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

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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!
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
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.
2006 Leeds Consent Discussion Checklist

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
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*
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.

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

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

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:


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/
