

Guidelines for the Blood Transfusion Services

Chapter 4: Premises and quality assurance at blood donor sessions

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Chapter 4:

Premises and quality assurance at blood donor sessions

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

4.1: Premises

Premises used for the collection of blood and components 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*^A to ensure the quality and safety of the collected blood and components, and to ensure the health and safety of donors and staff.

Premises must be of sufficient size, construction and location to allow proper operation, cleaning and maintenance in accordance with the blood service's procedures and national policies for infection prevention and control.

There must be provision for:

- the resuscitation equipment required by the blood service's policy
- a telephone so the emergency services can be called if required

4.1.1: Selecting a venue

4.1.1.1: Collection process factors

Account must be taken of the space, services, equipment, and facilities required for the process of blood and component collection to ensure safety and minimise the risk of errors. The requirements include:

- registration of donors
- waiting area(s) with seats for donors
- privacy for confidential assessment of the fitness and suitability of individuals to donate
- care of donors, including those who suffer reactions

- storage of equipment, reagents and disposables
- storage of blood and components prior to transportation
- a reliable electrical supply and adequate supply points for electrical equipment
- a reliable telecommunications network system

There must be an associated local contact whose details are available with the venue information for the designated person in charge of the blood collection team, for use if conditions or facilities are not suitable on arrival.

4.1.1.2: Health and safety factors

The blood service has the responsibility to ensure that venues comply with the Health and Safety at Work Act², that staff are fully aware of their responsibilities under this and any other relevant legislation, and that safe systems of work are in place and are upheld thereby minimising the risk of accidents and injuries. All venues should be formally assessed for suitability with an appropriate plan documented to manage risks. Premises should be safe, clean, comfortable and convenient for donors and staff in regard to the following:

- **Access:** the venue should be located conveniently for the population being served. It should be possible for the session 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 should 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.
- Flooring should be non-slip
- Furniture and equipment should be arranged to allow a smooth and logical workflow without any obstruction to activities and movement within the session space, whilst also allowing adequate supervision
- Fire exits must be unobstructed and operational. All session staff must be aware of the location of the fire extinguishers and exits.
- Lighting must 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. Supplementary cooling fans and heating appliances should be carried on session 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 donors and staff should be provided
- Separate handwashing 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 (2007)*.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 and point of attendance by volunteering their name, date of birth and permanent address. For subsequent identification during the same attendance, provision of their name and date of birth during the process of blood collection is sufficient. The identity of the donor must be recorded and linked to the donation record. The donor record must be current and active to allow donation, and duplicate donor records identified.

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 collection pack(s) and the sample tubes from the same donor to allow full traceability.

The working practice should be designed to minimise the risk of error including crossover. The blood or component bags and corresponding samples must not be removed from the donor area until a satisfactory check on correct labelling has been carried out. It is recommended that each donor area 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.

Labels must comply with relevant regulations, ideally machine as well as eye-readable, and allow a system of complete traceability to all donor and donation information held by the blood service.

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 made manually and archived for the required period in law, with relevant portions transcribed electronically whenever convenient operationally.

4.6.1: Donor session records

The session venue, the date and the identity of all donors attending must be recorded.

The relevant medical history of all donors must be documented for any donors who are deferred or withdrawn, and the full details including the reasons must be recorded.

All donations must be recorded including type collected (blood or component(s)) and the reason for any unsuccessful donations.

The records should allow identification of each important step associated with the donation.

All adverse reactions must 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 and review by those responsible for the organisation and management of blood collection sessions.

4.7: Equipment and consumables

All equipment used for the collection of blood and components must be validated, calibrated, maintained and cleaned, and records kept. Use must be in accordance with the manufacturer's instructions. Faulty, defective, or damaged equipment or consumables must not be used and must be reported and managed through the blood service's quality system.

4.7.1: Specification and inspection of blood bags

Blood must be collected by aseptic techniques using a sterile closed system and a single venepuncture.

The integrity of the system must be checked prior to use looking for signs of damage or defects and/or contamination. Measures must be taken to prevent non-sterile air entering the system.

The containers must be pyrogen-free and sterile, containing sufficient licensed anticoagulant for the quantity and purpose of blood to be collected.

Manufacturers' directions regarding storage, use and expiry dates of packs must be adhered to.

Batch numbers of the blood packs used must be recorded.

The donation number on the pack and associated sample tubes and donor health questionnaires should be checked at the end of the donation that they are 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 and reported 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/UKCA/UKNI 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 fluids that are not connected. (e.g. citrate anticoagulant).

A record must be kept of all lot and/or batch numbers of all the apheresis set components and injectable /infused 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/UKCA/UKNI 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 1974² and the Good Automated Manufacturing Practice (GAMP) *Guide for Validation of Automated Systems in Pharmaceutical Manufacture*.³

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).⁶

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

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 and any defect reported in accordance with local quality systems.

4.8: Protection and preservation of donation quality

All blood and components must be transported, tested and stored in accordance with the specifications in Chapter 7.

4.9: References

1. Medicines and Healthcare products Regulatory Agency (2017). *Rules and Guidance for Pharmaceutical Manufacturers and Distributors 2017*. London: Pharmaceutical Press. Also available at www.mhra.gov.uk/publications/regulatoryguidance/medicines/othermedicinesregulatoryguidance/CON2030291
2. Health and Safety at Work Act 1974. Available at www.legislation.gov.uk
3. Good Automated Manufacturing Practice (GAMP) *Guide for Validation of Automated Systems in Pharmaceutical Manufacture*. Available at www.ispe.org
4. *Standards for Medicines Management* (2007). Available at www.nmc-uk.org/publications/standards
5. Nursing and Midwifery Council (NMC). *Code of Professional Conduct*. Available at www.nmc-uk.org
6. Medicines and Healthcare products Regulatory Agency publications, available at www.mhra.gov.uk
 1. DB 9801, *Medical Device and Equipment Management for Hospital and Community-based Organisations*
 2. DB 9801 Supplement 1, *Checks and Tests for Newly Delivered Medical Devices*
 3. DB 2000(02), *Medical Device and Equipment Management: Repair and Maintenance Provision*.