Blood safety and HIV

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UNAIDS *Best Practice* Collection

At a Glance

- Millions of lives are saved each year through blood transfusions. Nevertheless, people have an increased risk of becoming infected with HIV and other infections, such as hepatitis B and hepatitis C, through transfusions of blood and blood products that have not been collected and tested correctly.
- It is estimated that between 5% and 10% of all HIV infections worldwide have been acquired through transfusion of contaminated blood and blood products.
- HIV and other transfusion-transmissible infections (TTIs) can be eliminated or substantially reduced through a blood safety programme which ensures:
  - the establishment of a national blood transfusion service (NBTS), accountable to the government or to a government-appointed non-profit organization, having its own budget and trained staff;
  - recruitment and selection for blood donations from unpaid, voluntary, low-risk donors;
  - the screening of all donated blood for HIV and other TTIs;
  - the appropriate and rational use of blood.
- Donor selection is of the utmost importance. Family replacement and paid or professional donors are more likely to carry TTIs and should be excluded from giving blood.
- Any information obtained during the recruitment and selection of donors—or through screening blood—is strictly confidential. It must never be used as a basis for stigmatization or discrimination in the community.
- It is important to minimize the number of inappropriate blood transfusions so as to reduce the risk of TTIs and other possible adverse reactions from transfusions. People who prescribe and use blood should be trained to avoid unnecessary or inappropriate transfusions.
- The use of blood substitutes, such as crystalloids and colloids, for volume replacement should be encouraged as appropriate. Such substitutes will not transmit infections and are much cheaper than whole blood.
- Preventing the causes of anaemia and blood loss is important. Children, for instance, are often given transfusions for chronic anaemia, a condition that can be caused by malnutrition or malaria. By improving nutritional and health standards, and controlling malaria, the incidence of chronic anaemia—and the consequent number of blood transfusions—can be reduced.

UNAIDS *Best Practice* materials

The Joint United Nations Programme on HIV/AIDS (UNAIDS) is preparing materials on subjects of relevance to HIV infection and AIDS, the causes and consequences of the epidemic, and best practices in AIDS prevention, care and support. A *Best Practice* Collection on any one subject typically includes a short publication for journalists and community leaders (Point of View); a technical summary of the issues, challenges and solutions (Technical Update); case studies from around the world (*Best Practice* Case Studies); a set of presentation graphics; and a listing of key materials (reports, articles, books, audiovisuals, etc.) on the subject. These documents are updated as necessary.

Technical Updates and Points of View are being published in English, French, Russian and Spanish. Single copies of Best Practice materials are available free from UNAIDS Information Centres. To find the closest one, visit UNAIDS on the Internet (http://www.unaids.org), contact UNAIDS by email (unaids@unaids.org) or telephone (+41 22 791 4651), or write to the UNAIDS Information Centre, 20 Avenue Appia, 1211 Geneva 27, Switzerland.

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1. Acquired immunodeficiency syndrome—transmission
1. Acquired immunodeficiency syndrome—prevention and control
2. Blood transfusion

WC 503.3

Background

Millions of lives are saved each year through blood transfusions. Various shortcomings, though, in the way blood is collected, tested (or not tested) for infections such as HIV, and transfused, mean that people in many countries have an increased risk of becoming infected with HIV and other diseases through transfusions. It is estimated that between 5% and 10% of all HIV infections worldwide have been acquired through transfusion of contaminated blood and blood products. If the proper steps are taken, such infections can be easily prevented.

Apart from HIV infection, other diseases can also be transmitted through transfusions of blood or blood products. These include two other viral infections—hepatitis B (HBV) and hepatitis C (HCV); syphilis; malaria, which is endemic in many tropical areas; HTLV-I/II in endemic areas; and Chagas disease, which is common in rural areas of South and Central America.

While 80% of the world's population live in developing countries, people in developing countries are supported by only 20% of the world's blood supply.

In developing countries, most transfusions are given to: women, to treat haemorrhage as a complication of pregnancy; children with severe anaemia; and serious trauma victims.

