCJD: mad cow disease). For this reason, a thorough donor selection process is essential.

Why do you ask such personal questions during the donor selection process?

A major component of our screening process is designed to identify those people who are at a greater risk of transmitting blood-borne infections. In order to safeguard the blood supply it is imperative that these people do not give blood. All donor selection measures must meet stringent regulatory requirements. While the process is lengthy and may seem intrusive, it is absolutely necessary to safeguard the blood supply.

Annex 14

Example of a blood donor survey

Blood Transfusion Service
Street address
Postal address
Postcode
Telephone number
Fax number
E-mail address
Website address

(Insert date)

(Insert donor name)
(Insert donor address)

Dear

I am writing to seek your assistance. The Blood Transfusion Service regularly reviews its procedures to provide the best possible service to blood donors and recipients of blood and blood products.

In [insert year] you were contacted by the Blood Transfusion Service in relation to the test results on your blood donation. It would be greatly appreciated if you could assist us by reflecting on your experience and completing the attached survey.

Please be assured that this survey is confidential and you cannot be identified from the information you provide on this form. The results of this survey will allow the Blood Transfusion Service to continue to improve its services to blood donors in the future.

Thank you for taking the time to provide us with your feedback. Please return the completed survey in the enclosed envelope by [insert date]. A postage stamp is not required.

Yours sincerely

Name
Donor Services Manager

BLOOD DONOR SURVEY

Thank you for taking the time to complete this survey. Please return the form in the enclosed envelope, or send to:

Blood Transfusion Service
(Insert year) Donor Survey
Postal address

Please tick the correct response

1 Background information

1.1 In which [state/region/city/district] did you last donate blood? (insert a list of states/regions/city/district that can be selected)

1.2 Are you

Male ❑
Female ❑

1.3 Please indicate your age range (years)

Under 21 ❑
21–30 ❑
31–40 ❑
41–50 ❑
51–60 ❑
Over 60 ❑

1.4 Was this your first blood donation?

Yes ❑
No ❑

1.5 Which test result was abnormal?

Hepatitis B ❑
Hepatitis C ❑
HIV ❑
Syphilis ❑
Other ❑

2 The recall letter you received

2.1 You should have received a letter asking you to contact the Blood Transfusion Service to discuss your test results.

I was satisfied with the process

Strongly agree ❑
Agree ❑
Neither agree nor disagree ❑
Disagree ❑
Strongly disagree ❑

The letter I received was reasonable

Strongly agree ❑
Agree ❑

Neither agree nor disagree ❑
Disagree ❑
Strongly disagree ❑

Comments: _____

2.2 Would you have preferred to be contacted differently?
Yes ❑
No ❑

2.3 If yes, how? (e.g. by telephone, SMS, e-mail): _____

3 The test results

3.1 Were you given your test results?
In person ❑
By telephone ❑

I was given sufficient information about the test results
Strongly agree ❑
Agree ❑
Neither agree nor disagree ❑
Disagree ❑
Strongly disagree ❑

3.2 Were you given or sent written information about your test results?
Yes ❑
No ❑

I was given/sent sufficient written information
Strongly agree ❑
Agree ❑
Neither agree nor disagree ❑
Disagree ❑
Strongly disagree ❑

I was given/sent useful written information
Strongly agree ❑
Agree ❑
Neither agree nor disagree ❑
Disagree ❑
Strongly disagree ❑

3.3 Were you given a referral to your family doctor?
Yes ❑
No ❑

3.4 Were you given a referral to a specialist?
Yes ❑
No ❑

I was satisfied with the process
Strongly agree ❑

Agree	❑
Neither agree nor disagree	❑
Disagree	❑
Strongly disagree	❑

3.5 What was the outcome? (e.g. further testing, referral, treatment):

_____

4 How can we improve?

4.1 What did you like least about the process?

_____

4.2 What did you like most about the process?

_____

4.3 How could we improve the process?

_____

4.4 Do you have any other comments?

_____

Thank you for completing the survey. Please return it in the envelope provided by [insert date].

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