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National Comparative Audit of Blood Transfusion: report on the 2014 audit of patient information and consent

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SUMMARY

Objectives: The aim of this study was to assess current practices around obtaining consent for blood transfusion and provision of patient information in hospitals across the UK and identify areas for improvement.

Background: Recommendations from the Advisory Committee on the Safety of Blood, Tissues and Organs (SaBTO) (2011) state that valid consent should be obtained for blood transfusion and documented in clinical records. A standardised source of information should be available to patients. Practices in relation to this have historically been inconsistent.

Methods: The consent process was studied in hospitals across the UK over a 3-month period in 2014 by means of an audit of case notes and simultaneous surveys of patients and staff.

Results: In total, 2784 transfusion episodes were reviewed across 164 hospital sites. 85% of sites had a policy on consent for transfusion. Consent was documented in 43% of case notes. 68% of patients recalled being given information on benefits of transfusion, 38% on risks and 8% on alternatives and 28% reported receiving an information leaflet. In total, 85% of staff stated they had explained the reason for transfusion, but only 65% had documented this. 41% of staff had received training specifically on transfusion consent in the last 2 years.

Conclusions: There is a need to improve clinical practice in obtaining valid consent for transfusion in line with existing national guidelines and local Trust policies, with emphasis on documentation within clinical records. Provision of patient information is an area particularly highlighted for action, and transfusion training for clinicians should be strengthened.

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The UK healthcare system is increasingly moving away from a paternalistic, physician-led service to a model of patient-centred care in which individuals are fully involved in decisions about their treatment. Central to this is the need to obtain informed, valid consent for medical interventions. The UK General Medical Council (GMC) issued guidance in 2008 which set out the principles for good practice in making decisions, including the need to discuss the available options for treatment and give information about the potential benefits, risks and burdens of each (GMC, 2008). Obtaining valid consent for treatment is a legal requirement under common law, as detailed by the UK Department of Health guidance (Department of Health, 2009). This was further strengthened by the case of Montgomery vs. Lanarkshire in 2015, which found that doctors had failed to fully inform the plaintiff of a potential medical complication and emphasised the responsibility of healthcare professionals to engage in dialogue with patients and discuss any material risks inherent in their treatment (Supreme Court, 2015).

Blood transfusion may occur either as a sole clinical intervention or be part of another treatment such as a surgical procedure, in which case it may carry a lower risk than the primary intervention. GMC and the Department of Health guidance did not specify whether separate consent was required. Practice was historically known to be inconsistent, and opinions of professionals were divided. In 2010, the Advisory Committee on the Safety of Blood, Tissues and Organs (SaBTO) carried out a public consultation of healthcare professionals and patients regarding consent for blood transfusion and subsequently issued a series of recommendations (SaBTO, 2011). These state that valid consent for blood transfusion should be obtained and documented in the patient's clinical record. A standardised source of information should be available to patients. A further recommendation was that a UK National Audit of consent should be carried out to establish baseline practice and highlight areas for improvement. This was completed in 2014 by the National Comparative Audit of Blood Transfusion.

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Aims of the national audit

This large UK audit was intended to provide a snapshot of current practice regarding consent for blood transfusion and provision of patient information. It aimed to assess the extent to which patients are involved in the decision to transfuse, whether they are provided with sufficient information to enable a fully informed choice, in what form information is given and whether the discussion and final decision are clearly documented in the patient's notes.

The audit standards were drawn from the 2011 SaBTO recommendations, namely:

1 The patient's record should contain evidence that consent was obtained for transfusion; that benefits, risks and alternatives were discussed; and that written information was provided.
2 Staff involved in prescribing and administering transfusion should be aware of the availability of patient information leaflets in clinical areas and as a web-based resource.

From this comprehensive overview, priorities for action to improve practice could be ascertained.

MATERIALS AND METHODS

All NHS hospitals in England were asked to take part, and hospitals in Scotland, Wales and Northern Ireland were also invited by using the blood services in these regions to encourage participation. Data were collected over a 12-week period from January 13th to April 4th 2014 using four tools:

1 Organisational questionnaire: To assess hospitals' existing policy of consent for transfusion, availability and nature of written patient information and the provision of training for staff.
2 Case note audit: A retrospective evaluation of the documentation of discussions, consent and the provision of written information to patients who had undergone a blood transfusion.
3 Patient survey: Given to the recipients of those transfusions to gather their recollections of discussions beforehand and the information they had received.
4 Staff survey: Given to the individual prescribers of those transfusions to determine what discussions they had had with patients and what written information they had provided. This was also used to assess which professionals were involved and what transfusion training they had received.

