

Chapter 2

Donor selection

2.0. Overview

Donor selection is a critical process in the chain from a safe blood donation to a safe blood product with high quality. This chapter considers the principles for the selection of donors of whole blood and also donors of components obtained by different apheresis procedures.

2.1. Responsibilities of blood establishments in the selection process

2.1.1. Principle of voluntary non-remunerated donation

STANDARD

- 2.1.1.1.** Measures must be taken to promote the collection of blood and blood components from voluntary non-remunerated donations according to the principles set out in the Convention for the Protection of Human Rights and Dignity of the Human Being with Regard to the Application of Biology and Medicine (Convention on Human Rights and Biomedicine, ETS No. 164). Further guided by the Council of Europe Committee on Bioethics (CD-BIO) Guide for the implementation of the principle of prohibition of financial gain with

respect to the human body and its parts from living or deceased donors.*

Council of Europe Recommendation No. R (95) 14, Article 2 states that ‘Donation is considered voluntary and non-remunerated if the person gives blood, plasma or cellular components of his or 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. This would include time off work other than that reasonably needed for the donation and travel. Small tokens, refreshments and reimbursements of direct travel costs are compatible with voluntary, non-remunerated donation.’

2.1.2. Sex and gender

STANDARD

2.1.2.1. Blood establishments should have systems in place that accommodate both the gender and sex of the donor to allow donors to be appropriately addressed, to enable determination of appropriate sex-related biological parameters to ensure donor and recipient safety and to assess donor eligibility. Safety considerations include, for example, donor haemoglobin values, total blood volume estimation and pregnancy-related risks, including risks for HLA/HNA-antibodies (*Evidence level C, E*).

The term sex is generally used to refer to physical or genetic attributes that comprise biological sex, including male, female or intersex, and is generally assigned at birth. Gender, on the other hand, refers to how a person identifies with the various socially constructed roles, behaviours, expressions and identities of girls, women, boys, men and gender-diverse people, including those outside of gender spectrums.

In blood donation and transfusion practice the sex/gender of donors and recipients has traditionally been defined as a binary variable based on the biological and physiological differences between male and female individuals.

* Available at: <https://rm.coe.int/guide-financial-gain/16807bfc9a>.

Accurate use of donor gender by blood establishments in both written records and verbal communications is necessary to allow donors to be appropriately addressed. Accurate knowledge of donor sex is necessary to determine appropriate sex-related biological parameters to ensure donor and recipient safety and to assess donor eligibility.

2.1.3. **General requirements**

STANDARDS

- 2.1.3.1.** Procedures for safe donor identification, suitability interview and eligibility assessment must be implemented and maintained. They must take place before each donation and comply with the requirements set out in Annex II and Annex III to Directive 2004/33/EC (*Directive 2005/62/EC, Annex 6.1.1*).
- 2.1.3.2.** Blood establishments are ultimately responsible for the quality and safety of the blood and blood components collected, and must be entitled to decide on the final acceptance or deferral of a donor or a prospective donor, taking into account Resolution CM/Res (2008) 5 on donor responsibility and on the limitations to donation of blood and blood components.

2.1.4. **Information to be provided to donors of blood or blood components**

STANDARDS

- 2.1.4.1.** Information must be provided to prospective donors of blood or blood components. This information provides the basis for informed consent that must be obtained from the donor before proceeding to donation (*Directive 2004/33/EC, Annex II*).
- 2.1.4.2.** Accurate educational materials, which are understandable for members of the general public, about the essential nature of blood, the blood donation procedure, the components derived from whole blood and apheresis donations and the important benefits to patients must be provided (*Directive 2004/33/EC, Annex II*).

2.1.4.3. The following information must be provided:

- For both allogeneic and autologous donations: the reasons for requiring a medical assessment, health and medical history, the testing of donations and the significance of ‘informed consent’.
- For allogeneic donations: self-deferral, temporary and permanent deferral and the reasons why individuals must not donate blood or blood components if there could be a risk for the recipient or the donor.
- For autologous donations: the possibility of deferral and the reasons why the donation procedure cannot take place in the presence of a health risk to the individual, whether as a donor or recipient of the autologous blood or blood components. (*Directive 2004/33/EC Annex II*).

2.1.4.4. Information on the protection of personal data: no unauthorised disclosure of the identity of the donor, of information concerning the donor’s health or of the results of the tests performed must be provided (*Directive 2004/33/EC, Annex II*).

2.1.4.5. The reasons why individuals must not make donations that may be detrimental to their health must be provided (*Directive 2004/33/EC, Annex II*).

2.1.4.6. Specific information on the nature of the procedures involved in the allogeneic or autologous donation process and their respective associated risks must be provided. For autologous donations, information on the possibility that the autologous blood and blood components may not suffice for the intended transfusion requirements must be provided (*Directive 2004/33/EC, Annex II*).

2.1.4.7. Information on the option for donors to change their mind about donating before proceeding further, or the option to withdraw or self-defer at any time during the donation process without undue embarrassment or discomfort must be provided (*Directive 2004/33/EC, Annex II*).

- 2.1.4.8.** The reasons why it is important that donors inform the blood establishment of any subsequent event that may render any prior donation unsuitable for transfusion must be provided (*Directive 2004/33/EC Annex II*).
- 2.1.4.9.** Information on the responsibility of the blood establishment to inform the donor, through an appropriate mechanism, if test results show any abnormality of significance to the donor's health must be provided (*Directive 2004/33/EC, Annex II*).
- 2.1.4.10.** Information why unused autologous blood and blood components are discarded and not transfused to other patients must be provided (*Directive 2004/33/EC, Annex II*).
- 2.1.4.11.** Information that test results detecting markers for viruses, such as HIV, HBV, HCV or other relevant blood-transmissible microbiologic agents, will result in donor deferral and destruction of the collected unit (*Directive 2004/33/EC, Annex II*) and, when required by law, that the results should be reported to the relevant health authorities must be provided.
- 2.1.4.12.** Information on the opportunity for donors to ask questions at any time must be provided (*Directive 2004/33/EC, Annex II*).
- 2.1.4.13.** All blood donors should be provided with information about behaviours associated with an increased risk of blood-borne infectious agents, such as HIV/AIDS and hepatitis transmission, and be given the opportunity for self-exclusion so that those persons refrain from donating.

2.2. Medical assessment of donors

2.2.1. Donor eligibility

STANDARDS

- 2.2.1.1.** Upon arrival at the blood establishment, donors should provide evidence of their identity. All donors must undergo a systematic screening process to assess their suitability (*GPG 6.1.3.*).
- 2.2.1.2.** There must be an area for confidential personal interviews with and assessment of individuals to assess their eligibility to donate. This area must be separated from all processing areas (*Directive 2005/62/EC, Annex 3.2.*).
- 2.2.1.3.** There should be secure and unique identification, as well as recording of the contact details, of donors (*GPG 6.1.2.*).
- 2.2.1.4.** Only healthy persons with an acceptable medical history can be accepted as donors of blood or blood components (*GPG 6.1.4.*).
- 2.2.1.5.** Relevant acceptance/deferral criteria should be in place at the blood establishment to control acceptance and deferral of donors (*GPG 6.1.7.*).
- 2.2.1.6.** The selection process should include assessment of each donor carried out by a suitably qualified individual who has been trained to use accepted guidelines and who works under the responsibility of a physician. This assessment involves an interview, a questionnaire and further direct questions, if necessary (*GPG 6.1.5.*).
- 2.2.1.7.** Procedures should be in place to ensure that any abnormal findings arising from the donor selection process are properly reviewed by a qualified healthcare professional and that appropriate action is taken (*GPG 6.1.13.*).

