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Consent for Blood Transfusion and Patient Information

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Mothers, Babies and Blood. January 27th 2016

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Maternity Services

Good at gaining consent?

Place of birth

Management of labour

Administration of Anti-D

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Definitions

- **Consent:** permission for something to happen or agreement to do something (OED)

- **Informed consent:** consent to medical procedures/treatment given by a patient after the potential risks, hazards, and benefits of the treatment have been explained

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9 fundamental points of consent (GMC, 2008)

- Should be obtained at time and place that enables patients to best retain information
- Allow time for reflection before and after decisions
- Tailor approach to individual wishes, making no assumptions about information needs, levels of understanding, or about the importance patients attach to different outcomes
- Use clear, simple, and consistent language
- Give information about risk in a balanced way, avoiding bias

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9 fundamental points of consent (GMC, 2008)

- Provide the likelihood and uncertainties of benefits, risks, and the side effects of each option
- Tell patients about serious adverse outcomes, even if the likelihood is very small
- Use written material and visual aids—accurate and up to date—and refer to other sources
- Check that patients understand the information they are given

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Informed Consent

- Voluntary
- Informed
- Given by a person with capacity
- Taken by a practitioner adequately trained in the procedure for which the consent has been given

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What about consent for Blood Transfusion?

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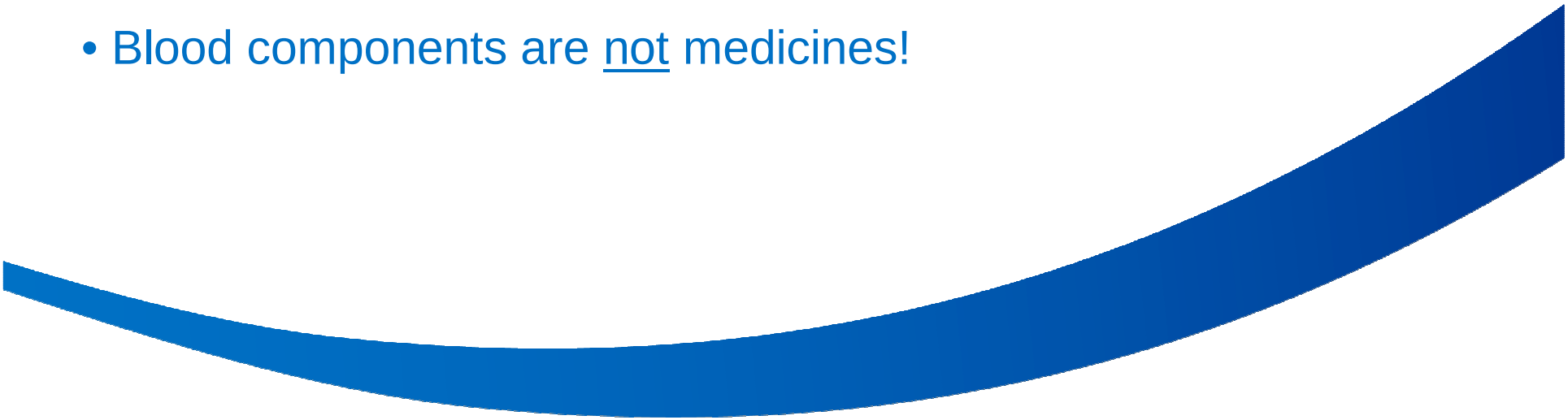
Blood Transfusion

- "The transfer of blood components from one person (the donor) into the bloodstream of another (recipient)"

A Liquid Transplant

- Blood components are not medicines!



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SaBTO

- *Advisory Committee on the Safety of Blood, Tissues & Organs (a DH expert committee)*
- *Advises UK Ministers and Health Departments on the most appropriate ways to ensure the safety of blood, cells, tissues and organs for transfusion/transplantation*
- *Publishes advice and guidance, reports and statements*

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Background

- March 2010: SaBTO initiated a public consultation on patient consent for blood transfusion.

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Why?

- **Patient Choice**: Many patients may not wish to receive a blood transfusion and / or may wish to know what the alternatives are.

