
Blood

Donor

Selection

**Guidelines on Assessing
Donor Suitability for
Blood Donation**



World Health
Organization

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Executive summary

Blood transfusion services (BTS) have the responsibility to collect blood only from donors who are at low risk for any infection that could be transmitted through transfusion and who are unlikely to jeopardize their own health by blood donation. A rigorous process to assess the suitability of prospective donors is therefore essential to protect the safety and sufficiency of the blood supply, and safeguard the health of recipients of transfusion and blood donors themselves, while ensuring that suitable donors are not deferred unnecessarily.

These World Health Organization (WHO) guidelines, *Blood donor selection: guidelines on assessing donor suitability for blood donation* have been developed to assist blood transfusion services in countries that are establishing or strengthening national systems for the selection of blood donors¹. They are designed for use by policy makers in national blood programmes in ministries of health, national advisory bodies such as national blood commissions or councils, and blood transfusion services.

WHO guidance on criteria for the selection of blood donors was first published in the distance learning materials, *Safe Blood and Blood Products, Module 1: Safe Blood Donation (1)* in 1994. These earlier recommendations were developed on the basis of international best practice but did not have a clear evidence base. In 2009, the WHO Blood Transfusion Safety programme (WHO/BTS) convened a guideline development group (GDG) to prepare evidence-based recommendations on criteria for assessing the suitability of blood donors. The GDG also recognized the need to provide guidance on establishing national systems for blood donor selection. Details of the members of the GDG and their areas of expertise are provided in the *Acknowledgements*.

WHO/BTS also established an external review group (ERG) to review and comment on the draft guidelines at various stages of the developmental process. The ERG comprised members of the WHO Expert Advisory Panel on Blood Transfusion Medicine and experts from WHO Collaborating Centres in Transfusion Medicine as well as directors of national blood transfusion services and blood programme managers from each WHO region (see *Acknowledgements*). The role of the ERG was to review the draft guidelines and advise WHO on the relevance, applicability and feasibility of the recommendations. An advanced draft was reviewed by participants and facilitators during an inter-regional workshop on blood donor selection and donor counselling for priority countries in the African and Eastern Mediterranean regions, June 2011, Nairobi, Kenya.

The guidelines are presented in two parts. Part 1 (Sections 2 and 3) addresses the requirements for an effective national system for blood donor selection; policy recommendations are provided on p. 5. Part 2 provides guidance on specific criteria for blood donor selection in relation to general donor assessment, donor

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

medical history and risk assessment for transfusion-transmissible infections (TTI); technical recommendations on donor selection criteria are summarized on pp. 6–15 and elaborated in Sections 4 to 7.

Blood donor selection: guidelines on assessing donor suitability for blood donation was developed in accordance with the WHO guidelines development process, which requires systematic review of new evidence for key questions and recommendations, as well as a consideration of programme feasibility and the cost implications of potential new recommendations. A systematic review of the published and “grey” literature was conducted covering the period 1995–2011, and also in 2012 for selected topics. Particular efforts were made to identify systematic literature reviews and evidence related specifically to blood donor selection in low- and middle-income countries. Detailed literature search strategies and the decision-making process for the formulation of recommendations are available in Annex 3 on the WHO website (2).

High quality evidence on which to base decisions on the suitability of prospective donors for blood donation is, however, limited or even lacking in relation to many medical conditions and risk behaviours. Where published evidence is lacking, recommendations are based on international best practices and the knowledge and expertise of members of the guideline development group and external review group in the fields of human physiology, pathology and clinical medicine. In conditions where emerging evidence suggests that deferral criteria may be relaxed, a precautionary approach is recommended until good evidence of safety becomes available. It is anticipated that the recommendations in this document will remain valid until 2017 when a review of these guidelines will be undertaken to explore any new evidence, particularly in relation to controversial issues or where changes in practice may be appropriate.

Acronyms

AIDS	Acquired immunodeficiency syndrome
BTS	Blood transfusion service(s)
CDC	United States Centers for Disease Control and Prevention
CJD	Creutzfeldt-Jakob disease
CUE	Confidential unit exclusion
DIID	Donation-induced iron deficiency
HAV	Hepatitis A virus
HBV	Hepatitis B virus
HCV	Hepatitis C virus
HEV	Hepatitis E virus
HIV	Human immunodeficiency virus
HTLV I/II	Human T-cell lymphotropic viruses I/II
IFRC	International Federation of Red Cross and Red Crescent Societies
MSM	Men who have sex with men
TTI	Transfusion-transmissible infection(s)
UNAIDS	Joint United Nations Programme on HIV/AIDS
vCJD	Variant Creutzfeldt-Jakob disease
WHO	World Health Organization

Preface

The safety and availability of blood and blood products for transfusion requires the recruitment and selection of voluntary non-remunerated blood donors, the quality-assured screening of all donated blood and the safe and rational clinical use of blood. The World Health Organization (WHO) recommends the following integrated strategy for blood safety and availability (3).

- 1 Establishment of well-organized blood transfusion services that are coordinated at national level and that can provide sufficient and timely supplies of safe blood to meet the transfusion needs of the patient population.
- 2 Collection of blood from voluntary non-remunerated blood donors at low-risk of infections that can be transmitted through blood and blood products, the phasing out of family/replacement blood donation and the elimination of paid donation.
- 3 Quality-assured screening of all donated blood for transfusion-transmissible infections, including HIV, hepatitis B, hepatitis C and syphilis, blood grouping and compatibility testing, and preparation of blood components.
- 4 Rational use of blood to reduce unnecessary transfusions and minimize the risks associated with transfusion, the use of alternatives to transfusion, where possible, and safe clinical transfusion procedures.
- 5 Implementation of effective quality systems, including quality management, documentation, training of all staff and assessment.

Each country should establish a national system for blood donor selection for the donation of whole blood, red cells, platelets, plasma and other blood components, donated as whole blood or apheresis donations. The assessment of donor suitability should be undertaken in accordance with national criteria for blood donor selection. These criteria should be consistently applied in every blood donation setting on each occasion of donation to *all* blood donors, including voluntary non-remunerated donors and even where systems are still based on family/replacement donors and paid donors.

These guidelines on blood donor selection should be used in conjunction with other WHO resources, in particular *Towards 100% voluntary blood donation: A global framework for action* (4), *The Melbourne Declaration on 100% voluntary non-remunerated donation of blood and blood components* (5), *Blood donor counselling: Implementation guidelines* (6) and *Screening donated blood for transfusion-transmissible infections* (7).

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Policy recommendations

- 1 Each country should establish a national system for blood donor selection for the donation of blood or blood components.
- 2 All prospective blood donors, either donating as whole blood donations or through apheresis donations, should be assessed, prior to blood collection, for their suitability to donate on each occasion of donation, in every blood donation setting.
- 3 National donor selection guidelines and criteria should be based on epidemiological and/or scientific evidence or, where evidence is limited or lacking, on best practices.
- 4 Donor acceptance and deferral policies for the prevention of TTI should be based on up-to-date information on the local epidemiology of infections, the markers screened for, the availability of suitable blood screening and confirmatory assays, and the technologies in use.
- 5 Blood transfusion services should have mechanisms for surveillance to monitor emerging infections and diseases associated with transmission through transfusion, and assess the risk of transmission and the possible consequences to the blood supply of excluding “at-risk” donors.
- 6 National donor selection criteria should define conditions of acceptance and deferral for each criterion.
- 7 Adequate resources, including a sufficient number of qualified and trained staff, should be made available for the consistent and reliable assessment of donor suitability for blood donation.
- 8 Quality systems should be in place for blood donor selection, including selection criteria, staff training and documentation.
- 9 Blood transfusion services should have systems for the notification and counselling of individuals who have been deferred from blood donation and for their referral for further management if any abnormalities are found.
- 10 Blood transfusion services should establish mechanisms for monitoring and evaluation to assess the implementation and effectiveness of donor selection criteria.
- 11 National regulatory mechanisms for the oversight of the functions of blood transfusion services should include activities related to blood donor selection.
- 12 National procurement policy and supply systems should encompass the equipment and consumables required for assessing the suitability of blood donors.

Technical recommendations

These technical recommendations provide a summary of recommendations on donor selection criteria in Sections 4–7, by condition.

Condition	Acceptance or deferral criteria	Page numbers
Abortion	Defer for up to 6 months	46–47
Acne	Accept provided venepuncture site is unaffected Also refer to Section 6.2	60–61, 64–65
Acupuncture	Defer for 12 months following last procedure	68, 90
Age limits for blood donation	Usually 18 to 65 years Refer to Section 4.1	39–40
Alcohol intake	Accept if no signs of intoxication	40–41, 89
Allergy	Accept if symptom free Defer permanently if history of anaphylaxis	57
Anaemia	Accept if past history of iron deficiency anaemia, with a known cause not a contraindication to donation, when treatment completed and fully recovered Accept vitamin B ₁₂ or folate deficiency when fully recovered and on maintenance treatment Defer if does not meet minimum haemoglobin level for blood donation or under investigation or on treatment for anaemia Defer permanently if chronic anaemia of unknown cause or associated with systemic disease	43–44, 49–50
Anaphylaxis	Defer permanently	57
Antibiotics	Accept 14 days after completion of treatment Accept if on long-term antibiotics for acne	41, 55, 60, 65
Ankylosing spondylitis	Defer permanently Also refer to Section 5.10	60
Arthritis	Refer to Sections 5.6 and 5.10	57, 60

Asthma	Accept provided asymptomatic on maintenance dose of non-steroid and/or inhaled steroid medication Defer for 14 days after full recovery from acute exacerbation Defer for 14 days after completion of course of oral or injected steroid	54–55, 57
Babesiosis	Defer permanently	82
Biopsy	Accept when normal activities resumed Also refer to Section 6.4	67
Blood transfusion	Defer recipient of blood and blood products for 12 months following transfusion Defer permanently if on regular treatment with plasma-derived coagulation factors Also refer to Section 6.3.1	65–66
Bronchitis	Defer for 14 days after full recovery from acute attack and completion of treatment Also refer to Section 5.3	55
Brucellosis	Defer permanently	84
Burns	Accept if fully healed	61
Campylobacter	Defer for 28 days following full recovery	85
Cardiovascular diseases	Accept surgically corrected simple congenital cardiac malformation with no residual symptoms Accept asymptomatic disorder: e.g. functional murmurs, mitral valve prolapse Defer permanently all other conditions Also refer to Section 5.2	52–53
Central nervous system diseases	Accept if history of epilepsy or seizures provided off medication and seizure-free for 3 years Defer permanently all other conditions	58–59
Cerebrovascular diseases	Defer permanently Also refer to Section 5.8.1	58–59
Chagas disease	Refer to Section 7.4.2	81–82, 87
Chickenpox	Defer for 14 days following full recovery Also refer to Section 7.3.6	78
Chikungunya virus	Refer to Section 7.3.5	77
Cholecystitis	Accept when fully recovered	55

Coagulation disorders	Accept if carrier for haemophilia A or B provided normal coagulation factor levels and no history of bleeding or treatment with blood products Defer permanently if coagulation factor deficiencies	52
Coeliac disease	Accept if fully treated	55–56
Colitis	Accept irritable bowel syndrome without debility Defer active inflammatory bowel disease unless well, in long-term remission and meets minimum haemoglobin levels for blood donation	55
Common cold	Refer to Section 4.3	41
Cosmetic treatment (invasive)	Defer for 12 months following last procedure	68, 90
Creutzfeldt-Jakob disease (CJD)	Defer permanently sporadic and familial CJD and first-degree relatives Defer permanently if history of treatment with pituitary-derived human growth hormone, human gonadotrophin, dura mater graft, corneal transplantation, neurosurgery Also refer to Section 7.7.1	58, 65, 86–87
Crohn's disease	Refer to Section 5.4	55
Dementia	Defer permanently Also refer to Section 5.8.3	58–59
Dengue virus	Refer to Section 7.3.5	77
Dental treatment	Accept 24 hours after simple procedures and 7 days after extraction or endodontic procedures	67
Depression	Accept if feeling well	61–62
Dermatomyositis	Defer permanently	57, 60–61
Diabetes	Accept diabetes mellitus controlled by diet or oral medication provided no history of orthostatic hypotension and no evidence of infection, neuropathy or vascular disease Defer permanently if requires insulin treatment or has complications with multi-organ involvement	56
Diagnostic procedures	Defer following minor diagnostic procedure including rigid endoscopy until normal activity resumed Defer for 12 months following invasive diagnostic procedure using flexible endoscopy	67

Diarrhoea	Accept 14 days after full recovery and completion of therapy, including antibiotics Accept chronic diarrhoea due to irritable bowel syndrome without debility; otherwise defer Defer for 28 days if symptoms suggestive of <i>Yersinia enterocolitica</i>	41, 82, 83, 84–85
Diverticular disease	Accept if well	55
Drug use	Injecting drug use: Defer permanently individuals with a history of injecting drug use Also refer to Section 7.9.2	88–89
	Non-injected drugs and alcohol use: Accept if no signs of intoxication Defer if displaying signs and symptoms of intoxication	89
Eczema	Refer to Section 5.11	57, 61
Epilepsy	Accept if off medication and seizure-free for 3 years	58–59
Epstein-Barr virus	Defer until 28 days after full recovery Also refer to Section 7.3.4	76
Erythrocytosis	Accept secondary erythrocytosis if diagnosis of polycythaemia rubra vera excluded	51
Essential thrombocythaemia	Defer permanently	60
Fever (non-specific)	Defer until 14 days after full recovery Also refer to Section 4.3	41, 42, 72, 79–81, 82, 83, 84
Fracture	Accept when plaster removed and mobile	60
Frequency of donation	For whole blood, minimum of 12 weeks for males, 16 weeks for females Also refer to Section 4.6.2	44–46
Gallstones	Accept if well	55
Gastro-oesophageal reflux	Accept if mild	55
Gonorrhoea	Defer for 12 months following completion of treatment and assess for high-risk behaviour Also refer to Section 7.5.1	74, 83–84
G6PD deficiency	Accept if no history of haemolysis Defer permanently if history of haemolysis	50–51

Haemochromatosis	Accept provided meets other criteria	45, 52
Haemoglobin level for blood donation	Not less than 12.0 g/dl for females Not less than 13.0 g/dl for males Also refer to Sections 4.6 and 4.10	43–44, 48
Haemoglobinopathies	Defer permanently thalassaemia major or sickle cell disease Also refer to Section 5.1.2	50
Haemophilia	Refer to Section 5.1.7	52
Hepatitis A, hepatitis E and hepatitis of unknown origin	Defer for 12 months following full recovery Also refer to Section 7.3.1	73–74
Hepatitis B	Refer to Section 7.3.1	72–73, 87–90
Hepatitis C	Refer to Section 7.3.1	73, 87–90
Herpes	Accept cold sores and genital herpes provided no active lesions Defer symptomatic individuals for at least 28 days following full recovery Defer permanently individuals with HHV8 infection and current or former sexual contacts Also refer to Section 7.3.4	76
Hiatus hernia	Accept mild cases, provided well	55
HIV/AIDS	Refer to Section 7.3.2	74–75, 83, 87–90
HTLV	Refer to Section 7.3.3	75
Hypertension	Accept stable uncomplicated hypertension controlled by medication Defer if recently started or changed anti-hypertensive medication until 28 days after blood pressure stabilized Defer permanently if hypertensive heart or renal disease	53–54
Hypogammaglobulinaemia	Defer permanently	57
Immunization	Refer to Section 6.1	63–64
Immunological diseases	Refer to Section 5.6	57
Infections (acute bacterial)	Accept 14 days after full recovery and completion of antibiotic treatment Defer for 28 days following full recovery and completion of treatment if symptoms suggestive of infection with salmonella, campylobacter, streptococcus or staphylococcus	41, 85

Influenza	Accept asymptomatic individuals with no close contact with those having active infection Defer for 14 days after full recovery and cessation of any therapy Defer for 48 hours after vaccination Also refer to Section 7.3.7	78
Inoculation injury	Defer for 12 months following exposure	73
Iron deficiency	Refer to Section 5.1.1	43–46, 49
Irritable bowel syndrome	Accept, if without debility	55
Leishmaniasis	Refer to Section 7.4.4	82–83
Leukaemia	Defer permanently	59–60
Lyme disease	Defer for 28 days following full recovery and completion of treatment, whichever is longer	84
Lymphoma	Defer permanently	59–60
Malaria	Local criteria depending on endemicity Refer to Section 7.4.1	79–81, 87
Malabsorption syndromes	Defer permanently except treated coeliac disease	55–56
Malignant diseases	Accept malignancy “in situ” (e.g. basal cell carcinoma, cervical carcinoma in situ), if successfully treated, regularly monitored and in good health Defer if current diagnosis of malignancy or less than 5 years since completion of treatment Defer permanently if malignant melanoma, lymphoproliferative or haematological disorders Also refer to Section 5.9	59–60
Measles	Defer for 14 days following full recovery Also refer to Section 7.3.6	78
Medications	Take account of indication for treatment Accept long-term low-dose antibiotics for acne Defer for 14 days following antibiotic use Retinoids, dutasteride, finasteride, aspirin and non-steroidal anti-inflammatory drugs: also refer to Section 7.7	64–65
Menstruation	Accept	46–47
Minor illnesses	Defer for 14 days after full recovery from acute infection and completion of antibiotic treatment	41

Multiple sclerosis	Defer permanently Also refer to Section 5.8.4	58–59
Mumps	Defer for 14 days following full recovery Also refer to Section 7.3.6	78
Musculoskeletal disorders	Accept acute or chronic simple disorders (e.g. mild rheumatoid arthritis, back pain, sciatica, frozen shoulder, osteoarthritis) if mobile Defer permanently if systemic disease affecting joints: e.g. severe rheumatoid arthritis, psoriatic arthropathy, ankylosing spondylitis	60
Myelodysplastic syndrome	Defer permanently	59–60
Nephritis	Refer to Section 5.7	57–58
Peptic ulcer	Defer until completion of treatment and full recovery	55
Piercing	Defer for 12 months following last acupuncture, piercing, tattoo, scarification or invasive cosmetic procedure	68, 90
Platelet disorders	Refer to Section 5.1.4	51
Polycythaemia	Accept secondary erythrocytosis Defer permanently polycythaemia rubra vera	51, 59–60
Pregnancy and lactation	Defer during pregnancy and lactation and up to 6 months following delivery or termination	46–47
Prisons and penal institutions	Refer to Section 7.9.4	89–90
Psoriasis	Refer to Section 5.11	60–61
Psoriatic arthropathy	Defer permanently Also refer to Section 5.10	60
Psychiatric disorders	Accept anxiety disorder or mood disorder provided in generally good health, not obviously over-anxious, depressed or manic on the day of donation, regardless of medication Defer permanently psychotic disorder requiring maintenance treatment	61–62
Pulmonary embolus	Refer to Section 5.2.2	54
Red cell membrane defects	Accept if no history of haemolysis Defer permanently if history of haemolysis	50–51

Renal diseases	Accept if fully recovered from acute self-limiting condition (e.g. acute nephritis) provided renal function normal Defer permanently if chronic renal disease causing ill-health or anaemia or associated with chronic or recurrent infection	49–50, 53–54, 57–58
Respiratory diseases	Defer acute respiratory infection for 14 days following full recovery and completion of therapy, including antibiotics Defer permanently if breathless at rest or minimal exertion or if cyanosed, has severe obstructive airways disease (including if on long-term oral steroid therapy), or chronic or recurrent respiratory infection Also refer to Section 5.3	41, 54–55, 57
Rickettsial infection	Defer for 6 months following completion of treatment or cessation of symptoms Defer acute Q fever for 2 years following completion of treatment and full recovery, whichever is longer Defer permanently chronic Q fever	85–86
Rocky Mountain spotted fever	Refer to Section 7.6	85–86
Rubella infection	Defer for 14 days following full recovery Also refer to Section 7.3.6	78
Salmonella infection	Defer for 28 days following full recovery	85
Scarification	Refer to Section 7.9.5	68, 90
Scleroderma	Defer permanently	60–61
Sex workers	Defer permanently	87–88
Sexual behaviour (high-risk)	Refer to Section 7.9.1	87–88
Sickle cell disease	Accept sickle trait provided haemoglobin above required lower limit Defer permanently sickle cell disease Also refer to Section 5.1.2	50

Skin diseases	<p>Accept mild common skin disease (e.g. acne, eczema, psoriasis) if lesions not infected, venepuncture site is unaffected</p> <p>Defer if generalized skin disease and on systemic medication</p> <p>Defer if contagious skin disease</p> <p>Defer permanently if systemic disease affecting skin (e.g. scleroderma, systemic lupus erythematosus, dermatomyositis, systemic cutaneous amyloidosis)</p> <p>Also refer to Sections 5.11 and 6.2</p>	60–61, 64–65
Streptococcus infection	<p>Defer for 28 days following full recovery</p> <p>Defer for 14 days following full healing if recent superficial but significant wounds</p>	85
Stroke	<p>Defer permanently</p> <p>Also refer to Section 5.8.1</p>	58–59
Surgery	<p>Defer following minor surgery until treatment is complete and successful and normal activity resumed</p> <p>Defer for 12 months following major surgery</p> <p>Defer permanently following neurosurgical procedure, dura mater graft or corneal transplant</p> <p>Also refer to Sections 6.4 and 7.7</p>	67, 86–87
Syphilis	<p>Defer permanently if has ever had a diagnosis of syphilis</p> <p>Also refer to Section 7.5.1</p>	83–84
Systemic lupus erythematosus	<p>Defer permanently</p> <p>Also refer to Section 5.11</p>	57, 60–61
Tattoos	Refer to Section 7.9.5	68, 90
Thalassaemia	<p>Accept thalassaemia trait provided well and haemoglobin above required lower limit</p> <p>Defer permanently thalassaemia major</p> <p>Also refer to Section 5.1.2</p>	50
Thrombocytopenia	<p>Accept past history of acute autoimmune thrombocytopenia more than 5 years previously, if well and not on treatment, except prophylactic antibiotics following splenectomy</p> <p>Defer permanently if thrombocytopenia of unknown cause or associated with long-term haematological or systemic disease</p>	51, 59–60
Thrombosis	Refer to Section 5.2.2	52–53, 54

Thyroid disorders	Accept if benign disorder and euthyroid (with or without treatment) Defer if under investigation for thyroid disease, if hyper- or hypo-thyroid, or with a history of malignant thyroid tumours (also refer to Section 5.9) Defer permanently if history of thyrotoxicosis due to Graves' disease	56–57
Transient cerebral ischaemic episodes	Defer permanently Also refer to Section 5.8.1	58–59
Transplantation	Defer for 12 months following transplantation of allogeneic tissues Defer permanently if transplanted with allogeneic cells or tissue sourced since 1980 from a country in which risk of vCJD has been identified Defer permanently following stem cell or organ transplantation, dura mater graft, corneal transplant or xenograft	65–67
Tuberculosis	Defer for 2 years following confirmation of cure Also refer to Section 7.5.6	85
Ulcerative colitis	Refer to Section 5.4	55–56
Urinary tract diseases	Accept lower urinary tract infections 14 days after full recovery and completion of treatment Also refer to Section 5.7	57–58
Vaccination	Refer to Section 6.1	63–64
Variant Creutzfeldt-Jakob disease (vCJD)	Defer permanently variant Creutzfeldt-Jakob disease (vCJD) Refer to Section 7.7.2	58, 86–87
Vitiligo	Accept	57
Weight	Refer to Section 4.4	41–42
West Nile virus	Refer to Section 7.3.5	76–77, 87
Yersinia enterocolitica infection	Defer for 28 days following full recovery if recent abdominal symptoms, particularly diarrhoea, suggestive of <i>Y. enterocolitica</i> infection	84–85

1 Introduction

1.1 BLOOD DONOR SELECTION

The primary responsibility of a blood transfusion service is to provide a safe, sufficient and timely supply of blood and blood products. In fulfilling this responsibility, the BTS should ensure that the act of blood donation is safe and causes no harm to the donor (3,5,8). It should build and maintain a pool of safe, voluntary non-remunerated blood donors and take all necessary steps to ensure that the products derived from donated blood are efficacious for the recipient, with a minimal risk of any infection that could be transmitted through transfusion.