In practice, a complete medical and physical examination of the donor is not possible. It is necessary to rely on the donor's appearance, their answers to questions concerning their medical history, general

health and relevant risk factors (e.g. risk behaviour, travel history, epidemiological factors), and on laboratory tests.

Based on this information, a decision on the eligibility of the donor will be made using accepted guidelines. Conditions that are not covered by guidelines should be referred to the physician in charge with responsibility for making the final decision.

2.2.2. Donor age

STANDARDS

- 2.2.2.1.** The age limits for donation are a minimum of 18 years and maximum of 65 years (*Directive 2004/33/EC, Annex III*).
- 2.2.2.2.** Where allowed by national legislation, blood donation may be considered from donors aged 17.
- 2.2.2.3.** Donation by first-time donors above the age of 60 years is at the discretion of the physician in the blood establishment (*Directive 2004/33/EC, Annex III*).
- 2.2.2.4.** Donation by donors over 65 years is with permission of the physician in the blood establishment, given annually (*Directive 2004/33/EC, Annex III*). This can be given either individually to each donor, or based on a medical risk assessment for a given donor population.

2.2.3. Donor haemoglobin

STANDARDS

- 2.2.3.1.** Haemoglobin concentration must be determined each time the donor donates whole blood or cellular components (*Directive 2004/33/EC, Annex III*).
- 2.2.3.2.** Haemoglobin values at donation must not be lower than the values shown in the table below (*Directive 2004/33/EC, Annex III*):

Table 2-1. **Haemoglobin values**

	Female	Male
Whole blood and cellular components	125 g/L or 7.8 mmol/L	135 g/L or 8.4 mmol/L

Individual donations may be accepted below these levels after consultation with the responsible physician or as established by a competent authority based on norms for their specific populations.

Haemoglobin should be measured preferably before the donation, but always before donation when donors were deferred from donation at the last visit because of its low level.

Abnormally high and low haemoglobin values should be confirmed by full blood count and subsequently investigated, as should a fall in haemoglobin concentration of more than 20 g per L (1.24 mmol/L) between two successive donations.

2.2.4. **Iron stores**

There is increasing awareness of the risk of iron deficiency following regular whole blood donation. This is particularly apparent in female donors of childbearing years, frequent whole blood donors and in donors with inadequate dietary iron intake who may present as a first-time donor with low or borderline iron stores. Each whole blood donation results in the loss of 200 to 250 mg of iron. Replenishment of this may take up to 6 months based on a normal healthy diet.

Iron deficiency may occur despite a normal pre-donation haemoglobin measurement.

STANDARD

- 2.2.4.1. Blood establishments should have measures in place to minimise iron depletion in frequent blood donors.

Measures to prevent iron depletion and to protect donor health may include:

- Provision of materials for donor education, particularly in regard to the impact of blood donation on iron stores;
- Individual tailoring of donation frequency or the interval between donations and/or of the type of blood component donation based on sex, age, Hb values and iron status (*Evidence level C, E*);
- Use of tests to assess iron status, such as ferritin, soluble transferrin receptor and red blood cell (RBC) indices;
- Iron supplementation taking into account the risk of delaying the diagnosis of unapparent underlying diseases and adverse effects of the iron preparations;
- In plasmapheresis donations destined for plasma for fractionation: the use of samples taken from the plasma collection container (instead of whole blood samples from the donor) for mandatory laboratory screening tests in order to avoid a loss of iron from testing samples (see also [Chapter 3, Standard 3.6.2.2](#)) (*Evidence level C*);
- Saline wash-back of residual red cells in the apheresis harness.

2.2.5. Questionnaire and interview

STANDARDS

- 2.2.5.1.** The questionnaire should be designed to elicit information relevant to the medical history, general health and other known or probable risk factors related to the donor. It should be designed to be understandable by the donor and given to all donors each time they attend. On completion, it should be signed by the donor (*GPG 6.1.6.*).
- 2.2.5.2.** The donor interview must be conducted in such a way as to ensure confidentiality (*Directive 2005/62/EC, Annex 6.1.2.*).
- 2.2.5.3.** The confidential interview should be conducted by specifically trained staff who may also ask further direct questions to supplement the information in the questionnaire. The person who carries out

the assessment should certify that the relevant questions have been asked (*GPG 6.1.9.*).

2.2.5.4. During the interview the donor should be evaluated for physical attributes, such as cyanosis, dyspnoea, undernutrition and intoxication from alcohol or drugs, that may suggest an underlying condition where donation is not safe.

2.2.5.5. Records of suitability and final assessment of donors must be signed by a qualified healthcare professional (*Directive 2005/62/EC, Annex 6.1.3.*).

The key topics for donor eligibility to be covered by the questionnaire or by direct questions, the intentions of the interview questions, and examples of sample questions are included in Appendix 1.

2.3. Donor deferral

2.3.1. General remarks

Donors with hazardous occupations or hobbies should be advised to wait for an interval of not less than 12 hours between donation and returning to the occupation or hobby. Examples of such hazardous occupations or hobbies include piloting, bus or train driving, crane operation, climbing of ladders or scaffolding, gliding, climbing and diving.

Donors presenting with a medical condition or under medical treatment should be assessed to determine their eligibility. Reasons for donor deferral may include non-infectious medical conditions, infectious diseases and medical or surgical treatments.

STANDARD

2.3.1.1. Deferred individuals should be given a clear explanation of the reasons for deferral.

2.3.2. Non-infectious medical conditions

STANDARD

- 2.3.2.1.** Prospective donors with serious active, chronic or relapsing disease must be permanently deferred (*Directive 2004/33/EC, Annex III*)

Allergy and anaphylaxis

STANDARD

- 2.3.2.2.** Donors with local/non-generalised allergic symptoms which are controlled with medication (except for oral corticosteroids or other immunosuppressive medical treatment) or without medication are accepted as donors (*Evidence level C, E*).
- 2.3.2.3.** Donors who have had a recent episode of anaphylaxis or severe allergic reaction should be deferred for 2 weeks after recovery (*Evidence level C, E*).

Donors with severe, widespread atopic eczema should be temporarily deferred until cessation of the symptoms (*Evidence level C, E*).

Donors requiring oral corticosteroids, or other immunosuppressive medical treatment should be deferred temporarily until such treatment has stopped. Some treatments will also require a period of deferral post-cessation (*Evidence level C, E*).

Donors with any known allergy to agents used in blood collection (skin disinfection agents, other material used in the collection process) should be deferred unless there is alternative material available (*Evidence level E*).

