New Zealand Blood Service
The gift of life

Cryoprecipitate audit within six centres in New Zealand.

Final Report

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INTRODUCTION

When treating patients with actual or potential bleeding, it is important to be sure that the patient has the ability to clot. As fibrinogen is the protein that forms the framework for a clot, it is essential that adequate amounts of fibrinogen are present. It is generally accepted that clot formation may be impaired or unstable if the fibrinogen concentration is less than 1.0 g/L. Such a deficiency of fibrinogen may arise in a number of clinical settings. Because of its high concentration of fibrinogen, the optimal replacement therapy for such a deficiency of fibrinogen is cryoprecipitate.

The cryoprecipitate component produced by NZBS is collected by apheresis from donors with high fibrinogen levels, with the aim of producing a high-fibrinogen cryoprecipitate component. This is unlike many other transfusion services that prepare cryoprecipitate from random donors. Each unit of cryoprecipitate has on average 1.4 g fibrinogen (range: 0.75 – 2.0g) in 80-120ml. The recommended dose of the NZBS component is 1 unit per 30kg bodyweight to achieve an fibrinogen increment of 1.0g/L.

To guide clinical practice the National Health and Medical Research Council (NHMRC)[1] and the Australia and New Zealand Society of Blood Transfusion (ANZSBT)[2] have published guidelines for the appropriate use of blood components and products.

The clinical indications for the use of cryoprecipitate recognised by the National Health and Medical Research Council (NHMRC)[1] and the Australian and New Zealand Society of Blood Transfusion (ANZSBT)[2] include:

- Disseminated Intravascular Coagulation: where there is a fibrinogen level <1.0g/L and clinical bleeding cryoprecipitate may be indicated to maintain levels above 1.0g/L.
- Fibrinogen deficiency and dysfibrinogenaemia: where there is clinical bleeding in the event of an invasive procedure, trauma or DIC, cryoprecipitate maybe indicated. A dose of 1 unit/30kg is expected to produce an increment of approximately 1g/L, however the dose should be adjusted depending upon the patient's pre transfusion fibrinogen level, the patient's response to cryoprecipitate and the nature of the bleeding.
- Coagulation Factor Deficiencies: as an alternative product for the treatment of bleeding associated with Von Willebrand Disease, Haemophilia A and a Factor XIII deficiency.
- Bleeding associated with uraemia: cryoprecipitate may be useful to stop bleeding.

To assess appropriateness of transfusions of cryoprecipitate, an audit was conducted in 6 main centres, Auckland, Manukau, Hamilton, Wellington, Christchurch and Dunedin.

METHOD

Transfusion Nurses Specialists in the 6 main centres prospectively collected episodes of transfusion of cryoprecipitate from May to July 2004. Where the centre was unable to obtain 30 prospective episodes, data was collected retrospectively to make a total of 30 episodes per centre.

During the study period of each centre, data on patients who had fibrinogen levels less than 1.0g/L on coagulation screening and who did not receive cryoprecipitate was also collected. These patients will be referred to as non-recipients.

An episode was defined as each time Blood Bank issued one or more units of cryoprecipitate or, for the non-recipients, one fibrinogen level less than 1.0g/L per 24 hour period.

Data collection for each episode included patient demographics (date of birth, gender and weight); laboratory data (pre and post transfusion fibrinogen levels with dates and times, Hct,

INR, PTT, platelet count and platelet function. An estimate of the fibrinogen fall rate was also made from this data.); transfusion data (date, time and number of units of cryoprecipitate transfused for this episode; units of red cells, fresh frozen plasma, platelets and cryoprecipitate transfusion in the previous 12 hours); and clinical data (the patient's diagnosis, indication for the use of cryoprecipitate and location, rate of blood loss, and comorbidities).

Weight-adjusted doses and increments were calculated on patients with weights over 15kg to exclude paediatric patients who are transfused less than the entire unit. A dose was considered low if it was less than 0.5 units per 30 kilograms bodyweight, and a high dose more than 1.5 u per 30 kg bodyweight.

For increment calculations the pre and post transfusion fibrinogen tests had to be within 6 hours of the transfusion commencement. This interval was arbitrary but chosen to minimise issues of acute phase response vs fibrinogen consumption. The increment was adjusted to reflect what the increment would have been if the correct dose, 1 unit per 30 kilograms bodyweight, had been given. Those episodes where weight, pre or post transfusion fibrinogen levels were not available, were excluded.

