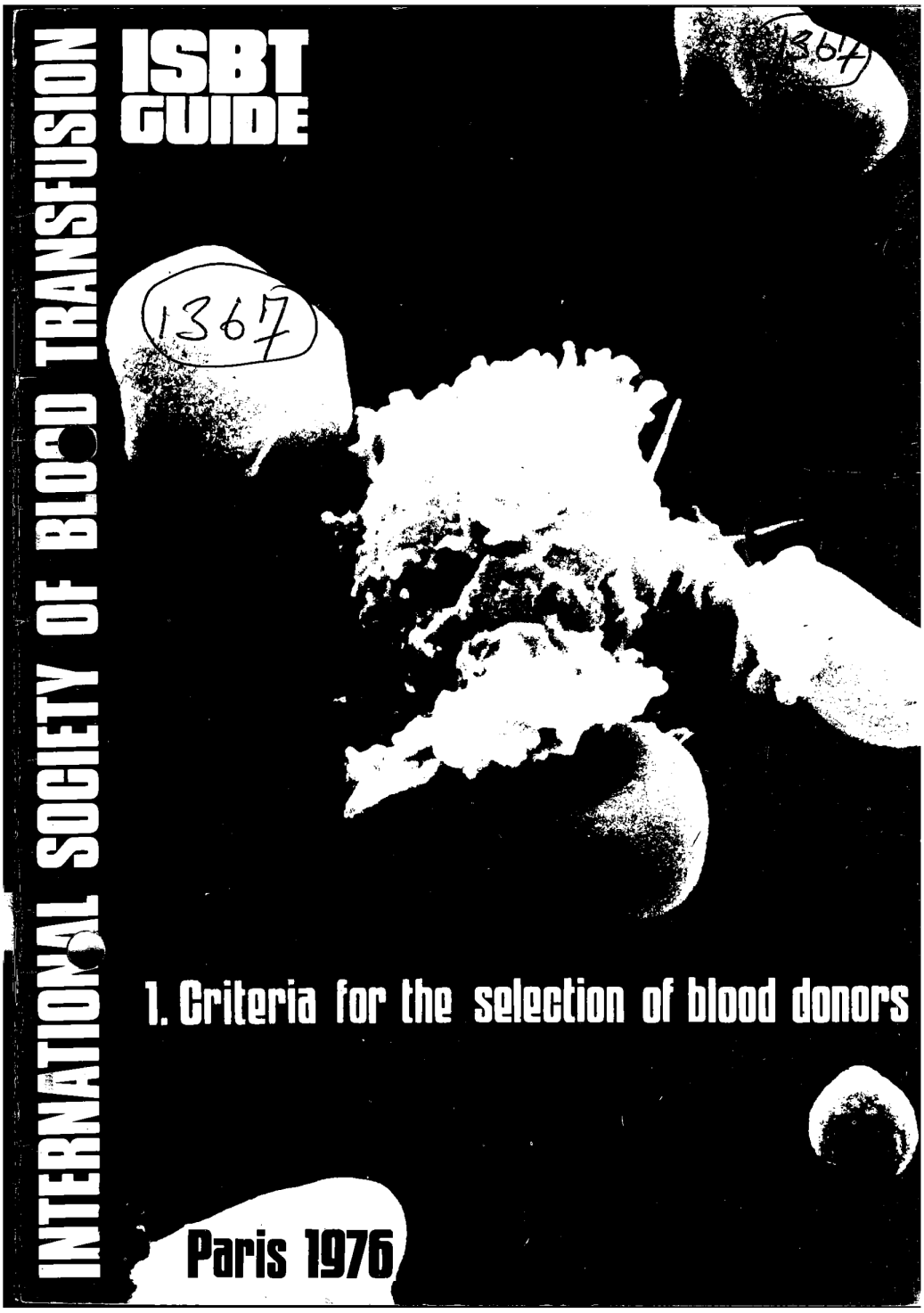

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ISBT GUIDE

1. Criteria for the selection of blood donors

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The electron micrograph of the cover was made by Professor Peter Biberfeldt, Stockholm, and shows a monocyte phagocytosing antibody-coated red cells; lay-out by Suzanne Öhman.

