NORTH EAST & YORKSHIRE
REGIONAL TRANSFUSION COMMITTEE

NHS
Blood and Transplant

Legislation and Consent for Blood Transfusion

Presented by the North East & Yorkshire Non-Medical Authorisation working group

Caring Expert Quality

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Learning Outcomes

- Understanding the legal and professional responsibilities around informed consent
- Explain what should be discussed with patients and what information is available to support decision making
- Explain the importance of documentation and what information should be recorded
- Explain what to do for patients who have received an unexpected transfusion
- Identify what patient information leaflets are available and where to source them.

"Consent is a fundamental legal and ethical principle. All patients have the right to be involved in decisions about their treatment and care and to make informed decisions if they can."

UK General Medical Council (GMC) 2020

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Guidance and Recommendations


STATUTORY INSTRUMENTS

2005 No. 50

HEALTH AND SAFETY

The Blood Safety and Quality Regulations 2005

The Blood Safety and Quality Regulations BSQR SI 2005 No.50 and British Society for Haematology (BSH)

- Blood components are therapeutic constituents of blood
- Medicines Act excluded whole human blood and components from the legal definition of medicinal products
- Blood components are NOT medicines and are thus incapable of prescription in strict legal terms – but they can be 'authorised'

".. there are no legal barriers to other appropriately trained, competent, registered practitioners ordering, authorising and administering blood." (BSH 2009)

NICE

- Transfusion Guidelines NG24 (2015)
  - Provide verbal and written information to patients who may have or have had a transfusion
  - Document discussions in the patient's notes
  - Provide the patient and their GP with copies of the discharge summary or other written communication
- QS138 (2016)
  - People who may need or have had a blood transfusion are given verbal and written information about blood transfusion

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SaBTO Advisory Committee on the Safety of Blood, Tissues and Organs

- Informed and valid consent for transfusion is completed for all patients who will likely, or definitely, receive a transfusion
- Patients who received a transfusion and were not able to give informed consent prior, are informed of transfusion prior to discharge
- Details of transfusion and any adverse events should be included in the hospital discharge to ensure the patient and GP are aware.
- The patient should also be informed that they are no longer eligible to donate blood
- The UK Blood Services provide a standardised information resource for patients to facilitate consent for transfusion discussions
- Informed consent training is included in all relevant undergraduate healthcare practitioners training, followed by regular updates.
- All UK healthcare organisations who provide blood transfusions employ mechanisms to monitor the implementation and compliance with SaBTO recommendations

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Supreme Court Decision

“reasonable care to ensure that the patient is aware of material risks involved in any recommended treatment and of any reasonable alternative or variant treatments”

Montgomery v Lanarkshire March 2015

"The dialogue needs to be focused on the individual to ascertain what risks are or are not acceptable to that individual’s circumstances... What is not a material risk for one patient may be a material risk to another."

SaBTO (2020)

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NCA 2014

In 2014, Consent for Blood Transfusion:

- 81% had documentation of the clinical indication for transfusion in the notes
- 85% of staff stated that they had explained the reason for transfusion to the patient, but only 65% stated that they had documented this
- Documentation of consent was only evident in 43% of notes reviewed, and patient recall was variable

Major improvement still needed!

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Obtaining Consent

- Healthcare practitioners trained and deemed competent (as per local hospital policy) to undertake consent should be:
  - Familiar with the key principles of good practice in obtaining consent
  - Have sufficient knowledge and experience of transfusion to be able to provide the information needed for the patient to make a decision
  - Able to answer any questions that may be raised
  - Aware of the range of ethical issues that commonly arise in transfusion practice.

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Valid Consent

- **Voluntary** – the patient makes their decision without influence or pressure
- **Informed** – the person has all the information, including the benefits, risks, any alternative treatments, and potential consequences of refusal of treatment.
- **Capacity** – is the patient able to give consent, can they understand and retain the information provided and use it to make an informed decision.

*"…**informed and valid consent is the process by which a patient learns about and understands the purpose, benefits, and potential risks of the transfusion**"* (SaBTO, 2020)

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Informed Consent

- The reason for the transfusion and the transfusion process
- The benefits of the transfusion and the possible consequences of refusing a blood transfusion
- The risks of transfusion – both short- and long-term risks
- 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

The patient is entitled to withdraw their consent at any point and this should be documented and managed appropriately.

