Change Notification for the UK Blood Transfusion Services

Date of Issue: 17 February 2026 **Implementation:** to be determined by each Service

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Chapter 3:

Care and selection of whole blood and component donors (including donors of pre-deposit autologous blood)

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. 3.4: Informed consent	○	○	○	○	○	○	●

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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 3: Care and selection of whole blood and component donors (including donors of pre-deposit autologous blood)

(sections 3.1 to 3.3 are unchanged)

3.4: Informed consent

«3.4.1: Background information

Consent is legally and ethically required for blood and blood component donation. The relationship between a donor and blood service is different to the patient setting; however, the approach to consent is the same.

In the UK, consent is governed under common law. In addition, blood services must comply with the Blood Safety and Quality Regulations 2005. A recent case law (known as Montgomery) was an important update to the law regarding consent. Montgomery states that there is a duty to 'take reasonable care to ensure that the patient is aware of any material risks involved in any recommended treatment, and of any reasonable alternative or variant treatments' [Montgomery, 2015]. A material risk is 'one that a reasonable person in the patient's position is likely to attach significance to, or if the doctor is or should reasonably be aware that their patient would be likely to attach significance to it'. That is, when seeking consent for blood and component donation, the question of whether the information given to a donor is adequate is judged from the perspective of a reasonable person in the donor's position, rather than a health professional.

The principles of consent are included in the General Medical Council (GMC) professional standards and the Nursing and Midwifery Council (NMC) code. To be valid, consent must be voluntary and fully informed, and the individual giving consent must have the capacity to do so as per the Mental Capacity Act 2005.

3.4.2: General Principles

Blood services should have a consent policy including roles and responsibilities (these may differ between whole blood donation and donation via apheresis). Consent may need to be adapted for specific donation types, e.g. pre-operative autologous donation. The policy should set out monitoring and quality assurance requirements to ensure standards in training, and practice of consent, are maintained.

Consent must be obtained by a trained person familiar with the Montgomery principles. In practice, this means donors should be asked what they would like to know, and if they have any questions. Donors must be aware that there is an alternative to proceeding with donation, i.e. they can withdraw consent or stop the donation at any point before its completion.»

~~*For consent to a procedure to be legally valid the donor must as a matter of good principle have been told the nature and purpose of the procedure as well as being warned of any substantial or unusual adverse event risk. Therefore, informed consent must be obtained by a trained person, fully conversant with the procedure. A consent form must be signed by each donor before donation.*~~

«Consent is an ongoing process between a donor and blood service staff; it is not simply obtaining a signature. The process of consent starts when a donor registers to give blood and continues throughout the donor journey. Information provided prior to the donor's attendance, for example via the organisation's website, contributes to the consent process. Leaflets or equivalent materials should be comprehensive and comprehensible; that is, they should be presented in everyday language.

Informed consent must be obtained before every donation, including for experienced or frequent donors. Privacy and confidentiality must be ensured, and donors should have the time they need to consider consent. Donors should be informed of any recent updates to processes, including testing, or risks involved. The individual seeking consent must satisfy themselves that the donor has reviewed, understood, and had the opportunity to ask questions relating to the information provided.

3.4.3: Donor information

~~*Leaflets or equivalent material about donation appropriate to the procedure should be available at the session and should be studied by prospective donors to assist in the process of obtaining fully informed consent. In obtaining donor consent, the consenter must satisfy themselves that the donor has gone through the material provided and has understood the following information:*~~

«The following information should be provided to blood and component donors:

- A safe blood supply relies on voluntary, non-remunerated donation. Donors may have a sense of fulfilment associated with an act of altruism. However, any perceived or actual benefit to the donor must not be an incentive for donation.»

- The purpose of the donation and the use of the «component,» ~~*product (clinical, research or other).*~~ «including clinical and non-clinical issue, research and commercial use. Donors should be aware if further manufacturing may be undertaken by external companies (for example, fractionation of plasma). If commercial products are to be made from a donation, the benefit to patients should also be included in the information provided.»

- A description of the procedure and its likely duration.

- «The purpose of donor selection criteria and deferral in ensuring the safety of recipients and donors, and that donors have a responsibility to answer all questions fully and honestly.»

- ~~*An explanation that a voluntary donor can withdraw consent at any stage of the procedure or of an apheresis programme.*~~

- «Donations will undergo mandatory testing for transfusion transmissible infections (TTI). Additional testing for microbiological agents may be required, e.g. after travel or to meet the needs of specific patients. Donors should be informed what to expect in the event of a positive result, including the statutory requirement to report notifiable diseases to public health authorities, and that their GP and/or other relevant healthcare provider will be informed (if required). Testing may not be completed in certain circumstances, e.g. if insufficient blood obtained.

- On rare occasions, new testing may be rapidly introduced to meet blood safety requirements. By giving blood, the donor is consenting to any new testing required.

- A small sample of blood will be stored in case it is required for a look-back investigation, which may include testing for new markers of infection introduced at a future date.

- Blood will be 'typed', which may include genotyping, to find the best match for a patient. Services should detail the purpose and nature of any genotyping to be undertaken.

- Additional testing which may be carried out on some or all donations, e.g. haemoglobinopathy screening or leucocyte antibody screening. Donors should have access to further information on the implications of any testing undertaken.

