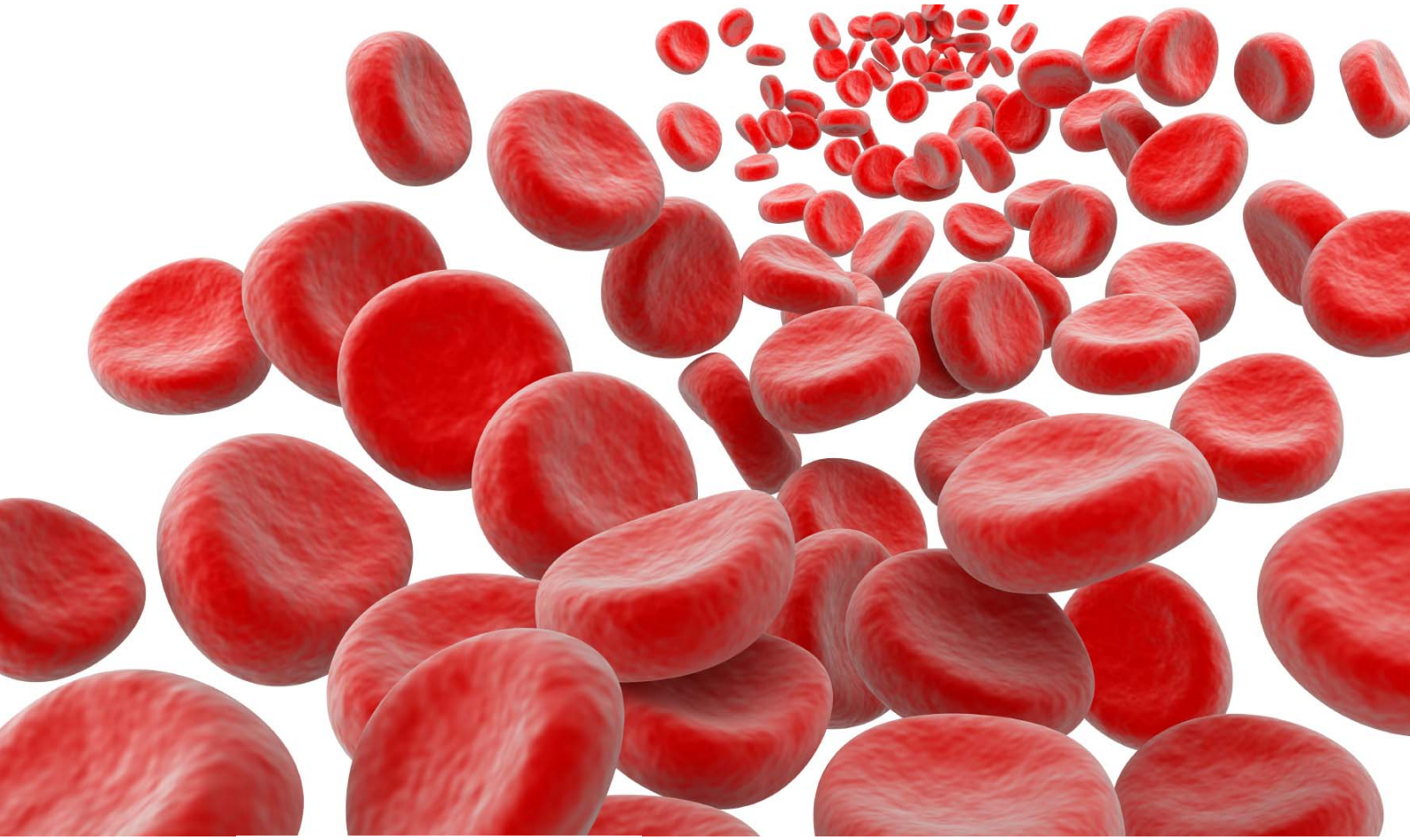
health

Patient blood management in elective orthopaedic surgery 2009

REVISED

Blood Matters Program



State Government Victoria

Australian Red Cross BLOOD SERVICE

Department of Health

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Foreword

We are pleased to rerelease the *Blood management in elective orthopaedic surgery 2009* report. It became necessary to rerelease the report after it became evident that a number of reporting hospitals inadvertently submitted data only on patients receiving a blood product (allogeneic, autologous, or cell salvage) as a result of elective orthopaedic surgery, rather than data on 30 consecutive orthopaedic patients undergoing hip or knee joint replacement whether a transfusion took place or not. This difference in patient selection will have an impact on reported transfusion rate for elective orthopaedic surgical patients. Consequently, Blood Matters undertook to rerun the data (after excluding data where there was methodological uncertainty) to more accurately reflect transfusion rates in elective orthopaedic surgical patients.

Data from 26 Victorian, Tasmanian, Australian Capital Territory, and Northern Territory hospitals that performed elective orthopaedic surgery in 2009 is summarised in this report. These hospitals provided the Blood Matters program with data on blood management in 755 elective orthopaedic procedures performed from the period 1 January through to 31 December 2009. This report will allow individual hospitals to review their own performance in comparison with other participating hospitals and provide an opportunity for Blood Matters to report a summary of health sector performance in this important area of clinical practice.

Measurement and public accountability are requisite steps in all quality improvement processes in healthcare. Publishing reports such as this is one of the strategies we plan to use in our concerted and collaborative efforts to measure and reduce clinically unwarranted variation in the use of blood products across Victorian hospitals.

It is hoped that these efforts will help to promote best practice for patient blood management, including implementation of strategies that optimise blood product use and help ensure safe and appropriate transfusion practices.

Acknowledgements

Thank you to the very many people who contributed to this audit of blood management in elective orthopaedic surgery. Their efforts to collect and analyse data have made it possible for us to present this cumulative report. We trust that making such data accessible will help to improve the safety and appropriateness of transfusion for the ultimate benefit of our patients.

Thanks to those in the project team who have been involved at various stages, including:

Dr Marija Borosak, Transfusion Medicine Specialist, Australian Red Cross Blood Service
Dr Shuh Ying Tan, Haematology Registrar, Australian Red Cross Blood Service

Abbreviations

ANZSBT	Australian and New Zealand Society of Blood Transfusion, formerly ASBT
ASBT	Australasian Society of Blood Transfusion; the Society changed its name in late 2002 to ANZSBT
NBA	National Blood Authority
NHMRC	National Health and Medical Research Council
PAD	Pre-operative autologous donation
RBC	Red blood cell
THR	Total hip replacement
TKR	Total knee replacement
VAED	Victorian Admission Episode Data

Definition list

Intra-operative transfusion	A blood transfusion that takes place while in the operating theatre or within 24 hours of surgery
Post-operative transfusion	A blood transfusion that takes place 24 hours or more after surgery
Over transfusion	A blood transfusion that results in a post-transfusion Hb greater than 115 g/L

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Introduction

The Blood Matters program seeks to improve outcomes in patients requiring blood product transfusion by enhancing the safety and appropriateness of blood and blood product use. The program is a collaborative initiative of the Victorian Department of Health and the Australian Red Cross Blood Service. This audit is part of the annual audit program to assess alignment against national guidelines and should be considered in relation to the National Blood Authority (NBA) Patient Blood Management Guidelines (Module 2 – Peri-operative) currently being developed.

