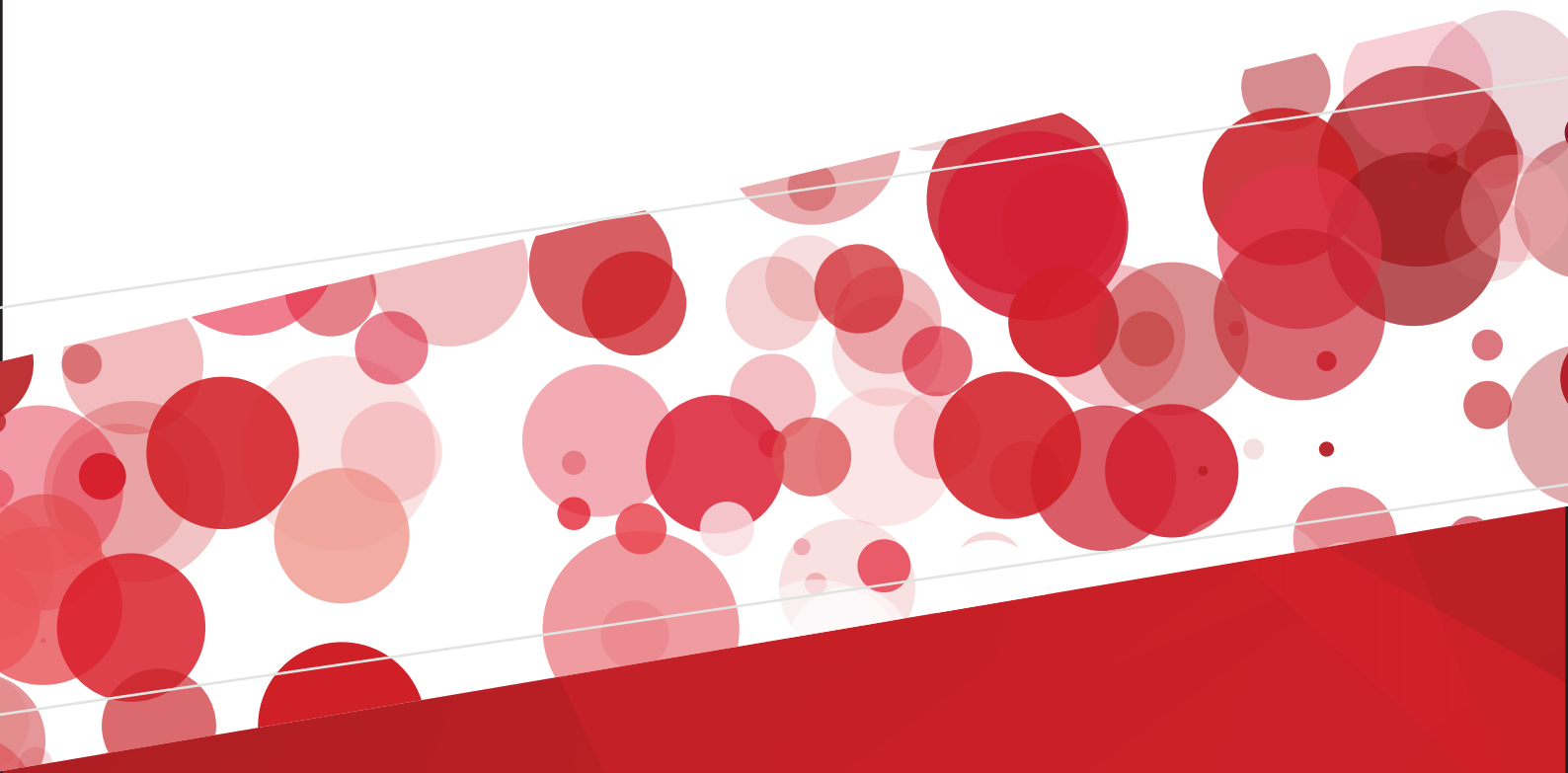
Consent for blood transfusion 2022 audit report

November 2022



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Contents

Acknowledgement

Blood Matters would like to thank everyone who contributed to this audit on consent for blood transfusion. Your efforts to collect and report data especially at a time when health services were in the post COVID-19 recovery phase is greatly appreciated.

