Chapter 4: Premises and quality assurance at blood donor sessions

This chapter applies to the collection of donations of whole blood and components at permanent sites or by mobile blood collection teams.

4.1: Premises

Premises used for the preparation of components from blood and plasma have been subject to scrutiny by the Competent Authority, the Medicines and Healthcare products Regulatory Agency (MHRA), since 2005. Such facilities must comply with the principles embodied in the Rules and Guidance for Pharmaceutical Manufacturers and Distributors 2007.\(^1\)

Notwithstanding the fact that premises used for mobile donor sessions may often be accepted, from necessity, as the only local venue available, they must be of sufficient size, construction and location to allow proper operation, cleaning and maintenance in accordance with accepted rules of hygiene and in compliance with the WHO Expert Committee on Biological Standardization 43rd Report.\(^2\)

The designated person in charge of the blood collection team should in all cases be provided with a written plan of action appropriate to each venue. This can be used if conditions on arrival are not found to be acceptable. Care must be taken to avoid disturbances of any other activities within the venue if it is being shared.

4.1.1: Selecting a venue

Whole blood and donor component procedures for the collection of plasma, platelets, red cells or combinations of these may be carried out at fixed or mobile collection sites.

Leucapheresis procedures to collect, for example, granulocytes, lymphocytes or peripheral blood progenitor cells, should only be performed at fixed component units.

In any apheresis unit, or at any blood donor session, a telephone must be immediately available so that the emergency services can be called at any time.

Resuscitation equipment, as required by local and national guidelines for blood donor sessions, must be available at all sessions undertaking routine component procedures.

Account must be taken of the following activities/requirements when selecting a venue:

- registration of donors and all other necessary data processing
• appropriate facilities to assess the fitness of individuals to donate

• withdrawal of blood from donors without risk of contamination or errors

• social and medical care of donors, including those who suffer reactions

• sufficient seating should be provided for donors and staff, with allowance made for possible queues during busy periods

• storage of equipment, reagents and disposables

• storage during the session of blood and components, if they are not to be transferred immediately to the blood processing centre or to appropriate storage in the team vehicle

• access to an adequate electrical supply to support all electrical equipment used for the session

• the space required for these activities will depend on the anticipated workload

• flooring should be non-slip.

4.1.2: Health and safety factors

The requirements of the Health and Safety at Work Act 1974\(^3\) must be taken into account when selecting sessional venues. Each organisation has the responsibility to ensure that venues comply with the Health and Safety at Work Act and that staff are fully aware of their responsibilities under this legislation. It is the responsibility of all staff with supervisory or line management responsibility to ensure that safe systems of work are in place at all times. All venues should be formally assessed for suitability with an appropriate plan to manage risks. Premises should be safe, clean and comfortable for donors and staff. In particular, the following points should be borne in mind:

• The venue should be as close as possible to the centre of population being served. It should be possible for the sessional vehicle(s) to park in close proximity to the access doors, to facilitate off-loading if required. The ground to be covered by staff carrying equipment shall be even and well lit. The space to be used should preferably not entail carriage of equipment on stairs. A similar safe approach should be ensured for donors, with as much provision as possible for car parking. Notices should be displayed, directing donors to the appropriate entry point of the building, and to the room being used.

• Furniture and equipment within the available space should be arranged to minimise crowding (with the increased risk of mistake or accident), enable adequate supervision and ensure a smooth and logical workflow.

• Fire exits must be unobstructed and operational. All sessional staff must be aware of the location of the fire extinguishers and exits.

• Lighting should be adequate for all the required activities. Provision should be made for the use of emergency lighting in the event of interruption of the electricity supply.

• Environmental control may not be within the power of a mobile team, but every effort should be made to ensure that the space does not become too hot, cold or stuffy. Subsidiary cooling fans and heating should be carried on sessional vehicles, and used as necessary. This equipment should be subjected to a planned maintenance programme.
Facilities for the provision of refreshments for donors and staff should be separated from the other activities of a donor session whenever possible. Every effort should be made to ensure that equipment used in this area poses the minimum threat of danger to all persons.

Toilet facilities for male and female donors and staff should be provided.

Separate washing facilities are desirable for those staff involved in ‘clean’ procedures.

Adequate facilities must be available for the disposal of waste. On mobile sessions, all waste should be collected and contained in a suitable manner for subsequent disposal in accordance with relevant regulations.

