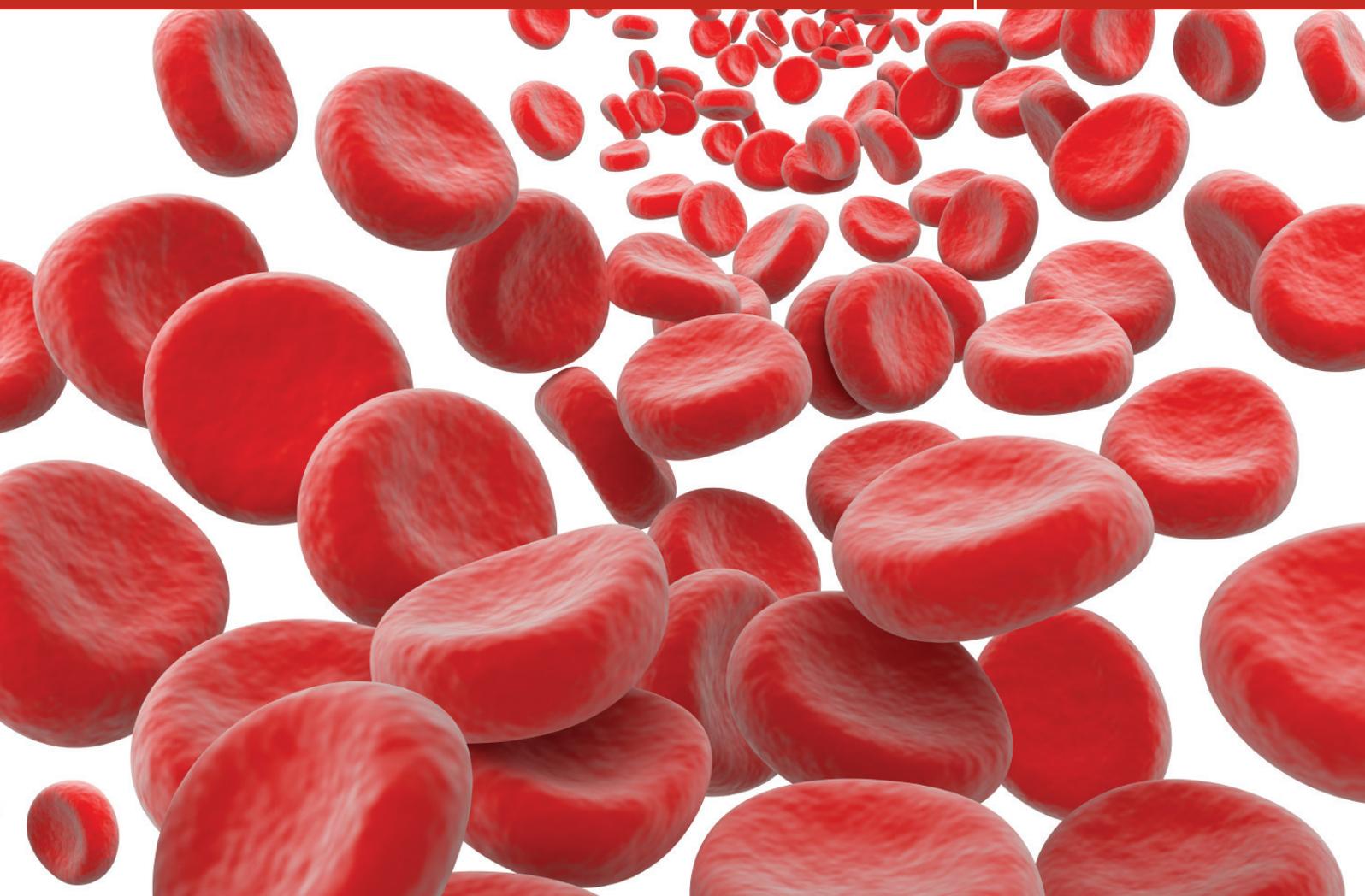


Department of Health

health

# Consent for blood transfusion audit 2012





Consent for blood  
transfusion audit 2012

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Blood Matters Patient Blood Management Steering Group

Blood Matters Consent Working Party

Department of Human Services Privacy and Policy Corporate Integrity, Information and Resolutions Unit

Ms Linley Bielby, Blood Matters Program Manager

Ms Lisa Stevenson, Blood Matters Transfusion Nurse

Ms Jo Perillo, Blood Matters Transfusion Education Coordinator

Ms Bridget Glazebrook, Blood Matters Data and Information Manager

Mr Peter Beard, Blood Matters Data and Information Manager

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If you would like to receive this publication in an accessible format, please phone 03 9694 0102 using the National Relay Service 13 36 77 if required, or email: [lbielby@redcrossblood.org.au](mailto:lbielby@redcrossblood.org.au)

This document is available as a PDF on the internet at: [www.health.vic.gov.au/bloodmatters](http://www.health.vic.gov.au/bloodmatters)

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## Abbreviations, acronyms and definitions

ACSQHC	Australian Commission on Safety and Quality in Health Care
AIHW	Australian Institute of Health and Welfare
ANZSBT	Australia and New Zealand Society of Blood Transfusion
AHMC	Australian Health Ministers' Conference
national standards	National Safety and Quality Hospital Standards
hospital-wide policy	Stand-alone policy, included as part of hospital blood transfusion policy, or contained within and overall consent policy
informed consent	<p>'Informed consent for transfusion means a documented dialogue has occurred between the patient and a prescriber and which includes:</p> <ul style="list-style-type: none"><li>• the reason for the proposed blood product transfusion</li><li>• the nature of the proposed blood product transfusion</li><li>• the risks and benefits of the blood product as well as the risks or consequences of not receiving the product</li><li>• the availability and appropriateness of any other blood management strategies</li><li>• an opportunity to ask questions</li><li>• use of a competent interpreter when the patient is not fluent in English</li><li>• use of written information or diagrams where appropriate.</li></ul> <p>Consideration of the patient's language and cognitive ability should influence the written information provided. A range of written information for the Australian and New Zealand context, including in languages other than English, and specific information for parents and children is available.'<sup>1</sup></p>
RCNA	Royal College of Nursing, Australia
the Blood Service	Australian Red Cross Blood Service
the department	Victorian Department of Health
validity	The documentation required and timeframe identified within the hospital blood transfusion consent policy

### Limitations

Limitations identified in this audit include the fact that auditors are not formally instructed to collect the data in a consistent way, and Blood Matters relied on them to follow the audit tool instructions to ensure accuracy of data (Appendix 2).

Patient selection was at the auditor's discretion and this may have influenced the clinical speciality audited. The majority of patients interviewed (92 per cent) spoke English as their first language.

The documentation of refusal of consent within the consent policy was not addressed in this audit.

## Executive summary

The Blood Matters program is a collaboration between the Victorian Department of Health (the department) and the Australian Red Cross Blood Service (the Blood Service). The Blood Matters program is founded on the principle that providing relevant, timely information will support the community by promoting better transfusion practice.

Blood and blood component transfusions are not without risk, and patients should be informed of the risks and benefits of receiving such a treatment. Their consent to, or refusal of, treatment should be documented.

The Australian Commission on Safety and Quality in Healthcare (ACSQHC) has introduced National Safety and Quality Hospital Standards. Standard 7 relates to the use of blood and blood products. This puts an increased emphasis on hospitals to have a policy that formalises informed consent for the transfusion process. The policy should be based on the Australian and New Zealand Society of Blood Transfusion (ANZSBT) / Royal College of Nursing Australia (RCNA) *Guidelines for the administration of blood products*, 2<sup>nd</sup> edition, 2011; and the Australian Health Ministers' Conference (AHMC) *Statement on national stewardship expectations for the supply of blood and blood products*.

In 2012, the Blood Matters program invited 140 health services (public and private) across Victoria, Tasmania, Northern Territory and Australian Capital Territory to participate in a three-part audit of consent for blood transfusion. The audit aimed to check current practices against guidelines and patients' understanding of the consent process. There is little published literature available about patients' understanding of the consent process.

Of the invited hospitals, 110 submitted data to at least one part of the audit. Four hospitals did not participate in Parts B and C as no transfusion occurred in the hospital during the audit timeframe.

Part C involved a patient interview and several hospitals required hospital ethics approval to undertake this part of the audit. This requirement delayed or impeded collection of this data in these health services.

Transfusion policy that included a requirement for informed consent was reported in 105 (95 per cent) hospitals, with 46 (48 per cent) having a designated transfusion consent form. Red blood cells were the most common product transfused (92 per cent), with informed consent documented in 1,345 (75 per cent) of the episodes.

In Part C, patients described being asked to give consent in 1,086 (80 per cent) episodes, with 945 (69 per cent) reporting being involved in the decision-making process.

Patients recalled:

- receiving verbal information in 1,167 (86 per cent) episodes
- being given written information in 439 (32 per cent) episodes
- having the risks explained in 931 (68 per cent) episodes
- having the risks of not receiving a transfusion explained in 672 (49 per cent) episodes.

Only 89 (7 per cent) reported being offered alternatives to transfusion; however 1,187 (87 per cent) felt they received enough information about the transfusion.

---

In summary, the majority of hospitals complied with current Australian transfusion consent guidelines in regard to policy; however in practice, consent was documented in 1,345 (75 per cent) of episodes. Sixty-nine per cent of patients report they were involved in the decision-making process. Alternatives to transfusion were offered in seven per cent of episodes. The results highlight that improvement is required in the areas of documentation of consent and provision of information to patients including the risks of, and alternatives to, transfusion.

