Consent for Blood Transfusion
&
Patient Information

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This presentation

- Valid (or informed) consent – what is it?
- Current national consent for transfusion guidance
- What is SaBTO?
- Why is SaBTO looking at consent for blood transfusion?
- SaBTO consent consultation and key recommendations
- Patient information

Informed consent – what is it?

- Consent can be defined as "...a patient's agreement for a health professional to provide care."

- 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."

Current national guidance: General guidance on consent

- General legal and ethical principle that valid consent should be obtained before starting treatment for a patient
- DH, GMC, RCN etc all produce guidance on obtaining consent

Current guidance for transfusion

- Department of Health mention blood transfusion in generic surgical consent form
- General Medical Council mention transfusion as a consideration

- British Committee for Standards in Haematology (BCSH):

  '*patients who may require a transfusion should have the reasons for and the risks, benefits and alternatives to transfusion explained to them. All information given, written and verbal, and consent to proceed, should be clearly documented in the patient's clinical record'*.

  (BCSH Blood Administration guidelines 2009)

SaBTO

SaBTO = Advisory Committee on the **Sa**fety of **B**lood, **T**issues and **O**rgans

Advise Ministers of the UK Government (and the Devolved Administrations) on the most appropriate ways to ensure the safety of blood, cells, tissues and organs for transfusion / transplantation

SaBTO

Produce advice and recommendations, taking into account:

- Evidence
- Scientific uncertainty
- Sufficiency of supply
- Cost effectiveness
- Risk assessments
- Consistency with other relevant legislation
- Potential impact on donors and recipients

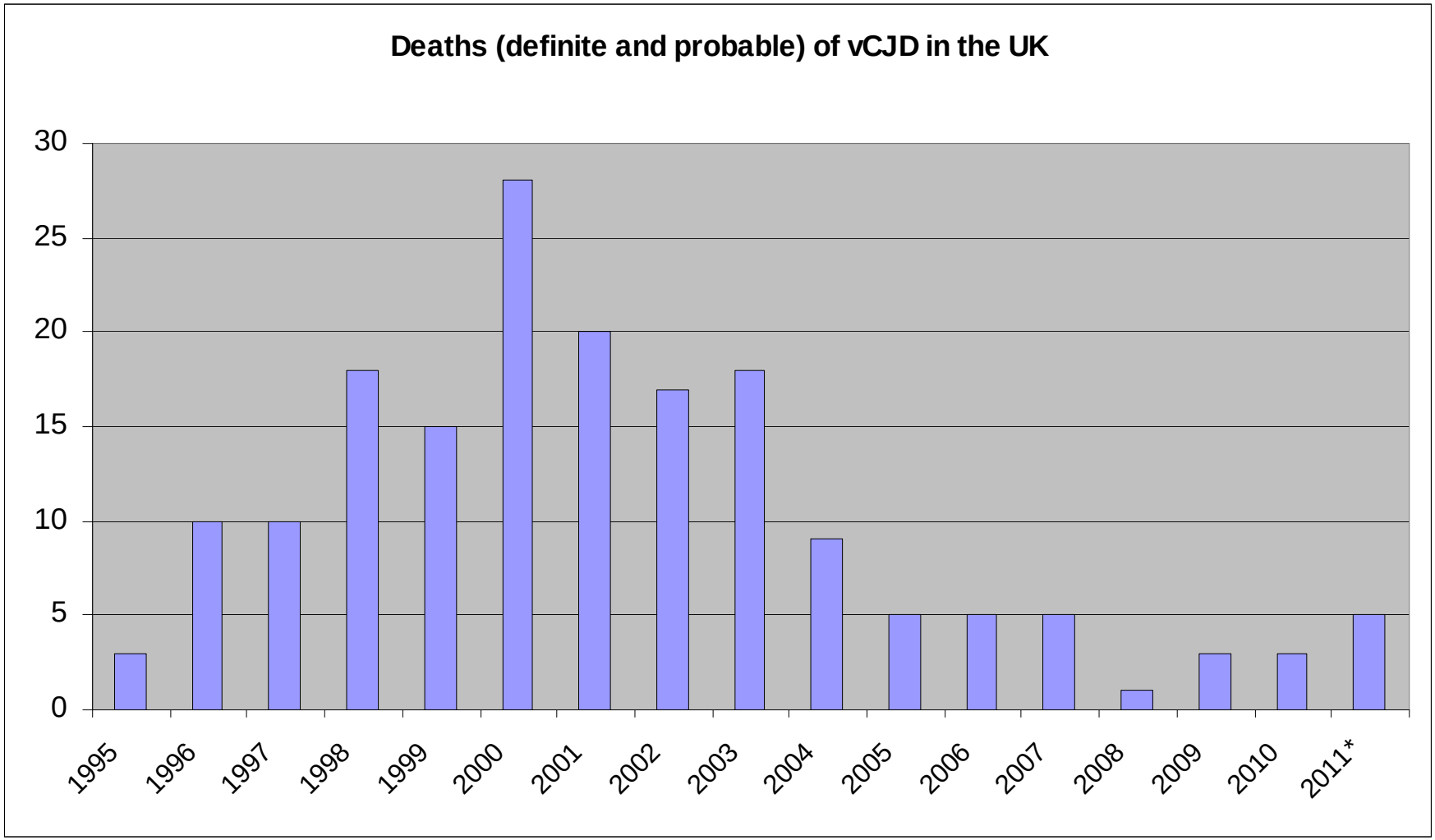
Consent for transfusion
Why are SaBTO looking at this ?