Each year, up to 4 million blood donations worldwide are not tested for HIV or HBV. Very few donations are tested for HCV.

While in developed countries, whole blood donations are mainly from voluntary unpaid donors, in developing countries 80% of the donated blood comes from paid or replacement donors, who in general are more likely to carry transfusion-transmissible infections (TTIs). As a result, the risk of disease from blood transfusions is much higher in developing countries.

Whole blood and blood products

Whole blood can be separated into blood products which consist of plasma and cellular components (red cells, white cells and platelets). Plasma contains water, electrolytes, proteins and clotting (coagulation) factors—the latter being valuable for certain medical conditions such as haemophilia. Plasma needs to be frozen within 6–8 hours of the collection of whole blood and maintained, frozen solid, at a temperature of –20 °C or colder.

Whole blood and packed red cells must always be stored at a temperature of between +2 °C and +8 °C. If special anticoagulants are used, blood stored at this temperature can be kept for up to 35 days. Platelets must be kept at 20 °C ± 2 °C, and stored no longer than 5 days. Plasma derivatives may be shared internationally, while whole blood and red cells, with a short shelf-life, are usually used nationally.

Screening of blood

The process of testing blood for transfusion-transmissible agents is known as "screening". Implicit in the practice of screening blood for infectious agents is the concept of "good laboratory practice", to ensure correct blood grouping, compatibility of donor and recipient, and all processes leading to the provision of safe and effective blood and blood products.

In the case of HIV, several types of tests—based on different technologies—exist to detect HIV antibodies. Detailed information on the types of HIV tests and testing strategies is available in the UNAIDS Technical Update on *HIV Testing Methods*.

In general, ELISAs are more suitable for blood banks processing daily a large number of blood units, while simple and/or rapid tests are more appropriate for smaller blood banks with a limited number of donations each day. Several simple/rapid tests perform just as well as ELISAs and are also highly appropriate for use in emergency situations.

The test selected for screening donated blood units should preferably be a combined HIV-1/HIV-2 test which is highly sensitive. A test with a high sensitivity will not produce—or will only rarely produce—false-negative results, which is important for safeguarding the blood supply.

HIV infection is most frequently diagnosed by detecting antibodies which the body

produces as it tries to resist the virus. These antibodies usually begin to be produced within 3 to 8 weeks after the time of infection. The period following infection but before the antibodies become detectable is known as the "window period". If a person donates blood during this window period, the usual antibody test may give a false-negative result even though the person is infected. Increasingly sensitive anti-HIV tests have shortened the window period to 21 days.

Tests also exist that detect the virus itself rather than antibodies to it; these are called HIV p24 antigen tests. With a test of this kind it is sometimes possible to detect HIV p24 antigen during the window period, if by coincidence the blood donor happens to be tested during the short peak of high levels of circulating virus particles. Although in theory the HIV antigen test can shorten the window period by an additional 6 days, its use is of limited value and there still remains a window of one to two weeks. (See Bush & Alter, 1995 in the Key Materials.)

Several studies have shown that for minimizing the TTI risk, careful selection of donors is more efficient than HIV antigen testing. In addition, a well-functioning quality assurance programme will reduce the possibility of false-negative results resulting from technical errors. In most settings, HIV p24 antigen testing of the blood supply is not cost-effective and is not recommended by WHO.

Donated blood should be tested not only for HIV but also for syphilis, hepatitis B surface antigen, and—if funds permit—hepatitis C antibodies. According to their geographic prevalence, screening for Chagas disease, HTLV-I/II and other TTIs may also need to be carried out.

Some industrialized countries have suggested ending screening for syphilis because its prevalence in their donor populations is very low and because the agent does not survive if the blood is stored at between +4 °C and +8 °C for at least 72 hours. However, in many countries, blood is stored for only a short time before being transfused. In some of these countries the prevalence of syphilis in blood donors is high. Although syphilis is not a marker for HIV infection, it does indicate donors who have not deferred themselves, yet who are at risk of sexually transmitted diseases, including HIV. Thus the syphilis test serves as a marker of donor suitability.

