NHS Blood and Transplant

Information for clinicians

Patient consent and shared decision-making for blood transfusion

There is a legal and ethical duty to obtain informed consent from patients prior to any treatment. Involving the patient in the consent process respects the rights of the patient to be included in decisions about their treatment. From a clinical perspective, the process of obtaining informed consent is a key constituent in the formation of an effective, therapeutic relationship with the patient.

Informed (or valid) consent should be:

"Voluntary, denoting an absence of control by others, and informed, requiring sufficient information and understanding to allow autonomous choice. Three elements of consent therefore, include agency (capacity), liberty (absence of coercion), and autonomy."
(Expert Report to the Infected Blood Inquiry, 2020)[1]

Guidance from the Advisory Committee on the Safety of Blood, Tissues and Organs (SaBTO)

Following a working group review, the SaBTO recommendations on patient consent and decision making for a blood transfusion were revised in September 2025[2]. The new publication supersedes the previous SaBTO Patient Consent for Blood Transfusion Guidelines (November 2020).

The updated guidance extends its remit to adults and children and includes treatment with blood components and blood products. Blood components can be defined as the therapeutic constituents of blood, e.g. red cells, platelets, plasma, granulocytes, cryoprecipitate. A blood product is any therapeutic substance derived from human blood and plasma-derived medicinal products, e.g., (non-recombinant) coagulation factor concentrates, human albumin. The same consent process applies for blood components and blood products, as such the term 'transfusion' within the guidance refers to the use of either treatment.

The recommendations underline the need for an effective process in any healthcare setting where patients may be exposed to transfusion, taking lessons from the Infected Blood Inquiry Report[3]. They ensure that healthcare staff involved are adequately trained, patients are informed and empowered, shared decision-making is enabled, and good documentation of transfusion records is maintained.

Key aspects of the SaBTO guidance are:

- **Informed (valid) consent**

  Informed and valid consent for transfusion must be completed for ALL patients who may, are likely to, or will receive a transfusion. This covers situations where transfusion might occur during a procedure when the patient is incapacitated, e.g. where a sample for pre-transfusion testing has been taken pre-procedure

- **Policy**

  Hospitals must have a policy which defines the shared decision and consent process that consent-trained healthcare staff should follow for transfusion. The policy/policies must differentiate between the process for adults and children and include the refusal of consent. It is recommended that the process for patients under the age of eighteen should reference consultation of local legal teams where concerns arise

- **Training for healthcare practitioners**

  Healthcare practitioners involved in consenting for transfusion must undergo training and assessment of consent for transfusion which must be renewed every three years

- **Shared decision making**

  Patients are given age appropriate, accessible, verbal and written information about transfusion and any available alternatives. Patients are given the opportunity to consider and ask any questions they may have, wherever possible as part of a shared decision discussion. This may result in consent, part-consent, or refusal of certain blood components/products. The duration of the consent must be agreed and the patient made aware that they can change their mind about transfusion at any time. The outcome of the discussion must be documented in the patient record and treatment managed accordingly

- **Pre-transfusion final check**

  Healthcare staff have a duty to check that there is documented evidence of informed and valid consent before a transfusion is started. Hospitals must facilitate this check by providing a standardised format and location to record consent. Where electronic patient records are used, this documentation must be digitised

- **Documentation and retrospective information of transfusion episode**

  This can be categorised into three scenarios:

i) **Where informed (valid) consent was obtained in advance and transfusion was known to be taking place**
All patients must be provided with details of the transfusion and informed of any adverse events that occurred. All relevant information must be documented in the patient's notes and included in the discharge summary

ii) **Where informed (valid) was obtained in advance but there was uncertainty whether a transfusion would take place e.g. during a surgical procedure**
In circumstances where a patient is told that they may need a transfusion during a procedure, the outcome must be discussed with the patient. If a transfusion took place, follow the guidance in i)

iii) **Where informed (valid) consent could not be obtained in advance**
If a patient receives a transfusion before they were able to give informed and valid consent, they must be retrospectively informed of the details of the transfusion as indicated in i). The patient must be provided with the relevant information in a face-to-face discussion prior to discharge. The patient must be made aware that they are no longer eligible to donate blood in the UK. Documentation of the discussion must be made in the patient's notes and included in the discharge summary

- **Standardised source of information for patients who may receive a blood transfusion in the UK**