All prospective blood donors should therefore be assessed for their suitability to donate blood, on each occasion of donation. The purpose of blood donor selection is to:

- Protect donor health and safety by collecting blood only from healthy individuals
- Ensure patient safety by collecting blood only from donors whose donations, when transfused, will be safe for the recipients
- Identify any factors that might make an individual unsuitable as a donor, either temporarily or permanently
- Reduce the unnecessary deferral of safe and healthy donors
- Ensure the quality of blood products derived from whole blood and apheresis donations
- Minimize the wastage of resources resulting from the collection of unsuitable donations.

Information provided by 164 countries to the WHO Global Database on Blood Safety indicates that, worldwide, more than 92 million blood donations are collected annually. Of these, an estimated 1.6 million units are discarded due to the presence of infectious markers for TTI, including HIV, hepatitis B, hepatitis C and syphilis. In addition, at least 13 million prospective donors are deferred from donating blood due to anaemia, existing medical conditions or the risk of infections that could be transmitted through transfusion (9). The scale of these discards and deferrals highlights the need for effective blood donor selection to minimize the unnecessary deferral of suitable donors, and the donation of blood by unsuitable donors that subsequently has to be discarded; this will reduce the wastage of resources, including donor and staff time, consumables and screening tests, and also avoid needless discomfort to donors.

Significant variations have been observed between countries in the extent to which national donor selection criteria are defined, prospective donors are assessed and the quality and effectiveness of the donor selection process are monitored. In some countries, national systems of blood donor selection are not well-developed and donor selection criteria are not clearly defined or applied uniformly. This may result in blood being collected from donors who have not been properly assessed for their suitability to donate; this may affect their health and pose a higher risk of transmission of infections through transfusion.

In many countries, donor selection criteria are still based on tradition and customary practice rather than on evidence (10,11) and criteria from one country are often adopted in other countries without due consideration of the profiles

of the general and potential donor populations, the prevailing epidemiology of infections and diseases, local culture and available resources. Some countries take a highly precautionary approach to the selection of donors for the safety of blood products, donors and patients. Policies for donor selection should take into account the need for a balance between the safety and sufficiency of the blood supply and available resources (11,12,13).

In 2005, World Health Assembly resolution WHA58.13 (14) urged Member States, inter alia, to establish or strengthen systems for the recruitment and retention of voluntary, non-remunerated blood donors and the implementation of stringent criteria for donor selection. World Health Assembly resolution WHA63.12 (15) in 2010 also urged Member States to take all necessary steps to update their national regulations on donor assessment and deferral. However, there are relatively few internationally-recognized guidelines on blood donor selection (Annex 1) and all of these have been developed to address the needs of specific regions or countries. There is therefore a need for global guidance on the development of systems and criteria for blood donor selection that could then be adapted at national level.

1.2 AIM AND OBJECTIVES

Aim

The aim of *Blood donor selection: guidelines on assessing donor suitability for blood donation* is to guide and support countries in establishing effective national systems for blood donor selection, including policies, guidelines and criteria in order to ensure the safety of the recipients of blood and blood products and protect donor health and safety.

Objectives

These guidelines are intended for use in countries which have not yet established national systems for blood donor selection or which are in the process of developing or revising donor selection guidelines and criteria. The specific objectives are to:

- 1 Provide guidance on the measures needed to develop and implement effective systems for assessing the suitability of individuals to donate blood.
- 2 Review the available evidence base and provide recommendations on criteria for blood donor selection.

The donor selection criteria recommended in these guidelines apply to donors of whole blood, red cells, platelets, plasma and other blood components, donated as whole blood or through apheresis, including plasma for fractionation. These include a) criteria that have worldwide applicability and should be applied uniformly, and b) criteria that require local adaptation in the light of epidemiological data, demography, the health of the population, the screening and confirmatory tests performed and the available technology.

Whilst these guidelines are designed to promote best practice in blood transfusion services to ensure the collection of donations from the lowest risk donors possible, consideration should always be given to the issue of sufficiency, balancing any risk of infection against the risk of blood shortages resulting from the development of too stringent national guidelines. Infectious risks are not the same in all countries, or even within individual countries, and it is crucial that selection guidelines are developed according to the circumstances and needs of each country.

1.3 TARGET AUDIENCE

The target audience includes personnel and representatives from the following institutions and organizations:

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

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

1.4 METHODOLOGY

In 2009, the WHO Blood Transfusion Safety programme scoped the guidelines to define the content and assess the topics on which recommendations on blood donor selection were required. It identified three key questions to be addressed:

- 1 What are the components of an effective national system for assessing the suitability of prospective donors to donate blood?
- 2 What are the criteria for the acceptance or deferral of prospective blood donors to avoid blood donation by unsuitable individuals in order to protect the health and safety of recipients of transfusion and ensure patient safety?
- 3 What are the criteria for the acceptance or deferral of prospective blood donors to protect donor health and safety while avoiding the unnecessary deferral of suitable donors?

WHO/BTS convened a guideline development group (GDG) whose members were selected on the basis of their specialist expertise in haematology, transfusion medicine and blood donor management (refer to *Acknowledgements*) (16). The role of the GDG, in conjunction with WHO/BTS, included identification of priority questions and outcomes; retrieval of the evidence; assessment and synthesis of the evidence; identification of issues that are controversial or where change of practice is recommended; review of internationally-recognized guidelines and current practices worldwide; formulation of recommendations; preparation of the text; and planning for the dissemination, implementation, impact evaluation and updating of the guidelines. WHO/BTS also established an external review group (ERG) comprising members of the WHO Expert Advisory Panel on Blood Transfusion Medicine and experts from WHO Collaborating Centres in Transfusion Medicine as well as directors of national blood transfusion services and blood programme managers from each WHO region (refer to *Acknowledgements*). The composition of the ERG was designed to ensure a wide range of specialist expertise and

experience from blood transfusion services in all regions at different stages of development. The role of the ERG was to review the draft guidelines and advise WHO on their relevance and applicability in their countries in the context of epidemiology, risk behaviours and activities, cultural practices and available blood screening and confirmatory testing technologies.

An early draft of the guidelines was pilot-tested in Ethiopia in 2010 and revised drafts were circulated electronically to members of the ERG in 2010 and 2011; their comments were carefully reviewed by the GDG and incorporated into the guidelines. The guidelines were submitted for review and approval to the WHO Guidelines Review Committee (GRC), which reviewed and provided guidance on the process and methodology for evidence retrieval and the assessment and synthesis of evidence to ensure that the evidence collected was unbiased, up-to-date and relevant. Detailed comments received from the GRC were addressed systematically and the guidelines were modified to incorporate these comments.

A further external review of the advanced draft of the guidelines to assess the feasibility of their implementation was undertaken by participants in an inter-regional workshop on blood donor selection and donor counselling for priority countries in the African and Eastern Mediterranean regions, June 2011, Nairobi, Kenya (17) (refer to *Acknowledgements*); and, relevant comments were addressed by the GDG in developing the final draft.

Evidence base

A systematic literature search was conducted to collect and review the evidence (1995–2011, and also in 2012 for selected topics) on defined physiological conditions, diseases and risk behaviours in relation to the suitability of individuals for blood donation. The literature search covered the more widely consulted published literature from peer-reviewed journals, regional journals, book chapters, institutional and other knowledge databases, as well as lesser-known published literature and unpublished and non-reviewed “grey literature”.

As these guidelines have been developed particularly for use in countries that have not yet established national systems for blood donor selection, the literature search strategy was specially designed to collect literature from low and middle-income countries.

Searched domains

A systematic search of the following databases was undertaken: PubMed, Cochrane Library, WHO Library Database (WHOLIS), Institute for Scientific Information (ISI) Web of Knowledge, World Bank eLibrary and WHO regional databases: African Index Medicus (AIM), Index Medicus for the Eastern Mediterranean (IMEMR), Index Medicus for South-East Asia (IMSEAR), Western Pacific Region Index Medicus (WPRIM), Virtual Health Library – Latin American and Caribbean Literature on Health Sciences Information (VHL-LILACS), Virtual Health Library – MEDCARIB and the Pan American Health Organization.

The “grey literature” was retrieved using the public search engines Google and Yahoo mainly to collect literature from low and middle-income countries, focusing on a) the existence and availability of national guidelines and criteria for blood donor selection, and b) current practice in blood donor selection in countries.

Keywords and medical subject heading (MeSH) terms, and key authors and institutions were used to retrieve relevant citations on each topic from various databases. Detailed search strategies with the date and time of the search,

databases searched, keywords and MeSH terms used and the search strings are documented in Annex 3 on the WHO website (2).

A preliminary screen by review of titles was carried out by the searcher to eliminate obviously irrelevant and duplicate citations. Citations of possible relevance were then forwarded to the chair of the GDG who undertook a further review of the titles and the abstracts, where appropriate. Key papers that addressed each of the study questions were then selected and the full text of these papers was reviewed.

Quality of evidence

The evaluation of the quality of evidence, the safety profiles of interventions, the assessment of current medical and scientific knowledge and practice, and the cost-effectiveness of practices was undertaken by the guideline development group and WHO/BTS. This formed the basis for the formulation of recommendations on criteria for the acceptance and deferral of prospective blood donors.

It is recognized that there is a paucity of high quality evidence on which to base decisions on blood donor selection. While some attempts have been made to apply the principles of evidence-based medicine (EBM) to transfusion medicine (10,11,18,19), the randomized controlled trial, the major tool of EBM, cannot apply to donor selection, and there are few directly relevant published clinical, epidemiological and observational studies, systematic reviews and audits on criteria for blood donor selection.

Many long-established donor selection criteria are based on medical knowledge of the disease process and human physiology, the haemodynamic effect of blood donation and the potential for harm to either the donor or the recipient. In general, acceptance criteria specify conditions in which there is no or minimal risk to donor or recipient, based either on published evidence of safety from observational studies or on general medical principles. Deferral criteria are based almost entirely on general principles aimed at minimizing any risk to the donor or recipient. Evidence is rarely available because observational studies of blood donation in many such conditions would be unethical.

Given the paucity of the evidence on donor selection criteria, formal assessment of the quality of evidence to support the recommendations was undertaken only for three topics, because of their controversial nature, discrepancies between international guidelines or the potential impact of a change of practice on the blood donor base, i.e. individuals with a history of epileptic seizures; men who have sex with men (MSM); and injecting drug users.

Key citations that had important and relevant information on these topics were analysed for the quality of evidence, using the GRADE system (<http://www.gradeworkinggroup.org>) that considers factors such as study design, quality, consistency, directness and precision to assess the quality of the collected evidence. Summaries of evidence tables were made to assist in the development of recommendations on these topics.

Where published evidence is lacking, recommendations on donor selection criteria are based on international best practice and the medical knowledge and expertise of members of the guideline development group and external review group. In conditions where emerging evidence suggests that deferral criteria may be relaxed, a precautionary approach is recommended until good evidence of safety becomes available.

Recommendations

The document is presented in two parts. Part 1 (Sections 2 and 3) addresses the requirements for an effective national system for blood donor selection; policy recommendations are provided on pp. 12. Part 2 provides guidance on specific criteria for blood donor selection in relation to general donor assessment, donor medical history and TTI risk assessment; technical recommendations on donor selection criteria are summarized on pp. 13–22 and elaborated in Sections 4 to 7.

Review and updating of the guidelines

It is anticipated that the guidelines will remain valid until 2017. The WHO Blood Transfusion Safety Team will be responsible for initiating a review of the document at that time.

Part 1

National system for blood donor selection

2 Establishing a national system for blood donor selection

The selection and management of blood donors is an essential part of the blood donation process. National health authorities and blood transfusion services are responsible for ensuring that a national system is in place for the selection of all blood donors through an assessment of their suitability to donate blood.

The national system for blood donor selection should include:

- National policy and legislative framework
- National guidelines and criteria on blood donor selection
- Public information and donor education
- Suitable infrastructure and facilities
- Adequate financial and human resources
- Quality system, including standard operating procedures, documentation and records
- Donor haemovigilance
- Monitoring and evaluation.

2.1 NATIONAL POLICY AND LEGISLATIVE FRAMEWORK

Every country should have a national blood policy that defines the strategies for blood donor recruitment, selection, deferral, blood screening for TTI, confirmatory testing, donor notification, counselling and referral. The national blood policy should be supported and enforced by a legislative and regulatory framework and implemented through national guidelines. The legislative framework should define the fundamental principles and ethics of blood donation and donor selection. It should address the responsibilities of the BTS in:

- Protecting the health and safety of blood donors and ensuring confidentiality, privacy, self-determination and non-discrimination
- Protecting the health of recipients of blood and blood products and ensuring the safety, quality and availability of blood and blood products.

Blood donors have a responsibility to self-defer if they are aware of having been exposed to any risk of an infection or a known health condition or treatment that could influence their suitability to donate blood. Blood donors also have the right to withdraw at any stage of the donation process.

Patients have a right to be protected from avoidable adverse effects of transfusion. Thus, while anyone may offer to become a blood donor, no one has the right to donate blood (20,21).

2.2 NATIONAL GUIDELINES AND CRITERIA ON BLOOD DONOR SELECTION

National guidelines on blood donor selection should be developed through a full consultative process. A mechanism such as a national expert advisory

group should be established with a remit to develop and periodically review the guidelines and criteria on blood donor selection, in consultation with key stakeholders including:

- National policy makers
- National blood programme managers
- Senior BTS personnel
- Experts in transfusion medicine and science, including clinical users of blood, microbiologists and social scientists
- Representatives of the regulatory agency.

National guidelines on blood donor selection should include the criteria for blood donor selection and their implementation in the BTS for assessing donor suitability. The formulation and implementation of donor selection criteria will protect the health of blood donors and the recipients of transfusion. It will also help to maintain and raise standards of donor management and care and minimize unnecessary donor deferrals. Guidelines on blood donor selection should be comprehensive, relevant to the local situation and simple to apply in practice. The BTS should consider the feasibility of their implementation in day-to-day routine settings, in both fixed and mobile blood collection sites.

In developing national guidelines, a review of existing international guidelines, relevant literature and best practices would help to identify the medical and scientific principles underlying donor selection criteria. National guidelines should be based on evidence and risk assessment, taking into account national data on the epidemiology of medical conditions and transfusion-transmissible infections, and risk behaviours (22). It is also important to consider the nutritional and health status of the population and cultural practices.

National guidelines and criteria on blood donor selection should comply with national legislative and regulatory requirements and should be reviewed regularly and updated in response to changes in epidemiology, advances in technology, the latest medical and scientific information and new evidence. Emerging infections and other situations that may influence donor and patient safety should be monitored and may necessitate the revision and modification of donor selection criteria. Donor acceptance and deferral criteria and blood screening procedures have to be balanced to provide optimal safety for both donors and recipients while at the same time ensuring an adequate supply of blood and blood products (23,24).

National health authorities should assess whether, and to what extent, any criteria for donor selection could be relaxed in order to maintain adequate blood supplies in an emergency situation, such as pandemic influenza. However, any deviation from national guidelines and criteria on blood donor selection should be limited to a defined period in managing the emergency situation (25).

Donor questionnaire

A donor questionnaire is the key tool in donor selection for assessing donor health and safety and for reducing the risk of transmission of infection, in particular for infections for which no suitable screening tests are available. A standardized donor questionnaire incorporating selection criteria is now widely accepted as being necessary for uniformity and consistency in approach and for ease of implementation in assessing donor suitability. It ensures that the same information is collected systematically about each donor on each occasion of donation and forms the basis for a one-to-one confidential interview with a trained member of staff. The use of a donor questionnaire prompts donor selection

staff to ask important questions and carefully assess the donor's health. By presenting all relevant information in a standard format, a donor questionnaire facilitates decisions on the acceptance or deferral of the donor.

A standard questionnaire that elicits a prospective donor's demographic, medical and risk history should be used throughout the country. The design and implementation of the donor questionnaire is the responsibility of the BTS. The questionnaire should be simple, unambiguous, culturally acceptable, easy to complete and available in local languages where appropriate. Donor selection staff should be trained to recognize donors having difficulty in understanding any questions, for example, due to low literacy levels, and to explain the questions and facilitate the process for donors to provide accurate responses. A donor selection questionnaire takes considerable time to develop and should be piloted and validated as fit for purpose to ensure that all ambiguity is removed and that it yields the expected results. The questionnaire should be reviewed at frequent intervals to ensure that it is effective and should be revised in accordance with changes in the selection criteria in the national guidelines (26). Revised versions should be introduced and used uniformly in all blood donation settings. An example of a donor questionnaire is included as Annex 2.

2.3 PUBLIC INFORMATION AND DONOR EDUCATION

Effective public information and donor education are the first steps in the process of donor selection. The dissemination of information on donor suitability through public awareness campaigns and donor information and education materials will help to ensure that individuals who volunteer as blood donors are well-informed and likely to be accepted.

Informing potential donors about the health conditions and risk behaviour that would make them unsuitable as blood donors and the screening tests that are performed on donated blood enables prospective donors to assess their own suitability and provides an opportunity for them to self-defer (27,28). It should be made clear that there is no discrimination in donor selection on the grounds of gender, race or religion, and neither the donor nor the recipient has the right to require that any such discrimination be practised (29).

Towards 100% voluntary blood donation: a global framework for action (4) provides guidance on strategies to foster a culture of voluntary blood donation, including donor information and education, for building a safe, sustainable voluntary donor base.

Information materials on the donor selection process and criteria should be developed, including an explanation of their rationale and objectives. These materials should be simple and easy to understand, and written in languages suitable for the donor population.

2.4 INFRASTRUCTURE AND FACILITIES

It is essential that suitable infrastructure and facilities are made available in which blood donor selection can be performed in a friendly and conducive environment. Whether it is carried out in a fixed location or mobile setting, the venue for donor selection should provide adequate privacy and confidentiality.

A pleasant atmosphere for blood donation will encourage donors to relax and help to reduce anxiety. Space used for donor selection should be arranged to maximize the opportunities for confidential discussion between BTS staff and donors.

Sufficient, suitable and well-maintained equipment for donor health assessment should be available. This may include equipment for haemoglobin screening, sphygmomanometers, weighing scales and essential consumables, such as disposable sterile lancets, disinfectants and stationery.

2.5 FINANCIAL AND HUMAN RESOURCES

A system of adequate and sustainable finances is imperative for a stable and sufficient supply of safe blood and blood products. The cost of public information programmes, donor education and donor selection is an important component of the BTS's operating costs. A dedicated budget should therefore be allocated for training of staff, the development of information, education and communication materials, and the supply of equipment and consumables required for assessing donor suitability. Effective donor education, recruitment and selection contribute to minimizing the collection of blood from unsuitable donors, thus reducing the wastage of blood, consumables, and donor and staff time.

The responsibility for donor selection and care lies with a physician or registered nurse in attendance at the donation session. An adequate number of staff should be employed to ensure proper donor assessment and selection. Staff involved in donor selection should be appropriately qualified, well-trained and skilled in providing information, advice and counselling in order to assess donor suitability for blood donation.

Staff working in donor selection should have an understanding of the principles and basis for donor selection criteria and have the technical and clinical skills required to perform the health and risk assessment. The key skills, knowledge and competencies required for staff involved in donor selection include:

- Understanding of the donor selection criteria
- Pre-donation information and counselling
- Interview and assessment based on a standardized donor questionnaire
- Ability to explain questions in the donor questionnaire, ensure understanding and allay donors' apprehensions
- Basic health check, including haemoglobin screening
- Counselling of deferred donors
- Post-donation advice and care.

