

Guidelines for Blood Donor Counselling on Human Immunodeficiency Virus (HIV)

International Federation of Red Cross and Red Crescent Societies

World Health Organization Global Programme on AIDS

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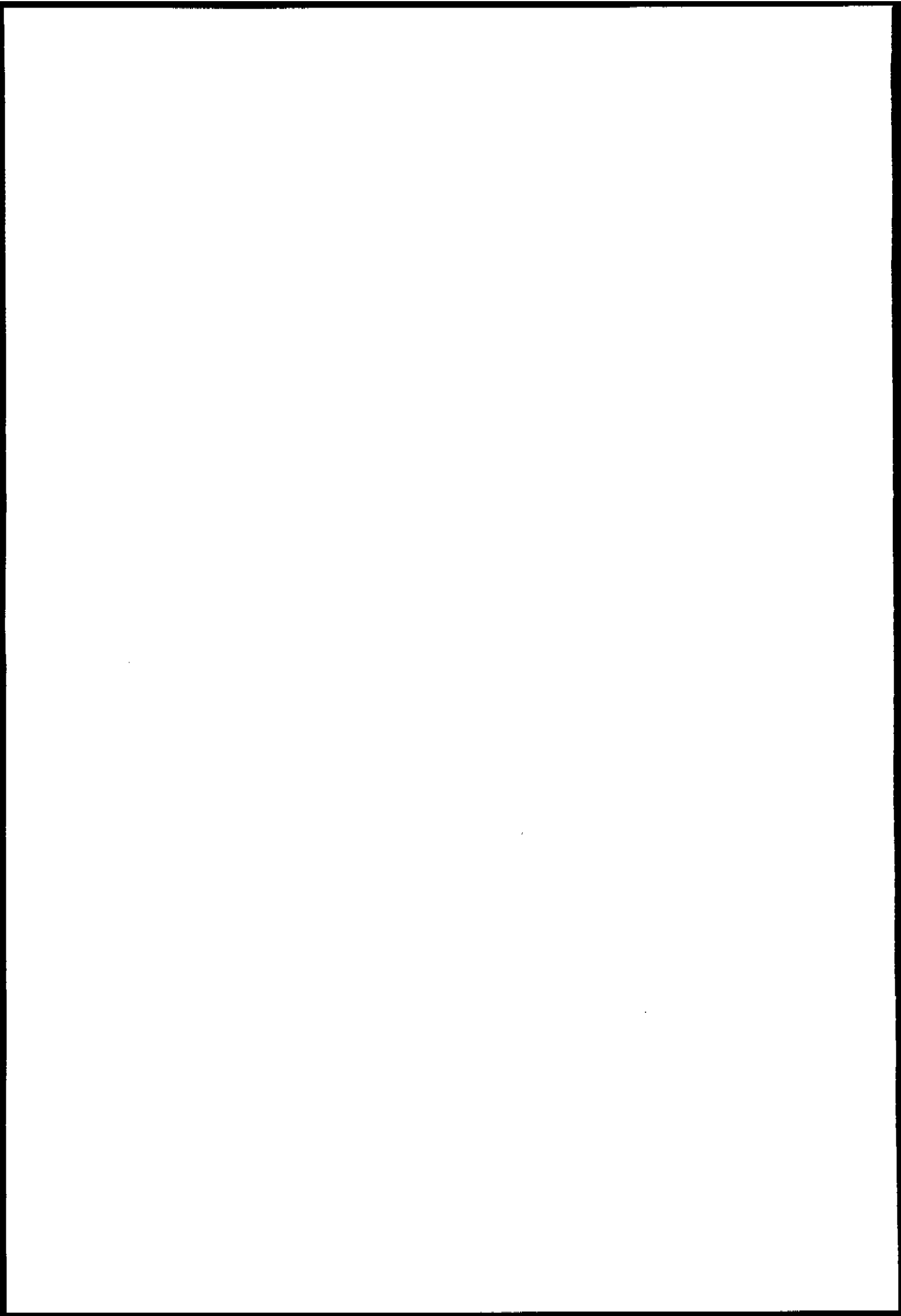
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Definitions

Transfusion transmissible infections (TTIs) are those infections that may be passed through donations of blood and blood products, including human immunodeficiency virus (HIV), hepatitis B and C, and syphilis. Throughout this document, HIV is the main focus. Nevertheless, recommendations for educating, counselling and notifying donors about HIV apply to other TTIs as well. This type of counselling will apply to other conditions the donor may have that may affect either the health of the donor at donation or the health of the recipient. Such conditions include diabetes, hyperthyroidism, pregnancy, current use of penicillin and so on.

HIV/AIDS counselling is a confidential dialogue between a client and a care provider aimed at enabling the client to cope with stress and make personal decisions related to HIV and acquired immunodeficiency syndrome (AIDS). The counselling process includes an evaluation of personal risk of transmitting or acquiring HIV and the facilitation of preventive behaviour.

Pre-donation information is the written or oral information given to potential donors, usually groups, by recruiting teams some time before the donation. Information may also be given by teachers, educators and mass media, and includes discussion of the need for regular, safe donations; the fact that blood is tested for HIV, what HIV is and how it may be avoided; the possible consequences of learning that one has HIV; procedures for confidentiality in information management; and where to go if a potential donor requires a test for HIV.

Pre-donation counselling is the counselling provided to potential donors in privacy before blood is taken. It involves an explanation of the HIV test; the possible consequences of learning one is infected with HIV; the need to stay uninfected if one is currently uninfected; encouragement to self-defer to an alternative counselling and testing site if there is a recent risk history and the potential donor wants a test; information on how test results can be received and securing informed consent to proceed with donation (and testing) if appropriate.

Post-donation counselling and referral is private face-to-face counselling at which HIV test results and other types of information are given. Post-donation information includes advice on avoiding future HIV transmission, on healthy living and on negotiating risk-reduction with others. Post-donation counselling may also include advice on locations where other family members may receive counselling and testing, where material support may be obtained and where those with positive test results may meet other people with HIV, if such a facility is available. When bad news is being given, counselling aims to give the donor enough time to ask questions, to help with the immediate practical and emotional impact of the result and to offer options for extended follow-up and care (including for loved ones and family) by appropriate referral to complementary organizations and facilities. Because of the possible need to recognize and manage acute psychological reactions in the post-donation phase, this service should be provided only by staff specifically trained in counselling.

Donor staff are all blood transfusion service (BTS) staff involved in any phase of education, motivation, recruitment, assessment, donation, notification and retention of blood donors. Staff at clinical and laboratory levels (and volunteers under supervision) may provide information and counselling to the donor before and during the blood-giving period. Staff who provide such information are required to have special skills and training in HIV awareness, counselling and follow-up procedures.

Clinical staff are those professionally trained clinicians and nurses who provide donors with a physical check and decide about acceptance or referral/deferral of the potential donor immediately before blood is taken. "Clinical" means that medical and/or nursing procedures and management are involved. Clinical staff may also be involved in the management of psychosocial issues with donors.

Informed consent is the voluntary agreement given by donors for their blood to be taken and tested for HIV, after they have been told (informed) and understand that HIV testing will be done, and the meaning and possible implications of the test results. It is the policy of WHO and the Federation that donors should be made aware that their blood will be tested for HIV.

Referral is the procedure by which blood donor staff recommend that a donor approach, or introduce the donor to, HIV/AIDS care and support services or a "voluntary" counselling and testing facility, because the donor—

- has an equivocal or positive HIV test result;
- has clinical signs and symptoms of HIV infection and/or disease;
- has an identified history of risk for HIV;
- has approached the BTS facility primarily in order to have a test for HIV.

Deferral is the decision, during or after discussions with blood donor staff, that the potential blood donor will not donate. Deferral is normally referred to as a temporary status, whereas exclusion is seen as a more permanent decision. Exclusion involves conditions that are unlikely to change, making the donor unsuitable on a permanent basis. This may be for reasons included under "referral". When the potential donor makes this decision voluntarily, eg, during pre-donation discussion or counselling, this is called "self-deferral". For the purposes of this document, deferral includes self-deferral and exclusion. However, deferral may include situations and conditions of a temporary nature such as pregnancy, anaemia, malaria, treatment with an antibiotic for an infection and other transient conditions. Thus deferral can be either self-deferral or deferral by the donor or clinical staff. However, in this document deferral implicitly incorporates exclusion.

Health care and support services are those services and facilities within the community that may receive referrals and deferrals from BTSs of people whose history of risk for HIV suggests that they should receive counselling and testing for HIV outside the BTS setting. Health care and support services provide an opportunity for counselling and testing, and for ongoing counselling and support, for potential donors and their family members and loved ones when positive results are found. They also include those sites where people who receive positive results may receive medical care and material support.

Care of the donor includes, among other things, that —

- donation is voluntary and non-remunerated, and that no pressure of any kind is placed on the donor;
- the donor shall not be harmed by the procedures, and that the donor understands the risks connected with the procedures;
- there is no discrimination resulting from the donation, and that test results are confidential;
- the donor is treated with respect and consideration;
- an adequate period of rest and, where possible, refreshment is provided after the donation;
- whenever possible counselling and referral is provided for those donors who require this service.

(See Annex 1)

PART 1

Introduction

The primary objective of blood transfusion services (BTSs) is to provide a safe and adequate blood supply. Counselling of blood donors is an essential part of achieving this objective.

1 Rationale

The International Federation of Red Cross and Red Crescent Societies (the Federation) and the World Health Organization (WHO) have produced these guidelines for blood donor counselling on human immunodeficiency virus (HIV), in collaboration with blood transfusion specialists from many parts of the world. They are designed specifically for persons in charge of blood transfusion services (BTSs) and of blood donor recruitment programmes, whether these programmes are a part of or separate from BTSs. Specific guidelines were necessary because blood donors are regularly tested for HIV in BTS settings, and there are serious implications, both medical and psychological, for those who receive positive HIV results, as well as for those who test positive but are not informed of their status.

The BTS's prime responsibility is to ensure a safe and adequate supply of blood and blood products. Safe blood is taken from voluntary, non-remunerated regular blood donors.

