Leeds: *Written* Consent for Transfusion – why on Earth not?

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Leeds Teaching Hospitals NHS Trust

Thank you for inviting me....

Overview

- Why Leeds introduced written consent
- How we introduced it
- Audit of practice
- Have patients benefitted
- The national picture
- 2014 National Comparative Audit
- The future of written consent

2005 Transfusion Consent at Leeds...

- Audit of medical staff showed (response rate: 78/230 (34%));
  - 11% did not know if consent had been given
  - 64% did not discuss risks, benefits, alternatives
  - 1% provided written information
  - 99% respondents did not provide written information to patients as per BCSH & HSC BBT guidance
- "Improvement needed"

- Risk management not impressed with these results & concerned by the risk vCJD transmission (litigation)!

- "Written Informed Consent must be introduced"
  - Pro's & con's discussed by the Transfusion Committee

Defining Informed Consent…

- The individual giving consent has to have the mental capacity to be able to make the decision in question
- Consent has to be given voluntarily – consent where an individual has been coerced into making the decision will not be valid
- Sufficient information also has to be offered to enable the individual to understand the nature of the decision and its likely consequences, including the consequences of declining the treatment or intervention - BMA 2014

Written Consent: why on Earth not?

- Getting a patient signature is unlikely to detract from the process of obtaining *valid* consent
- Doesn't take much longer to obtain than verbal consent
- It is feasible in hospital practice and achieves a more robust documentation or *evidence trail*
- Puts patients at the heart of decisions made about transfusion
- May improve standards of information exchange & in the decision to transfuse (couldn't make it worse!)
- Red herring of emergency situations and

  patients who lack capacity- the same issues

  and regulations apply as for verbal consent

What do patients get from written consent?

- Many patients today expect to participate more in decision making * and are generally more informed on transfusion matters – of the mistakes/health concerns that is…wouldn't it be good to have the opportunity to allay fears and answer patient questions…. "power to the people"
  - Isn't that what we'd want as a patient (if not as a clinician)?

*National Voices: 9 Big Shouts (2011)

Speaking as a nurse and a relative and as a patient…

Receiving Information is Important!

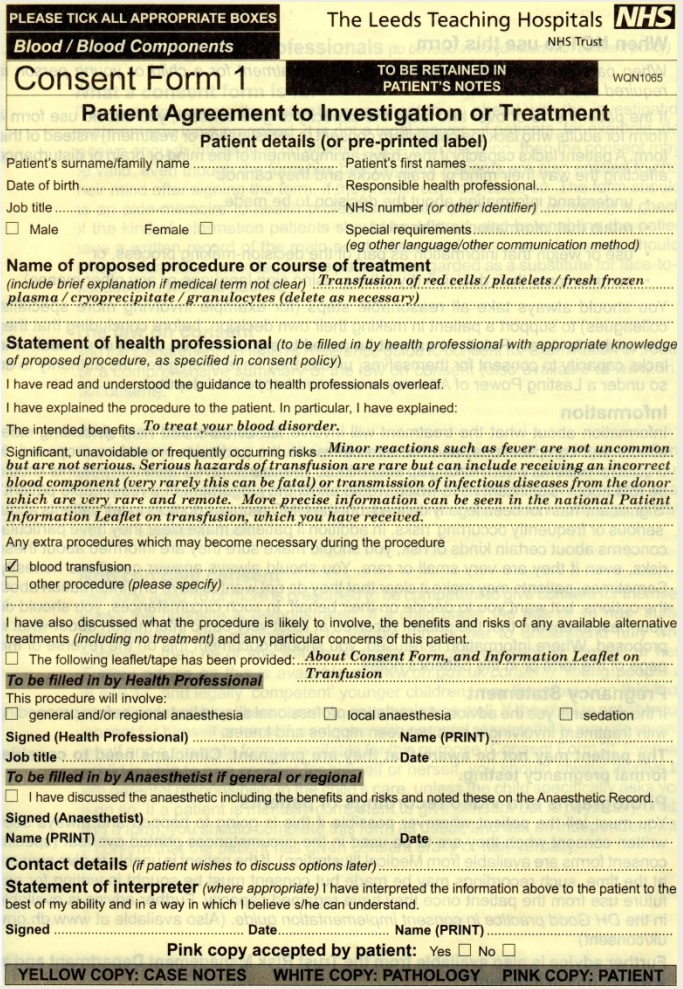
How we did it!

