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Chapter 3: Care and selection of whole blood and components donors (including donors of pre-deposit autologous blood)

This change applies to the Guidelines for the Blood Transfusion Services in the United Kingdom 8th Edition.

The Department of Health and Social Care has asked the UK Blood Services to start collecting plasma for the manufacture of medicines. The Standing Advisory Committee on the Care and Selection of Donors have reviewed and rewritten Chapter 3 of the Guidelines for the Blood Transfusion Service in the United Kingdom (Red Book). The changes include specific guidance on the collection of Plasma by apheresis.

This new chapter will replace the current chapter on the JPAC website.

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Chapter 3: Care and selection of whole blood and component donors (including donors of pre-deposit autologous blood)

3.1: Introduction

All blood donors in the UK are voluntary non-remunerated donors. These guidelines relate to the collection of (a) whole blood and (b) components by automated apheresis. Their purpose is to:

- Ensure the safety of volunteer donors and the quality of collected components.
- Protect recipients of blood transfusions from adverse effects, such as transmission of infectious diseases or other medical conditions and unwanted effects caused by any medications taken by the donor.

They relate only to whole blood collection and the apheresis of healthy volunteer donors and not to the clinical use of cell separators for plasma exchange and other therapeutic procedures.
A medically qualified consultant must be ultimately responsible for the selection, health and welfare of the donors. He or she should ensure that all staff are appropriately trained and that clinical standards are maintained. Extreme care should be taken to ensure that undue pressure is not put on persons to donate.
The criteria for selecting blood donors are laid down in the current Joint UKBTS Professional Advisory Committee's (JPAC) Donor Selection Guidelines.[1] These apply to donors of (a) whole blood and of (b) components (cells and/or plasma) collected by apheresis. Other than in exceptional circumstances (to be decided by a designated clinical support officer), donors for apheresis procedures shall meet the usual criteria for ordinary whole blood donations. First-time donors may give components by apheresis. Donors who will be giving platelets should have given at least one sample for mandatory infection screening within the last 2 years and at least 8 weeks prior to their platelet donation. In addition, the following criteria should be observed for apheresis donors:

- The minimum pre-donation platelet count must be 150×10^9/L.
- The predicted post-procedure platelet count must not be less than 100×10^9/L.
- Deferral periods for platelet donors following ingestion of drugs affecting platelet function (e.g. aspirin or non-steroidal anti-inflammatory drugs) should be in accordance with the *JPAC Donor Selection Guidelines*.[1]

Guidelines for donors of pre-deposit autologous donations are outlined in section 3.16. The criteria for donors of tissues and stem cells are found in Chapters 20 and 22.

More detailed and frequently updated criteria are found in the JPAC *Donor Selection Guidelines*.[1] These form a constituent part of this chapter and must be consulted.

3.2: General principles

Only persons in good health shall be accepted as donors of blood or components for therapeutic use.

A prospective donor's medical history must be evaluated on the day of donation by a suitably qualified person who has been trained to use the JPAC *Donor Selection Guidelines*.[1]

If there is any doubt about the suitability of a prospective donor, a donation should not be taken and the details should be referred to the designated clinical support staff.

Each Blood Establishment responsible for the collection of blood should include a medical consultant who will take professional responsibility for the care and selection of donors. The immediate responsibility is that of the healthcare professional in attendance at the session. Patients referred for therapeutic venesection shall not be accepted at donation sessions (but see section 3.9.1 on donors with genetic haemochromatosis).

3.2.1: Donors with hazardous occupations or hobbies

Occupations where a delayed faint may present a hazard either to the donor or to others can be accepted only when the individual is going off duty. This would apply, for example, to train, HGV or bus drivers; heavy machine or crane operators; work involving climbing ladders or scaffolding; and miners working underground.

'Hazardous 'hobbies (e.g. gliding, powered flying, car or motor cycle racing, climbing, diving etc.) should not be undertaken on the day of donation.