The data has made it possible for Blood Matters to present this report on aspects related to blood transfusion consent policy and practice.

Abbreviations, acronyms and definitions

ACN	Australian College of Nursing
ACSQHC	Australian Commission on Safety and Quality in Healthcare
AHMC	Australian Health Ministers Consensus
ANZSBT	Australian and New Zealand Society of Blood Transfusion
FFP	fresh-frozen plasma
HDU	high-dependency unit
ICU	intensive care unit
MTDM	medical treatment decision maker
NP	nurse practitioner
PBM	patient blood management
RBC	red blood cells

Limitations

Auditors were not formally instructed for consistent data collection; accuracy of data depends on auditors following the audit tool instructions provided by Blood Matters (Appendix 1).

Patient selection was at the auditor's discretion, and this may have influenced the clinical speciality audited.

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

Executive summary

Blood component and blood product transfusions are not without risk, and patients should be informed of the risks and benefits of receiving such a treatment. There is an expectation that consent to, or refusal of, treatment is documented as evidence of a consent process being followed.

The Australian Commission on Safety and Quality in Healthcare (ACSQHC) *National Safety and Quality Hospital Standards, Blood Management Standard* requires health service 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/Australian College of Nursing *Guidelines for the administration of blood products* (ANZSBT/ACN 2019); and the Australian Health Ministers' Conference (AHMC) *Statement on national stewardship expectations for the supply of blood and blood products* (2010).

Ten years ago, Blood Matters undertook a similar audit, and this report indicates that there have certainly been improvements. Conversely, there are some areas where further improvements could be made, and these are reflected in the recommendations. In general tightening policies and practice to include:

- duration of consent and documenting this on the consent form
- indicating which blood components/products are being consented to and the condition for which the transfusion is indicated
- documenting risk related to or consequences of not receiving the product, and availability of other blood management strategies
- use of interpreters and the provision of written information.

To assist health services acknowledge their achievements or address gaps, participating health services have been provided reports outlining their individual performance to policy criteria per the ANZBST/ACN 2019 guidelines, and how their practice aligns with their policy and guidelines.

Introduction

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

Blood Matters conducted an audit of consent policy, practice and patient understanding in 2012. Since the first audit, the *Guidelines for the administration of blood products* (ANZSBT/ACN 2019) and *National safety and quality health service standards* (ACSQHC 2021) have been revised.

Health service policies developed to guide practice should be consistent with the *Guidelines* (ANZSBT/ACN 2019), *National standards* (ACSQHC 2021) and the Australian Health Ministers Consensus Statement (AHMC 2010) on national stewardship expectations for the supply of blood and blood products.

Informed consent is a process that 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. 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 (ANZSBT/ACN 2019).

Ensuring informed consent is properly obtained is a legal, ethical and professional requirement on the part of all treating health professionals and supports person-centred care. Good clinical practice involves ensuring that informed consent is validly obtained and appropriately timed (ACSQHC 2020).

The aims of the 2022 audit were to:

- identify if health service blood transfusion consent policies are available and consistent with guidelines and standards
- measure current practice against guidelines.

The objectives of the audit were to determine if:

- blood transfusion consent policies and practices have improved since the 2012 audit
- the health service transfusion consent policy aligns with the ANZSBT/ACN *Guidelines for administration of blood products 2019*
- consent is undertaken prior to transfusion and all elements are completed, as per guidelines, for a valid consent

Due to COVID-19 protocols in place at the time of the audit, and the potential requirement for individual health services to request ethics approval to interview patients, the 2022 audit did not include patients' (or parent/guardian) understanding of consent.

Results will 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.

Method

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

The two parts (see Appendix 1) included:

- Part A 'Audit of hospital-wide blood transfusion consent **policy**'
- Part B 'Audit of blood transfusion consent **practice**'.

Data collection occurred between 27 June and 12 August 2022.

The 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/ACN 2019).

Part B 'Audit of blood transfusion consent practice' measured the consent rate and quality of informed consent for transfusion documented in the medical record of up to 30 individual randomly selected patients who received a fresh blood component transfusion between 1 July 2021 and 30 June 2022.

