Change Notification for the UK Blood Transfusion Services

Date of Issue: 28 February 2025 **Implementation:** to be determined by each Service

No. 04 – 2025

Clinical supervision at donor sessions

This notification includes the following changes:

	BM-DSG Bone Marrow & Peripheral Blood Stem Cell	CB-DSG Cord Blood	GDRI Geographical Disease Risk Index	TD-DSG Tissue – Deceased Donors	TL-DSG Tissue – Live Donors	WB-DSG Whole Blood & Components	Red Book Guidelines for the BTS in the UK
1. **Chapter 4.2** Staffing and training principles for donation sessions	○	○	○	○	○	○	●
2. **Chapter 4.3** Collection of the donation	○	○	○	○	○	○	●
3. **Chapter 4.7** Equipment and consumables	○	○	○	○	○	○	●
4. **Chapter 4.9** References	○	○	○	○	○	○	●

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Chair of Standing Advisory Committee on Care & Selection of Donors (SACCSD)

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Professional Director of JPAC

Changes are indicated using the key below. This formatting will not appear in the final entry.

original text	«inserted text»	~~deleted text~~

1. Changes apply to the **Red Book**

Chapter 4: Premises and quality assurance at blood donor sessions

(no changes to 4.1)

4.2: Staffing and training principles for donation sessions

A consultant with responsibility for «blood and component» ~~*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 «donation» ~~*procedures*~~ receive «annual» basic life-support training ~~*annually*~~.

At sessions where component collection is performed «one or more suitably trained healthcare professionals must be responsible for the selection of the collection procedure, supervising the performance of venepunctures and for the ongoing supervision of machine procedures. Planned» ~~*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.*~~

2. Changes apply to the **Red Book**

4.3: «Clinical leadership at donor sessions» ~~*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 «at the donation session.»~~*, who must be a registered nurse or medical practitioner.*~~

«At the time of writing, the clinical lead is usually a nurse registered with the Nursing and Midwifery Council (NMC). Services may wish to consider individuals from other professional groups registered with a similar professional register. Examples include, but are not limited to, the General Medical Council (GMC) or the Health and Care Professions Council (HCPC).

If Services decide to use an individual who is not a registered nurse, they must have a policy detailing which professional groups can perform the clinical lead role at their donor sessions. This policy must describe any practical skills, training and experience required to perform the role. Such a policy must also consider relevant healthcare regulations and legislation for that service; these will vary between different UK countries.

As detailed in BSQR, donor eligibility must be assessed by a registered nurse, doctor or an individual who has successfully completed donor carer training for that service.»

~~*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.*~~

(no changes to 4.4 – 4.6)

3. Changes apply to the **Red Book**

4.7: Equipment and consumables

(no changes to 4.7.1 – 4.7.2)

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 1974*[2] 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).[«4»~~6~~] *(note change in citation number)*

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.

(no changes to 4.7.4 – 4.8)

4. Changes apply to the **Red Book**

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*~~

«4»~~6~~. Medicines and Healthcare products Regulatory Agency publications, available at www.mhra.gov.uk

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