Royal College of Physicians

National Comparative Audit of Blood Transfusion

NHS Blood and Transplant

National Comparative Audit of Blood Transfusion

2014 Audit of Patient Information & Consent

Foreword

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

In March 2010, SaBTO initiated a public consultation on patient consent for blood transfusion. Whilst it was concluded that mandating written consent would not improve the level of informed consent, the committee published a series of recommendations to strengthen the governance and oversight of consent for blood transfusion in the UK.

SaBTO commissioned the National Comparative Audit of Blood Transfusion to conduct an audit of the extent to which patients undergoing blood transfusion are involved in the decision to transfuse; are provided with sufficient information to allow them to make an informed choice, and the extent to which we can demonstrate patient-centred care through our medical records. Recent inquiries into NHS care, such as the Francis Report (2010) and Sir Bruce Keogh's inquiry into 14 underperforming Trusts, have served to highlight the need to ensure that we move away from institutional centred care towards patient-centred and then, ultimately, person-centred care.

This audit report provides encouraging evidence of the extent to which we engage our patients in their transfusion experience. Much good work is in evidence, but improvements can be made in areas of policy, training and practice to drive up the disappointingly low results achieved in documenting, for example, the discussion of risks, benefits and alternatives to transfusion.

It should be borne in mind when reading this report that the responses obtained from patients were limited by the fact that it was not possible to survey those who were not able to use the English language. Many patients were disadvantaged by this and, should this audit be repeated, consideration should be given to how we can overcome language barriers. A second consideration is that the survey was completed at some point in the patient's journey through the transfusion care pathway; discussion about transfusion may therefore have taken place at some other point in time or at some other place not covered by this audit. Further, many of the staff surveyed stated they had not discussed transfusion or given information because they had assumed someone else had done so, or that they felt it was not part of the role they were performing when they had contact with the patient.

Thus, the only way we can truly capture data on, measure, and improve the provision of information and the obtaining of consent is via the patient record. Each organisation needs to make their processes clear to staff and provide clarity about who is responsible for ensuring they are carried out. Standardised documentation will go a long way towards not only prompting the behaviour but in recording it. Ultimately, it will help us all to demonstrate our commitment to, and our achievement of, our shared goal of putting the person at the centre of the decision to transfuse.

GRO-C

Professor John Forsythe
Chair, SaBTO

GRO-C

Catherine Howell
Chair of SaBTO Consent Working Group

Acknowledgements

We wish to thank all those who have participated in the 2014 Audit of Patient Information & Consent. We recognise that those giving up their valuable time have been many and that this will inevitably have been on top of a heavy workload. This audit would clearly not be possible without their support. We are equally grateful to many colleagues for their valuable and constructive comments.

HOSPITALS THAT AGREED TO PILOT THE AUDIT

Addenbrooke's Hospital; Central Manchester University Hospitals NHS Foundation Trust; Doncaster Royal Infirmary; George Eliot Hospital; Kingston Hospital; Royal Lancaster Infirmary; The James Cook University Hospital and West Middlesex Hospital.

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Contents

Executive Summary

This is the largest UK audit to date of practice around the provision of patient information and consent for blood transfusion. The SaBTO recommendations 2011 were used as a standard for this audit of practice in adult patients receiving elective transfusions.

132 sites were able to contribute both organisational and clinical data, while some provided either one or the other: 141 sites completed the organisational survey with the majority (85%) indicating that they had a policy on consent for transfusion, which included the need to provide information to patients. 164 sites provided patient data on 2784 cases for the case note documentation audit. The demographics were representative of the wider patient population requiring blood transfusion.

Of these, 81% had documentation of the clinical indication for transfusion in the notes. Evidence for documentation of patient consent for transfusion was found in only 43%; this was largely verbal consent.

In nearly 80% of cases, consent was obtained by doctors and of these 72% were FY1 and FY2 trainees.

While 85% of staff stated that they had explained the reason for transfusion to the patient, only 65% stated that they had documented this; it was only evident in 37% of notes reviewed that the reason for transfusion had been explained to the patient.

The proportion of patients stating that they received information on risks was only 38% and even lower at 8% for alternatives. These low levels are reflected in the case note audit with documentation that information was given on risks in 23% and on alternatives in 17%.

The lack of provision of written information to patients on transfusion should be of particular concern. These low levels were highlighted by the case note audit (19% documented as receiving these) as well as the patient feedback (28% recalled receiving these) and staff feedback (18% of staff provided these), demonstrating a major discordance with written policies within Trusts.

Despite the deficiencies as highlighted above, 75% of patients felt they had been given enough information on transfusion and had been able to ask questions. However 21% stated that they did not feel at all involved in the decision making process around receiving a blood transfusion.

The uptake of the eLearning module on patient consent and transfusion is low with only 38% of medical and 24% of nursing respondents using this.

In conclusion

- 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 and emphasis on documentation within the clinical records.
- 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. This is in keeping also with SHOT recommendations highlighting junior doctor errors.
- 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.

Summary of recommendations

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

2) The indication for transfusion should be documented in the patient records in all cases as a minimum requirement.

3) Written consent is not needed but the patient should be informed of the indication for transfusion, risks, benefits and alternatives with documentation of the above in the clinical records.

4) This particular audit captured information on elective transfusion in adults. Further audits are recommended to assess practice around retrospective information for transfusion given in the emergency setting. Paediatric practice should also be audited.

5) Hospitals should review systems for improving their practice in relation to obtaining valid consent such as incorporation of consent in patient pathways for different disciplines in the medical and surgical setting.

6) Hospitals should review training provided for blood transfusion to all healthcare professionals prescribing blood to ensure inclusion of the provision of valid consent.

7) Trainee doctors in particular FY1 and FY2 grades seem to prescribe a large proportion of blood. 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.

8) There is limited awareness and use of the LearnBlood Transfusion patient consent eLearning module. This should be promoted as part of transfusion induction and training for nurses and doctors.

9) While the blood services produce comprehensive patient information leaflets on transfusion, these are largely not being used as shown by the feedback from healthcare professionals and patients. It is now timely to review the development and dissemination of written patient information leaflets.

10) Where feasible patient information on transfusion should be incorporated into other specialist information leaflets that are provided for particular conditions e.g. different type of surgery, various haemato-oncology conditions, renal disease, etc.