It was expected that the hospital transfusion committee or equivalent would 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 webpage via an online survey tool on the LimeSurvey platform. The data was imported into a customised Microsoft Access database, before cleaning and analysing the data.

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

Results and discussion

This section highlights aspects of the data reported and discusses these results as they relate to the ANZSBT/ACN, *Guidelines for the administration of blood products* (2019) and ACSQHC *National safety and quality health service standards* (2021).

Some health services with multiple campuses responded under a single code, whereas other health services submitted responses for each campus. One-hundred and one health services submitted a response for either Part A and/or Part B, representing 110 campuses.

Part A: Hospital transfusion consent policy

Ninety-eight health services submitted a response regarding their policy.

Six health services submitted multiple policy responses with conflicting information from different personnel. All respondents from the health services were contacted to resolve. One conflict was, in part, due to the source of the information: namely, the consent policy versus the blood administration policy.

This highlights that both sources of information should be consistent, and where one policy has less detail, it should refer clinicians to the more detailed policy for further information.

Of the 98 health services submitting a response, three (3 per cent) did not have a policy regarding consent for transfusion of blood and blood products. Although they reported no policy, they all stated there was a policy statement in other sources: namely, a section within the blood administration policy that directs obtaining informed consent prior to administration of blood or a blood product (n = 2) or under 'health legal' (n = 1).

The policy is important for outlining the governing principles of the consent process, including the blood components and/or 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. This enables staff to understand health service expectations, and to ensure compliance with best practice and national guidelines and standards.

All health services with a policy (n = 95) included the method of documenting the transfusion consent. Eighty-eight (93 per cent) defined the blood components requiring consent.

ANZSBT/ACN guidelines (section 2.2) state that consent must be documented by the clinician and recorded as per facility requirements, for example:

- **on a generic or transfusion-specific consent form, or**
- **in the healthcare record**.

Table 1 shows the types of consent forms and documentation processes used at responding health services, all (100 per cent) complying with current national recommendation.

Table 1: Type of consent form and documentation required for transfusion consent

Type of documentation	Public, n = 63 (%)	Private, n = 32 (%)
Specific consent form	58 (92)	27 (84)
Generic consent form	19 (30)	26 (81)
Medical record notation	15 (24)	4 (13)
Other – blood component admin chart	1 (2)	–

Note: Multiple responses were allowed.

Fifty-one health services reported only one method of consent documentation in the policy, which was predominately a specific consent form (n = 41); 34 policies included two methods of consent documentation, with 10 policies covering all three methods of documentation.

The current ANZSBT/ACN guidelines (ANZSBT 2019) state that the clinician is required to document consent, whereas in previous versions, this was the prescriber's responsibility.

New South Wales Health consent to medical and healthcare manual (2020) clearly states:

> Consent for a blood transfusion or the administration of blood products must be obtained by the Admitting Medical Officer or a Health Practitioner to whom the task is properly delegated. In most cases, it should be obtained by a Medical Practitioner.

Recently, the ANZSBT (2021) released a framework outlining the role of nurse practitioners (NP) to prescribe and obtain consent for blood and blood product transfusion, where included in their scope of practice.

NPs have become a recognised part of the clinical workforce, with their extended scope of practice including prescribing medications within a defined formulary, according to their education and expertise. NPs are senior nursing staff, with specialist qualifications, responsible for overseeing all aspects of care of their patients. Where there is a need, health services may include the prescription of blood and blood products within an NPs scope of practice.

In addition, some health services may support registered midwives to prescribe RhD immunoglobulin, within their scope of practice and as noted in Table 2. The Victorian Department of Health states that an authorised midwife is authorised to obtain, possess, use, supply or prescribe medicines in Schedules 2, 3, 4 or 8 that are 'approved by the Minister' (for Health) in the lawful practice of his or her profession as an authorised midwife.

Clinicians given the responsibility for obtaining blood and blood product consent within policies are outlined in Table 2.