Although the tests available to detect HIV antibodies are very specific and very sensitive, there is still the risk that HIV-infected blood will not be detected in a situation in which the infection has only recently been acquired and detectable antibodies have not yet developed (referred to as the "window period"). Thus there is a need for adequate pre-donation information and counselling to ensure deferral or self-deferral of donors with a history of risk

behaviour, especially a recent (within the past three months) history.

BTSs and blood donor programmes are responsible for notifying donors confidentially of positive test results. The provision of results of HIV testing to those donors who wish to know is part of the BTS's role of caring for donors.

In addition to HIV, the commonly notified transfusion transmissible infections (TTIs) include hepatitis B (HBsAg test) and syphilis (VDRL test). Notification of positive tests for these infectious agents has been done through a confidential letter advising donors to attend an outpatient clinic where sexually transmitted diseases are treated and where advice about and care for hepatitis B or syphilis can be provided. However, the advent of HIV and the necessity for sensitive and careful post-donation counselling has created an entirely new challenge for BTSs.

Given the increasing recognition of HIV in all communities and the fact that BTS facilities are often the only places routinely testing for the HIV antibody, there is concern that BTS facilities may be used as HIV test sites by individuals worried about their risk. This practice has the following implications:

- Significant amounts of HIV-infected donated blood may be discarded, resulting in wastage of vital supplies and collection resources.
- Because of the potential for test inaccuracies, HIV-infected blood may not test antibody positive and may be placed in the blood supply.
- Opportunities for engaging individuals at risk for HIV infection in personally relevant preventive education and for providing necessary psychological support are lost, particularly when no donor information

and pre-donation counselling is provided and where there is no complementary or alternative network of community-based counselling and testing facilities to which these individuals can be referred.

At present, many countries have no clear policy on donor HIV counselling and care in the context of blood donation, and guidance is necessary in the formulation of national strategies and related policies for dealing with these blood donor counselling and care issues. These important issues have been recognized and have been the subject of a collaborative effort to develop these guidelines.

A fully implemented blood donor information and counselling programme has the following potential benefits:

- Wastage of blood units collected and wasted costs from collection of HIV-infected blood would be minimized.**
- Blood donor HIV prevalence would be reduced to below the national average.**
- An uninfected donor pool would result.**

These guidelines are not designed as a training guide for HIV counselling. Such information is available from the *Source Book for HIV/AIDS Counselling Training* by WHO.

Rather than recommending that specific personnel be called on to do blood donor counselling, flexibility should be encouraged. The ideal stages of blood donor information and counselling are presented in Figure 1.

However, given the shortage of resources in many settings, the guidelines encourage BTSs to start by providing a minimum of pre-donation information to groups and pre-donation counselling to individual donors, using the existing blood donor staff in each setting. It is recognized that these human and material resources will differ considerably from country to country.

During the initial phase, the process of post-donation counselling can be delegated to the existing health care service. As more resources become available, this process can be taken on by the BTS.

2 Aims of the guidelines

These guidelines aim to illustrate how BTSs can develop blood donor counselling on HIV according to the needs and resources of the country they serve. They identify steps to enable appropriate, confidential and ethical counselling management when people donating blood wish to learn their HIV status, wish to discuss HIV or are found to be HIV infected in BTS settings. The guidelines also outline a strategy for referral and deferral of individuals who may wish to donate blood primarily in order to have an HIV test.

Most countries will have limited resources and may have only a limited potential for developing blood donor counselling at present. The approach suggested in this document is to proceed within current resource limits, using whatever structural elements are available, while at the same time working towards a full, supportable system of blood donor counselling.

3 Target audience

These guidelines are designed for use by persons in charge of BTSs and persons in charge of blood donor recruitment programmes, whether these are a part of or separate from BTSs.

The term BTS in this document refers to organised programmes encompassing all aspects of blood transfusion (transfusion medicine), including the education and recruitment of blood donors and the collection and testing of blood. BTS settings are all those in which blood donation is discussed with the intention of recruiting donors, in which blood is donated and in which the result of the blood test becomes the basis for post-donation discussion, counselling and/or referral. BTS personnel included within the scope of this document in-

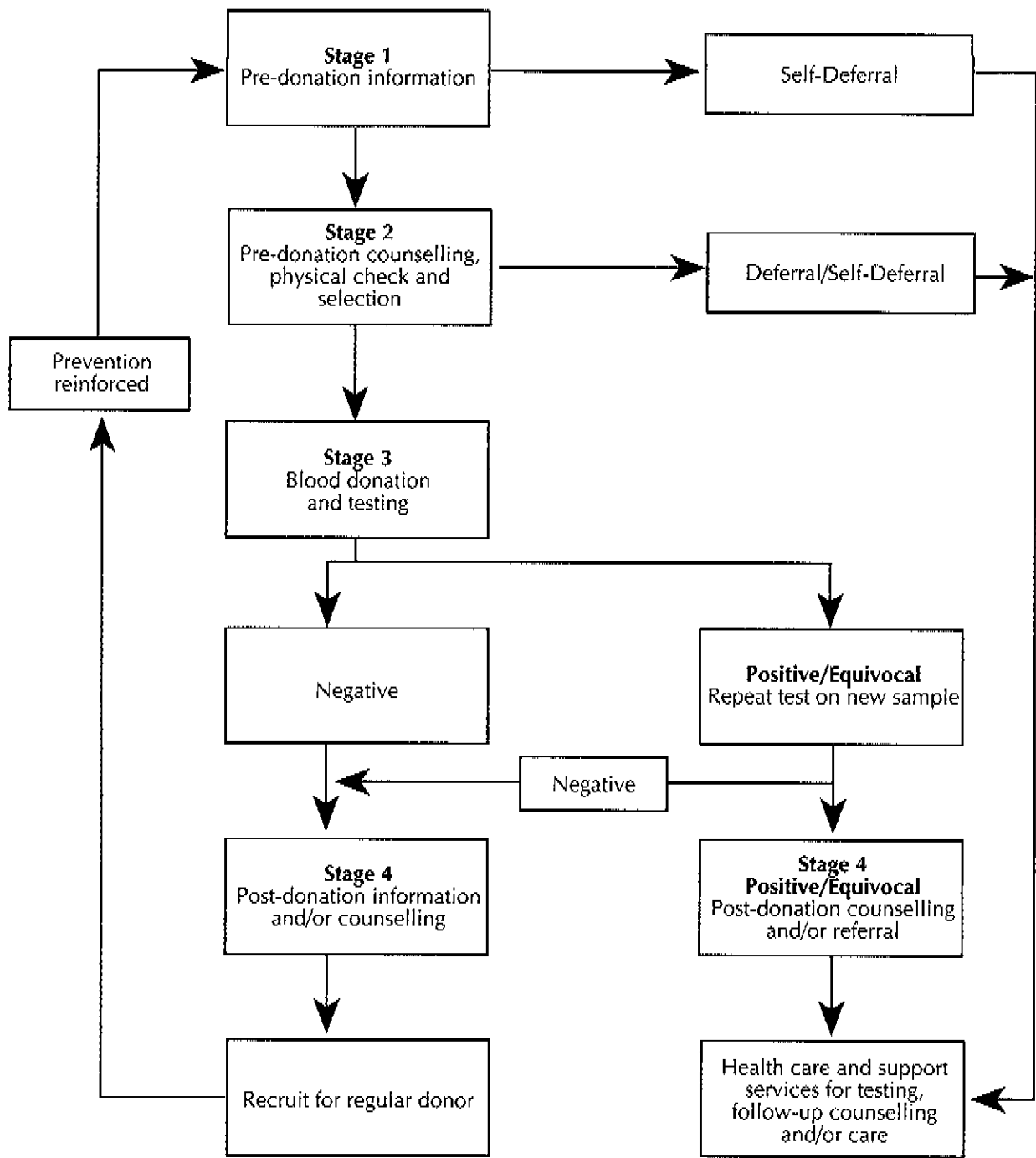


Figure 1—Flow Chart of Stages in Blood Donor Counselling

clude medical and nursing staff, blood donor recruiters, technical staff and volunteers within blood transfusion facilities.

4 Background

Advice and background information for these guidelines have been drawn from national Red Cross and BTS staff, the Federation/AIDS Programme and Blood Programme, WHO/

GPA, the Global Blood Safety Initiative (GBSI), National AIDS Programme (NAP) staff and counsellors and blood donors from many countries. In addition, detailed case studies were commissioned to assess the potential for counselling in BTS settings in six¹ countries, and these guidelines draw very closely on the data

¹Uganda, Botswana, Zimbabwe, Rwanda, India (Maharashtra State) and Thailand.

obtained. In particular, structural recommendations for developing blood donor counselling in countries are a direct response to needs identified in the case studies. Draft versions of these guidelines have been reviewed in the field by experts and BTS personnel in eight² countries.

5 Other transfusion transmissible infections (TTIs)

While this document refers primarily to blood donor counselling on HIV, these guidelines may be used as a standard for counselling on other diseases transmitted by transfusion, such as syphilis and hepatitis. Donor discussion and counselling for hepatitis B has been a routine practice in some BTS sites for years. If procedures for HIV counselling are in place in BTS settings, then counselling and referral for other TTIs can be adapted from them and managed there also.

6 What is blood donor counselling?

The primary objective of BTSs is to provide a safe, continuous and adequate blood supply. Counselling voluntary blood donors about HIV is essential to achieving this objective.

Blood donor counselling is necessary before (pre-donation counselling) and after (post-donation counselling) blood is tested, and should be preceded by pre-donation information and discussion. Effective pre-donation discussion and pre-donation counselling are vital activities of the BTS, and are needed to encourage appropriate donor self-deferral. Post-donation counselling is not only a necessary part of care for the HIV-positive donor but is also important in promoting health maintenance and regular donation in HIV-negative donors.

Following a positive HIV test result, counselling in the context of blood donation is provided up to the immediate post-test phase. The person is then referred to existing health care facilities or AIDS Service Organizations (ASOs) for ongoing counselling. These referrals are made because BTSs do not have the capacity or the mandate to provide ongoing counselling for HIV-positive donors and their families. These alternative resources are therefore necessary for ongoing counselling and testing of those donors found to have HIV.

A phased approach is proposed to develop blood donor counselling. Initially the BTS should assess the existing level of resources (money, space and staff) for blood donor education, including pre-donation counselling and donor notification of test results.

