Guidelines for the Blood Transfusion Services

Chapter 5: Collection of a blood or component donation

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Chapter 5:

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: Donor Adverse Events

5.10.1: Definitions

Term		Definition
DAE	Donor Adverse Event	An event where harm occurs to a donor as a result of the blood donation process.
SDC	Serious Donor Complication	A DAE which is graded at Grade 3 or above using the Severity Grading Tool
SAED	Serious Adverse Event of Donation	A DAE which meets the previous severity criteria agreed by the UK Blood Services

A donor adverse event (DAE) which is graded as either a serious donor complication (SDC) or a serious adverse event of donation (SAED) meets the Medicines and Healthcare products Regulatory Agency (MHRA) definition of a Serious Adverse Reaction: *"An unintended response in a donor or in patient associated with the collection or transfusion of blood or blood components that is fatal, life-threatening, disabling, incapacitating, or which results in, or prolongs, hospitalisation or morbidity."*

5.10.2: DAE classification, investigation, and reporting

DAEs are classified according to the categories included in the Standard for Surveillance of Complications Related to Blood Donation (2014)[3]. In 2023/24, the UK Blood Services agreed to implement the validated donor severity grading criteria developed by the AABB Donor Haemovigilance Working Group and endorsed by ISBT, IHN and EBA[4,5]. This records the severity of donor adverse events by Grades 1-5, with 1 through 5 being roughly associated with mild, moderate, severe, life-threatening and death. Further details of DAE classification, grading and assignment of imputability scores are given below (see sections 5.10.3 – 5.10.5).

Management of all SDCs or SAEDs should include appropriate incident investigation to ensure that proper preventative and corrective actions are implemented. This supports optimal learning from reported incidents.

The Blood Safety and Quality Regulations (BSQR) mandate that blood establishments report serious adverse events or reactions, including those which occur in donors. Each Blood Service is therefore required to submit an annual report to the MHRA covering any DAE which are classified as SDCs. During the transition period for introduction of the Severity Grading Tool, Services may alternatively choose to report using the previous SAED categories (see 5.10.6).

Blood Services must also ensure that:

- All DAEs are documented and reported according to standard procedures.
- For DAEs which are Grade 3-5 (or identified as SAEDs), written procedures are in place documenting expected donor follow up.
- Processes are in place for investigation of appropriate DAE. This should include those of Grade 3-5 or SAEDs. Any investigation should apply human factors and systems thinking principles. Lessons learnt should be shared widely.

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

Blood Services are encouraged to collect all DAE data in a format which will allow analysis of DAE trends over time both within and between services (benchmarking). This will also enable monitoring of the effectiveness of any interventions to reduce event rates.

A summary of the serious donor adverse events reported in the 4 UK Blood Services is included in the donor haemovigilance chapter in each Annual SHOT Report – these can be accessed here: www.shotuk.org/shot-reports.

5.10.3: Classification of Donor Adverse Events

(based on Standard for Surveillance of Complications Related to Blood Donation[3])

Code	Description
A	**Complications mainly arising from local symptoms**
A.1	Complications mainly characterised by the occurrence of blood outside the vessels • Haematoma (bruise) • Arterial puncture • Delayed bleeding (rebleeding)
A.2	Complications mainly characterised by pain • Nerve injury/irritation • Other painful arm
A.3	Localised infection/inflammation
A.4	Other major blood vessel injury • Deep vein thrombosis • Arteriovenous fistula • Compartment syndrome • Brachial artery pseudoaneurysm
B	**Complications mainly with generalised symptoms: vasovagal reactions**
	• Without loss of consciousness • With loss of consciousness Recording of the additional subcategories below is recommended. • With or without injury • Occurring at the donation site or after the donor has left the donation site
C	**Complications related to apheresis**
	• Citrate reaction • Haemolysis • Air embolism • *Infiltration (only relevant for procedures using volume replacement)*
D	**Allergic reactions**
	• Allergy • Generalised allergic reaction / anaphylaxis

E	**Other serious complications related to blood donation**
	Major cardiovascular event such as acute cardiac symptoms, myocardial infarction, cardiac arrest, transient ischaemic attack, cerebrovascular accident, death
F	**Other complications**
	Systemic reactions or complications which do not fit into any of the categories listed above

5.10.4: Donor Adverse Event Severity Grading

(based on Severity Grading Tool for Blood Donor Adverse Events[5])