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# Introduction

The Blood Matters program works with hospitals to ensure that blood components are administered to patients appropriately and safely.

The Blood Matters Program Patient Blood Management Steering Group identified blood transfusion consent as an area to audit, to measure current practice against national guidelines, standards and expectations. The policies developed to guide practice should be consistent with the *Guidelines for the administration of blood products* (ANZSBT/RCNA, 2011),<sup>1</sup> ACSQHC *National safety and quality health service standards*<sup>2</sup> and the AHMC Statement on national stewardship expectations for the supply of blood and blood products.<sup>3</sup>

Risks are associated with blood and blood component transfusions. Patients should be provided sufficient information about risks, the potential benefits and available alternatives in order to make an informed decision to consent to, or to refuse, the treatment, and this should be documented.<sup>1</sup>

Informed consent is the process by which the patient is provided with information, advice and warnings about the treatment, risks, benefits and alternatives. The process involves a two-way conversation with the patient. The conversation should take into consideration the patient's preferred language and cognitive ability, giving them the opportunity to ask questions and make statements about what is important to them. Provision of written material is also recommended to supplement verbal information.<sup>4</sup>

The aims of the audit were to measure current practice against guidelines, and determine patients' understanding of the consent process. Results would inform the recommendations to improve the quality of care provided to patients by ensuring blood and blood product transfusion consent policies are available, appropriate, understood and practised within hospitals.

The objectives of the audit were to determine:

- if blood and blood product transfusion consent policies are available within hospitals and are consistent with the ANZSBT/RCNA *Guidelines for the administration of blood products* (2011)
- if blood and blood product administration is undertaken with consent
- patients' understanding of the information given to them as part of the consent process.

## Method

One-hundred and forty hospitals across Victoria, Tasmania, Northern Territory and Australian Capital Territory that transfuse blood and blood products were invited to participate in this three-part audit.

The three audit forms (see Appendix 1) include:

- Part A 'Audit of hospital-wide blood transfusion consent **policy**'
- Part B 'Audit of blood transfusion consent **practice**'
- Part C 'Audit of **patients**' (**parent/guardian**) **understanding** of consent'.

The audit was conducted between August and December 2012.

For the purposes of the audit definitions of a hospital-wide blood transfusion consent policy, informed consent and validity were included in the audit instructions (Appendix 2).

The desktop audit tool Part A 'Audit of hospital-wide blood transfusion consent policy' was designed to determine if the hospital consent policy for blood transfusion was consistent with the *Guidelines for the administration of blood products*' (ANZSBT/RCNA 2011).

Part B 'Audit of blood transfusion consent practice' measured the documented consent rate for transfusion in up to 30 individual randomly selected transfused patients. This audit could be undertaken either at the time of transfusion, anytime during the admission, or following discharge.

Part C 'Audit of patients' (parent/guardian) understanding of consent for transfusion' required engaging the patient or parent/guardian during their admission either at the time of transfusion, within 72 hours of transfusion, or prior to discharge, to ask a series of questions around the information given to them. These questions could be asked of the patient, parent or guardian regardless of a documented consent process in the medical record. No individual patient-identifying data was collected, so consent to participate was not required. Some hospitals needed hospital ethics committee approval to undertake this part of the audit, and we developed a patient information sheet (Appendix 3) for hospitals to provide consistent information to participating patients. We asked each hospital to complete up to 30 audits.

We asked the hospital transfusion committee or equivalent to designate the staff to collect and report data. The auditors were not trained; however Blood Matters staff were available to provide guidance and clarification throughout the audit. Auditors entered data electronically through the Blood Matters website via an online survey tool on a SelectSurvey platform.<sup>5</sup> We then imported the data into a customised Microsoft Access database, before cleaning and analysing the data.

Following the end of the audit, each participating hospital was sent a preliminary summary of their data for verification, and invited to correct any discrepancies or incomplete records.

A number of episodes were removed from the sample set due to being duplicate patients or incomplete (25 records in Part B and 49 records in Part C).

## Results and discussion

The following section will highlight aspects of the data reported, and discuss these results as they relate to the ACSQHC National Safety and Quality Health Service Standards (2011), and ANZSBT/RCNA, *Guidelines for the administration of blood products* (2011). A full summary of the results is included in Appendix 4.

## Part A: Hospital transfusion consent policy

One-hundred and five hospitals (95 per cent) responded that their policy included a specific statement about obtaining consent for transfusion. The policy is important for outlining the governing principles of the consent process, including the products requiring consent, clinical staff responsibilities for obtaining and documenting consent, the type of information that should be offered to ensure a valid informed-consent process and the method of documentation.

A clear policy outlining these important points enables staff to understand hospital expectations, and to ensure compliance with best practice and national guidelines and standards.

The majority of respondents (n = 88, 84 per cent) have policies that define the products covered by their transfusion consent policy, in line with the National Blood and Blood Product Standard.

### **The ACSQHC National Standard 7 defines blood and blood products as:**

- fresh blood components – red cells, platelets, clinical fresh frozen plasma, cryoprecipitate, cryodepleted plasma
- plasma derivatives and recombinant products – albumin, immunoglobulins (including immunoglobulin replacement therapy (for example intravenous immunoglobulin) and hyperimmune globulins and clotting factors).

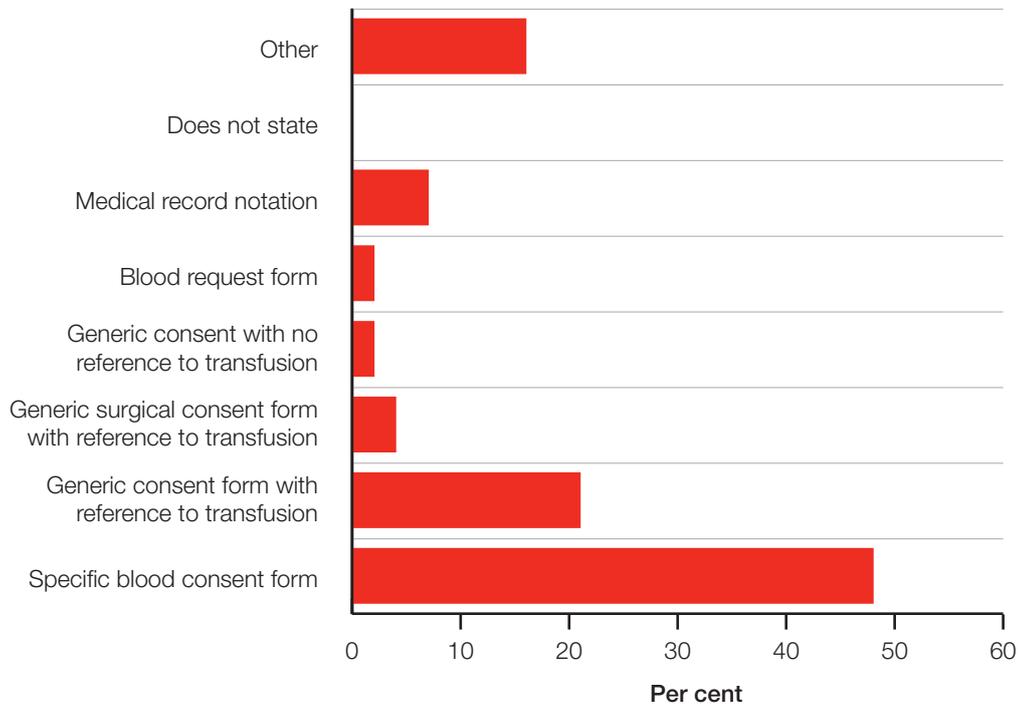
The method of documenting the transfusion consent process was included in 95 (90 per cent) of all policies.

### **ANZSBT/RCNA guidelines (section 2.2) recommend that consent must be documented in the patient's medical record either:**

- on a generic or transfusion-specific consent form or
- in the progress notes.

Figure A1 shows the types of consent forms and documentation processes of consent used at hospitals, 100 per cent complying with current national recommendation. Those hospitals reporting 'other' (n = 15) were in fact documenting consent appropriately in the medical record, or noted that they had multiple places of documentation such as consent form and medical notes (the survey tool did not allow hospitals to make multiple selections).

**Figure A1: Documentation of transfusion consent**



A policy should also specify the role of the person who is responsible for documenting and witnessing the transfusion consent. Table A1 demonstrates that medical staff are the main group responsible for this in line with their legal responsibility when prescribing blood.

The 'other' category included a variety of descriptions for medical officers and also registered nurses (RNs). The legal implications of the RN role as a person responsible for obtaining consent should be considered. It is not possible to determine from the data if legal implications have been considered by the hospitals that expanded the scope of responsibility for obtaining consent to include RNs.

Bearing this in mind, the RN role in supporting and or obtaining consent could be an interesting area to explore in future audits.

**Table A1: Policy statement on who can obtain transfusion consent**

Responsible for obtaining and documenting consent	n (%)
Consultant medical officer	61 (58)
Registrar	15 (14)
Intern	13 (12)
Nurse practitioner	3 (3)
Not stated	14 (13)
Other*	34 (32)

**Notes**

Multiple responses were allowed by the hospitals.

\* 'Other' included 31 different iterations of prescribing medical officer, and three RNs (in this instance, the hospitals had also reported a consultant medical officer as responsible).