Units of donated blood yielding reactive or indeterminate test results must be considered as probably infected and must be discarded according to universal safety instructions. If a blood donor is to be notified of a test result, reactive screening results must be confirmed (see WHO/ UNAIDS. Revised recommendations for the selection and use of HIV antibody tests. *Weekly Epidemiological Record,* 1997; **72**,12 (March 21):81–88.

The Challenges

There are three principal factors which contribute to an unsafe blood supply, particularly with regard to HIV and other TTIs.

Lack of safe donors and unsafe blood donations

Paid donors are common in developing countries. They often come from the poorest sectors of society, and may be in poor health, undernourished and at risk of having TTIs. In some places, paid donors sell blood mainly to buy drugs to inject themselves with. This practice—if they share needles and syringes that are not sterilized—is in itself a high-risk activity for contracting HIV and other TTIs.

In addition, paid donors are likely to give blood more often than is recommended. This can be a considerable risk to the donor and will limit the benefit to the recipient.

Another type of donor is the replacement donor, or family replacement donor. In the replacement donor system, families of people needing a transfusion are asked to donate the same quantity as that given to their relative. This blood may be used directly, where compatible, or else placed in the blood bank. The "relatives" giving the blood are often hidden paid donors, and not related at all. Even if they are relatives, the normal criteria for selecting or deferring donors may not be strictly applied, so that the safety of their blood is in doubt.

The safest blood donor is the voluntary, unpaid donor. Such donors give blood out of altruism, and are not under pressure to donate blood. On the whole, they are more likely to meet national criteria for low-risk donors. And they are also more likely to be willing to donate blood on a regular basis and at properly-spaced intervals—subject to donor selection and deferral techniques. This is important for maintaining an adequate stock of safe blood.

Lack of screening

In many developing countries, blood is screened only in the main urban areas.

Lack of screening is most often the result of a lack of funding—because screening is often wrongly perceived as being expensive. Good organization, planning and management are also required, and these are equally difficult to find. Trained staff at all levels are likely to be lacking, as are test kits to screen blood.

Inappropriate testing

Some countries that import blood products wish to test these for HIV and other infectious agents in order to validate the product.

However, this is neither necessary nor advisable. Blood products produced by reputable fractionators can generally be regarded as safe. There are two reasons for this. First, plasma or serum used in the preparation of plasma products will already have been screened before processing. Second, modern inactivation processes—used by all reputable fractionators—destroy HIV. Standard HIV and other antibody tests are designed for screening serum or plasma, not final blood products such as immunoglobulins, albumin and other plasma derivatives. The use of such assays on blood products will often give non-specific false-positive results.

Blood used inappropriately or incorrectly

Transfusions are not always necessary or appropriate. Minimizing unnecessary transfusions reduces the risk of transmitting HIV and other TTIs, especially in places where there is inadequate blood screening. Unnecessary transfusions also create an avoidable shortage in the blood supply—which encourages professional donors to become more active, in turn reducing the safety of the supply.

Create a national blood transfusion service

Creating a national blood transfusion service (NBTS) means making all transfusion centres and blood banks part of a national network, accountable to the government or to a government-appointed non-profit organization. Such a service should be developed within the framework of the country's health care infrastructure.

There should be a national policy and plan for the NBTS, with the proper legislative and regulatory control and an adequate financial budget. The NBTS should be recognized as a clearly identified unit of the health care system (separate from general laboratory systems) and have its own budget and trained staff. Important steps in setting up a NBTS include the following:

- obtain formal government commitment and support;
- develop a national blood policy and plan;
- identify an appropriate organization for the NBTS;
- appoint an executive committee and a chief medical officer for the NBTS, as well as—where necessary—an advisory committee of medical specialists;
- select and train staff with organizational, management, medical and technical skills;
- draw up a budget, and develop an appropriate financing system to make the blood programme sustainable;
- develop and implement a quality management system;
- develop and implement monitoring and evaluation systems for the service.

