Guidelines for the Blood Transfusion Services

Chapter 5: Collection of a blood or component donation

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Collection of a blood or component donation

This chapter describes the steps involved in the collection of a blood or component donation from the information to be provided to a donor to the follow up of the donor post donation.

Sections 5.1 and 5.2 are closely based on the Blood Safety and Quality Regulations 2005.[1]

5.1: Information to be provided to prospective donors of blood or blood components

The following information must be provided to all donors:

- Accurate educational materials, which are written in terms which can be understood by members of the general public, about the essential nature of blood, the blood donation procedure, blood components and the important benefits to patients.
- For both allogeneic and autologous donations, the reasons for requiring a medical history, the testing of donations and the significance of informed consent.
- For allogeneic donations, the criteria for self-deferral, temporary and permanent deferral, and the reasons why individuals are not to donate blood or blood components if there could be a substantive risk for them or the recipient.
- For autologous donations, the possibility of deferral and the reasons why the donation procedure would not take place in the presence of a health risk to the individual whether as donor or recipient of the autologous blood or blood components.
- Information on the protection of personal data, including confirmation that there will be no disclosure of the identity of the donor, of information concerning the donor's health and of the results of the tests performed, other than in accordance with the requirements of these regulations.
- The reasons why individuals are not to make donations which may be detrimental to their health.
- Specific information on the nature of the procedures involved either in the allogeneic or autologous donation process and their respective associated risks. For autologous donations, the possibility that the autologous blood and blood components may not suffice for the intended transfusion requirements.

- Information on the option for donors to change their mind about donating prior to proceeding further, or the possibility of withdrawing or self-deferring at any time during or after the donation process, without any undue embarrassment or discomfort.

- 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.

- 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.
- Information explaining why unused autologous blood and blood components will be discarded and not transfused to other patients.

- 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.

- Information on the opportunity for donors to ask questions at any time.

- If the donated blood is to be used for purposes other than clinical transfusion or uses specified in the general consent materials, specific information must be provided.

5.2: Information to be obtained from donors by Blood Establishments at every donation

5.2.1: Donor identification

Donors must positively identify themselves by volunteering their name, date of birth and permanent address. The identity of the donor must be recorded and linked to the donation record.

5.2.2: Health and medical history of the donor

The donor's health and medical history, obtained by a questionnaire and a confidential personal interview must be assessed by a suitably trained person. This will include relevant factors that may assist in identifying and screening out persons whose donation could present a health risk to others, such as the possibility of transmitting diseases, or health risks to themselves. Donors must be selected in accordance with the current JPAC *Donor Selection Guidelines*[2] which form a constituent part of Chapter 3.

5.2.3: Signature of the donor

The donor must sign the donor questionnaire. This must then be countersigned by the qualified health professional responsible for obtaining the health history confirming that the donor has:

- read and understood the educational materials provided

- had an opportunity to ask questions

- been provided with satisfactory responses to any questions asked

- given informed consent to proceed with the donation process (see Chapter 3)
- been informed, in the case of autologous donations, that the donated blood and blood components may not be sufficient for the intended transfusion requirements
- acknowledged that all the information provided by the donor is true to the best of their knowledge.

Where a suitable electronic system has been implemented, signatures from the donor and the qualified health professional can be accepted electronically. Any such system must meet quality and regulatory compliance standards, including verification of the identity of the individual signing the document.

5.3: Haemoglobin screening

A validated haemoglobin screen should be applied to all donors prior to donation. The objective is to ensure that prior to each donation the donor has a minimum acceptable haemoglobin concentration (see section 3.15).

5.4: Preparation of the venepuncture site

Blood must be drawn from a suitable vein in the antecubital fossa in an area that is free of skin lesions. The veins can be made more prominent by using appropriate means of venous occlusion.

Although it is not possible to guarantee sterility of the skin surface for venepuncture, a strict standardised and validated procedure for the preparation of the venepuncture site should be in operation (see section 9.5).

The antiseptic solution used must be allowed to dry completely after application to the donor’s skin. Thereafter, the prepared area must not be touched with fingers before the needle is inserted.

5.5: Preparation of the blood pack

5.5.1: Whole blood pack

The blood collection set must be in date and inspected for any defects. These are sometimes obscured by the label attached to the container, so careful inspection is required.

Moisture on the surface of a plastic pack after unpacking should arouse suspicion of a leak and if one or more packs in any packet is found to be abnormally damp, none of the packs in that container can be used. The solution in the set should be checked for clarity and must be clear before accepting the packs for use.

The blood pack is positioned below the level of the donor’s arm and the blood collection tube must be clamped off.