**The ANZSBT/RCNA guidelines (section 2) recommend:**

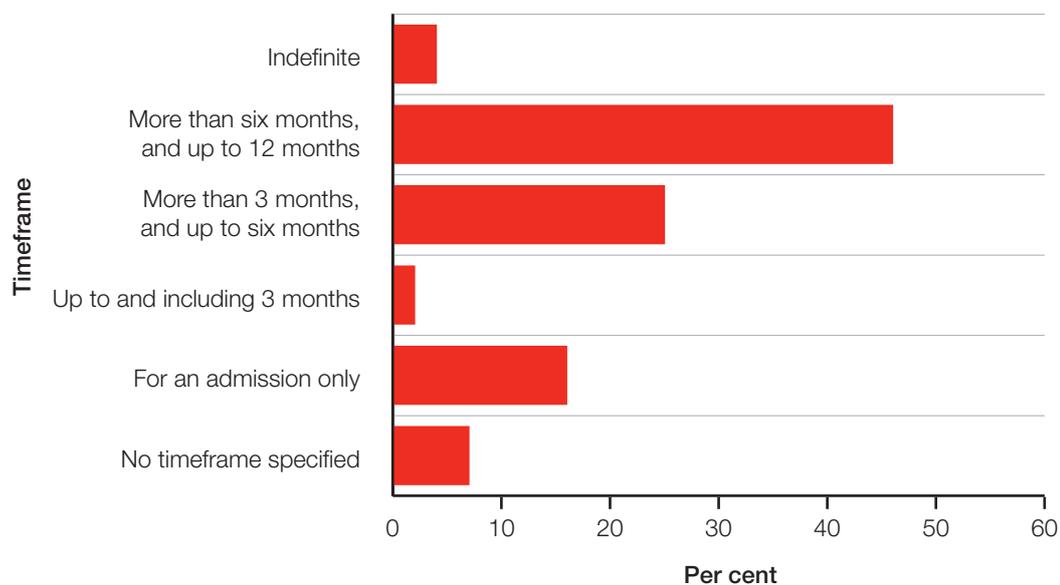
- that consent is valid for a specific timeframe, for example a single prescription or an episode of care.

Only 53 (50 per cent) of the respondents indicated that a timeframe was specified for the length of time the consent remained valid.

For patients requiring transfusions for ongoing care and management of their condition, their consent may be considered appropriate for an episode of care rather than single prescription where there is no change to the management of their condition. From the data, nine hospitals have policies that require consent for each admission, which would increase workload and may be unnecessary if the patient situation and blood product transfused remained consistent.

Of note, two hospitals (four per cent) responded having a policy outlining an indefinite timeframe of validity. Figure A2 outlines the many variations of the time frame for valid consent, with 26 (46 per cent) advocating 6–12 months validity.

**Figure A2: Timeframes of transfusion consent validity for an episode of care**



Obtaining consent should be an informed process for patients that outlines the risks and benefits and any alternatives to the transfusion to enable the patient to make an informed choice about their treatment. The Australian Charter of Healthcare Rights in Victorian hospitals includes ‘Communication – a right to be informed about services, treatment, options and costs in a clear and open way’.<sup>6</sup>

**ANZSBT/RCNA guidelines (section 2.1) recommend:**

Informed consent for transfusion means a documented dialogue has occurred between the patient and a prescriber and which includes:

- the reason for the proposed blood product transfusion
- the nature of the proposed blood product transfusion
- the risks and benefits of the blood product as well as the risks or consequences of not receiving the product
- the availability and appropriateness of any other blood management strategies
- an opportunity to ask questions
- use of a competent interpreter when the patient is not fluent in English
- use of written information or diagrams where appropriate.

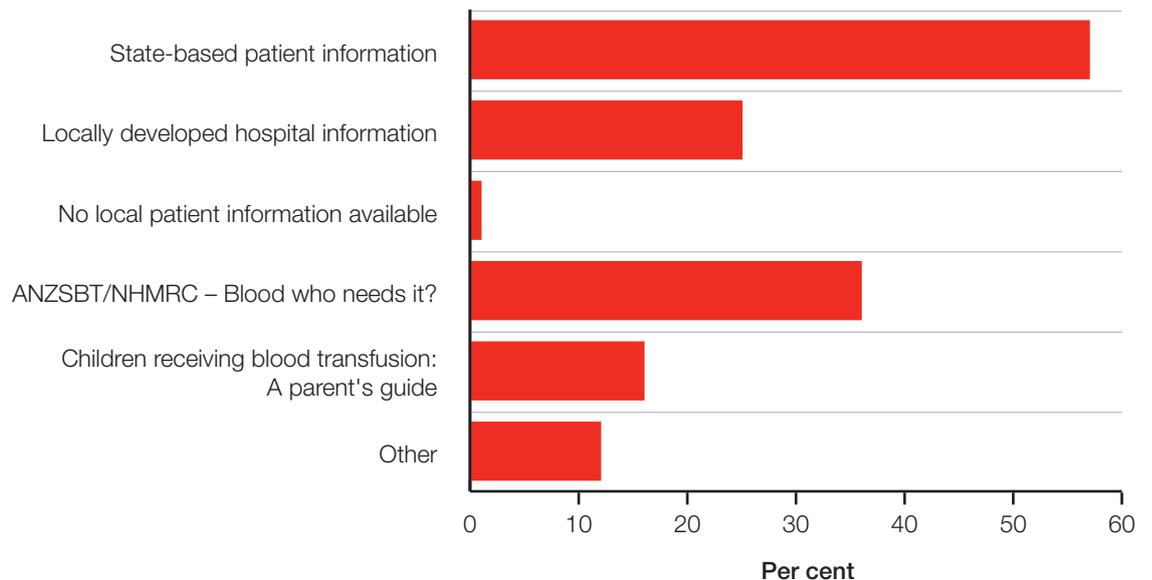
Table A2 outlines the discussion points that should be included in the verbal information offered to patients as part of the policy. The provision of an accredited interpreter was only included in less than half (n = 50) of the policies. The use of competent interpreters should be part of all transfusion consent policies to ensure that culturally and linguistically diverse patients receive transfusion information in their preferred language so they understand the process, and can make an informed decision.

**Table A2: Transfusion consent discussion points**

Discussion points	n (%)
Reasons for proposed blood product transfusion	81 (77)
Risks and benefits of the blood product	88 (84)
Risks or consequences of not receiving the product	71 (68)
Availability of other blood management strategies	62 (59)
An opportunity to ask questions	75 (71)
Use of a competent interpreter, where appropriate	50 (48)
Use of written information, where appropriate	68 (65)

In 68 (65 per cent) of the policies, it is stated that written information should be offered if appropriate. Pleasingly, a majority of responses reported written information was made available in a standard format based on state and national information (Figure A3).

**Figure A3: Specific written information tools for transfusion consent**

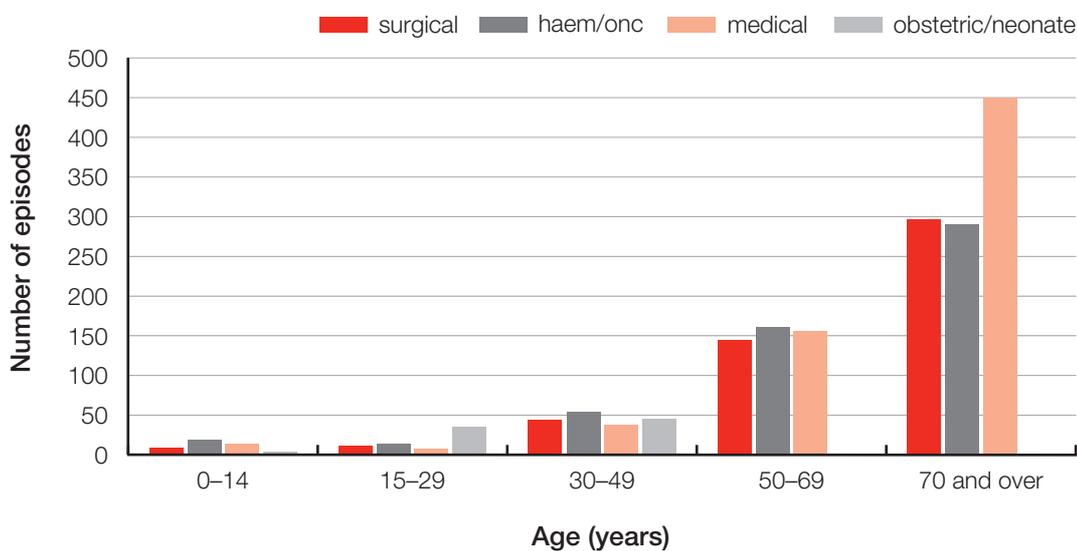


## Part B: Audit of blood transfusion consent practice

There were a total of 1,788 transfusion episodes reported by 103 hospitals (75 public hospitals and 28 private hospitals). Of the transfusion episodes reported, 809 recipients (45 per cent) were to male patients and 979 (55 per cent) to females. The average age of the patients reported was 68 years with a range of less than one year to 98 years. Fifty-eight per cent of the patients were over 70 years of age.

Of the episodes reported the majority were a medical speciality (n = 666, 37 per cent), followed by haematology/oncology (n = 532, 30 per cent), surgical (n = 505, 28 per cent) and obstetrics (n = 85, five per cent). Figure B1 outlines the clinical specialty related to age grouping.