- **Public Health**: Recipients may not be aware that they have received blood and then go on to donate.

- **General legal and ethical principle**: Valid consent should be obtained from a patient before they are treated.

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Objectives:

- Identify the preferred option for recording consent
- Explore the potential operational impact of implementing a standardised form of consent for transfusion
- Confirm what type of information patients should receive

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Key issues identified

- Not always given information on risks, benefits, and alternatives to transfusion, or the right to refuse transfusion
- Not always made aware that they have had a transfusion
- Those unaware that they have received a transfusion may go on to donate blood when they should not
- There is inconsistent practice across the UK

Action Plan

14 recommendations / 3 broad categories:

Clinical practice:
What should be done / hospital policy
Recommendations 1-6

Governance:
Review of clinical practice
Recommendations 7 -10

Education:
To help support clinical practice
Recommendations 11-14

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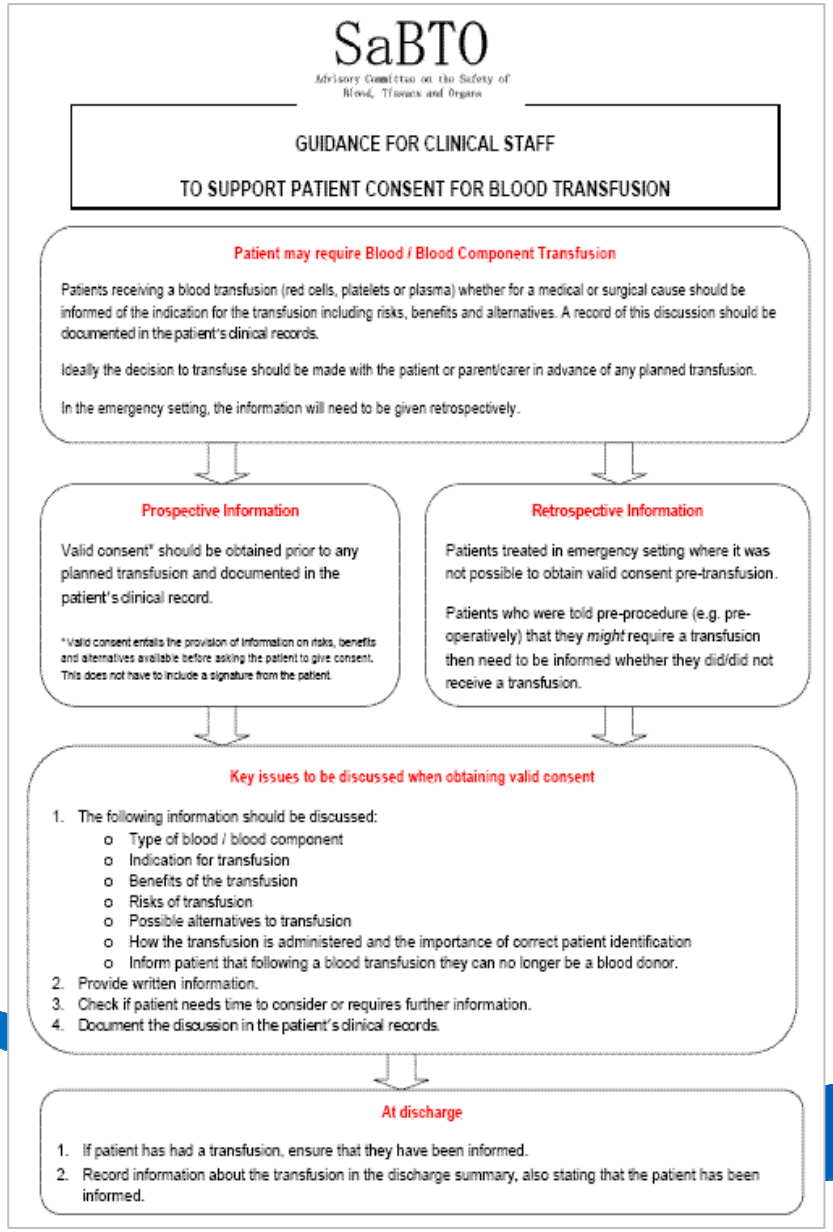
1. *Valid consent for blood transfusion should be obtained and documented in the patient's clinical record by the healthcare professional*