Planning should be made to reallocate resources and train staff in order to start blood donor counselling. A BTS can start by using existing resources to provide the following blood donor counselling activities.

- Organising donor recruitment to allow time for discussion of HIV, and spreading blood donor information (including HIV issues) through the existing health care system.
- Delegating BTS or volunteer staff with HIV counselling skills to discuss HIV with each donor and encourage appropriate self-deferral and referral to an alternative counselling and testing site if necessary.
- Establishing links between the BTS and the health care system so that donors who wish to know their HIV status can be referred for post-donation counselling under conditions of confidentiality.

Finally, ongoing efforts should be made to achieve an adequate counselling capacity for the BTS. This will require trained BTS staff members with time and space to give test results and emotional support during the immediate crisis. The staff should have good links with and be prepared to make referrals to the health care system for ongoing counselling. The BTS counselling staff should also have time to engage HIV-negative donors in discussions of health maintenance and regular donations.

² Thailand, India (Maharashtra State), Cameroon, Zimbabwe, Botswana, Congo, Uganda and Honduras.

While the processes in blood donor counselling have a distinctive character, counselling blood donors involves features that are essential in all counselling activities:

- adequate time for counselling;
- acceptance of the donors and respect for their specific concerns;
- accessible counsellors and facilities;
- provision of consistent and accurate information to donors;
- maintenance of donor confidentiality at all times and in all settings, as appropriate to the culture.

To enable the best possible development of blood donor counselling, a number of goals must be worked for, such as training, coordinating and surveying.

A flow chart illustrating the various stages of blood donor counselling, and points of deferral and referral, is shown in Figure 1. The resources required and activities involved at each stage are described further in Tables 1, 2 and 3.

7 Costs and benefits of a blood donor counselling programme

Although starting a blood donor counselling programme will cost money and other valuable resources, the programme might achieve savings in the long term that could offset the initial costs. Implementation of the **minimal** (see Table 2) requirements (pre-donation information, pre-donation counselling and referral for post-donation counselling) suggested in these guidelines should be possible at little extra cost. In addition to improved blood safety, the country's health status may benefit in other ways. The cost and benefits of implementing blood donor counselling are as follows:

Costs

- Training existing staff;

- Adding extra or new staff;
- Time required at pre- and post-donation stages;
- More transport;
- Review and improvement of recording systems and reporting and follow-up arrangements;
- Extra overhead and utility costs;
- Additional HIV tests for blood samples (with positive or equivocal results) of donors who wish to know.

Benefits

- Minimal wastage (especially financial) resulting from collection of HIV-infected blood;
- Reduction of blood donor HIV prevalence to below national average;
- Regular, healthy donor pool;
- Improved national health education and HIV prevention coverage and efficacy.

8 Responsibilities of BTS facilities, staff and donors

HIV has necessitated a reappraisal of BTS responsibilities towards donors, and of donors towards BTS agencies. For example, BTS facilities and all staff involved in blood donation have a responsibility to inform donors of the following:

- their donated blood will be tested for HIV;
- the reasons for this testing;
- the potential consequences of learning of a positive result;
- the availability of post-donation counselling, testing, care and support agencies.

The BTS has a responsibility to blood transfusion recipients to do everything possible to encourage informed donor self-deferral if a

history of HIV risk is identified in pre-donation discussion or in pre-donation counselling. Similarly, the BTS has a responsibility to do all it can to make it possible for donors to receive their results, if this is what they wish, in those settings where resources permit.

At the same time, donors have responsibility to do the following:

- give accurate information to BTS staff about their history of possible exposure to HIV;
- heed advice about being tested at alternative counselling and testing facilities if their identified risk so indicates or if blood donation is a secondary motivation to having an HIV test.

Aims and Stages of Blood Donor Information and Counselling

The following minimum steps may be taken at each stage of blood donor counselling:

- **Pre-donation information:** Organising donor recruitment to allow time for discussion of HIV; spreading blood donor information (including HIV issues) through the existing health care system.
- **Pre-donation counselling:** Delegating BTS or volunteer staff with HIV counselling skills to discuss HIV with each donor and encourage appropriate self-deferral and referral to an alternative counselling and testing site if necessary.
- **Post-donation information/counselling:** Having a trained BTS staff member give the test results and help during the immediate crisis; having good links with the health care system to enable test results to reach donors who are unable to return to the BTS.
- **Referral for follow-up counselling:** Having links with reliable sites for ongoing counselling; having BTS staff prepared to make such referrals.

Pre-donation discussion and counselling of blood donors has two main aims:

1. **To increase donor awareness**
 - of HIV;
 - of the fact that they will have their blood tested for HIV;
 - of the implications and possible consequences of that process.
2. **To discourage blood donation**
 - by self-deferral of people wishing to use the BTS only for the HIV test;
 - among people who may have a history of risk for HIV and where alternative sites for counselling and testing are available.

Indeed, even where alternative counselling and testing sites do not exist, donor self-deferral should be encouraged if individual histories indicate this is appropriate. If donors are deferred by the BTS on clinical or behavioural criteria, they should be given information about the reasons for deferral and about where to obtain ongoing supportive counselling, medical care and appropriate testing.

These various stages of discussion and counselling are presented in Figure 1 and Table 1 and are explained in the following section. These stages are not a new responsibility for BTSs, but rather a logical extension of existing responsibilities.

Effective pre-donation discussion and pre-donation counselling is needed to encourage appropriate donor self-deferral and to promote health maintenance and regular donation in HIV-negative donors. Alternative resources to which referrals can be made are necessary for ongoing counselling of those donors found to have HIV.

1 Pre-donation information

This is oral or written information for individuals or groups of potential donors, usually given by the donor recruiting team some time

Stage	Activity	When	By Whom	Skills
1. Pre-donation information.	Explain HIV prevention and testing and why it is done. Explain deferral to alternative counselling and testing facilities.	Early enough to allow an unpressured, informed decision about donation.	BTS-trained educator or volunteer recruiter. NACP- and BTS-approved mass media materials.	Knowledge of how to give information about HIV, blood need and use, and BTS procedures.
2. Pre-donation counselling.	Review donor understanding of HIV test, possible consequences of testing and personal risk history. Discuss with donors how they will learn of results if they wish.	Just before donation.	Donor care staff.	(See above.)
Physical check.	Check general health and signs of HIV illness.			Clinical.
Donor selection.	Defer to community agency or ask to donate.		Clinical staff.	Clinical.
3. Blood donation.	Blood donation and discussion of follow-up.	At donation.	Donor care staff.	Clinical.
Plus testing.	Blood testing.	At testing.	Laboratory staff.	Laboratory.
4. Post-donation information/counselling and/or referral.	When appropriate, make results conveniently available in line with health policy of the country. With seropositive persons— – discuss the results – provide crisis support – discuss prevention of HIV transmission and care for the carrier – refer if appropriate With seronegative persons— – discuss the result – discuss and/or give materials of HIV prevention – recruit as a regular donor	After testing.	BTS staff or trained counsellor (includes volunteer). Trained staff recognised by NACP and BTS and as agreed to by the donor.	Counselling. Counselling.

Note: HIV = human immunodeficiency virus; BTS = blood transfusion service; NACP = National AIDS Control Programme.

Table 1—Activities in blood donation procedures and donor care

before blood donation takes place. School teachers, health educators and mass media can also distribute pre-donation information.

Continuing public education about procedures of donor selection, testing, deferral and referral may be done effectively as part of mass media campaigns. Pre-donation information should cover the following:

- the need to recruit people for a regular, safe donor pool;
- the procedures involved in giving blood;
- the fact that blood is tested for HIV and other infectious agents, and why it is tested;
- possible consequences of learning that one has HIV;
- information about HIV and other blood-transmissible infections, including routes of transmission, natural history and prevention;
- procedures to ensure confidentiality of test results;
- why and where to go, other than the BTS, if the donor thinks he or she may have been exposed to HIV and wants an HIV test or more information.

Whenever possible, sufficient time should be allowed between recruitment and donation sessions to allow potential donors to absorb the information.

Pre-donation discussions are an important first attempt at encouraging donors at risk to self-defer from BTS facilities. These sessions also provide an important opportunity to engage the potential donor in discussion of prevention messages, which may then be carried on to others in and beyond the community.

2 Pre-donation counselling

This is the counselling provided to individuals before blood is taken. In some cultures this activity may be adapted to include other people, such as spouses or other family

members. Pre-donation counselling involves the following:

- explaining the HIV test;
- explaining the implications of knowing one's HIV status: the emotional, social and financial consequences, as well as the effects on family and work, that may result from learning one has HIV infection;
- explaining to uninfected donors the need to avoid future infection by maintaining low-risk behaviour;
- encouraging self-deferral if donors think they may have been exposed to HIV, and advising on where else donors can be tested if they wish;
- explaining post-donation procedures for both infected and uninfected donors;
- securing the donors' informed consent to donate;
- discussing the possible options for referral and future care if the test result is positive.

Informed consent is the donor's **voluntary agreement** to have his or her blood tested after sufficient information has been given. Prisoners and other persons with no choice as to whether they donate blood cannot give informed consent to blood donation, and thus to testing, and should not be recruited or permitted to act as blood donors.

3 Blood donation and testing

Procedures for HIV-antibody testing in BTS settings are detailed in "Recommendations for the Selection and Use of HIV-Antibody Tests" (WER 20, 1992; 67: 145-149 [see Annex 2]). That document specifies testing strategies, including appropriate test selection, for purposes of counselling, diagnosis and follow-up in areas of high and low prevalence. Advice on counselling donors when equivocal results are obtained is given in the section "Counselling Processes in BTS Settings".

4 Post-donation information/counselling and referral

This is the individual face-to-face counselling that is provided by staff with appropriate training for giving such important information. The counselling should take place as soon as possible after a positive result is reliably obtained. Post-donation counselling is intended to help the donor cope with the psychological impact of a positive result. In some settings, post-donation information is provided together with counselling to encourage low-risk behaviour for those found to be HIV negative. Post-donation counselling and referral involves the following:

- giving the donor time to grasp the news about the status;

- giving enough time and an opportunity to ask questions;
- helping the donor with the emotional and practical impact of the positive result;
- offering options for continued care for infected donors and their families and/or partners through referral to appropriate organisations and facilities.