Table 2: Policy statement on who can obtain transfusion consent

Responsible for obtaining and documenting consent	Public, n = 63 (%)	Private, n = 32 (%)
Consultant medical officer	39 (62)	28 (88)
Registrar	22 (35)	15 (47)
Intern	18 (29)	6 (19)
Nurse practitioner	10 (16)	1 (3)
Registered midwife	5 (anti D only) (8)	1 (3)
Other	18 – medical officer (29) 1 – health/accredited practitioner (2) 1 – prescriber (2)	3 – medical officer (9) 2 – accredited practitioner (6)
Not specified	3 (5)	1 (3)

Note: Multiple responses were allowed.

The ANZSBT/ACN guidelines (section 2) recommend:

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

Of the health services with a policy (n = 95), 85 (89 per cent) include a specified timeframe for which consent is valid, and 10 health services reported no timeframe (10 per cent). Tables 3 and 4 outline the timeframe variations for valid consent.

Forty-five health services reported that the period specified was the same for all patients in all settings. However, of these health services, 26 went on to report multiple timeframes.

Sixty-six (69 per cent) health services reported multiple durations with all including admission only as an option. Where there was only one period specified it was either up to 12 months (n = 12, 13 per cent), for the admission only (n = 6, 6 per cent), or indefinite (n = 1, 1 per cent).

Where multiple durations are specified, this is likely related to clinical diagnosis, with patients with ongoing transfusion needs often having a longer period of valid consent (12 months or indefinite).

Table 3: Policy statement on the period of time consent remains valid: single period reported

Period of time consent remains valid	Public, n = 10	Private, n = 9
For an admission only	4	2
Up to 12 months only	5	7
Indefinite only	1	–

Table 4: Policy statement on the period of time consent remains valid: multiple periods reported

Period of time consent remains valid	Public, n = 48	Private, n = 18
Admission or indefinite	1	–
Admission or up to 12 months	45	18
Admission or up to 12 months or indefinite	2	–

ANZSBT/ACN guidelines (section 2.1) recommends:

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

- **the reason for the proposed blood product transfusion**
- **the proposed blood product for transfusion**
- **the risks and benefits of the blood product, and 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 health service approved interpreter where the patient has limited proficiency in English**.

This is consistent with the Australian Charter of Healthcare Rights (2019). The ANZSBT/ACN 2019 guidelines also outlines in the recommendations that health services transfusion consent policy should include the inability to give consent, including in an emergency situation.

In Victoria, the *Medical Treatment Planning and Decisions Act 2016* specifies who has legal authority to make medical treatment decisions where the patient may not have capacity. The Australian Commission on Safety and Quality in Health Care (ACSQHC) 2020 fact sheet for clinicians on *Informed consent in health care* includes principles for assessing legal capacity and points of contact for further information across Australia.

It is expected that written consent is obtained for significant treatments/procedures including blood transfusions and where a medical treatment decision maker (MTDM) is signing on behalf of a patient.

Table 5 lists the discussion points that should be included in the dialogue with the patient in each health service policy.

Table 5: Discussion points in policy to obtain informed consent

Discussion points	n (%)
Reasons for proposed blood product transfusion	94 (99)
Risks and benefits of the blood product	95 (100)
Risks or consequences of not receiving the product	86 (91)
Availability of other blood management strategies	87 (92)
An opportunity to ask questions	89 (94)
Use of an approved interpreter	76 (80)
Meeting all points above	66 (69)

Sixty-six health service policies (69 per cent) included all discussion points.

In 82 (86 per cent) policies, it is stated that written information should be offered and appropriate to the patient's health literacy. The majority of responses reported written information was made available in a standard format based on state and/or national information.

Overall, as shown in Table 6, health services have improved their policies regarding consent for transfusion since the previous audit in 2012.

Table 6: Comparison of policy meeting guideline criteria

Policy criteria	2022 (%)	2012 (%)
Total policy responses	98	110
Consent policy in place	95* (97)	105 (95)
Method for documenting consent	95 (100)	95 (90)
Who can obtain transfusion consent	91 (96)	91 (87)
Period that consent is valid is stipulated	85 (89)	53 (50)
Complete discussion points	66 (69)	37 (35)
Process outlined when patient unable to give consent	89 (94)	Not asked

In 2022, three health services reported no policy, however a statement regarding consent could be found in other sources.