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Duration of Consent

- Short-term consent - For example, where consent is obtained at the start of a patient's admission, as part of a procedure-specific consent, or pre-operatively, where transfusions may be required at various points during that admission
- Long-term consent - long-term multi-transfused patients where transfusions are administered over successive admissions or out-patient treatments
- Where patients are alert and orientated, verbal agreement to the transfusion should be obtained from the patient by the healthcare practitioner administering the transfusion at the time of each transfusion episode prior to administration.
- Consent should be formally renewed if the patient raises any concerns or expresses a wish to review consent, or if new information has become available

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Exceptions

- The patient requests not to be informed
- Clinical situation means consent cannot be obtained
- There is a genuine and significant risk of harm associated with providing the patient the information at that time

Being too busy is not an adequate reason!!

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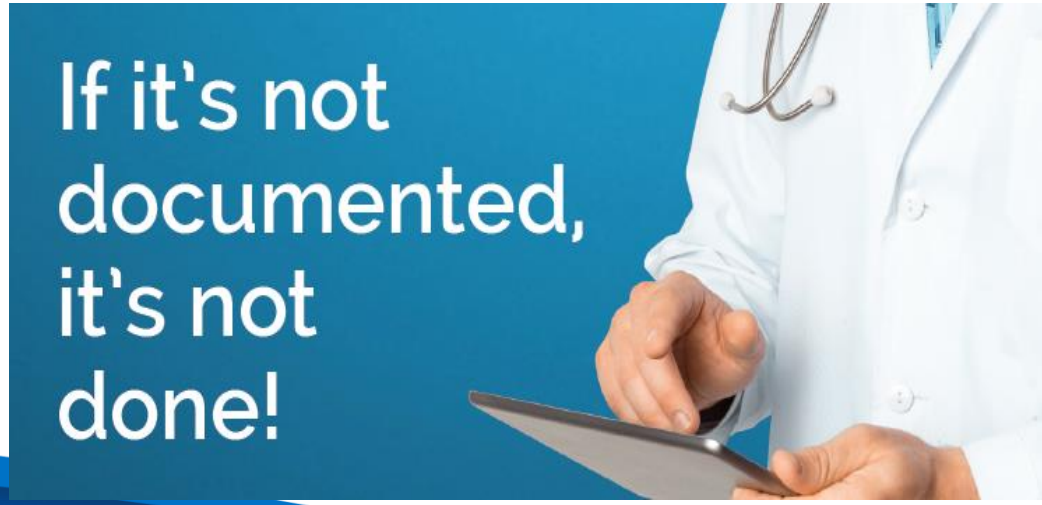
Documenting Consent

- All reasons for transfusion must be clearly documented
- If a patient is unaware that they received a transfusion (e.g. in theatre), the practitioner must document why a transfusion was deemed in the patients best interest and then provide the patient with retrospective information
- Special considerations arise for those patients who may wish to refuse blood transfusion.



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Refusal of Transfusion

- Some individuals may refuse blood transfusion for personal reasons or due to religious beliefs
- Advance Decision to Refuse Treatment
  - should state exactly what is being refused.
- When a patient refuses treatment/transfusion, you must check local policies and national guidance for your own area of practice. When required, escalate or seek further senior or specialist advice.
- It is important to ensure that your patient understands the consequences of their decision. However, if your patient has capacity and chooses to refuse a treatment their decision must be respected, even if it may result in their death or that of their unborn child.

