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 information required from 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

Health and medical history, provided on a questionnaire and through a confidential personal interview performed by a qualified health professional, must be assessed. 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 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.

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 (currently at least 125 g/L in females and at least 135 g/L in males, 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 antisepctic solution used must be allowed to dry completely after application to the donor’s skin, or the skin must be wiped dry with sterile gauze before venepuncture. 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 shall not be used and these and missing numbers shall be reported via a designated senior manager to the printer concerned and to the Chair of the National Working Party or equivalent on machine-readable labels.

5.6: Performance of the venepuncture

Venepuncture should only be undertaken by authorised and trained personnel. If local anaesthetic is used, this should be a licensed medicinal product and injected in a manner which avoids any chance of donor-to-donor cross-infection (e.g. using individual disposable syringes and needles). A record of the batch number(s) should be made at each blood collection session and be capable of being related to individual donors.

Containers of local anaesthetic should be inspected for any leakage and if glass, inspected for cracks. Any suspect containers should be rejected.

Unused material must be discarded at the end of each donor session.

An aseptic technique must be used for drawing up the local anaesthetic into the syringe and the needle must be changed prior to the injection of the local anaesthetic.

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 30 mL (up to 45 mL in some circumstances) 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 haematological and serological testing without compromising the environmental integrity of the blood in the main pack.

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

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.

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.
For pack systems designed for in-line leucodepletion in which the donor line becomes detached from the final red cell pack, and hence unavailable for compatibility testing, the line should be sealed close to the collection pack, according to clearly defined procedures. This sealing may be done without expressing the contents of the line into the main pack if the contents of the line are deemed to be of no further use.

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. The practice of 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 donation. The methods employed shall ensure an aseptic technique with no risk of contamination and be clearly defined in the sessional procedures SOP manual.

Completion of the donation and quality control samples: A length of tubing should be left attached to the collection pack(s) as required for laboratory testing purposes. 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. An example of the preventative measures that can be implemented are described in ‘Points of care’ used within one UK Blood Service (see Appendix I at the end of this chapter). This is a donation care pathway designed to minimise vasovagal events, bruising and re-bleeding from the venepuncture site.

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 of DAEDs (Appendix II) or similar and a standard data set for Serious Adverse Events of Donation (SAEDs) that is in line with the IHN definitions of SAEDs (Appendix III). This will allow comparison over time and between services of event rates, and monitor the effectiveness of any interventions to reduce event rates. SAEDs should all be fully investigated with a root cause analysis or similar tool 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 via the head of department to the Department of Health 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.

Online reporting to the MHRA is available at www.mhra.gov.uk.

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


Appendix I Points of care

Update notice: Chapter 5 - Appendix I has been updated following the issue of Change Notification 25 - 2014

AI.1 Welcomer

- A principle role of the Welcomer is to reduce potential anxiety in the donor, observe for donors in a 'hyper vigilant' state and refer where appropriate.

- Professionalism, including appearance, is crucial in order to assure the donor of a safe and positive experience.

- The Welcomer should greet the donor with a warm welcome, thank them for attending the session and giving up their time to donate blood.

- The Welcomer needs to promote drinks to the donors. Offer the donor 500mls of fluid to stretch the stomach (gastric dilation) and raise blood pressure reducing the risk of vaso vagal (VV) episodes. This offer or promotion of drinks must be emphasised quite strongly in order for the donor to understand the importance of taking the fluid. Ideally the fluid should be consumed over 5 minutes rather than sipped, and should be taken no longer than 20 minutes prior to donation for best effect. The nurse or supervisor may wish to change the position of the water area on session in line with donor waiting times. An information leaflet for donors is available.

- If possible, donors who are queuing to give their details must be offered fluids along with an explanation of why there is a delay. Back pod support/ nurses should help the Welcomer give drinks if the start of the session is busy.

- Donors who are waiting to be screened must not be seated facing the front of the donation chairs. The eyes of all waiting donors ideally need to be focused away from clinical activity.