It is pleasing to see that overall, there has been a significant improvement in the quality of consent policy when compared to 2012 audit.

Part B: Audit of blood transfusion consent practice

A total of 1,891 individual patient transfusion episodes were reported by 87 health services (60 public and 27 private health services). A small number of health services (n = 2) reported that they did not participate in part B of the audit as there were no transfusions during the reporting period.

Of the transfusion episodes reported, 891 recipients (47 per cent) were male patients and 1,000 (53 per cent) females. The average age of the patients reported was 65 years with a range of less than one year to 101 years.

As shown in Table 7, the highest proportion of transfusion episodes audited were in a medical area (n = 694, 37 per cent), followed by haematology/oncology, surgical, obstetrics, emergency department and ICU/HDU.

Table 7: Reported clinical area of patients audited

Clinical area	Public, n = 1302 (%)	Private, n = 589 (%)
Medical	547 (42)	147 (25)
Haematology/oncology	295 (23)	216 (37)
Surgical	217 (17)	186 (32)
Emergency department	106 (8)	5 (1)
Obstetrics	96 (7)	21 (4)
ICU/HDU	41 (3)	14 (3)

Ninety-three per cent (n = 1762) of the 1,891 transfusion episodes were red blood cells (RBC), 10 per cent (n = 180) platelets, 2 per cent (n = 40) fresh-frozen plasma, and two per cent (n = 39) cryoprecipitate (see Table 8). In addition, 25 (1 per cent) reported the blood component was 'unknown or not documented'. One-hundred and fifteen (six per cent) patients received more than one blood component during the reported transfusion episode, and when multiple components were transfused, the largest proportion of these were RBC.

Table 8: Reported blood components transfused

Blood component	Public, n = 1,302 (%)	Private, n = 589 (%)
Red blood cells	1,198 (92)	564 (96)
Platelets	128 (10)	52 (9)
Fresh-frozen plasma	31 (2)	9 (2)
Cryoprecipitate	32 (2)	7 (1)
Unknown or not documented	24 (2)	1 (0.2)

Note: Multiple responses were allowed.

All blood components and blood products must be traceable to the recipient. For those patients reported as blood component unknown or not documented, we have no additional information.

It is important that all health services have processes in place to trace all blood components and products as specified in the Victorian Department of Health *Traceability requirements of blood and blood products* <https://www.health.vic.gov.au/traceability-requirements-of-blood-and-blood-products>.

Consent found

Evidence of consent was found for 1,823 (96 per cent) patients. However, this does not necessarily mean the consent was completed as per the guidelines to make it a valid consent.

In 2012, the rate of informed consent as documented and valid for the product administered was self-reported to be 1,345 (75 per cent). For this current audit, health services reported on individual elements of the consent. An algorithm was developed to determine if each consent was valid and met the requirements as detailed in the ANZSBT/ACN guidelines (2019).

The designation of the person who obtained consent can be seen in Table 9. Table 10 shows if the patient or MTDM signed the consent, and Table 11 has the reported reason for consent not being signed.

Table 9: Designation of who obtained consent

Designation	Public, n = 1,256 (%)	Private, n = 567 (%)
Medical officer	823 (66)	471 (83)
Registrar	242 (19)	56 (10)
Intern	84 (7)	10 (2)
Nurse practitioner	14 (1)	1 (0.2)
Cannot identify	89 (7)	24 (4)
Unsigned	4 (0.3)	5 (1)

As shown in Table 9, a medical officer most frequently (n = 1,294, 71 per cent) obtained consent. At four health services, 15 patients who received a transfusion had consent obtained by a nurse practitioner.

Recently, the role of nurse practitioners, in prescribing and obtaining consent for blood and blood products has been clarified with a supporting guideline (ANZSBT/ACN 2021).

Table 10: Consent signed by patient

Person who signed	Public, n = 1,256 (%)	Private, n = 567 (%)
Patient	1,070 (85)	532 (94)
Medical treatment decision maker	104 (8)	24 (4)
Unsigned	82 (7)	11 (2)

Of the 93 consent forms unsigned by patients or MTDM, 22 did not provide further information on reasons they were unsigned.