2.6 QUALITY SYSTEM

The implementation of a quality system is a pre-requisite for a consistent approach to donor selection. Essential elements of a quality system in the donor selection process include:

- An organizational structure that defines the authority, responsibility and reporting channels of all personnel, including written job specifications
- Donor selection criteria, as part of the national guidelines for the BTS, to ensure uniform application in every facility in which blood donations are collected
- Standard operating procedures (SOPs) that guide every process, procedure and task to ensure consistency, accuracy and donor adherence, including information on the necessary staff, facilities, forms, worksheets and references, such as:
 - Donor interview and assessment based on a standardized donor questionnaire

-
- Basic health check, including haemoglobin screening
 - Staff training and competency assessment, including a training curriculum and training records
 - Records system (electronic or manual) that ensures traceability and confidentiality, including:
 - Donor records associated with each donation, including completed donor questionnaires
 - Results of basic health check and haemoglobin screening
 - Donor deferrals and reasons for deferral
 - Adverse donor reactions
 - Periodic monitoring and evaluation of the donor selection process.

The confidentiality of donor records and the traceability of donations should be assured at all times through the use of unique identification numbers for donors and donations, and a mechanism linking donors to donations.

All instruments and equipment used in the donor selection process, such as weighing scales and devices for the measurement of body temperature, blood pressure and haemoglobin, should be maintained and calibrated in accordance with quality requirements. The health and safety of staff should be safeguarded, including protection from sharps injuries during haemoglobin screening (30,31). Special attention should be given to the disposal of sharps, effluent copper sulphate and other waste materials (32).

The education and training of staff and regular quality monitoring are necessary for continual quality improvement.

2.7 DONOR HAEMOVIGILANCE

Donor haemovigilance is a continuous process of data collection and analysis of adverse donor events and reactions in order to investigate their causes and outcomes; haemovigilance data should be utilized for clinical and public health decision making. All adverse events and reactions in donors should be identified, documented and reported. These data should be regularly analysed in order to undertake possible corrective and preventive actions. The goal of donor haemovigilance is to reduce the occurrence of adverse events and reactions and improve the outcomes both for donors and patients.

All donors should be advised to inform the BTS of any ill-effects they suffer after donating, such as a delayed faint, or if they recall an illness or information that should have been declared before donation. Donors should also be asked to notify the BTS if they become unwell within 28 days of donation, particularly with an illness that they may have been incubating at the time of donation. This is especially important with an infection such as hepatitis A where prompt action may prevent infection in the recipient (33).

Donor haemovigilance is a requirement of the quality system (34) and contributes to:

- Improved donor safety through the implementation of corrective and preventive actions to avert the occurrence or recurrence of adverse donor events and reactions
- Tracing of donors and withdrawal of donations that may have or could contribute to serious adverse reactions in recipients
- Improved patient safety through better donor selection criteria and processes

-
- Epidemiological follow-up of the donor population.

A rapid response system should be in place to share any relevant information related to adverse donor events and reactions for appropriate action to be taken for improving donor and patient safety.

Information about any adverse effects in the recipients of transfusion should also be fed back into the donor haemovigilance system to improve donor selection.

Also refer to Section 3.5 on adverse donor reactions and post-donation care.

2.8 MONITORING AND EVALUATION

The process of donor selection requires on-going monitoring and evaluation to ensure that it achieves its objectives of ensuring donor and patient health and safety and a sufficient supply of safe blood and blood products. The main parameters to be monitored include:

- Donor demographics and characteristics
- Donor deferrals
- Donor adverse reactions
- Confidentiality, including facilities, procedures and documentation
- Complaints
- Blood screening results
- Transfusion reactions in recipients of blood and blood products
- Errors and untoward events
- Staff competency assessment and training needs.

Quantitative and qualitative data collection methods including focus group discussions could be considered to assess the effectiveness of blood donor selection.

In order to maintain a balance between sufficiency, safety and emerging risks, donor selection criteria and the reasons for donor deferrals should be regularly evaluated to identify whether any criteria need to be removed, modified or extended to provide improved protection of donors and recipients, and to minimize the deferral of suitable donors. The application of the criteria should also be monitored to ensure they are being interpreted correctly and to identify any areas where additional staff training may be required.

Epidemiological monitoring of infection rates in blood donors, including age and gender-specific prevalence rates in new and repeat donors, contributes to a better understanding of donor behaviour and assessment of risk. Knowing and understanding confirmed infection rates in blood donors helps to ensure that donor selection, donor deferral and blood screening strategies are up-to-date and effective.

Post-donation counselling may reveal the probable exposure histories of infected donors and can help identify populations at risk of infection. This can provide information on the possible routes of infection and the effectiveness of the donor education and donor selection, including whether donor education materials give sufficient information about TTI risk and why the donor decided to donate. This kind of information aids in understanding patterns of infection in “asymptomatic” individuals and can be used to improve donor education, the donor selection criteria and donor selection process.

The following indicators may be used to monitor and evaluate the system of donor selection:

- Total number of individuals presenting to donate blood
- Number and percentage of deferrals from donation, by types of deferral:
 - Permanent deferral
 - Temporary deferral
- Number and percentage of deferrals from donation, by reasons for deferral:
 - Low haemoglobin
 - Other medical conditions
 - High-risk behaviour
 - Travel
 - Other reasons
- Number and percentage of deferrals from donation, by age and gender of donors
- Percentage of donors who self-deferred following donor assessment and counselling
- Percentage of incomplete donor questionnaires
- Rate of adverse donor reactions, by types of reaction
- Prevalence of markers of transfusion-transmissible infection in screened donations:
 - HIV
 - Hepatitis B (HBV)
 - Hepatitis C (HCV)
 - Syphilis
 - Others
- Number and percentage of confirmed positive donors, by age, gender and types of donor.

While the donor questionnaire and interview process is intended to elicit relevant information on which to assess donor suitability for blood donation, the process sometimes may not be effective (35) and operational research may be required to identify mechanisms for improving the process of donor selection and to address issues such as:

- How to improve donor selection criteria
- How to improve the effectiveness of donor education
- How to assess the sensitivity and specificity of certain questions in the donor questionnaire
- How to ask donors culturally-sensitive questions
- Whether donors understand the donor questionnaire
- How to increase donor adherence to selection criteria
- How to reduce blood discard rates
- How to improve donor retention.

3 Assessing donor suitability

Donors should be in good health at the time of donation and free of infections transmissible by blood. The BTS should provide clear and unambiguous guidance for staff involved in donor selection. Rigorous donor selection should be consistently applied to all blood donors either donating whole blood or through apheresis, whether first-time or repeat donors. The process should be planned to make best use of staff and donor time, and make blood donation as convenient as possible for blood donors, without long waiting periods.

Key principles of blood donor selection are as follows:

- The health and safety of the donor as well as the recipient must be safeguarded
- Only individuals in good health should be accepted as donors of whole blood and blood components
- The selection of blood donors should be based on regularly reviewed selection criteria, without discrimination of any kind including gender, race, nationality or religion
- A prospective donor's health status and medical history should be evaluated for each donation, on the day of donation prior to blood collection
- The BTS should provide appropriate donor information and a simple donor questionnaire for health and risk assessment and obtain the donor's informed consent to blood donation
- Staff should be suitably qualified and trained in the donor selection process
- Good communication should be established between the BTS staff and the donor, and donor confidentiality should be assured
- The BTS has a duty of care to provide counselling to all deferred donors and referral for their further management.

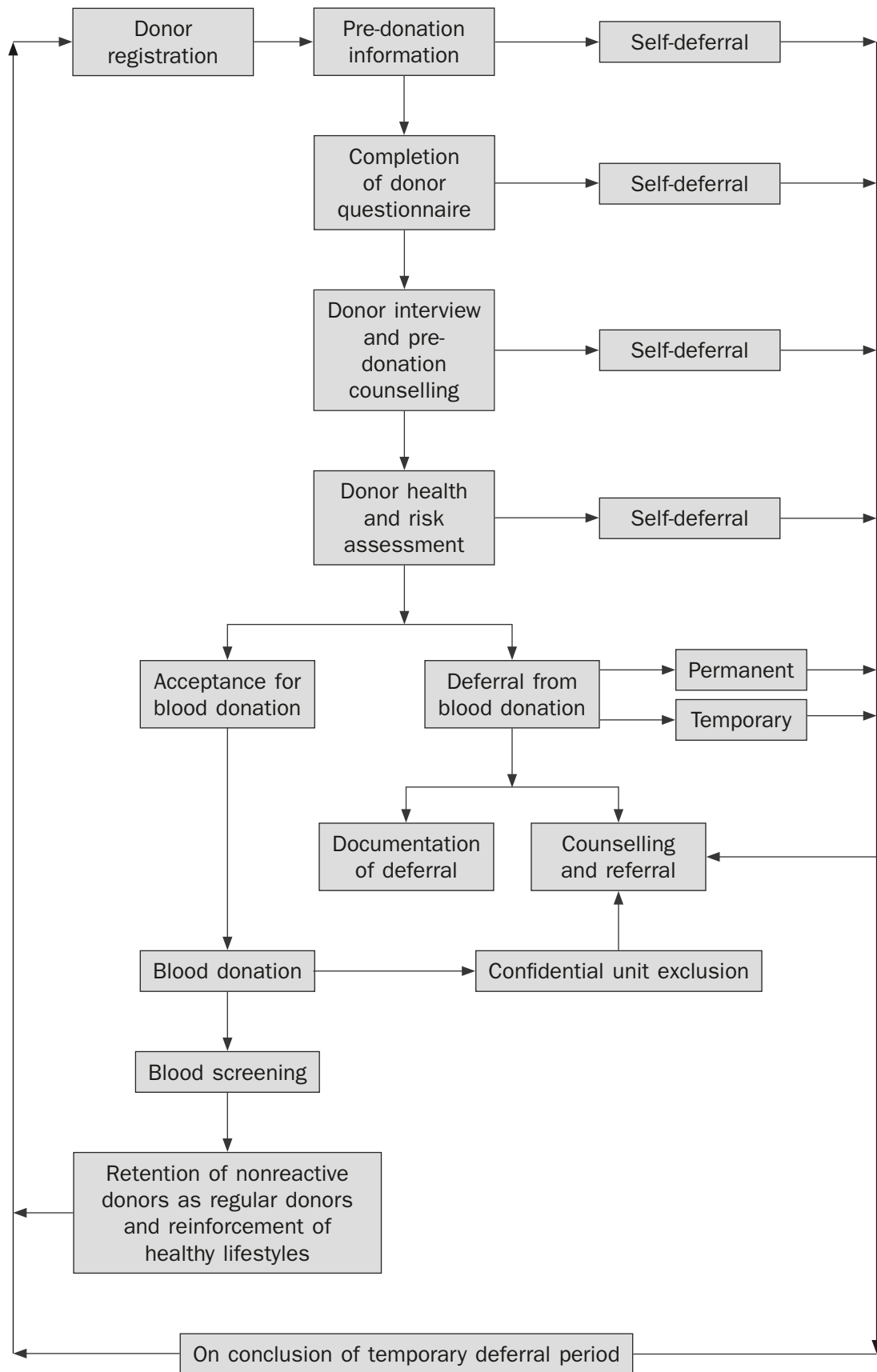
3.1 DONOR SELECTION PROCESS

The purpose of donor selection is to assess the suitability of an individual to be a blood donor so that blood donation is safe for the donor and the blood products derived from this donation are safe for the recipients. The donor selection process should be carried out in accordance with written standard operating procedures.

The steps involved in the donor selection process, prior to blood collection, are shown in Figure 1:

- 1 Donor registration
- 2 Pre-donation information
- 3 Completion of donor questionnaire
- 4 Donor interview and pre-donation counselling
- 5 Donor health and risk assessment
- 6 Informed consent.

Figure 1: The blood donor selection process



Compliance with all donor selection criteria is crucial to ensure a safe blood donation process and outcomes. All potential and existing donors should be asked to adhere to the blood donor selection criteria by providing accurate information and answers to all questions asked, both for the protection of their health and that of patients who receive transfusion.

Donor registration

All prospective donors who meet the general criteria for blood donation such as age and good health should be registered when they attend a blood donation session, even if they are subsequently not accepted for donation.

Essential donor registration information includes the individual's full name, date of birth, gender and contact details. A unique donor number should be assigned at first registration. At each occasion of donation, a unique identifier using a numeric or alphanumeric system should be allotted to the donation; this should be attached to the donor questionnaire, primary blood collection bag, its corresponding satellite bags and the blood sample tubes. During donor registration, prospective donors should be provided with donor information and education materials and the donor questionnaire, which should be completed on each occasion of donation.

Pre-donation information

Pre-donation information is an important step in the blood donor selection. The process of donor selection begins even before donors come to give blood through public awareness campaigns and donor education. At the donation session, pre-donation information should be provided either orally or through printed, graphic, audio-visual or online materials, presented in a simple and clear format and in appropriate languages.

Pre-donation information provides an opportunity for the prospective donors to know about health conditions or high-risk behaviour that would make them unsuitable to donate blood. This information assists the donors in deciding whether to self-defer; it may also assist in donor return if they understand the reason why they should not donate blood on this occasion (36,37).

Pre-donation information has the following objectives, to:

- Increase donor awareness of the donor selection criteria, the process of blood donation and the tests that will be performed on donors' blood
- Encourage prospective donors to inform the BTS of any medical conditions or TTI-related risks that may affect their suitability to donate blood
- Encourage individuals to self-defer from blood donation if they recognize that they are not suitable to donate blood due to general health or medical conditions or risk for TTI.

Pre-donation information should cover:

- Nature and use of blood and its components; the need for voluntary non-remunerated blood donors; and the importance of maintaining healthy lifestyles
- The blood donation process, including the donor questionnaire, donor medical history, health and risk assessment, venepuncture, blood collection as whole blood or apheresis procedure, post-donation care and the screening tests performed on donated blood
- Rationale for the donor questionnaire and pre-donation health assessment and the importance of donor compliance in the donor selection process; and donor's duties, responsibilities and rights (21)

-
- Options for the donor to decide about blood donation prior to proceeding further, to withdraw or self-defer at any time during or after the donation process, without any undue embarrassment or questioning
 - Transfusion-transmissible infections, including HIV, HBV, HCV and syphilis, routes of their transmission, natural history and prevention; types of screening tests performed; and window period of infection and alternative testing sites for individuals seeking to ascertain their infection status
 - Possible consequences for donors and the donated blood in the case of abnormal TTI test results; the mechanism for notification about abnormal test results and post-donation counselling, assurance of confidentiality and if necessary, referral for further testing, treatment and care
 - The possibility of adverse donor reactions.

Completion of donor questionnaire

Each prospective blood donor should complete a donor questionnaire to provide information in relation to the donor selection criteria defined in the national guidelines. In most situations, the donor questionnaire is given to donors at the time of registration for completion before the donor interview and assessment.

Alternatively, the donor questionnaire may be sent to the donor's residence to be completed before donation. This has the advantage of allowing donors time to think about the answers and saves time at a blood donation session. However, donors may misunderstand some of the questions and self-defer for the wrong reasons.

The donor questionnaire may also be administered electronically as a computer-based questionnaire. A wide literature is developing around computerized questionnaires and computer assisted self-interviews (CASI). CASI is shown to elicit more information on risk behaviour than traditional face-to-face interviews and may reduce the proportion of donors with a history of high-risk behaviour by encouraging personal disclosure and self-deferral (38,39).

A particular focus is required on first-time donors as they are not familiar with the questionnaire and its purpose and may take longer to complete it; however, it has been reported that regular donors may take less care in filling in the questionnaire (40).

It is essential that donors are aware of the importance of the questionnaire, the significance of the questions and the need for providing accurate information (41). The information provided by the donor can then be further elaborated on during the interview.

Donor interview and pre-donation counselling

The completed donor questionnaire should be reviewed prior to donation in a one-to-one confidential interview between the donor and a donor selection staff member so that an assessment can be made of the donor's general health, medical history and any TTI risks. It also provides an opportunity to check whether the donor has understood the questions and has answered them correctly. Many people do not understand medical terms and may be so eager to give blood that they do not recognize the significance of their answers for their own health. Assistance should therefore be provided to anyone who has difficulty in understanding the questions.

Assurance about the confidentiality of the donor's medical history is essential. If donors understand why it is in their own interests to give accurate and

complete information about their health, it will reassure them that their welfare is important to the BTS and may motivate them to become regular donors. The donor's ability to understand the blood donation process and provide informed consent should be assessed.

Whenever possible, the medical history should be further elaborated by a donor selection staff member, particularly for new donors. An initial question such as "When did you last see a health care professional?" may avoid multiple questions and lead to further information about the donor's medical history. Similarly, relevant travel information may be elicited by a simple question such as "When did you last travel to another region or country?"

Pre-donation counselling is an integral part of the donor interview. It enables donor selection staff to:

- Check that the donor has understood all questions and responded accurately to the questionnaire
- Answer the donor's questions and provide reassurance in case of anxiety
- Explain reasons for any deferral and give advice about further medical care, if needed
- Ensure that the donor is able to give informed consent to donate and recognizes that his/her signature is an affirmation that responses provided to the questionnaire are accurate.

Donor health and risk assessment

The assessment of the donor health and TTI risks requires privacy, a sensitive, non-judgemental approach and an assurance of confidentiality. The reason for questions aimed at eliciting any health and TTI risks should be explained and the donor should be offered an opportunity to self-defer. The assessment of donor suitability and deferral, where appropriate, aims to exclude donations from individuals at risk of TTI, particularly from those with recently acquired infection that cannot or may not be detected by routine screening tests or with infections for which no effective blood screening tests are available. An in-depth discussion may be needed, particularly with new donors who may not know about the "window period" or the signs and symptoms of an infection. Individuals who visit the BTS to obtain HIV testing pose a risk to the blood supply (42).

The donor assessment not only enables the review of the donor's medical history and medications, but also provides an opportunity for a basic health check to assess whether the donor is in general good health. Any signs of debility, under-nutrition, pallor, jaundice, cyanosis, dyspnoea or intoxication from alcohol or drugs should also be noted (also refer to Section 4.2 on donor appearance and inspection).

Physical examination, weighing and/or measurement of vital signs (pulse, blood pressure) are part of the basic health check and are carried out at this stage. The venepuncture site should be examined to check that the donor's veins are accessible and suitable to enable easy venepuncture.

The basic health check also enables an assessment to be made of any physical disabilities that may impede the donation process, such as:

- Mobility: the donor should be able to easily access the donor bed or couch
- Sight or hearing impairment: assistance should be provided by a staff member.

Issues that require special attention during donor health and risk assessment include:

- The prevalent culture and context of the environment for donation; in some situations, a donor may simply be overawed by the medical setting and procedures
- The provision of sufficient privacy and assurance of confidentiality to make the donor comfortable when answering probing and sensitive questions
- Identifying and overcoming language barriers or lack of understanding of questions in the donor questionnaire
- Ensuring good communication by using simple jargon-free language and explaining any medical terms.

Informed consent

Informed consent is a voluntary agreement given by the prospective donor to the donation of blood, to the testing of a blood sample for TTI, for the transfusion of the donated blood to patients and if required, for the use of the blood for additional tests, quality assurance or research purposes. To obtain informed consent, the BTS should provide the following minimum information to the potential donor:

- The donation process and potential adverse donor reactions
- The tests that will be performed (TTI and others) on the samples taken from the donated blood and the reasons for these tests
- Confidentiality of all personal information, including test results.

The donor should sign and provide informed consent to the donation of blood or blood components on a voluntary basis. Informed consent signifies that the donor has understood the questionnaire, has provided accurate answers and is willing to donate blood (43). It also indicates that the donor understands the blood donation process, the possibility of adverse reactions to blood donation, the risks of the transmission of infections through donated blood and the implications of any abnormalities that may be detected during the donation process and blood screening, and is providing consent for post-donation notification and counselling, if detected to have a positive viral infection marker or any other abnormality. The donor's understanding of the questionnaire and its implications is of particular importance in countries where donors may be held legally liable if they give incorrect information.

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

3.2 DONOR DEFERRAL

Donors who do not to meet the selection criteria should be deferred on a temporary or permanent basis. All deferred donors should be treated with respect and care in a confidential manner and should be given a clear explanation of the reason for deferral and an opportunity to ask questions. They should be informed whether the deferral is to safeguard their own health and/or that of the recipient. It is the responsibility of the BTS to ensure that donors who are deferred due to medical conditions are referred for further investigations and management, as appropriate.

Studies have found that deferral has a negative impact on future donor return, particularly by first-time donors and those deferred for more than a year (37,44).

Temporarily deferred donors should be advised on when they could donate and encouraged to return. Donors are less likely to return to donate blood if unclear or unsatisfactory information is given about the reason for deferral. Many temporarily deferred donors do not spontaneously return to donate blood and may need to be recalled after the deferral period is over. Counselling of deferred blood donors could enhance the compliance of donors to seek follow-up medical care (45).

A system should be in place for donor counselling and referral if any further investigations, treatment and care are indicated. Refer to *Blood donor counselling: Implementation guidelines* (6).

3.3 DONOR RECORDS

The record of the donor's general health, medical history and TTI risk assessment as part of the donor questionnaire should always be signed by the donor as being correct. The questionnaire becomes part of the donor's records and documents the informed consent.

Records should be kept of each activity associated with blood donation, ideally in an electronic database capable of generating reports. In addition to donor identification, assessment and selection, records should reflect donor deferrals, adverse reactions or unexpected events and any unsuccessful donations.

Donor records should be confidential, easily retrievable and should allow traceability: from the donor to the patient receiving transfusion and vice versa. Records should be retained for a period of time defined by local or national legislation or guidelines. Donor records should be reviewed regularly and donor data (e.g. male: female ratio, donor deferrals, adverse donor events and reactions) should be analysed in order to monitor the effectiveness of donor selection so that remedial action can be taken, where necessary.

Key records, including dates, times and signatures, to be maintained and retained during the donor selection process include:

- Donor registration information
- Completed donor questionnaires and informed consent
- Outcomes of donor interview and assessment
- Donor deferral records
- Unique donation number for each donation
- Donor counselling and follow-up records
- Adverse donor events and reactions
- Donor deferral registry.

Data on donor deferrals should be collected and regularly reviewed to enable the BTS to assess the major causes of deferral, particularly those that result in the greatest numbers of donor deferrals and those presenting high risk to patients. These vary from country to country; hence there is a need to collect local data on which to base relevant decisions. The most common causes of donor deferral are of particular interest as these will indicate whether donor information and education may need to be improved or donor selection criteria should be reviewed. A deferral database will also indicate whether staff are interpreting the selection guidelines correctly and where further education and training should be focused.