3.3: Assessment of fitness to donate

The combination of assessing each donor clinically (at every attendance) and testing each donation for markers of infection is essential to maximise donor and recipient safety.

Each donor must undergo an assessment based on the JPAC *Donor Selection Guidelines*[1] to determine his/her eligibility to donate. This requires each donor to complete a questionnaire and answer a series of standard questions relating to their general health, lifestyle, travel history, past medical history and medication.

In addition, as a minimum requirement for all donors on entry to a component donation programme, their pulse and weight must be assessed and recorded.

If necessary, with the donor's consent, his/her general practitioner or other health care practitioner may be contacted for further information.

3.4: Informed consent

For consent to a procedure to be legally valid the donor must as a matter of good principle have been told the nature and purpose of the procedure as well as being warned of any substantial or unusual adverse event risk. Therefore, informed consent must be obtained by a trained person, fully conversant with the procedure. A consent form must be signed by each donor before donation.

Leaflets or equivalent material about donation appropriate to the procedure should be available at the session and should be studied by prospective donors to assist in the process of obtaining fully informed consent. In obtaining donor consent, the consenter must satisfy themselves that the donor has gone through the material provided and has understood the following information:

- The purpose of the donation and the use of the product (clinical, research or other).
- A description of the procedure and its likely duration.
- An explanation that a voluntary donor can withdraw consent at any stage of the procedure or of an apheresis programme.

- A description of the common risks and discomfort involved in the procedures. These include:
    - for all donors:
      - dizziness and fainting
      - haematoma formation
      - other venepuncture-related injuries, including nerve damage, arterial puncture and tendon injury
    - for donors of components by apheresis:
      - citrate toxicity
      - red cell loss if the procedure has to be aborted and it is considered unsafe to return the red cells
      - chilling on reinfusion.
      - rare complications, such as anaphylaxis, haemolysis and air embolism

It is the responsibility of session staff to ensure that donors clearly understand the nature of the donation process and the associated risks involved as explained in the available literature. The donors must also understand the health check and other medical information presented to them. Donors are asked about confidential and sensitive aspects of their medical history and lifestyle. It is therefore important that blood collection sessions have facilities that offer privacy for donor interviews and that donors are assured of the confidentiality of any information they provide. For the donor's consent to be valid the donor must have capacity to consent. Capacity is defined in the Mental Capacity Act 2005.[2]

The five principles of this act state that:

- The person must be assumed to have capacity unless you can establish that they have not.
- No-one should be treated as being unable to make a decision unless the Blood Service has made all practical steps to ensure that they are able to make that decision without success.
- The person may not be deemed unable to make a decision just because they appear to make an unwise decision.
- Any act done or decision made under the Act on behalf of a person who lacks capacity must be done in the best interests of that person.
- One must always consider whether you can do the same thing in a way that is less likely to infringe that person's rights and freedom of action.

We must therefore presume that every donor that we deal with has capacity to make decisions. To have capacity the person must, with the appropriate help and support, be able to understand, retain, use and/or weigh up the information they are given to make the decision or to communicate their wishes. Just because a person is of a certain age, or has a disability, communication difficulty or medical condition we cannot assume that they lack capacity. Thus staff who consent donors must understand and apply these principles. All donors, be they 17 or 70, should have capacity when they sign their consent and it is the duty of the attending carers and healthcare professionals at the session to ensure that they do have that. Since the Family and Law Reform Act 1969 children have capacity to give consent in medical matters from the age of 16. (Applies to England and Wales. Equivalent legislation applies in Scotland and Northern Ireland.) Third-party interpreters should not be used except as laid down in the current JPAC *Donor Selection Guidelines*[1] as there is no guarantee of understanding or the accuracy of information provided to or given by the interpreter, particularly if they are a friend, family member or are otherwise known to the donor. Blood Service staff gain sensitive medical and personally identifiable information about donors. They must not disclose information to a third party about a donor without the donor's consent. This includes members of their family and includes the fact that they have attended for donation. All services should have a procedure in place for management of third party information relating to a donor and their eligibility to donate. All members of staff should be clear that they must protect a donor's personal information.