The data was collected from the NZBS Progesa computer system, the local DHB laboratory information system and a review of clinical notes. The local haematology laboratory provided a list of patients with low fibrinogens. The cases were discussed with relevant DHB staff when necessary. Data was entered from a standardised coding form.

Two medical assessors, New Zealand Blood Service Transfusion Medicine Specialists with ongoing experience in managing and giving advice on treatment for patients with bleeding disorders, reviewed each episode. The review was initially independent and then together to seek a consensus on the appropriateness of each episode.

Key points used in the assessment were the rate of blood loss, as identified from general comments and the volumes of various blood components and other fluids infused, together with measurements of haemostatic data: platelet count, fibrinogen, APTT, PT, information on platelet function abnormalities where present, and the time interval between the tests and the request for cryoprecipitate. Where laboratory assessment of haemostasis had not been performed within several hours of the time of supply of cryoprecipitate, any available data was used to extrapolate to the likely situation, but this frequently resulted in insufficient information for a sound decision and the use of cryoprecipitate was classified as 'maybe indicated'. Where extensive blood loss had occurred but no information on fibrinogen levels was available prior to supply of cryoprecipitate, the request was usually classified as 'maybe indicated', except where subsequent laboratory testing showed high fibrinogen levels that demonstrated pre-transfusion levels would have been entirely adequate for haemostasis and cryoprecipitate was clearly not needed.

When evaluating patients with low fibrinogen levels who did not receive cryoprecipitate, weight was attached to the underlying condition, together with recent and ongoing treatment, and the risk for clinically significant bleeding. These evaluations were frequently more difficult and may sometimes have lacked critical clinical information affecting treatment decisions.

RESULTS

All centres captured 30 episodes of transfusion of cryoprecipitate apart from Middlemore Hospital (table 1). Both Middlemore and Auckland only collected prospective episodes with the remaining centres needing to capture episodes retrospectively. The longest retrospective audit was performed by Dunedin, auditing back to 20th November 2003.

Table 1. *Time to recruit episodes by centre*

Centre	Episodes n=181	Units infused n=349	Time to recruit episodes (Weeks)
Auckland	44 (24%)	96 (28%)	6
Wellington	33 (18%)	46 (13%)	14
Christchurch	30 (17%)	65 (19%)	32
Middlemore	7 (4%)	17 (5%)	9
Dunedin	36 (20%)	57 (16%)	30
Waikato	31 (17%)	68 (19%)	13

Of the 181 cryoprecipitate recipient episodes, 7 (3.9%) were used to make fibrin glue and 22 (12.2%) as part of paediatric cardiac bypass surgery protocol (all in Auckland) and will not be discussed in this report.

The remaining 152 episodes, involving the administration of 316 units of cryoprecipitate, were assessed as non-elective transfusions in response to a coagulopathy.

Non-recipients, patients who did not receive cryoprecipitate despite a fibrinogen less than 1.0g/L, involved 86 patients with 134 episodes (1 to 19 episodes per patient).

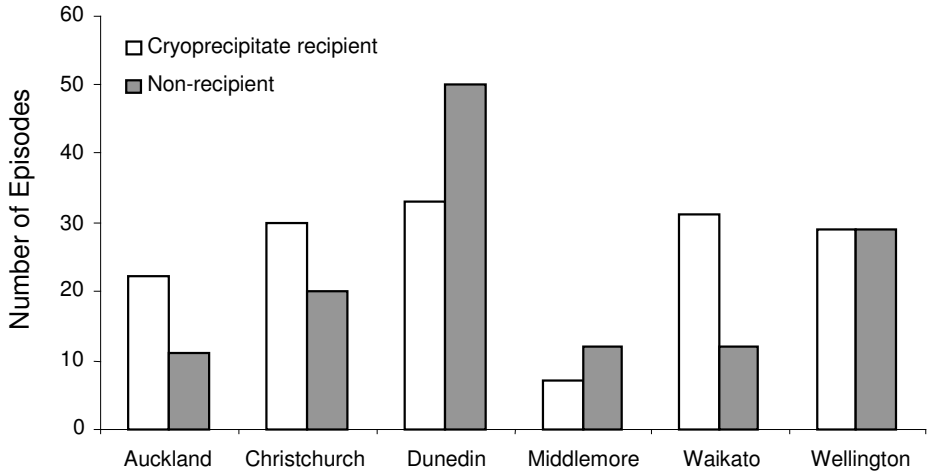

Figure 1. *Number of Recipient and Non-recipient episodes by centre*

The ratio of recipients to non-recipients showed significant variation across the six DHBs with Middlemore and Dunedin having the lowest ratios (p=0.003).