2. *There should be a standardised information resource for clinicians indicating the key issues to be discussed by the healthcare professional when obtaining valid consent from a patient for a blood transfusion*

Standardised Information Resource



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GUIDANCE FOR CLINICAL STAFF

TO SUPPORT PATIENT CONSENT FOR BLOOD TRANSFUSION

Patient may require Blood / Blood Component Transfusion

Patients receiving a blood transfusion (red cells, platelets or plasma) whether for a medical or surgical cause should be informed of the indication for the transfusion including risks, benefits and alternatives. A record of this discussion should be documented in the patient's clinical records.

Ideally the decision to transfuse should be made with the patient or parent/carer in advance of any planned transfusion.

In the emergency setting, the information will need to be given retrospectively.

Prospective Information

Valid consent* should be obtained prior to any planned transfusion and documented in the patient's clinical record.

*Valid consent entails the provision of information on risks, benefits and alternatives available before asking the patient to give consent. This does not have to include a signature from the patient.

Retrospective Information

Patients treated in emergency setting where it was not possible to obtain valid consent pre-transfusion.

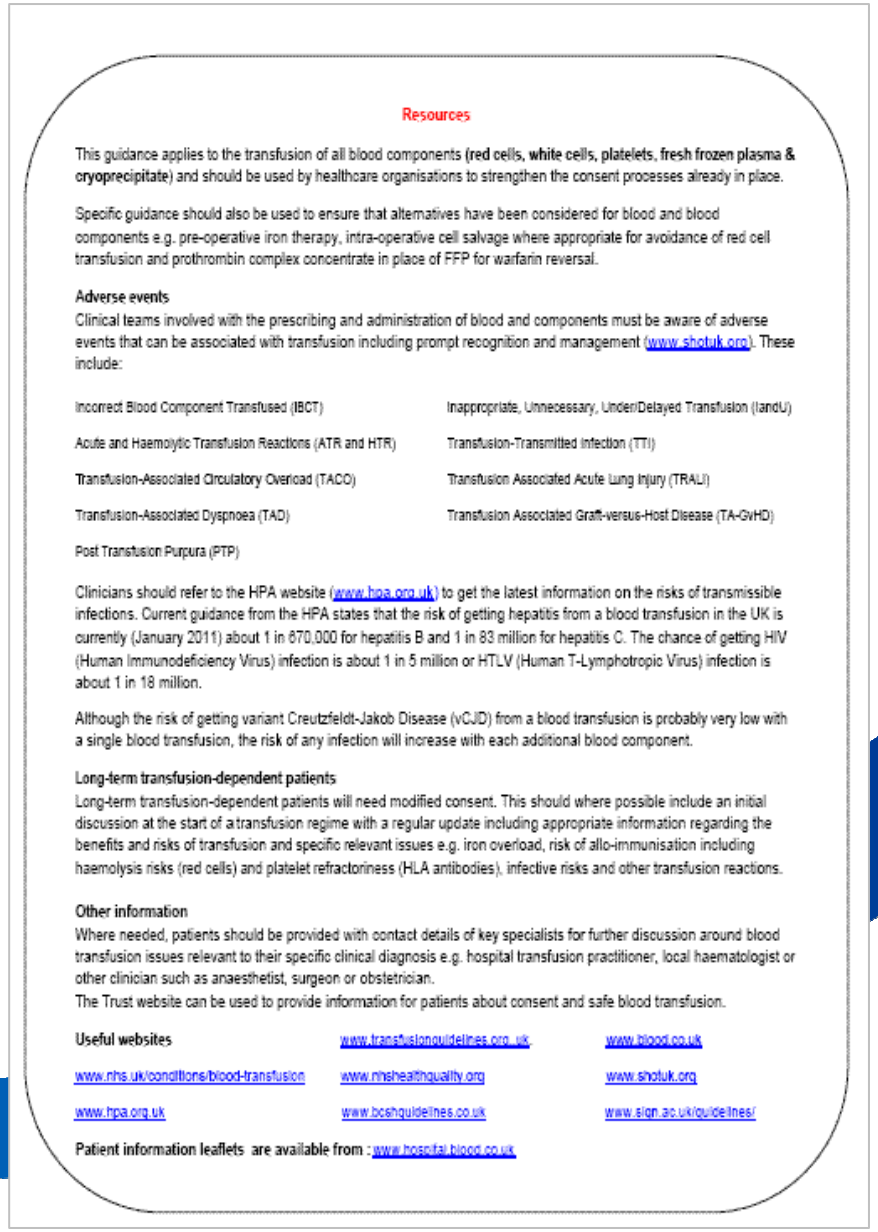
Patients who were told pre-procedure (e.g. pre-operatively) that they *might* require a transfusion then need to be informed whether they did/did not receive a transfusion.