Potential donors who are unable to read the literature should be informed of its contents by a suitably trained member of staff.

3.5: Donor age

Donors shall be between the ages of 17 and 65 years; i.e. from their 17th to 66th birthday inclusive.
Regular and returning donors (as defined in the JPAC *Donor Selection Guidelines*[1]) may be allowed to donate beyond their 66th birthday with permission of a physician in the Blood Establishment, given annually.
It is normal practice to set an upper age limit of 60 years (up to 61st birthday inclusive) for first-time donors. However, older donors may be accepted at the discretion of the physician in the Blood Establishment.

3.6: Frequency of donation

3.6.1: Whole blood

An interval of 16 weeks between donations of whole blood is reasonable. The minimum interval is 12 weeks. Normally, no more than three donations should be collected from a female donor and four from a male donor during any 12-month period.

3.6.2: Plasmapheresis and plateletpheresis

A donor should not undergo a total of more than 26 plasma- and/or plateletpheresis procedures per 12-month period. There should normally be a minimum of 2 weeks between plasma- and/or plateletpheresis procedures.
After a whole blood donation, or the loss of an equivalent number of red cells during an apheresis procedure, a donor should not normally donate plasma or platelets for a period of 4 weeks. Further information is given in the 'Frequency of Donation' entry in the JPAC Donor Selection Guidelines.

3.6.3: Double red cell donations

The interdonation interval for donation of double red cells by apheresis should not be less than 26 weeks (6 months) in the absence of iron supplementation. A shorter interval may be acceptable only if confirmation of iron-replete body stores can be accurately demonstrated and monitored.

3.7: Volume of donation

3.7.1: Whole blood

A donation of 450 mL±10% is required to ensure the final red cell component meets specification. No more than 15% of the donor's estimated blood volume (EBV) should be taken during any one donation. In general 470–475 mL of blood, excluding samples, is collected into the main pack.

3.7.2: Component donation

The final volume of collected components should not exceed 880ml (including anticoagulant).

The Extra-Corporeal Volume (ECV) should not exceed 16% of the donors EBV at any point in the procedure. Estimation of the ECV excludes the volume of anticoagulant in the collected component(s). See JPAC Donor Selection Guidelines Appendix 3[1]

Attention must be paid during apheresis to the ECV in order to avoid rendering the donor significantly hypovolaemic. Consideration must be given to the following factors:

- donor weight and estimated blood volume
- type of apheresis procedure: intermittent flow or continuous flow
- donor's haematocrit: this influences volume of plasma collected during any one cycle of an intermittent flow procedure.

In practice, modern component collection systems automate most of the calculations required to ensure donor safety during an apheresis procedure. All procedures should be carried out in line with the operating instructions for the collection system in use.

To avoid citrate toxicity, the reinfusion rate of citrated blood or plasma should not exceed 0.015 mmol citrate/kg/min for intermittent flow cell separator machines (or 0.010 mmol citrate/kg/min for continuous flow cell separator machines). The anticoagulant ratio during collection influences the final volume of anticoagulant in collected plasma. This may be relevant to the intended use of the collected components.

The collection system used must be capable of adjustment to suit each individual donor's safety tolerance limits.

3.8: Medical history of donors

3.8.1: General considerations

All donors should clearly understand any information and questionnaire presented to them and must sign an appropriate document which also attests to their consent for the blood to be taken, tested and used for the benefit of patients. Any condition declared shall be discussed with the clinician in attendance at the blood collection session unless clear, unequivocal instructions regarding the responses are available to the member of staff conducting the questioning.

For details of information to be supplied to and obtained from donors see Chapter 5.

