Consent & Patient Information

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Consent

- **Is a the general legal and ethical principle that a person must give permission before they receive any type of medical treatment or examination.**

- **This should be based on a preliminary explanation by a clinician**

Consent (2)

- Should be given voluntary
- Can be given verbally or in writing
- The person should have the capacity to make this decision, or parental consent should be sought
- Patient's decision should be respected

Consent (3)

- **When a patient is incapable of giving informed consent (Mental Capacity Act 2005):**
  - **make the care of your patient your first concern**
  - **treat patients as individuals and respect their dignity**
  - **support and encourage patients to be involved, as far as they want to and are able, in decisions about their treatment and care**
  - **treat patients with respect and not discriminate against them (GMC 2008)**

Consent (4)

Also consider:

- **whether the patient's lack of capacity is temporary or permanent**
- **which options for treatment would provide overall clinical benefit for the patient**
- **which option, including the option not to treat, would be least restrictive of the patient's future choices**
- **any evidence of the patient's previously expressed preferences, such as an advance statement or decision**
- **the views of anyone the patient asks you to consult, or who has legal authority to make a decision on their behalf, or has been appointed to represent them**
- **the views of people close to the patient on the patient's preferences, feelings, beliefs and values, and whether they consider the proposed treatment to be in the patient's best interests**
- **what you and the rest of the healthcare team know about the patient's wishes, feelings, beliefs and values. (GMC 2008)**

Consent – GMC (1)

- **Consent: patients and doctors making decisions together**

GMC Guidance for doctors: June 2008

Consent – GMC (2)

GMC Good medical practice (2013):

- **You must work in partnership with patients, sharing with them the information they will need to make decisions about their care, including:**
  - **their condition, its likely progression and the options for treatment, including associated risks and uncertainties**
  - **the progress of their care, and your role and responsibilities in the team**
  - **who is responsible for each aspect of patient care, and how information is shared within teams and among those who will be providing their care**
  - **any other information patients need if they are asked to agree to be involved in teaching or research.**

Consent- NMC (1)

Code of Practice (2008): Ensure you gain consent

- You must ensure that you gain consent before you begin any treatment or care.
- You must respect and support people's rights to accept or decline treatment and care.
- You must uphold people's rights to be fully involved in decisions about their care.
- You must be aware of the legislation regarding mental capacity, ensuring that people who lack capacity remain at the centre of decision making and are fully safeguarded.
- You must be able to demonstrate that you have acted in someone's best interests
- if you have provided care in an emergency.

Consent NMC (2)

Midwives rules and standards 2012

Rule 5: Scope of practice

- **This rule requires that in providing care to a woman or a baby during childbirth, you must do so in accordance with The code: Standards of conduct, performance and ethics for nurses and midwives (NMC, 2008).**

Consent & blood transfusion:

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

- **As an outcome of a public consultation in 2010 a series of recommendations were proposed and supported by the SaBTO committee regarding patient consent for blood transfusion (2011).**

SaBTO Consultation (1)

- **Audits presented to SaBTO had identified that the practice of obtaining any form of valid consent for blood transfusion was highly variable in the UK:**
  - **Patients are not always given information on the risks, benefits, and alternatives to transfusion, or the right to refuse transfusion**
  - **Patients are not always made aware that they have received a transfusion**
  - **Patients who are unaware that they have received a transfusion may go on to donate blood when they should not**
  - **There is inconsistent practice across the UK.**

SaBTO Consultation(2)

SaBTO CONSULTATION on patient consent for blood transfusion 3rd March until 27th May 2010.