Donor deferral records also enable the previous deferral status of donors to be checked and decisions made on the re-entry of temporarily deferred donors.

A donor deferral registry (DDR) is a confidential list of donors who are positive for a transfusion-transmissible infection and who have been permanently deferred. A DDR is used to monitor the incidence and prevalence of such infections in the donor population and may also assist in identifying areas that require strengthening in the donor selection process.

3.4 CONFIDENTIAL UNIT EXCLUSION (CUE)

The system of confidential unit exclusion (CUE) offers donors the opportunity to inform the BTS immediately after donation or subsequently if they consider that their blood may be unsafe for transfusion; this may be particularly useful if donors have been persuaded or coerced to donate. Where CUE is used, donors should be given information to enable them to contact the BTS and to communicate that their blood should not be used for transfusion.

The CUE system is designed to add an additional level of safety to the donor selection and blood screening processes and has been found to be effective in some settings (46). However, there is some evidence that it may have limited effect on reducing the transmission of infections through window-period donations (47) and may lead to the discard of safe donations (48,49). One study suggested that its use may have negative consequences by reducing the perceived responsibility of staff in eliciting a history of high-risk behaviour (40).

3.5 ADVERSE DONOR REACTIONS AND POST-DONATION CARE

Donors should be managed in a way that ensures high standards of care and assures them of the importance accorded to their health and well-being by the BTS. Nevertheless, there are recognized adverse reactions that can occur during blood donation; these can generally be minimized or avoided by appropriate donor selection and care, and appropriately trained staff (50,51). Donors who have suffered an adverse reaction have been shown to be less likely to return to donate again (37).

Vasovagal episodes and soft tissue injuries (bruises and haematomas at the venepuncture site) are the most common donor reactions. The majority of these are minor and donors usually recover quickly; however, these reactions can be of concern to donors and reassurance should be provided. In some cases, a reaction may prompt the donor to reveal a relevant medical history. A minority of adverse reactions may require medical care outside the BTS and may lead to prolonged symptoms or incapacity.

Staff should be trained in the recognition and management of adverse donor reactions, including the provision of first aid. The incidence of bruising should be monitored so that further venepuncture training may be provided to staff as necessary. A system for the reporting and investigation of adverse donor events and reactions should be in place as part of the donor haemovigilance system.

Donors should be provided with oral and written advice on the management of bruises and delayed vasovagal events and should also be given information about how to contact the BTS for further advice, if necessary.

Part 2

Criteria for blood donor selection

4 General donor assessment

Only individuals in good health should be accepted as blood donors. Good health is difficult to define, but certain associated parameters may be established from a brief medical history, observation and simple tests. Staff undertaking donor health and risk assessment should be well-trained in the observation of donor appearance and detection of signs of ill health. Staff should receive explicit guidance on what to look for and when to refer a donor to a health-care professional for further medical attention.

Donors should feel well on the day of donation and be able to perform their routine daily activities. Information about minor illnesses, exposure to communicable diseases, travel to disease endemic areas, pregnancy and lactation and medical and surgical interventions should be elicited so as to determine suitability for blood donation or the need for deferral. The BTS physician may request additional information and advice about the health of a prospective donor from the donor's own doctor or specialist.

Sections 4, 5, 6 and 7 contain recommendations on acceptance and deferral of donors based on selection criteria which fall into four broad categories:

- Conditions that are acceptable
- Conditions that require temporary deferral for defined periods of time
- Conditions that require permanent deferral
- Conditions that require individual assessment.

4.1 AGE

4.1.1 Lower age limit

A lower age limit should be set for blood donation, taking into account national legal requirements for consent, the increased risk of vasovagal reactions in younger donors, and the increased iron requirements of adolescents and young menstruating females.

The lower age limit for blood donation in most countries is 18 years, although in some countries national legislation permits 16–17 year-olds to donate provided that they fulfil the physical and haematological criteria required and that appropriate consent is obtained.

Studies of adverse events in blood donors have shown an increased rate of vasovagal reactions in younger donors (50,52); a study conducted in the United States of America in 2006 reported a 10.7% risk of a vasovagal reaction in donors aged 16–17 years, compared with 8.3% in 18–19 year-olds and 2.8% in donors aged 20 years or older (53). The age of 16 should therefore be an absolute lower limit for blood donation to ensure donor health and safety.

Adolescents of either gender are at risk of iron deficiency during the pubertal growth spurt when the average daily total requirement of absorbed elemental iron is 1.50 mg/day for males aged 15–17 years and 1.62 mg/day for females (54,55).

Recommendations

- The usual lower age limit for blood donation is 18 years
 - Where permitted by national legislation or in setting a lower age limit of 16 or 17 years for blood donation, the BTS should consider:
 - The age of legal consent below which parental permission is required and the need to inform parents/guardians about the process, benefits and risks of blood donation so that informed consent can be obtained
 - The balance between the benefit of an increased blood supply by recruiting younger donors against the increased risk of adverse reactions in this age group
 - The increased iron requirement of adolescents and the possible compromise of their iron status by frequent blood donations
-

4.1.2 Upper age limit

Upper age limits for blood donation of between 60 and 70 years have been implemented in the past because of concerns regarding the increasing incidence of cardiovascular disease with age and the potential risk of adverse reactions, which are more likely in first-time donors.

There is now extensive published literature on the safety of blood donation in older individuals in both the allogeneic and autologous setting, indicating that vasovagal and other adverse reactions are infrequent in older donors who fulfil normal donor selection criteria (56,57,58,59,60). The upper age limit has been safely removed for regular blood donors in countries where healthy life expectancy is high (56,61,62,63,64). Nevertheless, many BTS have an upper age limit of 60 years for *first-time* donors.

Recommendations

- In setting an upper age limit for blood donors, the BTS should consider the healthy life expectancy of the population
 - The usual upper age limit for blood donation is 65 years
 - First-time donors older than 60 years and regular donors over the age of 65 may be accepted at the discretion of the responsible physician
 - First-time donors over 60 years should make their first donation at a donation site where a physician is available
-

4.2 DONOR APPEARANCE AND INSPECTION

The prospective donor should appear generally well and should not be febrile, breathless or suffering from a persistent cough. Donors should be observed to rule out malnutrition or any debilitating condition. They should have a sound mental status and not be under the influence of alcohol or drugs.

The colour of exposed skin and mucous membranes should be normal, with no jaundice, cyanosis, flushing or pallor, and no signs of skin infection, rash or obviously enlarged lymph nodes. If body piercings or tattoos are present, the risk of transfusion-transmissible infections (TTI) should be assessed (also refer to Section 7.9.5 on cosmetic treatments and rituals).

The venepuncture site should be clean, free from any skin lesions or scars and the arms should be examined for signs of injecting drug use. Antecubital veins should be easily visible or palpable to enable proper venepuncture, thus avoiding any discomfort to the donor and minimizing the risk of major bruises or other soft tissue injury at the venepuncture site.

Donors with sight or hearing impairment may be accepted provided clear and confidential communication can be established. If assistance is required, it should be provided by a staff member or other independent person and not a family member or friend.

Recommendation

- Prospective donors should be accepted only if they appear to be in good health and comply with donor selection criteria
-

4.3 MINOR ILLNESSES

Minor non-specific symptoms (e.g. general malaise, pain, fever, headache, cough, diarrhoea) may indicate the presence of an acute infection that may be transmissible by transfusion. Donors should be asked to confirm that they are free from such symptoms on the day of donation and that they have fully recovered from any recent infection(s). Individuals suffering from minor illnesses and not feeling well should not donate blood.

There is no evidence that minor infections such as common upper respiratory infections can be transmitted by transfusion, but it is nevertheless advisable as a precautionary measure to defer blood donation until any such infection has resolved (65).

Recommendation

Defer

- Individuals with a history of recent infection: defer for 14 days following full recovery and cessation of any therapy, including antibiotics
-

4.4 WEIGHT

It is important to set weight limits for blood donation to protect donors from adverse effects, in particular vasovagal episodes and anaemia. Low body weight and low blood volume have been shown to be independent predictors for vasovagal reactions (50,66).

It is generally accepted that the volume of whole blood donated should not exceed 13% of blood volume: e.g. a donor should weigh at least 45 kg to donate 350 ml ($\pm 10\%$) or 50 kg to donate 450 ml $\pm 10\%$ (67,68). There are no defined upper weight limits for blood donation; however, gross obesity may be a reason for deferral if veins are inaccessible, or if the donor's weight exceeds the safe loading capacity of the blood collection bed or impairs his/her mobility or the capacity of staff to provide care in the event of an adverse reaction. The estimation of blood volume is more difficult in obese individuals as fat contains proportionately less blood than muscle. Hence, blood volume may be overestimated (69), resulting in an increased risk of an adverse reaction.

For apheresis procedures, the total volume of donated plasma, platelets and red cells collected should not exceed 13% of total blood volume (70) and the maximum extracorporeal blood volume should not exceed 15% of the donor's total blood volume at any stage of the procedure. In practice, this requires that plateletpheresis and plasmapheresis donors should weigh at least 50 kg. Prospective donors of double red cell apheresis donations should have an estimated blood volume of more than 5 litres; this requirement is generally met by non-obese individuals weighing more than 70 kg.

The reasons for any obvious rapid weight loss should be ascertained.

Recommendations

- In determining a lower weight limit for blood donors, the BTS should consider norms for the weight of the population; if a significant proportion of the donor population weighs less than 45 kg or 50 kg, collection volumes may be reduced accordingly, while ensuring that blood collection bags and their anticoagulant content are adjusted to be compatible with the volumes collected
 - Prospective donors of whole blood donations should weigh at least 45 kg to donate 350 ml \pm 10% and 50 kg to donate 450 ml \pm 10%
 - Prospective donors of apheresis platelet or plasma donations should weigh at least 50 kg
 - Prospective donors of double red cell apheresis donations should have an estimated blood volume of more than 5 litres; this requirement is generally met by non-obese individuals weighing more than 70 kg.
-

4.5 VITAL SIGNS

4.5.1 Pulse

A normal pulse rate of 60–100 per minute and a regular rhythm are indicators of good health; many BTS recommend that these are examined prior to donation. The ability to detect significant abnormalities of pulse rate or rhythm depends on the skill and experience of staff. The usefulness of this examination in a blood donation setting needs to be assessed.

4.5.2 Body temperature

A prospective donor who is febrile – defined as a core oral temperature more than 37.6°C (71) – is by definition unwell and should be deferred. Fever can indicate any number of medical conditions and infections, but is usually associated with other symptoms (also refer to Section 4.3 on minor illnesses).

4.5.3 Blood pressure (BP)

A normal blood pressure (systolic 120–129 mmHg, diastolic 80–89 mmHg) is generally regarded as an indicator of good health (72).

The measurement of BP is required by many national guidelines on donor selection and some BTS set an upper limit of BP for blood donors (70) on the basis that uncontrolled hypertension is an independent risk factor for cardiovascular disease. However, a systematic review of the literature found no evidence that raised baseline blood pressure, treated hypertension or low blood pressure were

predictive of increased adverse reactions, although the level of evidence was limited (73).

BP may be measured routinely for the purposes of health screening; however, the blood collection session is not the ideal setting for this. Donor anxiety may result in the temporary elevation of systolic BP. Accurate BP measurement requires the availability of calibrated equipment, suitable facilities, adequate time and appropriately skilled staff.

Recommendations

- In assessing whether pulse, temperature or blood pressure should be measured routinely, selectively or not at all at the time of blood donation, the BTS should consider:
 - Clinical value of these parameters in the blood donation setting
 - Availability of adequate equipment (calibrated and sterile, where appropriate), space and time. If blood pressure is used as a selection criterion for blood donation, arbitrary acceptable limits of systolic BP of 100–140 mmHg and arbitrary acceptable limits of diastolic BP of 60–90 mmHg are suggested
 - Competence and experience of staff and their ability to perform techniques correctly
-

4.6 DONOR IRON STATUS

4.6.1 Haemoglobin screening

There are no rapid, simple and direct bedside methods for determining iron status. The pre-donation assessment of donor haemoglobin remains the best approach. Normal ranges for haemoglobin and red cell indices differ between ethnic populations, and in males and females, and are also affected by age, especially in women (74,75). International and national guidelines (Annex 1) commonly recommend minimum haemoglobin levels of 12.5 g/dl for females and 13.5 g/dl for males but further studies are needed to justify the selection of these levels. In some countries, the same haemoglobin level is used for males and females (76). Individuals with haemoglobin levels below the normal range are, by definition, anaemic (77). The WHO Global Database on Anaemia (55) defines haemoglobin thresholds for anaemia as 12.0 g/dl for non-pregnant women (≥ 15.00 years) and 13.0 g/dl for men (≥ 15.00 years). There are many causes of anaemia and anaemia due to iron deficiency is the most prevalent. The aim of haemoglobin screening is to ensure that the prospective donor is not anaemic. The lower limit of acceptable haemoglobin for blood donation should be set at a level that prevents the selection of anaemic individuals as blood donors and also minimizes the exclusion of healthy donors.

Haemoglobin screening safeguards anaemic individuals from donating blood and also protects returning donors from donation-induced iron deficiency (DIID), the depletion of iron stores by repeated donations (78,79). Collecting a unit of blood from a donor with a normal haemoglobin level also provides good quality blood components, with adequate and consistent haemoglobin content in the collected blood.

Haemoglobin and/or haematocrit are easily estimated by validated, simple, rapid and inexpensive methods, but are insensitive in assessing iron deficiency as

values start to fall only when iron stores are depleted. Nevertheless, they remain the most convenient measurement parameters at blood donation session and when recorded at each subsequent attendance, can detect anaemia and DIID.

Donor haemoglobin and/or haematocrit levels should be measured immediately before each donation using a validated technique that is subject to quality control. Donors who do not meet the minimum haemoglobin levels for blood donation should be referred for further haematological investigation and treatment. They should be encouraged to return to donate when the anaemia has been successfully treated.

Recommendations

- In determining the lower limits of haemoglobin for whole blood donation and implementing haemoglobin screening, the BTS should consider:
 - Normal haemoglobin range among healthy individuals in the local population
 - A haemoglobin level of not less than 12.0 g/dl for females and not less than 13.0 g/dl for males as the threshold
 - Selection of a validated haemoglobin screening technique that is subject to quality control, the feasibility of its implementation, the availability of equipment and the training and skills of staff
 - Only sterile disposable lancets should be used for blood sampling
 - Donors whose haemoglobin levels are below the nationally-defined threshold should be deferred, counselled and referred for medical assessment
-

4.6.2 Frequency of donation and iron supplementation

Iron deficiency is common worldwide and donation-induced iron deficiency is of particular concern in relation to women of childbearing age and adolescents. Adolescents of both sexes are also at risk of iron deficiency during the pubertal growth spurt, when the average daily total requirement of dietary elemental iron to be absorbed is 1.50 mg/day for males and 1.62 mg/day for female (54,55). A donation of 450 ml of blood removes 200–250 mg of haem iron. The average amount of stored iron (ferritin and haemosiderin) in a woman of reproductive age in the developed world is about 300 mg; hence, the donation of a unit of blood requires the subsequent mobilization of much or all of this reserve (80). In developing countries, many women have depleted iron stores and will inevitably be precipitated into negative iron balance by blood donation (54,55,76).

Across the world, the minimum interval between whole blood donations varies between 56 days (8 weeks) and 16 weeks and different donation intervals are usually followed for male and female donors; in practice, some female donors are unable to give blood more than once or twice per year due to iron deficient states. There is a high prevalence of iron depletion in frequent blood donors; increasing the inter-donation interval would reduce the prevalence of iron depletion and deferral due to low haemoglobin (76,81,82).

The standard approach for preventing donation-induced iron deficiency is universal screening and deferring those whose pre-donation haemoglobin is below a certain threshold. It is important to detect and manage the donation-induced iron depletion that inevitably accompanies regular blood donation (78). Reducing the frequency of blood donation is likely to reduce the prevalence of iron deficiency among blood donors, as might implementing routine iron supplementation (83).

The onset of DIID may be determined using full blood cell counts and red cell indices, including red blood cell distribution width (RDW), when measured serially in healthy donors from populations with a low prevalence of inherited conditions such as thalassaemia trait. The more sophisticated red cell parameters on modern cell counters are even better indicators of DIID onset, even possibly in the co-presence of thalassaemia trait, but are more expensive and usually not available at blood donation sites.

Haemoglobin estimation alone in regular blood donors may not be adequate and serum ferritin estimations may need to be done to detect pre-clinical iron deficiency state. Regular ferritin measurement is a useful indicator for iron depletion in blood donors. (84,85,86,87,88).

If the BTS has access to facilities for monitoring donor iron stores by measuring serum ferritin concentrations, individual donor algorithms for donation frequency and iron supplementation may be developed (78,80,81,83,85,89,90,91,92,93). In some circumstances, the more expensive but informative determination of serum soluble transferrin receptor concentrations (STR) gives an even better indication of DIID.

Iron supplementation of blood donors has been proposed for routine implementation and several pilot operational and clinical trials have been conducted (83). Donor iron stores may be replenished by giving oral iron supplements and this particularly needs to be considered for repeat and regular blood donors.

Indiscriminate long-term supplementation with iron salts at a high dose is, however, not recommended, because of:

- Possible masking of other pathological causes of iron deficiency, such as gastro-intestinal bleeding
- Risk of giving iron salts to people with undiagnosed hereditary haemochromatosis or other inherited iron-overloading tendencies (78)
- Toxicity if accidentally ingested by children.

Some of these concerns may be avoided by using low-dose iron preparations or carbonyl iron. Such preparations are better tolerated, less toxic and can be safely used to reduce donation intervals.

Donors giving platelets or plasma by apheresis may donate more frequently than whole blood donors. A minimum inter-donation interval of 4 weeks for platelet donors and 2 weeks for plasma donors is generally recommended, provided that haematological and biochemical parameters are monitored and remain within acceptable limits (94). The interval before an apheresis platelet or plasma donation should be at least 4 weeks following a whole blood donation, an apheresis red cell donation or a failed return of red cells during apheresis (70).

The inter-donation interval between double red cell donations should be 6 months. If a double red cell donation is given following whole blood donation, the interval should be 12 weeks for males and 16 weeks for females.

Recommendations

- The minimum interval between donations of whole blood should be 12 weeks for males and 16 weeks for females
- The minimum interval between donations of platelets should be 4 weeks
- The minimum interval between donations of plasma should be 2 weeks

-
- The minimum interval before an apheresis platelet or plasma donation should be 4 weeks following a whole blood donation, an apheresis red cell donation or a failed return of red cells during apheresis
 - In determining the frequency of donation and whether iron supplementation is given, the BTS should consider:
 - The need for longer donation intervals for young donors and female donors of childbearing age
 - Assessing the feasibility and affordability of providing iron supplementation to donors susceptible to donation-induced iron deficiency, especially women, adolescents, and repeat and regular donors
 - Exploring access to facilities for monitoring serum ferritin concentration and the feasibility of developing and implementing individual donation intervals
-

4.7 FLUID INTAKE AND FOOD

Most BTS guidelines recommend that donors should maintain their usual food and fluid intake before donation but should avoid heavy or fatty meals which may result in a lipaemic donation that may need to be discarded. The risk of adverse events in fasting donors has not been investigated, but there is evidence that an intake of 500 ml of drinking water immediately before donation may reduce the risk of a vasovagal reaction (95,96,97). Where possible, donors should have access to drinking water in the blood centre before donating. Fasting donors should have had some fluid intake in the four hours prior to donation. In countries where prolonged fasting is practised, blood collection sessions may be scheduled after they have taken food and fluid.

Recommendation

- The BTS should consider providing 500 ml drinking water to donors before donation to minimize the risk of vasovagal reactions
-

4.8 GENDER

4.8.1 Pregnancy, lactation and menstruation

The average woman needs about 350–500 mg additional iron to maintain iron balance during pregnancy (54,55). Female donors should be deferred during pregnancy and for a sufficient time after delivery (or following abortion or miscarriage) and during lactation to allow for the recovery of iron stores.

Menstruation is not a reason for deferral. However, women who report regular excessive menstrual bleeding and are found to have low haemoglobin levels should not donate blood and should be referred for medical assessment (90).

Contracting and relaxing the muscles in the legs, arms and abdomen during donation may reduce the risk of vasovagal reactions, particularly among female donors (98,99,100,101).

Recommendations

- The BTS should encourage donors to practise applied muscle tension during blood donation

Accept

- Female donors during menstruation, provided that they feel well and meet the minimum haemoglobin level for blood donation

Defer

- Female donors during pregnancy and up to 6 months after delivery or termination of pregnancy
 - Female donors during lactation
-

4.8.2 Reducing the risk of transfusion-associated acute lung injury (TRALI)

The gender of the donor may influence the type of blood component prepared from the donation. Plasma-rich blood components from multiparous women are more likely to cause TRALI and related disorders than those from males, because plasma from such women is likely to contain alloimmune-reactive antibodies; these include antibodies to human leucocyte antigens (HLA) or to human neutrophil antigens (HNA), which are transferred passively during transfusion, to the possible detriment of a recipient who possesses the corresponding antigen (102,103,104).

Recommendations

- The BTS should consider:
 - Maximizing the collection and production of plasma and platelet concentrates from male donors
 - Screening multiparous female donors for HLA and/or HNA antibodies
-

4.9 OCCUPATION AND LEISURE ACTIVITIES

Delayed vasovagal reactions, defined as occurring after the donor leaves the blood donation site but within 24 hours of donation, are uncommon (reported as 46:100 000) (105). However, if the donor is in a hazardous situation, a delayed vasovagal reaction may put the donor and others at risk of harm. For this reason, most BTS advise donors in hazardous occupations (e.g. emergency services, working at heights) not to resume work for at least 24 hours after blood donation. Air crew are subject to their own regulations which do not permit blood donation within specified time limits (106). Similarly, donors are generally advised not to undertake strenuous physical activities for up to 24 hours after blood donation.