Background

Transfusion of blood products has the potential to improve clinical outcomes by increasing oxygen-carrying capacity in the case of red cells. Transfusion, however, also comes with potential adverse clinical outcomes related to immunomodulation and storage lesion (Isbister 2011). Therefore guidance for clinicians on the optimal use of these products is essential.

Red cell transfusions are given to restore the blood's oxygen-carrying capacity by raising the haemoglobin concentration. Red blood cells may be given to a person who is bleeding or who has severe anaemia. Previous studies have shown variation in clinical practice in the transfusion of red cells. The level of haemoglobin (Hb) is often used as the only indicator for red-cell transfusion because of its easy accessibility. There is no clear evidence indicating the optimal haemoglobin 'trigger'. Hébert's (1999) study of patients in intensive care showed better outcomes when a restrictive transfusion policy was used (that is, maintaining the Hb between 70–90 g/L). The study suggested that this was as safe, or even safer than a liberal transfusion strategy (to an Hb of 100–120 g/L). Consideration should be given to the causes of anaemia and whether it can be managed by alternatives other than red cell transfusion. According to the National Health and Medical Research Council/ Australasian Society of Blood Transfusion (NHMRC/ASBT) clinical practice guidelines for the appropriate use of blood components, if a patient's Hb is less than 70 g/L transfusion should rarely be withheld. Similarly, at the other end of the spectrum, with a Hb greater than 100 g/L transfusion should rarely be given (NHMRC 2001). The draft guidelines for peri-operative patient blood management, which will eventually replace the current clinical practice guidelines, state that red blood cell transfusion should not be dictated by a haemoglobin 'trigger', but based on an assessment of the patient's clinical status. The practice points in the document recommend that patients should not receive a transfusion when the haemoglobin level is ≥ 100 g/L; and in the absence of acute myocardial or cerebrovascular ischemia, post-operative transfusion is inappropriate for patients with a haemoglobin level of > 70 g/L. Transfusion may be appropriate in post-operative patients with acute myocardial or cerebrovascular ischaemia and a haemoglobin level of 70–100 g/L.

In 2009, Blood Matters conducted a repeat of the 2005 audit to determine whether current red cell use in elective orthopaedic surgery in a sample of Victorian, Tasmanian, and Australian Capital Territory hospitals was consistent with contemporary best practice clinical guidelines. Forty-one hospitals regularly performing orthopaedic surgery (as determined by Victorian Admitted Episodes Data Set [VAED]) were invited to contribute data on 30 consecutive orthopaedic patients undergoing hip or knee joint replacement between 1 January 2009 and 31 December 2009 within their institutions.

This report presents the overall findings from analysing the data provided by all of the contributing hospitals. In addition, participating hospitals are provided with a summary and analysis of data collected in their organisation.

Aims and objectives

The overall aim of the audit was to improve the quality of care provided to patients by ensuring the appropriate use of red cells in hospital patients undergoing elective orthopaedic surgery.

Objectives

The objectives were:

1. to determine if blood management and red cell transfusion in orthopaedic patients undergoing hip or knee joint replacement is aligned to clinical practice standards developed from 2001 NHMRC/ASBT clinical practice guidelines
2. to determine if effective alternative treatments are being used.

Methodology

A one-page data collection form (audit proforma, Appendix 1) was prepared with instructions (Appendix 2) for use. The proforma collected basic demographic data, morbidity, pathology and blood product use with dates and quantities.

Auditors

Each hospital's transfusion committee (or equivalent), was advised to designate a member of staff to record the information requested on the proforma provided. The designated data collector in each participating hospital was required to review the patient case notes and collect the relevant data using the audit proforma. It was also suggested that a clinical sub-group identified by the Hospital Transfusion Committee (or equivalent) review the local data on red cell transfusion.

Data collection

Participating hospitals were asked to collect data over a twelve-month period (between 1 January 2009 and 31 December 2009). Hospitals were asked to audit 30 consecutive patients undergoing hip or knee replacement even if they had not received a blood transfusion. For hospitals that have high rates of surgery, it was suggested that every third procedure be audited, up to a maximum of 30 episodes. All patients in the sample were to be audited even if they had not received a blood transfusion. Included were patients undergoing a primary or revision procedure, and on an elective basis.

Data was submitted electronically via a web-based form. There was a return rate of 73 per cent from the hospitals invited to submit data.

Data processing and analysis

Data was imported into a custom designed Microsoft ACCESS database. The data was checked for inaccuracies and inconsistencies using frequency and cross-tabulation procedures. The data check focused on dates, haemoglobin levels, and missing data. Each submitting hospital was given a summary report and a copy of raw data submitted, and provided with an opportunity to amend data as appropriate. The statistical analyses were performed using PASW Statistics 18 (SPSS Inc, Chicago, IL). Significant changes in patterns from 2005 to 2009 data were analysed statistically by the Pearson chi-square test; $p < 0.05$ was considered statistically significant. Some analyses of subgroups (e.g., revision of total knee replacement, PAD, over-transfusion) result in small sample sizes, and therefore caution should be taken when interpreting results.

Data Exclusion

Data was contributed by 30 individual hospitals, reporting on aspects of blood management in 907 episodes of care. Full analysis was completed on 755 audits (579 public hospital patients and 176 private hospital patients); 15 audits were excluded due to incomplete data submission, duplicate data, or excessive audits

submitted (beyond the prescribed 30) per hospital. An additional 121 audits (all patient episodes from 4 hospitals) were excluded from the revised analysis after it was discovered patient selection was not performed as stated in audit methodology and instruction sheet.

Medical reviewer

An independent primary medical reviewer assessed all audits. In addition, a random 10 per cent of the audits were reviewed by a second medical reviewer.

The medical reviewer assessed each transfusion episode as either aligned or not aligned with the clinical practice guidelines (NHMRC/ASBT) based on the information provided by the auditors on the audit proforma (See Appendix 3) as well as for over-transfusion.

The inter-rater reliability between the reviewers for episodes involving transfusion (were adequate information provided) was 83 per cent for alignment and 97 per cent for evidence of over-transfusion.

Summary of findings

This report presents findings from analyses of data provided to Blood Matters by 26 individual hospitals from Victoria, Australian Capital Territory, Northern Territory and Tasmania (20 public hospitals and six private hospitals). These hospitals are routinely performing relatively high numbers of elective orthopaedic surgery.

The report provides the data collected for each specific hospital, and makes this available to those individual organisations. It then presents the overall findings resulting from analysing the data provided by all of the contributing hospitals.

Table 1 shows the breakdown of the 755 episodes of care analysed in this report. Sixty per cent of the patients were female. The average age was 70 years (range: 13 to 98 years). The majority (52 per cent) of these patients reported one or more comorbidities.