**Figure B1: Age group of transfusion episodes reported by clinical specialty**



Of the 1,788 patient transfusion episodes 1,636 (92 per cent), received red blood cells (RBC), 68 (four per cent) platelets, 53 (three per cent) fractionated products, with fresh-frozen plasma and cryoprecipitate making up the remainder (n = 31). In 547 of the transfusion episodes (31 per cent), the patient received more than one blood product on the day, and when multiple products were transfused, the largest proportion of these were RBC.

Overall, informed consent was reported to be documented and valid for the product administered in 1,345 (75 per cent) of the episodes. For hospitals (n = 105) with a reported policy on consent, 75 per cent of the transfusions performed were reported as having documented and valid consent (1,291/1,725). For hospitals (n = 5) with no consent policy, documented and valid consent was reported in 86 per cent (54/63).

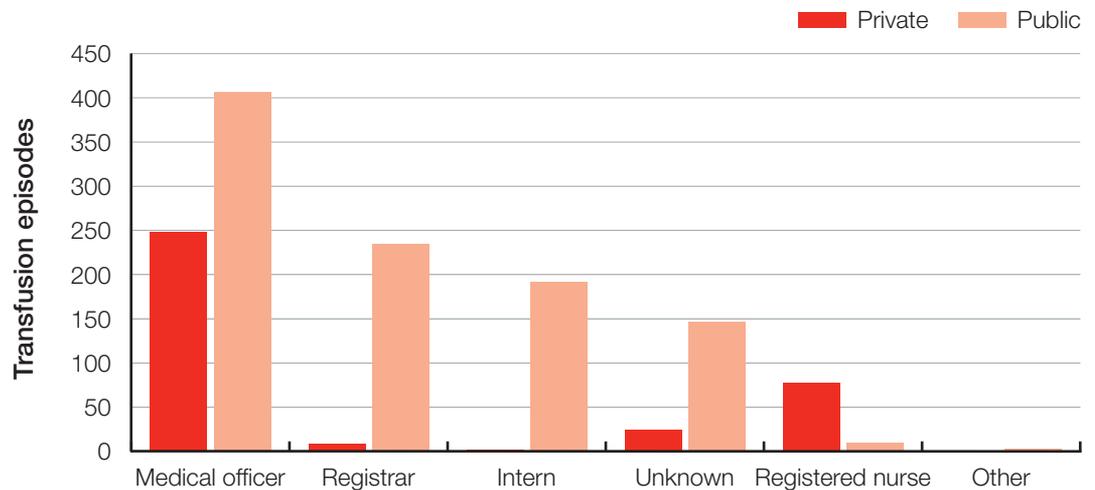
Interestingly, one hospital without a consent policy reported 100 per cent documented consent (n = 23), and two other hospitals without consent policies reported more than 80 per cent documented consent (n = 21/26 and 9/10).

Of the hospitals that documented the presence of a transfusion consent policy, one hospital (n = 5) reported no documented consent with the transfusion episodes reported, and ten other hospitals (n = 250) reported more than 70 per cent of their episodes had no documented consent.

Policies are necessary to guide practice across organisations, but staff must be aware of the policy and understand what is expected of them to ensure compliance. Health services must provide education and reinforce the necessity of putting the policy into practice. They should also measure compliance and provide feedback on performance.

Forty-four per cent (n = 45) of the participating hospitals reported a 100 per cent documented consent rate. Of the public hospitals participating in the audit, 55 per cent reported 100 per cent documentation (41/75), with 11 per cent of private hospitals (3/28) achieving the same level. Eleven hospitals reported an undocumented consent rate of greater than 70 per cent. Four of these were public hospitals (4/75, or five per cent of public hospitals participating in the audit) and seven were private hospitals (7/28 or 28 per cent of private hospitals). In the private sector most consultant medical officers are not located onsite. They may visit at various times of the day depending on their schedules and their patients' condition, and so access to complete consent documentation at the time of transfusion may be limited. For these private hospitals, it is not known if consent may have been obtained and documented and retained in the consultant's rooms. Feedback from a number of private hospitals involved in the audit indicated they had only recently implemented their transfusion consent policy or were yet to, and this may also account for differences in compliance.

**Figure B2: Who obtained informed consent?**



**Notes**

Within the category of 'other', auditors specified general practitioners, visiting/house medical officer, and these have been included in the 'medical officer' category (n = 136); 'other' also included resident which was reclassified into the 'registrar' category; 'registered nurses' (including those also identified as midwife and nursing unit manager) were pulled out of 'other' to create a new category, including those reported as nurse practitioner (n = 87). Five hospitals reported that nurse practitioners obtained consent; however following clarification these were determined to be registered nurses in all instances.

There is a significant difference between public and private hospitals in who obtained consent, with consent obtained mainly by consultant medical officers in private hospitals and a spectrum of doctors in public hospitals (Figure B2). The medical workforce in the private setting is mostly consultant medical officers with very limited numbers of registrars employed, and usually no interns working within this setting. Currently the responsibility for consent for transfusion rests with the prescriber. From the data, only two hospitals (39 per cent of episodes) had broadened the scope of responsibility within their policy beyond the prescriber to allow RNs to acknowledge consent. Further details of what form this acknowledgement involved were not gathered in the audit.

The ANZSBT/RCNA *Guidelines for administration of blood products* states that all patients requiring a blood transfusion must be involved in an informed-consent process that includes documentation of the same by the prescriber.

**ANZSBT/RCNA guidelines (Sections 2.1 and 2.2)** state that 'Informed consent for transfusion means a documented dialogue has occurred between the patient and a prescriber; and must be documented by the prescriber in the patient's medical record either on a generic or transfusion-specific consent form or in the progress notes'.

Where consent was reported as documented and valid, only 687 (81 per cent) could be verified to have been completed by a potential blood prescriber. As previously mentioned in the report, the role of RN documenting consent is an interesting area to be explored in the future. Providing information to support consent and patient understanding is considered part of the RN role in providing care and education to patients receiving a transfusion.

**The ACSQHC National Standard 7.11.1 requires that:**

- informed consent is undertaken and documented for all transfusion of blood and blood products in accordance with the informed-consent policy of the health service organisation.

Of the 87 transfusion episodes with consent documented by a RN, 34 (39 per cent) of the episodes occurred within hospitals (n = 2) that had policies that stated that a RN could complete the acknowledgement of consent. A further 37 (43 per cent) were at hospitals (n = 4) that did not identify whose responsibility it was, or had no policy surrounding consent, and the remaining 16 (18 per cent) occurred at hospitals (n = 9) that had policies which stated obtaining informed consent was the responsibility of the consulting medical officer.

When patient understanding was audited in Part C, 720 (52 per cent) of the patients did not recall receiving written information and 439 (32 per cent) recalled receiving it.

Written information was given to the patient and this was documented in 430 (24 per cent) of the transfusion episodes. Of those patients, 188 (66 per cent) who received written information could recall receiving it; an additional 151 patients reported receiving written information, although it was not documented in the patient record.

## Part C: Audit of patients' (parent/guardian) understanding of consent for transfusion

Patients who had received a transfusion were asked to provide feedback on the information given to them and their understanding of the consent for transfusion process. A total of 1,386 patient episodes were reported from 93 hospitals. Twenty-two patients (or relevant spokesperson) did not recall receiving a transfusion in the previous 72 hours and as instructed by the audit tool no further questions were asked.

The gender mix was relatively even with 661 (48 per cent) of the respondents male and 725 (52 per cent) female. English was reported as the first language in 1,278 (92 per cent) of the episodes. The audit was completed directly with 1,309 patients (94 per cent), 28 (two per cent) with a parent and 49 (four per cent) with a guardian.

Of the patients interviewed, 945 (69 per cent) felt they were involved in the decision-making process to receive a transfusion, 225 (16 per cent) felt they were involved to a certain degree, while 138 (ten per cent) reported they were not involved and four per cent could not recall.

**Table C1: How patients recall receiving information about transfusion**

	Yes (%)	No (%)	Cannot recall (%)
Verbal	1,167 (86)	75 (5)	122 (9)
Written form (e.g. brochure)	439 (32)	720 (53)	205 (15)
Verbal and/or written	1,195 (88)	56 (4)	113 (8)

**The ANZSBT/RCNA guidelines (Section 2.1) recommend informed consent should include:**

- use of written information or diagrams where appropriate and consideration of the patient's language and cognitive ability should influence the information provided.

Where patients (n = 1,195, 88 per cent) reported receiving any form of information about transfusion, 110 (nine per cent) reported receiving information at two or more points of care. Approximately half (n = 606, 51 per cent) reported receiving it at the time they were informed they required a transfusion, and 212 (18 per cent) at the time of consent. Another 235 (20 per cent) received it prior to admission and 217 (18 per cent) on admission. In addition, 56 patients provided an 'other' response including ongoing consent (n = 10) and five patients reported receiving information after the transfusion had commenced.

The ACSQHC national standards and the ANZSBT/RCNA guidelines for administration, both state patients should be given information about risks and potential benefits, along with possible alternatives, before undergoing this treatment.

**The ACSQHC national standards state that this can be achieved by:**

- 7.9 – the clinical workforce informing patient and carers about blood and blood product treatment options and the associated risk and benefits
- 7.9.1 – patient information relating to blood and blood products, including risk, benefits and alternatives is available for distribution by the clinical workforce
- 7.10 – providing information to patients about blood and blood products use and possible alternatives in a format that can be understood by patients and carers
- 7.10.1 – information on blood and blood products is provided to patient and their carers in a format that is understood and meaningful.