Some occupations (e.g. health-care workers, police, military personnel, workers with animals) carry an increased risk of exposure to blood-borne infections, although confirmed transmission is relatively rare (107,108,109,110,111). While such individuals should have been immunized against relevant diseases, where possible, donors in these occupations should be questioned about possible exposure risk (e.g. needlestick injuries, blood splashes, bites) and a deferral

period, usually of 6–12 months applied, based on the incubation period of the relevant infection.

Sex workers are at particular risk of transfusion-transmissible infections and should not be accepted as blood donors (also refer to Section 7.9.1 on high-risk sexual behaviours).

4.10 SPECIAL CONSIDERATIONS FOR DONOR SELECTION FOR APHERESIS DONATIONS

Apheresis is the process by which the required component of whole blood is separated and collected from the donor using an automated blood cell separation device. Components that can be donated by apheresis include platelets (plateletpheresis), plasma (plasmapheresis), leucocytes (leucapheresis) and red blood cells (erythrocytapheresis).

Medical criteria for the acceptance of blood donors in respect of the donor's health should be the same for donors of whole blood and of blood components obtained by apheresis. Additional donor selection criteria pertaining to apheresis donations are recommended in the relevant sections in this document. Detailed recommendations regarding the volume and frequency of apheresis donations are outside the scope of these guidelines.

In addition to meeting the selection criteria required for whole blood donation, donors giving apheresis donations should also meet requirements that are specific for the type of apheresis procedure and the component collected (70,112,113,114). For apheresis platelet donation the donor's platelet count should be above $150 \times 10^9/L$. For apheresis plasma donation, the donor's total protein level should be greater than 60 g/L. For double red cell apheresis, donors of either gender require a minimum haemoglobin level of 14.0 g/dl (68).

5 Donor medical history I: Non-communicable diseases

Having ascertained the potential suitability of the donor on the basis of the general criteria outlined in Section 4, a detailed medical history should be taken, using a structured donor questionnaire and interview. This is aimed at identifying and deferring, either temporarily or permanently, any donor with a medical condition that may predispose the donor to immediate or long-term harm, affect the safety or quality of the product derived from the blood or compromise patient safety.

5.1 HAEMATOLOGICAL DISORDERS

Assessment of the suitability of prospective donors with haematological disorders is based on the need to avoid any risks of anaemia, bruising and haematoma or thrombosis as a result of the venepuncture.

Chronic anaemia may be associated with ill health and such individuals are not suitable to donate blood. Also refer to Sections 5.9 on malignant diseases and 6.3 on blood transfusion and transplantation.

5.1.1 Anaemia, including haematinic (iron, B₁₂ and folate) deficiency

The history of anaemia should be assessed in relation to its cause, current status and any treatment that has been received. Individuals who suffer from haematinic deficiency anaemia of whatever etiology should not be accepted as donors until the cause of the anaemia has been identified and the anaemia has been successfully treated.

Recommendations

Accept

- Individuals who:
 - Have a past history of iron deficiency anaemia, with a known cause that is not a contraindication to donation, and who have completed treatment and are fully recovered
 - Have a past history of B₁₂ or folate deficiency, are fully recovered and are taking maintenance treatment with B₁₂ or folic acid

Defer

- Individuals who:
 - Do not meet the minimum haemoglobin level for blood donation
 - Are under investigation or on treatment for anaemia

Defer permanently

- Individuals who have chronic anaemia of unknown cause or associated with systemic disease: e.g. renal failure, rheumatoid disease
-

5.1.2 Haemoglobinopathies

The prevalence of inherited haematological conditions in different countries should be taken into account in defining donor acceptance and deferral criteria.

Individuals with thalassaemia major and sickle cell disease are not suitable as blood donors (70). The sickle cell trait impairs the effective filtration of blood for leucodepletion (115,116). Most BTS do not accept donors with sickle cell trait for apheresis donations or for whole blood donations if the blood is to be leucofiltered. Blood from donors with sickle cell trait is not suitable for intrauterine transfusion or neonatal exchange transfusion (64); it is also unsuitable for patients with sickle cell disease (67) as it may exacerbate sickling of the red cells.

Recommendations

Accept

- Individuals with:
 - Thalassaemia traits, provided they are well and meet the minimum haemoglobin level for blood donation
 - Sickle cell trait: accept for whole blood donation provided they meet the minimum haemoglobin level for blood donation; blood donated by sickle cell trait individuals is, however, not suitable for leucodepletion, intrauterine transfusion, neonatal exchange transfusion or for patients with sickle cell disease

Defer permanently

- Individuals with:
 - Thalassaemia major or sickle cell disease
 - Sickle cell trait for blood donation by apheresis procedure or for whole blood donation if the blood is to be leucofiltered
-

5.1.3 Enzymopathies and inherited red cell membrane defects

Glucose-6-phosphate dehydrogenase (G6PD) deficiency is the most common red cell enzyme defect, with hundreds of molecular variants. Most variants have only slightly subnormal red cell survival; however, others (e.g. the Mediterranean variant) render the cells highly susceptible to oxidative stress. Blood from individuals with G6PD deficiency (with a history of haemolysis) is therefore unsuitable for transfusion as haemolysis may be precipitated if the recipient develops an infectious illness or ingests an oxidative drug or fava beans (117). People with the next most common inherited enzyme defect, pyruvate kinase deficiency, will usually be too anaemic to donate, even if asymptomatic.

Red cell membrane disorders are inherited diseases due to mutations in various membrane or skeletal proteins, resulting in decreased red cell deformability, reduced life span and premature removal of the erythrocytes from the circulation. Red cell membrane disorders include hereditary spherocytosis, hereditary elliptocytosis, hereditary ovalocytosis and hereditary stomatocytosis (118).

Recommendations

- Policies for the assessment of prospective donors should be developed by BTS in regions where there is a high incidence of enzymopathies and inherited red cell membrane defects

Accept

- Individuals with G6PD deficiency or other inherited red cell membrane defects, without a history of haemolysis; however, their blood is not suitable for intrauterine transfusion, neonatal exchange transfusion or for patients with G6PD deficiency

Defer permanently

- Individuals with G6PD deficiency or inherited red cell membrane defects, with a history of haemolysis
-

5.1.4 Thrombocytopenia

Individuals with thrombocytopenia should not be accepted as blood donors because of the risk of bleeding at the venepuncture site and because chronic thrombocytopenia may be associated with serious underlying haematological or other systemic disease. A past history of autoimmune thrombocytopenia is not a contraindication to blood donation, even if treated by splenectomy, provided that the prospective donor has been well for five years with no evidence of relapse (64).

Recommendations

Accept

- Individuals with a past history of acute autoimmune thrombocytopenia more than 5 years previously, provided they are well and no longer require treatment, other than prophylactic antibiotics following splenectomy

Defer permanently

- Individuals with thrombocytopenia of unknown cause or associated with long-term haematological or systemic disease
-

5.1.5 Secondary erythrocytosis

Donors with secondary erythrocytosis due to smoking may be accepted provided that polycythaemia rubra vera has been excluded and other donor selection criteria are fulfilled.

Recommendation

Accept

- Individuals with secondary erythrocytosis, provided that a diagnosis of polycythaemia rubra vera is excluded
-

5.1.6 Hereditary haemochromatosis

This inherited condition of iron overload through excessive iron absorption of dietary iron can be treated by phlebotomy; individuals who are otherwise healthy and meet all other donor selection criteria may be accepted as blood donors (119) and indeed bled more frequently before donation-induced iron deficiency supervenes (67). However, special arrangements are needed if the maintenance therapy requires reduction of the inter-donation interval (120,121).

Recommendation

Accept

- Individuals with hereditary haemochromatosis who fulfil all other donor selection criteria
-

5.1.7 Coagulation disorders, including haemophilia A and B

These disorders are usually due to inherited deficiency of coagulation factors. Patients with such disorders are not acceptable as blood donors because of the risk of excessive bruising at venepuncture sites and because treatment is usually with blood products.

Known carriers of coagulation disorders may be accepted provided they have normal or near normal coagulation factor levels and no bleeding or bruising tendency.

Acquired coagulation disorders are rare and usually associated with serious underlying disease.

Recommendations

Accept

- Individuals with *carrier states* for inherited coagulation disorders including haemophilia A or B, provided they have normal or near normal coagulation factor levels, do not have a history of abnormal bleeding and have not received treatment with blood products

Defer permanently

- Individuals with coagulation factor deficiencies, whether inherited or acquired
-

5.2 CARDIOVASCULAR DISEASES

Assessment of the suitability of individuals with cardiovascular disease should be based on the effect of the condition on the individual's ability to tolerate haemodynamic changes due to blood donation.

5.2.1 Cardiovascular diseases

Observational studies from the United States of America suggest that patients with cardiovascular disease (122,123,124,125,126) may safely donate blood but these studies were of pre-operative autologous blood donation, mostly in a hospital setting using isovolaemic techniques; only one study is applicable to voluntary blood donors (127). Some blood services in the United States currently accept voluntary donors with a history of myocardial infarction more than 6

months previously and who are asymptomatic, or with ischaemic heart disease that has been successfully treated, e.g. by angioplasty or coronary artery bypass grafting (128). Until additional evidence of safety for donors with such conditions is available more generally, these donors should not be accepted for donation unless the circumstances are exceptional and the donation is well-monitored.

Recommendations

- Asymptomatic individuals with a history of cardiovascular disease should have written permission from their cardiologist or physician to donate blood

Accept

- Individuals with:
 - Surgically corrected simple congenital cardiac malformations who have no residual symptoms
 - Asymptomatic disorders such as functional murmurs and mitral valve prolapse

Defer permanently

- Individuals with:
 - Symptomatic ischaemic heart disease
 - Symptomatic peripheral vascular disease, including history of arterial thrombosis
 - History of myocardial infarction
 - Severe cardiac arrhythmia
 - Rheumatic fever with evidence of chronic heart disease
 - Acquired valvular disease with stenosis or regurgitation
 - Valve replacement
 - Hypertrophic cardiomyopathy
 - Palliated (i.e. uncorrected) congenital heart disease
-

5.2.2 Hypertension

There is no evidence that raised baseline blood pressure, treated hypertension or low blood pressure are predictive of increased adverse reactions to blood donation, although the level of evidence is limited (50,73). In addition, there is no evidence of harm to recipients of blood from donors taking anti-hypertensive medication. Individuals whose blood pressure is well-controlled by medication and meet other donor selection criteria can be accepted as blood donors. Donors who have recently started taking anti-hypertensive medication or for whom the dose of anti-hypertensive medication has been adjusted, should be deferred for a period of 28 days after the blood pressure has been stabilized.

Also refer to Section 4.5.3 on blood pressure.

Recommendations

Accept

- Individuals with stable uncomplicated hypertension controlled by medication

Defer

- Individuals who have recently started taking anti-hypertensive medication, or whose dose of anti-hypertensive medication has been adjusted: defer for 28 days after the blood pressure has been stabilized

Defer permanently

- Individuals with hypertensive heart or renal disease
-

5.2.3 Venous thrombosis and thrombophlebitis

Unexplained venous thrombosis may indicate underlying malignancy or thrombophilia. Thrombophilia is a condition in which there is an increased tendency for blood clots to form, usually due to an inherited deficiency or abnormality of a circulating anticoagulant. It may be discovered through family studies; not all individuals with a thrombophilic condition will suffer from blood clots.

Recurrent thrombophlebitis (inflammation of a vein) may be associated with occult malignancy.

Recommendations

Accept

- Individuals who have:
 - Been identified as having a thrombophilic condition, but with no history of a thrombotic episode, and are not on anticoagulant treatment
 - Had a single episode of deep vein thrombosis or pulmonary embolus with an identifiable cause, provided that they are fully recovered and anticoagulant therapy has been stopped for at least 7 days
 - Had a single episode of thrombophlebitis in the last 12 months, provided they are otherwise well and off treatment for at least 7 days

Defer permanently

- Individuals who have had:
 - Two or more episodes of venous thrombosis requiring treatment
 - Axillary vein thrombosis or thrombophlebitis affecting the upper limb
 - Two or more episodes of thrombophlebitis in the last 12 months
-

5.3 RESPIRATORY DISEASES

Assessment of the suitability of individuals with respiratory disease requires consideration of the health of the donor and assessment of the risk of transmission of infection to the recipient.

Also refer to Section 7.5.6 on tuberculosis.

Recommendations

Accept

- Individuals with asthma provided they are asymptomatic on a maintenance dose of non-steroid and/or inhaled steroid medication

Defer

- Individuals with:
 - Asthma during an acute exacerbation: defer for 14 days after full recovery
 - Asthma on a course of oral or injected steroids: defer for 14 days following full recovery and cessation of oral or injected steroids
 - Acute respiratory infections such as bronchitis: defer for 14 days following full recovery and cessation of any therapy, including antibiotics

Defer permanently

- Individuals with:
 - Respiratory disease if they are breathless at rest or on minimal exertion or are cyanosed
 - Severe obstructive airways disease, including those on long-term oral steroid therapy
 - Chronic or recurrent respiratory infections
-

5.4 GASTROINTESTINAL DISEASES

Assessment of the suitability of individuals with diseases of the gastro-intestinal tract should be based on whether the condition is associated with malabsorption and/or acute or chronic blood loss, or may be a portal of entry for infection.

Recommendations

Accept

- Individuals with:
 - Irritable bowel syndrome without debility
 - Diverticular disease, if well
 - Mild gastro-oesophageal reflux
 - Mild hiatus hernia
 - Treated coeliac disease
 - Gallstones
 - Cholecystitis, when fully recovered

Defer

- Individuals with:
 - Active peptic ulceration: defer until completion of treatment and full recovery
 - Active inflammatory bowel disease (ulcerative colitis or Crohn's disease): may be accepted if they are well, in long-term remission and meet the minimum haemoglobin levels for blood donation

Defer permanently

- Individuals with malabsorption syndromes (except treated coeliac disease)
-

5.5 METABOLIC AND ENDOCRINE DISEASES

For the purposes of these guidelines, only two commonly occurring conditions, diabetes mellitus and thyroid disease, are considered.

5.5.1 Diabetes mellitus

Consideration should be given to the donor's general state of health and ability to tolerate a blood donation, as well as the possibility of intercurrent infection that may affect the safety of the blood.

There are no reports suggesting increased adverse donor reactions in diabetic donors. A systematic literature review found no studies investigating diabetes as a possible risk factor for adverse reactions in voluntary blood donors; two studies on pre-operative autologous donation and three experimental studies found that blood donation was well tolerated (73).

Individuals with diabetes who require insulin should be permanently deferred from blood donation (70) because of concerns regarding diabetes-related complications and an increased risk of hepatitis and other infections if safe injection practices cannot be assured.

Recommendations

Accept

- Individuals with diabetes mellitus well-controlled by diet or oral hypoglycaemic medication, provided they have no history of orthostatic hypotension and no evidence of infection, neuropathy or vascular disease, in particular peripheral ulceration

Defer permanently

- Individuals with:
 - Diabetes who require insulin
 - Complications of diabetes with multi-organ involvement
-

5.5.2 Thyroid disease

There is no published evidence about any adverse effects from blood donation to individuals with a history of thyroid disease. Individuals with successfully treated benign thyroid disorders who are euthyroid may safely be accepted as blood donors (64).

Recommendations

Accept

- Individuals with benign thyroid disorders (provided they are euthyroid) such as:
 - Asymptomatic goitre
 - History of viral thyroiditis

-
- Autoimmune hypothyroidism

Defer

- Individuals:
 - Under investigation for thyroid disease
 - If hyper- or hypo-thyroid
 - With a history of malignant thyroid tumours (also refer to Section 5.9 on malignant diseases)

Defer permanently

- Individuals with thyrotoxicosis due to Graves' disease
-

5.6 IMMUNOLOGICAL DISEASES

Individuals with systemic immunological diseases are generally unwell and are therefore not suitable to donate blood. Donors should be questioned about severe allergy to materials used in blood collection, such as latex or skin disinfectant, so that contact with these materials can be avoided. Passive transfer of IgE by blood transfusion has been reported but does not alter acceptance criteria (129,130,131).

While there is no evidence of harm resulting from blood donation by individuals with a history of anaphylaxis, the permanent deferral of such individuals is recommended as a precautionary measure (70).

Recommendations

Accept

- Individuals with:
 - Mild, localized or inactive conditions, such as vitiligo or mild rheumatoid arthritis without systemic symptoms
 - History of allergy, provided they are well and free from allergic symptoms on the day of donation
 - Asthma (also refer to Section 5.3 on respiratory diseases)
 - Eczema (also refer to Section 5.11 on skin diseases)

Defer permanently

- Individuals with:
 - Severe debilitating autoimmune disorders such as systemic lupus erythematosus, dermatomyositis or severe rheumatoid disease
 - Immunosuppression due to congenital or acquired hypogammaglobulinaemia or immunosuppressive medication, with the exception of individuals with IgA deficiency
 - History of anaphylaxis
-

5.7 RENAL AND URINARY TRACT DISEASES

Assessment of the suitability of prospective donors with renal and urinary tract disorders should take into account the well-being of the donor and the risk of bacterial infection which may enter the bloodstream.

Recommendations

Defer

- Individuals with lower urinary tract infections: defer for 14 days after full recovery and completion of treatment
- Individuals with acute self-limiting renal diseases such as acute nephritis when fully recovered and renal functions are normal; this may require deferral for as long as 5 years after full recovery

Defer permanently

- Individuals with chronic renal disease causing ill-health or anaemia, or associated with chronic or recurrent infection
-

5.8 CENTRAL NERVOUS SYSTEM DISEASES

Assessment of the suitability of prospective donors with central nervous system conditions should take into account the well-being of the donor and the risk of transfusion-transmission of variant Creutzfeldt-Jakob disease (vCJD).

5.8.1 Cerebrovascular disease

The usual and predictable fall in blood pressure associated with blood donation (132,133), especially during sleep the night after donation, may be detrimental to individuals with a history of transient cerebral ischaemic episodes or completed stroke; such individuals should be permanently deferred.

5.8.2 Epilepsy

Donors with a history of epilepsy or seizure disorder are generally deferred because of concerns that vasovagal syncope associated with blood donation may precipitate an epileptic seizure. This has not been substantiated by observational studies (134,135,136), showing no detriment and recommending acceptance of donors with epilepsy who are well-controlled: i.e. seizure-free for a defined period, with or without medication.

5.8.3 Dementia and other neurodegenerative disorders

Individuals with dementia or neurodegenerative disease due to any cause should be permanently deferred due to reasons such as inability to give a reliable medical history and the possibility of vCJD (137).

While there is no evidence of transmission of sporadic or familial CJD through transfusion, individuals with symptoms suggestive of CJD or a family history of CJD should be permanently deferred (also refer to Section 7.7 on prion diseases).

5.8.4 Multiple sclerosis

Individuals with multiple sclerosis should be permanently deferred because of the progressive nature of the condition and uncertainty regarding the etiology.

Recommendations

Accept

- Individuals with a history of epilepsy who have been off medication and seizure-free for a period of at least 3 years

Defer permanently

- Individuals with:
 - Cerebrovascular disease (a history of transient cerebral ischaemic episodes or stroke)
 - Dementia or neurodegenerative disease due to any cause
 - Multiple sclerosis or other demyelinating diseases
-

5.9 MALIGNANT DISEASES

Acceptance criteria for prospective donors with a past history of treated solid tumours vary widely. Some BTS accept donors who are disease-free for a specified period (128,138), while others permanently defer on the basis that there is a theoretical possibility of transfusion-transmission of tumour cells or of oncogenic viruses (139,140), although these policies are currently under review.

A large retrospective cohort study of cancer incidence among patients who received blood from donors deemed to have a subclinical cancer at the time of donation (diagnosed with cancer within five years of the donation) showed no excess risk of cancer among recipients of blood from pre-cancerous donors compared with recipients of blood from non-cancerous donors (141). However, the transmission of donor melanoma by organ transplantation has been reported (142). Transfusion-transmitted cancers have never been convincingly demonstrated, but most BTS continue to take a precautionary approach and do not accept blood from people who have had a malignancy as many malignancies spread through the blood stream and by invading surrounding tissues (64,70). Blood donations should not be taken from people with recently active malignancies, except in the case of basal cell carcinoma or cervical carcinoma in situ.

A recent literature review concluded that there is now ample evidence to consider accepting selected donors with a history of malignant disease (except for those where there are specific safety concerns, such as haematological malignancy and melanoma) on the basis of a minimum (suggested 5-year) interval after the completion of successful curative treatment (143).

Healthy adults with a remote history of treated malignant conditions from which they can be regarded as cured may be able to donate under certain well-monitored circumstances. Further studies in this field are indicated.

Recommendations

- For individuals with a past history of solid malignant tumour, BTS may consider acceptance if 5 years or more since completion of successful curative treatment

Accept

- Individuals with a history of “in situ” malignant disease such as basal cell carcinoma or cervical carcinoma in situ, if regularly monitored and considered successfully treated and in good health

Defer

- Individuals with a current diagnosis of malignancy
- Individuals with past history of solid malignant tumour if less than 5 years since completion of treatment

Defer permanently

- Individuals with a history of malignant melanoma
- Individuals with current or past haematological malignancy, including:
 - Leukaemia: i.e. lymphoproliferative and myeloproliferative disorders
 - Lymphomas
 - Clonal haematological disorders such as:
 - Polycythaemia rubra vera and essential thrombocythaemia
 - Paroxysmal nocturnal haemoglobinuria
 - Myelodysplastic syndromes

5.10 MUSCULOSKELETAL DISORDERS

Assessment of the suitability of prospective donors depends on the nature and severity of the disorder and the mobility of the donor.

Recommendations

Accept

- Individuals with acute or chronic simple musculoskeletal disorders, such as:
 - Back pain
 - Sciatica
 - Frozen shoulder
 - Osteoarthritis

provided these conditions do not inhibit their daily routine activities and they are able to climb on and off a donation couch without assistance

Defer

- Individuals with fractures until plaster or external fixation is removed and they are fully mobile

Defer permanently

- Individuals with systemic diseases affecting joints, such as:
 - Rheumatoid disease
 - Psoriatic arthropathy
 - Ankylosing spondylitis
-

5.11 SKIN DISEASES

Assessment of the suitability of prospective donors with skin diseases should consider whether:

-
- The condition is a manifestation of systemic disease
 - The donor is receiving prescribed medication such as antibiotics, anti-inflammatory agents, immunosuppressants or vitamin A analogues
 - There is a risk of infection entering the bloodstream.