Table 1: Procedure type

	Total hip replacements (THR)		Total knee replacements (TKR)	
	2009	**2005**	**2009**	**2005**
Primary	361 (88%)	314 (89%)	323 (93%)	239 (93%)
Revision	45 (11%)	37 (11%)	14 (4%)	17 (7%)
Bilateral	2 (1%)	na	10 (3%)	na
Total	408 (100%)	351 (100%)	347 (100%)	256 (100%)

Major findings in this report include:

The overall rate of blood transfusion in elective orthopaedic surgery is comparative with many international reports. Transfusion rates, however, demonstrated wide variation between participating hospitals.

- Of the 755 patients audited, 32 per cent were transfused (either autologous or allogenic) (inter-hospital range: 10 per cent of all patients to 57 per cent of all patients). There was no change in transfusion rate compared to the 2005 audit.
- The rate of blood transfusion in the various procedure types was: 36 per cent in primary THR; 58 per cent in revision THR; 24 per cent in primary TKR and 14 per cent in revision TKR.
- The use of intra-operative and post-operative salvage techniques had no measurable impact (p=0.357) on the frequency of blood transfusion (overall transfusion rate = 32 per cent; transfusion rate for patients using salvage = 27 per cent).

Blood conservation strategies are currently not commonly applied in elective orthopaedic surgery. Such strategies are relatively more commonly used in the private hospital sector.

- Four per cent of patients overall participated in PAD. Transfusion of donated blood occurred in eight per cent of patients receiving transfusion. Use of PAD was reported by a third of the participating hospitals.
- Intra-operative salvage of blood or post-operative salvage of blood was performed in eight per cent of patients receiving transfusion. Use of cell salvage was reported by 14 of the participating hospitals (9 public hospitals and five private hospitals).
- One or more blood conservation strategies (PAD and/or salvage techniques) were applied in 95 patients (13 per cent).

Use of pre-operative autologous donation is associated with a significantly increased likelihood of transfusion during elective orthopaedic surgery. Transfusion episodes in these patients are also more likely to be deemed not aligned or examples of 'over-transfusion'.

- Of the total transfusions performed, PAD transfusions accounted for nine per cent.
- Patients participating in PAD programs received a blood transfusion 71 per cent of the time, while patients not participating in PAD programs received a blood transfusion only 31 per cent of the time ($p < 0.001$).
- The rate of non-aligned transfusion was 45 per cent in patients participating in PAD programs and 14 per cent in patients not participating in PAD programs ($p = 0.001$).
- The rate of over-transfusion was 10 per cent in patients participating in PAD programs and only four per cent in patients not participating in PAD programs however this is not statistically significant ($p = 0.275$).
- Eleven per cent (3 of 28) of patients participating in PAD programs received homologous blood in addition to autologous transfusion.

There remains an opportunity to improve the appropriateness of decision making regarding:

- **the trigger for initiating blood transfusion**
- **the amount of blood product transfused during elective orthopaedic surgery.**

- Overall, in 83 per cent of transfusion episodes (intra- or post-operatively) the clinical triggers for transfusion were assessed as conforming to clinical practice guidelines.
- In 84 per cent of transfusions occurring intra-operatively or within 24 hours of surgery, the clinical triggers for transfusion were assessed as conforming to clinical practice guidelines.
- In 82 per cent of transfusion occurring more than 24 hours after surgery, the clinical triggers for transfusion were assessed as conforming to clinical practice guidelines.
- Over-transfusion was deemed to have occurred in four per cent of transfusion episodes. Most instances of over-transfusion occurred intra-operatively rather than post-operatively (seven per cent versus two per cent).

A number of patients undergoing elective orthopaedic surgery were anaemic pre-operatively. Optimal management of these anaemic patients offers a further opportunity to enhance blood management in this patient population.

- Seventy-five per cent of patients had pre-operative haemoglobin performed within 30 days of surgery, including 20 per cent within two days of surgery.
- While the mean pre-operative haemoglobin was within the normal range overall (mean 132 g/L; range 78 to 174 g/L), 18 per cent of patients demonstrated pre-operative anaemia.
- Transfusion was more likely to occur in patients demonstrating pre-operative anaemia compared to those having a normal Hb level (70 per cent versus 25 per cent, $p < 0.001$).

Cumulative results from contributing hospitals

Demographics

The demographics and background clinical information of the 755 patients analysed in this report are shown in Table 2.

Table 2: Demographics

	2009		2005	
Total episodes	755		607	
Gender	59% female; 41% male		59% female; 41% male	
Age	Average = 70 years (Range 13 to 98 years)		Average = 69 years (Range 26 to 98 years)	
Comorbidity	52% recorded as having at least one comorbidity		55% recorded as having at least one comorbidity	
Procedure	THR 54% n = 408	TKR 46% n = 347	THR 58% n = 351	TKR 42% n = 256

Disease comorbidity (Table 3) was reported in 52% of patients undergoing elective orthopaedic surgery. There was a very wide variation in recorded comorbidity rates across contributing hospitals (range 16 per cent to 97 per cent).

Table 3: Frequency of hospitals reporting patients with at least one comorbidity by hospital type

Hospital type	2009		2005	
Public	321	(55%)	274	(59%)
Private	70	(40%)	60	(41%)
All hospitals	391	(52%)	334	(55%)

As shown in Table 4, coronary artery disease was the most common comorbidity. Comorbidities reported in ‘other’ included diabetes, hypertension, as well as liver, lung and renal diseases.

Table 4: Types of comorbidities recorded

Types of recorded comorbidity	2009		2005	
Coronary artery disease	161	(21%)	158	(37%)
Chronic lung disease	86	(11%)	56	(13%)
Chronic haematological disease	14	(2%)	18	(4%)
Other	228	(30%)	199	(46%)

* Some patients will have been recorded as having more than one comorbidity.

Use of blood conservation techniques

Pre-operative autologous donation

Pre-operative autologous donation (PAD) involves obtaining and storing a patient's own blood prior to surgery in order to administer it, if necessary, intra- or post-operatively. PAD usage was reported by 8 of the 26 contributing hospitals (two of the public hospitals and all of the six private hospitals). Four per cent of patients overall (n = 28) participated in PAD. These patients pre-deposited a median of two units of blood (range one to three units; total pre-deposit of 49 units).

Patients treated in a private hospital were more likely to participate in PAD than patients treated in a public hospital (14 per cent and one per cent, respectively, $p < 0.001$).

Table 5: Frequency of patients participating in pre-operative autologous donation

Hospital type	2009		2005	
Public	3	(1%)	6	(1%)
Private	25	(14%)	26	(4%)
All hospitals	28	(4%)	32	(5%)

Three per cent of TKR patients (12 of 347 patients) and four per cent of THR (16 of 408 patients) underwent PAD; with six TKR patients and 12 THR patients actually receiving their own blood either intra- or post-operatively (total 37 units transfused). Two THR patients and one TKR patient, in addition, received donor blood after their pre-donation was exhausted. Twelve units were presumed not transfused and discarded.

Of the 28 patients pre-donating blood, two also underwent intra-operative cell salvage and five patients also underwent post-operative salvage. Four of the post-operative salvage patients did not have their pre-donated blood transfused.