For the duration of the study period, sites were asked to select two adult, elective patients each week who had undergone a red cell transfusion. The auditor would ask the blood bank to identify red cell units recently issued and then visit clinical areas about an hour after the blood was collected. This enabled them to approach the patient receiving the transfusion, identify and locate the clinician prescribing the transfusion and access the case notes, thus completing and compiling the three surveys. Only patients alert, conscious and able to consent were included. Patients needing an emergency transfusion and those not able to understand the English language were excluded.

RESULTS

Data were obtained from 173 sites: 154 in England, 14 in Wales and 5 in Scotland; 132 provided both organisational and clinical data, 9 organisational data only and 32 clinical only. This covered 2784 transfusion episodes.

Organisational survey

In total, 141 sites completed the organisational questionnaire; 85% (120) indicated that they had a policy on consent for transfusion, with 93% (131) requiring staff to discuss the benefits, risks and alternatives of transfusion with patients and document this in the notes in line with SaBTO guidelines. Signed written consent was a requirement at 18% (25) of sites. Less than half delivered training sessions specifically on consent for transfusion to medical staff. 89% of sites (125) had a policy on the provision of patient information, with 77% (108) reporting that written information was given routinely to patients. Of these, 94% (101) provided a leaflet supplied by the respective national blood service.

Case notes audit

In total, 164 sites provided clinical data. The median number of cases submitted per site was 18 (IQR 10–24). Most transfusions took place during working hours – 08:00–20:00 (77%, 2146) – and 94% (2598) were on week days. The median age of patients was 74 years (IQR 61–82), and 53% were female. The largest specialty represented was medicine (42%) followed by surgery (33%) and haematology–oncology (20%).

The indication for transfusion was documented in 81% (2251) of cases. Overall, 43% (1192) had documentation of consent, which was similar for both inside or outside working hours. This was predominantly recorded as verbal consent, with a written consent form present in 22% (267). The documentation specified that there had been discussion of the reason for transfusion in 37% (1017), risks in 23% (629) and potential alternatives in 17% (474). Provision of written information was documented in 19% (519).

Table 1 shows which staff were responsible for obtaining consent. In the majority of cases, this was a doctor, and 72% of these doctors were junior trainees in their first 4 years of practice, middle grades or locums.

Patient survey

In total, 2243 patients completed the survey form, representing responses from 81% of those whose case notes were audited; 76% (1714) recalled somebody speaking to them about blood transfusion, with 74% (1659) feeling they were involved with

Table 1. Staff obtaining consent for transfusion

	Number (total 1192)	Percentage
Consultant	101	8
Registrar	150	13
FY1/2 – Middle Grade – CT – Locum	655	55
Nurse practitioner	215	18
Other[1]	45	4
Not stated	26	2

[1]Other included: not known (29), midwife (4), CNS (4), ward manager (2), dietitian (1), pharmacist (1), radiographer (1), deputy clinical leader of ward (1), blood transfusion pathway pilot (1).

Table 2. Reasons given by staff for not explaining the rationale for transfusion to the patient

	Number (total 228)
Someone else did it	85
Patient already on transfusion	42
Patient unable to understand	25
Patient unable to communicate	16
No time	4
Did not occur to me	4
Blood prescribed elsewhere	2
Lack of communication	2
Other	11
Not known	37

the decision to transfuse, although for 18% (407), this was only to some degree. Only 28% (631) reported receiving written information. 68% (1534) said the benefits of transfusion were discussed, 38% (858) had the potential risks explained, and just 8% (184) recalled that an alternative had been offered – in most cases this was iron supplementation. In total, 59% (1333) stated they were formally asked to give consent, and 17% (378) recalled signing a consent form.

Overall, 75% (1686) felt satisfied with the amount of information they had received.

Staff survey

This was completed by 1663 members of staff (60% of those involved). 85% (1419) reported explaining the rationale for transfusion to the patient, although only 63% (1051) had documented this. The reasons cited for not providing an explanation are given in Table 2.

