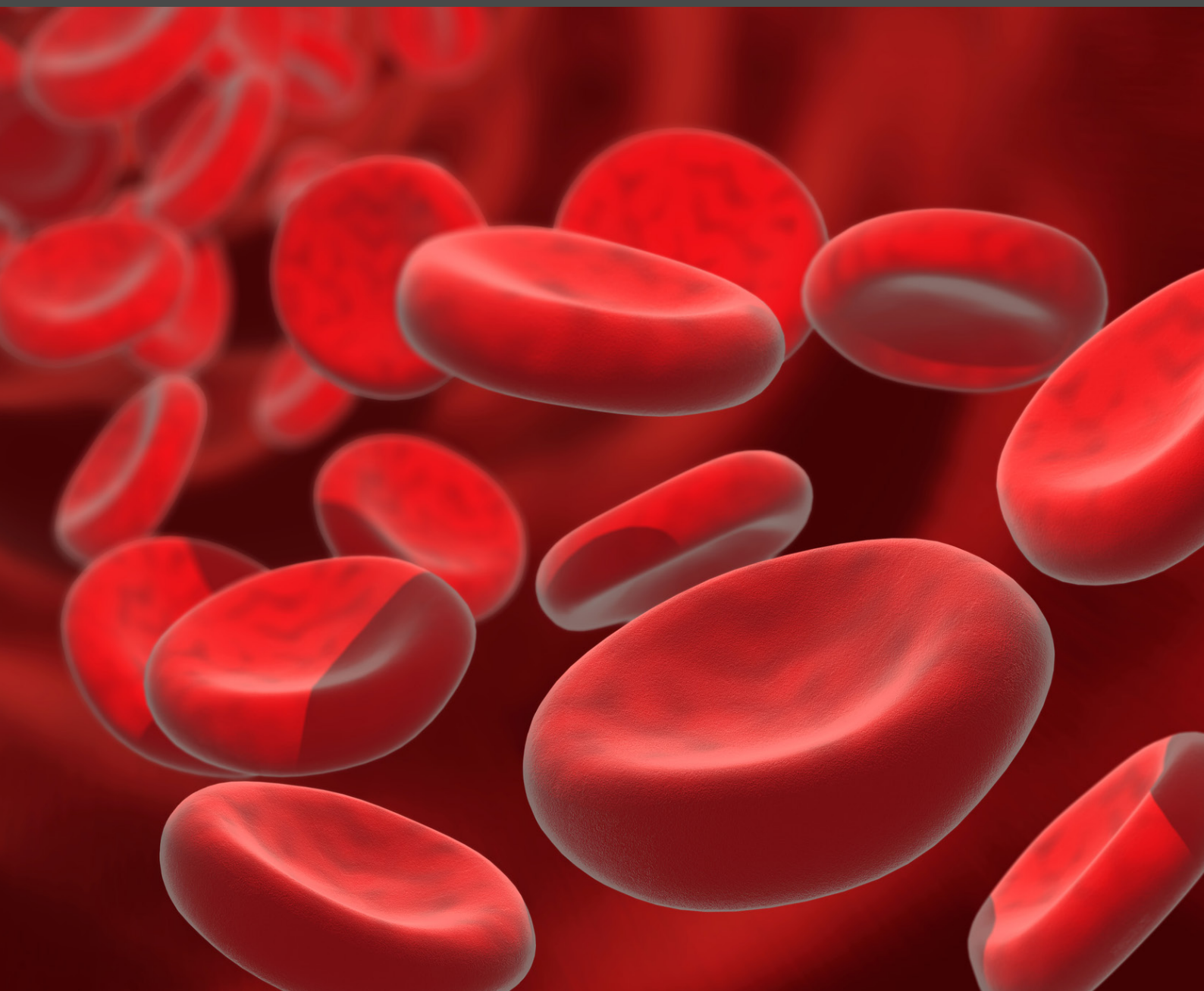
NZBLOOD
Te Ratonga Toto O Aotearoa

National Haemovigilance Programme

Annual Report 2012



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Disclaimer

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- Any information that becomes known solely as the result of Haemovigilance is confidential; and
- Any documents brought into existence solely for the purposes of Haemovigilance are confidential; and
- The persons who engage in Haemovigilance in good faith are immune from civil liability.