Post-donation counselling may involve recognising and managing—in the very short term—acute psychological reactions to the disclosure of HIV infection. It should therefore be provided only by staff who have received specific training in containing such events, or who have direct access to those who can do so, and who are capable of recognising the need for referral and follow-up. Appropriately trained volunteers could provide such counselling.

Counselling Processes in BTS Settings

While the processes in blood donor counselling have a distinctive character, counselling blood donors incorporates features that are essential in all counselling activities. There is a need for the following:

- adequate time for counselling;**
- acceptance of donors and respect for their specific concerns;**
- accessible counsellors and facilities;**
- provision of consistent and accurate information to donors;**
- maintenance of donor confidentiality at all times and in all settings, as appropriate to the culture.**

Blood donor counselling generally should not go beyond one or two post-donation sessions. Referral to complementary community-based counselling, testing and care services is necessary to maintain the flow of blood donation and BTS procedures.

1 Essential features in counselling activities

Adequate time

Concerns raised in counselling, whether the donor is HIV-infected or not, are complex and often very sensitive, and time is required for discussion. News of infection will change a person's life-view forever, and time spent in the initial stages may well determine the quality of adjustment thereafter. Providing sufficient time will enable the following:

- donor discussion of HIV as an issue of personal relevance and concern;

- development of trust and rapport to enable honest disclosure and discussion;
- opportunity for bad news and information to sink in and be reacted to.

Acceptance

People with HIV/AIDS, and those who have a history of possible exposure to HIV, should feel they are fully accepted by the counsellor, irrespective of their circumstances. Responses to donors' needs should be both technically sound and sensitive to their personal circumstances, and not affected by the counsellor's own feelings. If donors do not feel accepted, they will not come forward for donation, discussion or results.

Accessibility

Accessibility means counselling and counsellors are—

- easy to get to;
- using terms the donor understands, rather than jargon;
- relevant and sensitive to the circumstances, culture and needs of the communities and individuals they serve.

Consistency and accuracy

At all stages of blood donor counselling, information must be consistent with that given in pre-donation discussions and with that given by other BTS and related health staff throughout the identified referral system. This requires regular **liaison** among all staff in contact with the donor (including staff in complementary agencies).

2 Confidentiality

This is the necessary privacy given to personal information about donors and the results

of their tests. In daily practice, medical and other health workers have access to confidential information about a donor, and are bound to not divulge this information to any person, except when **the donors** request that the information be given to a person who is directly involved in their care. Confidentiality is a traditional professional and ethical requirement of health professionals and must be a part of the conduct and ethics of all BTS staff, including volunteers. Because of the stigma and discrimination that often arise from HIV and AIDS, it is essential that confidentiality be strictly observed and included in the training of all BTS staff.

Potential problems may make it difficult to ensure privacy at the site of donor information/counselling. However, no personal information given within the counselling context should be shared without the consent of the donor. All donor records and information should be carefully stored and kept out of sight of passers-by. Only those with direct responsibility for the care of the individual should have access to such records. Deferral or referral of blood donors must be carried out so that confidentiality is preserved. If this is not possible, then the usual donation process should take place, and the blood should be identified so that BTS staff recognise that it is to be safely disposed of.

3 Giving HIV test results to donors

Donors should be asked **before** the testing is done if they wish to be informed of the HIV test results. The BTS is not required to inform donors of results if they have indicated no desire to be informed. If the donors are told before donation that they must make the first step if they wish to receive the result, they should be clearly told how to do so. Donors should be told that if the test result is positive they will be deferred at the next attempt to donate.

If donors are under the legal age of consent, pre-donation information and counselling should be given. Any further intervention, such as giving post-donation results and counselling, must be reviewed on a country-by-country basis. Each country should determine policies on legal minors according to the culture and legal system. Guidelines on this matter should be incorporated into the national transfusion policy.

Paid donor systems are to be discouraged for both ethical and medical reasons. However, it is recognised that these systems operate in many countries. It is important to ensure that all collection facilities conform and comply with the same ethical and medical standards of care provided to voluntary non-remunerated blood donors.

Ideally, all donors should be made aware of their HIV results after they have agreed to donate their blood and to be informed of the results. When donors do not pursue results, valuable opportunities for providing support and assistance with prevention may be lost or wasted. Nevertheless, this is an active process on the donor's part only: BTS staff actively encourage donors to return for results (either at BTS or alternative facilities) but do not seek out donors to give them their results.

Donors may not be able to return for results for various reasons. They may be restricted by their mobility and by their limited access to facilities and staff that give test results. This is why co-ordination with the health care system and with community-based networks (including alternative counselling facilities) is of such vital importance. These facilities may be able to provide results in instances where BTS staff are unable to reach the donors. Despite such provisions, some donors may still not be reachable.

It is also important to consider that positive HIV results can be given only after an initial positive test result has been confirmed with repeated testing. Supplemental testing is particularly important when counselling healthy but seropositive blood donors.

4 Counselling after a reactive (positive or equivocal) test result

If the result of the HIV test is positive or equivocal, the counsellor has particular responsibilities to provide information. The person should be given a clear explanation of what such a test result means. HIV antibody tests should have levels of sensitivity and specificity approaching 99.5%, meaning that a non-reactive result with this technique can be regarded as a definite indicator that the person is not infected, except for tests done during the "window period". A reactive result suggests the possibility of HIV infection, and the usual procedure in that case is to perform a second test.

When giving test results to blood donors it is important to remember that only tests with a high *sensitivity* will have few false negative results. These tests are important for purposes of blood transfusion safety. Tests with a high *specificity* will have few false positive results and should be used to minimise the rate of false positive findings (eg, in diagnosing HIV-infected individuals).

Counselling donors after positive or equivocal (indeterminate) test results should be carried out only after consideration of the WHO recommendations on the selection and use of HIV antibody tests. Where blood donors are to be informed of their positive or equivocal (indeterminate) results, strategy II, and possibly strategy III, need to be considered (Annex 2).

Equivocal (indeterminate) results may be caused by one of the following: The test is cross-reacting with a non-HIV protein (usually, the

protein reaction is simulating the reaction associated with p24 core protein); or there has been insufficient time for full seroconversion since the person was exposed to HIV.

The period of uncertainty following an equivocal test result may be three months or longer. It is important for counsellors to stress essential messages related to prevention of transmission, ie, regarding sexual activity, drug use, donation of body fluids or tissues and breastfeeding. However, it is equally important to remember that the uncertainties associated with this period may lead to acute and severe psychosocial difficulties, and the counsellor must be prepared to assess and manage such issues or to make appropriate referrals, if possible.

5 The psychosocial impact of awareness of HIV infection

When giving HIV test results, it is extremely important to recognise the impact of the news on the life of the donor and its implications for every aspect of the donor's life. Potential implications at the domestic, occupational, legal, financial, social and spiritual levels will need to be assessed and managed by appropriate mechanisms and referral. Deferral, as such, may have a negative effect on the donor. Counselling after a positive result may be complex and time-consuming precisely because of these issues and their psychological correlates, including fear, sense of loss, grief, guilt, depression, denial, anxiety, anger, suicidal activity or thinking, loss of self-esteem and hypochondria.

Resource Requirements and Implications of Blood Donor Counselling

Counselling of blood donors is important before donation (pre-donation counselling) and after blood is tested (post-donation counselling), and may be complemented by pre-donation information and discussion. Following a positive HIV test result, counselling in the context of blood donation is provided up to the supportive phase, then referral for ongoing counselling is made to existing health care facilities and/or community or ASOs.

1 Developing blood donor counselling in smaller and mobile facilities

Smaller and less well-resourced settings and facilities, including mobile collection teams, may have difficulty achieving the level of blood donor counselling possible in larger, central units. This may be, for example, be-

cause of lack of time at collection, lack of staff or lack of privacy.

However, smaller blood collection facilities have the same responsibilities as larger units regarding confidentiality, information-giving and so on. The person in charge must examine the available resources and determine whether—and the level at which—information and counselling can be given. Existing staff can receive in-service training to fulfill their multiple functions, including the ability to make appropriate referrals at the post-donation stage.

2 Minimal resource requirements

In most countries it may not be possible to quickly develop blood donor counselling to the degree identified in Table 1. However, minimum steps for achieving an appropriate standard of intervention at each stage of blood donor counselling are suggested, and it is recommended that these be the first priorities for blood donor counselling development. Tables 2 and 3 show two different levels of resource requirements and the implications of each.

Stage	Minimal Requirements	Resource Implications
Stage 1 Pre-donation information.	Organisation of recruitment. Time for discussion. Information dissemination by existing health care services.	Adjustment of staff duties. Training in communication and HIV issues. Improved links with related services.
Stage 2 Individual pre-donation counselling. Physical check. Donor selection.	Staff with counselling skill to discuss HIV with donors. Identify mechanism and resources for deferral and referral.	Designated existing staff and space. Training. Defined procedures.
Stage 3 Blood donation and testing.	Confidential and accurate records.	Improved record management.
Stage 4 Post-donation information/ counselling and/or referral.	Staff training in counselling skills. Designated space to interview and give help during crisis. Linkage with reliable sites for ongoing counselling. Designated BTS staff to make referrals.	Training. Time and privacy. Donor deferral network.

Note: HIV = human immunodeficiency virus; BTS = blood transfusion service.

Table 2—Minimal resource requirements and implications for development of blood donation information, counselling and referral

Stage	Additional Requirements	Resource Implications
Stage 1 Pre-donation information.	Donor recruitment staff trained in HIV issues and BTS procedures. Voluntary staff trained as above. Time to discuss donor's concerns. SOP for HIV information-giving.	Training. Extra staff and space. Time adjustment in existing duties. HIV information materials.
Stage 2 Individual pre-donation counselling. Physical check.	SOP on counselling and donor testing. BTS staff with additional training in counselling skills. Time and space to ensure privacy in counselling. Confidential record system.	Time and research. Added training. Space. Added records management.
Stage 3 Blood donation and testing.	Rapid and accurate confidential record retrieval.	Data base system.
Stage 4 Post-donation/counselling and referral.	Links with existing health care services for confidential result-giving at selected sites. Active links with alternative counselling, testing and care facilities.	Training for, and clear referral networks to, designated staff of existing health care services in the community.