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LIST OF SUBJECTS

The non-remunerated blood donor is the essential element around which every blood transfusion service is shaped. None should join this select group whose blood may transmit disease to his fellows, or whose health may suffer as a result of his generosity. The necessary guidelines to ensure this state of affairs depend partly upon what infections are endemic and upon the average build and education of the population in the geographic area covered by the transfusion service, and partly upon the resources available to interview and examine prospective donors.

EXAMINATION OF THE DONOR

The aim donor examination is to determine whether the donor is in "good health". Its scope will naturally vary from country to country: the donor may be asked only to complete a questionnaire, or he may have to submit to a physical examination as well. A questionnaire, such as those in Tables I and II, is widely used; it may either form part of the donor's permanent record, or it may be used only as the basis for entries on a permanent registration sheet and for interrogation by nurse or physician. During the interview, the general demeanour of the donor, i.e. whether excited or nervous, should be noted. At this point, in some countries, it is customary to take the pulse rate and to measure the systolic and diastolic blood pressures. The pulse rate should be between 50 and 110 and regular, the diastolic pressure 50–110 mm Hg, and the systolic pressure 100 to 200 mm Hg. Pressures outside these limits or an abnormal diastolic/systolic ratio should be considered a cause for disqualification.

For haemoglobin determination see p. 14.

Table I
SAMPLE DONOR SELECTION FORM

These questions must be answered before you donate in order to protect both yourself and the eventual recipient of your blood. If you need help, the Registered Nurse will gladly assist you.

Age ..... Height ..... Weight .....

1. Is this your first donation?	Yes ☐	No ☐
2. Do you feel in good health?	Yes ☐	No ☐
3. Have you been ill in the last six months?	Yes ☐	No ☐
4. Have you been under the care of a physician during the last year?	Yes ☐	No ☐
5. Have you ever had hepatitis (yellow jaundice)?	Yes ☐	No ☐
6. Have you ever had malaria?	Yes ☐	No ☐
7. Have you been vaccinated or received any injection in the last twelve months?	Yes ☐	No ☐
8. Have you received a transfusion in the last year?	Yes ☐	No ☐
9. Have you had a cold or sore throat in the past week?	Yes ☐	No ☐
10. Do you suffer from any allergic condition (Hay-fever, asthma, etc.)?	Yes ☐	No ☐
11. Do you have, or have you ever had, heart disease or high blood pressure?	Yes ☐	No ☐
12. Have you ever had cancer?	Yes ☐	No ☐
13. Are you presently taking any medication or drugs of any kind?	Yes ☐	No ☐
14. Have you been tattooed, had your ears pierced, or experienced acupuncture within the last six months?	Yes ☐	No ☐
15. Have you travelled abroad in the past three years?	Yes ☐	No ☐
16. Are you pregnant, or have you had a baby in the last six months?	Yes ☐	No ☐

Table II
SAMPLE DONOR SELECTION FORM

Have you *ever* suffered from:	No	Yes	
Jaundice	☐	☐	When? .....
Syphilis	☐	☐	
Malaria	☐	☐	
Tuberculosis	☐	☐	
Rheumatoid arthritis	☐	☐	
Heart disease	☐	☐	
pain over the heart	☐	☐	
High blood pressure	☐	☐	
Convulsions as adult	☐	☐	
Fainting as adult	☐	☐	
Stomach diseases	☐	☐	
espec. stomach ulcer	☐	☐	
operation on stomach	☐	☐	
Renal diseases	☐	☐	
Diabetes	☐	☐	
Allergy	☐	☐	
Anaemia	☐	☐	
Malignant tumors	☐	☐	
Any other disease	☐	☐	
Have you *within the last twelve months:*			
Been ill	☐	☐	When? Which disease?
Been pregnant	☐	☐	When terminated?
Been tattooed, had your ears pierced, or experienced acupuncture	☐	☐	
Received a transfusion	☐	☐	
Been vaccinated	☐	☐	Which? .....
Within the last month, have you:			
Taken any medication or drugs	☐	☐	Which? .....
Have you previously *given blood* ...	☐	☐	
Do you believe that you are presently in good health	☐	☐	

Within the last three years, what other countries have you visited? .....

IS THE DONOR IN "GOOD HEALTH"?

Some very general concepts are given below. Regulations in individual countries may be more stringent; if that is the case, then, of course, such regulations must be followed.