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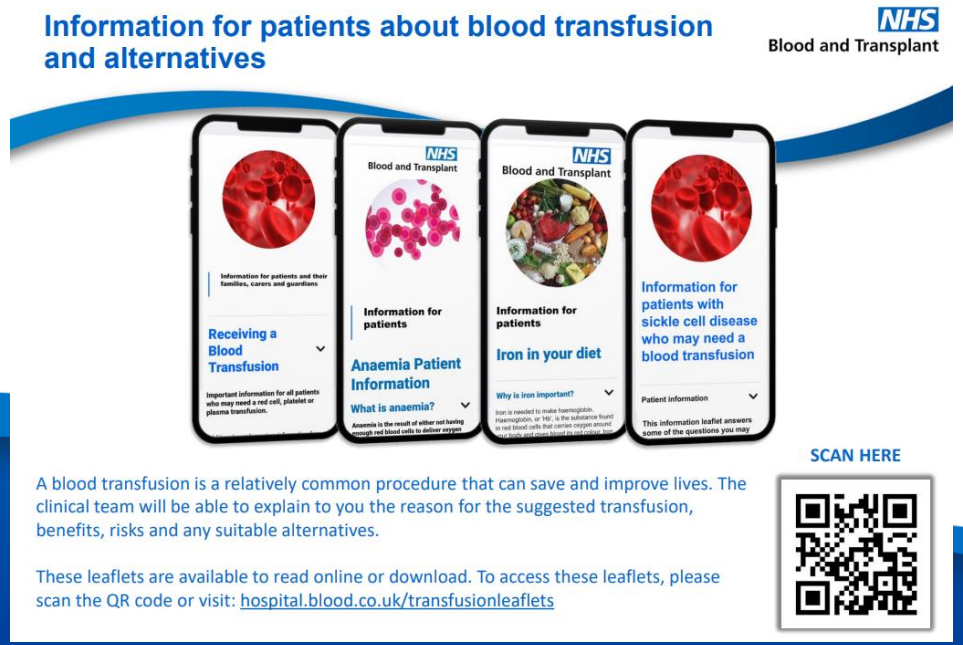
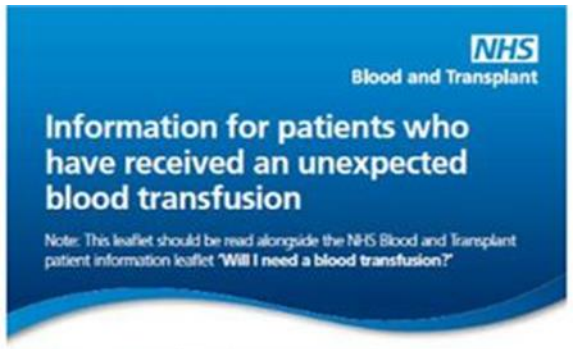
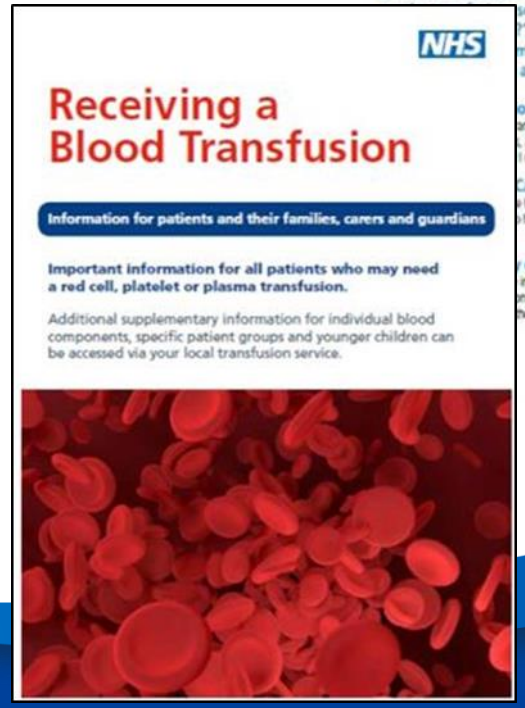
Consent Support Materials

- SaBTO provide ‘Guidance for clinical staff to support patient consent for Blood Transfusion’
  Consent for blood transfusion - Guidance for healthcare practitioners
- PBM consent pages on the Hospital and Sciences website
  Patient Blood Management - Toolkit
- NHSBT Patient Information Leaflets - Available via Hospital Transfusion Practitioner or direct from https://hospital.nhsbtleaflets.co.uk/







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Patients have received blood or blood products from the NHS since it began in 1948. Many of those treated with them, particularly between 1970 and 1998, died or suffered miserably, and many continue to suffer. This was not as a direct result of the underlying condition or illness that took them to the NHS in the first place, but as a result of the treatment itself. This would be catastrophic enough if they were the only victims. But the treatment has caused others to suffer too – partners, family, children, friends – some by being themselves infected, some by having to watch loved ones die, some by having to give their lives to caring; and almost every one of them, infected and affected, suffering in almost every aspect of their lives.

There can be no proper consent without adequate communication, in particular of the risks and alternatives, but also so that the care of the patient respects the patient's ownership of their own body and life.

Consent is not a matter of obtaining a tick or a signature on a sheet of paper, but a real process of information, discussion and co-decision.

It is a mistake to assume that patients truly know and understand something, unless their treating clinician has actually told them and in sufficient detail for them to deal with it.

Infected Blood Inquiry