Demographics

The 152 cryoprecipitate episodes occurred in 104 patients, 64% of which were males and the median age was 55 years (range 0-87). Most recipient episodes were in Theatre (45%), ICU (29%) or Wards (24%) with very few episodes in Emergency Department (2%).

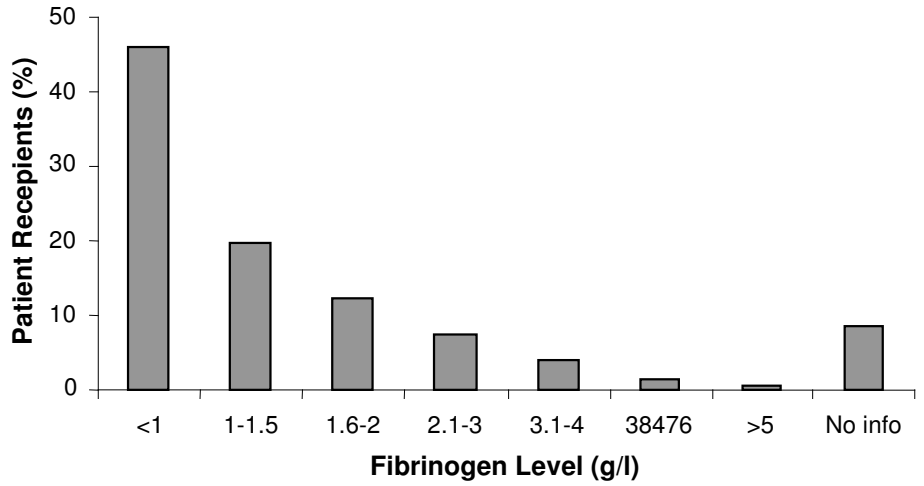

Figure 2. *Pre fibrinogen levels for cryoprecipitate recipients.*

46% of the cryoprecipitate episodes had a fibrinogen level below 1.0g/L, 26% had a level above 1.5g/l and pre-transfusion fibrinogen levels were not available in 9% of episodes (Figure 2). Mean levels did not differ across centres (p=0.294).

The median age for the non-recipients was 43 years (range 0 to 96) and 57% were male. Most episodes for non-recipients were in the Wards (52%) or ICU (31%) with much fewer in Theatre (14%) or Emergency Department (3%). Age and gender were similar to the recipients (p>0.05) but location of the episode differed (p<0.001). The median fibrinogen concentration of non-recipient episodes was 0.7 g/L (range 0.1 to 0.9). By definition, these patients had fibrinogen levels less than 1.0g/l.

Dose of cryoprecipitate used

116 (76%) of the episodes received 1 or 2 units of cryoprecipitate. The median number of units transfused was 2 per episode. The NZBS recommended dose is one unit per 30 kg bodyweight. For patients weighing >15 kg almost a quarter received less than half this recommended dose (Figure 3).

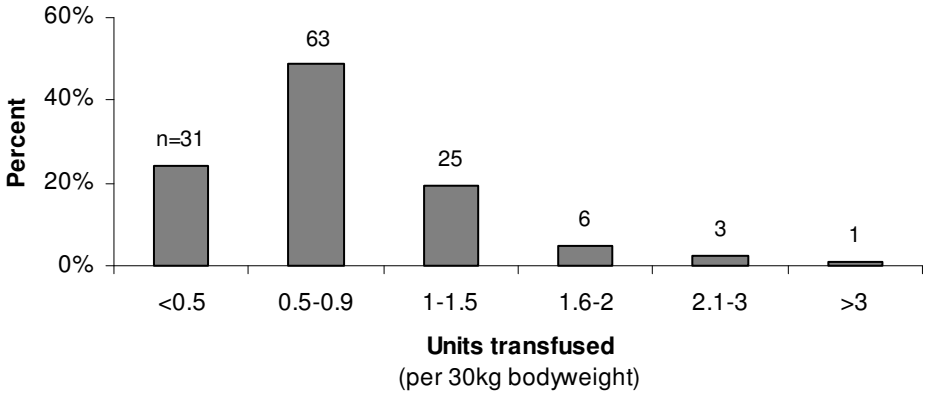

Figure 3. *Dose of cryoprecipitate transfused, adjusted for patient bodyweight*

Dosing varied significantly across centres with Auckland tending to overdose and Wellington to underdose. Only 68% of episodes had a dose of 0.5 to 1.5 u/30kg bodyweight and underdosing was more frequent than overdosing (24% vs 8%) (Table 2).