The NBTS can be financed either through an annual government allocation or through a cost-recovery fee. The cost-recovery fee is a charge for services to supply blood. It is paid by hospitals and other institutions using blood, and agreed upon in annual negotiations involving the government, hospital administrators and the blood transfusion service. The charge is intended to cover capital and recurrent cost items—such as buildings, salaries and test kits. The blood or blood product itself should always ideally be free for those receiving transfusions, or else paid for through government allocations or a health insurance scheme.

Educate, motivate, recruit and retain low-risk donors

Systems that use family replacement and paid blood donors are more likely to transmit TTIs. As a first step, paid donations should be prohibited and family replacement donors should be phased out. However, it is not always easy to change these practices. Consideration should be given to methods to detect and refuse paid donors, who will often persist in evading rules prohibiting them. Some form of identification system may thus be required.

Good donor selection is an important part of the process of collecting blood. When donors present themselves at blood donation centres they need to be interviewed by trained staff, so that those who appear to have a high risk of being infected, or appear to be paid donors, are excluded. Potential donors whose poor health or nutritional status makes them unsuitable should also be excluded, for the sake of their own health as well as the health of the recipients.

Educating people about the importance and responsibility of being a blood donor is essential so that prospective donors can make the correct decisions to donate, to *self-exclude*, or to *self-defer*. Self-exclusion means excluding themselves if they know or think that their blood may be unsafe as a result of risk behaviour, or because of the state of their own health. Self-deferral is postponing blood donation if there are temporary reasons for doing so.

Some donors may be unwilling to self-exclude or self-defer—even if they know that their blood may be unsafe. There may be peer group pressure on them to give blood, and they may not want others to know why they are unwilling to give blood. For this reason, it is important to give all donors an opportunity to tell clinic staff—*in the strictest confidence*—about their concerns. In cases where the clinic staff feel that a donor is unsuitable, they must have a mechanism to remove

and dispose of the unit of blood after donation. This is called "confidential unit exclusion" (CUE).

Educating the public, motivating and recruiting them, and retaining them as donors who give blood regularly are all necessary. The ability to do these effectively will depend on a well-staffed and well-funded blood donor recruitment unit, trained in dealing with mass media and in communication skills. Among other things, a blood donor recruitment team should do the following:

- write and produce educational materials for blood donors;
- plan and carry out educational campaigns—in workplaces, schools and colleges—to motivate, recruit and retain donors;
- set up a blood donor registry system;
- work out procedures for donor selection and deferral, as well as for donor notification;
- design mechanisms to retain donors (such as donor clubs);
- prepare guidelines and standard operating procedures, including procedures to ensure strict confidentiality for donors;
- train staff in counselling techniques and the ability to select donors;
- set up links with other health facilities to refer donors, where necessary.

Screen all donated blood

It is important that blood transfusion services move as rapidly as possible towards screening all blood. The tests should include at least HIV, HBV and syphilis—and other TTIs as determined according to the prevalence and epidemiological risk. National guidelines should be developed and implemented for screening all blood donations using the most appropriate and effective testing strategies for each type of infection (see UNAIDS Technical Update, *HIV Testing Methods*). Items to be considered here include:

- the development of standard operating procedures and guidelines for screening, testing strategies, and a quality assurance programme;
- training of NBTS technical staff;
- the purchase, supply, storage and distribution of reagents and other materials used in testing, so as to ensure continuous testing.

Reduce unnecessary blood transfusions

It is important to minimize the number of inappropriate blood transfusions so as to reduce the risk of TTIs as well as other possible adverse reactions from transfusions. The following activities should be considered:

- developing a national standard operating procedure and national guidelines or indicators for giving transfusions;
- training people who prescribe blood to avoid unnecessary or inappropriate transfusions;
- ensuring accessibility and availability of blood substitutes for volume replacement, such as crystalloids and colloids, for use where appropriate; these will not transmit infections and can be obtained at a fraction of the cost of whole blood.