- **The consultation had the following key 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.**

SaBTO Consultation(4)

- **The overall viewpoints expressed by respondents:**
  - **ensuring that best practice as outlined by the GMC is followed**
  - **a modified form of consent for long-term multi transfused patients, which should be reviewed on a regular basis with patients**
  - **a generic information resource for healthcare professionals to assist discussions on consent for transfusion**

SaBTO Consultation

- **standardised patient information leaflets in the UK**
- **retrospective information for patients who have received a blood transfusion**
- **improved training on consent and its relevance in transfusion for clinical staff to inform discussion with patients during the consent process.**

SaBTO Recommendations 2011 (1)

- Valid consent for blood transfusion should be obtained and documented in the patient's clinical record by the 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.

SaBTO Recommendations 2011(2)

- The consent standard developed by Health Improvement Scotland (formerly NHS Quality Improvement Scotland) should be adopted throughout the UK for consent for blood transfusion.
- 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.

SaBTO Recommendations 2011(3)

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

SaBTO Recommendations 2011(4)

- 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.
- The Care Quality Commission (CQC), NHS Litigation Authority (NHSLA) and equivalent organisations in Northern Ireland, Scotland and Wales should be aware of the consent standard for blood transfusion recommended by SaBTO.

SaBTO Recommendations 2011(5)

- A UK comparative audit of consent for transfusion should be carried out, facilitated by the National Comparative Audit of Blood Transfusion (a collaborative between the Royal College of Physicians and NHS Blood and Transplant).
- Depending on the role envisaged for Healthwatch, the potential role of patient groups in providing active oversight should be explored.

SaBTO Recommendations 2011(6)

- 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.
- Use of the LearnBloodTransfusion Landing Page e-learning package should be promoted by the UK Blood Services and Royal Colleges for all staff involved in the blood transfusion process.

SaBTO Recommendations 2011(7)

- The UK Better Blood Transfusion Network should explore the feasibility of developing a new module specific to consent and blood transfusion as part of its 2012/13 work plan.
- LearnBloodTransfusion Landing Page Completion of the e-learning package should be included in all undergraduate curricula. Reference to consent for blood transfusion should be included in the undergraduate curriculum as part of the learning objectives outlined for the principles of consent.

Consent for Blood Transfusion
Standard Recommended by SaBTO 2011

- 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.

Consent for Blood Transfusion
Standard Recommended by SaBTO 2011

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.

SaBTO

Advisory Committee on the Safety of Blood, Tissues and Organs

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)

Acute and Haemolytic Transfusion Reactions (ATR and HTR)

Transfusion-Associated Circulatory Overload (TACO)

Transfusion-Associated Dyspnoea (TAD)

Post Transfusion Purpura (PTP)

Inappropriate, Unnecessary, Under/Delayed Transfusion (IandU)

Transfusion-Transmitted Infection (TTI)

Transfusion Associated Acute Lung Injury (TRALI)

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

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

SaBTO Guidance for clinical staff to support patient consent for blood transfusion 2011

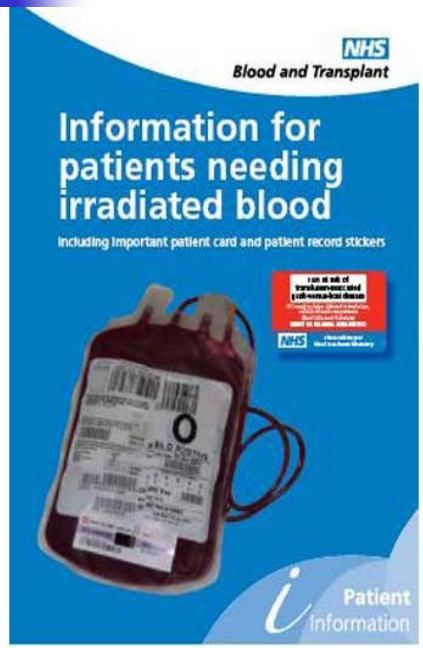
Key issues to be discussed when obtaining valid consent