- 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 know they have received blood and may go on to donate

So why (in the UK) shouldn’t people who have received a blood transfusion donate blood?

Answer: vCJD

Since 2004, exclusion of blood donors who have previously received a blood transfusion



* As of 5th December 2011

The National Creutzfeldt-Jakob Disease
Research & Surveillance Unit (NCJDRSU)
The University of Edinburgh
www.cjd.ed.ac.uk

Variation in transfusion practice

SNBTS Survey

One third of **UK** respondents did **NOT** discuss and obtain valid consent for blood transfusion

SaBTO was asked to consider the following:

- Is SaBTO content with the status quo ?

- If NO, which of the alternative options would SaBTO like further explored ?

Working Group established to further explore:

- Verbal consent recorded in patient's clinical records by Health Care Professional

- Documentation signed by patient confirming consent has been given

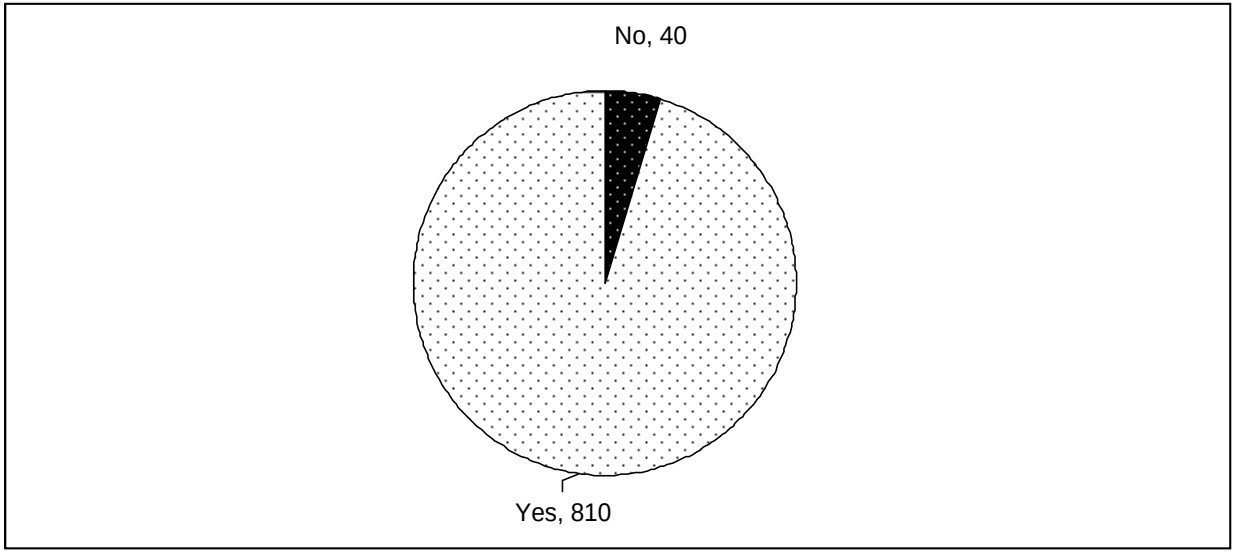
SaBTO Consent Consultation

- Launched on 3rd March 2010
- Closed on 27th May 2010
- Questionnaire for both HCPs and individuals with an interest in transfusion / patient safety
- Extensive stakeholder consultation