In total, 38% (629) of professionals said they had not explained any potential complications of transfusion, and just 14% (228) had discussed alternatives, with a further 24% (396) reporting they had advised that there were no suitable alternatives at this time. Only 18% (306) had provided written information.

Table 3. Training staff reported receiving in the last 2 years on appropriate use of blood

	Medical (1067)		Nursing (271)	
	Number	Percentage	Number	Percentage
e-Learning modules	676	63	114	42
Generic sessions on consent	552	52	144	53
Sessions specifically on transfusion consent	437	41	112	41

When asked about the transfusion training they had received in the last 2 years, 81% (1353) reported receiving some sort of training. This is further detailed in Table 3.

When assessed by the auditor, only 69% (1152) of prescribing healthcare professionals could summarise their hospital's consent policy, and 10% (171) were unable to locate it.

There was some discordance between the three sources of data (case notes, patient survey and staff survey). For example, 121 patients had a note in their records stating they had given consent, but they themselves said nobody had talked to them about blood transfusion. Similarly, 108 of those whose notes stated they were given written information denied receiving any, and 221 could not recall any explanation of risks being given, despite their notes documenting this. This may reflect problems with patient recollection or that the original explanation had not been understood.

In many instances, discussions appear to have taken place but were not documented; 849 patients stated having been involved in the decision to transfuse, 508 recalled having the risks explained, and 302 received written information with no mention of this in their case notes.

Comparison between the clinical specialties showed broadly similar results for rates of documentation in medical, surgical and haemato-oncology case notes, with the indication for transfusion stated in 83%, 80% and 77% of records, respectively. However, the patient survey suggested that a higher percentage of haemato-oncology patients received a full explanation of the risks and benefits of transfusion and were given written information (Fig. 1).

DISCUSSION

This observational study is the most comprehensive UK nationwide audit of practices regarding consent for blood transfusion to date, covering 2784 cases across a range of specialties at 164 sites. This included blood transfusions given both within and outside working hours and thus would seem to capture an accurate snapshot of overall blood product use and prescribing activity in the elective setting. Although the audit design was complex and labour-intensive to perform, there was a good overall participation rate, with contributions from 81% of the patients and 60% of the staff members involved.

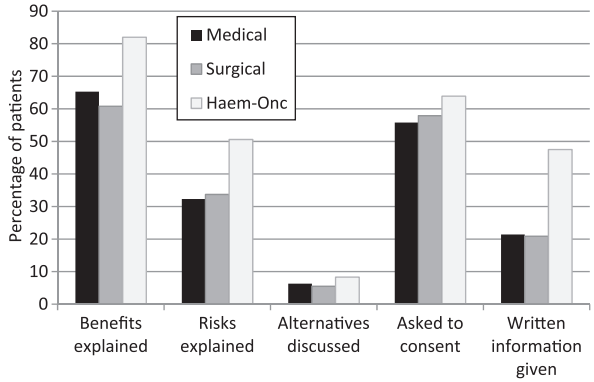

Fig. 1. Comparison between clinical specialties as reported in the patient survey.

In line with SaBTO recommendations, 85% of sites had a policy on consent for transfusion and 89% a policy on the provision of information. However, staff members were not always aware of the content of these policies or where to find them. Making hospital guidelines available on mobile devices, e.g., as a Smartphone App, can provide a convenient means for staff to locate and access information.

In the majority of cases (76%), the professional taking consent was a doctor, and of these, 72% were junior doctors below the level of Registrar. Although the survey did not collect detailed data to break down their level of training, many are likely to be in their first 4 years of practice. These individuals are generally the least experienced, and when combined with significant pressures on doctors' time, this might compromise their ability to have a detailed discussion with patients regarding the blood transfusion process and to document comprehensively in their notes. It also highlights the need to target junior doctors for education and training on local policies and the consent process.