Key issues to be discussed when obtaining valid consent

1. The following information should be discussed:
   - Type of blood / blood component
   - Indication for transfusion
   - Benefits of the transfusion
   - Risks of transfusion
   - Possible alternatives to transfusion
   - How the transfusion is administered and the importance of correct patient identification
   - Inform patient that following a blood transfusion they can no longer be a blood donor.
2. Provide written information.
3. Check if patient needs time to consider or requires further information.
4. Document the discussion in the patient's clinical records.

At discharge

1. If patient has had a transfusion, ensure that they have been informed.
2. Record information about the transfusion in the discharge summary, also stating that the patient has been informed.



Resources

This guidance applies to the transfusion of all blood components **(red cells, white cells, platelets, fresh frozen plasma & cryoprecipitate)** and should be used by healthcare organisations to strengthen the consent processes already in place.

Specific guidance should also be used to ensure that alternatives have been considered for blood and blood components e.g. pre-operative iron therapy, intra-operative cell salvage where appropriate for avoidance of red cell transfusion and prothrombin complex concentrate in place of FFP for warfarin reversal.

Adverse events

Clinical teams involved with the prescribing and administration of blood and components must be aware of adverse events that can be associated with transfusion including prompt recognition and management (www.shotuk.org). These include:

Incorrect Blood Component Transfused (IBCT)

Inappropriate, Unnecessary, Under/Delayed Transfusion (IandU)

Acute and Haemolytic Transfusion Reactions (ATR and HTR)

Transfusion-Transmitted Infection (TTI)

Transfusion-Associated Circulatory Overload (TACO)

Transfusion Associated Acute Lung Injury (TRALI)

Transfusion-Associated Dyspnoea (TAD)

Transfusion Associated Graft-versus-Host Disease (TA-GvHD)

Post Transfusion Purpura (PTP)

Clinicians should refer to the HPA website (www.hpa.org.uk) to get the latest information on the risks of transmissible infections. Current guidance from the HPA states that the risk of getting hepatitis from a blood transfusion in the UK is currently (January 2011) about 1 in 670,000 for hepatitis B and 1 in 83 million for hepatitis C. The chance of getting HIV (Human Immunodeficiency Virus) infection is about 1 in 5 million or HTLV (Human T-Lymphotropic Virus) infection is about 1 in 18 million.

Although the risk of getting variant Creutzfeldt-Jakob Disease (vCJD) from a blood transfusion is probably very low with a single blood transfusion, the risk of any infection will increase with each additional blood component.

Long-term transfusion-dependent patients

Long-term transfusion-dependent patients will need modified consent. This should where possible include an initial discussion at the start of a transfusion regime with a regular update including appropriate information regarding the benefits and risks of transfusion and specific relevant issues e.g. iron overload, risk of allo-immunisation including haemolysis risks (red cells) and platelet refractoriness (HLA antibodies), infective risks and other transfusion reactions.

Other information

Where needed, patients should be provided with contact details of key specialists for further discussion around blood transfusion issues relevant to their specific clinical diagnosis e.g. hospital transfusion practitioner, local haematologist or other clinician such as anaesthetist, surgeon or obstetrician.

The Trust website can be used to provide information for patients about consent and safe blood transfusion.