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Foreword

This is the 8th Annual Haemovigilance Report for New Zealand. Support for the scheme continues to be excellent and the contribution of the many health care professionals who complete and return the adverse event form is greatly appreciated. Dr Dorothy Dinesh who was responsible for overseeing the scheme left NZBS at the end of 2012. I would like to take this opportunity to thank her for her significant contribution to the development of the haemovigilance system in New Zealand. John Dagger continues to run the Haemovigilance Office in Wellington and he has also played a major role in the drafting of the current report. His on-going support is greatly appreciated.

The practice of transfusion is undergoing significant change. During the last couple of years there have been significant changes in the pattern of blood component use. Clinical use of red cell components has reduced by over 8% and this downward trend continues. A new section on this topic has been included in the report this year. The changes reflect emerging evidence that a restrictive transfusion approach results in at least equivalent clinical outcomes as a more liberal approach to transfusion and should therefore be associated with positive outcomes for patients.

The information contained in the report is highly useful to NZBS as we set out priorities for the year. The move to suspension of platelet component in additive solution was completed in mid-2012. This report includes an analysis of adverse reactions associated with platelet components. This shows a significant reduction in the frequency of allergic reactions with platelets suspended in additive solution compared to those suspended in plasma. This was an expected benefit of the introduction of platelet additive solution and is good to see this confirmed in practice.

Efforts continue to achieve 100% pre-release bacterial testing of platelet components. Ideally this will be introduced at the same time as an extension of the platelet shelf life to seven days. This will enable improved safety, improve utilisation and reduce expiry. These changes will require Medsafe approval prior to implementation.

The Haemovigilance Report provides an opportunity for all involved in transfusion to gain an improved understanding of risks associated with transfusion. The available evidence suggests there is still room to improve safety of the overall process. I hope you will find the report informative and look forward to your on-going support of the programme.

Dr Peter Flanagan
NZBS National Medical Director

1 Introduction

Council of Europe Definition of Haemovigilance

"…. The organised surveillance procedures related to serious or unexpected events or reactions in donors or recipients and the epidemiological follow up of donors …"

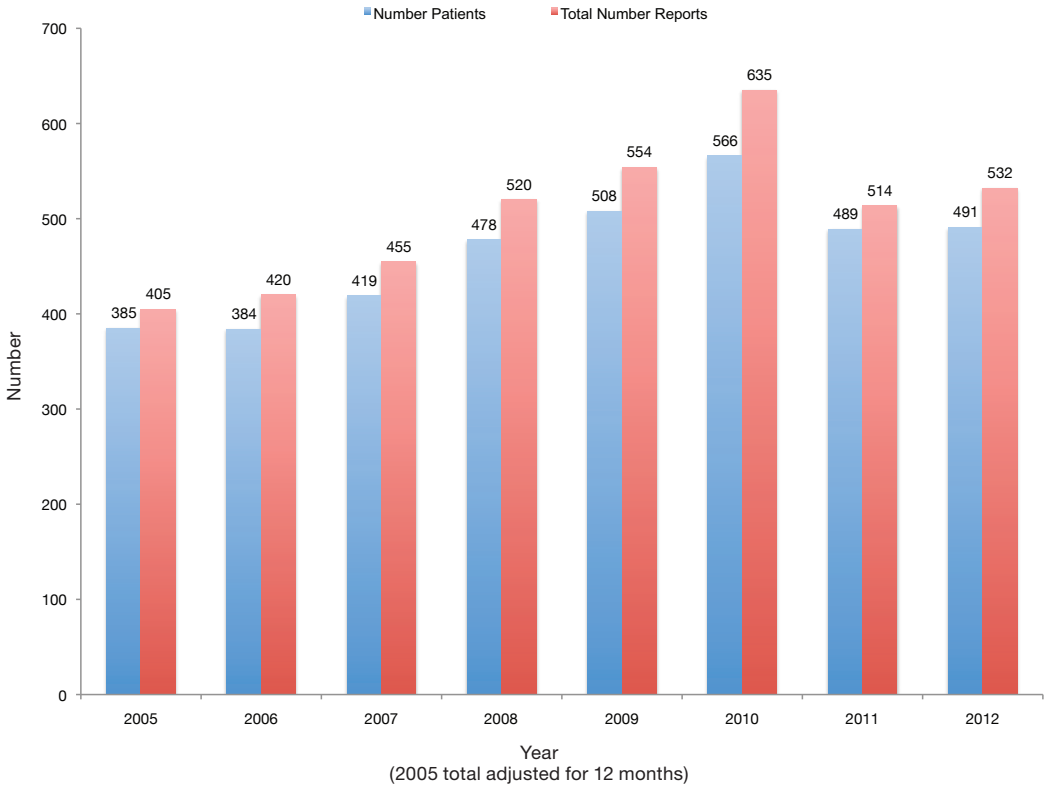
The New Zealand National Haemovigilance Programme was established in 2005. This is the eighth Annual Haemovigilance Report for New Zealand.