Also refer to Section 6.2 on medications for guidance on deferral following immunosuppressive or retinoid treatment.

Recommendations

Accept

- Individuals with common skin conditions, such as:
 - Mild eczema
 - Mild acne
 - Mild psoriasis

provided lesions are not infected, there are no systemic symptoms, the venepuncture site is unaffected and they have not received immunosuppressive or retinoid treatment; long-term low-dose antibiotic treatment for acne is not a contraindication to blood donation

- Individuals with burns, when fully healed

Defer

- Individuals with:
 - Psoriasis with infected lesions, systemic symptoms, affected venepuncture site or receiving immunosuppressive or retinoid treatment
 - Generalized skin disease(s) on systemic medication
 - Contagious skin diseases such as scabies and ringworm until cleared; while not a blood safety risk, there is a potential risk to blood collection staff

Defer permanently

- Individuals with systemic diseases affecting the skin, such as:
 - Scleroderma
 - Systemic lupus erythematosus
 - Dermatomyositis
 - Systemic cutaneous amyloidosis
-

5.12 PSYCHIATRIC DISORDERS

The acceptance of individuals with current or past mental health problems as blood donors depends on an assessment of their ability to fully answer the donor questionnaire and interview and to give informed consent to the donation process, including the testing of their blood.

In general, donors with anxiety disorders and mood (affective) disorders, such as depression or bipolar disorder, may be accepted provided they are stable and feel well on the day, regardless of medication (64). Individuals with psychotic disorders, such as schizophrenia and related conditions, are usually not suitable to donate blood.

Recommendations

Accept

- Individuals with anxiety disorders or mood (affective) disorders (e.g. depression, bipolar disorder), provided they are generally in good health and are not obviously over-anxious, depressed or manic when seen on the day of donation, regardless of medication

Defer permanently

- Individuals with psychotic disorders requiring maintenance treatment
-

6 Donor medical history II: Medical and surgical interventions

Assessment of the suitability of individuals to donate following medical and surgical interventions, including vaccinations, should take into consideration whether:

- The reason for the intervention is an indication for deferral
- The intervention puts the donor at increased risk of harm by blood donation
- The intervention could affect the quality or safety of the blood and blood products and patient safety.

6.1 IMMUNIZATIONS AND VACCINATIONS

6.1.1 Post-exposure prophylaxis

The deferral period is determined by the incubation period and “window period” of the infection and the sensitivity of the available screening tests.

Also refer to Section 7.3 on viral infections.

Recommendations

HEPATITIS B

Accept

- Individuals who have received hepatitis B post-exposure prophylaxis with vaccine and/or immunoglobulin: accept 12 months after exposure if they have been tested and found to be negative for HBsAg and negative for anti-HBc or, if anti-HBc positive, must have anti-HBs greater than 100 mIU/ml

Defer

- Individuals who have received hepatitis B post-exposure prophylaxis with vaccine and/or immunoglobulin: defer for 12 months after exposure

RABIES

Defer

- Individuals who have received rabies post-exposure prophylaxis with vaccine and/or immunoglobulin: defer for 12 months after exposure
-

6.1.2 Live attenuated viral and bacterial vaccines

Live attenuated viral vaccines include hepatitis A, Japanese encephalitis, influenza, measles, mumps, rubella, polio (oral), smallpox and yellow fever. Bacterial vaccines include BCG, cholera and typhoid.

Blood from a recently vaccinated donor may contain an infective agent which, although not harmful to the donor, is theoretically a risk if the blood is transfused to an immune-suppressed patient.

Some vaccines are not listed here as these vaccines are only given before the age of 16 years and should not be given after the age of 16; hence, they are not of relevance in blood donor selection (144,145).

Recommendation

Defer

- Individuals who have received live attenuated vaccines: defer for 28 days following vaccination
-

6.1.3 Inactivated vaccines

Non-live vaccines and toxoids include cholera, diphtheria toxoid, hepatitis B, human papillomavirus (HPV), influenza, meningococcal meningitis, pertussis, pneumococcal, polio (injected), rabies, tetanus toxoid, tick-borne encephalitis and typhoid.

These vaccines pose no risk to the recipients of blood; donors may be accepted provided they are well.

HBV is an exception as vaccination may cause transient HBsAg positivity. A 14-day deferral is therefore recommended provided the donor has not been exposed to infection (also refer to hepatitis B in Section 7.3 on viral infections).

Recommendations

Accept

- Individuals who have received non-live vaccines and toxoids (with the exception of HBV vaccine) with no history or known exposure and who feel well

Defer

- Individuals with no known exposure to hepatitis B who have recently received routine vaccination: defer for 14 days
-

6.2 MEDICATIONS

Deferral criteria for medications taken by donors should take into account the underlying condition for which the medication is taken, the pharmacokinetic properties of the medication and the effect of the medication on the quality or safety of the donated blood (146,147,148). Donors should not omit regular medication in order to attend a blood donor session.

There is no published evidence that medications in donated blood have caused adverse effects in a patient receiving transfusion, although it is unlikely that such events would be recognized. European Union legislation requires temporary deferral based on the “nature and mode of action” of the medication (149).

Recommendations

The BTS should consider the following principles in developing deferral criteria for medications:

- A plasma concentration of the medication below 10% of the therapeutic level is highly unlikely to be harmful.

-
- When blood components containing < 50 ml donor plasma are transfused to an adult or older child (12 years of age or more), the plasma concentration of any medications taken by the donor will be < 3% and can therefore be disregarded.
 - If more than 50 ml plasma from a single donor is transfused, or if the recipient is a child less than 12 years of age, the plasma concentration of any donor medication may be more than 10% of the therapeutic level. There is no evidence that this is likely to cause harm; however, BTS may wish to consider additional selection criteria for apheresis donations and for paediatric components. Further research is needed in this area.
 - Aspirin and non-steroidal anti-inflammatory medications (NSAIDs) irreversibly inhibit platelet aggregation; platelet components should not routinely be prepared using donations from donors who have taken aspirin within 5 days or other NSAIDs within 48 hours.
 - Teratogenic and fetotoxic medicines deserve particular consideration as there is a theoretical risk of causing a fetal abnormality in the unlikely event that the blood is transfused to a pregnant female during the first trimester. Retinoids (etretinate, acitretin, isotretinoin) are highly teratogenic. Dutasteride and finasteride (prescribed for benign prostatic hypertrophy) have been shown to cause genital abnormalities in male fetuses of experimental animals; there is no evidence of harm in humans.

Accept

- Individuals taking long-term low-dose antibiotics for acne

Defer

- Individuals taking prescribed treatment with injected medications, including self-administration, based on the underlying condition for which the medication is taken
- Individuals who have taken the following medications (150):
 - Aspirin: defer for 5 days
 - Other NSAIDs: defer for 48 hours
 - Acitretin: defer for 3 years
 - Isotretinoin: defer for 28 days
 - Dutasteride: defer for 6 months
 - Finasteride: defer for 28 days
 - Antibiotics for acute infections: defer for 14 days after completion of treatment

Defer permanently

- Individuals treated with human pituitary-derived growth hormone because of case reports of transmission of iatrogenic Creutzfeldt-Jakob disease
-

6.3 BLOOD TRANSFUSION AND TRANSPLANTATION

6.3.1 Blood transfusion

Despite all efforts to assure the safety of blood transfusion, it remains an important risk factor for transfusion-transmitted infections. Hence, anyone who

has received transfusion of any blood or blood product should not be accepted as a blood donor for a period of 12 months.

For precautions against the secondary transmission of vCJD and iatrogenic CJD by blood transfusion, also refer to Section 7.7 on prion diseases.

Recommendations

Accept

- Individuals whose sexual partners or close contacts have received blood transfusions

Defer

- Recipients of blood transfusion: defer for 12 months
- Former sexual contacts of individuals on regular treatment with plasma-derived coagulation factors: defer for 12 months after last sexual contact
- Current sexual contacts of individuals on regular treatment with plasma-derived coagulation factors

Defer permanently

- Recipients of blood transfusion or any other human-derived therapeutic products since 1980 in a country in which the risk of vCJD has been identified
 - Individuals on regular treatment with plasma-derived coagulation factors (64)
-

6.3.2 Organ, stem cell and tissue transplantation

A requirement for stem cell or organ transplantation indicates serious underlying disease and such patients should not be accepted as blood donors.

The same criteria apply to allogeneic tissue grafts as to allogeneic blood transfusion. Recipients of tissue grafts performed since 1980 in countries in which the risk of vCJD has been identified should be permanently deferred.

In some countries, recipients of dura mater grafts and corneal transplants are permanently deferred as a precaution against possible transmission of iatrogenic CJD (64,145) (also refer to Section 7.5 on prion diseases).

Recipients of xenografts and non-human organ perfusion should be permanently deferred from blood donation due to the unknown risks of the transmission of animal infections.

Recommendations

Defer

- Recipients of allogeneic tissues: defer for 12 months

Defer permanently

- Recipients of:
 - Stem cell or organ transplantation
 - Allogeneic cells or tissue sourced since 1980 from countries in which the risk of vCJD has been identified

-
- Dura mater graft
 - Corneal transplant
 - Xenograft
 - Non-human organ perfusion
-

6.4 DIAGNOSTIC AND SURGICAL PROCEDURES

The indication for the procedure may be a reason for donor deferral.

Invasive investigations, particularly if associated with tissue biopsy, carry a risk of infection. Flexible endoscopes have been associated with the transmission of hepatitis C (152), although a more recent study reported that this is not a problem provided that good infection control procedures are followed (153).

Individuals awaiting a surgical procedure that is likely to result in blood loss should be temporarily deferred so that iron stores are not compromised pre-operatively. A deferral period of 12 months following major surgery is usually sufficient to allow for the individual's full recovery, restoration of iron stores and resolution of any bacterial infection, and for routine donation testing to detect any transfusion-transmissible viral infections. For patients who receive blood transfusion during surgery, also refer to Section 6.3 on blood transfusion and transplantation.

Deferral criteria for surgical procedures should take into account the underlying condition for which the procedure is indicated. Prospective donors undergoing minor surgical procedures should be deferred until treatment is complete and successful and they have returned to normal activity.

Dental procedures, although minor, are associated with transient bacteraemia (154,155,156).

Recommendations

Defer

- Individuals who have undergone:
 - Minor diagnostic procedures including rigid endoscopy: defer until they have resumed normal activity
 - Invasive diagnostic procedures using flexible endoscopy: defer for 12 months
 - Minor surgical procedures: defer until treatment is complete and successful and they have resumed normal activity
 - Major surgery: defer for 12 months
 - Dental treatment: defer for 24 hours following simple procedures and up to 7 days following endodontic procedures (root canal therapy) or extraction
-

6.5 ALTERNATIVE, COMPLEMENTARY AND TRADITIONAL MEDICINE

Any therapy involving skin penetration (e.g. acupuncture or scarification) may cause blood-borne infection unless sterile techniques are used. The BTS should be aware of any procedures that are in use locally, including ritual practices and cosmetic treatments, and develop deferral criteria based on the standards of infection control employed and the sensitivity of donation testing (also refer to cosmetic treatments and rituals in Section 7.9 on high-risk behaviours).

7 TTI and donor risk assessment

The microbiological safety of blood donations may be affected by donors' exposure to HIV, hepatitis B, hepatitis C and syphilis and other transfusion-transmissible infections (TTI) via a number of different routes. These primarily include sexual contact and percutaneous exposure through high-risk sexual behaviours, and unsafe blood transfusion and injection practices, cosmetic treatments and rituals. Current or previous country of residence, and travel history also need to be analysed.

The BTS should assess the potential risks of infections present in its donor population and establish donor selection criteria aimed at minimizing the risk of transmission of infections from donors to recipients. These criteria should be based on the prevalence, incidence and epidemiology of TTI, up-to-date information on known and emerging infections, including expert advice regarding the nature of the disease and mode of transmission; taking into consideration the consequences to the blood supply of excluding "at-risk" donors while preserving the sufficiency of the blood supply (157):

- When there is a *proven* risk of transfusion-associated transmission but no appropriate screening assays are available, donor selection criteria *should* be developed to identify and defer potentially infected donors for an appropriate period of time
- When there is a *theoretical* risk of transfusion-associated transmission and no appropriate screening assays are available, donor selection criteria *may* be developed to identify and defer potentially infected donors for an appropriate period of time.

Procedures should be in place for the frequent review and re-evaluation of donor selection criteria in case of emerging infectious diseases, identification of new risks or changes to known risks, cultural practices and evidence from haemovigilance and other surveillance data.

Coordination and cooperation among key national institutions, agencies and major stakeholders, e.g. blood services, public health institutions, hospitals, regulatory agencies and professional bodies is essential for the recognition and control of known and emerging TTI. This includes knowledge of disease prevalence, incidence and epidemiology, active surveillance of emerging infections and potential new endemic areas, the implementation of appropriate donor selection criteria, quality-assured screening of all donations and the systematic monitoring of transfusion recipients (158,159,160,161). Information on the prevalence and epidemiology of certain transfusion-transmissible infections can be found in the WHO Global Health Atlas (162).

7.1 TRANSFUSION-TRANSMISSIBLE INFECTIONS

The microbial agents of importance to a BTS are those that are transmissible by blood transfusion and can cause morbidity and mortality in recipients. In order to be transmissible through transfusion, the infectious agent usually has the following characteristics:

- Presence of the agent in one or more components of blood for long periods and in an infectious form

-
- Stability at temperatures at which whole blood and blood components are stored
 - Generally long incubation period before the appearance of clinical signs and symptoms
 - Asymptomatic phase or only mild symptoms in the blood donor, hence not always identifiable during the blood donor selection process.

Many viruses, bacteria and protozoa can be transmitted by transfusion and new agents that potentially can be transmitted through transfusion continue to emerge (163,164).

WHO recommends that, at a minimum, screening of all blood donations should be mandatory for the following infections and using the following markers (7):

- HIV-1 and HIV-2: screening for either a combination of HIV antigen-antibody or HIV antibodies
- Hepatitis B: screening for hepatitis B surface antigen (HBsAg)
- Hepatitis C: screening for either a combination of HCV antigen-antibody or HCV antibodies
- Syphilis (*Treponema pallidum pallidum*): screening for specific treponemal antibodies.

The outcomes of the laboratory screening of donations remain the final decision point in the release of blood components for clinical use; however, even with the high quality assays and systems now available, the screening process cannot be considered to be totally effective because:

- An infection in donated blood may not be detected due to the collection of the donation during the window period of infection or failure due to assay sensitivity or error
- There are some emerging infections for which screening is not available or effective
- A donor may be infected with an infectious agent for which donations are not routinely screened; in such cases, the donor selection process may be able to identify and defer such an individual based on the symptoms or perceived risk.

Routine screening for generally less clinically significant TTI, such as hepatitis A virus or parvovirus B19 is generally neither practical nor cost-effective. The screening tests available, if any, may not be appropriate for blood screening, often being designed primarily to aid the diagnosis of infection in symptomatic individuals. In these situations, the donor selection process is a significant factor in the identification and deferral of donors who might harbour these infections in order to prevent them from entering the blood supply.

7.2 DONOR RISK ASSESSMENT

Blood donor selection is the first crucial step in the process of ensuring blood safety as it helps to significantly reduce risk through the deferral, prior to donation, of any individuals or groups of individuals with identified risks that may be associated with infection (165,166).

Understanding the timing of infection is important in the donor selection process: firstly, the length of the *window period* i.e. the time between infectivity and the first detection of a defined marker of infection; and secondly, the *incubation period*, i.e. the time between exposure to infection and the onset of any symptoms of illness. In settings with effective blood screening programmes, donors who donate

during the window period generally pose the greatest threat to blood safety and the selection process needs to be able to identify and defer such individuals. In cases where infections are more likely to be symptomatic, the shorter the period between infection and symptoms, the less likely it is that an infectious donation would be collected.

Prospective donors should be asked relevant questions to assess their general health, any history, signs or symptoms indicative of current or past infections, specific high-risk behaviours or activities, travel history, contact with infectious diseases and possible exposure to infection. Environmental factors and lifestyles associated with a high risk of exposure to infection are also discussed in Sections 7.8 and 7.9.

Individuals who have engaged in behaviours that pose a high risk for HIV, HBV and/or HCV infection should not be accepted as blood donors (also refer to Section 7.9 on high-risk behaviours).

Individual donor risk may be impossible to ascertain; the application of the precautionary principle may require that a donor is deferred on the basis of knowledge of the risks to which the donor may be exposed. This approach must be reconciled with the duty of the BTS to treat donors and prospective donors with respect, compassion and dignity, avoiding discrimination of any kind.

However, there are other occasions when a donor may have a known infection risk, either due to being infected or exposure through sexual or household contact or other close contact (having cared for, lived with or had direct contact with an individual with a suspected or diagnosed infection). As a general policy, donors should be deferred following any acute infection until they are fully recovered and no longer infectious. If a donor has been in close contact with an infectious disease, he/she should not donate within the incubation period of the infection, even if known to be immune. If the incubation period is unknown, an arbitrary deferral of 28 days from last contact may be implemented. Expert microbiology advice may be needed regarding the mode of transmission and appropriate deferral periods for specific infections, and may be obtained from WHO (<http://www.who.int>) and national and international health organizations.

Some infections are found only in certain parts of the world. Donor selection criteria will therefore be different in endemic and non-endemic regions. In non-endemic regions, deferral criteria may be applied to donors who have travelled to or lived in endemic regions. Deferral periods may be extended if donors have had any undiagnosed febrile illness during travel or since return (also refer to Section 7.3 on viral infections and Section 7.4 on protozoal infections for deferral periods for individuals who have travelled to and from regions that are endemic for dengue virus, Chikungunya virus, malaria and Chagas disease).

These guidelines are applicable to the selection of donors of whole blood and other labile blood components through whole blood collection and apheresis. In the case of plasma donation for large-scale fractionation purposes, there are circumstances in which plasma donations may be collected from individuals who would not otherwise be eligible to donate whole blood or other labile blood components on the basis of infectious disease risk and/or history.

7.3 VIRAL INFECTIONS

7.3.1 Hepatitis

Prospective blood donors should be given relevant information on the risk of hepatitis transmission in order to provide them with the opportunity to self-defer.

Prospective donors should be asked for a history of jaundice or hepatitis and whether they were further investigated to determine the cause. Individuals with a history of jaundice or hepatitis may, at the discretion of the physician, be accepted as donors based on the tests results.

To exclude donors at risk of transmitting hepatitis, the BTS should ask if the donor, currently or in the past, has had a hepatitis infection (HBV, HCV or other types), assess any specific risks of exposure through sexual and household contacts, and also enquire whether the donor has had an HBV vaccination within the last 14 days.

Individuals with hepatitis infection may be asymptomatic or present with fever, nausea, vomiting, loss of appetite, jaundice, abdominal pain or an enlarged and tender liver.

Hepatitis B

Hepatitis B is a potentially life-threatening liver infection caused by the hepatitis B virus (HBV). The virus is transmitted from human to human via blood and body fluids; consequently it may be transmitted by transfusion and transplantation, via needles and other items exposed to blood, and from mother to child in utero, at birth or perinatally (167,168,169).

The incubation period of the hepatitis B virus is 90 days on average, but can vary from 30 to 180 days. Most people do not experience any symptoms during the acute infection phase. However, some people have acute illness with symptoms that last several weeks. The virus may be detected 30 to 60 days after infection and persists for variable periods of time. Infection in childhood commonly results in chronic infection (more than 6 months) which may be life-long or resolve spontaneously at any time, whereas infection later in life is usually acute (170).

For individuals with confirmed HBV infection, a deferral period of 12 months from recovery is generally recommended, and suitability to donate blood is assessed based on the results of testing for hepatitis B surface antigen (HBsAg), hepatitis B core antibody (anti-HBc) and antibody to hepatitis B surface antigen (anti-HBs) levels.

All HBsAg positive donors should be considered to be at high risk of transmitting HBV. Additionally, some studies indicate that even when HBsAg is not detectable, some individuals may have low levels of detectable viral DNA which will be transmitted by blood and may cause infection in the recipient (171,172).

Recommendations

Accept

- The following individuals may be accepted for blood donation provided they have been tested and found to be negative for HBsAg, and negative for anti-HBc; if anti-HBc positive, they must have anti-HBs greater than 100 mIU/ml:
 - Individuals with a past history of HBV if more than 12 months ago
 - Current sexual contacts of individuals with a history of HBV infection if more than 12 months ago
 - Current and former household contacts who have been successfully immunized against HBV and are anti-HBs positive more than 100 mIU/ml but anti-HBc negative

-
- Donors with initially reactive results for HBsAg but confirmed to be non-reactive: re-entry procedures should be established and followed

Defer

- Individuals with active HBV infection or a history of infection within the last 12 months
 - Current sexual and household contacts of individuals with active HBV infection
 - Former sexual contacts of individuals with active HBV infection: defer for 12 months since last sexual contact
 - Former household contacts of individuals with active HBV infection: defer for 6 months since last contact
 - Health workers who have suffered an inoculation or mucosal injury: defer for 12 months following the exposure; health workers who have been vaccinated against HBV should be assessed individually
-

Hepatitis C

Hepatitis C is a liver disease caused by the hepatitis C virus (HCV). The hepatitis C virus is most commonly transmitted through exposure to infectious blood. This can occur through contaminated blood transfusions, blood products and organ transplants; injections given with contaminated syringes and needlestick injuries in health-care settings; injecting drug use; or being born to a hepatitis C-infected mother. Hepatitis C may also be transmitted through sex with an infected person or sharing of personal items contaminated with infectious blood, but these are less common (173,174,175,176,177).

The incubation period for hepatitis C is 2 weeks to 6 months. Following initial infection, approximately 80% of people do not exhibit any symptoms. About 75–85 % of newly infected persons develop chronic disease (178).