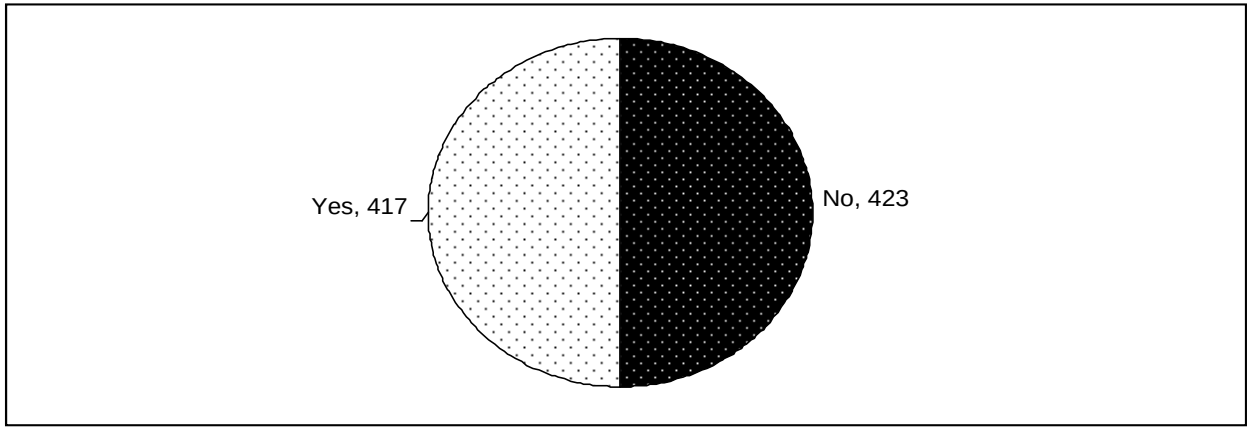
Summary of consultation results

- About 950 responses
- Good response from Professional Groups and Societies
- Good response from both patient groups and individuals
- Diverse views .....

- Do you believe that patients should be given the opportunity to consent to blood transfusion ?



- Should this be compulsory ?



Explore the potential operational impact of implementing a standardised form of consent for transfusion

- 46% or respondents stated hospital resource – finance, staff numbers and workloads.
- 35% stated patient factors – capacity, anxiety and information overload.
- 34% stated patient awareness – importance of well informed discussions, information sheets and patient leaflets.

Confirm what type of information patients should receive

- Both 72% HCP's and 82% patients thought that information on transfusions should be **both discussed and provided in writing.**

- 82% of HCP's said that **generic information or check list** would be useful to assist discussions on consent for transfusion.

- 79% of HCP's and 98% of patients thought that patients should receive **retrospective information**.

SaBTO Recommendations

- 14 Recommendations

- 3 broad categories:
  - Clinical Practice (recommendations 1-6)
  - Governance (recommendations 7-11)
  - Education (recommendations 12-14)

SaBTO Recommendations: Clinical Practice

- 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
- 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

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 who 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 letter and consider inclusion of the following statement: the patient has received a blood transfusion during this admission and has been informed that he / she can no longer be a blood donor.

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-op 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)

Pulmonary complications: Transfusion-Associated Circulatory Overload (TACO), Transfusion Associated Acute Lung Injury (TRALI) and 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 of 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 use of blood or blood component.

Long-term transfusion dependant patients

Clinicians should ensure that patients who require multiple transfusions are given appropriate information regarding the risks and benefits of transfusion. The following issues should be discussed; the overall risk of infection is increased, including unknown transmissible infections, iron overload, allo-immunisation effects including haemolysis risks (red cells) and platelet refractoriness (HLA antibodies) and febrile reactions etc.