Table 2. *Percentages of correct and incorrect dosing in the different DHBs studied. Underdosing was defined as < 0.5u/30kg and overdosing >1.5u/30kg bodyweight.*

Centre	n	Underdosing	Correct dose	Overdosing
Auckland	21	5%	71%	24%
Christchurch	25	20%	76%	4%
Dunedin	27	37%	63%	0%
Middlemore	7	0%	100%	0%
Waikato	27	11%	85%	4%
Wellington	22	55%	32%	14%
Overall	129	24%	68%	8%

There was no association between weight-adjusted dose and the patient's pre-transfusion fibrinogen level (Figure 4). This was also true when looking only at underdosed patients (r=0.19, p=0.434).

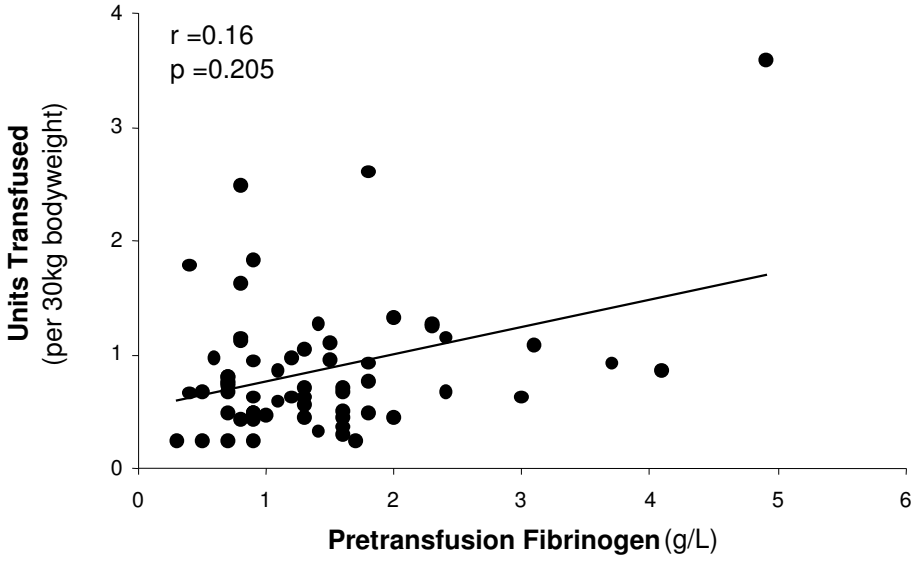

Figure 4. *Pre-transfusion fibrinogen vs weight-adjusted dose of cryoprecipitate transfused.*

Assessment of appropriateness of transfusion of cryoprecipitate

18%(n=27) of the cryoprecipitate transfusion were considered to be inappropriate on review by two Transfusion Medicine Specialists (Figure 5). 27% (n=42) of episodes of non-recipients were considered to have inappropriately not received cryoprecipitate.