- **Jan' 2006** Policy drafted covering:
  - Elective & emergency admissions
  - Patients unable to provide written consent
  - Details of what to discuss; benefits, risks outlined (including statistics) & alternatives available
  - When to seek consent (pre-assessment, on admission, on diagnosis)
  - Who should seek consent
  - How to record consent

2006 Leeds: Dedicated Consent Form

Consent should be documented by describing the risks & benefits for transfusion discussed with the patient or those with parental responsibility and whether or not they agree to the transfusion

Offer a copy of signed consent to the patient & file a copy in patient case notes



PLEASE TICK ALL APPROPRIATE BOXES

Blood / Blood Components

The Leeds Teaching Hospitals NHS
NHS Trust

Consent Form 1

TO BE RETAINED IN PATIENT'S NOTES

WQN1065

Patient Agreement to Investigation or Treatment

Patient details (or pre-printed label)

Patient's surname/family name ..... Patient's first names .....

Date of birth ..... Responsible health professional .....

Job title ..... NHS number *(or other identifier)* .....

☐ Male ☐ Female Special requirements ..... *(eg other language/other communication method)*

Name of proposed procedure or course of treatment
(include brief explanation if medical term not clear) *Transfusion of red cells / platelets / fresh frozen plasma / cryoprecipitate / granulocytes (delete as necessary)*

Statement of health professional *(to be filled in by health professional with appropriate knowledge of proposed procedure, as specified in consent policy)*

I have read and understood the guidance to health professionals overleaf.

I have explained the procedure to the patient. In particular, I have explained:

The intended benefits *To treat your blood disorder.*

Significant, unavoidable or frequently occurring risks *Minor reactions such as fever are not uncommon but are not serious. Serious hazards of transfusion are rare but can include receiving an incorrect blood component (very rarely this can be fatal) or transmission of infectious diseases from the donor which are very rare and remote. More precise information can be seen in the national Patient Information Leaflet on transfusion, which you have received.*

Any extra procedures which may become necessary during the procedure

☑ blood transfusion

☐ other procedure *(please specify)* .....

I have also discussed what the procedure is likely to involve, the benefits and risks of any available alternative treatments *(including no treatment)* and any particular concerns of this patient.

☐ The following leaflet/tape has been provided: *About Consent Form, and Information Leaflet on Tranfusion*

To be filled in by Health Professional

This procedure will involve:

☐ general and/or regional anaesthesia ☐ local anaesthesia ☐ sedation

Signed (Health Professional) ..... **Name (PRINT)** .....

Job title ..... **Date** .....

To be filled in by Anaesthetist if general or regional

☐ I have discussed the anaesthetic including the benefits and risks and noted these on the Anaesthetic Record.

Signed (Anaesthetist) .....

Name (PRINT) ..... **Date** .....

Contact details *(if patient wishes to discuss options later)* .....

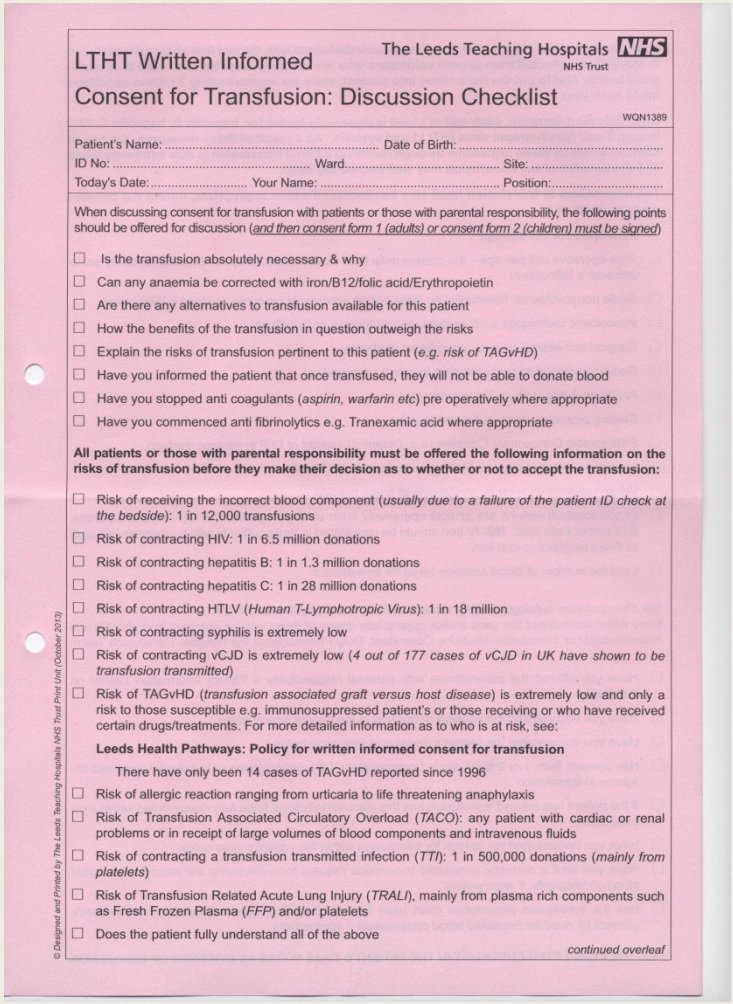
Statement of interpreter *(where appropriate)* I have interpreted the information above to the patient to the best of my ability and in a way in which I believe s/he can understand.