Based on current evidence, the major cause of anaphylaxis in a recipient is their own atopic condition and not transfusion-associated issues. Therefore, excluding donors based on their history of severe allergic/anaphylactic reactions is not an effective risk reduction strategy and may cause an unacceptable loss of donors.

However, some case studies suggest that blood components with a higher volume of plasma from donors with recurrent severe allergic/

anaphylactic reactions may carry a higher risk of anaphylaxis for the recipient. Therefore, consideration may be given to permanently deferring such donors from donating blood components with a high plasma volume, such as fresh frozen plasma (FFP) for clinical use and platelets in plasma (*Evidence level E*).

Autoimmune disease

A person requiring systemic immune-modulatory therapy should be deferred until such treatment has stopped. Asymptomatic donors without severe complications can be accepted.

Blood pressure

A person with a systolic blood pressure of 180 mm Hg or higher, or a diastolic blood pressure of 100 mm Hg or higher should be temporarily deferred.

Cancer/malignant diseases

STANDARD

2.3.2.4. Individuals with a malignant disease are permanently deferred, except donors with in situ carcinoma with complete recovery (*Directive 2004/33/EC, Annex III*).

There is evidence to support the acceptance of donors with a history of cancer. Large observational studies have provided convincing evidence that the risk of transmitting cancer via blood transfusions is undetectable or not significant (*Evidence level C*).

Therefore, the responsible physician may make exceptions other than in situ carcinoma if the donor has fully recovered with no expectation of recurrence (i.e. cured).

The following conditions apply:

- For cancers with negligible metastatic potential (e.g. basal cell carcinoma), the donor may be accepted following complete recovery.
- For other cancers, at least 5 years should have elapsed since completion of treatment (*Evidence level C, D, E*).

- No deferral is required for premalignant conditions.

Cardiovascular disease

STANDARD

- 2.3.2.5.** Donors with active or past serious cardiovascular disease, except congenital abnormalities with complete cure, must be permanently deferred (*Directive 2004/33/EC, Annex III*).
- 2.3.2.6.** Persons with a history of coronary disease, angina pectoris, severe cardiac arrhythmia, a history of cerebrovascular diseases, arterial thrombosis or recurrent venous thrombosis should be classified as having 'serious cardiovascular disease' and therefore be permanently deferred (*Evidence level E*).

Diabetes

STANDARD

- 2.3.2.7.** Donors with diabetes must be deferred if insulin therapy is required (*Directive 2004/33/EC, Annex III*).

Epilepsy

STANDARD

- 2.3.2.8.** Donors with repeated episodes of syncope or a history of convulsions must be deferred until 3 years off treatment and free of attacks (*Directive 2004/33/EC, Annex III*).

Kidney disease

STANDARD

- 2.3.2.9.** Following acute glomerulonephritis donors should be deferred for 12 months after full recovery (feeling well, no treatment and discharged from specialist care).

Pregnancy

STANDARD

- 2.3.2.10.** Pregnant donors must be deferred 6 months after delivery or termination. The responsible physician may make exceptions under exceptional circumstances (*Directive 2004/33/EC, Annex III*).

Pulse

A person with a pulse under 50 beats per minute (bpm), or above 100 bpm or presenting with an irregular pulse should be deferred. Exceptions may be made to accept donors with a lower pulse rate following individual medical review, e.g. athletes.

Respiratory disease

STANDARD

- 2.3.2.11.** Prospective donors with serious active, chronic or relapsing respiratory system diseases must be permanently deferred (*Directive 2004/33/EC, Annex III*).

Rheumatic fever

STANDARD

- 2.3.2.12.** Donors suffering from rheumatic fever must be deferred for 2 years following the last attack or permanently if any evidence of chronic heart disease (*Directive 2004/33/EC, Annex III*).

Thalassaemia

Donors with thalassaemia should be deferred permanently if they are not in good health or if the haemoglobin levels are below acceptable values. Individuals with thalassaemia trait may give whole blood provided they are in good health and have a haemoglobin level within acceptable values. Platelet or plasma collection by apheresis is not recommended as the process may cause mechanical haemolysis.

2.3.3. **Infectious diseases**

Transmission of infectious agents by transfusion can be minimised by careful and appropriate use of donor questionnaires, laboratory testing and pathogen inactivation technologies (PIT).

Other measures are needed for infections where there is a possibility of asymptomatic infection or existence of a carrier state. Questioning donors about symptoms in these circumstances does not always prevent transmission.

Donors should be questioned on their risk of exposure to infectious agents, which includes taking a travel history:

- For infections in which the agent has been fully cleared from the donor's blood on recovery, the donor should be deferred from donation until they are no longer infectious (usually 2 weeks from cessation of symptoms);
- In cases of known contact with an infectious agent, the donor should be deferred for approximately twice the length of the incubation period. In case of a geographical risk of exposure to multiple infectious agents, the longest deferral period applies;
- Many infections that can be transmitted by transfusion have defined geographical limits, and the risk of transfusion transmission can be minimised by temporary deferral or testing donors travelling from affected areas. Testing becomes especially relevant when deferral policies may potentially affect supply.

Blood services should maintain a watching brief on changes to risks of infectious diseases worldwide. Risk-benefit analyses should be carried out to determine appropriate measures to decrease the risks of transfusion transmission. The risk of importation of an infectious agent through donors visiting an affected area should be balanced by considering the likelihood of this occurring, and the impact of introducing a new donor deferral ruling on blood supply. This risk will vary between countries.

New and emerging infectious agents or those that have moved to infect a new geographical area can also pose a significant challenge to donor availability or blood component safety. In this situation, donor deferral may not be an option in the newly affected area. Donation testing is an important tool to reduce the risk of transmission. For plasma and platelets, PIT may also be considered.

Information about new and emerging infections should be communicated between countries without delay to allow blood establishments to consider their own risks and appropriate actions.

Babesiosis

STANDARD

- 2.3.3.1.** Donors with babesiosis must be deferred permanently (*Directive 2004/33/EC, Annex III*).

Deferral requirements may be waived if the donation is used exclusively for plasma for fractionation.

Brucellosis

STANDARD

- 2.3.3.2.** Donors with brucellosis must be deferred for at least 2 years following full recovery (*Directive 2004/33/EC, Annex III*)

Deferral requirements may be waived if the donation is used exclusively for plasma for fractionation.

Chikungunya virus

STANDARDS

- 2.3.3.3.** Donors visiting regions endemic for chikungunya virus infections should be deferred for 28 days after leaving the risk area.

Deferral requirements may be waived if the donation is used exclusively for plasma for fractionation.

- 2.3.3.4.** Donors suffering from chikungunya virus infections should be deferred for 120 days after resolution of the symptoms.

Common cold

Donors presenting with the common cold should be deferred until cessation of symptoms.

Creutzfeldt–Jakob disease

STANDARDS

- 2.3.3.5.** Individuals who have been treated with extracts derived from human pituitary glands and recipients of *dura mater* or corneal grafts must be deferred permanently (*Directive 2004/33/EC, Annex III*).
- 2.3.3.6.** Individuals with a family risk of Creutzfeldt–Jakob disease (CJD) or any other transmissible spongiform encephalopathy must be deferred permanently (*Directive 2004/33/EC, Annex III*).