Note: HIV = human immunodeficiency virus; BTS = blood transfusion service; SOP = standard operating procedure.
*See Table 2 for minimal resource requirements.

Table 3—Additional resource requirements and implications for development of blood donor information, counselling and referral^a

Monitoring and Evaluation

BTS counselling activities will require regular monitoring along with other service elements. Evaluating the impact of blood donor counselling will enable the BTS to assess its capacity to meet the needs of its donor population in view of the impact of HIV. Specific quality control mechanisms are also necessary to ensure consistency of the counselling. Internally, regular staff meetings and case discussion can help to monitor and improve counselling quality. These meetings will be the responsibility of the identified supervisor of counselling staff. External quality control will be the responsibility of the national or regional focal point or committee for counselling, which will also co-ordinate links between the formal and informal health and social resources involved in blood donor counselling.

Both quantitative and qualitative evaluation should be performed. Evaluation is easier to do when its design is incorporated in the initial development of blood donor counselling. Both forms of evaluation should be reviewed yearly to ensure that they are still relevant.

The following general questions may be considered in BTS counselling evaluation:

1. To what extent does pre-donation information/discussion result in donor self-deferral and donor uptake?
2. Does counselling reduce donations from those with HIV and other TTIs, and how is this reflected in cost benefits (eg, reduced wastage of kits)?
3. To what extent does counselling reveal psychosocial difficulties, and how does this alter the quality of blood donation procedures?
4. Do BTS-based information-giving, discussion and counselling affect subsequent risk behaviour or future intentions to donate blood?
5. What is the quality of links and consistency with companion agencies for counselling, testing and care?

6. What procedural and structural issues appear to aid or impede the development of blood donor counselling and the beneficial impact of counselling on donors?

Monitoring (also known as descriptive evaluation) is a descriptive process that generates descriptive statistics. For example, case files and records can be analysed to determine the following types of information:

- numbers given pre-donation information;
- numbers coming for pre-donation counselling and then donating blood;
- illness detected at physical check prior to donation;
- risk histories and numbers found HIV-positive;
- involvement of loved ones in the donation process;
- post-donation counselling and referral processes and where donors were referred;
- psychosocial issues raised in blood donor counselling;
- time taken for post-donation counselling;
- costs of providing blood donor counselling, and savings from reducing HIV-positive donations.

These descriptive statistics can then be used as baseline and follow-up indicators or measures from which the counselling can be characterised and updated. Information obtained can be used to improve the quality and relevance of the counselling activities, to help refine counselling training and for annual reports.

The use of donor surveys to enhance the relevance of blood donor counselling is discussed in the following section "Complementary Activities and Structures for Enabling Blood Donor Counselling".

PART 2

Complementary Activities and Structures for Enabling Blood Donor Counselling

To enable the best possible development of blood donor counselling, the following goals need to be worked for:

- development of expanded BTS aims and objectives;**
- identification of alternative counselling and testing sites;**
- co-ordination with the health care system throughout the country;**
- inclusion of blood donor counselling into BTS Policies;**
- development of protocols for blood donor counselling;**
- training of existing BTS staff;**
- delegation of responsibility for giving HIV test results, if necessary;**
- volunteer recruitment and involvement;**
- surveys of donors;**
- resources for donor information-giving;**
- development of an HIV-negative donor pool.**

Activities that can assist the development of blood donor counselling are described in this section. In all countries and settings, it is important to start with what is available rather than waiting for ideal resources to arrive before acting on the need for HIV counselling.

Table 1 describes ideal requirements needed for each stage of blood donor counselling. Table 2 lists minimal requirements, and Table 3 describes additional resource requirements.

1 Development of expanded aims and objectives of BTSs

The HIV pandemic demands changes in traditional BTS practices to ensure the original aim of generating a safe, adequate blood supply in all countries. Expansion required in many countries includes the following:

- HIV information-giving through pre-donation discussion with all potential donors;
- pre-donation counselling of all donors;
- provision of test results to donors;
- post-donation counselling;
- development of referral links with the health care system and with complementary ASOs;
- training and delegating staff for HIV counselling within BTSs.

In some areas, expansion might more appropriately be called reinforcement of current practices of informing donors about hepatitis B and syphilis, providing immediate counselling and referring them onwards for further management.

2 Identification of existing health care services for counselling, testing and care

BTS counselling must be linked to complementary services in the community that have a greater capacity for counselling and testing, and for ongoing care. These services may already exist, but in some settings they may need to be developed. These links to other services allow the following:

- donor self-deferral when high risk of exposure to HIV is recognised prior to blood donation and the donor wishes to have his or her blood tested for HIV;
- avoiding the use of the BTS as an alternative HIV testing site;
- referral from BTS facilities for long-term follow-up and care of those found HIV-infected;
- referral for those who are HIV-negative who wish to be re-tested and/or maintain a relationship with community agencies working on HIV prevention.

Such self-deferral and referral clearly require sound links and consistency between BTSs and other sites in counselling, referral, information management and observance of confidentiality.

3 Co-ordination with the health care system

Blood donor counselling should be co-ordinated with activities of health professionals and volunteers working within the health care system, especially in outlying areas. This co-ordination can occur at all levels of BTS activities, and requires the following:

- training of key persons in the aims of blood donor counselling;

- provision of supervision and feedback to those within other agencies working to achieve BTS aims;
- consultation with community services and programmes to determine what they can realistically achieve in this work.

For example, in some situations the health care system may be the only setting through which donors can receive their test results. In other situations it may not be possible to reach all donors because no network or system exists. This may be true even where community volunteers are involved.

4 Inclusion of blood donor counselling into BTS policies

Every country should have a national BTS policy, including a component on blood donor counselling, with an identifiable person responsible for management of that policy. The policy should be consistent with policies on HIV testing applied to more general settings and should reflect input from, and the realities of, the country's health care system, and HIV/AIDS and BTS activities.

Development of a coherent national policy will help to—

- maintain and raise standards of donor management and care;
- unify services and processes of information management, confidentiality, result-giving and referrals to HIV care agencies and facilities;
- overcome arguments against developing blood donor activities in the context of HIV;
- clarify and delegate roles and links, including the provision of alternative sites, between blood transfusion services, Red Cross, Red Crescent and other non-governmental agencies;
- provide a reference against which standards and levels of progress can be measured.

5 Generation of protocols and resources for blood donor information-giving and counselling

Evaluation instruments and/or checklists for pre-donation recruitment talks, pre-donation counselling, post-donation counselling and referral systems/processes should be developed and used by all services (including those to whom referrals are made by the BTS). An example of a pre-donation counselling checklist is given in Annex 3.

To give information effectively to donors, all discussion, information-giving and counselling requires instructional and educational materials as well as time, space and easy access to appropriate staff.

6 Training of BTS staff in counselling issues

Training staff about aspects of blood donor counselling must be distinguished from increasing the awareness about counselling issues of those involved: Not all BTS staff will be appropriate for providing blood donor counselling, so for some, simply raising awareness about HIV-infection issues will be appropriate. It is most important that all staff have the same basic awareness, however, to ensure that minimum standards of information-giving are maintained. Degrees of appropriate training for each stage of blood donor counselling are explained in Table 1.

Many existing staff have direct donor contact and will therefore need training in the special tasks involved in pre-donation and post-donation information and counselling. Training should include ability to explain and discuss the following:

- informed consent implications;
- means of HIV transmission;
- HIV epidemiology and the carrier state;

- sexual histories and other sensitive questions.

Staff will need to be trained to be non-judgmental in dealing with answers. They will also need skill in managing the psychological reactions of deferred donors and should be thoroughly familiar with the procedures for referral to alternative testing and counselling sites. Staff who show aptitude and skill for these tasks may be considered for additional training necessary for counselling those with positive test results.

Materials for training in HIV counselling may be obtained through the National AIDS Control Programme and recognised counselling organisations.

7 Delegation of responsibility for post-donation information and counselling

Giving test results—especially positive HIV results—can be very demanding and requires specialised training and skills. However, in some countries donors face real obstacles to receiving their HIV test results; for example, where it is believed that only people with medical qualifications can give such news. Where this is the case, and there are insufficient medically-trained personnel, moves should be made to allow post-donation counselling and referral by a broader range of personnel with counselling skills.

Where the BTS delegates the process of giving results to another organisation or to a volunteer, the BTS retains the responsibility for that process and should therefore help set criteria for the selection and training of volunteers and/or involved staff of these organisations.

8 Volunteer recruitment and involvement

Voluntary staff involved in the duties need careful supervision, close management and periodic training to ensure appropriate standards

of practice and confidentiality. Funds are required to reimburse volunteers for incidental costs incurred. The BTS is responsible for such guidance and co-ordination.

Staff who manage volunteers will need to have the appropriate skills and training in management, and the time for this activity. It may be helpful and necessary to provide materials, including skill checklists (eg, for pre-donation counselling) clearly explaining duties and tasks, which can be used to guide volunteers and to check the quality of their work (see Annex 3).

Appropriate BTS volunteers for pre-donation information-giving may include church personnel, industrial medical and health staff and peer counsellors in the community. Church organisations and personnel may be particularly appropriate for post-donation counselling and pastoral care.

Possible roles for qualified volunteers include the following:

- recruiting potential blood donors;
- providing pre-donation discussion and counselling;
- taking blood from donors;
- giving negative results.

Donors found to be HIV-positive may present volunteers with problems beyond their training or expertise, so using volunteers to give positive HIV results is not recommended.

Volunteers can form a vital part of the network between local and health care staff and the communities they serve. The recruitment and use of volunteers should therefore be seen as a long-term aim that could be a great help in integrating BTS activities more closely with a wide cross-section of community and primary care agencies caring for HIV-infected blood donors.

9 Conducting donor surveys

In each country, donor needs and attitudes towards blood donation (and towards HIV care

services) should be characterized early in the planning of blood donor care at the national level **and** after blood donor counselling services are implemented. Doing this will enable:

- provision of more relevant blood donor counselling;
- evaluation of the effectiveness of blood donor counselling in achieving its aims and potential benefits.