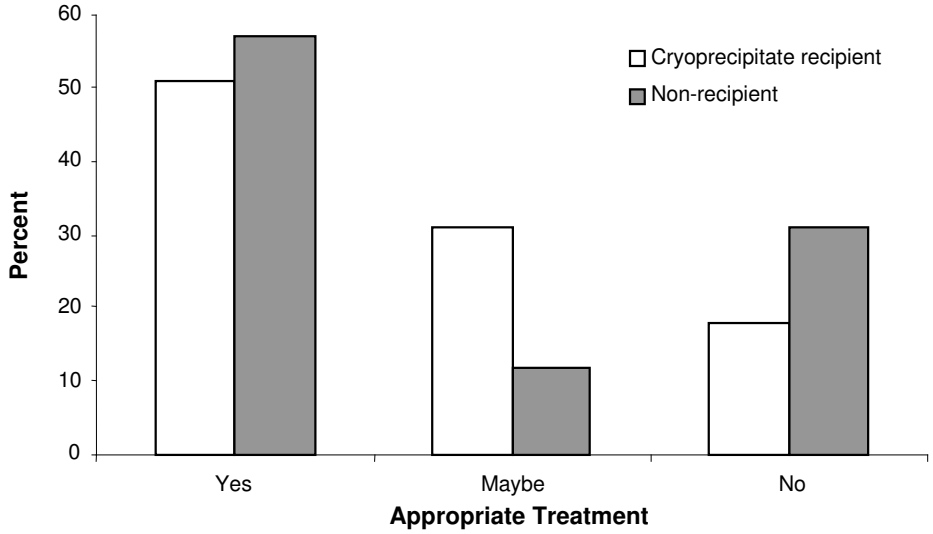

Figure 5. *Assessment of appropriateness in cryoprecipitate recipient and non-recipient episodes.*

There was no difference in the proportion of inappropriate transfusions across the DHBs ($p>0.05$), however there was significant variation in the proportion of non-recipients who were considered to have inappropriately not received cryoprecipitate (Table 3).

Table 3. *Assessment of appropriateness of episodes by Centre*

	Recipient *Transfusion appropriate?*			**Non-Recipient** *Non-transfusion appropriate?*		
	No	Maybe	Yes	No	Maybe	Yes
Auckland	5	7	10	9	2	0
Christchurch	5	12	13	2	3	15
Dunedin	7	12	14	1	5	44
Middlemore	0	1	6	5	1	6
Waikato	6	9	16	4	1	7
Wellington	4	6	19	21	4	4

Fibrinogen Increments in Response to Cryoprecipitate

Increments could be calculated for 43% of all episodes (Figure 8). Where the dose and indication were appropriate, the increment was 1.2g/L. Although low dose transfusions appear to give good increments, the wider 95% confidence intervals indicate the variation in response to low doses.

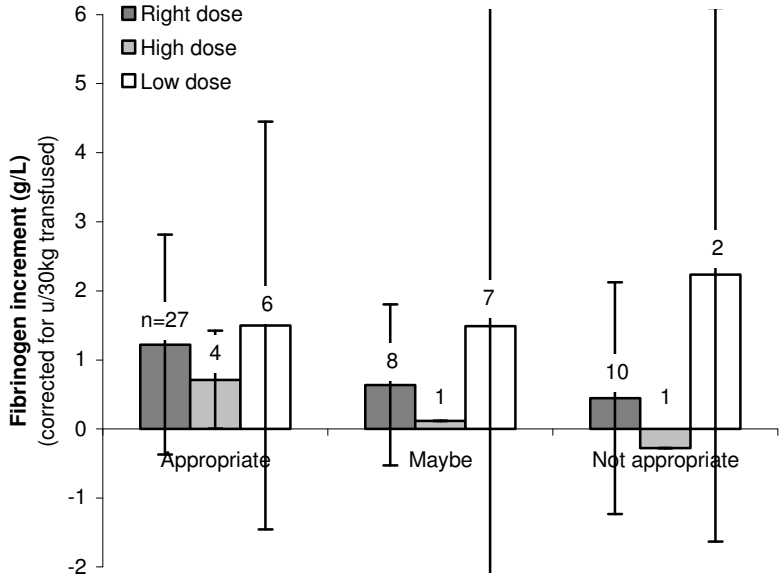

Figure 8. *Increment levels by appropriateness of transfusion and dose*

Increments by clinical indication were over 1.0g/L for all indications where there were more than 10 episodes (Table 4). With only 43% of episodes evaluable, small numbers makes interpretation of the increments of some of the indications difficult.

Table 4. *Increment levels by indication for transfusion.*

Indication	**Corrected increment** (Mean ± SD)	**n**
Bleeding actively	1.07 ±0.93	33
DIC and bleeding	0.87	1
DIC but not bleeding	0.46 ±0.58	6
Invasive procedure	1.18 ±1.37	13
Other	0.34 ±0.81	2
Trauma	1.27 ±0.99	11

Patients given a low dose initially showed a poorer response to transfusion, despite an appropriate indication. Compared with patients given the correct dose, patients given a lowe dose required more than twice as many transfusions of cryoprecipitate within the following two days (2.5 vs 1.1 respectively) ($p < 0.005$) (Figure 9).