Donors whose serum or plasma or cells are to be used for laboratory, as opposed to therapeutic, purposes shall be submitted to the same routine as other donors, but some decisions regarding their suitability to donate may be different (e.g. treatment with certain medications, or on the basis of their medical history). When this is the case, secure mechanisms must be in place to ensure that the donation cannot be released for clinical purposes.

Individuals currently undergoing medical investigations or who have been referred for a specialist opinion or are on a hospital waiting list should normally be deferred. If, however, the condition or potential condition concerned would not of itself be a contraindication to donation they may be able to donate.

Donors taking part in clinical trials cannot be accepted until their involvement in the trial has finished, or the designated clinical support officer has examined the trial protocol and agreed that donors participating in that trial can be accepted. A 'clinical trial 'normally implies that the donor is participating in an intervention programme – usually taking a drug or a potential drug which may be either active or a placebo. Participating in questionnaires does not constitute a clinical trial.

All donors should be made aware that recipients are at risk from transfusion, and shall be asked to report any illness that develops within 14 days of donation.

Information about either the donor or the donation which becomes available after the blood or any derivative has been issued or transfused, and which is, or may be, relevant to the safety of that blood for transfusion, should be reported to the appropriate individual, e.g. the consultant in charge of the hospital blood transfusion laboratory. Donor confidentiality must be respected.

The member of staff carrying out the donor assessment must confirm they have done so by signing the donation record. Any reason for deferral, whether temporary or permanent, must be explained to the donor and recorded.

3.9: Genetically determined conditions

An increasing number of genetically determined conditions that potentially affect donor health are being identified, and some donors have had specific tests which confirm that they possess variant genes. These include not only the haemoglobinopathies and thalassaemias, but also more recently discovered conditions such as the thrombophilias (e.g. factor V Leiden). Mere possession of such genetic variants does not exclude donation if the donor is otherwise healthy and fulfils all other selection criteria.

3.9.1: Genetic haemochromatosis

This is a special case. Blood from individuals with genetic haemochromatosis (GH) who have no symptoms arising from their GH is intrinsically safe for transfusion. However, before patients with GH who require

continued venesection for the maintenance of their health are accepted as blood donors, the consultant with responsibility for donors must ensure that the following criteria are met:

- The selection criteria/methods for all donors with GH preserve the principles of altruism.
- Blood donated for therapeutic use by any donor known to have GH meets all other criteria (except donation frequency) in the JPAC *Donor Selection Guidelines*.[1] If it is clinically necessary for individuals to donate more frequently than the minimum donation interval, specific permission must be obtained from the designated clinical support officer.
- The donor is under the continuing care of a physician who is able to offer alternative venesection facilities whenever, for any reason, the donor does not meet all other criteria in the JPAC *Donor Selection Guidelines*.[1]

3.10: Donors on treatment with medications (drugs)

Donor deferral for most drugs is based on the underlying illness suffered by the donor (e.g. cardiovascular disease, diabetes, anaemia and malignancies) rather than on the properties of the drug itself. Since, in general, traces of drugs in blood and blood components are believed to be harmless to patients, many people taking medications – even when prescribed – are acceptable as blood donors as long as the reason for which the medication is taken is acceptable.

A pragmatic view should be taken of treatment of infections with antimicrobials. Provided that the donor is in good health, deferral is limited to 2 weeks from full recovery and 1 week after cessation of antimicrobial therapy, whichever is the longer. This is based on what may be regarded as a reasonable recovery period for the infection and is not related to the antimicrobial therapy itself.

Donors taking drugs which are proven or potential teratogens (e.g. vitamin A derivatives) or who are taking drugs that accumulate in tissues over long periods, should not be accepted for blood donation. Some such drugs may be taken to prevent diseases to which the donor – though currently healthy – is prone. A decision to accept should be taken after considering the pharmacodynamics of the specific drug, and its mode of action. The period of deferral after finishing a course of treatment is set out in the JPAC *Donor Selection Guidelines*.[1]

The current JPAC *Donor Selection Guidelines*[1] must be referred to for all donors who have had immunisations recently.