11) While this audit only captured feedback from patients where English was their first language, the lessons of course apply more widely with appropriate attempts needed to overcome language barriers in better informing all patients who may need a transfusion.

12) Innovative methods of providing information to patients in addition to/alternative to written information should be explored including greater use of Information Technology.

Introduction

While there is a general legal and ethical principle that patient consent should be obtained prior to a medical intervention [1], the question of whether separate informed consent should be obtained for blood transfusion has provoked considerable debate. This issue has been specifically tackled by a stakeholder consultation undertaken by the Advisory Committee on the Safety of Blood, Tissue and Organs (SaBTO), in part prompted by inconsistent practice across the UK. The final recommendations re-enforced the need for valid consent for blood transfusion to be obtained and documented in the patient's clinical record by the healthcare professional. These recommendations were in part informed by the Scottish QIS standards[2]. While this does not entail specific written consent, valid consent does require the provision of information to patients on risks and benefits together with alternatives available with clear documentation in the clinical records [3].

There is now a plentiful supply of information leaflets on blood transfusion developed in particular by the UK Blood services but the provision of such leaflets to patients is not mandatory. The limited audit activity undertaken to date in this field has shown that although leaflets are readily available in hospitals, many patients who have been transfused do not receive this information [4, 5]. Active patient involvement is an important principle at the core of NHS policy [6,7]. This needs a robust framework for education and information not only for patients but also for the healthcare professionals involved. This National Comparative audit will help provide a comprehensive overview of current practice and highlight areas where further action is needed.

Aims of the audit

- To assess to what extent hospitals document the provision of information on blood transfusion to patients
- To assess to what extent and by what means the patient's consent to be transfused is captured in the medical record
- To survey patient awareness/recall of the information supplied to them
- To assess the knowledge of those providing information and taking consent, in respect of the local availability of information and the sort of information given
- To report on the extent to which current practice is in line with SaBTO guidance
- To facilitate improvement in documentation of consent and provision of patient information

Audit standards

The SaBTO recommendations for patient information and consent will be used as the standard for this audit.

The key standards adapted from the SaBTO recommendations to be used are as follows:

1) The patient's records contain evidence that consent for the transfusion had been obtained, that written evidence was provided and that benefits, risks and alternatives were discussed.
2). Awareness and knowledge amongst healthcare staff involved in prescribing and administering transfusion includes awareness amongst staff of availability of patient information leaflets in clinical areas and as a web based resource.

Methodology

The question set used was based on a similar audit conducted in Australia in 2012 [8] and we acknowledge their kind consent for us to replicate parts of their audit design in this audit. Sites were asked to identify 2 adult patients per week, who were having a red blood cell transfusion, and to select these patients from elective admissions only. This would allow for the information and consent process to have taken place, something which cannot always be achieved for emergency admissions or transfusions. The Site Auditor visited their blood bank to identify which clinical areas have recently collected blood for transfusion, and visited the clinical area about an hour after the blood was collected. This meant that all the clinical behaviour we are auditing should have take place by the time the auditor arrives. The auditor first checked that the transfusion was in progress and that the patient is conscious and is suitable to be approached and asked to complete a patient questionnaire. If the patient is not deemed suitable, then the auditor moved on to the next patient.

Next, the auditor reviewed the casenotes to see if there is documented evidence that consent had been obtained, written information given and that the benefits, risks and alternatives to transfusion had been discussed with the patient. If the notes indicated that it was not possible to obtain consent for some reason, then the auditor moved on to the next patient. The auditor then approached the patient and introduced himself/herself and explained the purpose of the visit. If the patient agreed to complete a patient questionnaire, then one was provided (together with a pen if needed), with an accompanying letter explaining the purpose of the survey and what the patient should do if they have any questions or concerns, and arrangements were made for the auditor to collect the questionnaire. The auditor could administer the questions at the patient's request but this was limited to reading out the questions as they are written and not providing explanations, so as to reduce the likely effects of the survey responses being influenced by the auditors' explanations.

Next, the auditor located the person who prescribed the red cells, since this person would normally be responsible for obtaining consent, etc. A staff questionnaire was given to that person and arrangements made for the auditor to collect the questionnaire. If the person prescribing the red cells was not present, then a staff questionnaire was sent to them, with

a covering letter, asking them to return the questionnaire to an agreed point within 14 days. The auditor could chase twice if necessary, but no more than this.

Finally, the auditor collated the casenote audit tool, the patient and staff questionnaires (which all contained the unique Audited Patient Number so they can be linked), and entered the data online.

Exclusions: Patients needing emergency transfusion for a surgical, medical or obstetric indication were not included. Patients who could not use the English language – consideration was given to using multiple language versions of the patient survey, but costs prohibited this and so the use of English only is acknowledged as a limitation of the audit design.

There was a concurrent project to collect data in relation to information and consent in paediatric patients but with only limited data available which will be analysed separately to this wider project in adult patients.

Organisational and clinical audit data were available for analysis from 132 sites, organisational audit data only from 9 sites and clinical audit data only from 32 sites.

Results – Organisational Survey

Organisational questionnaire data were available for 141 sites.
Your site did have organisational data

Policy on consent and information
Q1. Do you have policy on consent for transfusion?

85% (120 out of **141** sites) had a policy. Your site does have a policy

Table 1 – Nature of the policy on consent for transfusion

	National (120)		Your site
	%	n	
Q2: Hospital/Trust/Board wide?	99	119	Yes
Q3: Part of a transfusion policy?	95	114	Yes
Q4: Part of a general policy on consent?	44	53	No

Q5. Do you have policy on the provision of patient information?

89% (125 of **141** sites) had a policy, 11% (15) did not while 1 site did not state.
Your site does have a policy

Table 2 – Nature of the policy on the provision of patient information

	National (125)		Your site
	%	n	
Q6: Hospital/Trust/Board wide?	98	123	Yes
Q7: Part of a transfusion policy?	85	106	Yes
Q8: Part of a general policy on consent?	50	63	No

Q9. Do you a have specific policy for providing information if consent could not be obtained?

48% (67 of **141** sites) had a policy, 52% (73) did not while 1 site did not state.
Your site does have a policy

Q10. How is the provision of retrospective information to be documented?

