THE BLOOD DONOR AND TESTS ON DONOR BLOOD

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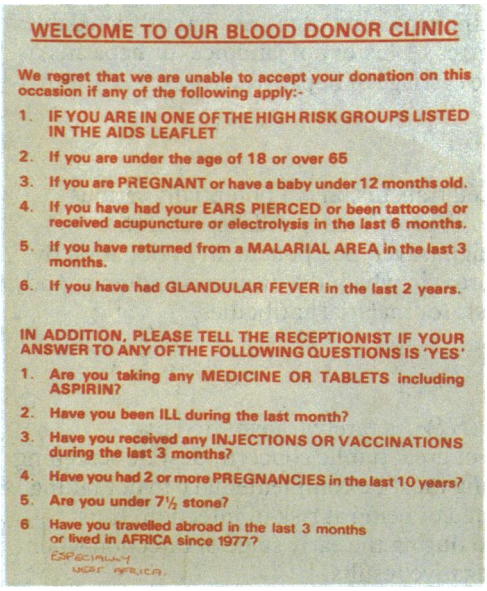
The blood donor



WELCOME TO OUR BLOOD DONOR CLINIC

We regret that we are unable to accept your donation on this occasion if any of the following apply:-

1. IF YOU ARE IN ONE OF THE HIGH RISK GROUPS LISTED IN THE AIDS LEAFLET
2. If you are under the age of 18 or over 65
3. If you are PREGNANT or have a baby under 12 months old.
4. If you have had your EARS PIERCED or been tattooed or received acupuncture or electrolysis in the last 6 months.
5. If you have returned from a MALARIAL AREA in the last 3 months.
6. If you have had GLANDULAR FEVER in the last 2 years.

IN ADDITION, PLEASE TELL THE RECEPTIONIST IF YOUR ANSWER TO ANY OF THE FOLLOWING QUESTIONS IS 'YES'

1. Are you taking any MEDICINE OR TABLETS including ASPIRIN?
2. Have you been ILL during the last month?
3. Have you received any INJECTIONS OR VACCINATIONS during the last 3 months?
4. Have you had 2 or more PREGNANCIES in the last 10 years?
5. Are you under 7½ stone?
6. Have you travelled abroad in the last 3 months or lived in AFRICA since 1977?

ESPECIALLY WEST AFRICA.

Information notice for potential donors, highlighting important exclusions.

All "fresh" blood components and manufactured blood products originate with blood donors, so the safety of blood transfusion begins with careful selection of donors.

To protect both donor and recipient from any ill effects donors should be:

- In good health
- Unpaid volunteers, as payment could encourage concealment of relevant medical history or personal behaviour.

A full medical examination cannot be performed on every volunteer; much reliance is therefore placed on answers to questions about general health, medical history, and drugs being taken. Simple visual assessment of the individual person, and selected laboratory tests of blood samples, are also carried out to try to ensure the safety of the donation. Several other factors concern the health and wellbeing of the donor.

Bottles of copper sulphate solution corresponding to haemoglobin concentrations of 125 g/l (blue) and 135 g/l (green).

- *Age*—The lower limit (18 years) takes account of the high iron requirements of adolescence, and the age of consent. An upper limit was arbitrarily set at 65 because of the increasing incidence of cardiovascular and cerebrovascular disease with age, which may make the removal of 450 ml of blood dangerous. First time donors, who have an increased incidence of ill effects, are not accepted after the age of 60; established donors may now be permitted to continue beyond 65.

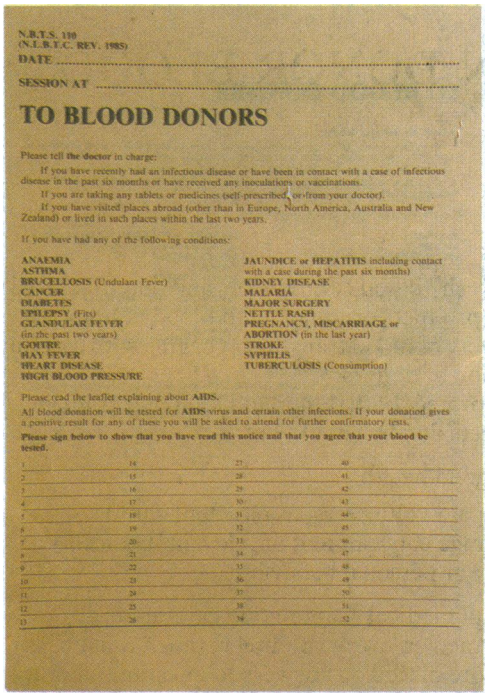
- *Frequency of donations* is normally two or three times a year. Women of childbearing age are especially liable to iron depletion; many men can donate more frequently without such an ill effect. Estimation of the haemoglobin concentration before donation (usually by a simple technique based on the specific gravity of a drop of blood introduced into a solution of copper sulphate) is designed to detect those subjects with established or borderline iron depletion. The acceptable minimum concentrations are 135 g/l for men and 125 g/l for women.