1. Surgery, serious injury, or pregnancy

Donors who have undergone major surgery or had a serious injury during the last six months should be deferred for a period to be decided by the physician in charge. Simpler surgical operations such as those for hernia, haemorrhoids, appendicitis, etc. should be a cause for deferment until at least three months after the operation. (If the donor received non-autologous blood or blood products as a patient, there should always be a quarantine period of six months.) Women who are pregnant should not be accepted; women recently delivered may be accepted six months post-partum or after weaning the child, whichever is the later.

2. Chronic diseases

Any chronic illness or infection such as tuberculosis (but not if the disease has been arrested for a period of at least one to two years); chronic renal disease (other than self-limited renal disease such as single attacks of glomerulonephritis, pyelitis, etc. from which recovery has been complete); diabetes or epilepsy or rheumatoid arthritis requiring medication; polycythaemia; thyrotoxicosis; liver disease; cancer: all are normally reasons for disqualifying the person as a blood donor. The decision should, however, be made in each individual case by the physician or nurse in charge.

3. Cardiovascular disease

This should be a cause for disqualification. A history of rheumatic fever is not normally a cause for disqualification if no cardiac damage is present and no medication is being taken.

4. Prolonged fevers

An attack of brucellosis at any time is a cause for disqualification. Donors who have had infectious mononucleosis may donate when free from all signs and symptoms of the disease, if liver function is normal.

5. Allergy

Prospective donors with pollen allergy should be deferred during the season when pollen counts are high. Persons with severe atopic diseases such as asthma and prurigo Besnier and persons with drug allergy should not be accepted as donors. Those receiving desensitization injections should be deferred until 72 hours after the last injection.

6. Other medical reasons for possible disqualification or deferment

Skin infection at the proposed site of the venepuncture, or a tooth extraction within 72 hours, are causes for deferment. A well-established bleeding tendency is generally cause for disqualification. Persons who fainted or who had an incipient vaso-vagal attack with marked pallor and perspiration after a previous donation may donate again if a special watch is kept for incipient signs of a repeat performance; two consecutive fainting spells are cause for permanent disbarment.

Persons who have been immunized with toxoids or killed virus, bacterial, or rickettsial vaccines are acceptable after 24 hours if symptom-free. After smallpox vaccine, donors may be accepted when the scab has fallen off, or two weeks after an immune reaction. After vaccination against measles, mumps, or yellow fever, persons should not donate for at least two weeks after the last dose; this period should be increased to three months after the last dose when vaccine against rubella has been received and to 12 months after rabies vaccine.

7. Medication or drugs

As a general rule, a decision to disbar a donor should be based on the underlying pathological condition for which the medication is taken. An exception is the occasional use of "Aspirin": Aspirin may have an adverse effect on platelet function, but it is thought by many that this is no reason for disqualification unless the donor is the only platelet donor to a recipient, e.g. by plateletpheresis; in such cases it is best to use donors who have not received Aspirin within the previous 72 hours.

It is not possible to give generally-acceptable rules for the deferment of persons receiving medication. Mild analgesics, minor tranquillizers, vitamins, birth-control or weight-reduction pills are not usually considered a reason for deferment. However, recipients of oral antibiotics should be deferred until at least two weeks after the last dose. For the convenience of staff, a list of drugs which would make deferment necessary should be

prepared by each Blood Transfusion Service. To be considered are: anti-psychotic drugs, digitalis preparations, nitro-glycerine, and anti-hypertensive preparations.

Those who admit to occasional use of marijuana, LSD, and similar hallucinatory drugs may be accepted if they have not taken any in the previous 72 hours and their arms show no signs of needle-puncture marks or scars indicating that they might have been taking drugs parenterally. Regular users of hallucinatory drugs may, however, be unable to give an accurate history with regard to injectable narcotics or exposure to hepatitis; for this reason they should be disqualified.

Persons clearly under the influence of alcohol must be deferred until sober.

8. Occupations hazardous to the donor

The flight crews of commercial or private aircraft should not be accepted as donors if they are to return to work within 24 hours of donation. If military flight crews are being considered as donors, there may be local rules extending the above period of time.

If the prospective donor has an occupation such as construction work on high buildings or the operation of particularly hazardous machines, etc., the above 24 hours deferment should apply.

9. Viral Hepatitis

In spite of recently developed tests for the detection of HB_sAg, only a relatively small proportion of carriers can presently be detected. No routine screening test is presently available for the detection of hepatitis A virus, or of other viral agents that cause transfusion-associated hepatitis. It follows, therefore, that some general precautions should be taken in an attempt to reduce the risk of such viral agents being transmitted from donor to recipient.