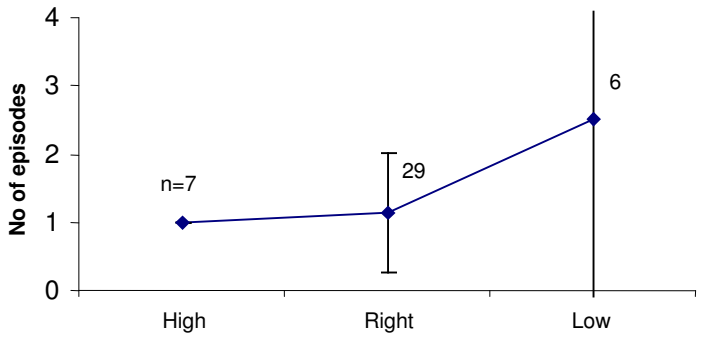

Figure 9. *Number of episodes within two days per patient by dose, for patients with an appropriate indication.*

Clinical features of patients related to the appropriateness of the transfusion
Appendix 1 tabulates the clinical features of both cryoprecipitate recipients and non-recipients, comparing various features for appropriateness and inappropriateness of the decision to transfuse or not transfuse.

Trends for inappropriate cryoprecipitate recipient episodes were for a higher fibrinogen, lower INR and PTT, higher platelet count, less red cell and platelet use, slower volume loss and rate of fibrinogen fall, less likely to have bleeding as an indication and more likely to be post bypass or uraemic.

Trends for inappropriate cryoprecipitate non-recipients were for a lower INR, PTT and platelet count, but with higher red cell and FFP use, higher volume loss, and more likely to occur in theatre, post bypass and with bleeding as the indication.

Appendix 2 tabulates the features of recipients vs non-recipients for comparison.

DISCUSSION

Limitations

The audit was originally intended as a prospective approach, but due to the slow acquisition of episodes in some centres it was decided to include retrospective data to capture 30 episodes from each centre involved. Therefore the audit period differed in each centre ranging from three months in Waikato to eight months in Dunedin. It is accepted that an audit provides a snap shot of activity over a determined period, so the variety in time needed to collect the required number of episodes may be of consequence.

The use of retrospective and prospective data may complicate interpretation of the data. In collecting prospective data the opportunity is available to clarify anomalies, whereas retrospective audits only allow for the examination of clinical notes.

Once the paediatric cardiac surgery patients and the fibrin glue episodes were excluded, the sets of data available were reduced to those indicated in table 2.

Incomplete data sets limited certain aspects of the analysis. Obtaining patient weights was frequently difficult and pre and post transfusion fibrinogen levels were not always available. Post transfusion fibrinogen levels were frequently not taken within 6 hours of transfusion. Together, this excluded over half the episodes from the analysis of increments. Related to this, the audit did not look for thromboelastograph (TEG) results as an indicator of fibrinogen concentration. This may have provided additional information about increments and appropriateness of use.

There were six Transfusion Nurse Specialists collecting data. This permitted a national audit to be performed, but an inherent problem with multiple collectors is that when an episode requires a comment, various interpretations can be placed on that comment. An attempt to reduce this from occurring was made with the format of the form used to collect data and regular telephone and face to face meetings to clarify problems raised during the audit period.

A single patient in a Haematology ward received cryoprecipitate on 12 occasions, contributing 7% to all episodes. This emphasises an issue affecting blood component usage analysis where a small number of patients may be using a large proportion of the component.

The Transfusion Medicine Specialist review was conducted based on the information provided by the audit. While key points were sought, the data is inevitably not as complete as

a full review of each patient's clinical record. This introduces a level of assumption into the assessment of appropriateness.

Lastly, this audit did not assess the clinical outcome other than the post-infusion fibrinogen concentration. While desirable, this would have added considerably to the complexity of the audit, beyond the resources available.

Comment

This audit looked at 315 episodes of cryoprecipitate transfusion and low fibrinogen cryoprecipitate non-recipients. Although 29 transfusion episodes were excluded as elective, for paediatric bypass and fibrin glue, this still left substantial number of episodes and nearly twice as many as the study by Pantanowitz[3] et al and nearly three times as many as the study by Schofield et al[4].

26% of pretransfusion fibrinogen levels in recipients were more than 1.5g/L, compared with Schofield's[4] 43%. The mean pre-transfusion fibrinogen concentration of 1.3g/L but with wide confidence intervals and all DHBs showed overlapping confidence intervals.