**The ANZSBT/RCNA guidelines (Section 2.1) recommend covering:**

- the risks and benefits of the blood product as well as the risks or consequences of not receiving the product
- the availability and appropriateness of any other blood management strategies.

The audit data confirms that the possible risks of receiving a transfusion are explained more often than the risks of not receiving a transfusion, or alternatives to transfusion. Table C2 demonstrates that significant improvement is required in these areas for hospitals to meet both the standards expected of them and to comply with the national guidelines.

**Table C2: Explanation of possible risks and alternatives to transfusion**

	Yes (%)	No (%)	Cannot recall (%)
Were the possible risks of blood transfusion explained to you?	931 (68)	246 (18)	187 (14)
Were the possible risks of not receiving a transfusion explained to you?	672 (49)	457 (34)	235 (17)
Were you offered an alternative to the blood transfusion?	89 (7)	1,039 (76)	236 (17)

As shown in Table C3, of the 89 patients who recalled being provided information on alternatives to transfusion, the predominant alternative offered was iron therapy (54 per cent). From the data, it cannot be determined if the low rate of alternatives to transfusion being offered is due to a lack of clinician knowledge about alternatives, or if alternatives are not available or appropriate.

**Table C3: Alternatives to transfusion offered to patients**

Alternatives offered	N = 89 (%)
Iron	48 (54)
Vitamins	7 (8)
Erythropoietin	1 (1)
Cell salvage	3 (3)
Change to medication	4 (4)
Other medication/procedure	9 (10)
Cannot recall	30 (34)

\*Patients were able to provide multiple responses to the types of alternative treatment offered.

**The ANZSBT/RCNA guidelines (Section 2.1) recommend that informed consent for transfusion should include:**

- an opportunity to ask questions.

In 1,111 (81 per cent) episodes, patients reported they were given the opportunity to ask questions, with 114 (eight per cent) reporting they were not, and 139 could not recall (ten per cent). Of those who asked questions (n = 857), 82 per cent (n = 701) felt their questions were answered. In the majority of transfusion episodes (n = 1,086, 80 per cent) patients reported they were asked to give consent, with 127 (nine per cent) reporting they were not asked and 151 (11 per cent) who could not recall.

From the data it is not possible to establish a link between documentation of consent and the patient not being able to recall providing consent. There could be many factors involved in this: consent may have been documented with little or no information provided to the patient, or the patient was overloaded with information, fatigued due to their illness, or some other factor that impacted the patient's memory and recall of the information. Where the patient recalls consent and it is not documented, there may be many factors that contributed to this. It could be due to the consent process not being fully completed at the time of discussion, poor documentation by the prescriber or missing documentation.

The reasons that the patients understood for receiving a transfusion are outlined in Table C4, with the most commonly stated reason as low haemoglobin (Hb) (33 per cent) and anaemia (26 per cent). Where the 'other' category was selected, patients described the following as some of the reasons for their transfusion:

- To keep me alive
- For my baby to have enough oxygen
- Low blood counts
- Condition will worsen if I don't have it
- Because I'm buggered
- To counteract kidney rejection
- To top me up
- My platelets are no good
- Heart disease

**Table C4: Outlines what the patients understood as the reason for the blood transfusion**

Reason	Number (%)	Reason	Number (%)
Low Hb	445 (33)	Renal failure	14 (1)
Anaemia	352 (26)	Liver disease	10 (1)
Blood loss / bleeding	291 (21)	Thalassaemia major	7 (1)
Cancer or cancer treatment (chemotherapy)	236 (17)	Drug effect e.g. warfarin, clopidogrel	8 (1)
Bone marrow failure	85 (6)	Trauma	3 (0)
Surgery	76 (6)	Factor deficiency	2 (0)
Low iron	52 (4)	Cannot recall	43 (3)
Thrombocytopenia	18 (1)	Other	113 (8)

\*Patients were able to provide multiple responses

The data shows that patients are able to recall the reasons for their transfusion with only a very small number (43, three per cent) unable to recall the reason.

While only 945 (69 per cent) of the patients felt they were involved with the decision-making process to receive a transfusion, it is notable that the majority of respondents 1,187 (87 per cent) felt that they received enough information about having a transfusion, with 98 (7 per cent) reporting they had not and 79 (6 per cent) could not recall.

# Recommendations

The following recommendations are based on an overview of practice across the participating jurisdictions. They will help hospitals to meet the standards and to comply with national guidelines by ensuring blood and blood product transfusion consent policies are available, appropriate, understood and practised.

Hospitals that participated in the audit will receive individual summary reports highlighting areas for improvement. These should be considered along with the general recommendations below.

## Policy

- Hospitals without an informed-consent policy should develop one. This could be part of the organisation's general consent policy, included in the blood and blood products transfusion policy or as a stand-alone policy. It should include the elements as outlined in the ANZSBT/ RCNA guidelines for administration of blood products, ACSQHC national standards and AHMC stewardship statement. A consent checklist is included on the following page to assist hospitals assess their policy with the national guidelines and standards.
- Hospitals that have an informed-consent policy should review it to ensure it includes all elements covered by the guidelines as outlined on the checklist (available page 17). The revisions should cover areas such as the length of time the consent is valid, the use of competent interpreters where appropriate, and the inclusion of other blood management strategies.
- The consent policy should include the documentation of refusal of consent. This was not specifically addressed in this audit.

## Practice to policy

- The responsibility for transfusion consent rests with the prescriber. Currently this includes medical officers and nurse practitioners (where specified in their scope of practice). The potential legal implications of expanding the scope of responsibility to include other RNs should be considered and, where included, the role should be clearly defined. With changes in the health system and workforce this is an area that could be explored further.
- Many hospitals require significant improvement in documenting informed consent according to existing policy.
- Documenting the provision of patient information is another area requiring significant improvement.
- Good practice requires increased patient involvement in the decision-making process for transfusion, including encouraging patients to ask questions.
- Hospitals need to improve the provision of information to patients about the possible risks and alternatives to transfusion (a list of resources is available page 19).
- Prescribers of blood and blood products need to increase their awareness and knowledge about the potential use of alternatives available.

## Consent for blood products checklist

The following checklist can be used as a tool for health services to support compliance with consent requirements as outlined in the ANZSBT/RCNA guidelines, ACSQHC national standard and AHMC stewardship statement.

Elements required to be included in your hospital blood transfusion consent policy	Yes	No	WIP*
<p>Is transfusion of blood or blood products included within the informed-consent policy of your hospital? (ACSQHC National Standard 7.11.1)</p>			
<p>Does your hospital blood transfusion consent policy clearly stipulate which type of blood and blood products it covers? The ACSQHC national standard defines blood and blood products as:</p> <ul style="list-style-type: none"> <li>• fresh blood components – red cells, platelets, clinical fresh frozen plasma, cryoprecipitate, cryodepleted plasma</li> <li>• plasma derivatives and recombinant products – albumin, immunoglobulins. Including immunoglobulin replacement therapy (e.g. intravenous immunoglobulin) and hyperimmune globulins and clotting factors.</li> </ul> <p>(ANZSBT/RCNA guidelines Section 2; ACSQHC)</p>			
<p>Does your hospital blood transfusion consent policy include a statement about how the informed consent for transfusion should be documented? For example: generic or dedicated transfusion consent form versus documentation in the patient’s medical record. (ANZSBT/RCNA guidelines Section 2.2; ACSQHC National Standard 7.11.1)</p> <p>And where the informed consent for transfusion should be documented? For example: medical records, electronic format, both medical record and electronic, other area</p>			
<p>Does your hospital blood transfusion consent policy specify the period of time that consent remains valid? For example: single prescription or an episode of care. (ANZSBT/RCNA guidelines Section 2)</p>			
<p>Does your hospital blood transfusion consent policy specify the patient’s capacity to give consent? For example: this should reflect local state, and territory legal requirements (ANZSBT/RCNA guidelines Section 2)</p>			
<p>Does your hospital blood transfusion consent policy specify the age of patients eligible to consent? For example: this should reflect local state, and territory legal requirements (ANZSBT/RCNA guidelines Section 2)</p>			

<p>Does your hospital blood transfusion consent policy state that the consent process should involve a discussion with the patient that includes the following:</p> <ol style="list-style-type: none"> <li>1. the reasons for the proposed blood product transfusion</li> <li>2. the risks and benefits of the blood product</li> <li>3. the risks or consequences of not receiving the product</li> <li>4. the availability and appropriateness of any other blood management strategies</li> <li>5. an opportunity to ask questions</li> <li>6. use of a competent interpreter when the patient is not fluent in English</li> <li>7. use of written information or diagrams where appropriate?</li> </ol> <p>(ANZSBT/RCNA guidelines Section 2.1; ACSQHC standard 7.9.1, 7.10)</p>			
<p>Does your hospital blood transfusion consent policy specify whose responsibility it is to obtain consent?</p> <p>**Note that consent must be documented by the prescriber. (ANZSBT/RCNA guidelines Section 2.2)</p>			
<p>Does your hospital blood transfusion consent policy specify the use of supporting written information in the consent process?</p> <p>For example: state-based patient information about transfusion (such as Blood Matters / BloodSafe / Blood Watch), locally developed hospital transfusion information, ANZSBT/NHMRC – <i>Blood: Who needs it?</i>, <i>Children receiving a blood transfusion: A parent's guide</i> (ANZSBT/ARCBS/NZBS/SA Department of Health) or other. (ANZSBT/RCNA Section 2.1; ACSQHC National Standard 7.9.1)</p>			
<p>Does your hospital blood transfusion consent policy specify the documentation of refusal of consent?</p> <p>For example: refusal of consent or where a patient refuses consent to transfusion of specific blood products – both should be clearly documented. (ANZSBT/RCNA guidelines Section 2.3)</p>			
<p>Does your hospital blood transfusion consent policy specify the actions where consent cannot be obtained?</p> <p>For example: this should reflect local state, and territory legal requirements regarding consent for a medical procedure, that is advanced directives or medical/welfare power of attorney. (ANZSBT/RCNA guidelines Section 2.4)</p>			