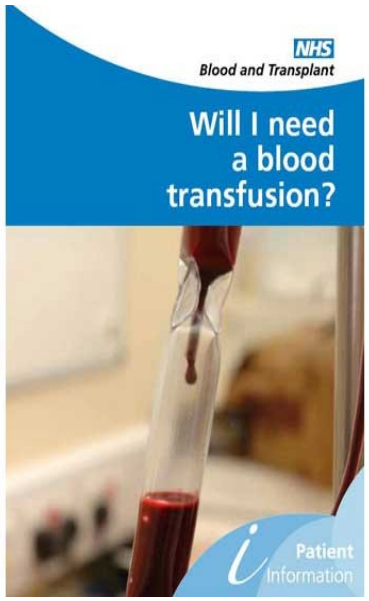
1. The following information should be discussed:
    - Type of blood / blood component
    - Indication for transfusion
    - Benefits of the transfusion
    - Risks of transfusion
    - Possible alternatives to transfusion
    - How the transfusion is administered and the importance of correct patient 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.

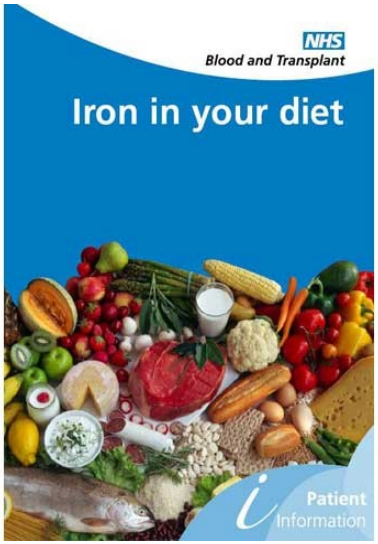
Patient Information

- **Leaflets available from NHS Blood and Transplant:**
- **nhsbt.nhs.uk**
- **Give Blood - Alternatives to blood transfusion**
- **Welcome to JPAC**

Patient Information leaflets







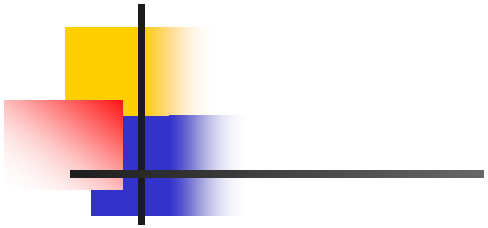
Risks of Transfusion

- Incorrect blood/component transfused (IBCT)
- Inappropriate, Unnecessary and Under/Delayed Transfusion (I&U)
- Handling and Storage Errors (HSE)
- Anti-D
- Acute transfusion reaction (ATR)- Allergic, anaphylaxis, febrile
- Delayed transfusion reaction (DTR)
- Transfusion-related acute lung injury (TRALI)
- Transfusion Associated Circulatory Overload (TACO)
- Transfusion Associated Dyspnoea (TAD)
- Post-transfusion purpura (PTP)
- Transfusion transmitted infection (TTI)

Alternatives to transfusion

- Cell Salvage
- Better Management/ Advanced Planning
- Iron/ B12/ Folate
- Reduce blood sampling
- Reduce use of drugs that affect haemostasis
- Erythropoietin
- Tranexamic Acid

Blood component prescription and observation sheet



TraceSafe BTV

BLOOD COMPONENT PRESCRIPTION AND OBSERVATION SHEET

Attach Patient Label

Full name

Hospital/NHS number

Date of Birth

Address

Consultant

GP

Ward

Date	Component / number of units	Duration / Rate	Prescribers Initials

Consent obtained by ..... Date/Time .....

Patient Leaflet offered No / Yes

Indication for transfusion: R1 ☐ R2 ☐ R3 ☐ R4 ☐ R5 ☐ R6 ☐ R7 ☐
(Tick relevant box – see Indication codes overleaf)

Pre Transfusion results: Date ..... Hb ..... g/dL Platelet count ..... Clotting Screen .....

History of Antibody / Transfusion Reaction / Allergy No / Yes (please specify) .....

Irradiated Blood required No / Yes (please specify) .....