Cell salvage

Peri-operative red cell salvage is defined as the collection of patient's blood in surgical procedures in which blood loss is significant. Intra-operative cell salvage can greatly reduce the need for donor blood and should be considered for surgery where blood loss greater than one litre is anticipated (Ashworth 2010).

The use of intra-operative blood salvage was limited in this audit. Intra-operative salvage use was reported by eight hospitals (six public hospitals and two private hospitals) in 17 patients (two per cent). See Table 6. The use of post-operative cell salvage was more common. Post-operative cell salvage was reported by ten hospitals (five public hospitals and five private hospitals) in 63 patients (8 per cent).

Patients treated at a private hospital were more likely to use intra-operative or post-operative cell salvage (n = 45, 26 per cent) compared to public patients (n = 35, 6 per cent) ($p < 0.001$).

Seven patients were reported to have used intra-operative and post-operative cell salvage in combination in these audit records.

Five patients received a combination of cell salvage and blood transfusion intra-operatively. Ten patients received a combination of cell salvage and blood transfusion post-operatively.

Table 6: Use of cell salvage

	2009		2005	
Intra-operatively				
Cell salvage	17	2%	9	1%
Cell salvage and transfusion	5	1%		
Post-operatively				
Cell salvage	63	8%	53	9%
Cell salvage and transfusion	10	1%		

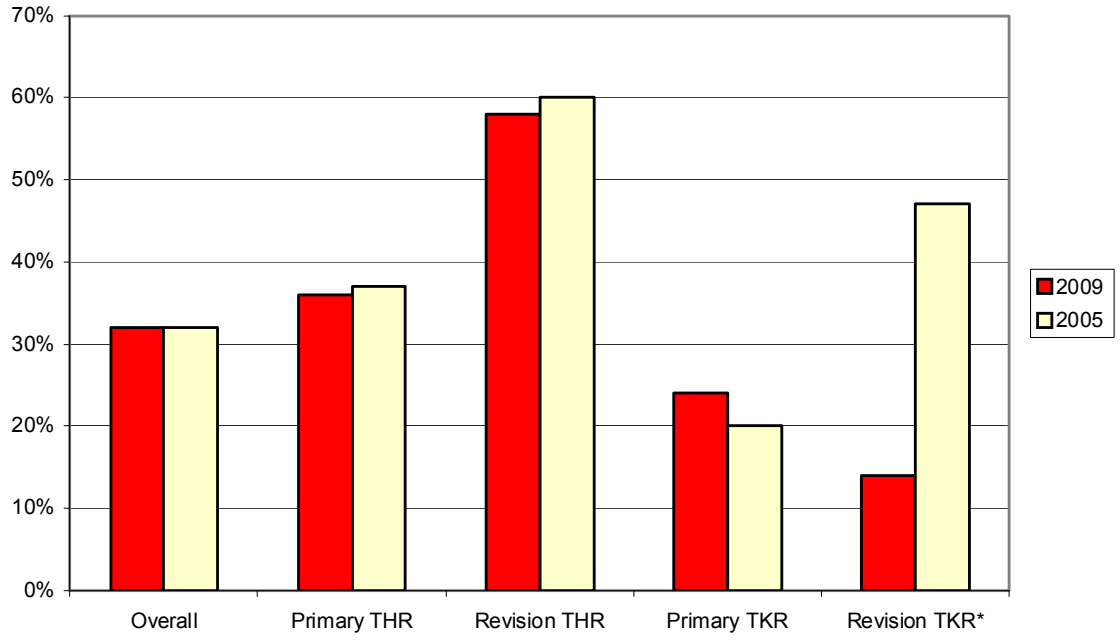
Transfusion practices

In 2009, 243 patients received intra- and/or post-operative transfusions. A total of 283 transfusion events were reported with 40 patients receiving both intra-operative and post-operative transfusion.

Overall transfusion rates

The overall likelihood of peri-operative transfusion in this series of elective orthopaedic surgery patients was 32 per cent, similar to the previous audit in 2005. As seen in figure 1, individual hospitals recorded widely varying overall rates of transfusion and also widely varying transfusion rates by particular procedure.

Figure 1: Transfusion rates by surgery type



* In 2009, ten TKR episodes of surgery had missing data and were not labelled as either primary or revision

Timing of transfusion events

Overall, 535 units of homologous blood and 37 units of autologous blood were given to the 243 patients receiving peri-operative transfusion support.

With homologous transfusion, nearly half (44 per cent) of blood transfused during that episode of care was transfused intra-operatively or within 24 hours of surgery and the other half (56 per cent) post-operatively. In contrast with autologous transfusion, the majority of blood transfused (90 per cent) was given intra-operatively or within 24 hours of surgery.

Forty patients were reported as receiving both intra- and post-operative transfusions. That is, 283 transfusions were reported in the audit sample for 243 unique patients.

Homologous versus autologous transfusion

Patients participating in PAD programs were more than twice as likely to be transfused as those not participating in these programs (see Table 7). Despite this 'liberal' transfusion practice, 24 per cent of pre-deposited units of red cells were not used during the patients' elective orthopaedic surgery. In the 2005 audit, 58 per cent of pre-deposited units were reported as not used.

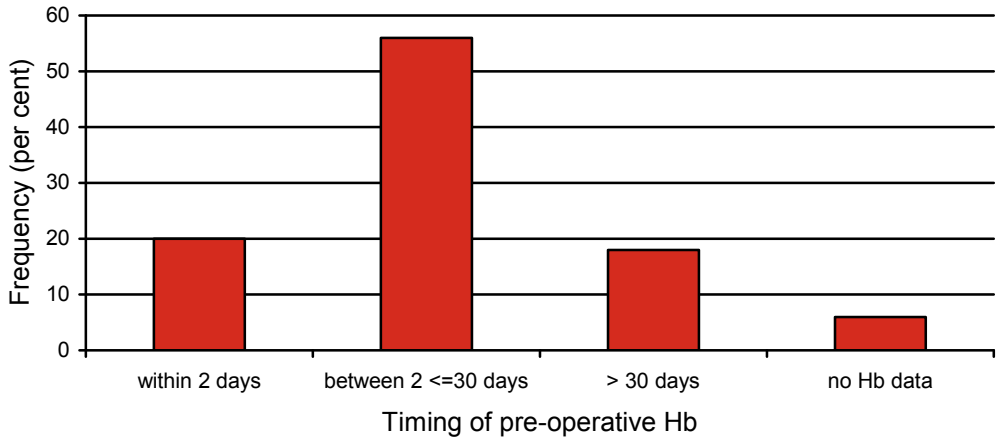
Table 7: Likelihood of transfusion by PAD

	PAD patients		Non-PAD patients	
	2009 (n = 28)	2005 (n = 32)	2009 (n = 727)	2005 (n = 575)
Elective orthopaedic surgery. Overall likelihood of any transfusion	71%	91%	31%	30%
Elective orthopaedic surgery. Overall likelihood of homologous transfusion	11%	9%	31%	30%

Haemoglobin records

Pre-operative haemoglobin level should be assessed and reported within 24 hours prior to surgery and before the infusion of the red cells. The data submitted, as shown in Figure 2, showed that six per cent of audits submitted had no pre-operative haemoglobin level documented in the medical records or pathology results available, a further 18 per cent reported on pathology which was greater than 30 days old, 56 per cent of pathology reported was greater than two days but equal or less than 30; and the remaining 20 per cent pre-operative haemoglobin pathology was within two days of the elective surgery.