4.2: Staffing and training principles for donation sessions

A consultant with responsibility for the donors in consultation with nursing and operational managers should ensure that there are adequate staffing levels and that staff are properly trained. This consultant may delegate day-to-day clinical responsibility to appropriately trained clinical staff. When donors are undergoing leucapheresis procedures (e.g. granulocyte, lymphocyte and peripheral blood progenitor cell collections) a suitably trained doctor must be immediately available to attend to the donor.

At sessions where component collection is performed one or more suitably trained doctors or registered nurses must be responsible for supervising the performance of venepunctures and for the supervision of machine procedures.

The administration of drugs (e.g. local anaesthetic and citrate) must be supervised by a registered professional in accordance with Standards for Medicines Management.4 During donation, donors should never be left in a room without the presence of an appropriately trained doctor or registered nurse.

Training and certification of registered nurses undertaking donation procedures including training and monitoring of staff, performing venepunctures and obtaining informed consent, must be in accordance with the current Nursing and Midwifery Council (NMC) Code of Professional Conduct.5

The consultant, in consultation with the nurse manager, must ensure that there is an appropriate staffing level and skill mix to ensure donor safety and adequate monitoring of the equipment in use. They must ensure that, as a minimum requirement, all healthcare professionals involved with component procedures receive basic life-support training annually.

At sessions where component collection is performed planned staffing levels should ensure that normally there is at least one member of suitably trained staff present for every two machines in use. For leucapheresis procedures, higher staffing ratios are required. A programme should be established for initial and continued training to ensure an appropriate level of proficiency.

The consultant with responsibility for donors must ensure that a manual of standard operating procedures (SOPs) is compiled in accordance with local quality assurance systems for whole blood collection and each type of component collection procedure. These SOPs must be regularly reviewed and updated and must take into account the machine manufacturer’s operating instructions. A current copy of the relevant manufacturer’s manual for each type of machine in use must be available on-site.

4.3: Collection of the donation
The ultimate responsibility for ensuring that every unit of blood and blood components has been collected in accordance with the Blood Safety and Quality Regulations (2005) rests with the ‘responsible person’ for the Blood Establishment. The advocacy and guardianship of high-quality care for donors is the responsibility of the designated clinical lead in attendance, who must be a registered nurse or medical practitioner.

Guidance for whole blood and component donation procedures is given in Chapter 5. Guidance for laboratory testing procedures is given in Chapters 9 and 12.

**4.4: Donor identification**

Donors must positively identify themselves at registration by volunteering their name, date of birth and permanent address. Once registered, for subsequent identification their name and date of birth is sufficient. The identity of the donor must be recorded and linked to the donation record.

**4.5: Labelling**

Session staff must ensure that a set of labels with a unique number is assigned to each donation and that the same unique number appears on the donor session record, the primary and secondary collection packs and all the sample tubes used. Great caution is necessary to avoid crossover or duplication of numbers. The working practice should be designed to minimise the risk of error. Arrangements should be such as to avoid the possibility of errors in the labelling of blood containers and blood samples. The blood or component bags and corresponding samples must not be removed from the donor couch until a satisfactory check on correct labelling has been carried out. It is recommended that each donor couch has its own individual facilities for the handling of samples during donation and labelling.

Packs, sample tubes and the donor session record must never be relabelled. Unused sets of numbers must be accounted for. Labels which have been discarded must not be retrieved.

**4.6: Records**

It is strongly recommended that all records pertaining to donor and donation identity be entered and maintained in an electronic format which can be accessed readily by approved and qualified personnel, and in a manner which preserves donor confidentiality in accordance with legal requirements. Machine-readable systems for identifying donors and donation derivatives are also recommended. Initial documentation – for example on session records – may be taken manually and archived for the required period in law, with relevant portions transcribed electronically whenever convenient operationally.

**4.6.1: Donor session records**

A record of the sessional venue, the date, the donation number and the identity of all donors attending must be maintained. For any donors who are deferred, rejected or retired, the full details must be recorded and the reasons given for the action taken.

The records of blood donation sessions should allow identification of each important step associated with the donation. All donations must be recorded including the reason for any unsuccessful donations. All adverse reactions must also be recorded together with the action taken. Full details of any other incidents, including those only involving staff, must be recorded.
These records should be used for the regular compilation of statistics which should be studied monthly by those responsible for activities concerned with the organisation and management of blood collection sessions.

4.7: Control of purchased material and services

4.7.1: Specification and inspection of blood bags

Blood collection shall be by aseptic techniques using a sterile closed system and a single venepuncture. The integrity of the system must be checked prior to use and measures must be taken to prevent non-sterile air entering the system.