Drug	Dose	Route	Frequency	Prescribers Initials	Date/time given	Given by

Unit No.	Checked / Set-up by	Date / Start time	Temp, BP, RR, and pulse at: Start	15 mins	End	Date / Finish time
Please affix donor pack number			Time T P BP RR	Time T P BP RR	Time T P BP RR	Max 4 hours from removal from fridge (Red cells)
Please affix donor pack number			Time T P BP RR	Time T P BP RR	Time T P BP RR	Max 4 hours from removal from fridge (Red cells)

Suspected Transfusion Reactions

Minor Reaction: Pyrexia 1-2°C from baseline and/or pruritus or rash WITHOUT other features: The transfusion can be continued with direct observation and possible treatment with oral paracetamol (Adult dose 500-1000mg) and/or antihistamines. (Adult dose of chlorphenamine 10mg IV). If hydrocortisone is required standard dose for an adult is 100mg by slow IV injection.

Moderate/Severe Reaction: Pyrexia of >2°C or >2°C rise from baseline and/or chills, rigors, tachycardia, hyper- hypo-tension, respiratory distress, collapse, chest/back/abdominal pain, nausea, flushing, urticaria, dermitis & anxiety: Stop transfusion and return implicated unit(s), call for medical assistance, maintain venous access, resuscitate and treat symptoms.

Hearthcare and Wexham Park Hospitals NHS

Trace Safe BTV

BLOOD COMPONENT PRESCRIPTION AND OBSERVATION SHEET

Unit No.	Checked / set-up by	Date / start time	Temp, BP, RR, and pulse at: start	15 mins	end	Date / Finish time
Please affix donor pack number			Time T P BP RR	Time T P BP RR	Time T P BP RR	Max 4 hours from removal from fridge (Red cells)
Please affix donor pack number			Time T P BP RR	Time T P BP RR	Time T P BP RR	Max 4 hours from removal from fridge (Red cells)
Please affix donor pack number			Time T P BP RR	Time T P BP RR	Time T P BP RR	Max 4 hours from removal from fridge (Red cells)
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Please affix donor pack number			Time T P BP RR	Time T P BP RR	Time T P BP RR	Max 4 hours from removal from fridge (Red cells)
Please affix donor pack number			Time T P BP RR	Time T P BP RR	Time T P BP RR	Max 4 hours from removal from fridge (Red cells)

Red cell transfusions must be completed within 4 hours of removal from fridge.

INDICATIONS FOR RED CELL TRANSFUSION

R1: Acute blood loss (>30-40%)
R2: Peri-operative anaemia: Maintain normovolaemia and consider transfusion if Hb <70g/L.
R3: Perioperative anaemia in patients with cardiovascular disease consider transfusion when Hb <80g/L
R4: Critical care, maintain Hb > 70g/L
R5: Chemotherapy. Guided by symptoms
R6: Radiotherapy, maintain Hb >100g/L
R7: Chronic anaemia, diagnose cause, transfusion guided by symptoms

Further copies of this document can be obtained from the Blood Transfusion department

NHS

Retrospective Information (1)

There are two key groups of patients for whom retrospective information will specifically be required:

- **1. Patients treated in an emergency setting, where it was not possible to obtain valid consent pre-transfusion due to the patient s clinical condition**