The National Haemovigilance Office receives reports from Blood Bank Scientists and Transfusion Nurse Specialists from hospitals within New Zealand. The reporting form (Appendix I) includes a severity score, an imputability score and definitions of reporting categories which are based on those agreed upon by the International Society of Blood Transfusion Working Party on Haemovigilance in collaboration with the International Haemovigilance Network (ISBT/IHN).

All reports received at the Haemovigilance Office are reviewed by a Team comprising a number of Transfusion Medicine Specialists and an experienced Scientist who is also responsible for overall management of the scheme. Where required, additional information is sought from the submitter of the report in order to accurately classify the type of adverse event, imputability and severity scores. The data is entered into a secure database; clinician and patient names are not included. The paper records are destroyed on publication of the annual report and the unique patient identifier is then deleted from the database.

The reporting of adverse events to the National Haemovigilance Programme is voluntary. During 2012 there were 532 reports received involving 492 patients. The number of reports received in 2012 was similar to that in 2011 (Figure 1.1). Prior to 2011 there was a steady increase in reported events and the year on year number of reports and the number of individual patients is shown in Figure 1.1. Compared to 2010 there has been a 19% reduction.

FIGURE 1.1. REPORTS RECEIVED BY HAEMOVIGILANCE PROGRAMME 2005 - 2012



2 Trends in Blood Component Transfusion in New Zealand

New Zealand has traditionally been a low user of blood components when compared to other developed countries. This is supported by data in Table 2.1 from an International Forum on Inventory Management published in Vox Sanguinis in 2010 (Vox Sanguinis (2010) 98: e295–e363).

TABLE 2.1. INTERNATIONAL COMPARISON OF BLOOD COMPONENTS ISSUED

Country	Component Issues per 1,000 Population (2009/10)		
	Red Cells	Platelets	Fresh Frozen Plasma
New Zealand	30.6	3.9	6.0
Australia	35.4	6.0	7.1
France	35.4	3.9	8.2
Denmark	59.3	6.2	12.2
Ireland	31.5	5.5	**
United Kingdom	39.5	4.75	5.24