  There is a standardised information leaflet for patients who may receive a blood transfusion in the UK. This information resource, developed by the UK blood services can be accessed via the NHSBT website

- **Centralised UK-wide information resource for healthcare practitioners to facilitate consent for transfusion discussions**

  The UK Blood Services have a central resource to support healthcare practitioners to engage in patient discussions about transfusion. This can be accessed via the JPAC website

- **Governance**

  All healthcare organisations providing blood transfusions should monitor implementation and compliance with these recommendations as a process of continuous improvement, intervening where required

The law on consent

Medical claims relating to inadequate consent procedures have been increasing in the NHS.[4]

Montgomery vs. Lanarkshire Health Board (2015)[5]

The legal test defined in the 2015 decision of the UK Supreme Court in Montgomery vs. Lanarkshire (UKSC 2013/0136) is 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. The test of whether a risk is material is whether "… a reasonable person in the patient's position would be likely to attach significance to the risk, or the healthcare professional is, or should reasonably be, aware that the particular patient would be likely to attach significance to it."

The assessment of material risk cannot be reduced to percentages, but is based on factors such as:

- The nature of the risk
- The effect on the life of the patient
- The importance to the patient of the benefits of the treatment
- Any possible reasonable alternatives
- The risk of those alternatives

The application of the professional practice test (i.e. *Bolam*, as qualified by *Bolitho*) is used to determine whether an alternative treatment is considered reasonable. In other words, the identification of which treatments are reasonable alternatives is a matter falling within medical expertise and professional judgment. This was clarified in 2023 in the UK Supreme Court in McCulloch v Forth Valley (UKSC/2021/0149)[6].

The assessment is fact-sensitive and sensitive to the characteristics of the patient. Crucially, the information must be 'comprehensible'.
There are exceptions, as follows:

- If the healthcare professional reasonably considers that disclosure would be seriously detrimental to the patient's health
- "…where the patient requires treatment urgently but is unconscious or otherwise unable to make a decision"[4]
- Where the patient states that they do not want to know and waives their right to full disclosure

Where an exception is relied upon this should be fully documented in the medical records.
This represents a more cooperative approach to consent between patients and healthcare practitioners, which is aligned with the long-standing General Medical Council (GMC) consent guidance[7].

The National Institute for Health and Care Excellence (NICE)

Transfusion Guidelines NG24 (2015)[8] and Quality Standard (4) QS138 (2016)

Recommendations on patient information for blood transfusion include:

- Provide verbal and written information to patients who may have, or who have had, a transfusion, and their family members or carers
- Document decisions in the patient's notes
- Provide the patient and their GP with copies of the discharge summary or other written communication

What should be discussed with the patient?

- The reason for the transfusion
- The risks and benefits
- The transfusion process
- Any transfusion needs specific to them
- Any alternatives that are available, and how they might reduce their need for a transfusion
- That they are no longer eligible to donate blood in the UK

- The duration of consent
- Any questions the patient might have, this should be encouraged
- That they have the right to refuse or withdraw consent at any time
- What happens if they refuse transfusion

What does this mean in practice?

- Does the patient understand the rationale for the proposed transfusion, the risks, and benefits?
- What risks would a reasonable person want to know about?
- What other risks would this patient want to know about?
- Is transfusion the only available treatment? Does the patient know about available reasonable treatment options?
- Does the patient understand all the information? Have I used complicated language, medical terms, or acronyms that the patient may not understand?
- Have I provided age-appropriate, accessible, written information to meet their needs?
- Have I given the patient enough time to process the information that I have shared?
- Have I given the patient the opportunity to ask questions?
- Can the patient make an informed choice with shared decision-making?
- Patient-signed consent is not a SaBTO requirement, but some hospital policies may require this. Consent may be implied or non-verbal. Have I documented patient consent (or refusal) to transfusion in the patient's clinical records according to local hospital policy?
- Have I made the relevant teams aware of the shared decision outcome?

Other considerations

- Standards for consent are available from the GMC, and these should be referred to for all aspects of consent, including capacity, refusal and consent in children[7,9.]
- Children: Local guidelines and policies should always be followed. Further guidance on consent in children and young people can be accessed on the NHS website. See also guidance for patients aged 0-18 on the GMC website
- Mental capacity: Local guidelines and policies should be followed. Further guidance on assessing mental capacity for consent to treatment can be accessed on the NHS website
- The consent process should never delay transfusion in medical emergencies, but a valid Advance Decision Document (ADD) must be followed.

Refusal

Following discussion about the risks and benefits of transfusion some people may decline transfusions for religious or personal reasons. It is important that the consequences of their decision are explained and understood by the patient, and wherever possible, an alternative to transfusion is offered. Refusal must be documented in the medical notes and brought to the attention of all health care professionals involved in the care of the patient. Patients who are

Jehovah Witnesses should be invited to provide a copy of their ADD for their medical notes and asked to clarify which blood components and products, if any, they would be willing to accept. Jehovah Witnesses have an established network to support clinicians treating Witness patients and this can be accessed through your Hospital Liaison Team.

Resources

NHS Blood and Transplant produce a range of patient information leaflets intended to support the consent process. It is important to note that they do not replace the shared decision-making discussion between the clinical team and the patient. These leaflets are available to download and details of how to order hard copies can be found on the PBM webpages

The **Serious Hazards of Transfusion** (SHOT) team have several resources to support patients. General patient information about blood transfusion can be accessed via the SHOT patient webpage.
The 'My Transfusion' information app contains key information about blood transfusions and was co-created with patients, for patients. You can access information on how to download the app on the SHOT My Transfusion webpage

The 2025 **SaBTO** guidelines on Patient Consent and Shared Decision-Making for Blood Transfusion[2] contain appendices listing its key recommendations and useful resources to support implementation.
Informed patient consent and shared decision-making for blood transfusion - Serious Hazards of Transfusion

The **UK and Ireland Blood Transfusion Network** led the development of resources for patients and healthcare practitioners to assist the consent process.

Transfusion information for patients - Consent for blood transfusion - Transfusion practice - JPAC

Guidance for healthcare practitioners - Consent for blood transfusion - Transfusion practice - JPAC

Nursing & Midwifery Council (NMC):
The Code - Professional standards of practice and behaviour for nurses, midwives and nursing associates can be accessed via the NMC website

Caring for patients who decline blood transfusion
Royal College of Surgeons (RCS) good practice guide for managing surgical patients who decline blood transfusion can be accessed via the RCS website

The **Jehovah's Witness** website provides information, guidance, and resources to support clinical staff and can be accessed via the JW.ORG website

References

1. Expert Report to the Infected Blood Inquiry: Medical Ethics (2020) INQY0000241

   https://www.infectedbloodinquiry.org.uk/sites/default/files/documents/INQY0000241%20-%20Expert%20Report%20to%20the%20Infected%20Blood%20Inquiry-%20Medical%20Ethics%20-%2001%20Apr%202020.pdf

2. Advisory Committee for the Safety of Blood, Tissues and Organs (SaBTO). (2025). Patient Consent and Shared Decision-Making for Blood Transfusion.

   https://www.gov.uk/government/publications/blood-transfusion-patient-consent

3. Infected Blood Inquiry (IBI), 2024. The Report HC 569-I, London: Crown.

   https://www.infectedbloodinquiry.org.uk/reports/inquiry-report

4. NHS Resolution (2018) Did you know? The benefits of supported decision making (consent) (2018)

   https://resolution.nhs.uk/wp-content/uploads/2018/09/Did-you-know-The-benefits-of-supported-decision-making-consent-WEB.pdf

5. Montgomery (Appellant) vs. Lanarkshire Health Board (Respondent) (Scotland) (2015) UKSC 104

   https://www.supremecourt.uk/cases/uksc-2013-0136.html

6. McCulloch (Apellant) v Forth Valley Health Board (Respondent) (Scotland) (2023) UKSC UKSC/2021/0149

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7. General Medical Council (2024) Consent: Decision Making and Consent.

   https://www.gmc-uk.org/professional-standards/the-professional-standards/decision-making-and-consent

8. National Institute for Health and Care Excellence (2015) Blood Transfusion {NG24}

   https://www.nice.org.uk/guidance/ng24

9. General Medical Council (2024) 0-18 Years

   https://www.gmc-uk.org/professional-standards/the-professional-standards/0-18-years

Disclaimer

Contact us

We would welcome your feedback and comments on this leaflet. You can contact us:

By post to:

Patient Blood Management, NHS Blood and Transplant

500 North Bristol Park
Northway
Filton
Bristol
BS34 7QH

By email to: **PBM.team@nhsbt.nhs.uk**

Or by phone: **01865 381010**

This leaflet was prepared by NHS Blood and Transplant

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