Patient records	By clinician	Deprivation of liberty form	Transfusion Request/Prescription	Discharge letter
40	1	2	13	10

**Some sites had multiple methods for documentation*

Requirement for consent in your Hospital/Trust/ Board

Q11. Do you require written, signed consent for transfusion (signed by medic and patient)?

18% (25 of **141** sites) had this requirement, 80% (113) did not while 3 sites did not state.
Your site does not have this requirement

Table 3 – Nature of the requirement for signed consent

	National (25)		Your site
	%	n	
Q12: Specific (stand alone) transfusion consent	40	10	
Q13: Part of a consent form with a small transfusion section	72	18	
Q14: Other	16	4	

Q15. Do you require staff to inform the patient about benefits, risks and alternatives and document the fact in the notes?

93% (131 of **141** sites) had this requirement, 7% (10) did not.
Your site does have this requirement

Training

Q16. What training is provided for the following staff groups?

Table 4 – Training provided

National data only	Appropriate use of blood					
	Medical		Nursing		Midwifery	
	%	n	%	n	%	n
eLearning Modules	84	118	63	89	56	79
Generic sessions on consent	47	66	40	56	33	46
Sessions specifically on transfusion consent	37	52	31	44	26	37
	Patient information & consent					
	Medical		Nursing		Midwifery	
	%	n	%	n	%	n
eLearning Modules	69	97	53	75	48	67
Generic sessions on consent	55	77	48	68	43	60
Sessions specifically on transfusion consent	42	59	35	49	28	40

Q17. How is training delivered?
9% (12) delivered Face to face training, **6% (9)** delivered online training and **83% (117)** delivered both, with 3 sites not stating.

Consent process

Q18. Are patients routinely given written information?

77% (108 of **141** sites) routinely gave information, 22% (31) did not while 2 sites did not state. **Your site does routinely give information**

Table 5 – Type of information given

	National (108)		Your site
	%	n	
Q19: Leaflet supplied by NHSBT	94	101	No
Q20: Own leaflet	17	18	Yes
Q21: Other	2	2	No

Q22. Where is written patient information available?

Table 6 – availability of written information

	National		Your site
	%	n	
On all wards	80	113	Yes
On selected wards	16	23	
Central patient information point	21	30	
Other	41	58	
Not available	0	0	
No response	1	2	

Q23. How are staff informed of the availability and re-supply of written information?

Table 7 – informing staff

	National
	n
Training	80
Transfusion Practitioner	46
Intranet	34
Policy	22
Email	8
Laboratory	6
Other	9
Not known	3

Q24. Is written information for patients (about blood transfusion) available on hospital intranet?

52% (74 out of **141** sites) had information available, 47% (66) did not, while 1 site did not state. **Your site does have information available**

Results – Clinical Casenotes Audit

164 sites contributed data on 2784 cases, median 18, IQR 10-24 cases.
Your site contributed 20 cases.

Time of transfusion
24% (670) of audit transfusions took place in January 2014, 33% (909) in February 2014, 34% (952) in March 2014 and 9% (241) in April 2014, not known for 12. 77% (2146) took place between 8am and 8pm with 18% (488) between 8pm and 8am, not known for 5% (150). Transfusion Day was: Sunday (4%, 113), Monday (15%, 426), Tuesday (23%, 654), Wednesday (21%, 594), Thursday (20%, 551), Friday (13%, 373), Saturday (2%, 61), unknown for 12.

Q1. What is the patient's year of birth?
This was used to obtain patient age (= year 2014 minus year of birth). Median (IQR) age was 74 (61-82) years, n=2776. **Your site median age was 68 years, range 39 - 94, n=20.**

Q2. What is the patient's gender?
53% (1471/2772) were female, 47% (1301/2772) were male, not stated for 12.
Your site: 45% (9/ 20) were female

Q3. In which clinical speciality was the patient cared for?
Table 7 – Clinical specialties

	National		Your site	
	%	n	%	n
Medical	42	1172	45	9
Haematology/ Oncology	20	570	0	0
Surgical	33	916	55	11
Obstetric	4	114	0	0
Not stated	0.4	12		0

Q6. Is the indication for transfusion documented?
This was documented for 81% (2251), not documented for 18% (511), not stated for 1% (22). **Your site: 85% (17) were documented.**

Q7. Is consent documented for the RBC transfusion?
This was documented for 43% (1192), not documented for 57% (1588), not stated for 4.
Your site: 5% (1) were documented.

Out of hours (8pm-8am) the consent rate was 43% (923/2146). In hours (8am-8pm) the consent rate was 41% (198/488). Consent rates for Monday through Friday ranged from 40-44%, overall 42% (1099/2598). For 76 sites that audited weekend transfusions their weekday consent rate was 50% (618/1241) and their weekend consent rate was 51% (88/174).
7a. If yes, how was the consent documented?

Table 8 – form of documented consent

	National (1192)		Your site (1)	
	%	n	%	n
Written consent	22	267	0	0
Documented as verbal consent	76	908	100	1
Not stated	1	17		0

7b. Time of consent.

The number of days between when the transfusion was done and when the consent was obtained was computed for 1073 of the 1192 cases. Consent was stated as being given on the day of transfusion for 70% (748), before day of transfusion for 29% (306) and after the day of transfusion for 2% (19).

Q8. If consent was obtained, who obtained it?

Table 9 – Staff obtaining consent

	National (1192)		Your site (1)	
	%	n	%	n
Consultant	8	101	0	0
Registrar	13	150	0	0
FY1/2 – Middle grade – CT – Locum	55	655	100	1
Nurse practitioner	18	215	0	0
Other *	4	45	0	0
Not stated	2	26		0

* Other responses comprised: Not known (29), midwife (4), Consultant and CNS (4), ward manager (2), Dietician (1), Pharmacist (1), Radiographer (1), Deputy clinical leader of ward (1), Blood transfusion pathway pilot (1), and 1 case where the patient was spoken to by an FY1 but it was apparent the patient had little English and she told the auditor that the person explaining to her i.e. when spoken to about transfusions and when asked to give consent was the dinner lady.

Q9. If there is no record of consent, is there a record that the patient was unable to give consent?

There was no record of consent for 1588, and in 4% (67/1588) of these there was a record that the patient was unable to give consent. **Your site 0% (0/ 19)**

Q10. Is it documented that written information was given to the patient?