Sporadic self-medication with some drugs (e.g. vitamins, aspirin, sleeping tablets) need not prevent a donation being accepted, as long as the donor is in good health.

If the donor has taken drugs affecting platelet function (e.g. aspirin) within the last 2 days (depending on the drug) the donation shall not be used for preparing platelets. A list of such drugs is in the JPAC *Donor Selection Guidelines*.[1] Other drugs or tablets may be acceptable. However, the taking of some drugs may indicate a disease that would automatically make a donor ineligible.

3.11: Transfusion-transmissible infectious diseases

Every effort is made to prevent transmission of disease by careful and appropriate selection of donors. This includes ensuring that the donor is provided with clear, understandable and up-to-date information and also ensuring that the donor has understood this information (see Chapter 5).

Donors must be assessed for their exposure to any risk of acquiring a transfusion-transmissible infection. The latest JPAC *Donor Selection Guidelines*[1] should be consulted for any donor with a relevant exposure history.

3.12: Travel history

Increased and rapid travel of the population may lead to asymptomatic people donating infectious blood. A clear and detailed travel history must be obtained from all donors to minimise the risk of transmission of malaria, *Trypanosoma cruzi* and emerging diseases such as West Nile Virus, Dengue Virus, Zika Virus and Chikungunya virus.

The latest JPAC *Donor Selection Guidelines*[1] should be consulted for any donor with a relevant travel history.

Horizon scanning is performed by UK Blood Services to identify new and emerging pathogens which may threaten the safety of donated products.[4]

3.13: Prion-associated diseases including sporadic Creutzfeldt-Jakob Disease (CJD) and variant CJD (vCJD)

Individuals who are identified as having an increased risk of developing a prion-associated disease must be permanently excluded from donation. This includes:

- individuals who have received human pituitary-derived hormones
- patients who have received grafts of human dura mater or cornea, sclera or other ocular tissue
- persons identified as being members of a family at risk of inherited prion diseases
- persons who are known to have received an allogeneic tissue or blood transfusion since 1980 (for these purposes, a transfusion is defined as any product containing red cells, platelets, granulocytes, fresh frozen plasma, cryoprecipitate-depleted plasma, buffy coat preparations and intravenous or subcutaneous human normal immunoglobulin and includes mothers whose babies have required intrauterine transfusion)
- persons who have been told that they have been put at increased risk from surgery, transfusion or transplant of tissues or organs
- persons who have been told that they may be at increased risk because a recipient of their blood or tissues has developed a prion-related disorder

The current edition of the JPAC *Donor Selection Guidelines*[1] provides detailed advice and should be consulted.

3.14: Physical examination of donors

3.14.1: General considerations

A detailed medical assessment procedure must be conducted on all donors, as referred to above, i.e. based on the JPAC *Donor Selection Guidelines*.[1] Particular attention is required for the assessment of first-time or 'returning 'donors. Returning donors are defined as those who – although formerly registered as a blood donor with one of the four national Blood Transfusion Services – have not been assessed for donation for 2 years or more.

Assessment of blood pressure is not recommended because the circumstances at blood collection sessions are not conducive to obtaining meaningful measurements. Routine measurement of blood pressure could also give the impression that Blood Establishments offer a general health screening service which might be construed as an inducement to donate.

Inspection of the donor: The donor should be in good health. Note should be taken of poor physique, debilitation, under-nutrition, plethora, jaundice, cyanosis, dyspnoea, intoxication and mental instability. When in doubt the donor should be deferred until further advice has been obtained from a designated clinical support officer.