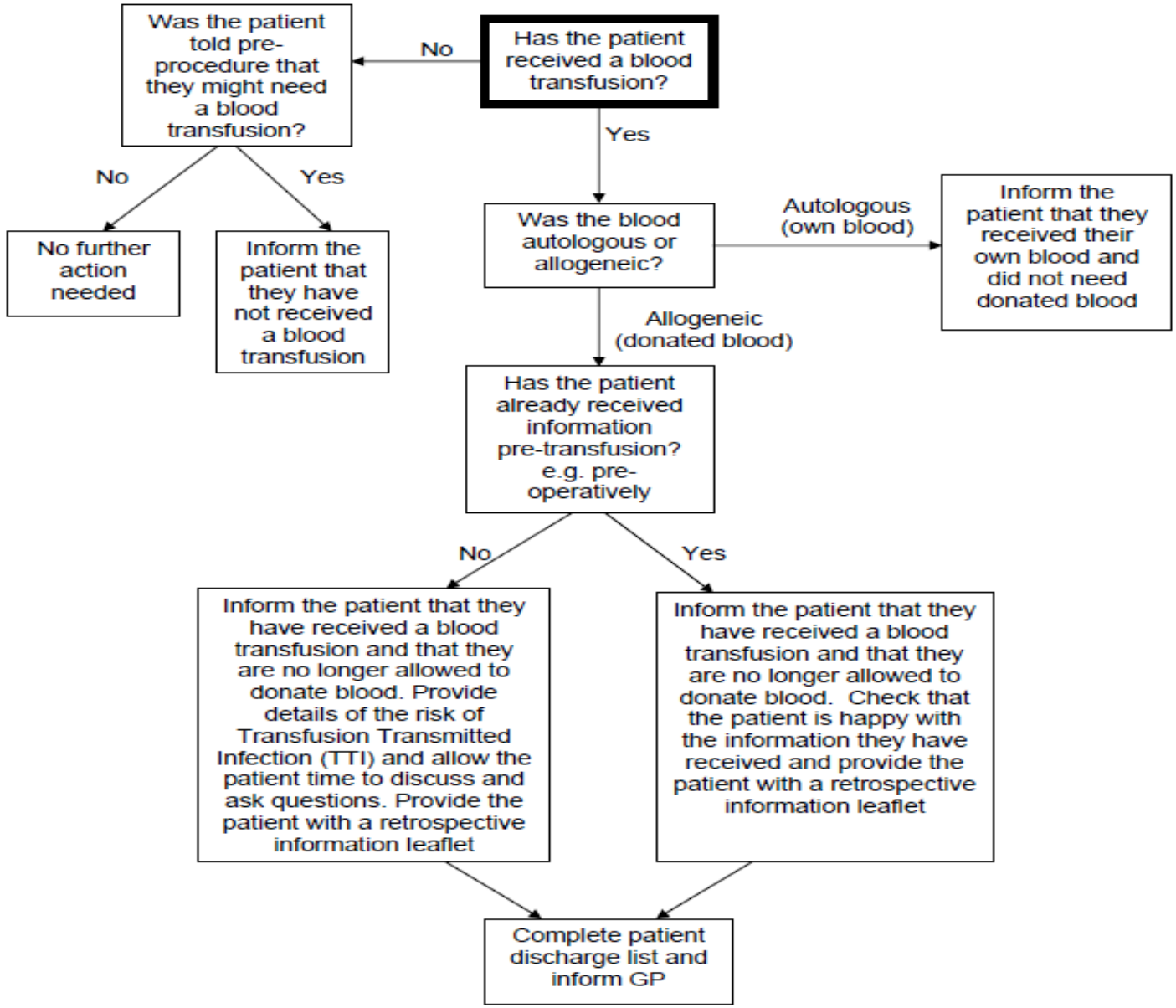
- **2. Patients who were told pre-procedure (e.g. pre-operatively) that they might require a transfusion as part of that procedure. These patients need to be informed whether they did or did not receive a transfusion.**

Retrospective Information (2)

When should patients be given retrospective information?

- **Retrospective information can be given to patients at any stage of their hospital treatment.**
- **However, in order to ensure that all patients are informed before their discharge from hospital, it is recommended that this should become part of the patient discharge procedure.**

Figure 1: Retrospective Information Flowchart



Retrospective Information (3)

- http://hospital.blood.co.uk/library/pdf/unexpected_tx_13_06_26.pdf

- **SaBTO Guidance 2011:**

  At discharge:

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