This was documented for 19% (519), not documented for 77% (2133), not stated for 5% (130). **Your site: 0% (0) were documented.**

10a. If yes, what was the nature of the written information?

	National (519)		Your site (0)
	%	n	n
Trust leaflet	15	80	
NHSBT leaflet	79	409	
Other *	3	18	
None of the above was ticked	4	22	

*Other responses comprised: Welsh blood org (4), unknown/not sure (8), Care pathway (1), Leaflet by the bed (1), Letter to the patient from the consultant (1), New pilot blood transfusion pathway (1), SNBTS leaflet (1), WBS leaflet (1).

Q11. Is it evident from the documentation that the reason for transfusion was explained to the patient?
This was documented for 37% (1017), not documented for 59% (1649), not stated 4% (118, of which 67 were unable to give consent). **Your site: 5% (1) were documented.**

Q12. Is it evident from the documentation that the risks of transfusion were explained to the patient?

This was documented for 23% (629), not documented for 73% (2043), not stated 4% (112, of which 67 were unable to give consent). **Your site: 0% (0) were documented.**

Q13. Is it evident from the documentation that alternatives to transfusion were explained to the patient?

This was documented for 17% (474), not documented for 79% (2194), not stated 4% (116, of which 67 were unable to give consent). **Your site: 0% (0) were documented.**

Patient surveys were obtained from 2243 patients, and not obtained from 541. Reasons for not being able to obtain a patient survey were stated by auditors for 395.

Q14. If no (patient survey) , what was the reason?

	National (395)		Your site (2)
	%	n	n
Patient declined	49	194	1
Patient unable to communicate	44	175	1
Patient unable to use English language	7	26	0

Results – Patient Survey

2243 patients from 162 sites (median 14 IQR 8-19) completed a patient survey form, giving a sample response of 81% of all patients whose casenotes were audited.

Your site contributed 18 patient survey forms.

Analysis

Analyses were performed to compare patient survey response by case-mix and clinical audit characteristics. There were some minor variations, though response was notably lower (defined as 70% or less) for those aged 85 and over (70%),

1. Were you involved with the decision making process about if you should receive a blood transfusion?

	National		Your site	
	%	n	%	n
Yes	56	1252	17	3
To a certain degree	18	407	22	4
No	21	462	56	10
Cannot remember	5	120	6	1
Not stated	0.1	2		0

2. Did anyone talk to you about blood transfusions?

	National		Your site	
	%	n	%	n
Yes	76	1714	44	8
No	17	384	56	10
Cannot remember	6	134	0	0
Not stated	0.5	11		0

3. If yes, can you remember who spoke to you?

	National (1714)		Your site (8)	
	%	n	%	n
Doctor	74	1270	63	5
Nurse	18	309	25	2
Other	2	26	0	0
Cannot remember	6	105	13	1
Not stated	0.2	4		0

4. Did you receive any written information about blood transfusion (leaflet, etc.)?

	National		Your site	
	%	n	%	n
Yes	28	631	0	0
No	62	1389	89	16
Cannot remember	9	210	11	2
Not stated	0.6	13		0

5. *If you answered Yes to either question 2 or 4,* when was this information given to you?
Unfortunately there was an error in the web tool that greyed out question 5 if the answer to question 2 was yes (Q2 Did anyone talk to you about blood transfusions?) Hence the response to question 5 was only applicable to those 631 who answered Yes to question 4 (Q4 Did you receive any written information about blood transfusion?)

	National (631)		Your site
	%	n	n
Before you came into hospital	13	82	
When you first came into hospital	20	125	
At the time you were told you needed a blood transfusion	59	375	
At some other time	8	49	
Cannot remember	3	18	
Not stated (Q5 left blank)	3	18	

Note: multiple responses were possible

6. Did you understand the information you were given?

	National		Your site	
	%	n	%	n
Yes	71	1600	33	6
No	9	203	22	4
Not stated	20	440	44	8

Note of caution: we are not sure why the number of unknowns should be so high for this question. This may be due to web-tool data entry problems.

7. Were the possible benefits of having a blood transfusion discussed with you?

	National		Your site	
	%	n	%	n
Yes	68	1534	44	8
No	19	434	50	9
Cannot remember	11	242	6	1
Not stated	1	33		0

8. Were the possible risks associated with a blood transfusion explained to you?

	National		Your site	
	%	n	%	n
Yes	38	858	6	1
No	44	998	89	16
Cannot remember	15	343	6	1
Not stated	2	44		0

9. Were you offered alternatives to blood transfusion?

	National		Your site	
	%	n	%	n
Yes	8	184	0	0
No	76	1714	100	18
Cannot remember	12	280	0	0
Not stated	3	65		0

10. *If yes*, can you remember what these alternatives were?

	National (184)		Your site (0)
	%	n	n
Iron	68	125	
Vitamins	8	14	
Erythropoietin	5	9	
Cell salvage	2	4	
Change to medication	3	6	
Other medication/procedure	11	20	
Cannot remember	11	21	
Not stated (Q10 left blank)	4	8	

Note: multiple responses were possible

11. Were you given the opportunity to ask questions?

	National		Your site	
	%	n	%	n
Yes	73	1628	56	10
No	16	363	33	6
Cannot remember	10	223	11	2
Not stated	1	29		0

12. If you did ask questions, do you feel your questions were answered satisfactorily?

	National (1628)		Your site (10)	
	%	n	%	%
Yes	63	1032	20	2
No	2	39	0	0
Cannot remember	4	68	10	1
Did not ask questions	28	459	70	7
Not stated	2	30		0

13. Were you asked to give your consent to have a blood transfusion?

	National		Your site	
	%	n	%	n
Yes	59	1333	33	6
No	23	508	61	11
Cannot remember	16	361	6	1
Not stated	2	41		0

14. Were you asked to sign a consent form for blood transfusion?

	National		Your site	
	%	n	%	n
Yes	17	378	6	1
No	63	1406	78	14
Cannot remember	19	428	17	3
Not stated	1	31		0

15. Do you feel you received enough information about having a blood transfusion?

	National		Your site	
	%	n	%	n
Yes	75	1686	72	13
No	15	343	22	4
Cannot remember	8	180	6	1
Not stated	2	34		0

Results – Staff Survey

1663 staff members from 163 sites completed a staff survey form, median 9 IQR 5-15, giving a sample of 60% of all patients whose casenotes were audited.
Your site contributed 11 staff survey forms.