Table 11 outlines the reasons documented for no signature, including 21 (23 per cent) from one health service where the policy does not state the need to obtain the patient signature. It is acknowledged that the signing of a consent is not necessarily evidence of a valid consent, although it does indicate that some level of discussion was entered into with the patient or MTDM.

Table 11: Reasons provided why consent unsigned by patient (or MTDM)

Reasons provided	Number, n = 93 (%)
Hospital policy does not require signature	21 (23)
Verbal consent with next of kin or MTDM*	17 (18)
Verbal consent with patient*	14 (15)
Patient did not have capacity	5 (5)
Verbal consent due to COVID-19 isolation*	4 (4)
Emergency transfusion	4 (4)
Signed by next of kin*	2 (2)
Patient anaesthetised	2 (2)
Signed in incorrect place*	1 (1)
Thought there was existing long-term consent	1 (1)
No reason provided	22 (24)

*Process and documentation considered to be appropriate and valid for the situation (n = 38).

The information provided shows that 35 of the patients, or their MTDM, or next of kin provided verbal consent for the transfusion, but for various reasons did not sign the form. As consent is a process and the form is documentation of that process, if all other required elements are in place this would constitute a valid consent given there is evidence of why the form could not be signed. There were five reported events where consent was not sought from a MTDM or next of kin for patients who did not have capacity, in addition there were two patients anaesthetised without obtaining consent for blood and blood product transfusion.

The audit instructions requested data related to non-urgent transfusions. Table 11 highlights four patients where consent was not signed due to it being reported as emergency transfusion, however one of the patients did have a surgical consent signed by the patient's MTDM (information provided in additional notes by the auditor).

Consent must be specific to an identified purpose. In this case, it is the blood component being recommended to the patient for transfusion. Table 12 lists the blood component reported as transfused and the components included on the consent form. Nine hundred and seventy-seven (54 per cent) consent forms included a generic statement covering all fresh blood components, the remaining 846 specifically stated for which blood components consent was being sought. Overall, 1,763 (97 per cent) consent forms documented the correct proposed blood components for transfusion.

Table 12: Reported components transfused is documented on consent

Component/s reported as transfused	Component /s documented on consent form Generic statement	Component /s documented on consent form All specific components covered	Component /s documented on consent form Some components covered	Component /s documented on consent form No component documented
Multiple components transfused (n = 114)	67	37	6	4
RBC only (n = 1596)	829	729	n/a	38
Platelets only (n = 74)	54	17	n/a	3
FFP only (n = 6)	3	1	n/a	2
Cryoprecipitate only (n = 12)	10	2	n/a	–
Unknown blood components (n = 21)	14	–	n/a	7
Total	**977**	**786**	**6**	**54**

Table 13 outlines the consent duration and if it was valid at the time of transfusion, based on the consent date, consent duration, and transfusion date.

Table 13: Consent duration: valid

Duration stated on consent form	Count of valid consents
12 months or more but not indefinite	16
For the admission only	945
Up to 12 months	475
Indefinite	22
Not stated but policy includes single time frame for all patients in all settings	35
Total	**1,493 (82%)**

Individual consents that did not have duration of validity included were considered as valid where the health service had a policy that included a single time frame for all patients in all settings.

Consent duration may have been deemed invalid due to consent occurring after transfusion, no date on consent form, consent validity had expired, or time period was not specified (Table 14).

Table 14: Consent duration: not valid

Reason not valid	Count of invalid consents
Transfusion occurred prior to consent	52
No date on consent	18
Transfusion occurred beyond consent duration	3
No time period specified on consent (multiple consent durations in policy) (see Table 15)	257
Total	**330 (18%)**

Where there was no time frame specified on the consent, a review of health service policy showed that not all health services clearly state the duration for which consent is valid. In addition, several health services policies had more than one time period the consent may be valid, and these consents would need to show which timeframe applied to be valid.

Table 15 shows the breakdown of the policy consent duration where a consent form did not state duration of validity.

Table 15: Consent policy statement specifying the time period transfusion consent remains valid, where no time frame specified on consent form (Table 14).