- Information may be obtained during testing or processing that may be relevant to the donor's health or eligibility to donate. Donors should be aware they may be contacted with further information, including relating to specific component type.

- Donations which do not meet testing and manufacturing specifications may be discarded.

- Details of how personal data, including relating to sex and gender, will be used, retained and protected for a minimum of 30 years (including data for individuals deferred from giving blood).

- Individuals should be informed of material risks of donation (see 3.4.4).»

- ~~*A description of the common risks and discomfort involved in the procedures. These include:*~~
  - ~~*for all donors:*~~
    - ~~*dizziness and fainting*~~
    - ~~*haematoma formation*~~
    - ~~*other venepuncture-related injuries, including nerve damage, arterial puncture and tendon injury*~~
  - ~~*for donors of components by apheresis:*~~
    - ~~*citrate toxicity*~~
    - ~~*red cell loss if the procedure has to be aborted and it is considered unsafe to return the red cells*~~
    - ~~*chilling on reinfusion*~~
    - ~~*rare complications, such as anaphylaxis, haemolysis and air embolism*~~

- «The importance of informing the blood service if, following donation, the donor becomes unwell, or is aware of new or previously undisclosed information that could impact blood safety.

- The donor can change their mind and withdraw consent to donate at any point until the donation is completed.

- The donor is encouraged, and welcome, to ask questions.

Further information which must be provided to and obtained from whole blood and component donors is detailed in the following chapters:

- 5.1: Information to be provided to prospective donors of blood or blood components

- 5.2: Information to be obtained from donors by Blood Establishments at every donation

3.4.4: Risks of donation

Donors should be counselled regarding recognised risks of harm. Risks of serious harm should be disclosed regardless of how rarely these occur (see GMC guidance on Decision making and consent and International Society of Blood Transfusion (ISBT) Code of Ethics Relating to Transfusion Medicine). Furthermore, donors should have the opportunity to ask about any risks of significance to them as individuals [Montgomery, 2015].

Side effects include iron deficiency, which can be symptomatic even in the absence of anaemia. Complications (adverse events) are classified according to the Standards for Surveillance of Complications Related to Blood Donation (2014), as described in Chapter 5.10. Reported adverse event rates are variable; any data provided should be applicable to the specific service. Individual donor circumstances should be considered when assessing the likelihood and impact of risk. Risk reduction strategies, and advice regarding recognition and management of complications and side effects, should be provided.

3.4.5: Capacity to consent»

~~*It is the responsibility of session staff to ensure that donors clearly understand the nature of the donation process and the associated risks involved as explained in the available literature. The donors must also understand the health check and other medical information presented to them. Donors are asked about confidential and sensitive aspects of their medical history and lifestyle. It is therefore important that blood collection sessions have facilities that offer privacy for donor interviews and that donors are assured of the confidentiality of any information they provide.*~~ For the donor's consent to be valid the donor must have capacity to consent. Capacity is defined in the Mental Capacity Act 2005.[2]

The five principles of this act state that:

- The person must be assumed to have capacity unless you can establish that they have not.
- No-one should be treated as being unable to make a decision unless the blood service has made all practical steps to ensure that they are able to make that decision without success.
- The person may not be deemed unable to make a decision just because they appear to make an unwise decision.
- Any act done or decision made under the Act on behalf of a person who lacks capacity must be done in the best interests of that person.
- One must always consider whether you can do the same thing in a way that is less likely to infringe that person's rights and freedom of action.

We must therefore presume that every donor that we deal with has capacity to make decisions. To have capacity the person must, with the appropriate help and support, be able to understand, retain, use and/or weigh up the information they are given to make the decision or to communicate their wishes. Just because a person is of a certain age, or has a disability, communication difficulty or medical condition we cannot assume that they lack capacity. Thus, staff who consent donors must understand and apply these principles. All donors, be they 17 or 70, should have capacity when they sign their consent and it is the duty of the attending carers and healthcare professionals at the session to ensure that they do have that. Since the Family and Law Reform Act 1969 children have capacity to give consent in medical matters from the age of 16 (applies to England and Wales. Equivalent legislation applies in Scotland and Northern Ireland).

«3.4.6:» ~~*3.4.1:*~~ Use of third-party interpreters

There is concern that the use of third parties during any exchange of confidential information between the donor and the qualified health professional may compromise the confidentiality of the donor and the safety of the blood supply. It is permissible for any third party to act as an enabler by helping to reassure the donor and to assist in establishing effective communication between the donor and the qualified health professional.

The third party must not participate in the health screening interview, including any exchange of confidential information, unless they are not personally known to the donor, and they are an accredited trained interpreter or a member of blood service staff with appropriate language skills. Confidential parts of the process include the evaluation of the health and medical history questionnaire, the medical interview and the obtaining of valid consent.

Professional interpretation services may be delivered remotely (e.g. telephone, video) instead of face to face. If blood services wish to use an interpretation service for verbal communication or translation service for written information, these must meet relevant healthcare standards. Services should ensure that:

- Interpretation is also available for pre-session and post-donation donor enquiries and follow-up of adverse events and abnormal results.

- Any written information for the donor can be provided in the correct language using an appropriate translation service.

«3.4.7: References

- Montgomery v Lanarkshire Health Board (2015). SC 11 [2015] 1 AC 1430.»

(sections 3.5 to 3.17 are unchanged)