Analysis

Analyses were performed to compare staff survey response by case-mix and clinical audit characteristics. There were some minor variations, though response was notably lower (defined as 50% or fewer) for those transfused at the weekend (49%), or out of hours 8pm-8am (50%).
A sample of 52% (1446) of all patients whose casenotes were audited had both a patient survey and a staff survey completed. Analyses were performed to compare response by case-mix and clinical audit characteristics. There were some minor variations, though response was notably lower (defined as 40% or fewer) for those transfused at the weekend (39%).

Q1. What is your professional group?
80% (1336) were doctors, 18% (303) were nurses, while 1% (21) were others, and 3 not stated. The 21 others comprised: health care assistant (6), midwife (4), consultant & CNS (2), radiotherapist (2), radiographer (2), pharmacist (2), dentist (1), scientist in MDT (1) and not stated (1).

Q2. What is your role?
86% (1271) were doctors, 13% (194) were nurses, and remaining 1% (16 staff members) were Case managers, Scientists, Healthcare Assistants, Pharmacists and Radiotherapists. Not known for 182.

Q3. In what speciality are you working?

	National		Your site	
	%	n	%	%
Haematology/ Oncology	22	365	0	0
Medical	42	700	45	5
Surgical	30	498	55	6
Obstetric	5	91	0	0
Not stated	0.5	9		0

Q4. Did you explain the rationale for transfusion to the patient?

	National		Your site	
	%	n	%	n
Yes	85	1419	82	9
No	14	228	18	2
Not stated	1	16		0

4a. If no, why not?

	National (n)
Someone else did it	85
Patient already on transfusion	42
Patient unable to understand	25
Patient unable to communicate	16
No time	4
Didn't occur to me	4
Blood prescribed elsewhere	2
Lack of communication	2
Other	11
Not known	37

4b. Did you document the rationale?

	National		Your site	
	%	n	%	n
Yes	63	1051	73	8
No	34	567	9	1
Not stated	3	45		2

Q5. What side effects / complications of transfusion did you discuss with the patient?

	National (n)
None	629
Reaction signs	618
Risks	232
What to do if unwell	52
Benefits	18
Not stated	114

Q6. What alternatives to transfusion did you discuss with the patient?

	National		Your site	
	%	n	%	n
I did not discuss alternatives	60	1006	91	10
I advised that there were no suitable alternatives at this time	24	396	0	0
I discussed alternatives	14	228	9	1
Not stated	2	33		0

Alternatives discussed

	National (n)
Oral or IV iron	143
Do nothing	41
Use EPO	14
Use cell salvage	7
Ensure good diet	5
Not stated	18

Q7. Did you provide the patient with written information on blood transfusion?

	National		Your site	
	%	n	%	%
Yes	18	306	0	0
No	80	1334	100	11
Not stated	1	23		0

7a. If yes, where did you get that written information from?

	National (n)
Ward	195
Blood service	55
Intranet	33
Blood bank	4
Not stated	19

Q8. Where can you find a copy of the hospital transfusion policy?
To aid analysis we asked site auditors to judge if the staff member answered the question satisfactorily.

	National		Your site	
	%	n	%	n
Answered satisfactorily	90	1492	91	10
Not answered satisfactorily	8	140	9	1
Not answered	2	31		0

Q9. Please briefly summarise your hospital's consent policy in your own words
To aid analysis we asked site auditors to judge if the staff member summarised the consent policy satisfactorily.

	National		Your site	
	%	n	%	n
Summarised satisfactorily	69	1152	64	7
Not summarised satisfactorily	28	463	36	4
Not answered	3	48		0

10. Have you received transfusion training within the last 2 years?
81%(1353) of staff stated that they had received training in the last 2 years, 16% (273) had not received training, 2% (37) did not state.

10a. If yes, what form did that training take?

	National (1353)					Your site	
	Appropriate use of blood					Appropriate use of blood	
	Medical (1067)		Nursing (271)		Midwifery (2)	Medical (10)	Nursing ()
	%	N	%	N	N	N	N
eLearning Modules	63	676	42	114	0	7	
Generic sessions on consent	52	552	53	144	1	8	
Sessions specifically on transfusion consent	41	437	41	112	0	2	
	Patient information & consent					Patient information & consent	
	Medical (1067)		Nursing (271)		Midwifery (2)	Medical (10)	Nursing ()
	%	N	%	N	N	N	N
eLearning Modules	38	410	24	65	0	5	
Generic sessions on consent	44	472	44	118	1	8	
Sessions specifically on transfusion consent	35	370	32	86	0	2	

Note: To get percentages it was necessary to relate this table to relevant denominators for doctors, nurses and midwives doing the survey – from question 1.

Comparing responses

We acknowledge that one of the complications of conducting an audit such as this is the joining together of responses so that we can build a picture of continuity and seamless service, and our ability to demonstrate that.

In this section we compare the responses from the survey forms with casenote data to reveal to what extent surveys and records can accurately reflect actual practice.

A) – Involvement in decision making and recording the taking of consent

2243 patients completed a survey question "Were you involved with the decision making process about if you should receive a blood transfusion?" 807 said they were, to some extent, and there is a note in their records that consent was obtained. However, in a further 849 cases where patients stated they were involved there was no documentation of consent being obtained in the clinical records. 154 patients had a note in their records stating that consent was obtained, but the patients themselves told us they had not been involved in decision making. In a similar vein, 121 patients said that no-one had talked to them about blood transfusion, whereas their notes indicate that consent was obtained.

Of course, it is possible that patients were unable to recall the information given, but it is also possible that patients were unclear as to the treatment proposed due to an inadequate explanation. It is also possible that staff involved are unclear about the process for obtaining consent and recording this. Overall this demonstrates the need for a more standardised approach for obtaining and documenting valid patient consent for transfusion.

B). Providing written information

We asked patients if they had been given written information, and then compared what had been recorded in their notes. 320 patients said they had been given information and there was a corresponding note to that effect in their medical records. But 108 patients whose record states that information was given denied receiving any. 302 patients said they received information, but this was not recorded in the notes.