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.ukwww.bcshguidelines.co.uk www.sign.ac.uk/guidelines/

Patient information leaflets are available from

http://hospital.blood.co.uk/library/patient_information_leaflets/leaflets/index.asp www.npsa.nhs.uk/pleaseask

SaBTO Recommendations: Clinical Practice

- 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**

Patients who have no idea that they have received blood e.g. during surgery / emergency

Patients who are told pre-operatively that they *might* need a transfusion and **did** – but because nothing more has been said, they don't think they have !

Patients who are told pre-operatively that they *might* need a transfusion **but did not** – but they still think that they have !

The type of information the patient should receive includes:

- Risks and benefits
- Why the transfusion took place
- The recipient can no longer donate blood

Retrospective information

- The type of information the patient should receive includes:
  - Risks and benefits (appropriate)
  - Why the transfusion took place
  - The recipient can no longer donate blood

SaBTO Recommendations: Clinical Practice

- 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 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

Good Practice Guidance for Retrospective Information

SaBTO

Advisory Committee on the Safety of Blood, Tissues and Organs

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

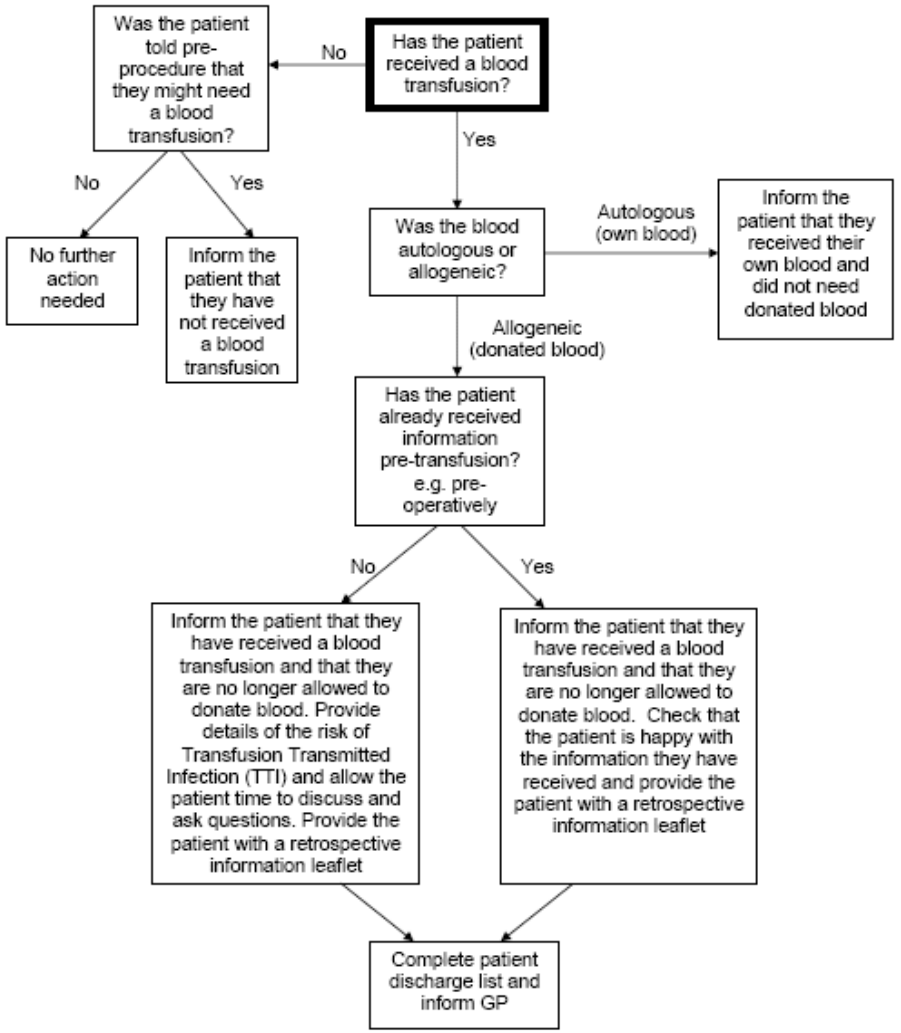
During 2010, SaBTO (the Advisory Committee on the Safety of Blood, Tissues and Organs) initiated a public consultation process to review the options for undertaking valid consent for blood transfusion and the potential operational challenges involved.

Two key recommendations resulting from this consultation process were:

- Valid consent for blood transfusion should be obtained and documented in the patients' 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.

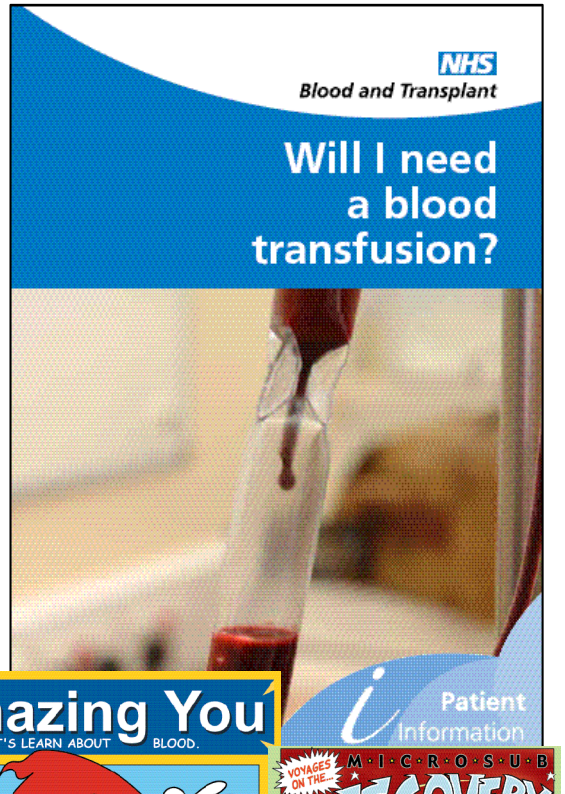
Figure 1: Retrospective Information Flowchart

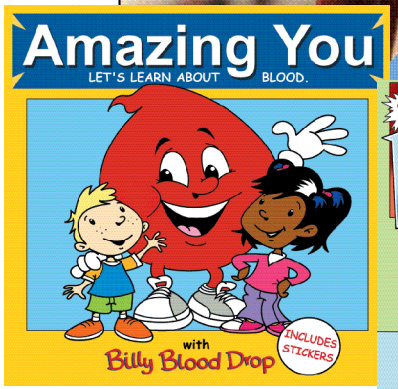


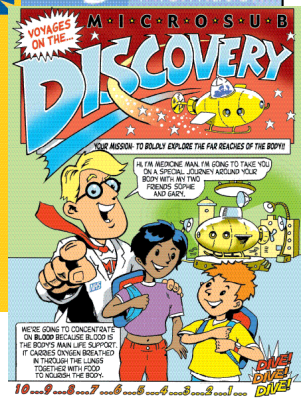
SaBTO Recommendations: Clinical Practice

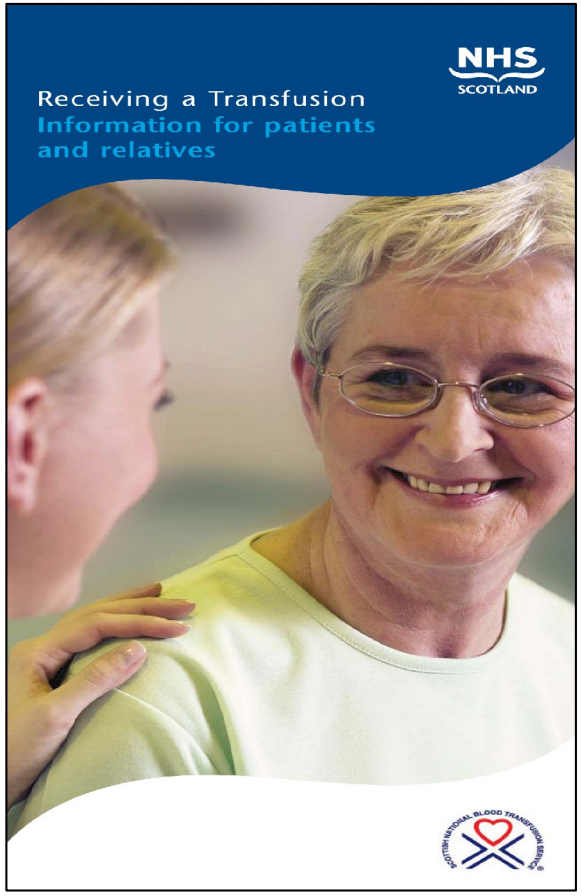
- Patients who have received a blood transfusion and who were not able to give valid consent prior to the transfusion should be provided with **information retrospectively**
- SaBTO consent working group should produce **good practice guidance** to help identify the most effective way of **providing information retrospectively** when patients were unable to give prior consent
- There should be a **standardised source of information for patients** who may receive a transfusion in the UK