- The Welcomer should ensure all donors are given the Welcome folder to read prior to screening.

AI.2 Screening

- The Screener should enquire as to whether the donor has had any previous problems when donating blood and try to relieve any anxiety.

- They should ask the donor about their preparation for giving blood e.g. have they had their usual meals today? If they have undertaken any strenuous activity or exercise, not usual for them, prior to attending are they fully recovered and rehydrated?

- If a previous adverse event is identified or the donor has an increased risk of an adverse event, a nurse should be asked to speak to the donor. The nurse will also instruct the donor on how to do applied muscle tension (AMT) exercises to raise the blood pressure if appropriate.
• The Screener should ask the donor if they have consumed the recommended volumes of fluid prior to the screening. If they have not, they should explain to the donor why drinking fluids is important and offer again. If the donor agrees to drink, give the fluids whilst talking.

• The Screener should ensure new donors and those with a previous history or higher risk of VV episode/s are asked for their permission to discretely identify them throughout their visit so they can receive extra attention. Ensure the vulnerable donor identification card is then included in the pack box.

• Once screening is complete, the Screener should show the donor to the waiting area, which must not have chairs facing the clinical area. Reading material should be available to provide a distraction for waiting donors. It is important to reduce tension and anxiety that will be experienced by many first time donors and those who may have had a problem donating or an adverse event in the past. Additional fluids could be offered too but not as an alternative to moving the main water station at busy times.

AI.3 Donation

• To preserve donor dignity and keep the viewing of clinical activity to a minimum donation chairs should not be facing each other.

• Staff should prioritise donors and provide appropriate therapeutic attention. Talking to donors will allow you to recognise their coping strategies and how best to put them at their ease.

• If required, in order to raise the donor’s blood pressure once they are on the chair, ask the donor to commence AMT exercises. This keeps their mind occupied as they are counting and their focus is away from the venepuncture (VP).

• The donation chair should be placed steadily into the R position to donate.

• If a vaso vagal episode occurs, call for help, reassure the donor and encourage them to commence AMT to prevent the vasovagal episode from worsening. The chair can be taken steadily into U position.

• A nurse should decide if it is clinically necessary to screen off the donor to ensure privacy for the person involved and to avoid raising anxiety levels in those who are waiting. Screens should be placed around the donor, but initially if necessary, place your body between the donor and the waiting donors to block their view until screens arrive. Donors should never be left unattended behind a screen.

• Non donating family/friends are welcome, but must sit at the other side of the chair from the agitator.

• Once the donation is complete, remove the needle and cover the VP site with gauze, asking the donor to apply firm pressure with 3 fingers to the dressing.

• Start the graduated recovery stage bringing the donor back up to O position in stages over a timed 2 minute period.

• Those who are identified as vulnerable may require more, smaller recovery stages.
• Encourage all donors to do AMT exercises during this stage to assist in the prevention of hypotension.

• A staff member should stay with the donor until they leave the chair. Use the time to complete any observations, give advice to the donor, assess pallor and ensure the donor is applying the correct pressure to their arm and the arm remains straight.

• If the VP site is observed then do so by lifting the gauze without removing it, to protect the donor from any blood splash. This also shields the donor from seeing the VP site, if there is no new bleeding, apply the dressing.

• Support the donation arm as the donor leaves the chair.

• Give vulnerable donors their identification card and ask them to place it in front of them as a place mat on the refreshment table.

AI.4 Appointments and teas

• Set the refreshment table up with chairs to three sides to enable clear observation of all recovering donors.

• Staff should ensure the computer does not obscure direct vision of the donors.

• Ensure there is adequate space around the tea table and chairs to reduce the risk of injury should any falls occur.

• Move any cages out of the refreshment area and ensure the safe placement of hot water boilers /cables.

• Emphasise to donors who refuse a drink, the importance of having a post donation drink to replace fluid depletion.

• Encourage those identified as vulnerable to have plenty of cold drinks and snacks.