Survey questions may include the following:

- Do people have particular beliefs or values about blood and reasons for giving or not giving blood?
- How do donors feel about having their blood tested for HIV?
- Do donors want to be told the results of the HIV test?
- Do donors come to give blood because it is a good way of being tested for HIV?
- What sort of information and advice would donors like to have about HIV and AIDS, and the HIV test, and what is the best way to make such information and advice available?
- What worries do donors have about receiving HIV information and discussion from the BTS?
- Are donors satisfied with the information and counselling they receive?
- What is the impact of blood donor information, discussion and counselling on donor knowledge, donation intentions and risk behaviour?
- Are donors accepting of the pre-donation deferral and post-donation referral processes available?
- How should donors be told that they have HIV?
- What are the main problems faced by donors and others with HIV?
- Why do people not keep appointments for advice and discussion about their test results?

- Where and to whom do donors and others with HIV go when they need support?

10 Development of a safe donor pool

Blood donor counselling on HIV contributes to the development of a safe donor pool by:

- registering identified negative donors;
- encouraging them to maintain HIV avoidance;
- encouraging them to engage in regular donations.

The success of such a scheme depends on good records to maintain registration of donors and regular recall.

Voluntary regular HIV-negative donors are a precious resource, and they must be re-educated and reinforced in their knowledge and practice of non-risk behaviour every time they are seen.

11 Family donors and replacement donors

Provision of blood, blood components and plasma derivatives from voluntary, non-remunerated donors should be the aim of all countries. The aim of BTS activities in general, and also of blood donor counselling, is to encourage voluntary non-remunerated regular blood donors. However, family donors and replacement donors should be managed in exactly the same way as other donors with respect to HIV-related information-giving and counselling before and after blood is donated.

Conclusions

In yet another sphere—that of blood donation—HIV has forced a need for change. The importance of reviewing BTS and blood donation processes to include blood donor counselling for HIV is obvious when the cost benefit implications for the BTS are examined. The cost of minimal structural requirements for development of blood donor counselling, donor self-deferral, referral, education, counselling and testing is quickly compensated by savings in otherwise wasted donations. National HIV prevention efforts are also reinforced, potential HIV care costs are reduced in the long term, blood donor HIV prevalence will be reduced to below the national average and the development of a safe, regular blood supply—the traditional major priority of BTSs—is much more likely.

Blood donor counselling therefore represents a major opportunity to enhance and strengthen the traditional aims of BTSs with relatively simple and achievable modifications of current procedures.

The scope and degree of change that blood donor counselling necessitates will vary from country to country. In some countries significant changes will not be possible without

wider recognition of the logic of such recommendations and of the need to develop complementary counselling and testing facilities so BTSs do not come to be viewed as HIV test sites.

However, these guidelines were developed after considerable field research, and the limits of resources and options for development within BTS contexts have informed the recommendations at every stage. The guidelines therefore suggest degrees of change and development appropriate to local and national needs and resources. They offer steps to implementation of blood donor counselling. They indicate the best issues to consider to ensure that blood donor counselling fits in with national and local HIV prevention and care, and the range of issues that need to be considered when choosing the personnel who may undertake this important task.

Perhaps most important, these guidelines illustrate that HIV can act as a catalyst for constructive change by necessitating a review of and renewed commitment to traditional aims of BTSs. Strengthening blood donation procedures using these guidelines will enhance blood safety and donor care in a way that might not have been possible otherwise.

Annex 1

INTERNATIONAL SOCIETY OF BLOOD TRANSFUSION

A CODE OF ETHICS FOR BLOOD DONATION AND TRANSFUSION. — 1980

The object of this code is to define the principles and rules to be observed in the field of Blood Transfusion; these should form the basis of national legislation or regulations.

I. — The Donor

- 1 - Blood donation shall, in all circumstances, be voluntary; no pressure of any kind must be brought to bear upon the donor.
- 2 - The donor should be advised of the risks connected with the procedure; the donor's health and safety must be a constant concern.
- 3 - Financial profit must never be a motive either for the donor or for those responsible for collecting the donation. Voluntary non-remunerated donors should always be encouraged.
- 4 - Anonymity between donor and recipient must be respected except in special cases.
- 5 - Blood donation must not entail discrimination of any kind, either of race, nationality or religion.
- 6 - Blood must be collected under the responsibility of a physician.
- 7 - The frequency of donations and the total volume of the blood collected according to the sex and weight of the individual, as well as the upper and lower age limits for blood donation, should be defined by regulations.
- 8 - Suitable testing of each donor and blood donation must be performed in an attempt to detect any abnormalities:
 - a) that would make the donation dangerous for the donor,
 - b) that would be likely to be harmful to the recipient.
- 9 - Donation by plasmapheresis should be the subject of special regulations that would specify:
 - a) the nature of additional tests to be carried out on the donor,
 - b) the maximum volume of plasma to be taken during one session,
 - c) the minimum time interval between two consecutive sessions,
 - d) the maximum volume of plasma to be taken in one year.
- 10 - Donations of leukocytes or platelets by cytapheresis should be the subject of special regulations that specify:
 - a) the information to be given to the donor about any drugs injected and about the risks connected with the procedure,
 - b) the nature of any additional tests to be carried out on the donor,
 - c) the number of sessions within a given time frame.
- 11 - Deliberate immunisation of donors by any foreign antigen with the aim of obtaining products with a specific diagnostic or therapeutic activity should be the subject of special regulations that would specify:
 - a) the information to be given to the donor about the substance injected and the risks involved,
 - b) the nature of any additional tests which have to be carried out on the donor.

N.B. - The purpose of the special regulations in items 9, 10 and 11 above is to safeguard the donor. After being told about the nature of the operation and the risks involved, a statement of informed consent must be signed by the donor. For donors immunised against red cell antigens, a special card should indicate the antibodies and specific details as to the appropriate blood to be used in case the donors need to be transfused.

- 12 - The donor must be protected by adequate insurance against the risks inherent in the donation of blood, plasma or cells, as well as the risks of immunisation.

II. — The Recipient

- 13 - The object of transfusion is to ensure for the recipient the most efficient therapy compatible with maximum safety.
- 14 - Before any transfusion of blood or blood products, a written request, signed by a physician or issued under his responsibility must be made, which specifies the identity of the recipient and the nature and quantity of the substances to be administered.
- 15 - Except for the emergency use of type O blood or red blood cells, every red cell transfusion necessitates preliminary blood grouping tests on the recipient, and compatibility tests between the donor and the recipient.
- 16 - Before administration, one must verify that blood and blood products are correctly identified and that the expiry date has not been passed. The recipient's identity must be verified.
- 17 - The actual transfusion must be given under the responsibility of a physician.
- 18 - In case of a reaction during or after the injection of blood or blood products, appropriate investigations may be required to ascertain the origin of the reaction and to prevent its recurrence. A reaction may require the interruption of the transfusion.
- 19 - Blood and blood products must not be given unless there is a genuine therapeutic need. There must be no financial motivation on the part of either the prescriber or of the establishment where the patient is treated.
- 20 - Whatever their financial resources, all patients must be able to benefit from the administration of human blood or blood products, subject only to their availability.
- 21 - As far as possible the patient should receive only that particular component (cells, plasma, or plasma derivatives) that is needed. To transfuse whole blood into a patient who requires only part of it may deprive other patients of necessary components, and may carry some additional risks to the recipient.
- 22 - Owing to the human origin of blood and to the limited quantities available, it is important to safeguard the interests of both recipient and donor by avoiding abuse or waste.
- 23 - The optimal use of blood and blood products requires regular contact between the physicians who prescribe and those who work in blood transfusion centres.

III. — Controls

- 24 - Appropriate controls should be required by the Health Authorities to verify that blood transfusion practices meet internationally accepted standards and that the guidelines or regulations issued in accordance with this code are effectively respected.
- 25 - The following should be regularly checked:
 - a) the proficiency of the staff,
 - b) the adequacy of the equipment and premises,
 - c) the quality of methods and reagents, source material and finished products.

Annex 2

GLOBAL PROGRAMME ON AIDS

PROGRAMME MONDIAL DE LUTTE CONTRE LE SIDA

Recommendations for the selection and use of HIV antibody tests

Several different types of laboratory test for detecting HIV antibody in human serum exist today. The selection of the most appropriate test or combination of tests to use (i.e., the testing strategy) depends on 3 criteria:

- (1) the objective of the test;
- (2) the sensitivity and specificity of the test(s) being used;
- (3) the prevalence of HIV infection in the population being tested.

Objectives of HIV antibody testing

There are 4 main objectives for which HIV antibody testing is performed:

- (1) *Transfusion/donation safety.* Screening of blood and blood products, and of serum from donors of tissues, organs, sperm or ova.
- (2) *Surveillance.* Unlinked and anonymous testing of serum for the purpose of monitoring the prevalence of, and trends in, HIV infection over time in a given population.
- (3) *Diagnosis of HIV infection.* Voluntary testing of serum from asymptomatic persons or from persons with clinical signs and symptoms suggestive of HIV infection or AIDS.
- (4) *Research.* Voluntary testing of serum from subjects of epidemiological, clinical, virological or other HIV-related studies.

Sensitivity and specificity of antibody tests (Table 1)

Sensitivity and specificity are 2 major factors that determine a test's accuracy in distinguishing between infected and uninfected persons. A test with a high *sensitivity* will have few false-negative results. Therefore, only tests of the highest possible sensitivity should be used when there is a need to minimize the rate of false-negative results (e.g., in transfusion/donation safety). A test with a high *specificity* will have few false-positive results and should be used when there is a need to minimize the rate of false-positive results (e.g., in diagnosis of HIV infection in an individual).

Recommandations concernant le choix et l'utilisation des tests de mise en évidence des anticorps anti-VIH

Il existe maintenant plusieurs types de tests de laboratoire pour la mise en évidence des anticorps anti-VIH dans le sérum humain. Le choix du ou des tests à utiliser, c'est-à-dire de la stratégie de dépistage la plus appropriée, repose sur 3 critères:

- 1) l'objectif du test;
- 2) la sensibilité et la spécificité du ou des tests utilisés;
- 3) la prévalence de l'infection à VIH dans la population testée.