This audit's results suggest 18% (n=27) of all cryoprecipitate transfusion episodes were considered inappropriate by the two reviewing Transfusion Medical Specialists. This compares with 24% in Pantanowitz et al's study[3] and 49% in Schofield et al's study[4]. However, Schofield defined an inappropriate transfusion dependent upon the patient's fibrinogen level, whereas this present audit took into consideration the overall clinical situation.

It is generally accepted that cryoprecipitate is useful when the fibrinogen level is below 1.0g/L[5,6,7] and in the clinical situation where the patient is bleeding or is at risk of bleeding. The routine use of cryoprecipitate in the presence of hypofibrinogenaemia without risk factors is not considered good transfusion practice. The trend suggested from this audit is that a significant proportion of cryoprecipitate usage is inappropriate (18%). Clinicians are encouraged to adhere to the recommended clinical guidelines for the use of cryoprecipitate. Interestingly, this percentage, which is not dissimilar to Panatowitz's study, did not show significant variation across the DHBs studied. This suggests that this may be a baseline created by the audit process.

A tendency to underdose patients was noted. With a recommended dose of one unit of cryoprecipitate per 30kg bodyweight, 24% of patients received less than half the recommended dose. There was no correlation between pre-transfusion fibrinogen levels and dose received. 8% of doses were more than 1.5 times the recommended dose with only 3 evaluable episodes showing more than twice the recommended dose. Underdosing would appear to be a much bigger problem than overdosing and has the potential for poorer outcomes. Related to underdosing, patients given a low dose initially showed a poorer response to transfusion, despite an appropriate indication, requiring more than twice as many transfusions of cryoprecipitate than those patients given the right dose.

The average increment level was 1.2g/L for those episodes where the transfusion was appropriate and the dose was the recommended dose. Although 53% of all recipient episodes were appropriate with the right dose, the lack of patient weights and fibrinogen levels made for small patient numbers and wide confidence intervals around the increment.

Unlike other studies, this audit also looked at the other side of the coin, that is, those patients with fibrinogens less than 1.0g/L but who did not receive cryoprecipitate. The non-recipients showed a similar pattern of fibrinogen levels to the recipients, indicating that the fibrinogen level alone was not the reason the patients were not transfused.

On review of these cases it was considered that 27% of these patients would have benefited from receiving cryoprecipitate. There was significant variation between DHBs possibly reflecting differences in practice and policy. For example, one DHB routinely checks fibrinogen levels after plasma exchange. The ratio of recipients to non-recipients did not appear to show a pattern, even when corrected for appropriate transfusion. This presumably reflects differences in case mix and possibly clinician practice.

In summary, this audit has shown good increments where cryoprecipitate is used correctly. However significant problems exist with transfusions at high fibrinogen levels, underdosing and inappropriate transfusions. Similarly, inappropriately not transfusing patients was also seen.

RECOMMENDATIONS

There appears to be a need to provide education to clinical staff regarding

- The correct dose of cryoprecipitate (1 u per 30kg bodyweight) to obtain a fibrinogen increment of 1.0g/L
- The importance of checking fibrinogen levels before giving cryoprecipitate to ensure the component is used appropriately
- Ensuring appropriate systems are available for monitoring fibrinogen levels when cryoprecipitate is being used in a massive transfusion setting (eg the use of TEG)

It is recommended that Blood Banks ask for the patient's weight before issuing cryoprecipitate. While this may be onerous, it would reinforce the need for weight-adjusted dosing and may provide clinical benefit to the patient.

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Appendix 1. *Comparing clinical features of appropriate and inappropriate episodes*