\*Work in progress

# Resources

## **Blood Matters**

[<www.health.vic.gov.au/bloodmatters>](http://www.health.vic.gov.au/bloodmatters)

## **BloodSafe**

[<http://www.health.sa.gov.au/bloodsafe>](http://www.health.sa.gov.au/bloodsafe)

## **BloodSafe eLearning Australia**

[<https://www.bloodsafelearning.org.au/>](https://www.bloodsafelearning.org.au/)

## **Australian and New Zealand Society of Blood Transfusion**

[<www.anzsb.org.au>](http://www.anzsb.org.au)

## **Australian Commission on Safety and Quality in Healthcare**

[<http://www.safetyandquality.gov.au/our-work/accreditation/>](http://www.safetyandquality.gov.au/our-work/accreditation/)

## **Australian Red Cross Blood Service**

[<http://www.transfusion.com.au/>](http://www.transfusion.com.au/)

[<http://www.mytransfusion.com.au/>](http://www.mytransfusion.com.au/)

## **National Blood Authority**

[<http://www.nba.gov.au/policy/stewardship-statement.pdf>](http://www.nba.gov.au/policy/stewardship-statement.pdf)

## **Patient Blood Management guidelines**

[<http://www.nba.gov.au/guidelines/review.html>](http://www.nba.gov.au/guidelines/review.html)

# Appendix 1: Consent Audit–Parts A, B and C

Hospital name

Please enter your email address

## Part A: Hospital-wide Blood Transfusion Consent Policy (Complete only one per Hospital)

A hospital-wide Blood Transfusion Consent Policy maybe a stand alone policy, included as part of your Blood Transfusion policy or contained within an overall consent to treatment policy.

Does your hospital policy include a statement regarding obtaining consent for transfusion?

Yes  No

————— If answer is No please proceed to Part B —————

**If yes, please complete the following questions about your Blood Transfusion Consent policy.**

Which products does your hospital Blood Transfusion Consent policy include?

- Blood and Blood products (fresh and fractionated)
- Blood (fresh) only
- Does not state

Does your hospital Blood Transfusion Consent policy include a statement regarding **how and/or where** the informed consent for transfusion should be documented?

Yes  No

**If yes**, according to your hospital Blood Transfusion Consent policy **how** is the informed consent documented?

- Specific Blood Consent form
- Generic consent form including a specific reference to transfusion
- Generic surgical consent form with a specific reference to transfusion
- Generic consent form without a specific reference to transfusion
- Blood request form
- Medical record notation
- Does not state
- Other (please state)

**If yes**, according to your hospital Blood Transfusion Consent policy **where** is the consent documentation maintained on completion?

- Medical record
- Electronic format
- Medical record and electronically
- Does not state
- Other (please state)

Does your hospital Blood Transfusion Consent policy specify how long transfusion consent remains valid?

Yes  No

For patients with conditions that require ongoing transfusions, does your policy state how long consent remains valid (e.g. a haematology/oncology patient receiving transfusions as supportive care for their current treatment regime)?

Yes  No

**If yes**, how long is the ongoing consent valid? (single answer).

- No time frame specified
- For an admission only
- Up to and including 3 months
- More than 3 months and up to and including 6 months
- More than 6 months and up to and including 1 year
- More than 1 year but not indefinite
- Indefinite

Does your hospital Blood Transfusion Consent policy state that the consent process should involve a discussion with the patient that includes the following?:

- |   |                              |                             |
|---|------------------------------|-----------------------------|
| The reasons for the proposed blood product transfusion                        | <input type="checkbox"/> Yes | <input type="checkbox"/> No |
| The risks and benefits of the blood product                                   | <input type="checkbox"/> Yes | <input type="checkbox"/> No |
| The risks or consequences of not receiving the product                        | <input type="checkbox"/> Yes | <input type="checkbox"/> No |
| The availability and appropriateness of any other blood management strategies | <input type="checkbox"/> Yes | <input type="checkbox"/> No |
| An opportunity to ask questions   | <input type="checkbox"/> Yes | <input type="checkbox"/> No |
| Use of a competent interpreter when the patient is not fluent in English      | <input type="checkbox"/> Yes | <input type="checkbox"/> No |
| Use of written information or diagrams where appropriate                      | <input type="checkbox"/> Yes | <input type="checkbox"/> No |

Does your hospital Blood Transfusion Consent policy specify whose responsibility it is to obtain consent?

- No one is specified
- Consultant Medical Officer  Registrar  Intern
- Nurse practitioner
- Other (please specify)

Does your hospital Blood Transfusion Consent policy specify what supporting written information is to be used in the consent process?

Yes  No

**If yes**, please indicate what 'supporting written information' is specified:

- State based patient information about transfusion (e.g. Blood Matters/BloodSafe/Blood Watch)
- Locally developed hospital transfusion information
- No local patient information leaflet for transfusion is currently available
- ANZSBT/NHMRC – 'Blood Who Needs It?'
- Children receiving a blood transfusion: A Parents Guide (ANZSBT/ARCBS/NZBS/SA DoH)
- Other (please state)

*Thank you for your involvement.*

## Part B: Audit of Transfusion Consent Practice

(Maximum of 30 Transfusion administration episodes per hospital)

Hospital name

Patient audit number

(Please number your audits sequentially from 1–30)

Patient age:

YEARS

Gender:  Male  Female

Clinical Specialty:  Medical  Haematology/ Oncology  Surgical  Obstetric

Please complete for A SINGLE UNIT transfused for an individual patient.

Date of Transfusion:

( DD / MM / YYYY )

Have you also completed Part C for this patient/ transfusion episode?

Yes  No

If yes, please enter the patient audit number allocated in Part C for this patient.

Type of Blood Component transfused:

- Red Blood Cells  
 Platelets  
 FFP  
 Cryoprecipitate  
 Fractionated blood product

Were other blood products ordered for that date of Transfusion?

Yes  No

If yes, please indicate the blood products requested:

- Red Blood Cells.  
 Platelets  
 FFP  
 Cryoprecipitate  
 Fractionated blood product

Was consent documented and valid for the product administered?

Yes  No

If yes, who obtained the consent?

- Consultant Medical Officer  Registrar  Intern  
 Nurse practitioner  Cannot identify  
 Other (please specify)

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

Yes  No

Thank you for your involvement.

## Part C: Patient/Parent/Guardian Understanding of the Consent Process

(Maximum of 30 Transfusion administration episodes per hospital)

Hospital name

Patient audit number  (Please number your audits sequentially from 1–30)

Date of survey  ( DD / MM / YYYY )

Patient age:  YEARS

Gender:  Male  Female

English as first language  Yes  No

Clinical Specialty:  Medical  Haematology/ Oncology  Surgical  Obstetric

Completed with  Patient  Parent  Guardian

Have you also completed Part B for this patient/ transfusion episode?

Yes  No

If **yes**, please document the patient audit number allocated in Part B for this patient.

Have you /your child/ your ward received a blood transfusion during this hospital admission?

Yes  No

**If patient/parent/ guardian answer NO they are not aware they have received a transfusion, please DO NOT proceed with the following questions.**

Did you feel you were involved with the decision making process to receive a blood transfusion?

- Yes  
 To a certain degree  
 No  
 Cannot recall

Do you have any comments on your involvement with the decision making process to receive a blood transfusion?

Can you recall if the information you received about the blood transfusion was verbal?

Yes  No  Cannot recall

Can you recall if the information you received about the blood transfusion was in written form (brochure etc)?

Yes  No  Cannot recall

**If yes to either question above**, when was this written and/or verbal information given to you?

- Prior to your admission  
 On admission  
 At the time you were informed that you needed a blood transfusion.  
 At the time you were asked to complete a consent form for a blood transfusion  
 Other please specify

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

Yes  No  Cannot recall

Were the possible risks of **not** having the blood transfusion discussed with you?

Yes  No  Cannot recall

Were you offered alternatives to the blood transfusion?

Yes  No  Cannot recall

**If yes**, can you recall what these alternatives were?

Iron  Vitamins  Erythropoietin

Cell salvage  Change to medication  Other medication/procedure

Cannot recall

Were you given the opportunity to ask questions?

Yes  No  Cannot recall

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

Yes  No  Cannot recall  Did not ask questions

Were you asked to give consent?

Yes  No  Cannot recall

What do you understand was the reason for your blood transfusion?

Cancer or cancer treatment (chemotherapy)

Bone marrow failure

Anaemia

Blood loss/bleeding

Low iron

Low Hb

Surgery

Trauma

Thalassaemia major

Thrombocytopenia

Factor deficiency

Liver disease

Renal failure

Drug effects e.g. for example Warfarin, Clopidogrel

Cannot recall

Other: (please specify)

Do you feel you received enough information about having a transfusion?