Severity Grade	Criteria
Grade 1	Did not require intervention from an external Health Care Practitioner (HCP) ***AND*** Duration <=2 weeks ***AND*** No limitation on Activities of Daily Living (ADL) ***AND*** Resolved with no or minimal intervention
Grade 2	Required intervention from an external HCP, no hospitalisation ***OR*** Duration >2 weeks and <=6 months ***OR*** Limitations on ADL <=2 weeks
Grade 3	Not life-threatening ***AND any of the following*** Hospitalisation ***OR*** Duration >6 months ***OR*** Limitations on ADL >2 weeks ***OR*** Require surgery ***OR*** Other serious complications (Category E)
Grade 4	Immediate medical intervention required to prevent death
Grade 5	Death

When assessing DAEs, assign the highest applicable severity grade. The Severity Grading Tool should be referenced for guidance on specific DAE categories.

5.10.5: Donor Adverse Event Imputability Scoring

Imputability in the context of blood donation means the likelihood that a DAE can be attributed to the donation. Imputability is scored according to the criteria below based on the SHOT Definitions (2023)[6].

Score	Imputability	Definition
N/A	Not Assessable	When there is insufficient data for imputability assessment.
0a	Excluded	When there is conclusive evidence beyond reasonable doubt for attributing the adverse reaction to causes other than the blood or blood components or where the evidence is clearly in favour of alternative causes.
0b	Unlikely	
1	Possible	When the evidence is indeterminate for attributing the adverse reaction either to the blood or

		blood component or where there may be alternative causes.
2	Likely / Probable	When the evidence is clearly in favour of attributing the adverse reactions to the blood or blood component.
3	Certain	When there is conclusive evidence beyond reasonable doubt attributing the adverse reactions to the blood or blood component.

5.10.6: Serious Adverse Events of Donation

Prior to implementation of the Severity Grading Tool, DAE were classified as Serious Adverse Events of Donation (SAEDs) if they fell into one of the categories listed in the table below. Mapping of SAED categories to the new classification and grading system is also shown. Note that if reporting under SAED criteria, fewer adverse events will be included.

During the transition phase for introduction of the Severity Grading Tool, services may continue to use SAED classifications for reporting of serious adverse reactions to SABRE and SHOT.

Code	SAED Category	Mapped to Classification and Severity Grading Tool
01	Death within seven days of donation	Any category, Grade 5
02	Hospital admission within 24 hours of donation	Any category, Grade 3 or 4
03	Injury resulting in a fracture within 24 hours of donation (including fractured teeth)	B, Grade 3
04	Road traffic collision within 24 hours of donations	B*, Grade 3 or 4 **If due to vasovagal reaction*
05a	Problems relating to needle insertion persisting for more than one year (this mainly includes suspected or confirmed nerve and tendon injuries)	A (usually A.2), Grade 3
05b	Problems relating to needle insertion requiring hospitalisation/intervention (this mainly includes vascular complications)	A (usually A.4), Grade 3 or 4
06	Acute coronary syndrome diagnosed within 24 hours of donation	E, Grade 3 or 4
07	Anaphylaxis (component donation)	D, Grade 3 or 4
08	Haemolysis (component donation)	C, Grade 3 or 4
09	Air embolism (component donation)	C, Grade 3 or 4
10	Other event related to donation resulting in: Hospital admission, Intervention, or Disability or incapacity lasting more than one year and not included above	F, Grade 3 or 4

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). Standard for Surveillance of Complications Related to Blood Donation. Available at https://www.aabb.org/docs/default-source/default-document-library/resources/donor-standard-definitions.pdf (accessed 04.09.24)
4. Townsend M, Kamel H, Van Buren N, Wiersum-Osselton J, Rosa-Bray M, Gottschall J, Rajbhandary S. Development and validation of donor adverse reaction severity grading tool: enhancing objective grade assignment to donor adverse events. *Transfusion*. 2020 Jun;60(6):1231-1242. Available at https://onlinelibrary.wiley.com/doi/10.1111/trf.15830 (accessed 04.09.24)
5. AABB Donor Hemovigilance Working Group (2020) Severity Grading Tool for Blood Donor Adverse Events, A User Brochure. Available at https://www.aabb.org/docs/default-source/default-document-library/resources/severity-grading-tool-for-donor-adverse-events.pdf (accessed 04.09.24)
6. SHOT Definitions 2023. Pg 20 Imputability. Available at https://www.shotuk.org/wp-content/uploads/myimages/SHOT-Definitions-2023-FINAL-VERSION.pdf (accessed 04.09.24)