NORTH EAST & YORKSHIRE REGIONAL TRANSFUSION COMMITTEE

NHS
The Newcastle upon Tyne Hospitals
NHS Foundation Trust

Legislation and Consent for Blood Transfusion

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Healthcare at its best
with people at our heart

Learning Outcomes

- Identify the Advisory Committee on the Safety of Blood, Tissues and Organs (SaBTO) recommendations for consent for transfusion
- Understanding the law and professional responsibilities around consent
- Explain what should be discussed with patients and what information is available to support the consent process
- Explain the importance of documenting consent and what information should be recorded
- Explain what to do for patients who have received an unexpected transfusion and what information is available for these patients
- Describe what patient information leaflets are available, when to use, and where to source them.

BSQR

- Blood Safety and Quality regulations 2005 (SI No.50) resulted in the amendment of the 1968 Medicines Act to exclude 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)

- standards for quality and safety for the collection, testing, processing, storage and distribution of human blood and blood components
- Individuals involved in any step of the process is qualified to carry out the task and receives regular training updates
- 100% Cold chain and traceability documentation must be maintained for blood components
- Blood establishments must report all serious adverse events and reactions relating to blood components
- Blood products are produced by a pharmaceutical process and are classed as Medicines, so are covered by the Medicines Act 1968


STATUTORY INSTRUMENTS

2005 No. 50

HEALTH AND SAFETY

The Blood Safety and Quality Regulations 2005

NICE

- NICE Transfusion Guidelines NG24 (2015) – “1.8 - Patient information : Provide verbal and written information to patients who may have or who have had a transfusion, and their family members or care, Document discussions in the patient's notes, Provide the patient and their GP with copies of the discharge summary or other written communication”
- NICE standard (4) QS138 (2016): - “People who may need or who have had a blood transfusion are given verbal and written information about blood transfusion”

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 have a been given a blood transfusion and were not able to give informed and valid consent prior to the transfusion are informed of the transfusion prior to discharge
- All patients who have received a transfusion have details of the transfusion, together with any adverse events associated with the transfusion, included in their hospital discharge summary to ensure both the patient and their family doctor are aware. The patient should also be informed that they are no longer eligible to donate blood
- The UK Blood Services provide a standardised source of information for patients who may receive a blood transfusion in the UK.
- Training in consent for transfusion is included in all relevant undergraduate healthcare practitioners training, followed by continuous, regular knowledge updates
- There is a centralised UK-wide information resource for healthcare practitioners to facilitate consent for transfusion discussions
- All UK healthcare organisations who provide blood transfusions employ mechanisms to monitor the implementation and compliance with these SaBTO recommendations

The Law on Consent

Montgomery *v* Lanarkshire March 2015

"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"

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.

Informed Consent

- The reason for the transfusion
- The benefits of the 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
- The possible consequences of refusing a blood transfusion
- The transfusion process
- That they are no longer eligible to donate blood
- That they are encouraged to ask questions

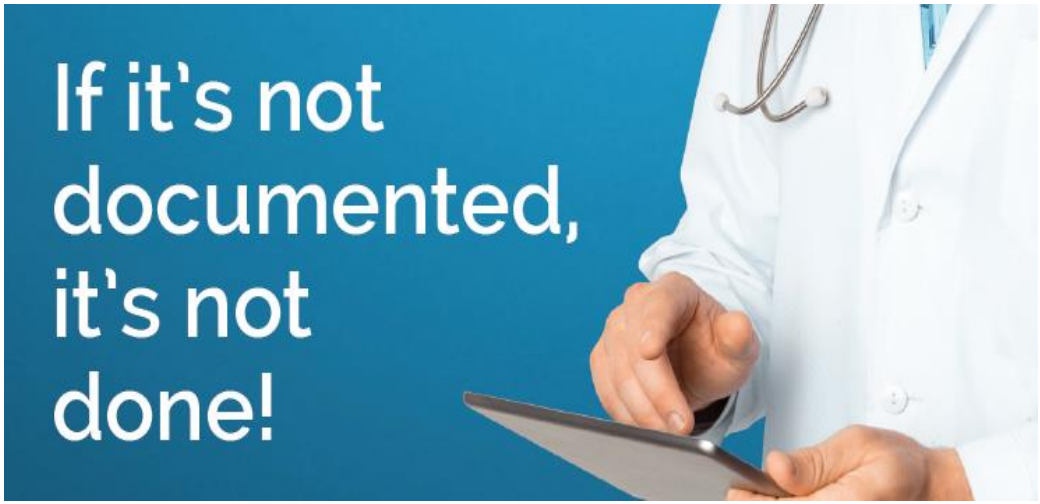
If the patient changes their mind at any point before the transfusion, they are entitled to withdraw their consent and this should be documented and managed appropriately.