***use Solvent Detergent FFP only*

Significant changes in clinical demand patterns have emerged over the last 2-3 years in New Zealand and overseas. In particular there has been a significant, and on-going, reduction in the number of red cell components transfused to patients. Figure 2.1 shows the moving annual total of red cell components transfused in New Zealand since 2008. A gradual increase was seen in the first 2 years. This is consistent with changes in overall population. Since 2010 however the rate of transfusion has fallen significantly amounting to an 8.9% reduction since June 2010. The number of recipients of red cells has also reduced by 5.1% over the same period (see Table 2.2). A number of factors will likely have contributed to the reduction. Changes in clinical practice will have played an important role. The medical literature increasingly supports a more restrictive approach to red cell transfusion with numerous studies demonstrating that this is associated with at least equivalent patient outcomes when compared to a conservative transfusion approach. This more restrictive 'transfusion trigger' along with a range of other transfusion sparing approaches are promoted in recently published patient blood management guidelines developed by the Australian National Blood Authority in conjunction with the Australian and New Zealand Society of Blood Transfusion (ANZSBT) and the Australian National Health and Medical Research Council (NHMRC). Similar falls in red cell transfusion rates have occurred in other developed countries.

Trends in Blood Component Transfusion in New Zealand continued

FIGURE 2.1. MOVING ANNUAL TOTAL RED CELLS UNITS TRANSFUSED 2008 – 2012

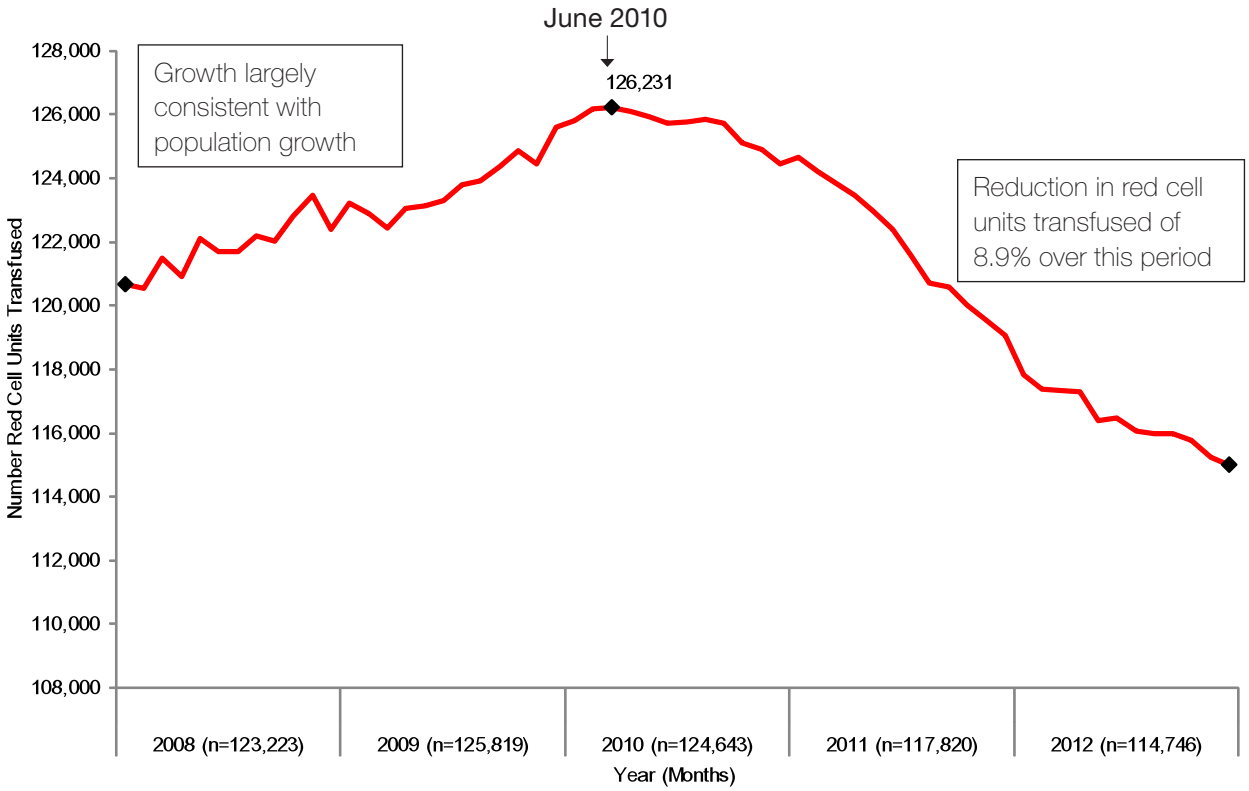


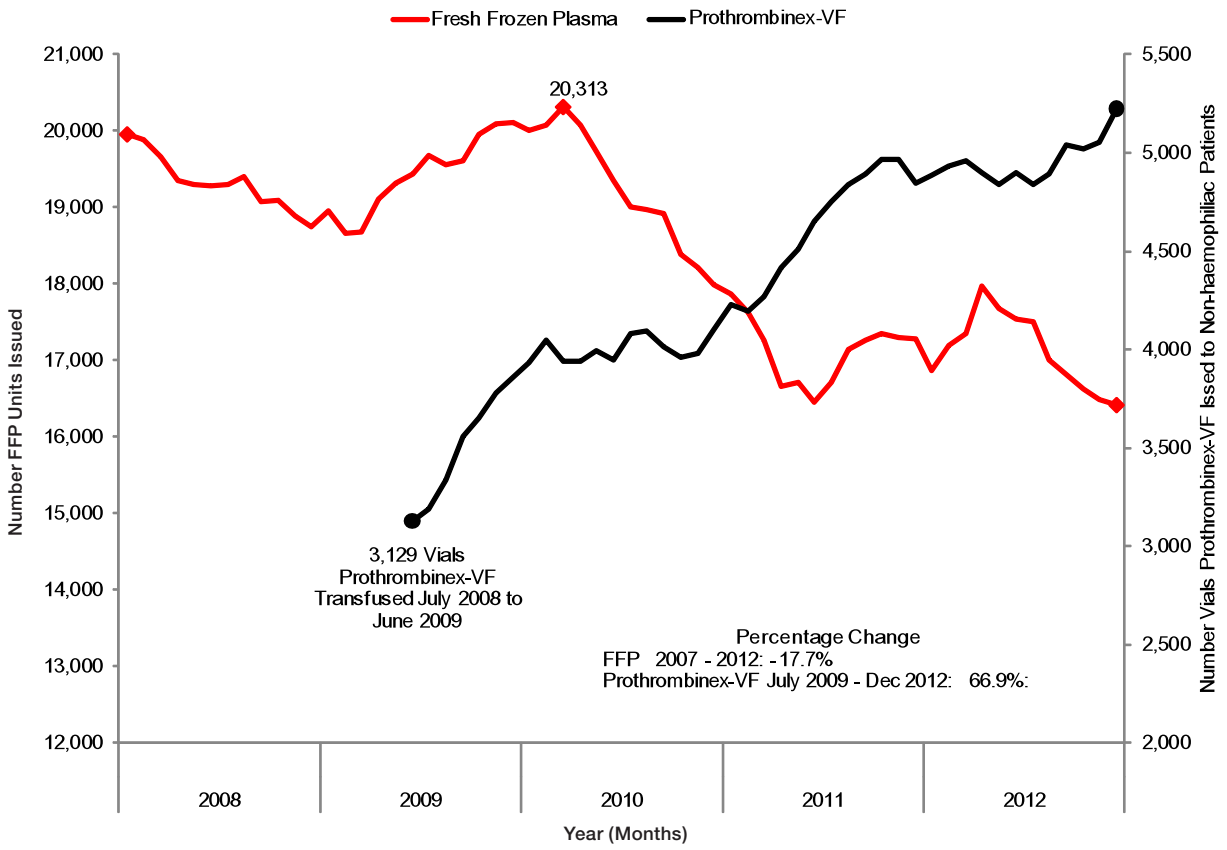
TABLE 2.2. RED CELL RECIPIENTS BY YEAR

Year	Number Red Cell Recipients
2009	28,118
2010	28,130
2011	27,101
2012	26,673

2 Trends in Blood Component Transfusion in New Zealand continued

Rates of transfusion of Fresh Frozen Plasma (FFP) have also fallen significantly as shown in Figure 2.2. This reduction in part is in response to an increased use of Prothrombinex-VF in warfarin reversal. The Australasian Society for Thrombosis and Haemostasis (ASTH) has recently published updated guidelines in this area which are likely to increase the shift away from FFP to Prothrombinex-VF further.