Yes  No  Cannot recall

*Thank you for your involvement.*

# Appendix 2: Consent Audit Instructions

## Audit of Consent for Blood Transfusion

### Background

The Blood Matters Program works with hospitals to ensure that blood components are administered to patients appropriately and safely. With the introduction of the Australian Commission on Safety and Quality in Healthcare (ACSQHC), National Safety and Quality Health Service Standards there is an increased emphasis for hospitals to have formalised informed consent processes in place.

The Blood Matters Program Patient Blood Management Steering Group has identified the area of 'blood transfusion consent' to audit to determine current practice across the State.

Blood and blood component transfusions are not without risk, and patients should be provided with information about these risks, and potential benefits along with available alternatives. Following these discussions the patients consent or refusal should be documented<sup>1</sup>.

Informed consent is the process by which the patient is provided with information, advice and warnings about the treatment, risks, benefits and alternatives. The process involves a two-way conversation with the patient that takes into consideration patient language and cognitive ability, giving them the opportunity to ask questions and make statements about what is important to them. Provision of written material is also recommended to supplement verbal information<sup>2</sup>.

Aim of this audit is to improve the quality of care provided to patients by ensuring blood and blood product transfusion consent policies are available, appropriate, understood and practised within hospitals. These policies should be consistent with the Australian and New Zealand Society of Blood Transfusion (ANZSBT)/ Royal College of Nursing Australia (RCNA) Guidelines for the Administration of Blood Products 2nd edition, 2011; ACSQHC – National Safety and Quality Health Service Standards and the Australian Health Ministers' Conference (AHMC) – Statement on National Stewardship Expectations for the Supply of Blood and Blood Products.

Objectives:

- To determine if blood and blood product transfusion consent policies are available within hospitals and are consistent with the ANZSBT/RCNA Guidelines for the Administration of Blood Products 2<sup>nd</sup> edition 2011
- To determine if blood and blood product administration is undertaken with consent
- To determine patients' understanding of the information given to them as part of the consent process.

Method:

- Three audit forms are provided, these include:
  - Part A – '**Audit of Hospital-wide Blood Transfusion Consent Policy**'.
  - Part B – '**Audit of Blood Transfusion Consent Practice**'
  - Part C – '**Audit of Patients (Parent/ Guardian) Understanding of Consent**'.
- Each electronic audit tool includes a hospital/hospital drop down box. This is to aid data analysis and to provide individual organisations who contribute data with their results once the audit is completed and analysed. All results published from the audit will be de-identified.
- We request that all the audit tools (Part A, B & C) be completed by all hospitals/health services.
- The desk audit tool Part A – '**Audit of Hospital-wide Blood Transfusion Consent Policy**' may be completed at any time within the specified time-frame. This audit is an assessment of the hospital consent policy for blood transfusion in line with the 'Guidelines for the Administration of Blood Products' ANZSBT/RCNA 2nd edition, 2011. Complete once for each hospital/health service.

Definition:

- A hospital-wide Blood Transfusion Consent Policy maybe a stand alone policy, included as part of your Blood Transfusion policy, or contained within an overall consent to treatment policy.
- 'Informed consent for transfusion means a documented dialogue has occurred between the patient and a prescriber and which includes:
  - The reason for the proposed blood product transfusion.
  - The nature of the proposed blood product transfusion.
  - The risks and benefits of the blood product as well as the risks or consequences of not receiving the product.
  - The availability and appropriateness of any other blood management strategies.
  - An opportunity to ask questions.
  - Use of a competent interpreter when the patient is not fluent in English.
  - Use of written information or diagrams where appropriate.

Consideration of the patient's language and cognitive ability should influence the written information provided. A range of written information for the Australian and New Zealand context, including in languages other than English, and specific information for parents and children is available<sup>1</sup>.

- Validity – is defined as the documentation required and timeframe identified within your hospital Blood Transfusion Consent Policy.

The Part B – '**Audit of Blood Transfusion Consent Practice**' is to determine the consent rate for transfusion with up to 30 individual randomly selected transfused patients.

For the purpose of this audit, it is recommended that only one unit per individual patient be recorded (if the patient is receiving more than one unit for the current prescription, please indicate this on the audit tool). This audit could be undertaken either at the time of transfusion, anytime during the admission or following discharge.

The Part C – '**Audit of Patients' (Parent/ Guardian) Understanding of Consent for transfusion**' requires engaging the patient, parent/guardian during their admission either at the time of transfusion, within 72 hours of transfusion, or prior to discharge, to ask a series of questions around the information given to them. If this audit is undertaken at the time of transfusion it is recommended that the audit not be performed by the person who has ordered, or is administering the transfusion.

These questions can be asked of the patient, parent/guardian whether the consent process was undertaken or not.

Some hospitals may require permission to undertake Part C of this audit: Patient/ Parent/ Guardian Understanding of the Consent Process. If gaining this permission will delay the timely return of audit data, please advise the Blood Matters program.

Please advise participants that at no stage will the individual be identified during the audit and that their name will not be provided to the Department of Health Blood Matters Program.

Part B & C could be completed on the same patient for the same transfusion episode. If so, please document the patient audit number as outlined on each part.

Guidelines/Standards supporting the consent process:

- Australian and New Zealand Society of Blood Transfusion (ANZSBT)/ Royal College of Nursing (RCN)–‘Guidelines for the Administration of Blood Products’ 2<sup>nd</sup> edition, 2011.
- Australian Commission on Safety and Quality in Health Care National Safety and Quality Health Service Standards, Blood and Blood Products, Standard 7.9 –7.11.
- Australian Health Ministers’ Conference – Statement on National Stewardship Expectations for the Supply of Blood and Blood Products – November 2010 <http://www.nba.gov.au/policy/stewardship-statement.pdf>

Data Set for Blood Product Consent:

The hospital transfusion committee (or equivalent), are asked to take this opportunity to ensure that the required steps for blood product consent are included in your hospital consent and blood transfusion administration policy and procedures. This includes adequate documentation in the medical record as stated in the ANZSBT/RCNA guidelines 2<sup>nd</sup> edition (2011) and ACSQHC – National Safety and Quality Health Service Standards.

Time Frame:

**Part A:** Can be completed at any time during from **20 August to 30 November 2012**.

**Part B:** Either 30 random transfusion episodes (single unit) of fresh blood products or all transfusion episodes from **20 August to 30 November 2012** (maximum 30).

**Part C:** Thirty patients who are/have received a transfusion, whether a consent process was undertaken or not, from **20 August to 30 November 2012** (maximum 30) or contact Blood Matters program if delayed in timely return of audit data.

Return date for audit data is **14 December 2012**.

Data is to be entered **electronically** using the hospital user name and password (provided) via the Blood Matters Program website located at <http://www.health.vic.gov.au/bloodmatters/audit.htm>. And can be entered anytime from Monday 20 August 2012.

For hospitals that do not have access to the internet or are having difficulties submitting data, completed forms can be posted to the Blood Matters program at:

Blood Matters Program  
Quality, Safety and Patient Experience Branch  
Department of Health  
GPO Box 4541  
MELBOURNE 3001

Data Collection:

The Transfusion Committee (or equivalent) should designate member(s) of staff to complete the information requested on the audit proformas provided (Part A: 'Audit of Hospital-wide Blood Transfusion Consent Policy', Part B: 'Audit of Blood Product Consent Practice' and Part C: 'Audit of Patients Understanding of Consent').

*The Department of Health (the department) is committed to protecting privacy. Information collected during this audit is not capable of identifying any individual and names will not be provided to the department.*

The Blood Matters secretariat will co-ordinate the audit, taking responsibility for the distribution of audit collection tools and analysis, and will disseminate results to the participating hospitals.

References:

1. Australian and New Zealand Society of Blood Transfusion/ Royal College of Nursing Australia – Guidelines for the Administration of Blood Products 2nd edition, 2011
2. Final Report on Survey Findings, July 2003, 'Blood Matters Breakthrough Collaboration Consumer Study', Department of Human Services, Victoria, Australia.

Acknowledgements:

New Zealand Blood Service, Patient Perceptions of Blood Transfusion Survey

Western Health, Consent to transfusion patient survey.

Australian and New Zealand Society of Blood Transfusion, Survey of Documentation of Consent for Transfusion (2010).

**If further information is required please contact:**

Ms Linley Bielby, Program Manager – Tel: 03 9093 9037

or email: [linley.bielby@health.vic.gov.au](mailto:linley.bielby@health.vic.gov.au)

Ms Lisa Stevenson, Transfusion Nurse – Tel: 03 9096 0476 or Ms Jo Perillo, Education Coordinator – Telephone 03 9096 1303

# Appendix 3: Consent for Transfusion Patient Information Sheet

## Audit of Consent for Blood Transfusion Patient Information Sheet

Thank you for taking the time to take part in the Blood Matters survey of patient understanding of the consent for transfusion process.

The Blood Matters Program works with hospitals to make sure that blood products are given to patients safely, appropriately and that correct processes are in place.

Informed consent is the process in which you are given information about the therapy, including the likely benefits and any risk. It also allows you a chance to ask questions about the therapy before you give consent.

Information can be given to you verbally by the doctor and/or in a written format.

This survey is voluntary and it does not impact on your care in any way. The survey only collects information about your sex and age, but not your name.

The survey should take about 15 minutes to complete. An interpreter can be provided if needed, and at any time during the survey you can choose not to take part.