A family history of CJD carries a presumption of family risk unless it is determined that:

- The affected family member had vCJD, not CJD; or
- The affected family member did not have a genetic relationship to the donor; or
- The cause of CJD in the affected family member was iatrogenic; or
- The donor was tested and is known to have a normal genetic polymorphism for PrPc.

STANDARD

- 2.3.3.7.** Deferral of donors as a preventative measure for vCJD should be based on appropriate risk assessment.

Variant CJD (vCJD) was first described in the UK in 1996. Estimating the potential size of the vCJD epidemic has been very difficult. Transfusion transmission of vCJD has been documented in animal studies and in humans. Endogenous risk of vCJD differs between countries. Therefore, the need for different measures to reduce risk will depend on each country's own risk assessment, balancing risk with sufficiency of supply.

Many countries outside the UK defer donors who have lived in the UK for a minimum defined period between 1980 and 1996; the European Medicines Agency (EMA) mandates 1 year of UK residence for donors of plasma for fractionation. In some instances, the deferrals have been extended to include donors from other countries with a significant number of cases.

Dengue fever

STANDARDS

- 2.3.3.8.** Donors visiting regions endemic for dengue fever should be deferred for 28 days after leaving the risk area.
- 2.3.3.9.** Donors suffering from dengue fever should be deferred for 120 days after resolution of the symptoms.

Deferral requirements may be waived if the donation is used exclusively for plasma for fractionation.

Fever above + 38 °C, flu-like illness

STANDARD

- 2.3.3.10.** Donors presenting with fever above + 38 °C or flu-like illness must be deferred for 2 weeks following cessation of symptoms (*Directive 2004/33/EC, Annex III*).

Hepatitis B (HBV)

STANDARDS

- 2.3.3.11.** Individuals infected with HBV must be deferred permanently unless HBsAg negative and demonstrated to be immune (*Directive 2004/33/EC, Annex III*).
- 2.3.3.12.** Persons who have been in close household contact with an individual infected by HBV (acute or chronic) must be deferred for 6 months (4 months if appropriate testing has been performed) from the time of contact unless demonstrated to be immune (*Directive 2004/33/EC, Annex III*).

2.3.3.13. Current sexual partners of people with HBV should be deferred, unless demonstrated to be immune.

2.3.3.14. Previous sexual partners of people with HBV are acceptable after 6 months since the last sexual contact. This can be reduced to 4 months if HBV nucleic acid amplification technique (NAT) and anti-HBc tests are performed and both test results are negative.

Hepatitis C (HCV)

STANDARD

2.3.3.15. Individuals infected with HCV or history thereof must be deferred permanently (*Directive 2004/33/EC, Annex III*).

HIV 1/2

STANDARD

2.3.3.16. Individuals infected with HIV 1/2 must be deferred permanently (*Directive 2004/33/EC, Annex III*).

HTLV 1/2

STANDARD

2.3.3.17. Individuals infected with HTLV 1/2 must be deferred permanently (*Directive 2004/33/EC, Annex III*).

Jaundice and hepatitis

STANDARD

2.3.3.18. Individuals with a history of jaundice or hepatitis may be accepted as blood donors at the discretion of the appropriate competent authority, provided a CE-marked test for HBsAg and anti-HCV is negative.

Hospital staff coming into direct contact with patients with hepatitis may be accepted provided they have not suffered an inoculation injury or mucous membrane exposure, in which case they must be deferred.

Leishmaniasis (kala-azar), visceral leishmaniasis

STANDARD

- 2.3.3.19.** Individuals with a history of visceral leishmaniasis (kala-azar) must be deferred permanently (*Directive 2004/33/EC, Annex III*).

Deferral requirements may be waived if the donation is used exclusively for plasma for fractionation.

Malaria

STANDARD

- 2.3.3.20.** A donor should be questioned to identify the country(s) they were born in, have lived in or have visited.

This is essential for effective detection of donors at increased risk of malaria who may need to be deferred. These deferral requirements may be waived if the donation is used exclusively for plasma for fractionation.

STANDARDS

- 2.3.3.21.** Blood establishments should have access to a current map or list of endemic areas and seasonal risk periods at the site of blood collection.
- 2.3.3.22.** The following rules should apply for individuals who give a history of malaria:
- They should be deferred for a period of at least 4 months following departure from a malarial area and 4 months following cessation of treatment/last symptoms. They may then be accepted if the result of a validated immunological test for antibodies to the malaria parasite is negative.
 - If the test is repeatedly reactive, the donor should be deferred and may be re-evaluated after a suitable period when the antibody test may have reverted to negative (a period of 3 years is suggested).
 - If the test is not performed, the donor should be deferred until the test is performed and negative.

2.3.3.23. The following rules should apply for individuals who report an undiagnosed febrile illness consistent with malaria during a visit to or within 6 months following departure from a malarial area:

- They should be deferred for a period of at least 4 months following departure from a malarial area and 4 months following cessation of treatment/last symptoms. They may then be accepted if the result of a validated immunological test for antibodies to the malaria parasite is negative.
- If the test is repeatedly reactive, the donor should be deferred and may be re-evaluated after a suitable period when the antibody test may have reverted to negative (a period of 3 years is suggested).
- If the test is not performed, the donor should be deferred until the test is performed and negative.

2.3.3.24. The following rules should apply for individuals who have lived in a malaria-endemic area for a continuous period of 6 months or more at any time in their life at the time of their first donation and after each return from a malarial area:

- They may be accepted as blood donors if the result of a validated immunological test for antibodies to the malaria parasite, performed at least 4 months after leaving the malarial area, is negative.
- If the test is repeatedly reactive, the donor should be deferred and may be re-evaluated after a suitable period when the antibody test may have reverted to negative (a period of 3 years is suggested).
- If the test is not performed, the donor should be deferred until the test is performed and negative.

2.3.3.25. The following rules should apply for all other individuals who have visited a malarial area without reporting any clinical symptoms consistent with malaria:

- They should be deferred for a period of 4 months following departure from the malarial area and may then be accepted as blood donors if the result of a validated immunological test for antibodies to the malaria parasite is negative.

- If the test is not performed, the donor may be accepted once a period of 12 months has elapsed following departure from the malarial area.
- If the test is repeatedly reactive, the donor should be deferred and may be re-evaluated after a suitable period when the antibody test may have reverted to negative (a period of 3 years is suggested).

Osteomyelitis

STANDARD

- 2.3.3.26.** Donors suffering from osteomyelitis must be deferred until 2 years after having been declared cured (*Directive 2004/33/EC, Annex III*).

Q fever

STANDARD

- 2.3.3.27.** Donors suffering from Q fever must be deferred until 2 years after having been declared cured (*Directive 2004/33/EC, Annex III*).

Deferral requirements may be waived if the donation is used exclusively for plasma for fractionation.

Syphilis

STANDARD

- 2.3.3.28.** Donors suffering from syphilis must be deferred until 1 year after having been declared cured (*Directive 2004/33/EC, Annex III*).