Preventing the causes that lead to individuals requiring blood transfusions will not only save unnecessary transfusions and reduce transmission of TTIs, but will improve health in the long term. Blood transfusions—often given for chronic anaemia—are unnecessary if the underlying condition is treated and the patient given corrective therapy. Preventing diseases such as malaria and worm infestations, and raising health standards generally, are important measures to reduce unnecessary transfusions. Similarly, proper care for women before, during and after delivery, will greatly reduce blood loss and in turn reduce the need for transfusions.

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Key Materials

Aide-Memoire for National Blood/ AIDS/STD Programmes. Aide-Memoire, WHO, Blood Safety Unit & Global Programme on AIDS. Version 1.6, November 1995. Useful checklist of key elements required to ensure blood safety.

Safe blood and blood products. Distance Learning Materials 1993. Five modules (647 pages) + 4 cards. WHO/GPA/CNP/93.2A–E. The five modules cover: guidelines and principles for safe blood transfusion practice; safe blood donation; screening for HIV and other infectious agents; blood group serology; trainer's guide. Each module is divided into sections. Each section contains specific learning objectives, summary ofinformation provided, and progress check allowing students to assess if objectives for section have been achieved.

Global Blood Safety Initiative. *Consensus statement on how toachieve a safe and adequate blood supply by recruitment andretention of voluntary, non-remunerated blood donors*. Geneva, 8–11 April 1991. Geneva: WHO, 1993. WHO/ LBS/ 93.2. Provides recommendations to help countries establish and maintain safe and adequate blood supplies. Guidelines are provided on: establishment of blood donor programmes and definition of responsibilities; influencing community beliefs and attitudes about blood donation; selection and retention of blood donors; staff selection and training; evaluation of blood donor programmes, including suggested indicators for monitoring.

Guidelines for Blood Donor Counselling on Human Immuno-deficiency Virus (HIV). WHO/GPA/ TCO/HCS/94.2. International Federation of Red Cross and Red Crescent Societies, World Health Organization, Geneva, 1994. Explores aims and stages of blood donor information and counselling; process of counselling; and resource requirements and implications of counselling. Complementary activities and structures for enabling blood donor counselling—such as coordination with other parts of the health care system, and volunteer recruitment—are also reviewed.

Consensus statement on screening of blood donations for infectious agents transmissible through blood transfusion, Geneva, 30 January to 1 February 1990. WHO/LBS/ 91.1. Guidelines for formulating and implementing appropriate screening policies to reduce risk of transmission of infectious agents by blood and blood products.

Schreiber GB, Busch M *et al*. The risk of transfusion-transmitted viral infections. *New England Journal of Medicine*, 1996; **334**, (26):1685–1690: Estimates risks for transmitting HIV, HBV, HCV and HTLV from screened blood units donated during window period.

Bush M, Alter H. Will human immunodeficiency virus p24 antigen screening increase the safety of the blood supply, and if so at what cost? *Transfusion*, 1995; **35**:536–539. Review of studies investigating costs and benefits of p24 antigen screening.

Issues discussed include high cost per transmission prevented and workload considerations.

Guidelines for Quality Assurance Programmes for Blood Transfusion Services. Geneva: WHO, 1993; 50 pp. ISBN 92 4 154448 1, SwFr 12.– (developing countries SwFr 8,40) Explores various aspects of quality assurance in the context of BTSs. Topics covered include: importance of documentation; preparation and implementation of standard operating procedures; donor selection and retention; laboratory aspects, including storage and transport of blood and blood components; quality and medical audits; and role of management in quality assurance. Chapter on blood collection includes component collection by apheresis, and special considerations in relation to autologous blood collections.

Guidelines for organizing national external quality assessment schemes for HIV serological testing. Geneva: WHO, 1996. WHO/UNAIDS/96.5.

Global Blood Safety Initiative. *Guidelines for the appropriate use of blood*. Geneva: WHO, 1989. WHO/LAB/89.10. Discusses appropriateness of using blood products in following cases: haemorrhage, burns, surgery, anaemia, hereditary haemolytic anaemia, neonatal disorders, pregnancy, and disorders of haemostasis. Guidelines for quality assurance and strategies for implementation of national guidelines also provided.