Standard 450 ml blood collection pack (left) and 250 ml blood collection pack (right).

- *Volume of donation* should not be more than 13% of the estimated blood volume to protect against vasovagal attacks. As collection bags are designed to contain between 405 and 495 (average 450) ml of blood, a minimum body weight of 47 to 50 kg is set unless a smaller donation may be taken into an appropriate pack.

- *Likelihood of ill effects during or after donation*—Some first time donors faint. Contributory factors such as anxiety, hot weather, and a previous history of fainting should be taken into account. Though such a faint is usually uncomplicated, the donor may have some ill effects—for instance, when it is delayed and the donor has left the care of the staff. A severe faint is a contraindication to future donation.

The recipient



N.B.T.S. 110
(N.I.B.T.C. REV. 1985)

DATE .....

SESSION AT .....

TO BLOOD DONORS

Please tell **the doctor** in charge:

If you have recently had an infectious disease or have been in contact with a case of infectious disease in the past six months or have received any inoculations or vaccinations.

If you are taking any tablets or medicines (self-prescribed or from your doctor).

If you have visited places abroad (other than in Europe, North America, Australia and New Zealand) or lived in such places within the last two years.

If you have had any of the following conditions:

ANAEMIA
ASTHMA
BRUCELLOSIS (Undulant Fever)
CANCER
DIABETES
EPILEPSY (Fits)
GLANDULAR FEVER (in the past two years)
GOITRE
HAY FEVER
HEART DISEASE
HIGH BLOOD PRESSURE
JAUNDICE or HEPATITIS including contact with a case during the past six months)
KIDNEY DISEASE
MALARIA
MAJOR SURGERY
NETTLE RASH
PREGNANCY, MISCARRIAGE or ABORTION (in the last year)
STROKE
SYPHILIS
TUBERCULOSIS (Consumption)

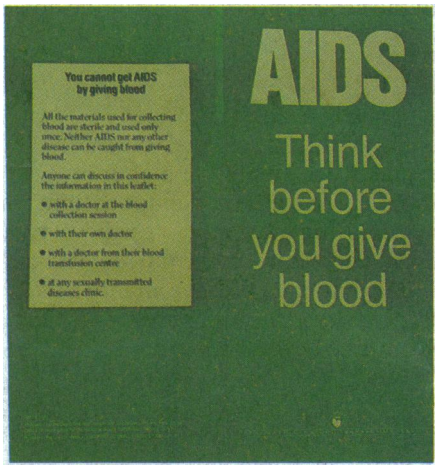
Please read the leaflet explaining about **AIDS**.

All blood donation will be tested for **AIDS** virus and certain other infections. If your donation gives a positive result for any of these you will be asked to attend for further confirmatory tests.

Please sign below to show that you have read this notice and that you agree that your blood be tested.

1	14	27	40
2	15	28	41
3	16	29	42
4	17	30	43
5	18	31	44
6	19	32	45
7	20	33	46
8	21	34	47
9	22	35	48
10	23	36	49
11	24	37	50
12	25	38	51
13	26	39	52

Notice to blood donors, which all individuals read and sign before giving blood.



You cannot get AIDS by giving blood

All the materials used for collecting blood are sterile and used only once. Neither AIDS nor any other disease can be caught from giving blood.