Figure 2: Time of pre-operative haemoglobin testing



Pathology reporting of post-operative haemoglobin was more reliably completed and documented with 93 per cent of audits reporting a timely pathology result. Discharge haemoglobin levels were less reliably done with 57 per cent of audits reporting a pre discharge result.

Table 8: Haemoglobin levels by surgery type: 2009

		Pre-op Hb (g/L) (within 30 days) (n = 568)	Post-op Hb (within two days) (n = 703)	Discharge Hb (after day four) (n = 332)
Overall elective orthopaedic surgery	Avg range % path avail*	132 (78–174) 76%	102 (58–158) 93%	102 (72–150) 44%
THR	Avg range % path avail	131 (86–170) 78%	99 (58–150) 91%	102 (73–132) 47%
TKR	Avg range % path avail	136 (78–174) 71%	106 (67–158) 95%	102 (72–150) 40%
PAD patients	Avg range % path avail	131 (107–167) 89%	99 (67–137) 86%	103 (98–109) 18%
Non-PAD patients	Avg range % path avail	133 (78–174) 75%	103 (58–158) 93%	102 (72–150) 45%

* % path available: pathology results were not reported for all patients.

Transfusion rates based on pre-operative haemoglobin levels

When defining anaemia as a haemoglobin level below normal for age and gender, it was found that transfusion was more likely peri-operatively when a patient was anaemic pre-operatively ($p < 0.0001$).

Table 9: Rates of transfusion based on pre-operative Hb level: 2009

Gender	Hb normal range	Number of patients with anaemia*	Transfusion rate	
			Anaemic pre-op	Non-anaemic pre-op
Male (n = 222)	130–180 g/L	49 (22%)	59%	12%
Female (n = 348)	110–165 g/L	56 (16%)	80%	32%
All		105 (18%)	70%	25%

* Based on 570 records which included a pre-operative Hb level 30 days or less prior to procedure

Alignment of transfusion decision making with clinical practice guidelines

Overall, the decision to transfuse was judged to be consistent with recommended clinical practice guidelines in 83 per cent of transfusions. There was a wide range of performance across participating hospitals, with transfusion alignment ranging from 23 per cent to 100 per cent. Transfusion episodes in the intra-operative or first 24-hour period were deemed to be aligned in 84 per cent of transfusion episodes versus 82 per cent of transfusion episodes in the post-operative period.

Of the 40 patients receiving transfusions both intra- and post-operatively, two patients were considered to have transfusions not aligned in both circumstances, and an additional four patients received non-aligned post-operative transfusions.

Table 10: Alignment rates for all transfusions

Alignment	Transfusion					
	All		Intra-operative		Post-operative	
2009						
Total unique transfusions	283		113		170	
	n	%	n	%	n	%
Aligned	235	83	95	84	140	82
Not aligned	36	13	8	7	28	16
Insufficient data/unable to determine	12	4	10	9	2	1
2005						
Total unique transfusions	111		47		64	
	n	%	n	%	n	%
Aligned	88	79	40	86	45	70
Not aligned	23	21	7	14	19	30

As shown in Table 10, there was a trend to overall improvement in alignment from 2005 and 2009; however, it was not statistically significant (p = 0.540).

Table 11: Alignment rates for PAD transfusions

Alignment	PAD transfusions					
	All		Intra-operative		Post-operative	
2009						
Total unique transfusions	20		18		2	
	n	%	n	%	N	%
Aligned	11	55	10	56	1	50
Not aligned	4	20	3	17	1	50
Insufficient data/unable to determine	5	25	5	28	0	0
2005						
Total unique transfusions	27		21		6	
	n	%	n	%	n	%
Aligned	13	48				
Not aligned	14	52				

For those patients receiving their own PAD blood, the alignment rate of transfusion was lower (but not statistically, p=0.113) at 55 per cent; compared to the alignment rate for all transfusion types (83 per cent).

Over-transfusion rates

Over-transfusion is an issue not just in regard to inefficient use of limited resource, but it can pose additional risks to the patient. The 2010 Annual Serious Hazards of Transfusion (SHOT) Report (Knowles 2011) noted an increase in cases where patients were transfused with too many red cells, given their underlying comorbidities, body weight or blood loss or where there had been a failure to adequately monitor the patient's vital signs or Hb response during the transfusion.

Overall, four per cent (n=12) of transfusion episodes were deemed to have been over-transfused (in that the post-transfusion Hb was greater than 115 g/L). Transfusions in the intra-operative period or within the first 24 hours of surgery were more likely to be judged over-transfusion than those administered in the post-operative period (7 per cent (n=8) over-transfusion in first 24 hours versus two per cent (n=4) in post-operative period; over-transfusion rates in autologous transfusions were 11 per cent during the intra-operative period (2 of 18), and zero per cent during the post-operative period). There was an overall trend for reduction in the rate of over-transfusion from 2009 (four per cent) compared to the results of the 2005 audit (ten per cent).

Impact of blood conservation techniques on transfusion practices

Table 12 shows that there is a variation in transfusion practice between patients participating in PAD and those not participating in blood conservation techniques. Results from the 2009 audit show that the transfusion rate is significantly greater for patients participating in PAD ($p < 0.0001$), with an alignment which is lower ($p = 0.001$) than for patients receiving no blood conservation techniques. Over-transfusion appears to occur more frequently in PAD patients; however, it was not considered to be significantly different ($p = 0.275$).

Table 12: Impact of blood conservation techniques on transfusion practices

Parameter	No blood conservation (no PAD and no cell salvage)		PAD		Intra-op or post-op cell salvage	
	2009	**2005**	**2009**	**2005**	**2009**	**2005**
Episodes	660	214	28	32	73	60
Post-op Hb*	99	104	89	102	106	107
Transfusion rate	31%	29%	71%	91%	27%	35%
Alignment rate	86%	79%	55%	48%	75%	79%
Over-transfusion rate	4%	10%	10%	16%	5%	10%

* Twenty-four audit episodes in 2009 did not contain post-op Hb data

The routine use of pre-operative autologous donation is not recommended because, although it may reduce the risk of allogeneic red cell transfusion it increases the risk of receiving red cell transfusion (allogeneic and autologous) (Forgie 1998),

Comparison of audit results to other studies

One study (Van Der Linden 2010) of 2,449 patients undergoing elective orthopaedic surgery in Belgium from 23 centres found only 17 per cent of patients were transfused (range per centre 2–53 per cent) with blood conservation techniques used in four per cent of patients. (Study demographics: mean age was 66, 61 per cent women and 51 per cent hip surgeries, with no bilateral surgery, and nine per cent involved surgical revisions).