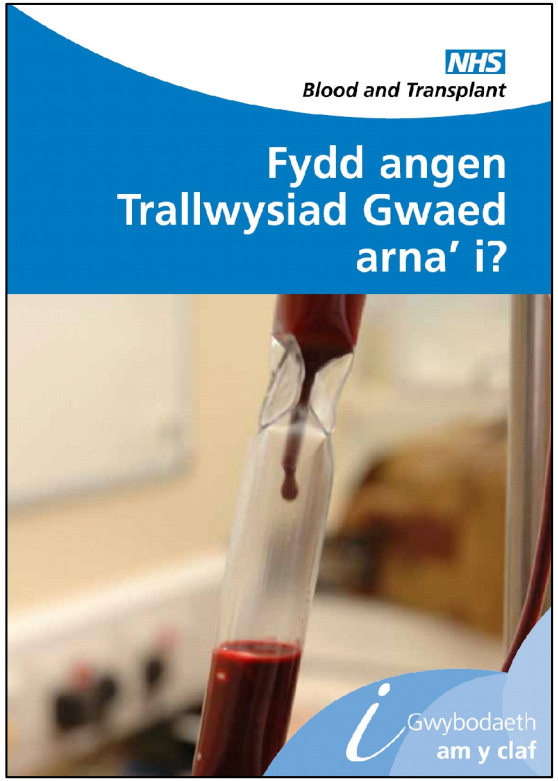
Standardised Source of Information for Patients











SaBTO Recommendations: Governance

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

Consent Standard

SaBTO

Advisory Committee on the Safety of Blood, Tissues and Organs

Consent for Blood Transfusion Standard

Consent Standard

The following standard (extract from NHS Health Improvement Scotland blood transfusion clinical standards) specifically relates to consent for blood transfusion and is the standard recommended for use in clinical practice by SaBTO.

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 HIS consent standard for blood transfusion.

Context

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, 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=

SaBTO Recommendations: Governance

- The **consent standard** developed by Health Improvement Scotland (formerly NHS Quality Improvement Scotland) should be adopted throughout the UK for consent for blood transfusion
- The **Care Quality Commission (CQC), NHS Litigation Authority (NHSLA)** and equivalent organisations in Northern Ireland, Scotland and Wales should be aware of the SaBTO consent standard for blood transfusion
- 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: Education

- 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’** e-learning package should be promoted by the UK Blood Services and Royal Colleges for all staff involved in the blood transfusion process

Learnbloodtransfusion

Current modules include:

- Safe Transfusion Practice
- Blood Components and Indications for Use
- Anti-D
- Good Manufacturing Practice for Transfusion Laboratory Staff