Useful websites

www.transfusionguidelines.org.uk

www.blood.co.uk

www.nhs.uk/conditions/blood-transfusion

www.nhshealthquality.org

www.shotuk.org

www.hpa.org.uk

www.bcshguidelines.co.uk

www.sign.ac.uk/guidelines/

Patient information leaflets are available from : www.hospital.blood.co.uk

www.transfusionguidelines.org.uk/transfusion-practice/consent-for-blood-transfusion-1

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3. The consent standard developed by Health Improvement Scotland should be adopted throughout the UK for consent for blood transfusion

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Consent for Blood Transfusion
Standard Recommended by SaBTO

The following standard, extracted from the NHS Health Improvement Scotland blood transfusion clinical standards, specifically relates to consent for blood transfusion. SaBTO recommends its use in clinical practice throughout the UK.

Standard Statement

The decision to transfuse is made following consideration of the potential risks and benefits of, and the alternatives to, transfusion. Where possible this is discussed between the clinician and patient (or their legal guardian) in advance of transfusion.

Rationale

- Treatment options (including valid alternatives to transfusion) should be discussed with the patient.
- Valid consent to treatment is an absolute requirement in all forms of healthcare.
- The principles governing the requirement for explanation and discussion, obtaining the patient's consent and documenting this information in the case record are the same for the transfusion of blood and blood components as for any other therapeutic intervention.

Essential Criteria

- The patient's records contain evidence that the reason for transfusion of blood or blood components has been explained and discussed with the patient. This includes discussion of valid alternatives to transfusion and the option to refuse.
- Leaflets explaining the risks and benefits of, and alternatives to, transfusion are readily available for patients who may require to be, or have been transfused.
- Where pre-transfusion discussion is not possible (e.g. in an emergency) there is a system, compatible with the patient's clinical needs, to investigate and act in accordance with the patient's treatment preferences. This includes compliance with an advance decision document.
- When pre-transfusion discussion has not taken place, the reason for transfusion (based on risks and benefits) are discussed with the patient and written information offered retrospectively.

Background

During 2010, SaBTO ran a consultation exercise looking at consent for blood transfusion in clinical practice. This consultation process resulted in the production of a number of recommendations, including the adoption of the NHS Healthcare Improvement Scotland consent standard for blood transfusion.

Context

NHS Healthcare Improvement Scotland is a health body with responsibility for supporting healthcare providers in Scotland to deliver high quality, evidence-based, safe, effective and person-centred care; and to scrutinise those services to provide public assurance about the quality and safety of that care.

Building on work previously carried out by NHS Quality Improvement Scotland and the Care Commission, NHS Healthcare Improvement Scotland's vision is to deliver excellence in improving the quality of care and experience of every person in Scotland every time they access healthcare.

In July 2005, following a detailed scoping exercise, which formed the evidence base for transfusion standards development, a project group was established. In September 2006, following extensive consultation, their Clinical Standards for Blood Transfusion[1] were developed and published.

Reference

1. NHS Quality Improvement Scotland. Blood Transfusion: clinical standards. 2006 Available at : www.healthcareimprovementscotland.org/system_pages/published_resources_search.aspx?source=pubform&ty=313&t=314&q=

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4. The Care Quality Commission (CQC) and the NHS Litigation Authority (NHSLA) and equivalent organisations will be made aware by SaBTO of this consent standard for blood transfusion

5. A UK comparative audit of consent for transfusion should be carried out, facilitated by the National Comparative Audit for Blood Transfusion

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NCA 2014 Audit of Patient Information and Consent

- Patient Consent Documented 43%
- Reason for Transfusion Documented 37%
- Patients didn't feel involved in decision 21%

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6. There should be a standardised source of information for patients who may receive a transfusion in the UK

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Patient Information Leaflets

- There is a list of key points that should be included in all adult patient information leaflets.

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7. Patients who have received a blood transfusion and who were not able to give valid consent prior to the transfusion should be provided with information retrospectively

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Don’t Forget

- Those patients who were told before an elective procedure that they “may” require a transfusion need to be told afterwards whether or not they received one!