A meta-analysis (Forgie 1998) found that patients who underwent PAD were much less likely than controls to receive allogeneic blood but were more likely to undergo any transfusion with autologous and/or allogeneic blood. The authors partly attributed the increased rate of transfusion due to a lower pre-operative haematocrit in patients undergoing PAD and a more liberal transfusion policy with autologous blood. In the data collected in the current Blood Matters audit, patients who underwent PAD were much more likely to receive a transfusion.

The British Committee for Standards in Haematology does not recommend the practice of PAD due to a number of disadvantages (over-collection, over-transfusion, break-through transfusion, outdating and wasting) unless the clinical circumstances are exceptional, including rare blood groups where allogeneic blood is difficult to obtain, children with scoliosis, patients whose mental health might be put at risk by using allogeneic blood and patients who refuse to consent to allogeneic transfusion but who would consent to PAD (Boulton et al. 2007).

Similarly, draft patient blood management guidelines (NHMRC/ANZSBT 2011b) do not recommend the routine use of pre-operative autologous donation because, although it reduces the risk of allogeneic red blood cell transfusion, it increases the risk of receiving a transfusion (allogeneic and autologous). Results of the Blood Matters 2009 audit reflect the concerns expressed by NHMRC/ANZSBT; however, the results from 2005 and 2009 show that there has been a trend to improvement in transfusions aligned with guidelines.

When considering the use of cell salvage as a method to reduce allogeneic blood transfusions, a meta-analysis (Huet 1999) showed that cell salvage devices decreased the proportion of patients who received a peri-operative allogeneic transfusion during orthopaedic surgery. Cell salvage did not appear to increase adverse events, although side effects were inconsistently reported, and the number of patients studied was relatively small. Similarly, a Cochrane Review (Carless 2010) found that cell salvage reduced the risk of exposure to allogeneic blood transfusion by 54 per cent in the setting of orthopaedic surgery.

However, new risks have arisen surrounding the use of cell salvage. Dutch researchers (Thomassen et al. 2011) reported at the 12th EFORT Congress in Copenhagen (June 2011) that transfusing blood back into patients who underwent local infiltration analgesia (ropivacaine) during total knee arthroplasty can accumulate harmful levels of analgesic. Thomassen stated that local anaesthetics in combination with infusion of ropivacaine are potentially safe, but noted that combining this process with cell salvage could lead to toxic levels.

Although few studies have examined the rate of over-transfusion in transfusion practice, Barr et al (2011) note that where it has been studied, levels of over-transfusion of the order of 24 to 75 per cent have been reported. In their own study of 1,474 individuals receiving allogeneic red cell transfusions, 19 per cent of all recipients were found to have been over-transfused (where over-transfusion was defined as occurring when the post-transfusion Hb level was more than 20 g/L above the relevant Hb transfusion threshold for that patient). These studies tended to include surgical and nonsurgical patients. However, Barr et al were able to analyse the data to determine that patients being treated for an orthopaedic condition or with additional peri-operative surgical bleeding were at lower risk of over-transfusion.

Although our audit did not enquire about pre-operative clinics and patient attendance, it would be interesting to include this in future audits in light of the recommendations in the draft peri-operative guidelines. Inclusion of this data would enable analysis of the impact of assessing anaemia pre-operatively on transfusion rate.

Pre-operative anaemia is associated with increased morbidity and mortality after orthopaedic surgery, and exposure to allogeneic blood transfusions. Admission haemoglobin levels have also been shown to have an impact on post-operative functional recovery in an elderly population with hip fractures and on the quality of life after total hip arthroplasty (Goodnough 2011). Our results found 18 per cent of patients had anaemia pre-operatively, which is not dissimilar to other studies. Draft patient blood management guidelines (NHMRC/ANZSBT 2011b) provide a recommendation to identify, evaluate and manage pre-operative anaemia to minimise red cell transfusion.

Development of new patient blood management guidelines

The National Health and Medical Research Council (NHMRC) and the then Australian Society of Blood Transfusion (ASBT) published guidelines for the appropriate use of blood components (NHMRC/ASBT 2001), including the use of red blood cells. These guidelines are currently being reviewed under the auspices of the Australian and New Zealand Society of Blood Transfusion ANZSBT and the NHMRC with funding and project management provided by the National Blood Authority (NBA). The review is being undertaken as a series of six modules.

It was considered that revision of the 2001 guidelines was needed because of:

- increasing evidence of transfusion-related adverse outcomes, leading to the emergence of new practices, including restrictive transfusion strategies and the increased use of alternatives to transfusion in the management of anaemia
- variable (and frequently poor) compliance with the recommendations of the 2001 guidelines, indicated by a high degree of variation in transfusion practices
- failure of the 2001 guidelines to address a range of clinical settings where blood management is commonly required, including chronic medical conditions, obstetrics, paediatrics, critical bleeding and massive transfusion (NBA 2010, p. 1).

The *Patient blood management guidelines: module 1 – critical bleeding/massive transfusion* was the first in the series of modules of patient blood management guidelines and was released in March 2011, following approval by the NHMRC on 12 November 2010. An initial public consultation occurred in March 2011 for *Module 2 – peri-operative patient blood management*. The draft guidelines for peri-operative patient blood management consist of recommendations where there was sufficient evidence available from published literature, and practice points where the literature review found insufficient high quality data to produce evidence-based recommendations; however it was felt that clinicians require guidance to ensure good clinical practice.

A sample of the recommendations and practice points included in the draft module for public consultation are shown in the table below.

Reference number	Recommendation/practice points
R3	In patients undergoing non-cardiac surgery, pre-operative anaemia should be identified, evaluated and managed to minimise red blood cell (RBC) transfusion, which is associated with an increased risk of morbidity, mortality, intensive care unit length of stay and hospital length of stay.
R11	The routine use of pre-operative autologous donation is not recommended because, although it reduces the risk of allogeneic RBC transfusion, it increases the risk of receiving RBC transfusion (allogeneic and autologous).
R15	In adult patients undergoing surgery in which substantial blood loss is anticipated, intra-operative cell salvage is recommended.
R20	In adult patients undergoing cardiac surgery or total knee arthroplasty, in whom significant post-operative blood loss is anticipated, post-operative cell salvage should be considered.

Reference number	Recommendation/practice points
PP1	To implement R3, a multimodal, multidisciplinary patient blood management program is required. All surgical patients should be evaluated as early as possible to coordinate scheduling of surgery with optimisation of the patient's haemoglobin and iron stores.
PP2	RBC transfusion should not be dictated by a haemoglobin trigger alone, but should be based on assessment of the patient's clinical status. In the absence of acute myocardial or cerebrovascular ischemia, post-operative transfusion is inappropriate for patients with a haemoglobin level of > 70 g/L.
PP3	Patients should not receive a transfusion when the haemoglobin level is ≥ 100 g/L. In post-operative patients with acute myocardial or cerebrovascular ischaemia and a haemoglobin level of 70–100 g/L, transfusion of a single unit of RBC, followed by reassessment of clinical efficacy, is appropriate.
PP4	All surgical patients should be evaluated as early as possible to manage and optimise haemoglobin and iron stores.
PP13	Intra-operative cell salvage requires a local procedural guideline that should include patient selection, use of equipment and reinfusion. All staff operating cell salvage devices should receive appropriate training, to ensure knowledge of the technique and proficiency in using it.