Contact NHSBT.CustomerService@nhsbt.nhs.uk for more information

SaBTO Recommendations: Education

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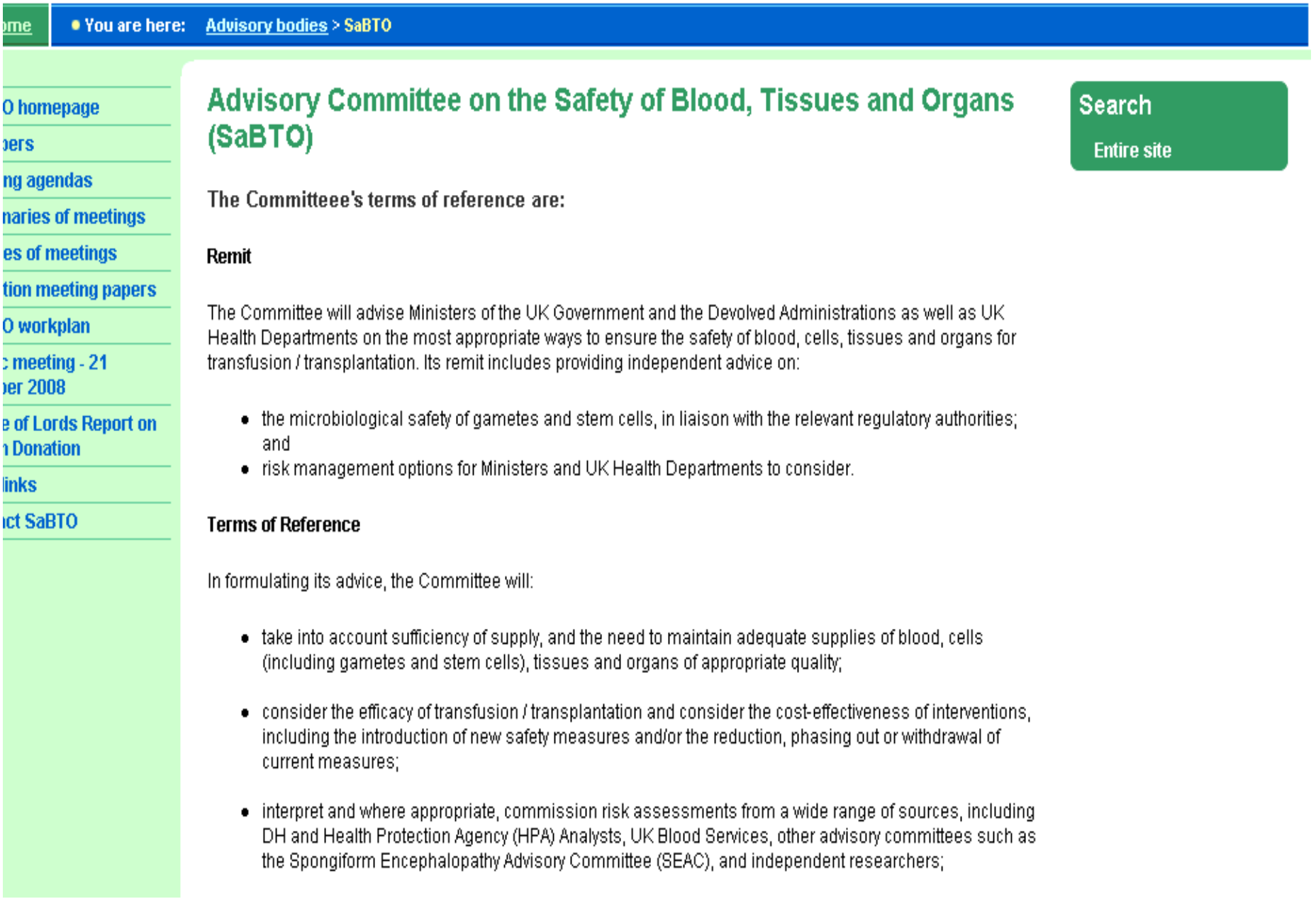
- Use of the **‘LearnBloodTransfusion’** e-learning package should be promoted by the UK Blood Services and Royal Colleges for all staff involved in the blood transfusion process
- Completion of the ‘LearnBloodTransfusion’ e-learning package should be included in all **undergraduate curricula**. Reference to consent for blood transfusion should be included in the undergraduate curriculum as part of the learning objectives outlined for the principles of consent
- 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 2011/12 work plan

www.dh.gov.uk and search for SaBTO



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The Committeee's terms of reference are:

Remit

The Committee will advise Ministers of the UK Government and the Devolved Administrations as well as UK Health Departments on the most appropriate ways to ensure the safety of blood, cells, tissues and organs for transfusion / transplantation. Its remit includes providing independent advice on:

- the microbiological safety of gametes and stem cells, in liaison with the relevant regulatory authorities; and
- risk management options for Ministers and UK Health Departments to consider.