C). Explaining risks

We asked patients if the risks of transfusion had been explained to them and then compared what had been recorded in their notes. 336 patients said the risks had been explained and there was a note to that effect in their medical records. But 221 patients whose record states that risks were explained denied receiving any explanation. 508 patients said they received an explanation, but this was not recorded in the notes.

Discussion

This audit was perceived to be challenging to design and execute and it is therefore particularly gratifying to see participation from 164 sites with a high level of responses obtained to the questionnaires for patient and healthcare professionals.

The organisation survey was completed by 141 sites with the majority indicating that they had a policy on consent for transfusion that also included the need to provide information to patients.

Of the 2784 cases from 164 sites, documentation within the patient's notes showed that the majority (77%) took place during 'core' working days and hours (8 am to 8 pm). The median age of patients of 74 (IQR 61-82) years reflects the ageing patient population and the demands that group place on the supply of blood components. The range of specialties represented in the audit mirrors the destination and usage of cross-matched units of blood, according to recent national blood transfusion data[9,10].

While the documentation of indication for transfusion was found to be relatively good at ~81% it must be argued that this should be 100% for all patients. Transfusion is a significant intervention and a rationale for its use and follow up together with assessment of its effectiveness as an intervention must be considered, along with consent, to be a minimum documentation requirement. In fact, documentation of consent was poor and was found in only 43% of case notes. This was largely obtained on the day of (70%) with the rest on the day before the transfusion (29%).

Where documentation was available, written consent had been obtained for ~ 22% of patients so, as expected, in the large majority of cases the consent was verbal. However, it is possible that written consent was obtained as part of another document, e.g. surgical consent, with reference to transfusion rather than specific 'stand alone' consent for transfusion, with the latter being the practice only in a minority of hospitals.

Unsurprisingly, the highest proportion of staff obtaining consent were junior doctors, which is likely to be related to their role in the prescription of blood. It is important to emphasise that in 72% of cases FY1 or FY2 trainees were involved. The increasing role of nurse authorisers is also reflected in these data representing 18% of cases. Accordingly, all these professional groups should be targeted for education and training in local consent policies.

The number of patients receiving written information is disappointingly low. The actual numbers may have been much higher with poor documentation but it is worth noting that only 28% of patients recall being given written information in the patient survey (see below). Also there were very low levels of documentation in the case notes that patients had been given an explanation on the risks and discussion of alternatives to transfusion. Not only are patients, of course, entitled to have this information explained but it can also serve as a trigger for the review of appropriate blood use, especially when this prompts a consideration of options for transfusion avoidance.
It was gratifying to note that 2243 patients from 162 sites completed a patient survey form. Of these, just over half (56%) stated that they were involved in the decision making process

while an additional 18% believed that they had been involved to a certain degree, with a further 5% of respondents stating they could not remember. So overall, 74% of patients reported some involvement in their treatment plan. In keeping with the findings of the documentation in this audit, unsurprisingly the majority of patients reported having the conversation about transfusion with a doctor (74%), while almost 20% of discussions involved a nurse. However, while 68% of patients clearly recall having the intended benefits of transfusion explained only 38% confirmed they had received information of the potential risks associated with transfusion. Of concern is that 44% of patients stated that no risks were ever explained.

Only 8% of those patients audited could confidently say that an alternative to conventional transfusion had been offered. Of course, it must be considered that a preferred alternative may not always be an option in the clinical circumstances presented. For the vast majority of patients the alternative appears to have been iron supplementation and 2% recall cell salvage being discussed with them.

In keeping with documented evidence as above, 62% of patients responded that they had not received any written information. None the less, 75% of patients who responded to the audit felt that they had received enough information about having a transfusion and encouragingly, the vast majority of patients (71%) felt that they understood the information provided. Similarly 73% reported that they were given an opportunity to ask questions. This could reflect the fact that information on transfusion could given at one or more stages in the patient's transfusion journey. It is, however, of concern that 21% of patients stated that they did not feel at all involved in the decision making process around receiving a blood transfusion.

Interestingly, 59% of respondents reported being asked to give their consent to have a blood transfusion whereas almost a quarter (23%) of those audited stated they had never been asked to provide any form of consent, verbal or written. This figure suggests a gap in documentation of consent having been obtained (since evidence of consent having being documented was found in only 43% of notes audited).

The staff and paired staff-patient response rate was markedly lower for transfusions undertaken out of hours or over the weekend. This is likely to be influenced by time limitations and tracing those staff participating in on call/shift systems.

The majority of respondents to the staff questionnaire were doctors (80%), with 18% nurses concurring with the data obtained from documentation within the case notes. While a high proportion (85%) of staff explained the rationale for transfusion verbally, fewer (63%) report documenting this in the clinical notes. This has implications both for informed consent and for clinical coding. SaBTO recommend that risks, benefits and alternatives to transfusion are discussed with the patient, but in our survey, only 14% of staff stated that they had discussed alternatives with a further 24% stating that they had advised the patient that no alternatives were available. With 60% of staff not discussing alternatives at all, there is a potential risk that these staff did not consider other suitable options and therefore did not provide the patient with an informed choice.
The staff response data regarding provision of written information is a key finding in this audit. Studies have shown information leaflets to be effective in informing patients (Court et

al, 2011, Davis et al, 2012)[4,5] and yet only 18% of respondents in this audit used this tool. This represents a missed opportunity, since information leaflets are widely available, free of charge to hospitals, and have proven benefits when consenting patients for transfusion. Their use is therefore strongly recommended. The responses from the organisational audit, with 77% of 141 sites stating that patients were routinely given written information, are not reflected in the actual practice found from documentation with notes and indeed the feedback from patients and staff.

Auditors were asked to judge satisfactory answers from healthcare professional to questions regarding the location and summary of their Trust consent policy. Whilst 90% of respondents could locate the policy, only 69% were able to summarise its content. Overall, eLearning appears to be underused for educating staff regarding patient information and consent. In 2013, eLearning for Health introduced a free eLearning module intended to be used by a range of Healthcare Professionals, but it seems that only 38% of medical staff learn about patient information and consent by this method. Such an online resource could easily be integrated into Trust induction programmes for those involved in blood transfusion, having the additional benefit that it can be completed at a time convenient to the learner and the module does not require a dedicated member of staff to deliver it. The Serious Hazards of Transfusion haemovigilance (SHOT) scheme has highlighted that lack of knowledge is an important factor in transfusion errors made by junior doctors. This audit confirms the pivotal role that junior doctors have in clinical transfusion practice across many disciplines emphasising the urgent need to strengthen their education to improve patient care.