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Appendix 1

Audit proforma

Blood Matters Program

Clinical Audit of Red Blood Cell Use in Orthopaedic Surgery

During the study period please complete a form for every patient who has undergone either a total hip replacement or a knee replacement **whether or not they are transfused.** Alternatively, for hospitals that perform THR or TKR very regularly, every third procedure may be audited instead.

Patient Details

Hospital Code: _____ Audit ID: _____

Sex: Male ☐ Female ☐ **Age:** (months or years) _____

Co-morbidities: Coronary artery disease ☐ Chronic Lung Disease ☐ Haematological Disorder ☐ Other ☐ .....

Surgery Details

Date of Surgery: -------/--------/---------- (DD/MM/YYYY)

Replacement of:		Replacement type:					
Total Hip :	☐	Bilateral:	☐	Primary:	☐	Revision:	☐
Total knee:	☐	Bilateral:	☐	Primary:	☐	Revision:	☐

Blood Management

Autologous pre-donation: YES NO Number of autologous units collected .....

Intraoperative Salvage: YES NO Postoperative Salvage: YES NO

Red Cell Transfusion

	Pre-transfusion Hb g/dL	Record of Pre-transfusion Symptoms *(please circle)*	Number of Units Transfused	
			Donor Blood (Number of allogeneic)	Pts own blood (Number of autologous)
Intraoperatively or within 24 hrs of surgery		YES NO		
24 hrs or more **AFTER** surgery		YES NO		

Haemoglobin and pre-op MCV Results

	Date of Test DD/MM/YYYY	Hb Result g/L	MCV Result fL	Not available *(please tick)*
Pre op Hb and MCV				
Post op Hb (within 48 hrs of surgery)				
Pre discharge Hb (72 hrs post surgery or last recorded Hb)				

PTO to add comments

Comments:

Please add any extra information that you feel is relevant or required to explain the patient's condition or results.

Office Use Only:

1. Was the transfusion episode aligned with the guidelines?
   - intraoperatively or within 24 hours of surgery — Yes — No
   - 24 hrs or more after surgery — Yes — No
2. Was the patient over transfused?
   - intraoperatively or within 24 hours of surgery — Yes — No
   - 24 hrs or more after surgery — Yes — No
3. Was the patient under transfused?
   - intraoperatively or within 24 hours of surgery — Yes — No
   - 24 hrs or more after surgery — Yes — No
4. For this episode was sufficient data provided to make an assessment of alignment with Guidelines?
   - intraoperatively or within 24 hours of surgery — Yes — No
   - 24 hrs or more after surgery — Yes — No

Appendix 2

Information provided to hospitals

Clinical Audit of Red Blood Cell Use in Orthopaedic Surgery

Background

Red cell transfusions are required to increase the oxygen-carrying capacity of the blood by raising the haemoglobin concentration. Previous studies have shown variation in clinical practice in the transfusion of red cells.

The level of haemoglobin (Hb) is often used as the only indicator for red cell transfusion because of its easy accessibility. There is no clear evidence indicating the optimal Hb 'trigger.'

Hébert's (1995) study of patients in intensive care showed better outcomes when a restrictive transfusion policy was used (i.e. maintaining the Hb between 70-90g/L). The study suggested that this was as safe, or even safer than a liberal transfusion strategy (to an Hb of 100-120g/L).

Consideration should be given to the causes of anaemia and whether it can be managed by alternatives other than red cell transfusion. According to the NH&MRC/ANZSBT guidelines, if an Hb is less than 70g/L transfusion should rarely be withheld. Similarly, at the other end of the spectrum, with a Hb greater than 100g/L transfusion should rarely be given. (NH&MRC, 2001)

The Blood Matters: better safer transfusion program wishes to work with hospitals to ensure that:

a) blood components and products are used appropriately and effectively, and

b) alternative blood management strategies are used to limit the need for transfusion where clinically appropriate and available.

The Blood Matters Advisory Committee has identified the area of blood management in orthopaedic patients undergoing major joint replacement surgery as an area for targeted clinical audit to determine current practice across the State.

Audit Aims

To improve the quality of care provided to patients by ensuring the appropriate use of blood management and red cell transfusion in orthopaedic patients undergoing hip or knee joint replacement. Medical record documentation relating to transfusion should also be relevant and accurate.

Objectives

i. To determine if blood management and red cell transfusion in orthopaedic patients undergoing hip or knee joint replacement is aligned to clinical practice standards developed from NH&MRC/ANZSBT guidelines.

ii. To determine if effective alternative treatments are being used.

Standards

Clinical practice standards have been developed from the NH&MRC guidelines for the clinical use of red cell transfusions (2001)

Use of Red Cell Transfusion:

Criterion	Exceptions	Standard
Treatment with red cells should NOT be given when effective alternatives exist		100%
Transfuse Patients with Hb <70 g/L	• Pts with Sickle Cell anaemia	100%
Patients with Hb >100g/L		0%
Patients with Hb between 70-90g/L	• Known cardiovascular disease. • Chronic anaemia with associated symptoms.	0%
Blood loss >1500 mL		100%

Data Set for Transfusion

Transfusion committees (or their equivalent) are asked to take this opportunity to ensure that the required dataset for each transfusion is documented in the clinical notes. According to NH&MRC/ANZSBT (2001) these are:

Indication for transfusion,

Amount of blood transfused,

Assessment of the effectiveness of the transfusion,

Methodology

The methodology is for an audit at each selected site of up to 30 orthopaedic patients undergoing hip or knee joint replacement. The Transfusion Committee should designate a member of staff to record the information requested on the proforma provided. The designated data collector in participating hospitals will review the patient case notes and using the audit proforma (Form 2: Clinical Audit of Red Blood Cell Use in Orthopaedic Surgery), collect the relevant data. It is suggested that a clinical sub-group identified by the Hospital Transfusion Committee (or equivalent) review their local data on red blood cell transfusion.

All data collection forms comply with the privacy acts.

Time Frame:

Either 30 consecutive orthopaedic patients undergoing hip or knee joint replacement (or in low frequency users, all patients undergoing these operations) between 1 January 2009 and 31 December 2009. For hospitals that perform THR or TKR very regularly, every third procedure may be audited, up to a maximum of 30 patients.

A designated member of Hospital staff will undertake data collection. Further details for data collection are provided on the attached Audit Information Sheet.

The Blood Matters secretariat will co-ordinate the audit, taking responsibility for the distribution of audit collection tools and data analysis, and will collaborate with the Blood Matters Advisory Committee in formulating the audit report. The Blood Matters Advisory Committee will disseminate results to the participating hospitals.