The method used for monitoring the volume of blood removed shall be checked to be in working order and the pack placed in the correct position for the method to be effective.

5.5.2: Apheresis sets

The complete apheresis set and individual packaging must be thoroughly inspected for faults prior to use and during the setting up procedure. The set must be in date and a search must be made for set faults such as kinks, occlusions, points of weakness or leaks that may only become detectable during the setting up and priming procedure before the donor is attached to the set.

If an occlusive kink that cannot be remedied or a leak becomes apparent during a procedure then that procedure must be abandoned and any blood constituents remaining in the disposables must not be returned to the donor.

Any faults detected before or during a procedure must be recorded in accordance with local quality systems. Any defects must be reported (see section 5.11).

If there is any doubt about the integrity of any set, it must not be used but should be retained for inspection and returned to the manufacturer if deemed necessary.

5.5.3: Labels

Labelling: Whole blood and apheresis packs and donor sample tubes must be labelled in accordance with local standard operating procedures (SOPs).

All donors' records and labels should be checked for printing errors. Duplicate number sets must not be used. Both these and missing numbers must be reported via a designated senior following documented local procedures.

5.6: Performance of the venepuncture

Venepuncture should only be undertaken by authorised and trained personnel.

Items used for venepuncture must be sterile, single-use and disposable. If the dry outer wrapping of sterile packs becomes wet the contents must not be used. Prior to use, session staff must ensure that the materials used for venepuncture are sterile, in date and suitable for the procedure to be undertaken. The sterile donor needle should not be uncovered and its tamper-proof cover should be checked for integrity immediately prior to the venepuncture.

As soon as the venepuncture has been performed, the clamp on the bleed line must be released.

It is important that a clean, skilful venepuncture is carried out to ensure the collection of a full, clot-free unit of blood suitable for the preparation of labile blood components.

The tubing attached to the needle should be taped to hold the needle in place during the donation.

5.6.1: Sample collection

At the start of the donation an aliquot of blood should be diverted into a pouch. It is recommended that this pouch has a means of access opposite the entry line which allows blood to be sampled for testing without compromising the environmental integrity of the blood in the main pack. Care should be taken that the volume of blood taken for samples does not lead to the total donated volume exceeding donation limits. For apheresis donors who give frequently, the total sample volume per year should also be considered.

5.7: Whole blood donation

If necessary, the donor should be asked to open and close his/her hand slowly every 10–12 seconds to encourage a free flow of blood.

The donor must never be left unattended during or immediately after donation and should be kept under observation throughout the phlebotomy.

5.7.1: Blood anticoagulation

The blood and anticoagulant should be mixed gently and periodically (at least every 60 seconds) during collection. Mixing should be achieved by manual inversion of the blood pack, or automatically by placing the blood pack on a mechanical agitator or by using a rocking device.

5.7.2: Blood flow

Blood flow should be constantly observed to ensure that the flow is uninterrupted.

The period of donation should not exceed 15 minutes.

5.7.3: Blood volume monitoring

The volume of blood withdrawn must be controlled to protect the donor from excessive loss of blood and to maintain the correct proportion of anticoagulant to blood.

The most efficient way of measuring the blood volume in plastic bags is by weight. The mean weight of 1 mL of blood is 1.06 g, and therefore, for example, a unit containing 470 mL of blood should weigh 470 × 1.06 g plus the weight of the pack(s) and the anticoagulant.

If it is not possible to adjust the weighing device in use for the tare weight of the container and anticoagulant solution it is advisable to record the minimum and maximum weight for the brand of pack in use as products from different manufacturers may vary considerably.

Several kinds of weighing equipment are available and such devices should be used according to the manufacturer’s instructions for weighing blood into its plastic pack and periodically calibrated by appropriate techniques.

5.7.4: Completion of the donation

If used, the pressure cuff must be deflated and the needle then removed from the arm. Immediate pressure must then be applied to the venepuncture site through a suitable clean dressing.

Local procedures must give clear instructions on sealing the pack and removal of the needle for all pack types used. The needle must be discarded into a special container designed to minimise risk to personnel.

The pack must be inverted gently several times to ensure the contents are thoroughly mixed.

The arm and general well-being of the donor should be checked before the donor leaves the session venue.

5.8: Component donation by apheresis

Guidance for collection procedures is identical to that for normal whole blood donations except for the points listed below.

Performance of the venepuncture: Once the venepuncture is performed subsequent procedures such as releasing clamps on the bleed line should follow the protocol for the particular type of apheresis procedure being undertaken.