Whilst this is the largest audit to date on the provision of information and obtaining patient consent for elective transfusion in adults, there are key areas that were not included. Accordingly, further work is needed to assess practice around retrospective information for transfusion given in the emergency setting with a need to also fully assess paediatric practice. Moreover, only patients whose first language was English were asked to respond to the patient questionnaire - there is a need to ensure fuller engagement of all patients in future projects by overcoming of language barriers.

Conclusions

Obtaining valid consent is an implicit part of good patient care in relation to transfusion practice. The SaBTO recommendations on patient information and consent for transfusion are explicitly clear with detailed recommendations.

This audit, while perceived to be challenging, did a have good level of participation enabling us to comment on current UK practice and make recommendations for change. While Trusts overall have policies in place covering key principles, actual practice does not reflect this as shown from the documentation within notes and the feedback from patient and staff. The need to document the indication for transfusion should be an absolute minimum requirement within hospitals, with the explicit need to communicate this indication to patients supported by discussion of risks, benefits and alternatives. The majority of prescribers currently are junior doctors and there is an urgent need to strengthen their training not only in relation to obtaining patient consent but also appropriate prescribing. There is a need to strengthen the content of training curricula and also the delivery of education. Strategies to increase the uptake and use of eLearning modules to support training needs to be reviewed, with perhaps incorporation into other types of learning including face to face sessions rather than as just as a stand-alone option.

The audit demonstrates a major discordance between hospital policies and actual practice in particular around the provision of written information to patients. The development and dissemination of such information should now be reviewed. Consideration should be given to the incorporation of transfusion information within leaflets on relevant specific conditions given to patients to help streamline the provision of information with greater exploration of information technology to increase patient and health care access.

Overall, the audit highlights the need for a more standardised and structured approach to the process of providing information and obtaining patient consent with emphasis on appropriate documentation.

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9. Tingate H . Where does blood go 2014 (personal communication)

10. Scottish Account for Blood data – (personal communication)

Organisational audit questionnaire

1. Do you have policy on consent for transfusion? Yes ☐ No ☐

If yes, go to Q2. If no, go to Q5

2. Is this Hospital/Trust/Board wide? Yes ☐ No ☐

3. Is it part of a transfusion policy? Yes ☐ No ☐

4. Is it part of a general policy on consent? Yes ☐ No ☐

5. Do you have policy on the provision of patient information? Yes ☐ No ☐

If yes, go to Q6. If no, go to Q9

6. Is this Hospital/Trust/Board wide? Yes ☐ No ☐

7. Is it part of a transfusion policy? Yes ☐ No ☐

8. Is it part of a general policy on consent? Yes ☐ No ☐

9. Do you a have specific policy for providing information if consent could not be obtained? Yes ☐ No ☐

If yes, go to Q10. If no, go to Q11

10. How is the provision retrospective information to be documented?

Requirement for consent in your Hospital/Trust/ Board

Do you require:

11. Written, signed consent for transfusion (signed by medic and patient)? Yes ☐ No ☐

If yes, go to Q12. If no, go to Q15

If yes, is it:

12. specific (stand alone) transfusion consent? Yes ☐ No ☐

13. part of a consent form with a small transfusion section? Yes ☐ No ☐

14. other? Yes ☐ No ☐

Do you require:

15. Staff to inform the patient about benefits, risks and alternatives and document the fact in the notes? Yes ☐ No ☐

Training

16. What training is provided for the following staff groups *(Tick as appropriate)*

	Appropriate use of blood			**Patient information & consent**		
	Medical	Nursing	Midwifery	Medical	Nursing	Midwifery
eLearning Modules						
Generic sessions on consent						
Sessions specifically on transfusion consent						

17. How is training delivered? *(Circle either or both options)*

Face to face Online

Consent process

18. Are patients routinely given written information? Yes ☐ No ☐

If yes, go to Q19. If no, go to Q22

If yes, is this:

19. Leaflet supplied by NHSBT Yes ☐ No ☐

20. Own leaflet Yes ☐ No ☐

21. Other, please state:

22. Where is written patient information available? *(tick as many options as apply)*

☐ On all wards?

☐ On selected wards?

☐ Central patient information point

☐ Other

☐ Not available

23. How are staff informed of the availability and re-supply of written information?

24. Is written information for patients (about blood transfusion) available on hospital intranet?

Yes ☐ No ☐

Thank you for completing this organisational questionnaire. Please email it to:
david.dalton@ **GRO-C**

Appendix Two – Casenote audit tool

2014 National Comparative Audit of Patient Information and Consent for Blood Transfusion

Audited patient no.

Casenote Audit Tool

Q1. What is the patient's year of birth? ☐

Q2. What is the patient's gender? Male ☐ Female ☐

Q3. In which clinical speciality was the patient cared for?

Medical ☐ Haematology/ Oncology ☐ Surgical ☐ Obstetric ☐

Please complete for the first red cell component transfused today - first transfusion in the transfusion episode

Q4. What was the date of the transfusion?

Q5. What was the time of the transfusion?

Q6. Is the indication for transfusion documented? Yes No

Q7. Is consent documented for the RBC transfusion? Yes No

7a. If yes, how was the consent documented?

Written consent ☐ Documented as verbal consent ☐

7b. What is the date of the recorded consent, if applicable?

7c. What is the time of the recorded consent, if applicable?

Q8. If consent was obtained, who obtained it?

- ☐ Consultant
- ☐ Registrar
- ☐ FY1/2 – Middle grade – CT – Locum
- ☐ Nurse practitioner
- ☐ Other (please specify)

Q9. If there is no record of consent, is there a record that the patient was unable to give consent? Yes No

Note to auditor

If the answer to Q9 is "Yes", do not go any further in auditing this patient, but retain this form for data entry. If the answer to Q9 is "No", please complete the rest of this casenote audit tool and then approach the patient to see if they are willing and able to complete the patient survey.

Q10. Is it documented that written information was given to the patient? Yes No

10a. If yes, what was the nature of the written information?