	Cryoprecipitate recipients		Low fibrinogen, cryoprecipitate non-recipients	
	Appropriate n=125	Not Appropriate n=27	Appropriate n=92	Not Appropriate n=42
Age, years	45.5 ±24.4	51.1 ±23.6	46.3 ±23.5	45.5 ±29.5
Female	32%	48%	45%	48%
Fibrinogen level, g/L	1.0 ±0.7	2.4 ±1.0	0.7 ±0.2	0.7 ±0.2
Hct	0.30 ±0.1	0.29 ±0.1	0.33 ±0.1	0.30 ±0.1
INR	2.1 ±2.3	1.4 ±0.2	2.5 ±1.8	1.8 ±1.1
PTT, secs	65 ±50.7	41 ±12.5	91±54.9	49±37.0
Platelet, $x10^9$/L	109 ±80.4	133 ±84.7	173 ±98.5	136 ±84.7
Preceding component usage				
RBC, units	6.6 ±8.5	4.6 ±4.8	0.8 ±2.6	3.3 ±4.6
FFP, units	3.2 ±3.7	3.2 ±3.6	0.6 ±2.1	1.1 ±3.0
Platelet, units	0.9 ±1.6	1.3 ±1.8	0.1 ±0.7	0.2 ±0.9
Cryoprecipitate, units	0.3 ±0.8	0.3 ±0.8	0.0 ±0.0	0.0 ±0.0
Location				
Emergency Department	2%	0%	1%	7%
Intensive Care Unit	28%	37%	32%	29%
Theatre	38%	44%	5%	33%
Ward	31%	19%	62%	31%
Platelet function				
Documented abnormal	12%	4%	7%	5%
Documented normal	13%	19%	2%	7%
No info available	67%	59%	87%	76%
Recent aspirin use	8%	19%	4%	12%
Blood volume loss				
Fast, >1litre per hour	38%	26%	4%	26%
No info available	21%	30%	28%	48%
Not falling	14%	4%	62%	2%
Slow, < 1litre per hour	27%	41%	5%	24%
Rate of fall of Fibrinogen				
Fast, >1g/l per 6 hours	20%	11%	7%	2%
No info available	36%	33%	22%	48%
Not falling	5%	30%	5%	10%
Slow, <1g/l per 6 hours	39%	26%	66%	40%
Indication				
Bleeding actively	45%	50%	7%	69%
Coagulopathy†	16%	0%	58%	10%
Dysfibrinogenaemia	0%	0%	2%	0%
Hypofibrinogenaemia	0%	0%	7%	7%
Hypofibrinogenaemia‡	13%	0%	22%	2%
Invasive procedure	14%	40%	3%	12%
Trauma	11%	10%	2%	0%
Co-morbidities				
Immature liver	3%	0%	10%	5%
Liver Disease	16%	15%	7%	5%
None	48%	33%	55%	78%
Post cardiac bypass	18%	37%	12%	1%
Sepsis	10%	4%	10%	9%
Uraemia, urea >20 mM	4%	11%	7%	1%

† but not bleeding
‡ drug-induced

Appendix 2. *Comparing recipients and non-recipient episodes: the decision to give cryoprecipitate*

	Cryoprecipitate recipients n=152	**Low fibrinogen, cryoprecipitate non-recipients** n=134
Age, years	47.5 ±24.3	46.2 ±25.4
Female	35%	46%
Fibrinogen level, all, g/L	1.3 ±0.9	0.7 ±0.2
Fibrinogen level where <1g/L, g/L	0.7 ±0.2	0.7 ±0.2
Hct	0.3 ±0.1	0.3 ±0.1
INR	2.0 ±2.1	2.3 ±1.6
PTT, secs	61 ±47	78 ±53
Platelet, $x10^9$/L	113 ±81	161 ±96
Preceding component usage		
RBC, units	6.3 ±8.0	1.6 ±3.5
FFP, units	3.2 ±3.7	0.7 ±2.4
Platelet, units	0.9 ±1.6	0.1 ±0.8
Cryoprecipitate, units	0.3 ±0.8	0.0 ±0.0
Location		
Emergency Department	2%	3%
Intensive Care Unit	30%	31%
Theatre	39%	14%
Ward	29%	52%
Platelet function		
Documented abnormal	11%	6%
Documented normal	14%	4%
No info available	66%	84%
Recent aspirin use	10%	7%
Blood volume loss		
Fast, >1litre per hour	36%	11%
No info available	22%	34%
Not falling	13%	43%
Slow, < 1litre per hour	30%	11%
Rate of fall of Fibrinogen		
Fast, >1g/l per 6 hours	18%	5%
No info available	36%	30%
Not falling	9%	7%
Slow, <1g/l per 6 hours	37%	58%
Indication		
Bleeding actively	46%	28%
Coagulopathy†	14%	38%
Dysfibrinogenaemia	0%	2%
Hypofibrinogenaemia	0%	7%
Hypofibrinogenaemia‡	11%	17%
Invasive procedure	18%	6%
Trauma	11%	2%
Co-morbidities		
Immature liver	3%	7%
Liver disease	16%	6%
None	45%	70%
Post cardiac bypass	22%	4%
Sepsis	9%	9%
Uraemia, urea >20 mM	5%	3%

† but not bleeding
‡ drug-induced