Recommendations

Accept

- Household contacts of individuals with HCV infection

Defer

- Current sexual contacts of individuals with current or past HCV infection
- Former sexual contacts of individuals with HCV infection: defer for 12 months since last sexual contact
- Health workers who have suffered an inoculation or mucosal injury: defer for 12 months following the exposure

Defer permanently

- Individuals with current or past HCV infection
-

Hepatitis A

Hepatitis A is a liver disease caused by the hepatitis A virus (HAV). The virus is transmitted primarily by the faecal-oral route, but sexual transmission can

occur. The virus can also be transmitted through close physical contact with an infectious person, although casual contact among people does not spread the virus. Cases of transfusion-transmission by blood and blood products have been reported (179,180,181,182).

The incubation period of hepatitis A is usually 14–28 days. Symptoms of hepatitis A range from mild to severe. Unlike hepatitis B and C, hepatitis A infection does not cause chronic liver disease and is rarely fatal, but it can cause debilitating symptoms and fulminant hepatitis (acute liver failure), which is associated with high mortality (183).

Hepatitis E

Hepatitis E virus (HEV) behaves in similar ways to HAV except that chronicity cannot be ruled out. Transfusion-transmission by blood and blood products has been reported (184). Cases of hepatitis E are not clinically distinguishable from other types of acute viral hepatitis (185).

Diagnosis of hepatitis E infection is therefore usually based on the detection of specific antibodies to the virus in the blood. Deferral periods are as for HAV.

Hepatitis of unknown origin

Most cases of hepatitis of unknown origin are due either to undiagnosed hepatitis A or hepatitis E, or to non-viral causes. Deferral periods are the same as for HAV.

Recommendations

Defer

- Individuals with active HAV, HEV or hepatitis of unknown origin: defer for 12 months after full recovery
- Sexual contacts, household and other close contacts of individuals with HAV, HEV or hepatitis of unknown origin: defer for 12 months since last contact

7.3.2 Human immunodeficiency virus/Acquired immunodeficiency syndrome (HIV/AIDS)

HIV can be transmitted via unprotected and close contact with a variety of body fluids of infected individuals, such as blood, breast milk, semen and vaginal secretions. Individuals cannot become infected through ordinary day-to-day contact such as kissing, hugging, shaking hands, or sharing personal objects, food or water.

Behaviours and conditions that put individuals at greater risk of contracting HIV include having unprotected anal or vaginal sex (186) (also refer to Section 7.9 on high-risk behaviours); having another sexually transmitted infection such as syphilis, herpes, chlamydia, gonorrhoea or bacterial vaginosis; sharing contaminated needles, syringes and other infected equipment and drug solutions for injecting drug use; receiving unsafe injections, blood transfusions or medical procedures that involve unsterile cutting or piercing; experiencing accidental needlestick injuries, including among health workers.

Infectivity estimates in case of transfusion of infected blood products are much higher (around 95%) than for other modes of HIV transmission owing to the much larger viral load per exposure than for other routes (187).

Recommendations

Accept

- Household contacts of individuals with HIV infection

Defer

- Current sexual contacts of individuals with HIV infection
- Former sexual contacts of individuals with HIV infection: defer for 12 months since last sexual contact

Defer permanently

- Individuals with present or past clinical or laboratory evidence of HIV infection
-

7.3.3 HTLV I and HTLV II

Human T-cell lymphotropic viruses (HTLV) are present in the bloodstream in lymphocytes. Non cell-associated virus is rarely found. The infectivity of blood and blood components is reduced but not removed by leucodepletion. HTLV can be transmitted from mother to child, primarily through breast-feeding, and it may also be transmitted through sexual contact (188,189). As infection is considered to persist for life, screening for anti-HTLV identifies donations that may transmit HTLV but does not in itself indicate the timescale of an infection.

Recommendations

Accept

- Household contacts of individuals with HTLV I and/or II infection
- Individuals whose mother or maternal grandmother has or had HTLV I and/or II infection, if blood screening for HTLV I and/or II infection is available
- Former sexual contacts of individuals with HTLV I and/or II infection if more than 12 months after the last sexual contact, and blood screening for HTLV I and/or II infection is available

Defer

- Current sexual contacts of individuals with HTLV I and/or II infection
- Former sexual contacts of individuals with HTLV I and/or II infection: defer for 12 months after last sexual contact

Defer permanently

- Individuals with HTLV I and/or II infection
 - Individuals whose mother or maternal grandmother has or had HTLV I and/or II infection, if blood screening for HTLV I and/or II infection is not available
 - Former sexual contacts of individuals with HTLV I and/or II infection, if blood screening for HTLV I and/or II infection is not available
-

7.3.4 Herpes viruses

Herpes viruses include herpes simplex types I and II, varicella-zoster, Epstein-Barr virus, cytomegalovirus and Kaposi's sarcoma-associated human herpes virus 8 (HHV8). All these viruses can give rise to latent infection and some are transfusion-transmissible (190,191). Symptomatic donors should be deferred until fully recovered. Because of the high prevalence of exposure to these viruses in donors and recipients, except in the case of HHV8, the exclusion of donors with a history of past infection is neither feasible nor useful.

HHV8 is transmitted by sexual and non-sexual routes and has been reported to be also transmitted by transfusion and transplantation (192,193,194).

Recommendations

Accept

- Individuals with cold sores and genital herpes, provided there are no active lesions

Defer

- Individuals who are symptomatic (except HHV8 infection): defer for at least 28 days following full recovery
- Contacts of individuals who are symptomatic (except HHV8 infection): defer for 28 days

Defer permanently

- Individuals with HHV8 infection
 - Current and former sexual contacts of individuals with HHV8 infection
-

7.3.5 Mosquito-borne viruses

West Nile virus

West Nile Virus (WNV) is a flavivirus primarily transmitted by mosquitoes, but also readily transmitted through blood donations from infected individuals (195). It is found in Africa, Europe, Western Asia, the Middle East and North America, although in many regions it is highly seasonal. It causes a rapid onset, acute infection with a relatively brief period of viraemia. Transfusion-transmission has been reported. Symptoms are non-specific and viraemic donors may be asymptomatic at the time of donation (196,197). In endemic areas with reported human cases, blood screening using molecular technology is the only means of preventing transfusion-transmission.

To identify "at-risk" donors for WNV in non-endemic areas, BTS should elicit information on travel history during the donor selection process and maintain up-to-date knowledge of disease epidemiology. Some countries have implemented a 28-day deferral after visiting an endemic area, extended to 6 months from full recovery if the donor has had any symptoms suggestive of WNV (198 199,200).

As a result of increasing numbers of cases of WNV in some countries where there were previously only sporadic cases, a number of non-endemic countries have introduced the identification and deferral of at-risk donors; and the screening of donations from these donors using molecular technology.

Recommendations

NON-ENDEMIC AREAS (IF BLOOD SCREENING IS NOT PERFORMED)

- At-risk donors with symptoms appearing within 14 days following donation should be advised to report to the BTS

Defer

- Individuals who:
 - Have known West Nile virus infection or symptoms suggestive of WNV: defer for 6 months from full recovery
 - Have visited an area endemic for WNV with human cases, in the WNV season within the last month: defer for 28 days following return
-

Dengue and chikungunya viruses

Dengue and chikungunya viruses are transfusion-transmissible mosquito-borne arboviruses. Both give rise to acute infections with no chronic infection, but re-infection with dengue virus can have very serious sequelae. Although both are potentially transmissible, there have been no proven cases of transfusion-transmission of chikungunya and relatively few reports of transmission of dengue (201,202).

Before 1970, only nine countries had experienced severe dengue epidemics. The disease is now endemic in more than 100 countries in Africa, the Americas, the Eastern Mediterranean, South-east Asia and Western Pacific. South-east Asia and the Western Pacific are the most affected (203).

Chikungunya occurs in Africa, Asia and the Indian subcontinent and outbreaks have been reported in all the three regions. There was a large number of imported cases in Europe and South East Asia during some of the outbreaks (204).

BTS in non-endemic areas wishing to exclude at-risk donors should include questions about travel history during the donor selection process and maintain up-to-date knowledge of disease epidemiology.

Recommendations

ENDEMIC AREAS

Defer

- Individuals with a history of dengue or chikungunya virus: defer for 6 months following full recovery from infection

NON-ENDEMIC AREAS

Defer

- Individuals who:
 - Have visited an area endemic for dengue or chikungunya: defer for 28 days following return
 - Have suffered a febrile illness during or following return from an endemic region: defer for 6 months following full recovery from infection
-

7.3.6 “Childhood illnesses”: measles, rubella, mumps and chickenpox

Infections with childhood illnesses such as measles, rubella, mumps and chickenpox are known to occur in adults. Individuals suffering from any of these childhood illnesses and their close contacts should be identified as ‘at-risk’ donors and should be deferred for a defined period of time (205,206).

Recommendations

Defer

- Individuals with measles, rubella, mumps or chickenpox: defer for 14 days after full recovery
 - Individuals in close contact with patients having active measles, rubella, mumps or chickenpox and who are asymptomatic: defer for 21 days following last day of close contact
-

7.3.7 Influenza

For sporadic cases, individuals with active infection should be deferred until 14 days after full recovery; susceptible contacts should be deferred for 7 days after the implicated individual has recovered.

In a pandemic situation the risk of blood shortage far outweighs any theoretical risk of transfusion transmission. The usual donor selection criteria for influenza and any specific measures relating to donor deferral should be carefully reviewed. Following the precautionary principle, selective donor deferral may be considered (25,207).

Recommendations

Accept

- Asymptomatic individuals with no close contact with those having active infection

Defer

- Asymptomatic household contacts and other close contacts of symptomatic individuals with active infection: defer for 7 days after last day of close contact
 - Symptomatic individuals with active infection: defer for 14 days after full recovery and cessation of any therapy
 - Individuals who have received vaccination against influenza: defer for 48 hours after vaccination; the deferral period should be extended as above if the donor is in a specific risk category
-

7.4 PROTOZOAL INFECTIONS

Protozoa are predominantly intracellular organisms. Prospective donors from non-endemic countries who are at risk of any of the following parasitic protozoal infections may be considered suitable to donate plasma for large-scale fractionation purposes only, until such time as they meet the specific criteria that would

allow the collection of whole blood and other labile blood components for direct clinical use.

7.4.1 Malaria

Malaria is caused by *Plasmodium* species. There are four parasite species that cause malaria in humans: *P. falciparum*, *P. vivax*, *P. malariae* and *P. ovale*, of which *P. falciparum* and *P. vivax* are the most common. *P. falciparum* is the most deadly. In recent years, some human cases of malaria have also occurred with *P. knowlesi* – a species that causes malaria among monkeys and occurs in certain forested areas of South-East Asia.

Malaria is primarily transmitted to humans through the bite of the female *Anopheles* mosquito. In many places, transmission is seasonal, with the peak during and just after the rainy season. Increased malaria prevention and control measures are dramatically reducing the malaria burden in many places. Non-immune travellers from malaria-free areas are very vulnerable to the disease when they become infected (208).

Malaria is also readily transmitted by blood transfusion through donations collected from asymptomatic, parasitaemic donors. The parasite is released into the bloodstream during its lifecycle and will therefore be present in blood donated by infected individuals. The parasites are stable in plasma and whole blood for at least 18 days when stored at +4°C and for extended periods in a frozen state (209). Donor selection criteria to exclude collecting blood from individuals with current or past history of malarial infection and at risk of transmitting malaria through transfusion, should be based on local epidemiological evidence and endemicity of the infection.

Endemic areas

Donor selection and deferral strategies should be developed to identify individuals with evidence of current malarial infection and defer them for a period of 6 months after symptoms (fever with rigors) or on completion of treatment and full recovery, whichever is longer. Alternatively, the BTS should screen all donations for parasitaemia using thick blood films or for evidence of malarial antigen using a highly sensitive enzyme immunoassay.

Non-endemic areas

Malaria is increasingly a matter of concern to BTS in non-endemic countries (210,211,212). Significant numbers of blood donors from non-endemic countries travel to malarious areas and there is wide migration from endemic areas to non-endemic areas where migrants may then become blood donors. Malaria is gradually spreading into non-endemic areas or regions where it had previously been eradicated.

Recommendations

ENDEMIC AREAS

- The BTS should develop:
 - Donor selection criteria to identify and collect blood from donors at the lowest risk of infection, both during the malaria season and during the rest of the year
 - Strategies to maximize the collection of blood from donors from geographical areas with low endemicity

-
- Screen all donations for parasitaemia using thick blood films (smear microscopy) or for evidence of malarial antigen using a highly sensitive enzyme immunoassay

Defer

- Individuals with a recent infection with malaria: defer for 6 months after completion of treatment and full recovery, whichever is longer

NON-ENDEMIC AREAS

The BTS should:

- Define the donor population with a risk of exposure to malaria and thus the potential for transmission through blood donations
- Implement donor selection and deferral strategies to identify individuals with a recent history of malaria or a specific identifiable exposure risk, such as travel to malarious areas; these donors should be deferred for a period defined by the country
- Question prospective donors regarding:
 - Place of birth
 - Previous residence in endemic areas
 - Travel during the previous 12 months
 - History of malaria or any undiagnosed febrile illness during or after visiting an endemic area

If sensitive and multi-specific antibody screening tests are *not* available

Defer

- Individuals who:
 - Have travelled to malaria endemic areas and who have had no symptoms: defer for 12 months from last return from a malarious area
 - Have travelled to malaria endemic areas and who have had febrile symptoms, but not diagnosed as malaria: defer for 12 months following full recovery or last return from a malarious area, whichever is the longer
 - Lived in a malaria endemic area in the first 5 years of life or for a continuous period of 6 months or more: defer for 5 years after last return from a malarious area

Defer permanently

- Individuals who have ever had a diagnosis of malaria

If sensitive and multi-specific antibody screening tests are available

Accept

- Asymptomatic individuals with identified malaria exposure risk (travel and/or residence): accept if more than 6 months after their last return from an endemic area

Defer

- Individuals with:
 - Identified malaria exposure risk (travel and/or residence), but *no symptoms*: defer for 6 months after last return from malarious area

-
- Identified malaria exposure risk (travel and/or residence) who have had *febrile symptoms*, but not diagnosed as malaria: defer for 6 months from cessation of symptoms or last return from a malarious area, whichever is the longer
 - A current infection or history of malaria: defer for 3 years following completion of treatment and full recovery, whichever is the longer
-

7.4.2 Chagas disease

Chagas disease, also known as American trypanosomiasis, is a potentially life-threatening illness caused by the protozoan parasite, *Trypanosoma cruzi* (*T. cruzi*). It is found mainly in Latin America, where it is mostly transmitted to humans by the faeces of triatomine bugs, known as “kissing bugs”, among other names, depending on the geographical area. *T. cruzi* can also be transmitted by food contaminated with *T. cruzi* through for example the contact with triatomine bug faeces, transfusion of blood from infected donors, passage from an infected mother to her newborn during pregnancy or childbirth, organ transplants using organs from infected donors and laboratory accidents.

Chagas disease is endemic throughout South and Central America, although effective vector control procedures have been implemented in recent years (213,214,215,216). In the past decades, it has also been increasingly detected in the United States of America, Canada, many European and some Western Pacific countries. This is due mainly to population mobility between Latin America and the rest of the world. Less frequently, it is due to infection through blood transfusion, vertical transmission (from infected mother to child) or organ donation (217).

Infection is life long and infected individuals may be asymptomatic; individuals with a history of *T. cruzi* infection should be permanently deferred.

Endemic areas

In endemic areas, donor selection is not feasible; the prevention of transfusion-transmission depends on the serological testing of all blood donations and treatment of the blood with trypanocidal agents (213,218,219).

Non-endemic areas

In non-endemic countries, individuals are identified as having been exposed to risk of infection if they, their mother or maternal grandmother were born in South or Central America (including Southern Mexico), have had a blood transfusion in these areas or have lived and/or worked in rural communities in these countries for a continuous period (arbitrarily 28 days or more). These individuals should be permanently deferred from blood donation unless a validated *T. cruzi* antibody test is available, in which case they may be accepted 6 months after the last exposure if sero-negative (220,221).

Recommendations

NON-ENDEMIC AREAS

If sensitive antibody assays for *T. cruzi* are not available

Defer permanently

- Individuals who have ever had a diagnosis of Chagas disease

-
- Individuals with an identified risk of Chagas disease:
 - Born in, resided in for 6 months or more, or have mother or maternal grandmother born in an endemic area
 - Received blood transfusion or organ transplant in an endemic area
 - Travel for 28 days or more in a rural community in an endemic area

If sensitive antibody assays for *T. cruzi* are available (184)

Accept

- Individuals with an identified risk of exposure to Chagas disease: accept if more than 6 months after last return from an endemic area

Defer

- Individuals with an identified risk of exposure to Chagas disease: defer for 6 months after last return from an endemic area

Defer permanently

- Individuals who have ever had a diagnosis of Chagas disease
-

7.4.3 Babesiosis

Babesiosis (*Babesia sp.*) is transmitted by tick-borne intraerythrocytic parasites. Most cases of *Babesia* infection are asymptomatic, but can include mild fever and diarrhoea. The symptoms are often unnoticed or unexplained. In more severe cases, the symptoms are similar to those of malaria. The infection may also have a chronic asymptomatic phase and the parasite can survive blood storage conditions. *B. microti* is endemic in parts of North America; the reservoir of infection is small rodents. Transfusion-transmission has been reported (222,223). Prevention relies on checking for a history of previous infection among residents or visitors to endemic areas (224,225,226).

Recommendation

Defer permanently

- Individuals who have ever had a diagnosis of babesiosis
-

7.4.4 Leishmaniasis

Leishmaniasis is a parasitic disease endemic in the tropics and subtropics, transmitted by the bite of infected sand-flies. The parasite (*Leishmania sp.*) has the potential for transfusion-transmission, but this has been only rarely reported, possibly because parasitaemia is transient and low level (227). The prevention of transfusion-transmission relies on the permanent deferral of infected individuals (228).

Recommendations

Defer

- Individuals who have spent extended periods in endemic areas: defer for at least 12 months since their last return

Defer permanently

- Individuals who have ever had a diagnosis of leishmaniasis
-

7.5 BACTERIAL INFECTIONS

Bacterial contamination of blood components with organisms carried by the donor may be exogenous, due to skin contaminants entering the donated blood at the time of collection, or endogenous, due to bacteria present in the donor's blood (229,230).

The role of donor selection in minimizing exogenous bacterial infection includes inspection of the skin at the venepuncture site and deferral of donors with obvious skin lesions (also refer to Sections 4.2 on donor appearance and inspection and 5.11 on skin diseases). Other techniques for bacterial reduction (231), including skin cleansing, venepuncture technique, use of diversion pouches and leucoreduction play an important role in preventing the contamination of blood components by exogenous bacteria. Guidance on safe phlebotomy techniques can be found in WHO *Guidelines on drawing blood: best practices in phlebotomy* (31).

Most prospective donors with endogenous bacterial infections present with symptoms, such as fever, rash, diarrhoea and malaise, and should be deferred from blood donation as part of the general health assessment (also refer to Section 4.2 on donor appearance and inspection).

Endogenous bacteria that are transfusion-transmissible include *Treponema pallidum*, *Borrelia burgdorferi*, *Brucella melitensis* and *Yersinia enterocolitica*, but blood donations are routinely screened only for *T. pallidum*.

7.5.1 Syphilis, yaws and gonorrhoea

Syphilis, yaws and gonorrhoea are common sexually-transmitted diseases; it should be noted that a history of sexually transmitted disease is an important indicator for sexual behaviours associated with HIV transmission. Controlling sexually transmitted infections is important for preventing HIV infection, particularly in people with high risk sexual behaviours (232).

The risk of transmission of syphilis (*T. pallidum*) through the transfusion of processed and stored blood is low as the spirochaetae are released into the bloodstream only intermittently during the course of infection, and are destroyed within 72 hours of storage at +40°C (63); however *T. pallidum* can be transmitted through fresh blood and platelets. It is not transmitted by plasma products fractionated from pooled plasma such as Factor VIII.

Yaws (*Treponema pallidum pertenuis*) is not transmitted through transfusion, but is serologically indistinguishable from syphilis. Serological tests for syphilis may remain positive for many years after successful treatment.

The causative agent of gonorrhoea (*Neisseria gonorrhoeae*) is not transmissible by blood transfusion. Nevertheless most BTS defer individuals with gonorrhoea for 12 months following completion of treatment.

Recommendations

Accept

- Household contacts of individuals with syphilis

Defer

- Current sexual contacts of individuals with syphilis
- Former sexual contacts of individuals with syphilis: defer for 12 months since last sexual contact
- Individuals with gonorrhoea: defer for 12 months following completion of treatment and assess for high-risk behaviour
- Current sexual contacts of individuals with gonorrhoea
- Former sexual contacts of individuals with gonorrhoea: defer for 12 months since last sexual contact

Defer permanently

- Individuals who have ever had a diagnosis of syphilis
-

7.5.2 Lyme disease

The spirochete *Borrelia burgdorferi* is carried by insect vectors including ticks, horseflies and mosquitoes. It can survive blood storage temperatures. Transfusion-transmission is possible but has not been reported. Infected individuals usually exhibit symptoms of rash, fever, lymphadenopathy, often progressing to chronic arthropathy and/or neurological involvement, and are likely to be identified and excluded by careful donor selection (222).

Recommendation

Defer

- Individuals with a current diagnosis of Lyme disease: defer for 28 days following completion of treatment and full recovery, whichever is longer
-

7.5.3 Brucellosis

Brucellosis (undulant fever) is caused by the bacterium *Brucella melitensis*. It is usually acquired from an infected animal source but is not usually transmitted from person to person. Transfusion-transmission has been reported in endemic regions. Infection is usually chronic; this may last for many years with bouts of sometimes quite serious illness.

Recommendation

Defer permanently

- Individuals who have ever had a diagnosis of brucellosis
-

7.5.4 Yersinia infection

This gram-negative bacterium (*Yersinia enterocolitica*) causes enteritis and is of particular concern as it can multiply at +4°C; thus a low-grade bacteraemia in a donor is capable of causing severe, sometimes fatal post-transfusion sepsis and toxic shock in the recipient. The incidence of this complication has been estimated at 1:6 million red cell transfusions (233).