Anticoagulation: This occurs automatically in apheresis, but instructions are needed to ensure apheresis machine operators monitor the flow of anticoagulant.

Consideration should be given to withdrawing donors who repeatedly show signs and/or symptoms of citrate toxicity from the apheresis panel. Prophylactic oral supplementation with calcium should be discouraged.

Blood flow and monitoring: Blood flow occurs automatically in apheresis, unless a satisfactory flow rate cannot be maintained.

Instructions are needed for the apheresis operator in the event of a low-flow or no-flow situation. Particular care is needed when monitoring the return flow rate since most apheresis procedures operate with a pumped red cell return such that haematomas can rapidly form unless appropriate action is taken to prevent this from occurring.

Sample collection: In apheresis sampling should take place at the beginning of a component donation.

Completion of the donation and quality control samples: Local procedures must give clear instruction on removal of the apheresis harness, sealing the component bag(s) and the removal of the needle for all harness types in use. All used disposable equipment must be discarded in such a way as to prevent any risk to personnel, according to Health and Safety regulations.

Final donation inspection: The collected apheresis components must be inspected routinely for the presence of haemolysis, unwanted red cell contamination, other abnormal appearance or evidence of clotting. Such changes may require a review of the apheresis procedure and/or equipment. Any suspected apheresis component abnormality must be recorded, and the donation must be identified and reported in accordance with local quality systems.

5.9: Information to be provided to the donor post-donation

The donor must be provided with information on care of the venepuncture site and requested to report any illness occurring within 14 days of donation. They will already have been made aware of the importance of informing the Blood Establishment of any event that may render their donation unsuitable for clinical transfusion.

5.10: Adverse reactions in donors

The care of all donors at blood collection venues should incorporate research-based therapeutic interventions to reduce the risk of adverse events of donation.

All adverse reactions in donors should be documented and reported according to standard protocols. It is recommended that as a minimum data are collected and reviewed on all donor adverse events of donation using the International Haemovigilance Network (IHN) definitions ofcomplications related to blood donation.[3] The blood services in the UK have also agreed definitions for Serious Adverse Events of Donation (SAEDs, see Appendix I). This will allow comparison over time and between services of event rates, and monitoring of the effectiveness of any interventions to reduce event rates. SAEDs should be investigated with root cause analysis or similar tools to ensure that proper preventative and corrective actions are implemented.

Serious adverse reactions occurring in donors during or post-donation must be reported to the Competent Authority according to the Blood Establishment protocol.

5.11: Adverse events

All adverse events must be documented and reported according to standard protocols.

All bag/harness defects (e.g. pinhole leaks) must be recorded and all defects should be reported to the Quality Assurance Manager. If the defect appears to be batch-related, all packs and blood collected in them must be set aside for further investigation.

Any safety-related defects in equipment, including single-use items, must be reported and escalated as per local procedures, in accordance with the requirements of the Competent Authority, currently the Medicines and Healthcare products Regulatory Agency (MHRA).

Serious adverse events must be reported to the Competent Authority according to the Blood Establishment protocol.

5.12: Donor compensation

The Blood Transfusion Services should have established procedures to ensure that any claim by a donor for compensation for any injury or loss allegedly attributable to having donated blood or components will be dealt with in a timely manner and within a legal framework.

5.13: References

1. Statutory Instrument 2005 No. 50. The Blood Safety and Quality Regulations 2005. Available at www.legislation.gov.uk
2. Joint UKBTS Professional Advisory Committee's (JPAC) Whole Blood and Component Donor Selection Guidelines. Available at www.transfusionguidelines.org
3. Working Group on Donor Vigilance of the International Society of Blood Transfusion Working Party on Haemovigilance (2014). Standards for the Surveillance of Complications Related to Blood Donation.

Appendix I

Serious Adverse Events of Donation – UK Blood Services Definitions

SAED categories	
01	Death within seven days of donation
02	Hospital admission within 24 hours of donation
03	Injury resulting in a fracture within 24 hours of donation (including fractured teeth)
04	Road traffic collision within 24 hours of donations
05a	Problems relating to needle insertion persisting for more than one year (this mainly includes suspected or confirmed nerve and tendon injuries)
05b	Problems relating to needle insertion requiring hospitalisation/intervention (this mainly includes vascular complications)
06	Acute coronary syndrome diagnosed within 24 hours of donation
07	Anaphylaxis (component donation)
08	Haemolysis (component donation)
09	Air embolism (component donation)
10	Other event related to donation resulting in: • Hospital admission, • Intervention, or • Disability or incapacity lasting more than one year and not included above