3.14.2: Weight

There is a minimum legal donor weight of 50kg at which a donation can be accepted.
In young women there is a significant risk of fainting if their donation exceeds 15% of their estimated blood volume (EBV). See Appendix 1 in the JPAC Donor Selection Guidelines Appendix 1[1]

For the collection of double units of red cells by apheresis, special considerations apply. Male and female donors must be greater than 70 kg in weight

3.15: Blood tests

3.15.1: Estimation of the concentration of haemoglobin in donor blood

The haemoglobin (Hb) concentration should be determined each time a potential donor presents.

For each component type, the acceptable lower limits for venous blood are listed below.

- Whole blood and component donation (except plasma only): 125 g/L for female donors and 135 g/L for male donors
- Plasma only donation (by apheresis): 120 g/L for female donors and 130 g/L for male donors
- Double red cell donation (by apheresis): 140 g/L for all donors

Several methods of screening donors for their blood Hb concentration are available (or in development). These include:

- gravimetric method using solutions of copper sulphate on blood samples obtained by fingerprick
- spectrophotometric devices using capillary or venous samples
- non-invasive technology
- full blood count using venous or capillary samples.

The final method chosen must be validated, and validation should include comparison to a full blood count measured on a venous sample.

A donor who fails their initial Hb screening test can be offered a further test for accurate determination of their Hb concentration. If the Hb concentration so determined is at or exceeds those quoted above the donor may be invited to give a full donation.

Donors whose Hb concentration is below the minimum values should not be bled. The reason for deferral should be explained and the donors advised to see their own general practitioner if this is considered to be appropriate as defined by Blood Service procedures.

If a quantitative method of Hb determination is employed, before or after the donation, individuals found to have a concentration of Hb above the normal upper limit as indicated in the JPAC *Donor Selection Guidelines*[1] should be referred for further investigations.

3.15. 2: Additional tests for component donors

All component donors must have a full blood count performed at the first donation and this must be repeated at least annually.

The platelet count should be performed at each visit for plateletpheresis donors.

Total serum protein must be measured at the first donation for all component donors who give plasma. As a minimum, total serum protein should be repeated with every eighth plasma donation thereafter. For donors who give less than eight plasma donations per year, testing must be repeated at least once every 12 months. Total serum protein must not be less than 60 g/L.

A system must be in operation for regular review of these results, together with a documented protocol for the management of donors with any abnormal findings.

All Blood Services should perform a risk assessment to evaluate the relative risks and benefits of implementation of leucocyte antibody screening of platelet donors. If leucocyte antibody screening is implemented, platelet donors with a subsequent history of pregnancy (regardless of the outcome) should be re-tested (see section 16.8.8).

3.16: Donors of pre-deposit autologous donations

Autologous pre-deposit donations must be collected according to the same requirements as allogeneic donations but the deferral criteria vary. These donations must be clearly identified as such and kept separate from allogeneic donations.

3.16.1: Deferral criteria

The deferral criteria for donors of autologous pre-deposit donations in the UK, originally agreed by the British Committee for Standards in Haematology Blood Transfusion Task Force, were updated in 2007.[5] The two main deferral criteria are serious cardiac disease (where the clinical setting of the blood collection must be taken into account) and active bacterial infection.

3.17: References

1. Joint UKBTS Professional Advisory Committee's (JPAC) *Donor Selection Guidelines*. Available at www.transfusionguidelines.org
2. The Mental Capacity Act 2005. Available at www.legislation.gov.uk. (Applies to England and Wales. Equivalent legislation applies in Scotland and Northern Ireland).
3. Nadler SB, Hidalgo JU, Block T (1962). Prediction of blood volume in normal human adults. Surgery, 51, 224–232.
4. JPAC Position Statement *Arrangements in place for monitoring threats to the UK blood supply from new/emerging infectious agents*. Available at www.transfusionguidelines.org
5. British Committee for Standards in Haematology Blood Transfusion Task Force (2007). Guidelines for policies on alternatives to allogeneic blood transfusion. 1. Predeposit autologous blood donation and transfusion. Transfusion Medicine, 17, 354–365.