Donors should be asked about any recent abdominal symptoms, particularly diarrhoea, and deferred if they have a history suggestive of *Y. enterocolitica*. They should be asked to inform the BTS if they develop such symptoms within 14 days of donation. As symptoms may be absent or non-specific, potentially infected donors cannot reliably be identified.

Recommendation

Defer

- Individuals with recent abdominal symptoms, particularly diarrhoea, suggestive of *Y. enterocolitica* infection: defer for 28 days following full recovery
-

7.5.5 Salmonella, campylobacter, streptococcus and staphylococcus

Post-transfusion sepsis may result from donor bacteraemia associated with gastrointestinal, urinary or wound infections (also refer to Section 4.3 on minor illnesses).

Recommendations

Defer

- Individuals with:
 - Symptoms suggestive of recent infection with salmonella, campylobacter or streptococcus: defer for 28 days following full recovery
 - Other evidence of potential infection with staphylococcus: e.g. recent superficial but significant wounds: defer for 14 days following full wound healing
-

7.5.6 Tuberculosis

There is no published report of transfusion-transmission of tuberculosis (*Mycobacterium tuberculosis*) even though the organism is blood-borne.

Recommendations

Defer

- Individuals with tuberculosis: defer for 2 years following confirmation of cure
 - Contacts of individuals with tuberculosis: defer household contacts and other close contacts until screened and confirmed clear of infection
-

7.6 RICKETTSIAL INFECTIONS

Rickettsiae are organisms that are smaller than bacteria and, except for Q fever (*Coxiella burnetii*), require an insect vector. Transfusion-transmissions of Q fever and Rocky Mountain spotted fever have rarely been reported. Deferral periods implemented for Q fever range from 2 years to permanent deferral (234).

Recommendations

Defer

- Individuals with:
 - Rickettsial infection: defer for 6 months following completion of treatment or cessation of symptoms
 - Acute Q fever: defer for 2 years following completion of treatment and full recovery, whichever is the longer

Defer permanently

- Individuals with chronic Q fever
-

7.7 PRION DISEASES

7.7.1 Creutzfeldt-Jakob disease

Creutzfeldt-Jakob disease (CJD) is the human form of transmissible spongiform encephalopathy. It exists in four distinct forms: sporadic, genetic (familial), iatrogenic and variant (vCJD).

There is no evidence of transfusion-transmission of sporadic and familial CJD; nevertheless, donors with symptoms suggestive of CJD or a family history of CJD should be permanently deferred (235). Iatrogenic CJD has been described following treatment with pituitary-derived human growth hormone, human gonadotrophin, dura mater grafts, corneal transplants and through contaminated neurosurgical instruments. There is no evidence of transfusion-transmission of iatrogenic CJD; however donors with a history of such interventions should be permanently deferred (236).

7.7.2 Variant Creutzfeldt-Jakob disease

Variant Creutzfeldt-Jakob disease (vCJD) emerged in the United Kingdom of Great Britain and Northern Ireland (UK) in 1996 as a result of oral transmission of spongiform encephalopathy from infected cattle. Data on the number of cases worldwide are collected and published by the UK National Creutzfeldt-Jakob Disease Research & Surveillance Unit (237). The outbreak of cases in the UK has declined but a “second wave” cannot be excluded and cases have occurred in other European Union countries (70).

Epidemiological evidence from the UK indicates that vCJD can be transmitted by blood transfusion, with important implications for public health worldwide (238,239,240,241). *WHO guidelines on tissue infectivity distribution in transmissible spongiform encephalopathies* (242) recommend that national authorities should prepare plans for measures to minimize the risk of transfusion-transmission of vCJD by blood and blood products, whilst not compromising the adequacy of the blood supply, and provide guidance on risk assessment.

To date, many countries have addressed this risk by excluding blood donors with a history of travel or residence in the UK and parts of Europe, for defined *cumulative* exposure periods. The United States Food and Drug Administration currently requires deferral of individuals who have spent 3 months or more cumulatively in the UK between 1980 and the end of 1996, when effective measures were implemented to prevent oral transmission, or who have spent 5 years or more cumulatively in Europe between 1980 and the present (236). In

the UK, France and Ireland, recipients of blood transfusion (including fractionated blood products) since 1980 are now permanently deferred. Other countries defer donors who have received blood transfusions in the UK or France since 1980.

Recommendations

- Countries should conduct a risk assessment and risk-benefit analysis taking into account national and international data on the epidemiology of vCJD in order to implement appropriate risk-mitigating measures to prevent the transmission of vCJD through blood transfusion
- The decision to defer blood donors with a history of travel or residence for defined cumulative exposure periods in specified countries or areas, as a measure to reduce the risk of transmitting vCJD by blood transfusion, should be based on the findings of the risk assessment and risk-benefit analysis and the impact on the blood supply

Defer permanently

- Individuals with sporadic or familial CJD
 - First-degree relatives of individuals with sporadic or familial CJD
 - Individuals with vCJD
 - Individuals who have received a transfusion or any other human-derived therapeutic products since 1980 in a country in which the risk of vCJD has been identified
 - Individuals with a history of treatment with pituitary-derived human growth hormone, human gonadotrophin, dura mater graft, corneal transplant or neurosurgery
-

7.8 COUNTRY OF RESIDENCE AND TRAVEL HISTORY

Donor exposure to TTI is affected by their current and previous country (or region) of residence and their travel history. In areas that are non-endemic for specific infections, travel history is of particular importance as prospective donors may be unaware of the geographical distribution of TTI such as malaria, Chagas disease, West Nile virus and vCJD. Donor selection and donation testing strategies should be based on up-to-date and readily available information on the epidemiology and prevalence of known and emerging TTI in specific geographical areas (243,244,245) (also refer to Sections 7.3 to 7.7). The deferral of prospective donors who have visited or been resident in disease-endemic areas should be balanced against the sufficiency of the blood supply.

7.9 HIGH-RISK BEHAVIOURS

7.9.1 High-risk sexual behaviours

Certain sexual behaviours have been shown by surveillance data to be associated with a high risk of transmission of HIV, HBV and HCV (246,247). It is essential that BTS identify and defer from blood donation individuals whose sexual behaviour puts them at high risk of acquiring infectious diseases that can be transmitted through blood. Deferral policies for high-risk behaviours should be supported by public education. Deferral criteria should be simple and easily understood by

staff and prospective donors and should ideally enable self-deferral, without the need for detailed intrusive questioning about an individual's sexual behaviour (248,249); they should be applied with sensitivity, a non-judgemental approach and assurance of confidentiality.

High-risk sexual behaviours include having multiple sex partners, receiving or paying money or drugs for sex, including sex workers and their clients, men having sex with men (MSM) (250,251) and females having sex with MSM (246,247,252). MSM account for the largest subpopulation of HIV-infected people in most developed countries (253,254,255,256) and many countries therefore permanently defer men who have ever had oral or anal sex with another man (254,257,258).

The permanent deferral of MSM has been criticized as being selectively discriminatory and lacking scientific rigour (253,259,260,261) and has undergone review in some countries in the light of increasingly sensitive and reliable technologies for donation screening (249,262). Studies using mathematical modelling to predict the effect of reducing deferral intervals for MSM to one or five years have suggested that the increased risk of an HIV-infected donation entering the blood supply is small, but not zero, with little gain in terms of additional donations (263,264,265,266). These studies rely on some assumptions, are applicable only to the populations studied, and relate to testing methodologies that are not available in some countries and have been superseded in others. However, no comparable evidence is currently available. The permanent deferral of MSM therefore continues to be endorsed as the default position based on the principle of risk reduction to "as low as reasonably achievable" (ALARA).

Deferral criteria for high-risk sexual behaviours in a particular country or region should be determined and reviewed frequently, based on the residual risk of transfusion-transmitted viral infections, taking into account changes in disease epidemiology, improvements in available technologies for donation testing and on-going research.

Recommendations

Defer

- Current sexual contacts of individuals whose sexual behaviours put them at high risk of transfusion-transmissible infections
- Former sexual contacts of individuals whose sexual behaviour put them at high risk of transfusion-transmissible infections: defer until 12 months since last sexual contact

Defer permanently

- Individuals whose sexual behaviour put them at high risk of transfusion-transmissible infections
-

7.9.2 Injecting drug use

The use of injected "recreational" drugs and non-prescribed steroids is commonly associated with unsafe practices such as the sharing and re-use of needles. It carries a high risk of blood-borne infections, most commonly HCV, but also HBV and HIV (246,267,268,269,270,271,272,273,274).

Many injected drugs are highly addictive and their use may be life-long. The safest policy is therefore permanent deferral of anyone who has ever injected

non-prescribed drugs. Deferral policies should be regularly reviewed as new evidence emerges.

Recommendations

Defer

- Current sexual contacts of injecting drug users
- Former sexual contacts of injecting drug users: defer for 12 months since last sexual contact

Defer permanently

- Individuals with a history of injecting drug use
-

7.9.3 Non-injected drugs and alcohol use

The use of alcohol and non-injected “recreational” drugs is widespread in most cultures, and many local practices exist.

Prospective donors who demonstrate signs and symptoms of intoxication should be deferred as their capacity to give informed consent is likely to be impaired. A further consideration is whether regular heavy drinking or use of illicit drugs and other dependence-producing psychoactive substances is a marker for other high-risk behaviours.

The use of intranasal cocaine has been found to be a risk factor for HCV (275).

There is no documented evidence that recent ingestion of a “recreational” drug (e.g. kava) or alcohol by a donor has caused harm to the recipient of their blood. As is the case for prescribed medication, the dilution factor is such that the blood recipient receives a very small residual quantity, which is unlikely to have any adverse effect.

Considerations regarding possible allergic reactions to non-prescribed drugs in recipients are the same as for prescribed medications (also refer to Section 6.2 on medications).

Recommendations

Accept

- If no signs of intoxication

Defer

- If displaying signs and symptoms of intoxication
-

7.9.4 Detention in prisons and penal institutions

Inmates of prisons and penal institutions should not be accepted as blood donors as there is evidence of a higher incidence of HIV, HBV and HCV in these populations (276,277). In addition, there is a risk that there may be undue coercion to donate blood in these settings and that the donation may not be voluntary. The acceptance of individuals with a history of previous imprisonment requires assessment of their exposure to risk from drug use, injuries or unsafe sexual practices with the consequent appropriate deferral period.

Recommendation

Defer

- Inmates of prisons and penal institutions
-

7.9.5 Cosmetic treatments and rituals

Any procedures involving penetration of the skin carry a risk of bloodborne infections, especially HIV, HBV and HCV, unless performed under sterile conditions. These include body piercing, tattooing, scarification, injections with collagen or botulinum toxoid (botox), electrolysis and semi-permanent make-up (267,268,270,271,278,279,280,281,282).

Individuals who present with a history of any procedures involving penetration of the skin should be assessed for the risk of TTI, based on when, where, by whom and how the procedure was performed. The BTS should define the deferral period, based on the sterility and safety of the procedure. If it is not possible to ascertain the sterility and safety of the procedure, the individual should be deferred for a period of 12 months.

Recommendation

Defer

- Individuals who have had acupuncture, piercing, tattoos, ritual scarification or any other invasive cosmetic procedures: defer for 12 months following the last procedure
-

Glossary

Apheresis

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

Blood donors

- **Voluntary non-remunerated blood donor:** A person who donates blood (and plasma or cellular components) of his/her own free will and receives no payment for it, either in the form of cash, or in kind which could be considered a substitute for money
- **Family/replacement blood donor:** A person who gives a replacement unit of blood only when a family member or friend requires transfusion
- **Paid “donor”:** A person who provides blood for money or other form of payment
- **Autologous donor:** A patient who donates his/her blood to be stored and reinfused, if needed, during surgery

Confidential unit exclusion

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

Directed donation

A donation that is given specifically for transfusion to a named patient

Donor deferral

The non-acceptance of a potential blood donor to donate blood or blood components, either temporarily or permanently, based on general health or medical condition, or the risk of exposure to pathogens

Donor haemovigilance

A set of surveillance procedures for the monitoring, reporting and investigation of adverse donor reactions and events which are designed to prevent their occurrence or recurrence

Donor selection

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

Extracorporeal blood volume

The volume of blood outside the donor’s body during an apheresis procedure and the small volume remaining in the cell separator, excluding the anticoagulant

Incidence

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

Men who have sex with men (MSM) (250)

Men who have sex with men is an inclusive public health construct used to define the sexual behaviours of males who have sex with other males, regardless of the motivation for engaging in sex or identification with any or no particular “community” (283). The words “man” and “sex” are interpreted differently in diverse cultures and societies, as well as by the individuals involved. As a result, the term MSM covers a large variety of settings and contexts in which male-to-male sex takes place. Perhaps the most important distinction to make is

one between men who share a non-heterosexual identity (i.e. gay, homosexual, bisexual or other culture-specific concepts that equate with attraction to other men) and men who view themselves as heterosexual but who engage in sex with other males for various reasons (e.g. isolation, economic compensation, sexual desire, gender scripts) (284). Settings with forced gender segregation (e.g. prisons, military establishments) are important contexts for male-to-male sexual activity not linked to homosexual identity. Given the conditions of imprisonment, including human rights violations and lack of access to condoms, the risk of HIV transmission in prisons is very high (285).

National blood policy

A statement of intent by the ministry of health that defines the organizational, financial and legal measures at the national level that will be taken to ensure the quality, safety, availability and accessibility of blood and blood products and their safe and appropriate use

Precautionary principle

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

Prevalence

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

Quality system

Organizational structure, processes, procedures and resources needed to implement quality requirements

Risk behaviour

Behaviour that exposes an individual to the risk of acquiring transfusion-transmissible infection

Self-deferral

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

Traceability

The ability to trace each individual unit of blood, or blood component derived from it, from the donor to its final destination, whether this is a patient, a manufacturer of therapeutic products or disposal, and vice versa

Transfusion-transmissible infection (TTI)

An infection that is potentially capable of being transmitted by blood transfusion

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DECLARATION OF INTERESTS

Declaration of interest statements were collected from all members of the Guideline Development Group, External Review Group and participants in the inter-regional workshop on blood donor selection and donor counselling for priority countries in the African and Eastern Mediterranean regions, June 2011, Nairobi, Kenya. No conflict of interest was declared by any contributors to the guidelines.

ANNEXES

The WHO Blood Transfusion Safety programme acknowledges with thanks the Zimbabwe National Blood Service for providing the example of a blood donor questionnaire for Annex 2.

GUIDELINES REVIEW COMMITTEE

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Annex 1

International and national guidelines

- 1 *Commission Directive 2004/33/EC of 22 March 2004 implementing Directive 2002/98/EC of the European Parliament and of the Council as regards certain technical requirements for blood and blood components.* EUROPA, 2004. <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2004:091:0025:0039:EN:PDF>
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Annex 2

Example of a blood donor questionnaire

BLOOD TRANSFUSION SERVICE		
DONOR QUESTIONNAIRE		
Please complete this form		
Panel name: _____	Donor no: _____	
Family name: _____	First name: _____	
Title: _____	ID No: _____	
Date of birth: _____	Gender: _____	
Occupation: _____		
Residential address: _____		
Postal address: _____		
Telephone no. Home: _____	Work: _____ Mobile: _____	
E-mail address: _____		
1 HEALTH ASSESSMENT		
Please tick the appropriate answer to each question		
	Yes	No
1.1 Are you feeling well and in good health today?	<input type="checkbox"/>	<input type="checkbox"/>
1.2 in the last 4 hours, have you had a meal or snack?	<input type="checkbox"/>	<input type="checkbox"/>
1.3 Have you already given blood in the last 16 weeks?	<input type="checkbox"/>	<input type="checkbox"/>
1.4 Have you got a chesty cough, sore throat or active cold sore?	<input type="checkbox"/>	<input type="checkbox"/>
1.5 Are you pregnant or breastfeeding?	<input type="checkbox"/>	<input type="checkbox"/>
1.6 Do you have or have you ever had:		
a Chest pains, heart disease/surgery or a stroke?	<input type="checkbox"/>	<input type="checkbox"/>
b Lung disease, tuberculosis or asthma?	<input type="checkbox"/>	<input type="checkbox"/>
c Cancer, a blood disease, an abnormal bleeding disorder, or a bleeding gastric ulcer or duodenal ulcer?	<input type="checkbox"/>	<input type="checkbox"/>

		Yes	No
	d Diabetes, thyroid disease, kidney disease, epilepsy (fits)?	<input type="checkbox"/>	<input type="checkbox"/>
	e Chagas disease, babesiosis, HTLVI/II or any other chronic infectious disease?	<input type="checkbox"/>	<input type="checkbox"/>
1.7	In the last 7 days, have you seen a doctor, dentist or any other healthcare professional or are you waiting to see one (except for routine screening appointments)?	<input type="checkbox"/>	<input type="checkbox"/>
1.8	In the past 12 months:		
	a Have you been ill, received any treatment or taken any medication?	<input type="checkbox"/>	<input type="checkbox"/>
	b Have you been under a doctor's care, undergone surgery, or a diagnostic procedure, suffered a major illness, or been involved in a serious accident?	<input type="checkbox"/>	<input type="checkbox"/>
1.9	Have you ever had yellow jaundice (excluding jaundice at birth), hepatitis or liver disease or a positive test for hepatitis?	<input type="checkbox"/>	<input type="checkbox"/>
	a In the past 12 months, have you had close contact with a person with yellow jaundice or viral hepatitis, or have you been given a hepatitis B vaccination?	<input type="checkbox"/>	<input type="checkbox"/>
	b Have you ever had hepatitis B or hepatitis C or think you may have hepatitis now?	<input type="checkbox"/>	<input type="checkbox"/>
	c In the past 12 months, have you been tattooed, had ear or body piercing, acupuncture, circumcision or scarification, cosmetic treatment?	<input type="checkbox"/>	<input type="checkbox"/>
1.10	In the past 12 months, have you or your sexual partner received a blood transfusion?	<input type="checkbox"/>	<input type="checkbox"/>
1.11	Have you or your sexual partner been treated with human or animal blood products or clotting factors?	<input type="checkbox"/>	<input type="checkbox"/>
1.12	Have you ever had injections of human pituitary growth hormone, pituitary gonadotrophin (fertility medicine) or seen a neurosurgeon or neurologist?	<input type="checkbox"/>	<input type="checkbox"/>
1.13	Have you or close relatives had an unexplained neurological condition or been diagnosed with Creutzfeldt-Jacob Disease or 'mad cow disease'?	<input type="checkbox"/>	<input type="checkbox"/>
1.14	Have you:		
	a Ever had malaria or an unexplained fever associated with travel?	<input type="checkbox"/>	<input type="checkbox"/>
	b Visited any malarial area in the last 12 months?	<input type="checkbox"/>	<input type="checkbox"/>
1.15	When did you last travel to another region or country (in months / years)? _____		

2 RISK ASSESSMENT

		Yes	No
2.1	Is your reason for donating blood to undergo an HIV test?	<input type="checkbox"/>	<input type="checkbox"/>
2.2	Have you ever been tested for HIV?	<input type="checkbox"/>	<input type="checkbox"/>
2.3	If "Yes" what was the reason? <input type="checkbox"/> Voluntary <input type="checkbox"/> Employment <input type="checkbox"/> Insurance <input type="checkbox"/> Medical advice Other: _____		
2.4	Have you ever had casual, oral or anal sex with someone whose background you do not know, with or without a condom?	<input type="checkbox"/>	<input type="checkbox"/>
2.5	Have you ever exchanged money, drugs, goods or favours in return for sex?	<input type="checkbox"/>	<input type="checkbox"/>
2.6	Have you suffered from a sexually transmitted disease (STD): e.g. syphilis, gonorrhoea, genital herpes, genital ulcer, VD, or 'drop'?	<input type="checkbox"/>	<input type="checkbox"/>
2.7	In the past 12 months:		
a	Has there been any change in your marital status?	<input type="checkbox"/>	<input type="checkbox"/>
b	If sexually active, do you think any of the above questions (2.1–2.6) may be true for your sexual partner?	<input type="checkbox"/>	<input type="checkbox"/>
c	Have you been a victim of sexual abuse?	<input type="checkbox"/>	<input type="checkbox"/>
2.8	Have you or your sexual partner suffered from night sweats, unintentional weight loss, diarrhoea or swollen glands?	<input type="checkbox"/>	<input type="checkbox"/>
2.9	Have you ever injected yourself or been injected with illegal or non-prescribed drugs including body-building drugs or cosmetics (even if this was only once or a long time ago)?	<input type="checkbox"/>	<input type="checkbox"/>
2.10	Have you been in contact with anyone with an infectious disease or in the last 12 months have you had any immunizations, vaccinations or jabs?	<input type="checkbox"/>	<input type="checkbox"/>
2.11	Have you ever been refused as a blood donor, or told not to donate blood?	<input type="checkbox"/>	<input type="checkbox"/>

3 DECLARATION

Please do not sign until you have answered all the questions and read the declaration below.

- a I confirm that, to the best of my knowledge, I have answered all the questions accurately and I consider my blood safe for transfusion to a patient.

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- b I understand that any wilful misrepresentation of facts could endanger my health or that of patients receiving my blood and may lead to litigation. I am aware that my blood will be screened for, among others, HIV, hepatitis B, hepatitis C and syphilis. I understand that these screening tests are not diagnostic and may yield false-positive results. If any of the tests give a reactive result, I will be contacted using the information I have provided, and offered counselling.
- c I understand the blood donation process, and I have been counselled regarding the importance of safe blood donation.
- d I confirm that I am over the age of 18 years.
- e I undertake that should there be any reason for my blood to be deemed unsafe for use at any stage, I will inform the Blood Transfusion Service.

Donor's signature: _____

Decision: Accept Defer

Donor weight: _____ kg

Blood pressure: _____ Haemoglobin/haematocrit: _____

Deferral period: _____

Reason for deferral: _____

Interviewed by (name and signature): _____

Venepuncture performed by (name and signature): _____

Date: _____

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