Consent duration stated in policy	Count of individual consents with no time frame specified (n = 257)	Number of health services
No duration included in policy/no policy	58	7
Multiple: Admission/up to 12 months/indefinite	5	2
Multiple: Admission/up to 12 months	194	30

For patients or their representative to make an informed choice regarding transfusion, they need to be provided with the details regarding the need for the transfusion, what the risks and expected benefits would be, and the risk of not having the transfusion.

Where there are other treatments available, this should also be discussed along with the discussion about other patient blood management (PBM) strategies that could reduce the need for transfusion. Even for some patients with reasonably good English proficiency, an interpreter will be needed to convey medical information. All patients should be offered written information in a format they can understand and be given the opportunity to ask questions.

Although the list of discussion points in Table 16 may have been documented on the consent form, it is always difficult to know the extent to which the patient has understood the information. When auditing the medical record, we must assume that the patient has been given the opportunity to ask questions and has understood the information provided as this audit was unable to verify the patients' experience of informed consent.

Table 16: Documented discussion with the patient

Discussion points	n (%)
Reasons for proposed blood product transfusion	1,583 (87)
Risks and benefits of the blood product	1,515 (83)
Risks or consequences of not receiving the product	1,263 (69)
Availability of other blood management strategies	1,230 (67)
Consent included all discussion points	1,130 (62)

Of the 1,823 consents reviewed, 1,536 (84 per cent) reported that an interpreter was not needed, with a further 218 (12 per cent) reported as unknown. Of the 69 patients reported with a limited proficiency in English and needing an interpreter, only 17 (25 per cent) had an interpreter provided.

Table 17: Interpreter needs met

Patient has limited proficiency in English (n = 69)	n (%)
Interpreter needed, and provided	17 (25)
Interpreter needed, and not provided	52 (75)

Written information or diagrams, where appropriate, was provided or offered to 835 patients (46 per cent). Some health services noted that frequently patients refused any written handouts. It should be noted that some patients will refuse t written information and will follow the recommendations of their treating clinician.

The validity of the consent depends on multiple factors being present at the one time and evidence of that process is in the documentation found. For consent to be valid, the ANZSBT/ACN guidelines require documentation of:

- the signature of the clinician obtaining consent
- the signature of the patient/MTDM, or notation of obtaining a verbal consent because the consenter could not sign the consent form
- the component/s offered and subsequently transfused
- all relevant information discussed, including the reason for the proposed transfusion
- the duration of consent
- the date consent was obtained
- the blood component is transfused after consent has been obtained and is within the duration specified
- the use of a health service approved interpreter where the patient has limited proficiency in English.

Table 18 summarises the results of the contributing elements for a valid and informed consent.

Table 18: Summary of elements contributing to informed valid consent

Components contributing to valid consent	n (%)
Signed by clinician (Table 9)	1,814 (99.5)
Signed by patient/MTDM (Table 10 & Table 11)	1,768 (97)
Components transfused are documented on consent (Table 12)	1,763 (97)
Consent duration is documented and valid (Table 13)	1,493 (82)
Fully documented dialogue with patient (Table 16)	1,130 (62)
Patient language needs met (proficient in English or interpreter provided when needed) (Table 17)	1,771 (97)
Total: consent valid and informed across all components	**969 (53)**

No consent found

It was reported documentation of consent could not be found for 68 transfusions. The reasons are listed in Table 19. Patients were located across all clinical areas: medical (n = 30), surgical (n = 13), haematology/oncology (n = 11), obstetric (n = 8), ICU/HDU (n = 4), and emergency department (n = 2).

Table 19: Reasons provided for no documented consent

Reason	n (%)
No explanation provided	33 (48)
Verbal consent only (documented in medical record)	5 (7)
Emergency transfusion*	13 (19)
Other: • 6 patients noted 'Patient unable to consent' was documented • 4 patients – consent was from previous admissions and no longer valid • 4 scanned consent forms could not be found • 2 patients with a generic form did not have blood transfusion consent indicated • 1 locum obstetrician who appears not familiar with protocol.	17 (25)

*Audit instructions excluded transfusions in the emergency situations

One health service expressed concern that with electronic medical records and consent forms being paper based, there were delays in scanning the form into the electronic medical record or forms misplaced.