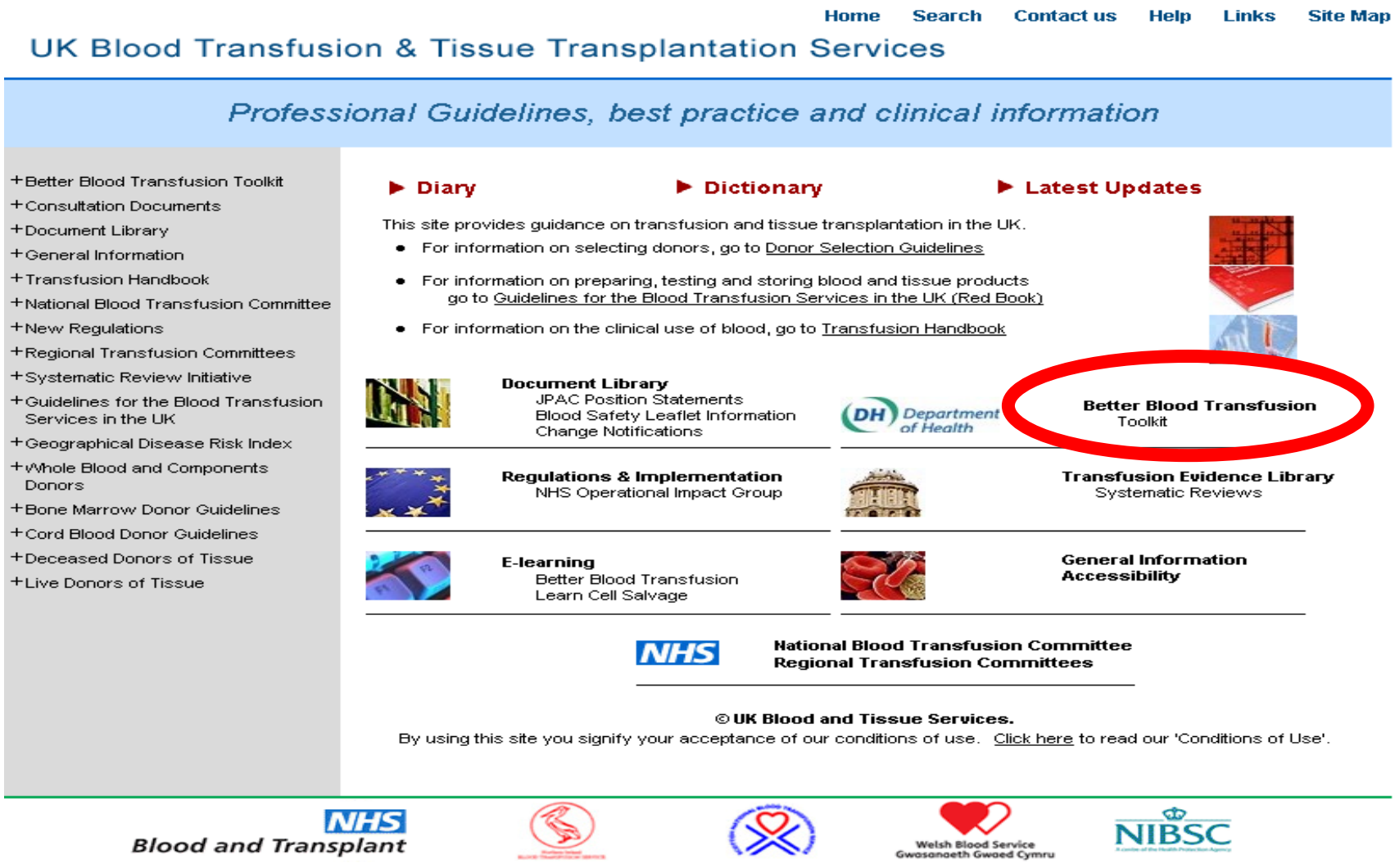
Terms of Reference

In formulating its advice, the Committee will:

- take into account sufficiency of supply, and the need to maintain adequate supplies of blood, cells (including gametes and stem cells), tissues and organs of appropriate quality;
- consider the efficacy of transfusion / transplantation and consider the cost-effectiveness of interventions, including the introduction of new safety measures and/or the reduction, phasing out or withdrawal of current measures;
- interpret and where appropriate, commission risk assessments from a wide range of sources, including DH and Health Protection Agency (HPA) Analysts, UK Blood Services, other advisory committees such as the Spongiform Encephalopathy Advisory Committee (SEAC), and independent researchers;

Better Blood Transfusion Toolkit

www.transfusionguidelines.org.uk



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