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8. SaBTO consent working group should produce good practice guidance to help identify the most effective way of providing information retrospectively when patients were unable to give prior consent

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Consent for Blood Transfusion

Retrospective Patient Information – Good Practice Guidance

Executive Summary

The provision of retrospective information for patients who were not able to give valid consent prior to a blood transfusion is important for three main reasons:

- To ensure patients are aware of the treatment they have received and informed of any associated potential risks relating to transfusion
- To ensure patients who have received a transfusion know they are no longer eligible to donate blood. Patients who are not aware that they have received a transfusion may subsequently go on to donate when they should not
- To reassure some patients who may think that they have received a transfusion, for example during surgery, when they have not.

This guidance has been produced to assist organisations to establish mechanisms to ensure that retrospective information is provided to those that need it. A process flowchart (figure 1) helps to identify which patients should be given retrospective information.

Background

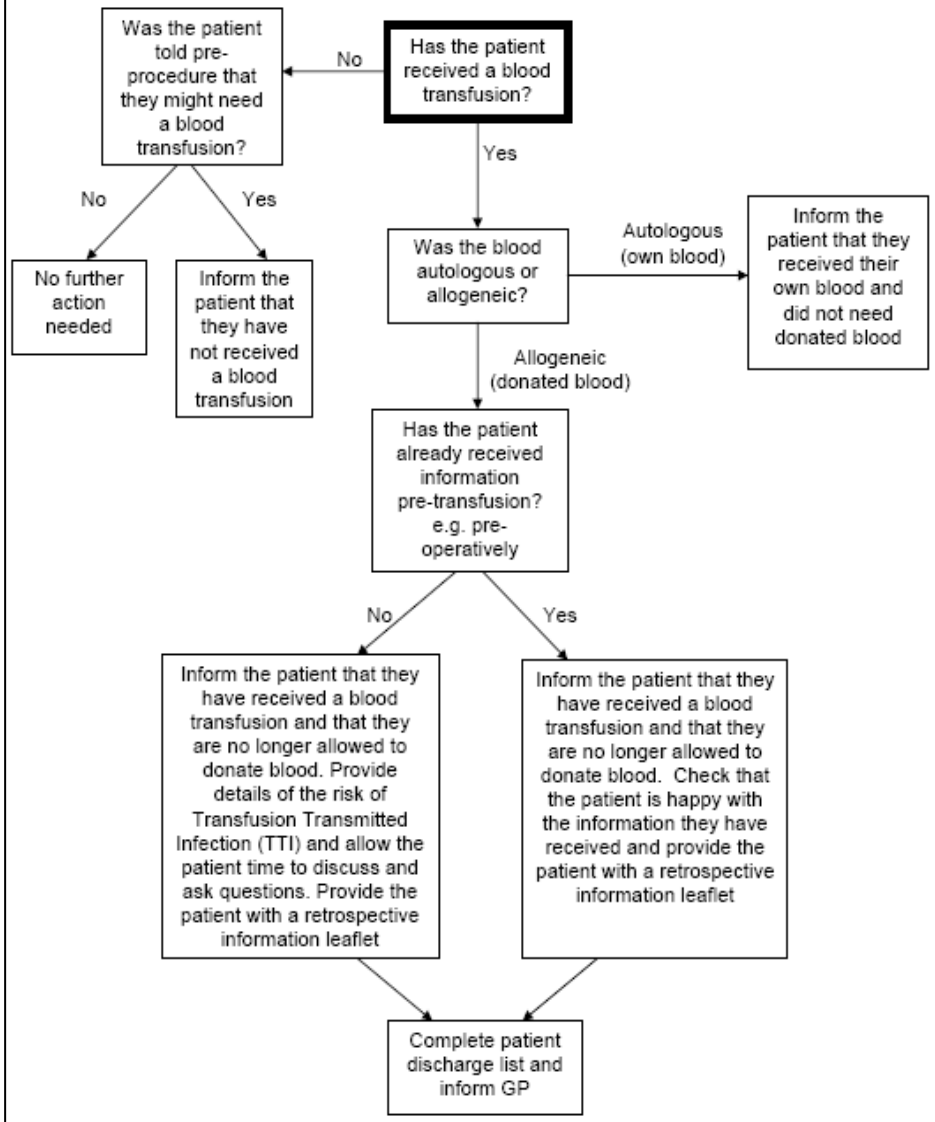
During 2010, SaBTO (the Advisory Committee on the Safety of Blood, Tissues and Organs) initiated a public consultation process to review the options for undertaking valid consent for blood transfusion and the potential operational challenges involved.