Audit reports are to be **returned (*online*) by 7 January 2010** to:

BLOOD MATTERS: better, safer transfusion program
Statewide Quality Branch, Department of Human Services
GPO Box 4057
MELBOURNE 3001

If further information is required please contact

- Karen Botting Blood Matters Project Manager on Tel: 9096 9037 or email: karen.botting@dhs.vic.gov.au
- or Lisa Stevenson, Transfusion Nurse Blood Matters on Tel: 9096 0476 or email: lisa.stevenson@dhs.vic.gov.au

Appendix 3

National Clinical Practice Guidelines

CLINICAL PRACTICE GUIDELINES

Appropriate Use of Red Blood Cells

Summary of NHMRC/ASBT guidelines

This summary is derived from the National Health and Medical Research Council (NHMRC)/Australasian Society of Blood Transfusion (ASBT) *Clinical Practice Guidelines on the Use of Blood Components* (red blood cells, platelets, fresh frozen plasma and cryoprecipitate). The guidelines were produced in cooperation with the Commonwealth Department of Health and Aged Care, the Royal Australasian College of Surgeons, the Australian and New Zealand College of Anaesthetists, and other relevant groups. The coalition of organisations involved in developing the guidelines demonstrates the degree of interest across the specialties in promoting the appropriate use of blood components.

The recommendations included in this summary have been endorsed by the NHMRC and the ASBT. The recommendations aim to support:

- clinical decisions about the use of red cells; and
- quality processes to promote appropriate use of blood components and optimise patient outcomes.

The clinical recommendations are summarised overleaf. For further details, consult the NHMRC/ASBT guidelines.

Organisational practice

Changing organisational practice through quality improvement is as important as changing clinical practice. A quality management system that includes monitoring, assessment, action and evaluation will allow audit of usage at the local level and eventual evaluation of changes in practice and effect on health outcomes.

Documentation used in ordering or administering blood components (eg request forms or blood administration forms) should summarise the clinical recommendations of these guidelines and collect standardised data items. Clinical and laboratory indications for blood components should be accurately recorded in that documentation and in the patient's medical record.

As well as a record of the clinical or laboratory indications for the use of blood components, other relevant data could include: reasons for giving blood components if not in accordance with the guidelines (eg if red blood cells are given when the haemoglobin level is >100g/L); and other relevant medical history of the patient's condition.

In all situations where blood component therapy is given, a process for clinical review should be in place to monitor the appropriateness and safety of its use and to develop systems for the implementation of these guidelines.

Clinical review groups or 'transfusion committees' should include senior representatives of relevant clinical specialties and administration, nurses, blood bank and staff involved in quality improvement. In larger hospitals this is likely to be a separate committee. However, this is not necessary and in smaller hospitals, the role could be undertaken by the medical advisory committee or through a local geographic or organisational network.

As part of the informed consent process, a patient should be given clear explanation of the potential risks and benefits of blood component therapy in his or her situation.

Community concern about blood issues and the safety of blood component therapy makes the consideration of consumer issues and processes for informed consent particularly important. Change at clinical and organisational levels within hospitals will help to standardise the use of blood components. Consumers can also be important drivers of change to practice, if they are aware of the issues surrounding use of blood components and know about the risks and benefits in their own situation.

Contact Details

This document is one in a series of documents developed by the NHMRC/ASBT about the use of blood components. These documents are available from:

- NHMRC Website at: http: //www.nhmrc.gov.au, or
- ASBT Website at: http://www.asbt.org.au

Print copies of all documents can be obtained by emailing:

- *HEALTH ADVISORY CTTEE NHMRC@nhmrc.gov.au* or by telephoning (02) 6289 9520 (24hr answering machine) or 1800 020 103. Alternatively you can contact the ASBT by telephoning (02) 9256 5456 or emailing to the secretariat@asbt.org.au.

NHMRC
National Health & Medical Research Council

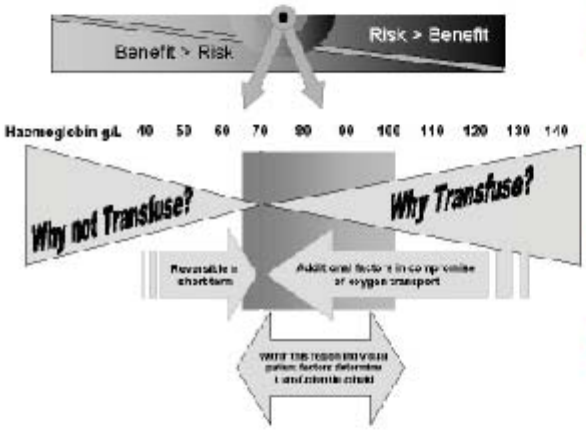
ASBT
AUSTRALASIAN SOCIETY OF BLOOD TRANSFUSION INC

Appropriate Use of Red Blood Cells

In deciding whether to transfuse red blood cells, the patient's haemoglobin level, although important, should not be the sole deciding factor. Patient factors, signs and symptoms of hypoxia, ongoing blood loss, the risk to the patient of anaemia and the risk of transfusion should be considered.

Hb*	Considerations
<70g/L	Lower thresholds may be acceptable in patients without symptoms and/or where specific therapy is available.
70–100g/L	Likely to be appropriate during surgery associated with major blood loss or if there are signs or symptoms of impaired oxygen transport.
>80g/L	May be appropriate to control anaemia-related symptoms in a patient on a chronic transfusion regimen or during marrow suppressive therapy.
>100g/L	Not likely to be appropriate unless there are specific indications.

* The use of red blood cells for indications not listed in this table is unlikely to be considered appropriate as prophylaxis or therapy. Consult the NHMRC/ASBT guidelines for further details. Clinical and laboratory indications should be documented.



Specific factors to consider

- Patient's cardiopulmonary reserve — if pulmonary function is not normal, it may be necessary to consider transfusing at a higher threshold.
- Volume of blood loss — clinical assessment should attempt to quantify the volume of blood loss before, during and after surgery, to ensure maintenance of normal blood volume.
- Oxygen consumption — this may be affected by a number of factors including fever, anaesthesia and shivering; if increased then the patient's need for red blood cell transfusion could be higher.
- Atherosclerotic disease — critical arterial stenosis to major organs, particularly the heart, may modify indications for the use of red blood cells.

Prescribing blood components: checklist for clinicians

Decisions should be based on the NHMRC/ASBT *Clinical Practice Guidelines for the Use of Blood Components*, taking individual patient needs into account. Before prescribing red blood cells, ask yourself the following questions.

1. **What improvement in the patient's condition am I aiming to achieve?**
2. **Can I minimise blood loss to reduce the patient's need for transfusion?**
3. **Are there any other treatments I should give before making the decision to transfuse?**
4. **Have cross-matching and any other relevant tests been carried out?**
5. **What are the specific clinical or laboratory indications for red blood cells for this patient?**
6. **What are the risks of transmitting infectious agents through the available blood products?***
7. **Do the benefits of transfusion outweigh the risks for this particular patient?**
8. **Will a trained person monitor this patient and respond immediately if any acute transfusion reactions occur?**
9. **Have I recorded my decision to transfuse and reasons for transfusion on the patient's chart and any documentation used in the ordering or administering of blood components?**
10. **Has the patient been given a clear explanation of the potential risks and benefits of blood component therapy in his or her particular case?**

* Note that the rates of non-infective complications are probably higher than those of infective complications.

Adapted from WHO (1998) *Transfusion Today* 38: 3–6.

Abbreviations: Hb = haemoglobin

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