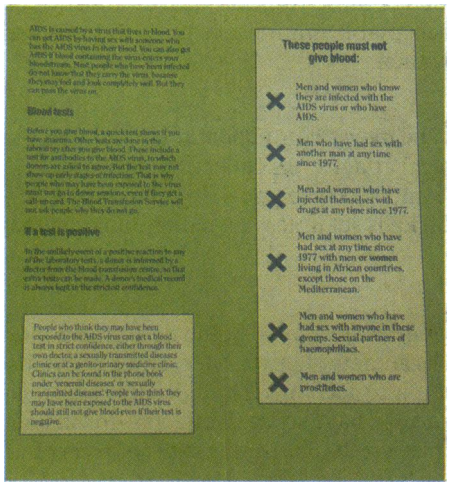
Anyone can discuss in confidence the information in this leaflet:

- with a doctor at the blood collection session
- with their own doctor
- with a doctor from their blood transfusion centre
- at any sexually transmitted diseases clinic.

AIDS

Think before you give blood

AIDS information leaflet, given to all potential donors to read before donation.



Blood tests

If a test is positive

People who think they may have been exposed to the AIDS virus can get a blood test in strict confidence, either through their own doctor, a sexually transmitted diseases clinic or at a genito-urinary medicine clinic. Clinics can be found in the phone book under 'venereal diseases' or 'sexually transmitted diseases'. People who think they may have been exposed to the AIDS virus should still not give blood even if their test is negative.

These people must not give blood:

- Men and women who know they are infected with the AIDS virus or who have AIDS.
- Men who have had sex with another man at any time since 1977.
- Men and women who have injected themselves with drugs at any time since 1977.
- Men and women who have had sex at any time since 1977 with men or women living in African countries, except those on the Mediterranean.
- Men and women who have had sex with anyone in these groups. Sexual partners of haemophiliacs.
- Men and women who are prostitutes.

The most important consideration is avoidance of transmission of infective agents, usually by a combination of strict criteria for the selection of donors and the use of laboratory screening tests.

- *Hepatitis*—Hepatitis A is not a disease associated with transfusion. Tests for hepatitis B surface antigen (HBsAg) are always done. Non-A, non-B hepatitis is now the most common potentially serious infective complication of blood transfusion, but no specific screening tests are currently available for routine use in transfusion centres. A history of jaundice (or hepatitis) is not a reliable indicator of possible carriage of hepatitis viruses.

- *Malaria* transmission by red cell transfusion is a potentially serious problem in the United Kingdom. Prevention depends on careful questioning of donors about foreign travel, postponement of donation by those who have recently visited areas in which the disease is endemic, and, in some cases, immunological tests for malarial antibodies.

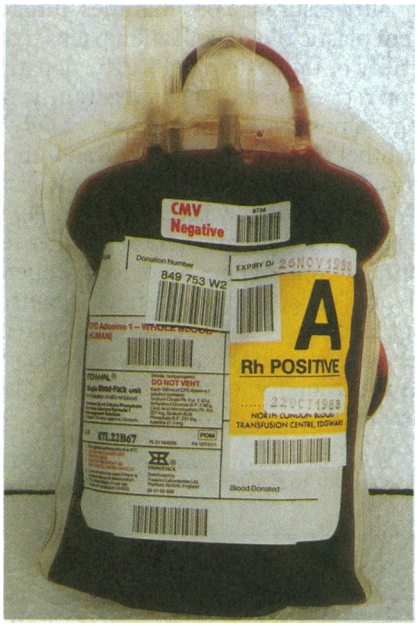
- *Human immunodeficiency virus (HIV)* is rarely transmitted by transfusion but remains a source of great public concern, despite screening of all donations since 1985. Testing must be complementary to not taking blood from those who are suspected of being at risk of infection, thus avoiding the use of blood donated during the early stage of infection when laboratory screening tests give negative results.

- *Syphilis* poses a theoretical rather than a practical problem, and donors are not questioned specifically about previous infection. Routine screening of blood donations continues to be carried out, though it is probably more useful for the detection of subjects at risk of any sexually transmitted infections (including HIV) than in the prevention of the transmission of syphilis.

- *Other infective agents* may be a hazard for specific recipients—for example, cytomegalovirus in immunosuppressed patients. Selective screening of donations before transfusion is indicated, as medical history is of no help in selecting "safe" donors.

- *Drugs and other illnesses*—Drugs present in the donor's bloodstream may adversely affect a recipient. The taking of any drug could indicate underlying illness, which in itself is reason to exclude the donor. Patients with chronic diseases and illnesses of unknown aetiology should not give blood. Malignancy is also a contraindication, though exceptions may be made in the case of locally invasive lesions that have been fully treated and have not recurred after adequate follow up (for example, rodent ulcers or carcinomas in situ of the cervix).