• Encourage those identified as vulnerable to stay in the refreshment area for a minimum of 15 minutes post donation and to continue with AMT exercises if necessary.

• It may be necessary for donors who want to use the toilet immediately after donating to be escorted by a member of staff.

• Deal with rebleeds promptly. Try to ensure nearby donors see as little as possible.

• If a donor becomes unwell, stay with them and call for assistance.

• Use the mat and wedge in order to get the donors legs elevated as soon as possible.

• Encourage AMT exercises to prevent the vasovagal episode worsening.

• When the donor is ready to transfer to the donation recovery chair assist them onto the chair and place in the U position. Slowly bring them through from U position to O giving the blood pressure time to adjust to each position.
Give post donation advice when the donor is ready, ensuring this advice is given in a confidential manner with regards to the dignity and well being of both the individual and other donors.

Appendix II International Haemovigilance Network categories for donor adverse events

All.1 Complications mainly with local symptoms

All.1.1 Complications mainly characterised by the occurrence of blood outside the vessels

Haematoma
A haematoma is an accumulation of blood in the tissues outside the vessels.

Arterial puncture
Arterial puncture is a puncture of the brachial artery or of one of its branches by the needle used for bleeding of the donor.

Delayed bleeding
Delayed bleeding is spontaneous recommencement of bleeding from the venepuncture site, which occurs after the donor has left the donation site.

All.1.2 Complications mainly characterised by pain

Nerve irritation
Irritation of a nerve by pressure from a haematoma.

Nerve injury
Injury of a nerve by the needle at insertion or withdrawal.

Tendon injury
Injury of a tendon by the needle.

Painful arm
Cases characterised mainly by severe local and radiating pain in the arm used for the donation and arising during or within hours following donation, but without further details to permit classification in one of the already more specific categories mentioned above.

All.1.3 Other kinds of categories with local symptoms

Thrombophlebitis
Inflammation in a vein associated with a thrombus.
Allergy (local)

Allergic type skin reaction at the venepuncture site caused by allergens in solutions used for disinfection of the arm or allergens from the needle.

All.2 Complications mainly with generalised symptoms

All.2.1 Vasovagal reaction

A vasovagal reaction is a general feeling of discomfort and weakness with anxiety, dizziness and nausea, which may progress to loss of consciousness (faint).

All.2.2 Immediate vasovagal reaction

Symptoms occurred before donor has left the donation site.

All.2.3 Immediate vasovagal reaction with injury

Injury caused by falls or accidents in donors with a vasovagal reaction and unconsciousness before donor has left the donation site.

All.2.4 Delayed vasovagal reaction

Symptoms occurred after donor has left the donation site.

All.2.5 Delayed vasovagal reaction with injury

Injury caused by falls or accidents in donors with a vasovagal reaction and unconsciousness after donor has left the donation site.

All.3 Complications related to apheresis

All.3.1 Citrate reaction

All.3.2 Haemolysis

All.3.3 Generalised allergic reaction

All.3.4 Air embolism

All.4 Other complications related to blood donation

Appendix III International Haemovigilance Network definition of severe donor adverse events

Conditions which define a case as severe are:
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- Hospitalisation: If it was attributable to the complication.

- Intervention:
  - to preclude permanent damage or impairment of a body function
  - to prevent death (life-threatening).

- Symptoms: Causing significant disability or incapacity following a complication of blood donation and persisted for more than a year after the donation (long-term morbidity).

- Death: If it follows a complication of blood donation and the death was possibly, probably or definitely related to the donation.

For the purpose of consistent reporting of SAEDs the UK Blood Transfusion Services have adopted these categories:

- death within 7 days of donation
- hospital admission within 24 hours of donation
- injury resulting in a fracture within 24 hours
- road traffic collision (RTC) within 24 hours of donation
- acute coronary syndrome (ACS) diagnosed within 24 hours of donation
- problems relating to needle insertion persisting for more than a year
- anaphylaxis, haemolysis or air embolism (component donors).