Tests and deferral periods may be waived if the donation is used exclusively for plasma for fractionation.

Toxoplasmosis

STANDARD

- 2.3.3.29.** Donors suffering from toxoplasmosis must be deferred until 6 months following clinical recovery (*Directive 2004/33/EC, Annex III*).

Deferral requirements may be waived if the donation is used exclusively for plasma for fractionation.

Trypanosomiasis cruzi (Chagas disease)

STANDARD

- 2.3.3.30.** Individuals with Chagas disease or who have had Chagas disease must be deferred permanently (*Directive 2004/33/EC, Annex III*).

In some countries, individuals who were born or have been transfused in areas where the disease is endemic are also deferred unless a validated test for infection with *T. cruzi* is negative.

Test and deferral requirements may be waived if the donation is used exclusively for plasma for fractionation.

Sexual risk behaviour

STANDARDS

- 2.3.3.31.** Individuals whose sexual behaviour puts them at a high risk of acquiring severe infectious diseases that can be transmitted by blood must be deferred permanently (*Directive 2004/33/EC, Annex III*).
- 2.3.3.32.** Sexual partners of people in 2.3.3.31. should be deferred for a period determined by national risk assessment for the infectious disease in question, and by the availability of appropriate tests.

Tuberculosis

STANDARD

- 2.3.3.33.** Donors suffering from tuberculosis must be deferred until 2 years after having been confirmed cured (*Directive 2004/33/EC, Annex III*).

West Nile virus (WNV)

STANDARDS

- 2.3.3.34.** Individuals visiting regions with ongoing transmission of WNV to humans must be deferred for 28 days after leaving the risk area unless an individual NAT is negative (*Directive 2014/110/EU*).
- 2.3.3.35.** Individuals with a diagnosis of WNV should be deferred until 120 days after recovery.

Tests and deferral periods may be waived if the donation is used exclusively for plasma for fractionation.

Zika virus

STANDARDS

- 2.3.3.36.** Individuals visiting regions with ongoing transmission of Zika virus infections to humans should be deferred for 28 days after leaving the risk area unless a validated NAT is performed.
- 2.3.3.37.** Individuals with a diagnosis of Zika virus infection should be deferred until 120 days after recovery.

Tests and deferral periods may be waived if the donation is used exclusively for plasma for fractionation.

2.3.4. Interventions and treatments

Acupuncture, tattooing, body piercing and aesthetic medical procedures

STANDARD

- 2.3.4.1.** Individuals having acupuncture (unless performed by a qualified practitioner and with sterile single use needles), tattooing or body piercing must be deferred for 6 months (or 4 months, provided a NAT test for hepatitis C is negative) (*Directive 2004/33/EC, Annex III*).

There is evidence that using a risk-based approach based on national transfusion-transmissible infection (TTI) disease prevalence and incidence, modifications to standard 2.3.4.1. can be accepted for acupuncture, tattooing, body piercing or skin/mucosa-penetrating aesthetic medical procedures. These may be implemented nationally or by decision of the responsible physician (*Evidence level C, E*).

Where modified standards are implemented, the following should be considered when assessing eligibility of such donors:

- The reason for acupuncture and complications of acupuncture, tattooing, body piercing and other aesthetic procedures;

- Secondary infection: inspect or ask about local complications, such as redness, swelling or skin lesions.

Tissue or cell transplant of human origin

STANDARD

- 2.3.4.2.** Individuals having a tissue or cell transplant of human origin must be deferred for 6 months (or 4 months, provided a NAT test for hepatitis C is negative) (*Directive 2004/33/EC, Annex III*).

Exceptions may be made according to national risk assessments.

Drugs

STANDARD

- 2.3.4.3.** Individuals with any history of intravenous or intramuscular non-prescribed drug use, including bodybuilding steroids or hormones, must be deferred permanently (*Directive 2004/33/EC, Annex III*).

Endoscopy with biopsy using flexible instruments

STANDARD

- 2.3.4.4.** Donors having an endoscopy with biopsy using flexible instruments must be deferred for 6 months (or 4 months, provided a NAT test for hepatitis C is negative) (*Directive 2004/33/EC, Annex III*).

Exceptions may be made according to national risk assessments.

Inoculation injury or mucosal splash with blood

STANDARD

- 2.3.4.5.** Individuals having an inoculation injury or mucosal splash with blood must be deferred for 6 months (or 4 months, provided a NAT test for hepatitis C is negative) (*Directive 2004/33/EC, Annex III*).

Exceptions may be made according to national risk assessments.

Medication

STANDARD

- 2.3.4.6.** Donors treated with drugs with proven teratogenic effect must be deferred for a period at least consistent with the pharmacokinetic properties of the drug.

The taking of a medication may indicate an underlying disease which may disqualify the donor. It is recommended that a list of commonly used drugs, with rules for acceptability of donors, approved by the medical staff of the blood establishment, be made available.

Surgery

STANDARD

- 2.3.4.7.** After major surgery, donors must be deferred for 6 months (or 4 months provided a NAT test for hepatitis C is negative) (*Directive 2004/33/EC, Annex III*).
- 2.3.4.8.** After minor surgery, donors must be deferred for 1 week (*Directive 2004/33/EC, Annex III*).

There is no clear evidence to specifically support the deferral periods of 4 to 6 months after major surgery and 1 week after minor surgery (*Evidence level C, E*). By using a risk-based approach, modifications to standards 2.3.4.7. and 2.3.4.8. can be accepted and implemented nationally or by decision of the responsible physician.

Where modified standards are implemented, the following should be considered when assessing eligibility of such donors:

- For major surgery: persons should not donate until they have fully recovered (which may be up to 6 months or longer). A shorter deferral period is possible after clinical evaluation, if the donor has totally recovered from the surgery (i.e. wound healed, no signs of postoperative infection and in a healthy condition) (*Evidence level C, E*).

- For planned major surgery: allogeneic whole blood donation should be avoided for an appropriate time interval before major surgery (*Evidence level, E*).
- For minor surgery: deferral until wound healed (stitches removed, no signs of infection) (*Evidence level C, E*).

When considering revised donor eligibility following surgery, the responsible physician should take into consideration the following:

- The indication for the surgery;
- Whether the donor received a transfusion of labile blood products; if so, refer to specific rules;
- The need to measure the haemoglobin level pre-donation after major surgery.

Dental care/Oral health care

STANDARD

- 2.3.4.9.** Individuals must be deferred for 1 week after tooth extraction, root filling and similar treatments (*Directive 2004/33/EC, Annex III*).
- 2.3.4.10.** Donors undergoing minor treatment by a dentist or dental hygienist must be deferred until the next day (*Directive 2004/33/EC, Annex III*).

The available evidence indicates that bacteraemia immediately following minor dental treatments is transient, lasting only up to 30 minutes. Poor oral health, such as acute or chronic gingivitis, is a risk factor for bacteraemia (*Evidence level C*). By using a risk-based approach, modifications to standard 2.3.4.10. can be accepted and implemented nationally or by decision of the responsible physician.