Many people who consider themselves in good health present as potential blood donors, yet a current or past illness may suggest that a donation could be inadvisable. It is often difficult to reconcile the constant need for blood, the paramount importance of the safety of donor and recipient, and the need not to worry or upset the volunteer by refusing his offer unnecessarily. Ultimately decisions are based on considerations of safety, always erring on the side of caution.



Units of red cells and platelets found negative for antibodies to cytomegalovirus and therefore suitable for transfusion to immunosuppressed recipients are specially labelled.

Serological tests

- ABO typing
- Rh D typing
- Rh C and E typing
- Screen for antibodies to red cell antigens
- HLA typing

Tests for agents of transfusion transmitted disease

Screening of all donations for HBsAg and antibodies to HIV and *Treponema pallidum* is routine. In addition selective screening for antibodies to cytomegalovirus is carried out to obtain both donations that do not contain antibodies (for transfusion to immunocompromised patients) and plasma with a high titre of antibody for the production of specific immunoglobulin. This regimen is discussed in the chapters on infectious complications of blood transfusion.

Microbiological testing might also include selective screening for high titre antitetanus antibodies to obtain plasma to act as a source of specific antitetanus immunoglobulin. Direct transfusion of donations containing these antibodies carries no risk to the recipient.

Other tests carried out on blood and its components

- *Serological tests* to ascertain the blood group (A, B, or O) and for Rh D typing are carried out on all donations, the result being checked against results previously obtained from that donor or by repeat typing with different batches of antisera and test cells. Most centres also test for the Rh C and E antigens—only donations negative for C, D, and E may be labelled *Rh negative*; those tested only for the D antigen and found negative should be labelled *Rh (D) negative*. With the typing sera in current use, especially the monoclonal sort—most weak and variant forms of the D antigen are detected on direct testing. Those below the limit of detection with monoclonal anti-D are not considered to be immunogenic to a D negative recipient, and extended testing to detect—for example, D^u in donors—is not universally carried out.

Screening of donations for antibodies to red cell antigens is designed to pick up antibodies that are clinically important. Any donation found to have a high antibody titre should not be used therapeutically, though it may be a valuable source of red cell typing serum. Detection of low titres of antibodies does not automatically exclude a donation from therapeutic use, as (*a*) the antibody would be further diluted on direct transfusion and (*b*) the plasma from most donations is removed and incorporated into a pool for fractionation. Any residual antibody entrapped in the original donation is further diluted before direct transfusion by resuspension of the cells in an additive solution such as saline adenine glucose mannitol (SAG-M). The comparatively unrefined antibody screening that is possible on automated blood grouping machines or with simple enzyme assays is therefore acceptable in the testing of blood donations, though it is not so in the screening for antibodies of samples from potential recipients.

Testing of group O blood for high titre haemolytic anti-A and anti-B is still carried out in some centres. This practice should not be allowed to override the principle that a patient should receive blood of his own group, and that group O donor blood should not be given to patients of other groups except in an emergency.

Typing for histocompatibility locus antigens (HLA) is increasingly being carried out on selected donors as the demand for HLA matched platelets escalates. Such platelets would be used in the treatment of a haemorrhagic, thrombocytopenic patient who, because of many exposures to blood components, has developed multispecific antibodies to the HLA series of antigens and has become refractory to random platelet treatment.

- *Quality assurance testing* in the transfusion centre is directed towards the issue of safe and effective blood and blood components. Unlike conventional pharmaceutical products and the products of physicochemical fractionation of pools of donor plasma, it is impossible to carry out within the transfusion centres themselves truly representative sampling of batches of donor blood or of the components derived from it. Each unit of blood, red cells, platelets, cryoprecipitate, and fresh frozen plasma is a batch in itself, and this must be recognised in the determination of type and frequency of the control test to be carried out. For example, the volume of a unit of cryoprecipitate can easily be estimated by an experienced eye during production, and this would therefore represent a control test on all units. Conversely, estimation of the factor VIIIc content of cryoprecipitate represents destructive testing of the unit and so this estimation will be

Quality assurance testing

- Whole blood—volume
- Red cell concentrates—volume and packed cell volume
- Red cells in additive solutions—volume and packed cell volume
- Leucocyte poor blood—residual leucocytes
- Platelet concentrates—volume, platelet count, residual leucocytes, pH
- Fresh frozen plasma—volume, factor VIIIc content
- Cryoprecipitate—volume, factor VIII content
- Sterility testing (selective)

carried out randomly and will take into account the amount of the component being used and its possible deterioration during storage. This type of consideration is given to each component prepared in the transfusion centre in the design of the overall programme of quality assurance testing.