Objectifs du test anti-VIH

La recherche des anticorps anti-VIH sert essentiellement 4 objectifs:

- 1) *Sécurité des transfusions et des dons d'organes.* Dépistage sur le sang et les produits sanguins de même que sur le sérum des donneurs de tissus, d'organes, de sperme et d'ovules.
- 2) *Surveillance.* Dépistage anonyme et banalisé sur le sérum, dans un but de surveillance de la prévalence et des tendances de l'infection à VIH au cours du temps, dans une population donnée.
- 3) *Diagnostic de l'infection à VIH.* Dépistage volontaire sur le sérum de personnes asymptomatiques ou de porteurs de signes cliniques et de symptômes évocateurs de l'infection à VIH ou du SIDA.
- 4) *Recherche.* Dépistage volontaire sur le sérum des personnes recrutées dans les études épidémiologiques, cliniques, virologiques ou autres, relatives au VIH.

Sensibilité et spécificité des tests anti-VIH (Tableau 1)

La sensibilité et la spécificité sont 2 éléments de première importance qui permettent de déterminer l'exactitude avec laquelle un test peut faire la distinction entre personnes infectées et personnes non infectées. Un test dont la *sensibilité* est élevée donne peu de résultats faussement négatifs. Aussi, seuls les tests ayant la sensibilité la plus élevée possible seront-ils utilisés lorsqu'il est nécessaire de réduire au minimum le taux de résultats faussement négatifs (sécurité transfusionnelle/dons d'organes). Un test qui a une *spécificité* élevée donne peu de résultats faussement positifs et ce genre de test sera utilisé lorsqu'il est nécessaire de diminuer le taux de résultats faussement positifs (diagnostic de l'infection à VIH chez une personne donnée).

Table 1 Sensitivity, specificity and predictive value of HIV serological tests

Tableau 1 Sensibilité, spécificité et valeur prédictive des tests sérologiques VIH

		True HIV status – Situation réelle vis-à-vis du VIH		
		+	-	
Test result – Résultats des tests	+	a True-positives – Vrais-positifs	b False-positives – Faux-positifs	a+b
	-	c False-negatives – Faux-négatifs	d True-negatives – Vrais-négatifs	c+d
		a+c	b+d	

Sensitivity = $a/(a+c)$. – Sensibilité = $a/(a+c)$.
 Specificity = $d/(b+d)$. – Spécificité = $d/(b+d)$.
 Positive predictive value = $a/(a+b)$. – Valeur prédictive positive = $a/(a+b)$.
 Negative predictive value = $d/(c+d)$. – Valeur prédictive négative = $d/(c+d)$.

Prevalence of HIV infection

The probability that a test will accurately determine the true infection status of a person being tested varies with the prevalence of HIV infection in the population from which the person comes.

In general, the higher the prevalence of HIV infection in the population, the greater the probability that a person testing positive is truly infected (i.e., the greater the positive predictive value [PPV]). Thus, with increasing prevalence, the proportion of serum samples testing false-positive decreases; conversely, the likelihood that a person showing negative test results is truly uninfected (i.e., the negative predictive value [NPV]) decreases as prevalence increases. Therefore, as prevalence increases, so does the proportion of samples testing false-negative.

Strategies for HIV antibody testing

The PPV is very low when one tests populations of low HIV prevalence, even if one uses a test of high specificity. For this reason a supplemental test is necessary to enhance the PPV. All samples found reactive by the first test are re-tested by a second test based on a different principle and/or a different antigen preparation (see Strategy II below). In some situations a third supplemental test may be considered necessary (see Strategy III).

At present, the most common strategy for HIV antibody testing uses a highly sensitive enzyme-linked immunosorbent assay (ELISA) followed by the Western blot (WB) assay. The ELISA test usually costs only US \$0.75-1.75 per test; and costs are further reduced when tests are bulk-purchased by WHO (Table 2). The WB, however, can cost up to US \$40 per test and still produce indeterminate results of uncertain diagnostic significance. Studies have shown that combinations of ELISA and/or rapid/simple assays such as dot immunoassays and agglutination tests provide results as reliable as, and in some instances more reliable than, the ELISA/WB combination, and at a much lower cost. WHO therefore recommends that countries consider testing strategies for HIV antibody detection which use ELISA and/or rapid/simple assays in place of ELISA/WB.

Recommendations

WHO recommends 3 testing strategies to maximize accuracy while minimizing cost. Which strategy is most appropriate will depend on the objective of the test and the prevalence of HIV in the population, as shown in Table 3.

Prévalence de l'infection à VIH

La probabilité qu'un test rende compte exactement de la situation d'un sujet testé vis-à-vis de la maladie varie avec la prévalence de l'infection à VIH dans la population dont le sujet est issu.

En règle générale, plus la prévalence de l'infection à VIH est élevée dans une population, plus grande est la probabilité que la personne donnée pour positive par le test soit réellement contaminée (la valeur prédictive positive [VPP] est alors élevée). Donc, quand la prévalence augmente, la proportion de résultats faussement positifs parmi les échantillons de sérum testés diminue; réciproquement, la probabilité qu'une personne dont le test est négatif ne soit pas réellement contaminée (c'est-à-dire la valeur prédictive négative [VPN]) diminue quand la prévalence augmente. Par conséquent, quand la prévalence augmente, la proportion d'échantillons donnant un résultat faussement négatif augmente aussi.

Stratégies de mise en évidence des anticorps anti-VIH

La VPP est très faible si l'on teste des populations où la prévalence du VIH est basse, même si le test utilisé a une spécificité élevée. Pour cette raison, et afin d'augmenter la VPP, il faut avoir recours à un test supplémentaire. Tous les échantillons trouvés positifs avec le premier test sont testés à nouveau avec un deuxième test basé sur un principe différent et/ou une préparation antigénique différente (voir plus loin, Stratégie II). Dans certains cas un troisième test supplémentaire peut être nécessaire (voir Stratégie III).

Aujourd'hui, la stratégie de mise en évidence des anticorps anti-VIH la plus couramment appliquée consiste en un titrage immuno-enzymatique (ELISA) ayant une grande sensibilité, suivi d'un test par immunotransfert (Western blot). Le coût des tests ELISA est en général de US \$0,75-1,75, ou moins lorsqu'ils sont achetés en gros par l'OMS (Tableau 2). Le Western blot, lui, coûte jusqu'à US \$40 le test, et donne cependant des résultats indéterminés, dont la signification diagnostique est incertaine. Un certain nombre d'études ont montré que les associations ELISA et/ou autres méthodes rapides/simples telles que les immunotitrages de type «dot» ou les tests d'agglutination, par exemple, donnent des résultats aussi fiables, et dans certains cas plus fiables, que l'association ELISA/Western blot, et qui plus est, pour un coût moins élevé. L'OMS recommande donc que les pays envisagent des stratégies de mise en évidence des anticorps anti-VIH reposant sur l'emploi de l'ELISA et/ou de méthodes rapides/simples, au lieu de l'ELISA/Western blot.

Recommandations

L'OMS recommande 3 stratégies de dépistage destinées à obtenir une exactitude maximale pour un coût minimal. Le choix de la stratégie dépend de l'objectif du dépistage et de la prévalence du VIH dans la population, comme indiqué au Tableau 3.

Table 2 Specifications of HIV test kits bulk-purchased by WHO

Test type Type de test	HIV specificity Spécificité VIH	Price (US\$) Prix (US\$)	Number of manufacturers Nombre de fabricants
Rapid/simple - Rapide/simple	HIV-1 - VIH-1	0.65	1
	HIV-1+2 - VIH-1+2	2.00-2.30	2
ELISA	HIV-1+2 - VIH-1+2	0.70	3
Western blot	HIV-1 - VIH-1	12.40	2
	HIV-2 - VIH-2	13.80	2

Tableau 2 Caractéristiques des tests de dépistage de VIH achetés en gros par l'OMS

Strategy I

All serum is tested with one ELISA or rapid/simple assay. Serum that is reactive is considered HIV antibody positive. Serum that is non-reactive is considered HIV antibody negative.

Strategy II

All serum is first tested with one ELISA or rapid/simple assay. Any serum found reactive on the first assay is re-tested with a second ELISA or rapid/simple assay based on a different antigen preparation and/or different test principle (e.g., indirect versus competitive). Serum that is reactive on both tests is considered HIV antibody positive. Serum that is non-reactive on the first test is considered HIV antibody negative. Any serum that is reactive on the first test but non-reactive on the second test is also considered antibody negative.

Strategy III

As in strategy II, all serum is first tested with one ELISA or rapid/simple assay, and any reactive samples are retested using a different assay. Strategy III, however, requires a third test if serum is found reactive on the second assay. The 3 tests in this strategy should be based on different antigen preparations and/or different test principles. Serum reactive on all 3 tests is considered HIV antibody positive. Serum that is non-reactive on the first test is considered HIV antibody negative as is serum that is reactive in the first test but non-reactive in the second. Serum that is reactive in the first and second tests but non-reactive in the third test is considered to be equivocal (see "Equivocal (borderline) test results" below for further details).

In the selection of HIV antibody tests for use in strategies II and III, the first test should have the highest sensitivity, whereas the second and third tests should have higher specificities than the first.

When diagnosis is the objective, an additional blood sample should be obtained and tested from all persons newly diagnosed as seropositive on the basis of their first sample. This will help eliminate any possible laboratory or clerical error.

For all 3 strategies, it is most important that quality assurance procedures be stringently complied with so as to maximize the accuracy of the laboratory results. Procedures for detecting both laboratory and clerical errors must be included in all protocols. For example, procedures that guarantee the correct identification of initially reactive units of donated blood, which must be discarded, are essential to the maintenance of a safe blood supply.

Any positive test results obtained with testing strategy I must not be used for purposes of diagnosis of HIV infection in an individual. If a blood or tissue donor is to be notified

Stratégie I

Tous les sérums sont testés au moyen d'un ELISA ou d'une méthode rapide/simple. Un sérum donnant une réaction positive avec le test est considéré comme positif pour les anticorps anti-VIH. Un sérum donnant une réaction négative avec le test est considéré comme négatif pour les anticorps anti-VIH.