Signed ..... **Date** ..... **Name (PRINT)** .....

Pink copy accepted by patient: Yes ☐ No ☐

YELLOW COPY: CASE NOTES **WHITE COPY: PATHOLOGY** **PINK COPY: PATIENT**

2006 Leeds Consent Discussion Checklist



LTHT Written Informed Consent for Transfusion: Discussion Checklist

The Leeds Teaching Hospitals NHS Trust

WQN1389

Patient's Name: ..... Date of Birth: .....
ID No: ..... Ward..... Site: .....
Today's Date:..... Your Name: ..... Position:.....

When discussing consent for transfusion with patients or those with parental responsibility, the following points should be offered for discussion (*and then consent form 1 (adults) or consent form 2 (children) must be signed*)

- ☐ Is the transfusion absolutely necessary & why
- ☐ Can any anaemia be corrected with iron/B12/folic acid/Erythropoietin
- ☐ Are there any alternatives to transfusion available for this patient
- ☐ How the benefits of the transfusion in question outweigh the risks
- ☐ Explain the risks of transfusion pertinent to this patient (*e.g. risk of TAGvHD*)
- ☐ Have you informed the patient that once transfused, they will not be able to donate blood
- ☐ Have you stopped anti coagulants (*aspirin, warfarin etc*) pre operatively where appropriate
- ☐ Have you commenced anti fibrinolytics e.g. Tranexamic acid where appropriate

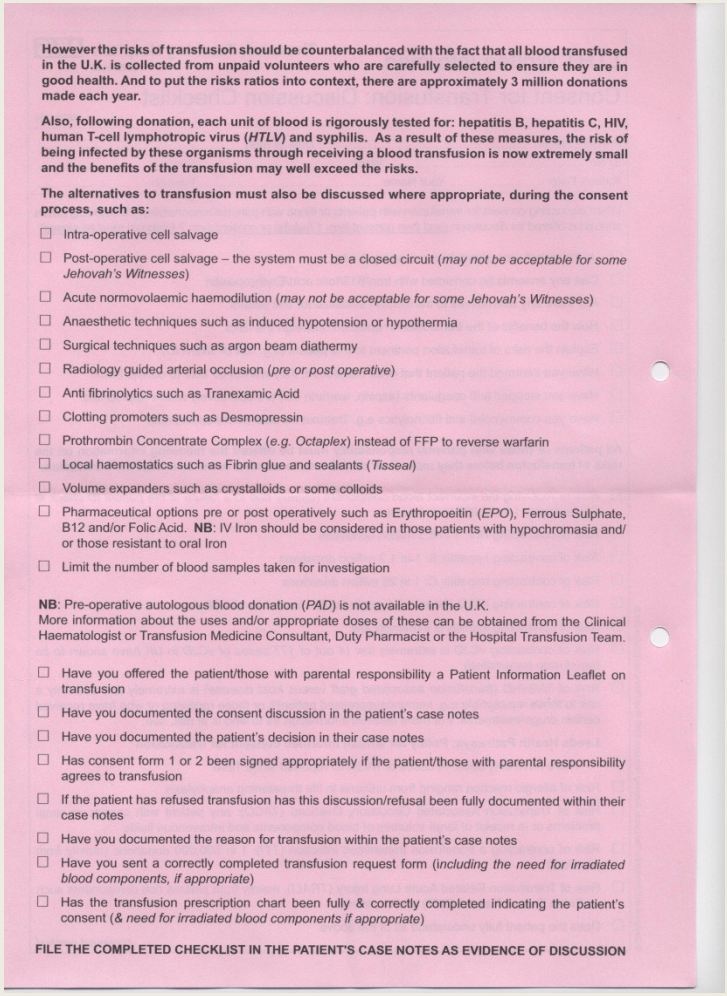
All patients or those with parental responsibility must be offered the following information on the risks of transfusion before they make their decision as to whether or not to accept the transfusion:

- ☐ Risk of receiving the incorrect blood component (*usually due to a failure of the patient ID check at the bedside*): 1 in 12,000 transfusions
- ☐ Risk of contracting HIV: 1 in 6.5 million donations
- ☐ Risk of contracting hepatitis B: 1 in 1.3 million donations
- ☐ Risk of contracting hepatitis C: 1 in 28 million donations
- ☐ Risk of contracting HTLV (*Human T-Lymphotropic Virus*): 1 in 18 million
- ☐ Risk of contracting syphilis is extremely low
- ☐ Risk of contracting vCJD is extremely low (*4 out of 177 cases of vCJD in UK have shown to be transfusion transmitted*)
- ☐ Risk of TAGvHD (*transfusion associated graft versus host disease*) is extremely low and only a risk to those susceptible e.g. immunosuppressed patient's or those receiving or who have received certain drugs/treatments. For more detailed information as to who is at risk, see:

  Leeds Health Pathways: Policy for written informed consent for transfusion

  There have only been 14 cases of TAGvHD reported since 1996
- ☐ Risk of allergic reaction ranging from urticaria to life threatening anaphylaxis
- ☐ Risk of Transfusion Associated Circulatory Overload (*TACO*): any patient with cardiac or renal problems or in receipt of large volumes of blood components and intravenous fluids
- ☐ Risk of contracting a transfusion transmitted infection (*TTI*): 1 in 500,000 donations (*mainly from platelets*)
- ☐ Risk of Transfusion Related Acute Lung Injury (*TRALI*), mainly from plasma rich components such as Fresh Frozen Plasma (*FFP*) and/or platelets
- ☐ Does the patient fully understand all of the above

continued overleaf



However the risks of transfusion should be counterbalanced with the fact that all blood transfused in the U.K. is collected from unpaid volunteers who are carefully selected to ensure they are in good health. And to put the risks ratios into context, there are approximately 3 million donations made each year.

Also, following donation, each unit of blood is rigorously tested for: hepatitis B, hepatitis C, HIV, human T-cell lymphotropic virus (*HTLV*) and syphilis. As a result of these measures, the risk of being infected by these organisms through receiving a blood transfusion is now extremely small and the benefits of the transfusion may well exceed the risks.

The alternatives to transfusion must also be discussed where appropriate, during the consent process, such as:

- ☐ Intra-operative cell salvage
- ☐ Post-operative cell salvage – the system must be a closed circuit (*may not be acceptable for some Jehovah's Witnesses*)
- ☐ Acute normovolaemic haemodilution (*may not be acceptable for some Jehovah's Witnesses*)
- ☐ Anaesthetic techniques such as induced hypotension or hypothermia
- ☐ Surgical techniques such as argon beam diathermy
- ☐ Radiology guided arterial occlusion (*pre or post operative*)
- ☐ Anti fibrinolytics such as Tranexamic Acid
- ☐ Clotting promoters such as Desmopressin
- ☐ Prothrombin Concentrate Complex (*e.g. Octaplex*) instead of FFP to reverse warfarin
- ☐ Local haemostatics such as Fibrin glue and sealants (*Tisseal*)
- ☐ Volume expanders such as crystalloids or some colloids
- ☐ Pharmaceutical options pre or post operatively such as Erythropoeitin (*EPO*), Ferrous Sulphate, B12 and/or Folic Acid. **NB**: IV Iron should be considered in those patients with hypochromasia and/ or those resistant to oral Iron
- ☐ Limit the number of blood samples taken for investigation

NB: Pre-operative autologous blood donation (*PAD*) is not available in the U.K.
More information about the uses and/or appropriate doses of these can be obtained from the Clinical Haematologist or Transfusion Medicine Consultant, Duty Pharmacist or the Hospital Transfusion Team.

- ☐ Have you offered the patient/those with parental responsibility a Patient Information Leaflet on transfusion
- ☐ Have you documented the consent discussion in the patient's case notes
- ☐ Have you documented the patient's decision in their case notes
- ☐ Has consent form 1 or 2 been signed appropriately if the patient/those with parental responsibility agrees to transfusion
- ☐ If the patient has refused transfusion has this discussion/refusal been fully documented within their case notes
- ☐ Have you documented the reason for transfusion within the patient's case notes
- ☐ Have you sent a correctly completed transfusion request form (*including the need for irradiated blood components, if appropriate*)
- ☐ Has the transfusion prescription chart been fully & correctly completed indicating the patient's consent (*& need for irradiated blood components if appropriate*)

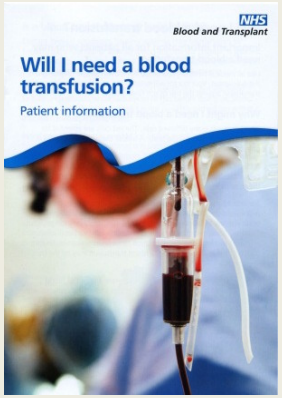
FILE THE COMPLETED CHECKLIST IN THE PATIENT'S CASE NOTES AS EVIDENCE OF DISCUSSION

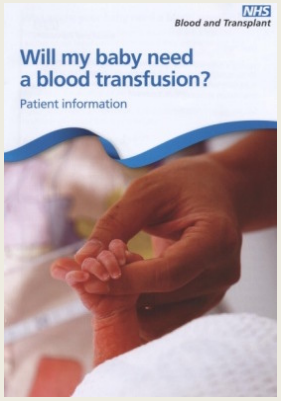
Standardised information resource indicating key issues to discuss e.g. risks & alternatives of transfusion