Trust leaflet ☐ NHSBT leaflet ☐ Other, please state ☐

Q11. Is it evident from the documentation that the reason for transfusion was explained to the patient? Yes No

Q12. Is it evident from the documentation that the risks of transfusion were explained to the patient? Yes No

Q13. Is it evident from the documentation that alternatives to transfusion were explained to the patient? Yes No

Please now approach the patient to see if they are willing and able to complete the patient survey, then complete Q14 below. Ensure that the Audited Patient Number is written on both the patient and staff survey forms.

Q14. Did the patient complete & return a survey form? Yes No

14a. If no, what was the reason?

☐ Patient declined

☐ Patient unable to communicate

☐ Patient unable to use English language

Appendix Three – Patient Survey Form

2014 National Comparative Audit of Patient Information and Consent for Blood Transfusion

Blood Transfusion Survey

Audited patient No.

1. Were you involved with the decision making process about if you should receive a blood transfusion?

- ☐ Yes
- ☐ To a certain degree
- ☐ No
- ☐ Cannot remember

2. Did anyone talk to you about blood transfusions?

- ☐ Yes
- ☐ No
- ☐ Cannot remember

3. If yes, can you remember who spoke to you?

- ☐ Doctor
- ☐ Nurse
- ☐ Other
- ☐ Cannot remember

4. Did you receive any written information about blood transfusion (leaflet, etc.)?

- ☐ Yes
- ☐ No
- ☐ Cannot remember

5. *If you answered Yes to either question 2 or 4*, when was this information given to you?

- ☐ Before you came into hospital
- ☐ When you first came into hospital
- ☐ At the time you were told you needed a blood transfusion
- ☐ At some other time
- ☐ Cannot remember

6. Did you understand the information you were given?

- ☐ Yes
- ☐ No

7. Were the possible benefits of having a blood transfusion discussed with you?

- ☐ Yes
- ☐ No
- ☐ Cannot remember

8. Were the possible risks associated with a blood transfusion explained to you?

☐ Yes
☐ No
☐ Cannot remember

9. Were you offered alternatives to blood transfusion?

☐ Yes
☐ No
☐ Cannot remember

10. *If yes*, can you remember what these alternatives were?

☐ Iron ☐ Vitamins ☐ Erythropoietin
☐ Cell salvage ☐ Change to medication ☐ Other medication/procedure
☐ Cannot remember

11. Were you given the opportunity to ask questions?

☐ Yes
☐ No
☐ Cannot remember

12. If you did ask questions, do you feel your questions were answered satisfactorily?

☐ Yes
☐ No
☐ Cannot remember
☐ Did not ask questions

13. Were you asked to give your consent to have a blood transfusion?

☐ Yes
☐ No
☐ Cannot remember

14. Were you asked to sign a consent form for blood transfusion?

☐ Yes
☐ No
☐ Cannot remember

15. Do you feel you received enough information about having a blood transfusion?

☐ Yes
☐ No
☐ Cannot remember

Thank you for your involvement. Please return this survey form to the member of staff who gave it to you.

Appendix Four – Staff Survey Form

2014 National Comparative Audit of Patient Information and Consent for Blood Transfusion

Audited patient No.

Staff questionnaire

Q1. What is your professional group?

Nurse ☐ Doctor ☐ Other (please state) ☐

Q2. What is your role/grade?

Q3. In what speciality are you working?

Medical Haematology/ Oncology ☐ Surgical ☐ Obstetric ☐

Q4. Did you explain the rationale for transfusion to the patient? Yes ☐ No ☐

4a. If no, why not?

4b. Did you document the rationale? Yes ☐ No ☐

Q5. What side effects / complications of transfusion did you discuss with the patient? *(If not discussed, write "None discussed")*

Q6. What alternatives to transfusion did you discuss with the patient?

☐ I did not discuss alternatives

☐ I advised that there were no suitable alternatives at this time

☐ I discussed the following alternatives:

Q7. Did you provide the patient with written information on blood transfusion? Yes ☐ No ☐

7a. If yes, where did you get that written information from?

Q8. Where can you find a copy of the hospital transfusion policy?

Q9. Please briefly summarise your hospital's consent policy in your own words:

Q10. Have you received transfusion training within the last 2 years? Yes ☐ o ☐

10a. If yes, what form did that training take? (*Please tick boxes as appropriate)*

	Appropriate use of blood			**Patient information & consent**		
	Medical	Nursing	Midwifery	Medical	Nursing	Midwifery
LearnBloodTransfuson Modules						
Generic sessions on consent						
Sessions specifically on transfusion consent						

Thank you for completing this survey form. Please return it to the member of staff who is conducting the survey.

Appendix Five – Letter to accompany Patient Survey Form

2014 National Comparative Audit of Patient Information and Consent for Blood Transfusion

We are keen to have your views on the information that hospitals give to patients about blood transfusions.

NHS Blood and Transplant is working with the Transfusion Team in the hospital to conduct a clinical audit of the way in which patients are given information about blood transfusion. Clinical audit is used by hospitals to improve the care and service they give to their patients.

When we do these surveys, we don't collect any personal information about you, about why you are in hospital or the treatment you are getting. Neither do we collect personal information about any particular doctor, nurse or other healthcare worker, so you can be assured that none of your personal details will be collected or used.

The clinical audit is being carried out by a member of this hospital's transfusion team, and he/she has given you a survey form to complete. You do not have to complete this survey if you do not wish to, and it will not affect the care you are given if you choose not to fill it in.

We hope that you will agree to complete this survey. If you have any questions about this survey or clinical audit, please do ask the person who handed you the survey form.

Thank you for your participation in this important survey.

With best wishes.

GRO-C

John Grant-Casey
Programme Manager

Appendix Six – Letter to accompany Staff Survey Form

2014 National Comparative Audit of Patient Information and Consent for Blood Transfusion

Dear Colleague,

You have been given or sent this letter because we are conducting a clinical audit on the information we give to our patients about blood transfusions.

NHS Blood and Transplant is working with the Transfusion Team in the hospital to conduct the clinical audit, which is based on the Department of Health's SaBTO recommendations.

The survey form attached to this letter asks you about the information given to, and consenting of, a patient you recently saw:

Patient Name

Location

Date patient seen

Thinking about when you saw this patient, please complete the survey form and return it within 2 weeks. If I have not heard from you, I will remind you during that 2 week period.

Please return the survey form to: