



Information for clinicians

Patient consent and information

There is a legal and ethical duty to obtain informed consent from patients prior to 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 can be defined as:

“an ongoing agreement by a person to receive treatment, undergo procedures or participate in research, after the risks, benefits and alternatives have been adequately explained to them.” (RCN 2006)

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

In 2011 SaBTO published recommendations regarding patient consent for blood transfusion. Key recommendations included:

- Valid consent for blood transfusion should be obtained and documented in the patient's clinical record by a healthcare professional
- There should be a modified form of consent for long-term multi-transfused patients, details of which should be explicit in an organisation's consent policy
- There should be a standardised source of information for patients who may receive a transfusion in the UK
- Patients who have received a transfusion and who were not able to give valid consent prior to the transfusion should be provided with information retrospectively

A SaBTO consultation exercise in 2010/11 identified inconsistent practice; patients are not always given information or made aware they have had a transfusion. Three years after these recommendations were made, the National Comparative Audit for Blood Transfusion (2014) found that implementation of informed consent for transfusion was sporadic and compliance with the SaBTO recommendations was generally low.

SaBTO is currently reviewing these 2011 recommendations, with new guidance expected later this year.

The law on consent

Montgomery vs. Lanarkshire Health Board (2015)

The 2015 decision of the UK Supreme Court in *Montgomery vs. Lanarkshire* (UKSC 2013/0136) is important when considering informed consent and the shared decision-making model practised in the UK.

The legal test defined in the case 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, and therefore to be disclosed, is whether 'in the circumstances of a particular case, a reasonable person in the patient's position would be likely to attach significance to the risk, or the doctor 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 and instead is based on a variety of 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 alternatives
- The risk of those alternatives

The assessment is therefore fact-sensitive and sensitive also to the characteristics of the patient. Crucially, the information must be 'comprehensible'.

There are exceptions, as follows:

- The doctor is entitled to withhold from the patient information as to a risk if "he reasonably considers that its disclosure would be seriously detrimental to the patient's health"
- The doctor is also excused from conferring with the patient in circumstances of necessity, "as for example where the patient requires treatment urgently but is unconscious or otherwise unable to make a decision"
- Where the patient expressly states that he does not want to know and waives his 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 GMC consent guidance

The National Institute for Health and Care Excellence (NICE)

Transfusion Guidelines NG24 (2015) 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?

- 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
- That they are encouraged to ask questions

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 particular patient want to know about?
- Is transfusion the only available treatment? Does the patient know about available alternatives? Have I given the patient an informed choice with shared decision-making?
- Have I tried to ensure that the patient understands all the information? Have I used complicated language, medical terms or acronyms that the patient may not understand? Have I provided written information?
- Have I documented patient consent to transfusion (or refusal) in the patient's clinical records correctly according to local hospital policy? (Patient-signed consent is not a SaBTO requirement, but some hospital policies may require this)

Other considerations

- Standards for consent are available from the General Medical Council and these should be referred to for all aspects of consent, including capacity to consent, patients who refuse treatment and consent in children
- Children: Young people aged 16-17 years can be presumed to have the capacity to consent to their own medical treatment. As with adults, consent must be valid (i.e. given voluntarily after appropriate advice). A competent consent to treatment cannot be overruled by a parent. In England the law on parents overriding young people's competent refusal is complex. Seek legal advice if you think treatment is in their best interests (GMC 2018)
- Mental capacity: Local guidelines and policies should be followed
<https://www.nhs.uk/conditions/consent-to-treatment/capacity/>

Refusal

Following discussion about the risks and benefits of transfusion some people may decline transfusions. This may be for religious or personal reasons. It is important that the consequences of not having a blood transfusion 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's Witnesses should be invited to provide a copy of their Advance Decision Document for their medical notes and asked to clarify which blood components and products, if any, they would be willing to accept. Jehovah's 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 produces 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 at:

<https://hospital.blood.co.uk/patient-services/patient-blood-management/patient-information-leaflets/>

The Jehovah's Witness website provides information, guidance and resources to support clinical staff:

<https://www.jw.org/en/jehovahs-witnesses/faq/jehovahs-witnesses-why-no-blood-transfusions/>

Nursing & Midwifery Council:

<https://www.nmc.org.uk/standards/code/>

Disclaimer

This toolkit is a guidance document only. If you are uncertain as to the legal position in relation to consent or any aspect of the care you are providing to your patient, then you should seek legal advice.

NHSBT cannot attest to the accuracy, completeness or currency of the opinions contained within this toolkit and does not accept any responsibility or liability for any loss or damage caused to any practitioner or third party as a result of any reliance placed on this toolkit.

References

1. Advisory Committee for the Safety of Blood, Tissues and Organs (SaBTO). 2011. Patient Consent for Blood Transfusion.
<https://www.gov.uk/government/publications/patient-consent-for-blood-transfusion>
2. General Medical Council (2020) Consent: Decision Making and Consent.
<https://www.gmc-uk.org/ethical-guidance/ethical-guidance-for-doctors/consent>
3. General Medical Council (2018) 0-18 Years: Guidance for all Doctors.
<https://www.gmc-uk.org/ethical-guidance/ethical-guidance-for-doctors/0-18-years>
4. Montgomery (Appellant) vs. Lanarkshire Health Board (Respondent) (Scotland) (2015) UKSC 104
<https://www.supremecourt.uk/cases/uksc-2013-0136.html>
5. National Institute for Health and Care Excellence 2015 Blood Transfusion {NG24}
<https://www.nice.org.uk/guidance/ng24>
6. Royal College of Nursing (2006) Informed consent in health and social care research: RCN guidance for nurses
<http://www.wansford.co.uk/gcp/INFORMED%20CONSENT%20guidance.pdf>

Contact us

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This leaflet was prepared by NHS Blood and Transplant in collaboration with the National Blood Transfusion Committee. Further supplies can be obtained by accessing <https://hospital.nhsbtleaflets.co.uk>

Individual copies of this leaflet can be obtained by calling 01865 381010.

NHS Blood and Transplant

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