Blood shall be collected into containers that are pyrogen free and sterile, containing sufficient licensed anticoagulant for the quantity and purpose of blood to be collected.

The container label shall state the kind and amount of anticoagulant, the amount of blood that can be collected and the required storage temperature.

Manufacturers’ directions regarding storage, use and expiry dates of the packs whose outer containers have been opened and resealed must be adhered to.

Batch numbers of the blood packs used shall be recorded.

The donation number on the pack and sample tubes should be checked at the end of the donation to ensure that those for a given donation are identical; that is, the donation number on the donor health and lifestyle questionnaire, the primary and secondary collection packs and the sample tubes must all be identical.

Prior to release from the blood collection session the pack and its associated tubing should be reinspected for defects and its integrity should be checked by applying pressure to the pack to detect any leaks. Any defective pack should be marked for disposal and held separately from intact packs. Details of the defect(s) should be recorded for future analysis and action (see section 5.11).

4.7.2: Specification of apheresis sets

Blood components must be collected by apheresis using sterile, single-use, disposable items that are licensed and CE marked. The apheresis set for collection of components for direct clinical use must have a preconnected access needle to ensure a sterile pathway, and incorporate a bacterial filter in all non-preconnected fluid lines (e.g. saline, SAGM, and the anticoagulant line [not required if the anticoagulant bag is preconnected]). For dual-needle procedures a preconnected needle is only essential for the access venepuncture.

A record must be kept of all lot and/or batch numbers of all the apheresis set components and injectable materials used, in accordance with local quality systems.

4.7.3: Specifications for automated donor apheresis machines (see also section 8.5)

Machines must be correctly installed and commissioned according to each manufacturer’s instructions. They must be CE marked.
The environment and operating area for each machine employed and the power supply available must conform to the manufacturer's recommendations for satisfactory machine performance.

Machines must comply with the relevant aspects of the Health and Safety at Work Act 1974 and the Good Automated Manufacturing Practice (GAMP) Guide for Validation of Automated Systems in Pharmaceutical Manufacture. Automated apheresis machines must have the following features:

- A manual override system so that the operator can stop the automatic cycle at any time during the procedure.
- A blood flow monitor, to monitor blood flow during blood withdrawal and return. The purpose is to ensure that the selected donor flow rate does not cause collapse of the donor's vein and to monitor the venous pressure during the donor blood return cycle such that if any obstruction to flow occurs the blood pump will automatically reduce speed and/or stop. In either event a visual and audible alarm system should operate.
- An in-line air detector to protect the donor from air embolism. In the event of air entering the extra-corporeal circuit a visible and audible alarm must be activated, the return blood pump must automatically stop and the venous return line must automatically be occluded.
- A blood filter integral with the harness to prevent any aggregates formed during the procedure from being returned to the donor.
- An anticoagulant flow indicator, providing a visible means of monitoring anticoagulant delivery throughout the procedure, and ideally an audible alarm if no anticoagulant is flowing.
- A device for pre-setting the collection volume, monitoring the collection volume during the procedure and automatically ending the procedure. A system with a visual and audible alarm to notify the operator of the completion of the procedure may be provided.
- In the event of a power failure the machine must automatically enter a standby mode once power returns.

Apheresis machines must be serviced in accordance with the manufacturer’s instructions. A planned maintenance scheme should be followed. Machine maintenance and servicing must be documented and be in accordance with the procedures outlined in the appropriate Medicines and Healthcare products Regulatory Agency publications: DB 9801, DB 9801 Supplement 1 and DB 2000(02).

Apheresis machines must be routinely cleaned with a suitable decontaminating agent on a daily basis. A standard procedure for dealing immediately with blood spillage must be in operation.

### 4.7.4: Anticoagulant

A licensed citrate anticoagulant must be used at a ratio which achieves a final plasma citrate concentration of 15–25 mmol/L in the collected component (see Chapter 3, Appendix II).

The anticoagulant must be in date, with no evidence of particles or leakage. Any suspect unit must not be used. The batch number must be recorded on the session record and any defect reported in accordance with local quality systems.
4.8: Protection and preservation of product quality

All whole blood and apheresis components must be transported, tested and stored in accordance with the specifications for blood components in Chapters 7 and 8.

4.9: References


- DB 9801, *Medical Device and Equipment Management for Hospital and Community-based Organisations*
- DB 9801 Supplement 1, *Checks and Tests for Newly Delivered Medical Devices*
- DB 2000(02), *Medical Device and Equipment Management: Repair and Maintenance Provision*. 