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!!

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.

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

Training Requirements

- To be an experienced practitioner
- Clinical lead who supports need for NMA
- Support from the HTC
- Professional Indemnity Insurance
- Attend the course, and work with a clinical mentor to complete and maintain a portfolio
- Maintain transfusion training /audit

NCA 2014

In 2014, the National Comparative Audit of Consent for Blood Transfusion found:

- 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

Consent in Practice - Summary

Does the patient understand the rationale for the suggested transfusion, the risks, and the benefits?

- Type of blood component
- Indication for transfusion
- Risks and Benefits of transfusion
- Possible alternatives to transfusion
- Administration and correct Positive Patient Identification
- Informing the patient that following transfusion they can no longer donate blood

SaBTO also recommended that prior to discharge a check is made to ensure that the patient is fully aware of the transfusion. Also, provide info on what to do/who to contact if they experience a delayed reaction

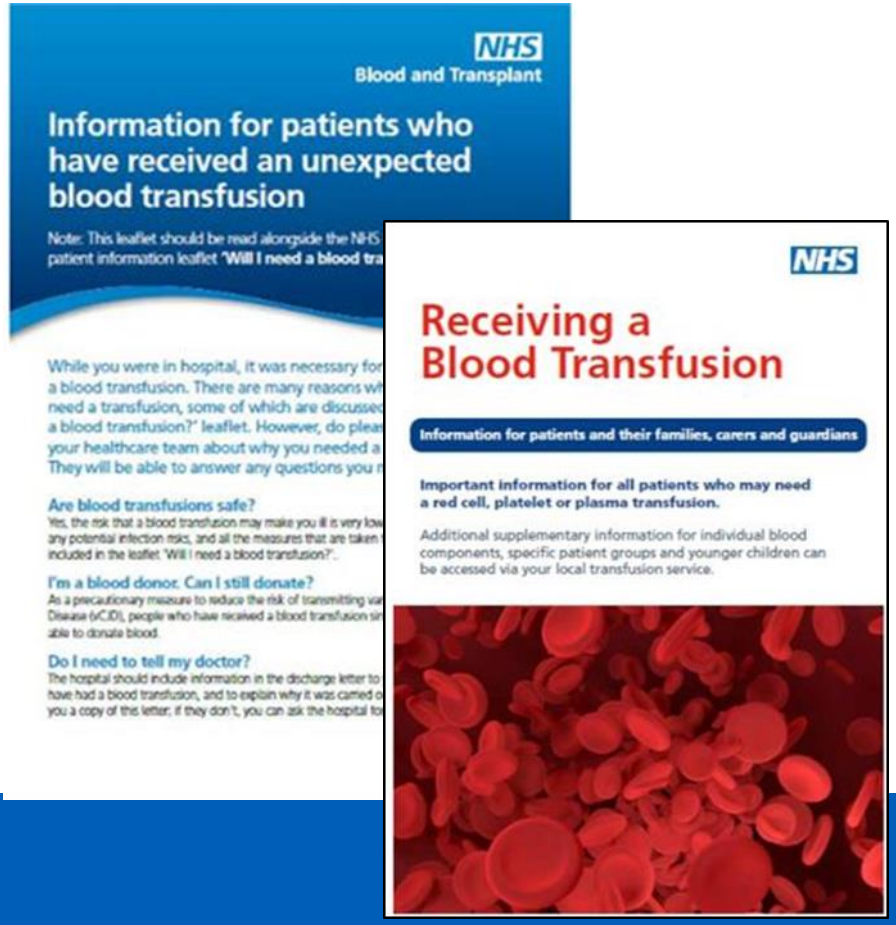
Consent Support Materials

- SaBTO provide 'Guidance for clinical staff to support patient consent for Blood Transfusion' http://www.transfusionguidelines.org.uk/transfusion-practice/consent-for-blood-transfusion-1

- PBM consent pages on the Hospital and Sciences website http://hospital.blood.co.uk/patient-services/patient-blood-management/consent-for-transfusion/

NHSBT Patient Information Leaflets

- Hospital Transfusion Practitioner
- Transfusion Laboratory
- Order free of charge from: https://hospital.nhsbtleaflets.co.uk/
- Download from: https://hospital.blood.co.uk/



Future ?

Infected Blood Inquiry