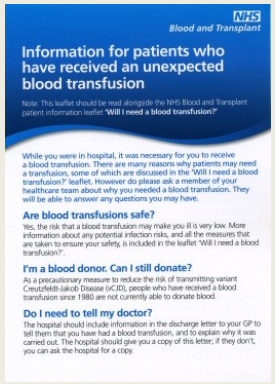
2006 Informed Consent:

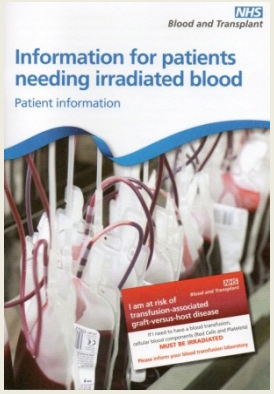
Ensure a Patient Information Leaflet (PIL) is offered and any questions are answered openly and honestly

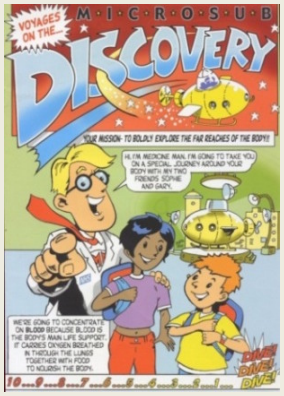
& Include PILs in pre-assessment info' packs

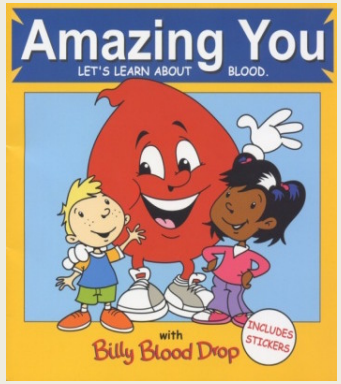












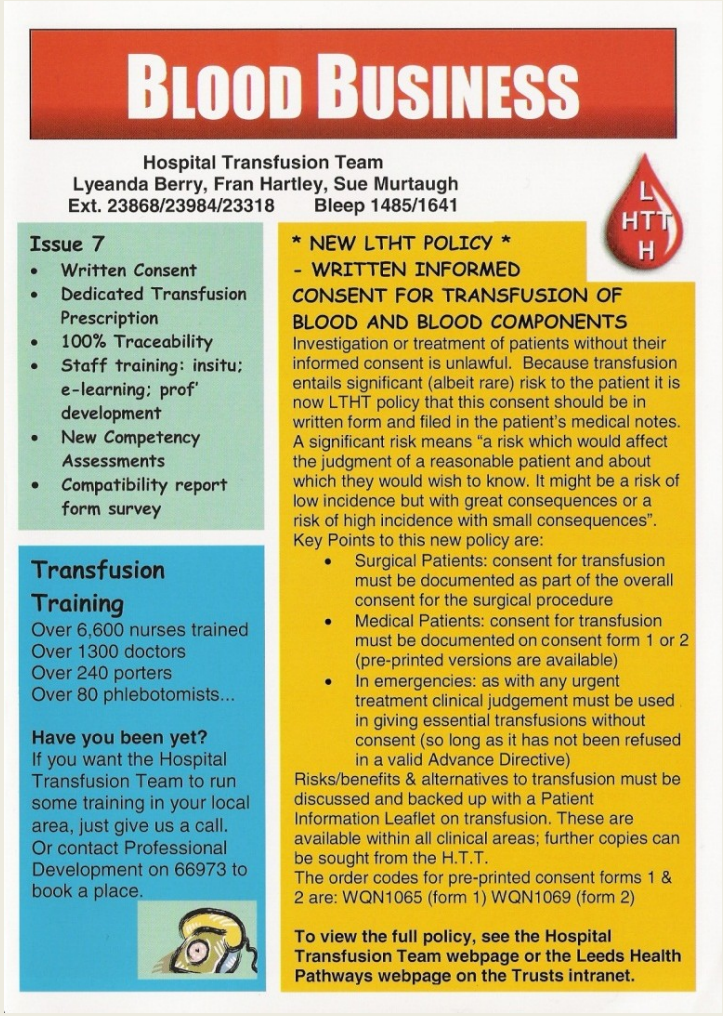
Aug' '06: Draft policy circulated to all Consultants/Heads of Nursing for comment - very little dissent (elderly care & ITU)

Nov' '06: Policy approved by Trust Board

Roll-out Action Plan:

- Publicise policy to Directors of anaesthesia, medicine, nursing, Foundation School, matrons, ward managers, educators and specialist nurses
- Train all new FY1s on consent
- Key points circulated
- Advertised on HTT webpage & newsletter and added to Trusts transfusion e-learning programme

2007: Written Consent Introduced



BLOOD BUSINESS

Hospital Transfusion Team
Lyeanda Berry, Fran Hartley, Sue Murtaugh
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L HTT H

Issue 7

- Written Consent
- Dedicated Transfusion Prescription
- 100% Traceability
- Staff training: insitu; e-learning; prof' development
- New Competency Assessments
- Compatibility report form survey

Transfusion Training

Over 6,600 nurses trained
Over 1300 doctors
Over 240 porters
Over 80 phlebotomists...

Have you been yet?
If you want the Hospital Transfusion Team to run some training in your local area, just give us a call. Or contact Professional Development on 66973 to book a place.

* NEW LTHT POLICY *
- WRITTEN INFORMED CONSENT FOR TRANSFUSION OF BLOOD AND BLOOD COMPONENTS

Investigation or treatment of patients without their informed consent is unlawful. Because transfusion entails significant (albeit rare) risk to the patient it is now LTHT policy that this consent should be in written form and filed in the patient's medical notes. A significant risk means "a risk which would affect the judgment of a reasonable patient and about which they would wish to know. It might be a risk of low incidence but with great consequences or a risk of high incidence with small consequences".
Key Points to this new policy are:

- Surgical Patients: consent for transfusion must be documented as part of the overall consent for the surgical procedure
- Medical Patients: consent for transfusion must be documented on consent form 1 or 2 (pre-printed versions are available)
- In emergencies: as with any urgent treatment clinical judgement must be used in giving essential transfusions without consent (so long as it has not been refused in a valid Advance Directive)

Risks/benefits & alternatives to transfusion must be discussed and backed up with a Patient Information Leaflet on transfusion. These are available within all clinical areas; further copies can be sought from the H.T.T.
The order codes for pre-printed consent forms 1 & 2 are: WQN1065 (form 1) WQN1069 (form 2)

To view the full policy, see the Hospital Transfusion Team webpage or the Leeds Health Pathways webpage on the Trusts intranet.

Re-audit 2008 (5 months after policy introduction)

Case notes reviewed of patients transfused over 7 days: 134 patients

- –81% cases with evidence of transfusion discussion (improved by 45% since 2005)
- –20% cases with evidence of PIL (improved by 19% since 2005)

We've proved that the process for written consent is feasible, that there is an improved *evidence* trail & at the very least, practice doesn't worsen

Clearly for consent to be valid it needs to be informed, to establish whether *informed* consent is being used ultimately we need to audit patient recall of the consent process – see 2014 NCA results

Maintaining Momentum...

- Informed consent is *policy* and is regularly reviewed
- Junior doctor transfusion consent etc training programme in place
- Transfusion consent training & awareness for all staff via HTT newsletters, generic training sessions, e-learning programme
- Regularly do leaflet drops to all wards and advertise other PILs available
- PILs included in cardiac, antenatal etc pre-assessment info' packs

Oct 2011 SaBTO* Recommendations:

Informed consent signed by HCP as a minimum – patient signature is recommended. Success assisted by:-

- Standardised Information:
  - Checklist of key issues to discuss
  - Modified consent for multiple transfused
  - Retrospective transfusion information

- Better patient education (risks & retrospective info) and Patient Information Leaflets

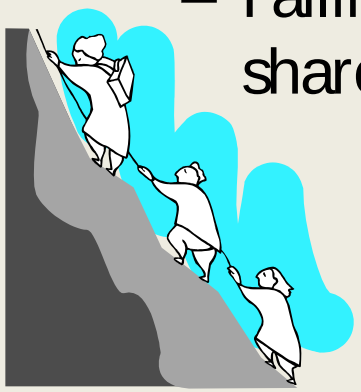
- Monitored by:
  - CQC / NHSLA / NCA / HTT

*Advisory Committee on the Safety of Blood, Tissues & Organs

Challenges…

- The concept of *documenting* the transfusion discussion (i.e. risks/ benefits) is still alien to a minority of some stalwart staff

- We all need to work out how to engage them – any ideas gratefully received!
  - Maybe the NCA results will convince them
  - Failing that, scary case studies could work…feel free to share them & any lessons learned



2014 National Comparative Audit Results

Key Findings:

This is the largest UK audit to date of practice around the provision patient information and consent for blood transfusion. SaBTO recommendations 2011 were used as the standards for this audit of practice

141 sites completed the organisational survey with virtually all indicating that they had a policy on consent for transfusion, which included the need to provide information to patients. The proportion of patients receiving written information on risks and benefits and alternatives to transfusion was overall low, demonstrating a major discordance with written policies within Trusts.

164 centres provided patient data on 2,784 cases for the case note documentation audit

Clinical Indication for Transfusion Recorded in Case Notes	Evidence of Consent	Consent Obtained by Doctors	Evidence of PIL being Offered
81%	43%	80% of which 72%=FY1/2s	19% in Case Notes 28% Patient Recall

NCA: Recommendations

1. All Trusts must have a policy for patient information and consent for transfusion in line with the SaBTO 2011 recommendations

2. While policies within Trusts highlight the need for obtaining valid patient consent, there is an urgent need to improve actual practice in all clinical settings with implementation of the existing guidance

3. Junior doctors in particular are involved in prescribing blood and this audit highlights an urgent need to strengthen their training in relation to consent and appropriate prescribing. Hospitals and professional bodies (i.e. medical undergraduate and foundation schools) must ensure that they receive transfusion training – in addition to patient consent this should include appropriate prescribing to overall improve appropriate use and transfusion safety

4. The development and dissemination of patient leaflets needs urgent review with a need to explore innovative methods to provide information to patients including use of information technology.

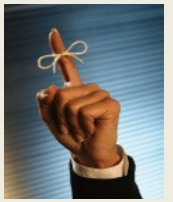
Leeds: Patient Responses in 2014 NCA

Leeds is such a large Trust & covers all main specialties perhaps we can be considered a snap shot for the positives of written consent.

Received 20 out of 24 responses

- 9 men
- 15 women
- Average age = 64 years old (range 26-90 years)
- 11 x Medical Patients
- 12 x Surgical Patients
- 1 x Obstetric Patient

Leeds: Patient Survey Results



*NB: survey of patient *memory*

	Involved in Transfusion Decision Making Process?	Did you Receive Written Information?	Were the Possible Risks of Transfusion Discussed?	Were the Benefits of Transfusion Discussed?	Were you Offered any Alternatives to Transfusion?	Were you Given the Opportunity to Ask Questions?	Do you Feel you Received Enough Information on Transfusion?
Yes	12 (60%)	10 (50%)	13 (65%) 83% in LTH case note evidence*	16 (80%) 88% in LTH case note evidence*	1 (5%) 25% in LTH case note evidence*	15 (75%)	15 (75%)
No	2	5	3 (!)	2	13 (!)	2	2
Certain Degree	4	-	-	-	-	-	-
Cannot Remember	2	5	4	2	6	3	3

Leeds: By providing a copy of the pre-printed consent form, patients at least receive information on risks and benefits to transfusion which bucks the national trend where the proportion of patients receiving written information was overall low

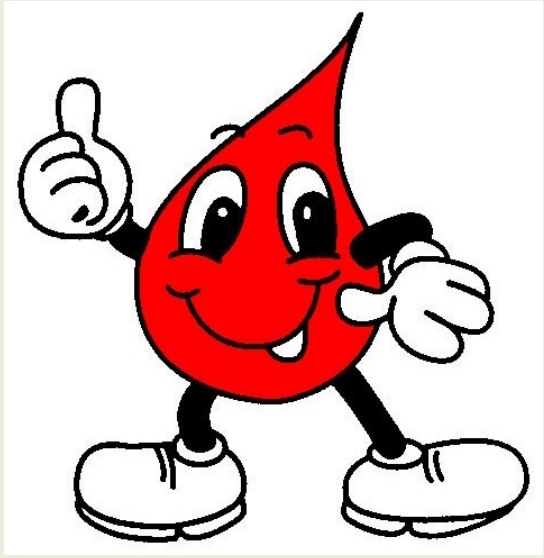
Leeds: The majority of patients (50%) remember they received written information on transfusion which again bucks the national trend of 28% and is much improved from our original audit in 2005 of 1%!

Leeds: We don't seem to have done very well in discussing alternatives to transfusion - gives us a focus for future work!