If you have any concerns or complaints about this process please contact:

*<insert name and phone number of relevant person>*

Information about the Blood Matters Program can be found at

<http://www.health.vic.gov.au/bloodmatters/>

## Appendix 4: Part A, B and C result summary

Table 1: Part A response summary

Part A Questions	Response count			%
<b>Number of returned audits:</b>	110			(100%)
<b>Does your hospital policy include a statement regarding obtaining consent for transfusion?</b>				
Yes:		105		(95%)
<b>Which products does your hospital blood transfusion consent policy include?</b>				
Blood and blood products			88	(84%)
Blood Only			11	(10%)
Does Not State			6	(6%)
<b>Does your hospital blood transfusion consent policy include a statement regarding how and/or where the informed consent for transfusion should be documented?</b>				
Yes:		95		(90%)
<b>If yes, according to your hospital blood transfusion consent policy how is the informed consent documented?</b>				
Specific blood consent:			46	(48%)
Generic consent with reference to transfusion:			20	(21%)
Generic surgical consent with reference to transfusion:			4	(4%)
Generic consent with no reference to transfusion:			2	(2%)
Blood request form:			2	(2%)
Medical record notation:			6	(6%)
Does not state:			0	(0%)
Other:			15	(16%)
<b>If yes, according to your hospital blood transfusion consent policy where is the consent documentation</b>				
Medical record:			73	(77%)
Electronic format:			2	(2%)
Medical record and electronically:			7	(7%)
Does not state:			12	(13%)
Other:			1	(1%)
<b>Does your hospital blood transfusion consent policy specify how long transfusion consent remains valid?</b>				
Yes		53		(50%)
<b>For patients with conditions that require ongoing transfusions, does your policy state how long consent remains valid? (e.g. haematology/oncology patient receiving transfusions as supportive care for current treatment regime.)</b>				
Yes		56		(53%)
<b>If yes, how long is the ongoing consent valid?</b>				
No time frame specified:			4	(7%)
For an admission only:			9	(16%)
Up to and including three months:			1	(2%)
More than three months, and up to six months:			14	(25%)
More than six months, and up to 12 months:			26	(46%)
More than one year but not indefinite:			0	(0%)
Indefinite:			2	(4%)
<b>Does your hospital blood transfusion consent policy state that the consent process should involve a discussion with the patient that includes the following?:</b>				
Reasons for proposed blood product transfusion:		81		(77%)
Risks and benefits of the blood product:		88		(84%)
Risks or consequences of not receiving the product:		71		(68%)
Availability of other blood management strategies:		62		(59%)
An opportunity to ask questions:		75		(71%)

Table 1: Part A response summary (cont.)

Part A Questions	Response count		%
Use of a competent interpreter, where appropriate:		50	(48%)
Use of written information, where appropriate:		68	(65%)
<b>Does your hospital blood transfusion consent policy specify whose responsibility it is to obtain consent?</b>			
Not stated:		14	(13%)
Consultant medical officer:		61	(58%)
Registrar:		15	(14%)
Intern:		13	(12%)
NursePract:		3	(3%)
Other:		34	(32%)
<b>Does your hospital blood transfusion consent policy specify what supporting written information is to be used in the consent process?</b>			
Yes:		67	(64%)
<b>If yes, please indicate what 'supporting written information' is specified:</b>			
State-based patient information:		38	(57%)
Locally developed hospital information:		17	(25%)
No local patient information available:		1	(1%)
ANZSBT/NHMRC Blood: who needs it?:		24	(36%)
Children receiving blood transfusion: A parent's guide:		11	(16%)
Other:		8	(12%)

Table 2: Part B response summary

Part B Questions	Response count		%
<b>Number of Patient audits done:</b>	1,788		(100%)
Average/hospital	17.3		(1%)
Min	1		
Max	30		(2%)
<b>Patient age</b>			
Oldest	98		
Youngest	0.5		
Age <14	45		(3%)
Age 14–29	66		(4%)
Age 30–49	180		(10%)
Age 50–69	460		(26%)
Age >70	1,037		(58%)
<b>Gender:</b>			
Male	809		(45%)
Female	979		(55%)
<b>Clinical Specialty:</b>			
Medical	666		(37%)
Haematology/ Oncology	532		(30%)
Surgical	505		(28%)
Obstetric	85		(5%)
<b>Type of Blood Component transfused:</b>	0		
Red Blood Cells	1,636		(92%)
Platelets	68		(4%)
FFP	26		(1%)
Cryoprecipitate	5		(0%)
Fractionated blood product	53		(3%)
<b>Were other blood products ordered for that date of Transfusion?</b>			
Yes	547		(31%)
No	1,241		(69%)
<b>If yes, please indicate the blood products requested:</b>			
Red Blood Cells		468	(86%)
Platelets		44	(8%)
FFP		43	(8%)
Cryoprecipitate		18	(3%)
Fractionated blood product		29	(5%)
<b>Was consent documented and valid for the product administered?</b>			
Yes	1,345		(75%)
No	443		(25%)
<b>If yes, who obtained the consent?</b>			
Consultant Medical Officer		517	(38%)
Registrar		218	(16%)
Intern		192	(14%)
Nurse practitioner		7	(0%)
Cannot identify		169	(13%)
Other – resident		24	(2%)
Other – GP, VMO		136	(10%)
Other – RN		87	(6%)
Other		2	(0%)
<b>Is it documented that written information was given to the patient?</b>			
Yes	430		(24%)
No	1,358		(76%)

Table 3: Part C response summary

Part C questions	Response count		%
Hospitals submitting data	93		
Patient audits (30 max per hospital)			(100%)
Total	1,386		
Average/hospital	14.9		
Max	30		
Min	1		
<b>Patient age:</b>			
Oldest	99		
Youngest	0.5		
Age <14	26		(2%)
Age 14–29	43		(3%)
Age 30–49	123		(9%)
Age 50–69	397		(29%)
Age >70	797		(58%)
<b>Gender:</b>			
Male	661		(48%)
Female	725		(52%)
<b>English as first language</b>			
Yes	1,278		(92%)
No	108		(8%)
<b>Clinical specialty:</b>			
Medical	499		(36%)
Haematology/ Oncology	477		(34%)
Surgical	363		(26%)
Obstetric	47		(3%)
<b>Completed with</b>			
Patient	1309		(94%)
<b>Parent</b>			
Guardian	28		(2%)
	49		(4%)
<b>Have you /your child/ your ward received a blood transfusion during this hospital admission?</b>			
Yes			(98%)
No	22		(2%)
<b>Did you feel you were involved with the decision-making process to receive a blood transfusion?</b>			
Yes		945	(69%)
To a certain degree		225	(16%)
No		138	(10%)
Cannot recall		56	(4%)
<b>Do you have any comments on your involvement with the decision-making process to receive a blood transfusion?</b>			
Comment made		485	(35%)
<b>Can you recall if the information you received about the blood transfusion was verbal?</b>			
Yes		1,167	(86%)
No		75	(5%)
Cannot recall		122	(9%)
<b>Can you recall if the information you received about the blood transfusion was in written form (brochure etc)?</b>			
Yes		439	(32%)
No		720	(53%)
Cannot recall		205	(15%)
<b>If yes to either question above, when was this written and/or verbal information given to you? (Multiple choice)</b>			
Prior to your admission			235 (20%)
On admission			217 (18%)
At the time you were informed that you needed a blood transfusion.			606 (51%)

Table 3: Part C response summary (cont.)

Part C questions	Response count		%
At the time you were asked to complete a consent form for a blood transfusion			212 (18%)
Other			56 (5%)
<b>Were the possible risks associated with the blood transfusion explained to you?</b>			
Yes	931		(68%)
No	246		(18%)
Cannot recall	187		(14%)
<b>Were the possible risks of not having the blood transfusion discussed with you?</b>			
Yes	672		(49%)
No	457		(34%)
Cannot recall	235		(17%)
<b>Were you offered alternatives to the blood transfusion?</b>			
Yes	89		(7%)
No	1,039		(76%)
Cannot recall	236		(17%)
<b>If yes, can you recall what these alternatives were?</b>			
Iron		48	(54%)
Vitamins		7	(8%)
Erythropoietin		1	(1%)
Cell salvage		3	(3%)
Change to medication		4	(4%)
Other medication/procedure		9	(10%)
Cannot Recall		30	(34%)
<b>Were you given the opportunity to ask questions?</b>			
Yes	1,111		(81%)
No	114		(8%)
Cannot recall	139		(10%)
<b>If you did ask questions, do you feel your questions were answered?</b>			
Yes	701		(82%)
No	39		(5%)
Cannot recall	117		(14%)
Did not ask questions	507		(59%)
<b>Were you asked to give consent?</b>			
Yes	1,086		(80%)
No	127		(9%)
Cannot recall	151		(11%)
<b>What do you understand was the reason for your blood transfusion? (Multiple choice)</b>			
Cancer or cancer treatment (chemotherapy)	236		(17%)
Bone marrow failure	85		(6%)
Anaemia	352		(26%)
Blood loss/bleeding	291		(21%)
Low iron	52		(4%)
Low Hb	445		(33%)
Surgery	76		(6%)
Trauma	3		(0%)
Thalassaemia major	7		(1%)
Thrombocytopenia	18		(1%)
Factor deficiency	2		(0%)
Liver disease	10		(1%)
Renal failure	14		(1%)
Drug effects e.g. warfarin, clopidogrel	8		(1%)
Cannot recall	43		(3%)
Other	113		(8%)
<b>Do you feel you received enough information about having a transfusion?</b>			
Yes	1,187		(87%)
No	98		(7%)
Cannot recall	79		(6%)

# References

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