For consent of any intervention to be considered fully informed and valid, the indication, benefits, risks and any alternatives must be explained. Although 85% of staff reported explaining the rationale for transfusion and 68% of patients could recall this, 38% of professionals acknowledged they did not discuss any risks. Worryingly, only 38% of patients responding to the survey could recollect this discussion. Even fewer professionals explored potential alternatives to transfusion – with just 14% reporting they had discussed other options. Although 59% of patients reported being asked to give their consent for blood transfusion, these findings raise the question of whether this can be regarded as fully informed consent in most cases. It may also reflect a lack of knowledge on the part of the healthcare professional involved, both of the steps in the consent process and the specifics relevant to blood transfusion. The fact that haemato-oncology patients appeared better informed might indicate a greater familiarity of clinicians working in a haematology specialty with transfusion issues and also the importance of transfusion for this patient group, who will almost inevitably receive blood products during the course of their treatment. It is also possible that more of these discussions had taken place in the outpatient setting prior to admission, where there is more time for detailed explanations and better access to written information.

Only 41% of medical staff reported receiving training sessions specifically on transfusion consent. There is a need to strengthen transfusion teaching in undergraduate training programmes so that emerging junior doctors have the confidence to undertake these discussions. Transfusion consent could be incorporated into the curriculum for Foundation trainees, which would then require them to provide evidence to demonstrate their competence in this skill. Thoroughly working through the consent process also acts as a prompt for a clinician to review the appropriateness of a blood transfusion and to actively consider other options. This should help to encourage multidisciplinary, patient-centred care, which is the key principle of Patient Blood Management.

The consent process should be a two-way discussion between patients and the clinician, reaching a consensus about the best path of care. Just over half (56%) of patients felt they had been involved in the decision-making process, with a further 18% reporting they had been involved to a certain degree. Although some individuals, particularly of the older generation, may prefer leaving decisions regarding their care entirely in the hands of the medical team, the fact that one in five patients stated they did not feel at all involved in the decision to give a blood transfusion remains a concern. This audit found some discrepancy between staff and patient reports of information giving. This may reflect difficulty with patient recollection or lack of understanding of information, particularly at a time when they are unwell, anxious or fatigued. Nonetheless, 75% of those patients interviewed felt they had received enough information about having a transfusion.

Despite the recommendation of local and national policies (77% of sites stating that patients were routinely given written information on transfusion), this audit found the provision of information leaflets to be particularly poor. This was a reproducible finding across the case notes audit (19% documented as having been given), patient survey (28% recalled receiving) and staff survey (18% stating they had given). Information leaflets have been shown to be an effective means of informing patients about blood transfusion (Court *et al.,* 2011), and NHSBT leaflets are provided free of charge to all hospitals in England. Given the limited time available for discussion between patients and healthcare professionals and poor patient recollection of information given at times when they are acutely unwell, this highlights an area for urgent action. Educational videos may improve patient understanding of the risks, benefits and alternatives to transfusion (Cheung *et al.*, 2014), and mobile devices could make these accessible in the in-patient setting. Although innovative methods of providing information, such as online or via Smartphone Applications, may be a future option, there could be challenges introducing these to hospitals due to technical capacity (particularly availability of wireless network or mobile signal). At present, not all patients will be familiar with or have access to this technology, including potentially more of the

older age group who make up the majority of blood transfusion recipients.

This study has highlighted a significant problem with documentation around the consent process. Consent is predominantly given verbally – written, signed consent was obtained from only 22% of patients, and only 18% of sites have a policy requiring this. This makes an accurate, permanent record even more essential. Although the indication for transfusion could be found recorded in 81%, consent was only documented in 43% of case notes. There was even poorer recording of the details of any discussion with the patients, with mention of explanations of the rationale, risks and alternatives documented in only 37%, 23% and 17%, respectively. There may be a role for proformas and checklists as a means of standardising information giving and documenting discussions, and as many centres move towards paperless practice, electronic systems may play a part in this. Making written consent for blood transfusion mandatory could be seen as a solution but is likely to meet with considerable resistance, and would have logistical implications when transfusion is needed urgently. Some centres have designed dedicated prescription charts for blood components that incorporate a section on patient consent. This could then be seen as an essential component of the prescription itself and form a part of the nurses' final bedside check before blood is connected to a patient. There has been a call for a standardised drug chart in all hospitals nationwide to reduce the incidence of drug errors. An analogous blood prescription chart might have similar benefits and could help to standardise practice across the country.

This was the first UK nationwide audit on the provision of information and obtaining consent for elective transfusion in adults. It achieved a wide coverage, including feedback from 173 sites and capturing transfusions given across a number of clinical specialties, at a range of times and days. The study design enabled verbal consent discussions to be assessed even if these had not been documented, and the three-part data collection provided a means of verification, using three separate sources of information to assess the consent process in each case rather than relying on the recollection of one individual.

There were a number of limitations to the design of this study. Patients receiving blood transfusion in the emergency setting (such as in trauma, surgery or intensive care) were excluded, as were those lacking capacity and therefore unable to give consent – e.g., due to confusion or impaired conscious level. Paediatric transfusions were also not covered. There is a need for further studies to assess practice in these groups, including how family members are involved and how transfusions are documented and communicated for future reference. Only patients able to understand the English language were included in the patient survey as costs prohibited the use of multiple language versions. These patients are a particularly vulnerable group, and many may not be adequately included in the consent process, with limited involvement in decisions regarding their care. Even where verbal discussion is carried out through an interpreter, the limited availability of information leaflets in other languages means that they will not have information to refer back to or to answer any remaining questions. Future projects will need to make provision to allow the inclusion of non-English speakers. By definition, this audit included only individuals who had received a blood transfusion, with no attempt made to capture information on patients who had had a discussion about transfusion but declined or had been offered an alternative and accepted. Finally, the patients included in this audit were not randomly selected but were likely chosen by individual site auditors on a pragmatic basis, influenced by practical considerations such as ease of accessibility. Although each site was asked to survey two patients each week, the response rate was variable, and all data supplied were included in the final analysis. Sites performing the most blood transfusions or those with the most motivated auditors may have had a disproportionate influence on the results, and there might be a relationship between these factors and compliance with consent recommendations.

Practice regarding consent for transfusion varies both nationally and internationally. In some countries, such as Japan and California in the United States (under the Paul Gann Act), it is a legal requirement to obtain written consent for transfusion. In most regions, there are less-formalised best practice recommendations akin to the UK, but few countries have assessed compliance with these. In 2012, the Australian Blood Service carried out a national audit, on which part of the UK study was modelled. This audit (Australian and New Zealand Society of Blood Transfusion, 2012) studied 1636 red cell transfusions across 140 public and private health services. Although 95% of hospitals had a policy including a requirement for informed consent for blood transfusion, they found documentation of consent in only 75% of cases. 80% of patients reported being asked for their consent, and 69% felt involved in the decision-making process. In common with the UK experience, only 32% of patients recalled receiving written information, and verbal explanations were often incomplete, with 68% being told about the risks and just 7% about alternatives. Smaller-scale local studies in many countries, including the United States (Friedman *et al.,* 2012), South Africa (Barrett *et al.,* 2014) and Uganda (Kajja *et al.,* 2011) have shown inconsistent communication of information to patients undergoing transfusion, suggesting that adequate consent for blood transfusion is a challenge that crosses national boundaries.

CONCLUSION

In conclusion, although SaBTO have issued clear guidance in relation to patient information and consent for transfusion, and the majority of Trusts have local policies in line with this, actual practices on the ground show poor adherence to the recommendations. The provision of written information and accurate documentation of consent discussions are key areas for improvement. As most prescribers are junior doctors, they should be the focus for training efforts. There is a need for a more standardised and structured approach to providing information and giving consent to help ensure a high level of care both within and across organisations.

Key points for action are for hospitals to review their training around blood transfusion to ensure they cover patient consent. Trainee doctors should be targeted specifically, and e-learning resources could be strengthened. The development and dissemination of written leaflets should be reviewed, and where possible, information on transfusion should be incorporated into other specialist information leaflets, such as those covering particular conditions (haemato-oncology, renal disease) or surgical procedures. Innovative methods of providing information, including greater use of Information Technology, should be explored. Hospitals that have instigated successful initiatives to improve the consent process should be encouraged to share their good practices. There is a need for particular consideration of consent and information giving in those vulnerable groups not included in this study, including non-English speakers, children and those unable to consent due to temporary incapacity or clinical urgency. Further audit work should be carried out to assess existing policies and current management of these individuals to help guide a uniform standard of care.

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C. B. wrote the paper. S. A., J. G. and E. C. designed the study. D. L. analysed the data.

CONFLICT OF INTEREST

The authors have no competing interests.

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