Two key recommendations resulting from this consultation process were:

- Valid consent for blood transfusion should be obtained and documented in the patient's clinical record by the health care professional
- Patients who have received a blood transfusion (red cells, platelets, fresh frozen plasma, cryoprecipitate or granulocytes) and were not able to give valid consent before the transfusion should be provided with retrospective information.

A SaBTO Consent for Transfusion sub-group (appendix 1) was established to look specifically at the provision of retrospective information and to produce this good practice guidance for healthcare professionals.

Figure 1: Retrospective Information Flowchart



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Information for patients who have received an unexpected blood transfusion

Note: This leaflet should be read alongside the NHS Blood and Transplant patient information leaflet **'Will I need a blood transfusion?'**

While you were in hospital, it was necessary for you to receive a blood transfusion. There are many reasons why patients may need a transfusion, some of which are discussed in the 'Will I need a blood transfusion?' leaflet. However do please ask a member of your healthcare team about why you needed a blood transfusion. They will be able to answer any questions you may have.

Are blood transfusions safe?

Yes, the risk that a blood transfusion may make you ill is very low. More information about any potential infection risks, and all the measures that are taken to ensure your safety, is included in the leaflet 'Will I need a blood transfusion?'.

I'm a blood donor. Can I still donate?

As a precautionary measure to reduce the risk of transmitting variant Creutzfeldt-Jakob Disease (vCJD), people who have received a blood transfusion since 1980 are not currently able to donate blood.

Do I need to tell my doctor?

The hospital should include information in the discharge letter to your GP to tell them that you have had a blood transfusion, and to explain why it was carried out. The hospital should give you a copy of this letter; if they don't, you can ask the hospital for a copy.

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9. UK blood services should have an ongoing programme for educating patients and the public about blood transfusion as part of their respective Better Blood Transfusion strategies

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Patient Blood Management

- Evidence-based
- Multidisciplinary approach
- Optimising the care of patients who might need a blood transfusion.
- Puts the patient at the heart of decisions
- Ensure that they receive the best treatment
- Avoid the inappropriate use of blood and blood components.

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Why does it matter?

- Improves care
- Reduces inappropriate transfusion
- Ensures availability where there are no transfusion alternatives available

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10. Learn Blood Transfusion e-learning should be promoted

11. The feasibility of developing a module specific to consent should be explored

A module on consent has been developed and is now available on the LearnBloodTransfusion website:
www.learnbloodtransfusion.org.uk

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12. Completion of the LearnBloodTransfusion e-learning package should be included in undergraduate curricula

The learning objectives for the principles of consent should include consent for blood transfusion

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- *The majority of blood transfusions go to elective patients where there is time to discuss transfusion and the alternatives available*

- *It is very important that you find time to give your patient a leaflet and discuss with them the risks and benefits of receiving a blood transfusion*

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Key issues

- Discuss indications, benefits, risks and alternatives
- How transfusion is administered and importance of positive patient identification
- Provide the patient with written information
- Document the discussion in the patient's clinical records
- Ensure patient knows that can no longer donate

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Local Resources

- ***Transfusion Practitioner***
- ***Transfusion Laboratory Staff***
- ***Hospital Transfusion Committee***
- ***YOUR Trust Transfusion policy***
- ***The Patient Blood Management Team***
- ***Regional Transfusion Committee***

Web based Resources

- ***www.transfusionguidelines.org***
- ***ww3.access-24.co.uk***
- ***http://hospital.blood.co.uk***
- ***www.blood.co.uk***
- ***www.learnbloodtransfusion.org.uk***

Patient information can also be found at NHS Choices at: *http://www.nhs.uk*
and via Facebook, Twitter and You Tube

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The keys to Informed Consent are Information and Communication