Prospective donors should be excluded if it is known that they:

1. Give a history of viral hepatitis at any time, except during the first months of life. (This rule may not be acceptable in all countries and may have to be modified where viral hepatitis is endemic.)
2. Have received a transfusion of blood or blood products within the last six months.
3. Have been in close, household contact with a case of "infectious hepatitis" in the last six months.
4. Have donated blood which was strongly suspected of having been responsible for a case of post-transfusion hepatitis.

5. Are suspected to be parenteral drug addicts.
6. Have been tatooed, had their ears pierced, or experienced acupuncture within the past six months.
7. Are inmates of a correctional institution.
8. Are HB_sAg positive.
9. Are working in high-risk areas such as haemodialysis centres.

10. Freedom from malaria

Endemic and previously-endemic areas are not clearly delineated. Maps supplied by the World Health Organization are the best presently available.

The suggestions which follow will not eliminate the occasional risk of infection by *Plasmodium vivax* or *P. malariae.*

Transfusion services in non-endemic areas

(i) Residents of and visitors to endemic and previously-endemic areas may donate blood for use as plasma fractions.

(ii) Short-term visitors (<2 months) to endemic and previously endemic areas may donate whole blood if they have remained asymptomatic:
   (a) for three years following recovery from one attack of malaria, or
   (b) for three years after the taking of antimalarial drugs (in the absence of a malarial attack), or
   (c) for six months after a visit provided that they took no anti-malarials (in the absence of a malarial attack).

Transfusion services in endemic areas

A different set of rules must obviously apply. In some such areas it is customary to premedicate both donor and recipient.

If immunological screening tests can be applied, the quarantine periods mentioned above may be shortened or omitted. The same is true for donors whose red cells are discarded and whose plasma is used for plasma fractionation.

11. Freedom from Syphilis, Yaws, Filariasis, Trypanosomiasis, Kala-Azar, Toxoplasmosis, etc.

Tests for syphilis must be routinely performed on each donation; whether examination for other transmissable diseases should be mandatory must be decided by peer review in the geographic area concerned. Patients suffering from toxoplasmosis should be quarantined for one year following clinical recovery.

PLASMAPHERESIS DONORS

Plasma donors for the production of IgG anti-D, Factor VIII concentrate, antisera, control reagents, etc. must be selected with greater care than ordinary blood donors. What plasmapheresis entails, particularly that an auto-transfusion will be necessary and that mis-identification of units is possible, should be explained to each potential participant and his or her informed consent obtained in writing.

The criteria for selection of ordinary blood donors should apply. It is recommended that the donor be investigated by a physician. A physician with special knowledge of the procedures should train the staff carefully and assume direct responsibility for the procedure. The haemoglobin level or haematocrit should be estimated in connection with each plasmapheresis.

For all immunization and hyper-immunization procedures, the antigenic material should be sterile and as free as possible from the risk of transmitting viral infection. Donors of antigenic material must give no history of jaundice and be HB_sAg negative as determined by RIA or a test of similar sensitivity; they should, if possible, be regular blood donors whose donations have never caused hepatitis in the recipients. If red cells are to be used as immunogens, care should be taken to avoid unevaluated incompatibilities; for further advice, see the W. H. O. Technical Report No. 468.

At admission to the programme, the total serum protein, albumin, and globulin levels of the donor should be determined.

The total donation of plasma by a well-nourished donor in normal health should not exceed 600 ml. on each occasion with a maximum of 15 l. per year. The interval between plasmaphereses should, in general, not be less than two weeks. Once a month or after the removal of each litre of plasma, whichever occurs first, the total serum protein should be estimated. Should the total protein level fall below the lower limit of normal of the method used, the donor must be rested until this level is well within established normal limits, and the albumin and globulin have reached at least the pre-plasmapheresis level.

More detailed estimations of the serum proteins should be done at regular intervals. If any of these values are above or below the established normal limits, the donor must be rested.

Other tests for those submitting to serial plasmapheresis include a test for syphilis and an RIA or RPHA test for HB_sAg at each apheresis. The donor's complete history should be subject to medical audit at regular intervals to determine whether he may remain in the programme.