Stratégie II

Tous les sérums sont d'abord testés avec un ELISA ou un test rapide/simple. Un sérum trouvé positif au premier test est retesté avec un deuxième ELISA ou un deuxième test rapide/simple, basé sur une préparation antigénique différente et/ou un principe différent (par exemple, méthode indirecte contre méthode par compétition). Un sérum trouvé positif avec les 2 tests est considéré comme positif pour les anticorps anti-VIH. Un sérum trouvé négatif à la première épreuve est considéré comme négatif pour les anticorps anti-VIH. Un sérum trouvé positif à la première épreuve mais négatif à la deuxième est également considéré comme négatif pour ces anticorps.

Stratégie III

Comme avec la stratégie II, tous les sérums sont d'abord testés avec un ELISA ou un test rapide/simple, et tout échantillon trouvé positif est retesté avec un test différent. Cependant, la stratégie III fait appel à un troisième test si le sérum est trouvé positif avec le deuxième test. Les 3 tests employés dans cette stratégie doivent utiliser des préparations antigéniques différentes et/ou reposer sur des principes différents. Un sérum trouvé positif avec les 3 tests est considéré comme positif pour les anticorps anti-VIH. Un sérum trouvé négatif avec le premier test est considéré comme négatif pour les anticorps anti-VIH, de même qu'un sérum trouvé positif avec le premier test et négatif avec le second. Un sérum trouvé positif avec le premier et le deuxième test mais négatif avec le troisième test est considéré comme douteux (voir plus loin «Résultats douteux (limites)»).

Le choix des tests de recherche des anticorps anti-VIH utilisés dans les stratégies II et III doit suivre la règle suivante: le premier test doit avoir la sensibilité la plus élevée, tandis que les deuxième et troisième tests doivent avoir une spécificité supérieure à celle du premier test.

Si le but de la recherche des anticorps est le diagnostic, un nouveau prélèvement de sang sera effectué et le test sera répété, chaque fois qu'un diagnostic de séropositivité est établi à partir d'un premier prélèvement. Ce faisant, on essaie d'éliminer une éventuelle erreur de manipulation ou d'écriture.

Quelle que soit la stratégie choisie (I, II, III), il est extrêmement important d'appliquer avec la plus grande rigueur les méthodes de l'assurance de la qualité, afin d'augmenter au maximum l'exactitude des résultats de laboratoire. Les procédures de vérification destinées à repérer les erreurs de manipulation et d'écriture seront incluses dans tous les protocoles. Par exemple, il est indispensable d'appliquer les procédures garantissant l'identification correcte des unités de sang donné trouvées initialement positives, lesquelles doivent être éliminées, pour assurer la sécurité transfusionnelle.

Un résultat positif avec la stratégie de dépistage I ne doit pas être utilisé pour porter un diagnostic d'infection à VIH chez une personne. Si les résultats d'un test pratiqué chez un donneur de sang

of test results, the testing strategies for diagnosis must be used (Table 3). Guidelines for counselling persons regarding HIV testing, infection and disease are available from WHO.

Users should note that differentiation between HIV-1 and HIV-2 infections cannot always be achieved with the currently available antibody tests, even when the 2 types (HIV-1 and HIV-2) of WB are used. WHO is currently undertaking studies aimed at the development and evaluation of testing strategies for differentiation using ELISA and/or rapid/simple assays.

ou d'organe doivent lui être notifiés, on utilisera alors les stratégies de dépistage applicables au diagnostic (Tableau 3). Des directives pour le conseil dans l'infection à VIH et le SIDA sont disponibles auprès de l'OMS.

Les utilisateurs doivent être attentifs au fait que la distinction entre les infections à VIH-1 et à VIH-2 n'est pas toujours possible avec les tests existants pour le dépistage des anticorps, même lorsque les 2 types (VIH-1 et VIH-2) de Western blot sont utilisés. L'OMS a entrepris des études visant à mettre au point et à évaluer des stratégies de dépistage qui permettront cette distinction en utilisant l'ELISA et/ou des méthodes rapides/simples.

Table 3 WHO recommendations for HIV testing strategies according to test objective and prevalence of infection in the population

Objective of testing – Objectif du test	Prevalence of infection Prévalence de l'infection	Testing strategy* Stratégie*	
Transfusion/donation safety – Sécurité des transfusions et des dons d'organes	All prevalences – Toutes prévalences	I	
Surveillance	>10%	I	
	≤10%	II	
Diagnosis – Diagnostic	Clinical signs/symptoms of HIV infection/AIDS – Signes cliniques/symptômes d'infection à VIH/SIDA	All prevalences – Toutes prévalences	II
		>10%	II
	Asymptomatic – Patients asymptomatiques	>10%	II
		≤10%	III

Tableau 3 Recommandations OMS concernant les stratégies de dépistage du VIH en fonction de l'objectif visé et de la prévalence de l'infection dans la population

Objective of testing – Objectif du test	Prevalence of infection Prévalence de l'infection	Testing strategy* Stratégie*	
Transfusion/donation safety – Sécurité des transfusions et des dons d'organes	All prevalences – Toutes prévalences	I	
Surveillance	>10%	I	
	≤10%	II	
Diagnosis – Diagnostic	Clinical signs/symptoms of HIV infection/AIDS – Signes cliniques/symptômes d'infection à VIH/SIDA	All prevalences – Toutes prévalences	II
		>10%	II
	Asymptomatic – Patients asymptomatiques	>10%	II
		≤10%	III

* Strategy I: All samples are tested with one ELISA or rapid/simple test (hereafter referred to as test). – Stratégie I: Tous les prélèvements sont testés avec un ELISA ou un test rapide/simple (désigné ci-après par «test»).
Strategy II: All samples are first tested with one test. Any reactive samples are subjected to a second test based on a different principle and/or a different antigen preparation. – Stratégie II: Tous les prélèvements sont soumis à un premier test. Un prélèvement trouvé positif est soumis à un deuxième test, basé sur un principe différent et/ou sur une préparation antigénique différente.
Strategy III: All samples are first tested with one test. Any reactive samples are retested with a different test. Samples found reactive by the second test are subjected to a third and different test. – Stratégie III: Tous les échantillons sont soumis à un premier test. Un prélèvement trouvé positif est testé à nouveau avec une épreuve différente. Les prélèvements trouvés positifs avec la deuxième épreuve sont testés une troisième fois avec une épreuve différente.

Equivocal (borderline) test results

Serum from persons being tested for the purpose of diagnosis should be retested if the results are equivocal, that is, neither clearly positive nor clearly negative. If the serum again produces equivocal results, testing with WB may be considered, especially for persons from low-prevalence (<1%) populations. A second blood sample should be obtained after a minimum of 2 weeks following the first sample and both should be retested using the appropriate strategy. If the second serum sample also produces an equivocal result, the person is considered to be HIV antibody negative.

Equivocal results obtained for surveillance should be reported and analysed separately.

Units of donated blood yielding equivocal test results must be discarded, as must units found reactive.

HIV antibody tests selected for bulk purchase

WHO has recently begun to bulk-purchase HIV tests in order to provide countries with tests giving the most accurate results at the lowest possible cost.

Table 2 summarizes the specifications and cost of rapid/simple HIV tests, ELISA and WB assays selected by WHO for bulk purchase and available to countries through WHO during 1992. Guidelines on selecting tests for use with the strategies outlined in Table 3 are available from the Diagnostics Unit, Office of Research, Global Programme on AIDS.

Tests other than those bulk-purchased by WHO are also suitable for use with the testing strategies shown in Table 3. Information concerning their selection is available upon request.

Résultats douteux (limites)

Le sérum des personnes testées dans un but diagnostique sera testé à nouveau si les résultats sont ambigus ou limites, c'est-à-dire ni nettement positifs ni nettement négatifs. Si le sérum donne encore des résultats douteux, on envisagera un test par Western blot, notamment quand la personne est issue d'une population où la prévalence est faible (<1%). Un deuxième prélèvement de sang sera pratiqué 2 semaines au moins après le premier, les 2 prélèvements étant retestés suivant la stratégie appropriée. Si le deuxième échantillon de sérum donne également des résultats douteux, le sujet sera considéré comme négatif pour les anticorps anti-VIH.

Quand des résultats douteux sont obtenus dans le cadre de la surveillance, ils seront enregistrés et analysés séparément.

Les dons de sang donnant des résultats douteux au dépistage doivent être éliminés, tout comme ceux trouvés positifs.

Tests de mise en évidence des anticorps anti-VIH sélectionnés pour achat en gros

L'OMS a commencé récemment à acheter en gros des tests de dépistage du VIH, de façon à fournir aux pays les tests qui donnent les résultats les plus exacts pour le prix le plus bas possible.

Le Tableau 2 résume les caractéristiques, coût compris, des tests rapides/simples de dépistage du VIH, de l'ELISA et du Western blot sélectionnés par l'OMS, achetés en gros, et mis à la disposition des pays par l'intermédiaire de l'OMS en 1992. Les directives sur le choix des tests à utiliser avec les stratégies indiquées au Tableau 3 peuvent être obtenues à l'adresse suivante: Unité Diagnostic, Bureau de la Recherche, Programme mondial de lutte contre le SIDA.

Les tests autres que ceux achetés en gros par l'OMS peuvent également être utilisés avec les stratégies du Tableau 3. Des renseignements concernant leur sélection sont disponibles sur demande.

Annex 3

Pre-Donation Counselling Checklist

1. Risk History Assessment

- Nature of sexual activities, frequency and partner numbers
- Injecting drug use and equipment sharing
- Recent illness and symptoms
- Family history of illness
- Blood and blood product transfusions, and invasive procedures (tattooing, scarification)
- Previous blood donations and payments

2. Knowledge of HIV and Other TTIs

- Transmission awareness and understanding
- Previous test requests: when and why
- Personal acquaintance and involvement with people with HIV

3. Donation and Test Information

- Donation procedure explained and understood
- The meaning of and reasons for donor self-deferral, and BTS deferral and referral
- Tests to be employed and why

HIV testing:

- Requires sufficient time since last high-risk behaviour
- Indicates exposure only, not when or how, or prognosis
- Procedures for result-giving clarified and agreed
- Informed consent to donate obtained

4. Psychosocial Factors and Knowledge

- Why is the person donating?
- Any symptoms of concern to the donor?
- Consideration of possible emotional, social, family, work and financial consequences and reactions to being found HIV positive
- Who could provide support to the donor?
- Significance and meaning of positive and of negative test results, including implications for behaviour change and prevention
- Potential for engagement in community-based prevention and support groups