Modifications to the standard can be made by the responsible physician as follows:

- Minor dental treatment by the dentist or dental hygienist: 60 minutes' deferral (*Evidence level C, E*);
- Acute oral infection (e.g. gingivitis requiring treatment): defer until cessation and/or 2 weeks after completion of oral course of antibiotics (*Evidence level C, E*).

Transfusion of blood components

STANDARD

- 2.3.4.11.** Individuals having a transfusion of blood components must be deferred for 6 months (or 4 months, provided a NAT test for hepatitis C is negative) (*Directive 2004/33/EC, Annex III*).

Injection of red cells as part of an approved immunisation programme will need clinical assessment.

Blood or blood components used for treatment other than transfusion

Donors who have received treatment with allogeneic blood or blood components for topical use or injections should be treated as though they had received blood components for transfusion (*Evidence level C, E*).

Vaccines

STANDARDS

- 2.3.4.12.** After vaccination with attenuated bacteria and viruses, e.g. BCG, yellow fever, rubella, measles, poliomyelitis (oral), mumps, live attenuated typhoid fever, vaccinia, live attenuated cholera vaccine, individuals must be deferred for 4 weeks (*Directive 2004/33/EC, Annex III*);
- 2.3.4.13.** After vaccination for smallpox and monkeypox individuals must be deferred for 8 weeks.
- 2.3.4.14.** Individuals may, if well, be accepted as donors after vaccination with (*Directive 2004/33/EC, Annex III*):
- Inactivated viruses, e.g. poliomyelitis (injection), influenza;
 - Killed bacteria, e.g. cholera, typhoid, capsular polysaccharide typhoid fever vaccine;
 - Polysaccharides, e.g. from pneumococcal polysaccharide;
 - Toxoids, e.g. diphtheria, tetanus;
 - Hepatitis A or tick-borne encephalitis vaccines, if no exposure is reported;

- mRNA vaccines, non-replicating/replication-deficient virus vector-based vaccines and protein subunit vaccines.
- 2.3.4.15.** Individuals receiving rabies vaccines are (*Directive 2004/33/EC, Annex III*):
- Accepted without deferral if well and no exposure;
 - Deferred for 12 months following exposure to rabies.
- 2.3.4.16.** Individuals should be deferred for 2 weeks following administration of hepatitis B or a combined hepatitis A and hepatitis B vaccine in order to prevent vaccine-related positivity in the HBsAg test.

Xenotransplantation

STANDARD

- 2.3.4.17.** After xenotransplantation individuals must be deferred permanently (*Directive 2004/33/EC, Annex III*).

2.4. Specific standards for donors of different types of components

Below are specific standards for donors of blood and blood components for both whole blood and apheresis collection. The intervals between donations are provided in [Table 2-3](#) at the end of the chapter.

2.4.1. Whole blood donation

Volume of whole blood donation

STANDARDS

- 2.4.1.1.** A standard donation of whole blood must not be collected from persons weighing less than 50 kg (*Directive 2004/33/EC, Annex III*).
- 2.4.1.2.** The volume of a standard donation of whole blood (excluding anticoagulants) should not exceed 500 mL and usually consists of a donation of 450 mL \pm 10 %. This does not include any allowance

for samples taken for laboratory tests and for retention of a donor sample.

2.4.1.3. The volume of a standard donation of whole blood (including samples) should not exceed 15 % of the calculated blood volume of the donor.

The total blood volume (TBV) of the donor can be estimated from their weight, height and sex using a validated formula. The estimates developed by the International Council for Standardization in Haematology (ICSH) are recommended and are available in [Appendix 2](#).

It is generally accepted that all males weighing ≥ 50 kg have a sufficiently large blood volume to donate a total 535 mL of blood (500 mL plus 35 mL for testing and retention of a donation sample), while all females weighing ≥ 50 kg have a sufficiently large blood volume to donate a total 485 mL of blood (450 mL plus 35 mL for testing and retention of a donation sample).

In the case of females weighing < 65 kg and donating a total of > 485 mL, the blood volume should be estimated. This volume should exceed the minimum acceptable blood volume for the volume of blood to be collected (see Table 2-2).

Table 2-2. Predicted minimum blood volume of a female donor donating 485 mL, 510 mL or 535 mL

Volume of blood to be collected	Maximum percentage of blood volume collected	Minimum acceptable blood volume
450 mL + 35 mL	15 %	3 233 mL
475 mL + 35 mL	15 %	3 400 mL
500 mL + 35 mL	15 %	3 567 mL

Frequency of whole blood donation

STANDARDS

- 2.4.1.4.** A maximum of 6 standard donations of whole blood per year can be taken from male and up to 4 per year from female donors with a minimum interval between standard donations of 8 weeks.
- 2.4.1.5.** These maximum limits of donation frequency should never be exceeded and should only be adopted after careful consideration of the dietary habits of the population concerned and in the knowledge that extra care may be necessary, beyond routine haemoglobin or haematocrit estimation, in the monitoring of donors for iron deficiency.

It is therefore recommended that an active donor panel of sufficient size be maintained to allow donors to be bled less often than the maximum annual rates.

2.4.2. Apheresis donation

Donors should be informed of the risks associated with the apheresis procedure and consent should be obtained before each donation.

STANDARDS

- 2.4.2.1.** The medical supervision and care of apheresis donors should be the responsibility of a physician specially trained in these techniques.
- 2.4.2.2.** Other than in exceptional circumstances (to be decided by the responsible physician), donors for apheresis procedures should meet the criteria for whole blood donations unless otherwise identified in this Guide.

The impact of prematurely terminated apheresis procedures, including consideration of a failed return of red cells resulting in a red cell loss and the amount of primary component already collected, needs to be taken into account when determining compliance with these requirements.

There are concerns about long-term effects in donors in intensive apheresis programmes. These include risks associated with citrate exposure in regular platelet apheresis donors, which might lead to problems with bone mineral density and reduced IgG levels. Regular monitoring of IgG in plasmapheresis donors for adjusting of donation frequency has been shown to improve donor safety.

Special attention should be given to the following conditions:

- Abnormal bleeding episodes;
- Adverse reactions to previous donations;
- Frequency of donation and maximal amounts of plasma and red cells to be collected.

STANDARDS

- 2.4.2.3.** The interval between one plasmapheresis or plateletpheresis procedure and a donation of whole blood or apheresis procedure incorporating collection of a single or double unit of red cells (whereby one unit is equivalent to a red cell component obtained from one whole blood donation) should be at least 48 hours.
- 2.4.2.4.** The interval between a whole blood donation, an apheresis red cell collection or a failed return of red cells during apheresis, and the next apheresis procedure without red cell collection should be at least 4 weeks.
- 2.4.2.5.** The interval between two single-unit red cell collections should be the same as for collections of whole blood.

Additional requirements for donors undergoing plasmapheresis

Sampling and residual blood remaining in the plasmapheresis devices can result in a non-negligible loss of red cells, with a consequent reduction in serum iron and ferritin. This is especially important for female donors.

Where frequent plasmapheresis is undertaken, consideration should be given to the implementation of measures to reduce residual blood loss in the equipment, e.g. post-procedure saline infusion. Loss of iron

in donors can also be mitigated by using samples from the plasma collection container (instead of whole blood samples) for mandatory laboratory screening tests (see also [Chapter 3](#), [Standard 3.6.2.2](#), Evidence level C).