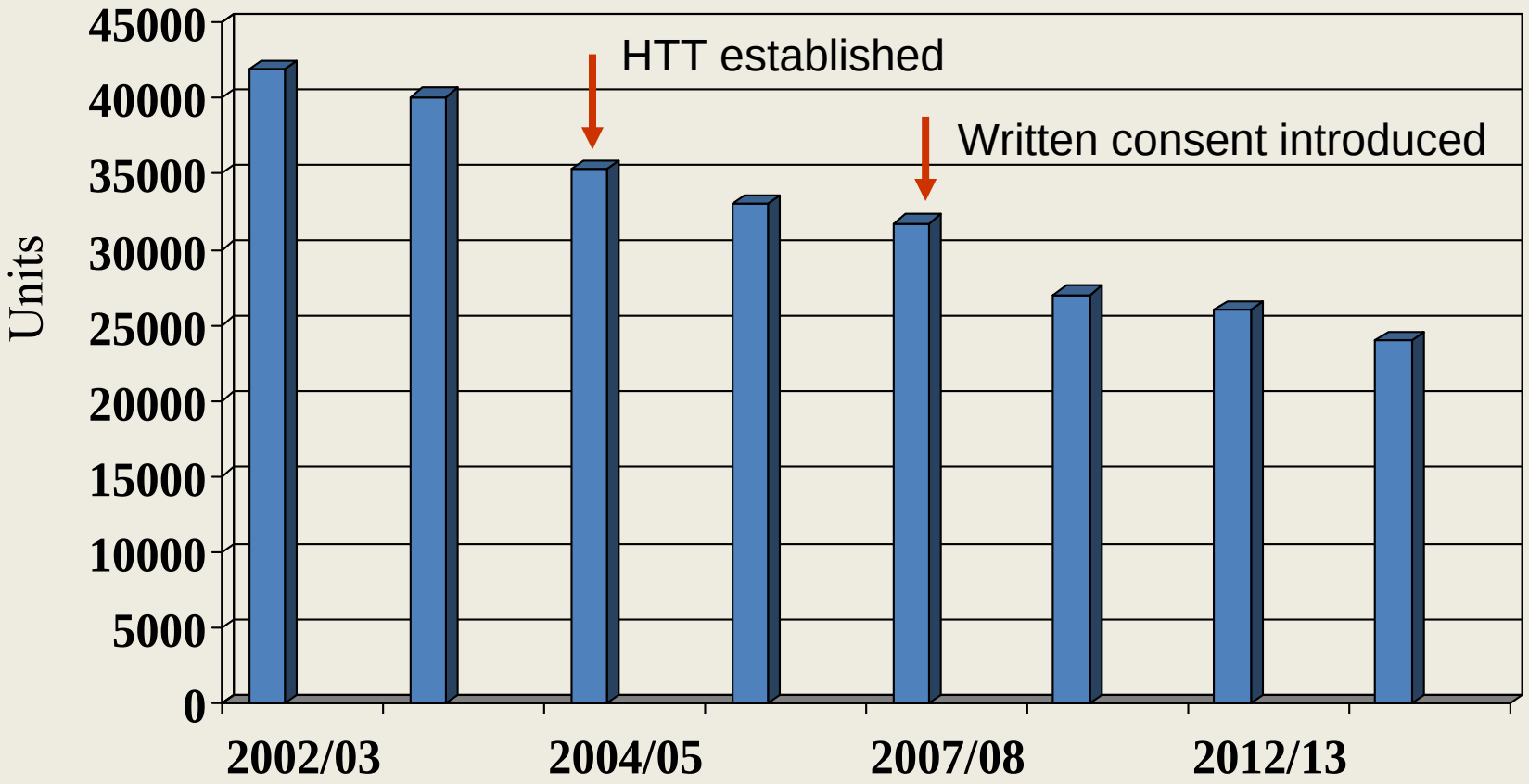
However…it would seem that Leeds patient feedback is saying that they have benefitted from the introduction of written consent and the improved 'information exchange'

& co-incidentally…

Since the introduction of written consent red cell in 2007 red cell usage in Leeds has reduced by 25% - perhaps because the 'speed bump' of obtaining written consent has helped clinicians to further rationalise the need for transfusion?

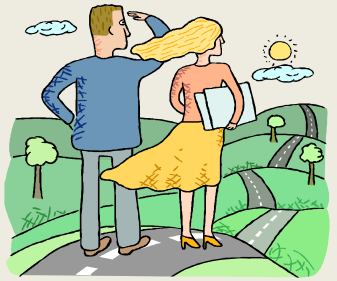


Change in Red Cell Issues
Leeds TH NHS Trust 2002-2014



- Co-incidental Reduction of 25% RBC, Saving £97,600 at 2014 prices

What does the future hold?...



Apart from possibly helping to reduce blood use, the use of written consent for transfusion doesn't detract from patient care, indeed it seems that patients have benefitted from the now ingrained practice of offering transfusion information and discussing its pro's and con's.

To continue improving the quality of the transfusion consent process we can:

- Further promote the use of alternatives to transfusion (October HTT Newsletter)
- Look into advanced nurses obtaining transfusion consent
  - Alleviate pressure on doctors
  - Training in both consent & indications for transfusion (alongside training for nurse 'authorisation' of blood components)
- Examine the use of local 'Champions' of informed consent for transfusion to embrace and encourage its use and value to patients

References:

BMA, 2014: http://bma.org.uk/practical-support-at-work/ethics/consent-tool-kit

National Voices, people shaping health & social care: www.nationalvoices.org.uk

NHSBT, Patient Information Leaflets:
http://hospital.blood.co.uk/patientservices/patient-blood-management-resources/patient-information-leaflets/

SaBTO (Department of Health) Report, 2011: Patient Consent for Blood Transfusion:
http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_130716?ssSurceSiteId=ab

Transfusion Guidelines Web & Consent:
http://www.transfusionguidelines.org.uk/Index.aspx?Publication=BBT&Section=22&pageid=7691

Thank You