Commendations and recommendations

Policy – commendations and recommendations

Area of consent	Commendation	Recommendation
Consent policy in place	95/98 (97 per cent) have a policy regarding consent for transfusion of blood and blood products	Nil
Statement on who can obtain consent	91/95 (96 per cent) designate who is responsible to obtain consent	Update policy to include who is responsible to obtain consent (4/95, 4 per cent)
Duration (timeframe) of consent	85/95 (89 per cent) have a policy that specifies the timeframe of consent	Update policy to include timeframe of consent (10/95, 11 per cent)
Discussion points as outlined in ANZSBT/ACN guideline	Inclusion of the reason for transfusion, risks and benefits, risks and consequences of not receiving the blood component or blood product, availability of other blood management strategies and the opportunity to ask questions were reported between 86-95/95 (91–100 per cent)	Update policy to include the use of an approved interpreter (19/95, 20 per cent)

Practice – commendations and recommendations

Area of consent	Commendation	Recommendation
Consent found	Evidence of consent was found for 1,823/1,891 patients (96 per cent)	Nil
Consent signed by patient or MTDM (Tables 10 and 11)	Consent signed 1,768/1,823 (97 per cent)	Nil
Components transfused are documented on consent (Table 12)	Documented 1,763/1,823 (97 per cent)	Nil
Consent duration is documented and valid (Table 13)	–	Consent duration not valid for 365/1,823 (20 per cent) transfusion episodes. In line with the recommended policy updates, educate staff to document consent duration when obtaining consent. Reaudit to document improvement.
Fully documented dialogue with patient/MTDM (Table 16)	–	Provide feedback and educate staff about the gaps in documentation of patient discussion. Reaudit to document improvement. All discussion points missing in 693/1,823 (38 per cent) transfusion episodes.
Interpreter provided when required (Table 17)	–	Provide feedback and educate staff about the gaps in providing an interpreter when required. Reaudit to document improvement. Interpreter needed and not provided for 52/69 (75 per cent) transfusion episodes.

References

Australian Charter of Healthcare Rights 2019, *My health care rights poster A4*, <https://www.safetyandquality.gov.au/sites/default/files/2019-06/Charter of Healthcare Rights A4 poster ACCESSIBLE pdf.pdf>, accessed September 2022.

Australian Commission on Safety and Quality in Healthcare 2020, *Informed consent: fact sheet for clinicians,* ACSQHC, Sydney, <https://www.safetyandquality.gov.au/sites/default/files/2020-09/sq20-030_-_fact_sheet_-_informed_consent_-_nsqhs-8.9a.pdf>, accessed October 2022.

Australian Commission on Safety and Quality in Healthcare 2021, *National Safety and Quality Heath Service Standards*, 2nd edition, ACSQHC, Sydney.

Australian Health Ministers Conference (AHMC) 2010, *Statement on national stewardship expectations for the supply of blood and blood products*, AHMC, Canberra.

Australian and New Zealand Society of Blood Transfusion/ Australian College of Nursing 2019, *Guidelines for the administration of blood products*, 3rd edition, ANZSBT/ACN, Canberra.

Australian and New Zealand Society of Blood Transfusion 2021, *Guidelines for the prescription of blood and blood products by nurse practitioners* (1st edition)

Department of Health 2022, 'Authorised midwives – legislative requirements', State Government of Victoria, <https://www.health.vic.gov.au/drugs-and-poisons/authorised-midwives-legislative-requirements>, accessed 2 November 2022.

Department of Human Services 2003, *Final report on survey findings: Blood Matters breakthrough collaboration consumer study*, State Government of Victoria, Melbourne.

NSW Ministry of Health 2020, *NSW Health consent to medical and healthcare treatment manual* <https://www.health.nsw.gov.au/policies/manuals/Publications/consent-manual.pdf>, accessed October 2022.

State Government of Victoria, *Medical Treatment Planning and Decisions Act 2016*, No. 69 of 2016, <https://www.legislation.vic.gov.au/in-force/acts/medical-treatment-planning-and-decisions-act-2016/009>, accessed October 2022.

Appendix 1

2022 consent for blood transfusion two-part audit and audit instructions and definitions <https://www.health.vic.gov.au/patient-care/blood-matters-audits>.