The following standards identify requirements for donors undergoing plasmapheresis.

STANDARDS

- 2.4.2.6.** The maximum number of plasma donations allowed is 33 per year (*Evidence level C*).
- 2.4.2.7.** The collection volume for each plasmapheresis should be based on estimation of an allowed/permitted volume for an individual donor. The limits for allowed volumes should be based on estimated TBV and/or body mass index (BMI) and can be set either by national/regional regulations or based on TBV estimation in [Appendix 2a](#) or BMI in [Appendix 2b](#).
- 2.4.2.8.** The collection volume for each plasmapheresis (including anticoagulant) should never exceed 880 mL.
- 2.4.2.9.** When the collection volume (including anticoagulant) is determined by the estimation of TBV ([Appendix 2a](#)) the donated volume (excluding anticoagulant) should not exceed 16 % of the estimated TBV and in any type of apheresis procedure the total volume of all components donated (plasma, platelets and red cells) should not exceed 16 % of the estimated TBV.
- 2.4.2.10.** The donation interval should be at least 1 week (see the IgG algorithm provided below).
- 2.4.2.11.** Haemoglobin values at plasmapheresis donation should not be less than 120 g/L or 7.5 mmol/L for female and not less than 130 g/L or 8.1 mmol/L for male donors.

Individual donations may be accepted below these levels after consultation with the responsible physician or as established by a competent authority based on norms for their specific populations.

- 2.4.2.12.** Total proteins must be measured at least annually and must not be less than 60 g/L (*Directive 2004/33/EC, Annex III*).
- 2.4.2.13.** IgG levels should be within local population reference ranges and should not fall below 6.0 g/L.
- 2.4.2.14.** IgG should be measured at least annually and at every 26th donation, whichever comes first (*Evidence level C, E*).

The maximum donation frequency for an individual donor should be guided by the results of the testing. An approach for the calculation of the maximum donation frequency for an individual donor based on their IgG levels could be as follows:

- IgG < 6.0 g/L results in a deferral from plasmapheresis of at least 3 weeks. Repeated measurements of < 6.0 g/L should lead to either a significant increase in the inter-donation interval or permanent deferral from plasmapheresis;
- IgG 6.0–8.0 g/L supports donations with a minimum interval of 2 weeks;
- IgG > 8.0 g/L supports donations with a minimum interval of 1 week.

Additional requirements for donors undergoing platelet apheresis

STANDARDS

- 2.4.2.15.** Platelet apheresis must not be carried out on individuals whose platelet count is less than $150 \times 10^9/\text{L}$ (*Directive 2004/33/EC, Annex III*).
- 2.4.2.16.** Haemoglobin values at plateletpheresis donation must not be less than 125 g/L or 7.8 mmol/L for female and not less than 135 g/L or 8.4 mmol/L for male donors (*Directive 2004/33/EC, Annex III*).

Individual donations may be accepted below these levels after consultation with the responsible physician or as established by a competent authority based on norms for their specific populations.

- 2.4.2.17.** Donors should not be subjected to a plateletpheresis procedure more often than once every 2 weeks.

An exception to the donation interval and platelet count may be made in the case of HLA-/HPA-matched donations and for IgA-negative donors at the discretion of the physician.

Additional requirements for donors undergoing double unit red cell apheresis

STANDARDS

- 2.4.2.18.** Minimum limits for haemoglobin values at double unit red cell apheresis donation should not be less than 140 g/L or 8.7 mmol/L for both female and male donors.
- 2.4.2.19.** The total amount of red cells collected should not exceed the theoretical amount of red cells that would reduce the donor haemoglobin level, in an isovolemic situation, to below 110 g/L (6.8 mmol/L).
- 2.4.2.20.** The donor should have an estimated blood volume of > 4.5 L which must be calculated on the basis of sex, height and weight (see [Appendix 2a](#), Tables 1 and 2).
- 2.4.2.21.** The interval following a whole blood donation and the subsequent donation of a double unit of red cells should be at least 12 weeks. The interval following a double unit red cell apheresis and a subsequent whole blood donation or double unit red cell apheresis should be at least 24 weeks for female and 16 weeks for male donors.
- 2.4.2.22.** The maximum volume of red cells collected should not exceed 400 mL (without resuspension solution) per collection procedure.
- 2.4.2.23.** Total red cell volume collected per year should not exceed that acceptable for whole blood donors.

Additional recommendations for granulocytopheresis

Clinical efficacy, indications and dosage of granulocyte transfusion have not been established. In view of this, provision of informed consent prior to collection of granulocytes is particularly important. Effective granulocyte collection involves administration of medication (corticosteroids and/or granulocyte colony-stimulating factor) to increase circulating granulocyte levels and the use of sedimenting agents (hydroxyethyl starch; HES) during the procedure itself. Both of these have potentially severe side-effects, identified below, that need to be communicated to the donor.

HES acts as a volume expander. Donors who have received HES may experience headaches or peripheral oedema because of expanded circulatory volume. HES may accumulate, which can result in pruritus, and allergic reactions are possible.

Corticosteroids may cause, for example, hypertension, diabetes mellitus, cataracts, peptic ulcer and psychiatric problems.

Granulocyte colony-stimulating factor (G-CSF): the most common short-term complication following G-CSF administration in peripheral blood stem cell (PBSC) donors is bone pain; although, on very rare occasions, splenic rupture or lung injury may occur. Concerns have also been raised relating to the development of acute myeloid leukaemia (AML)/myelodysplasia (MDS) after G-CSF administration. To date, however, registry data from Europe and the USA have not identified any increased risk of AML/MDS in healthy individuals who donated PBSCs and received G-CSF as a pretreatment. The median follow-up of these studies is, however, less than 5 years. Therefore, if G-CSF is given to a donor, a protocol for long-term follow-up should be in place.

Additional recommendations for donors of red cells for anti-RhD immunisation

Specific protocols for donors of red cells for anti-RhD immunisation should be in place and should at least include the following:

- Additional testing for markers of infectious disease, such as anti-HTLV-1/2, anti-HBc and NAT tests for pro-viral HIV-DNA and HIV-RNA, antibodies against HCV-RNA, HBV-DNA, parvovirus B19 DNA or parvovirus B19 antibodies, HAV-RNA;
- Extensive red cell phenotyping should be performed at least twice, and may be supplemented by genotyping;
- The red cells for immunisation should be stored for at least 6 months. After 6 months, all the infectious markers stated above should have been found to be negative (or indicate absence of infection) on a new donor sample before release of the stored red cells for immunisation.

In order to manage the impact of changes in donor selection criteria and infectious marker testing that may occur over time, protocols should require:

- Maintenance of retention samples from each donation suitable for future testing;
- Requalification of past donations by assessing conformance with additional donor acceptance requirements, including, where appropriate, testing of the donor and/or the retention sample.

Exemption of past donations from current standards is not recommended and should only be considered in exceptional circumstances after careful consideration of the risks to the immunised donors and ultimate plasma product recipients.