HOW MUCH? and HOW OFTEN?

How much?

The volume of blood donated should relate to the circulatory blood volume of the donor, which can be estimated from the height and weight. In many parts of the world, 450 ml±10% is the standard donation collected into either 67.5 ml of ACD (N. I. H. Formula A) or 63 ml of CPD (N. I. H.). In spite of the fact that smaller volumes of blood have been shown to be adequately preserved by the above volumes of preservative solution, it is recommended that the amount of preservative be proportionately reduced when the volume of blood routinely collected is less than 405 ml.

The formulae for estimating the circulating blood volume are:

Males : $0.3699\ H^3+0.03129W+0.6041\ \ell=(SD\pm500\ ml)$

Females: $0.3561\ H^3+0.03308W+0.1833\ \ell=SD\pm500\ ml)$

[Nadler (1962) cited by Mollison in *Blood Transfusion in Clinical Medicine,* 5th ed., p. 123, 1972]

It follows that, if no more than a certain proportion of the blood volume is to be withdrawn during blood donation, consideration should be given to minimum standards of both height and weight for each sex. It is suggested that no more than 13% of the blood volume should be taken. The following table offers such a guide.

Table III
Suggested minima for height and weight of blood donors

Sex	Height (m)	Weight (Kg)	Estimated BV (ℓ)	450 ml as % of estimated BV
Male	1.55	45	3.4184	13.2%
Female	1.70	45	3.4214	13.2%
	1.65	50	3.4369	13.1%
	1.60	55	3.4612	13.0%
	1.55	59	3.4611	13.0%

In countries where many donors are smaller than 1.55 m or lighter than 45 Kg, or both, it is possible to calculate from the above formulae what volume of blood would represent about 13% of the estimated BV, and to collect that amount.

How often?

It is generally agreed that without substitutional iron therapy, females of childbearing age should donate less frequently than males, because of physiological losses that may amount to rather more than the equivalent of one blood donation per year. To be on the safe side, a reasonable rule would be to request donations from females no more than twice in any twelve month period. Males, on the other hand, are generally accepted every three months.

The question is not so much whether donation of blood will result in frank anaemia, but whether donation will result in latent iron deficiency. Upon this point, there is a growing literature, but many of these investigations have not been carefully controlled. Whether iron therapy should be given following donation is debatable. In some countries, the iron balance should not be disturbed in the majority of individuals if donations are suitably spaced. Rather than have donors take supplemental iron and donate more frequently, a better policy might be to seek more donors and ask them to donate less often. No matter what the actual solution is, every effort should be made to avoid iron deficiency in donors, either by suitably spaced donations, or by supplemental iron therapy.

HOW YOUNG? and HOW OLD?

Clearly minimum and maximum age limits for blood donors have to be established. A working rule which would appear to suit most countries would be to establish the minimum level at 18 for both sexes; if this is below the legal minimum age of consent, then written parental approval will be needed.

The maximum age limit in most countries is between 60 and 65 years of age, although some countries accept donors up to 70. It would seem advisable to limit first-time donors to those below the age of 60, but to accept repeat donors up to the age of 65 provided that they are in good health, and show no signs of cardiovascular disease.

IS THE PROSPECTIVE DONOR ANAEMIC?

The approach most commonly used for acceptance of a donor is to take a predonation sample for haemoglobin determination, and to test it either

by a copper sulfate screening test or by colorimetric assay. Persons having a haemoglobin level less than 125 g/l should not be accepted. To supplement the screening test for haemoglobin, the microhaematocrit test is extremely useful and will result in the salvage of a significant proportion of donors who would otherwise be disqualified.

Another acceptable procedure used in some hospital associated blood centres is to collect blood from a regular donor without a predonation haemoglobin determination, provided that his or her previous haemoglobin value was normal and that the donor does not look pale. If this approach is used, a sample is collected in connection with the donation. If the haemoglobin is below the lower limit of normal, the donor is then submitted to appropriate investigation of the cause of the anaemia, and to therapy if this is indicated.

The suggested minimum standards for prospective donors of 400—450 ml. of blood are:

Minimum haemoglobin (screening test) 125 g/l for both sexes.

Minimum PCV (microhaematocrit for confirmation) 39% for both sexes.

[In some countries, a higher minimum standard for males (135 g/l) is used; in other countries, a minimum of 120 g/l is accepted for females.]

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