Testing of blood and its mechanically derived components for sterility remains a problem. Monitored quality assurance programmes initiated by manufacturers of the closed system plastic blood collection packs that are normally used should ensure sterility of the system before the donation is introduced. Because each donation represents a batch in itself, little may be gained by random sterility testing—a positive result would normally give no information on the state of the other donations in stock. Random testing may, however, give some security about the integrity of the pack system during the processing of blood. Validation of new procedures and of new equipment will obviously include a planned programme of sterility testing, as will the routine quality assurance of components prepared by open procedures—for example, washed red cells. The best defence against transfusion of an infected unit of blood (or one of its components) remains meticulous monitoring of storage and transport conditions, together with a visual check of all packs before transfusion for leakage (through splits or pinholes) and for haemolysis, discoloration, or clotting.

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Style Matters

Statements from the Vancouver Group

International Committee of Medical Journal Editors

The following statements were agreed by the International Committee of Medical Journal Editors at its 1989 meeting in Philadelphia.

Confidentiality

Manuscripts should be reviewed with due respect for authors' confidentiality. In submitting their manuscripts for review authors entrust editors with the results of their scientific labour and creative effort, upon which their reputation and career may depend. Authors' rights may be violated by disclosure of their ideas before publication or by revelation of the confidential details of the review of their manuscript. Reviewers also have rights to confidentiality, which must be respected by the editor. Confidentiality may have to be breached if there are allegations of dishonesty or fraud but otherwise must be honoured.

Editors should not disclose information about manuscripts, including their receipt, their content, their status in the reviewing process, their criticism by reviewers, or their ultimate fate. Such information should be provided only to authors themselves and reviewers.

Editors should make clear to their reviewers that manuscripts sent for review are privileged communications and are the private property of the authors. Therefore, reviewers and members of the editorial staff should respect the authors' rights by not publicly discussing the authors' work or appropriating their ideas before the manuscript is published. Reviewers should not be allowed to make copies of the manuscript for their files and should be prohibited from sharing it with others, except with the permission of the editor. Editors should not keep copies of rejected manuscripts.

Opinions differ on the anonymity of reviewers. Some editors of biomedical journals require their reviewers to sign the comments returned to authors, but most either request that reviewers' comments not be signed or leave that choice to the reviewer. When comments are not signed the reviewer's identity must not be revealed to the author or anyone else.

Some journals publish reviewers' comments with the manuscript. No such procedure should be adopted without the consent of the authors and reviewers. However, reviewers' comments may be sent to other reviewers of the same manuscript, and reviewers may be notified of the editor's decision.

The role of the correspondence column

All biomedical journals should have a section carrying comments, questions, or criticisms about articles they have published and where the original authors can respond. Usually, but not necessarily, this may take the form of a correspondence column. The lack of such a section denies readers the possibility of responding to articles in the same journal that published the original work.

Competing manuscripts based on the same study

The following statement has been issued as a discussion document. The committee would welcome debate and comment about the statement and may revise it in the light of comments received.

Editors may receive manuscripts from different authors offering competing interpretations of the same study. They have to decide whether to review competing manuscripts submitted to them more or less simultaneously by different groups of authors, or they

Members of the committee are Lois Ann Colaianni (*Index Medicus*), Edward J Huth (*Annals of Internal Medicine*), Kathleen King (*Medical Journal of Australia*), Stephen Lock (*British Medical Journal*), George D Lundberg (*Journal of the American Medical Association*), Magne Nylenna (*Tidsskrift for den Norske Laegeforening*), Gordon Reeves (*Lancet*), Arnold S Relman (*New England Journal of Medicine*), Povl Riis (*Journal of the Danish Medical Association, Danish Medical Bulletin*), Richard G Robinson (*New Zealand Medical Journal*), Bruce P Squires (*Canadian Medical Association Journal*), Ilkka Vartiovaara (*Finnish Medical Journal*), Malcolm S M Watts (*Western Journal of Medicine*).

Correspondence to: Dr E J Huth or Dr S Lock.

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