2.4.3. **Designated donations**

Although blood donation is voluntary, non-remunerated and anonymous, in some special circumstances it may be necessary to make use of designated donations. This should happen only for clear medical indications. Designated donors should be screened and tested like volunteer allogeneic donors.

Designated donations are those intended for named patients based on medical indications. Circumstances where designated donations may be indicated include:

- Patients with rare blood types, where no compatible anonymous donations are available;
- Where donor-specific transfusions are indicated for immune modulation or immunotherapy; for instance, in the preparation procedure for kidney transplants or for lymphocyte transfusions aimed at a graft-versus-leukaemia effect;
- In certain cases of alloimmune neonatal thrombocytopenia; for instance, if HPA-typed platelets are not available and intravenous immunoglobulin therapy is not sufficient.

These donations may involve family members, in which case the responsible physician should weigh up the risks and benefits for the patient.

The practice of transfusing parental blood to infants is not without risk. Mothers may have antibodies to antigens that are present on the infant's red blood cells, platelets or white blood cells. Therefore, maternal plasma should not be transfused. Fathers should not serve as cell donors to neonates because maternal antibodies to antigens inherited from the father may have been transmitted through the placenta to the foetus. In addition, due to partial histocompatibility, transfusions of cells from parental or family donors carry an increased risk of transfusion-associated graft-versus-host disease (TA-GVHD), even in the immunocompetent recipient, and so such components should be irradiated. In the case of platelets, PIT for components may be used as an alternative to irradiation.

2.4.4. **Directed donations**

Directed donations are those intended for named patients, where the request for the donation has been made by patients, relatives or friends. The public often believes that directed donations are safer than anonymous, voluntary, non-remunerated donations. However,

this is not the case, even if directed donations are screened and tested in the same manner as voluntary non-remunerated donations.

Directed donations are not considered good practice and should be discouraged.

2.5. Post-donation information

2.5.1. Overview

Blood establishments often receive information from blood donors after donation that should have resulted in their deferral and may attempt to retrieve distributed blood components that did not meet all quality standards and regulations.

Post-donation information (PDI) is largely a reflection of the inherent limitations of the current donor screening process, which uses broad, precautionary questions to guard against theoretical or extremely remote risks. Consequently, PDI is an important measure of the accuracy of donor suitability assessment and compliance with good practice.

2.5.2. Donor instruction

STANDARD

- 2.5.2.1.** Donors should be instructed to inform the blood establishment about any relevant information that was not previously disclosed or if signs or symptoms occur after a donation. This scenario indicates that the donation may have been infectious or that any other information not disclosed during the health screening may render prior donations unsuitable for transfusion (*GPG 6.1.12*).

PDI includes information provided by the donor or other source and received by telephone or other means of communication following a donation. Blood establishments should evaluate PDI that is revealed by a third party without the donor's knowledge, weighing the reliability of the source of the information against the direct responses from the donor.

2.5.3. **Control procedures**

Systems should be in place to define the actions to be taken if a donor informs the blood establishment that he/she previously donated blood but should not have done so in the light of donor selection criteria.

Blood establishments should have control procedures that provide for the receipt and documentation of PDI reports that identify the source of the information (e.g. from a donor or qualified healthcare professional).

Blood establishments should have control procedures that provide for the prompt medical evaluation by a qualified physician, following established criteria, to ensure that potential risks are consistently assessed and investigated for all donations potentially affected.

Blood establishments should have control procedures that provide for appropriate consignee notification and determination of the disposition of all affected products (in-date and expired), including those intended for transfusion and those intended for further manufacturing use where the quality of the final manufactured product may be compromised.

Blood establishments should have control procedures that provide for assessment of the donor's suitability to serve as a donor in the future.

Previous donation	Whole blood or 1 unit of RBC apheresis or 1 unit RBC and plasmapheresis or 1 unit RBC and 1 unit plateletpheresis or 1 unit RBC and platelet and plasmapheresis or failed return of red cells during apheresis	Plasmapheresis	Plateletpheresis	Plateletpheresis combined with plasmapheresis	2 units of RBC apheresis	Granulocyta- pheresis
Whole blood	8 weeks	48 hours	48 hours	48 hours	24 weeks female, 16 weeks male	8 weeks
Plasmapheresis	4 weeks	2 weeks (IgG 6.0–8.0 g/L) 1 week (IgG > 8.0 g/L)	48 hours	2 weeks (IgG 6.0–8.0 g/L) 1 week (IgG > 8.0 g/L)	4 weeks	4 weeks
Plateletpheresis	4 weeks	48 hours	2 weeks	2 weeks	4 weeks	4 weeks

<div>Previous donation</div> <div>Current donation</div>	Whole blood <i>or 1 unit of RBC apheresis or 1 unit RBC and plasmapheresis</i> <i>or 1 unit RBC and 1 unit plateletpheresis</i> <i>or 1 unit RBC and platelet and plasmapheresis</i> <i>or failed return of red cells during apheresis</i>	Plasmapheresis	Plateletpheresis	Plateletpheresis combined with plasmapheresis	2 units of RBC apheresis	Granulocyta-pheresis
Plateletpheresis combined with plasmapheresis	4 weeks	2 weeks (IgG 6.0-8.0 g/L) 1 week (IgG >8.0 g/L)	2 weeks	2 weeks	4 weeks	4 weeks
1 unit of RBC apheresis or failed return of red cells during apheresis	8 weeks	48 hours	48 hours	48 hours	24 weeks female, 16 weeks male	8 weeks

Previous donation	Whole blood or 1 unit of RBC apheresis or 1 unit RBC and plasmapheresis or 1 unit RBC and 1 unit plateletpheresis or 1 unit RBC and platelet and plasmapheresis or failed return of red cells during apheresis	Plasmapheresis	Plateletpheresis	Plateletpheresis combined with plasmapheresis	2 units of RBC apheresis	Granulocytapheresis
1 unit RBC and 1 unit plateletpheresis or 1 unit RBC and platelet and plasmapheresis	8 weeks	48 hours	2 weeks	2 weeks	24 weeks female, 16 weeks male	8 weeks
1 unit RBC and plasmapheresis	8 weeks	1 week	48 hours	1 week	24 weeks female, 16 weeks male	8 weeks
2 units of RBC apheresis	12 weeks	48 hours	48 hours	48 hours	24 weeks female, 16 weeks male	12 weeks

<div>Previous donation</div> <div>Current donation</div>	Whole blood or 1 unit of RBC apheresis or 1 unit RBC and plasmapheresis or 1 unit RBC and 1 unit plateletpheresis or 1 unit RBC and platelet and plasmapheresis or failed return of red cells during apheresis	Plasmapheresis	Plateletpheresis	Plateletpheresis combined with plasmapheresis	2 units of RBC apheresis	Granulocyta-pheresis
Granulocyta-pheresis	4 weeks	48 hours	2 weeks	2 weeks	24 weeks female, 16 weeks male	8 weeks*

* The interval should be individually set by a physician, depending on the health status of the donor and the details of the previous leukapheresis (particularly the stimulation of the donor).