FIGURE 2.2 MOVING ANNUAL TOTAL FRESH FROZEN PLASMA UNITS TRANSFUSED (2008 – 2012) AND PROTHROMBINEX-VF (JULY 2008 – DEC 2012)



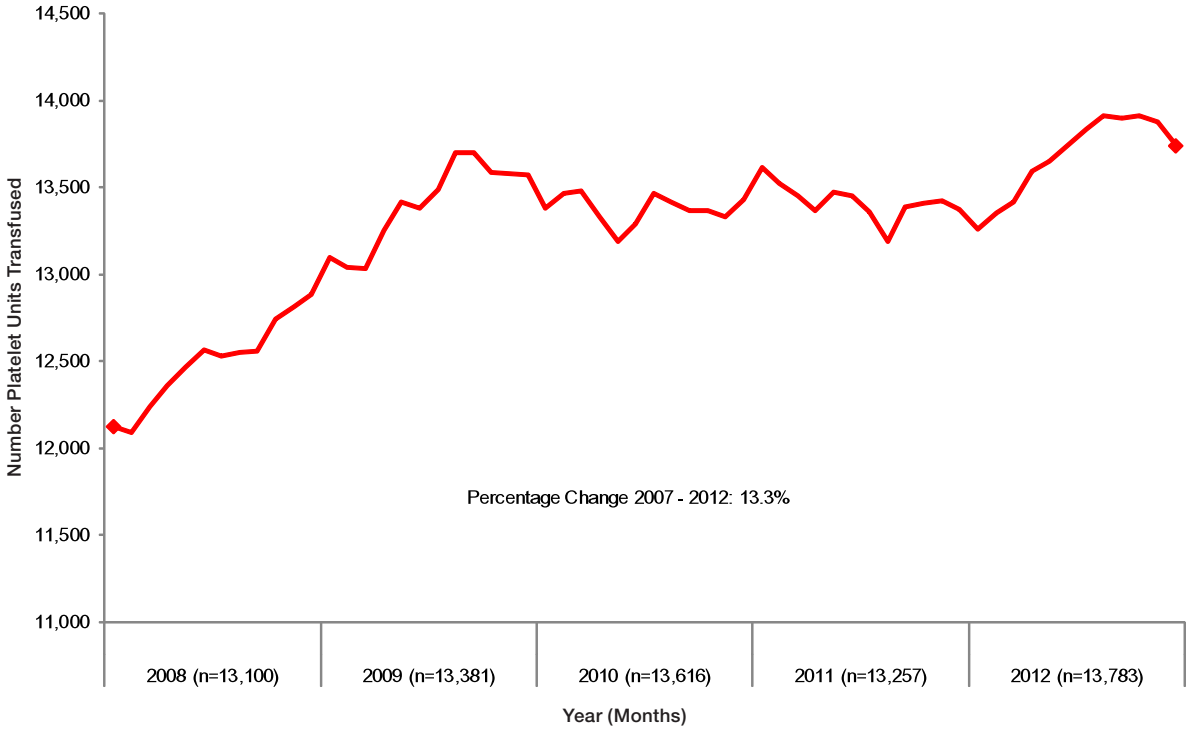
Trends in Blood Component Transfusion in New Zealand continued

In contrast there is an increase in the rate of 13.3% in the number of platelet components transfused over the period 2007-2012 (see Table 2.3, Figure 2.3). This largely relates to increased use in haemato-oncology and cardiac surgery.

TABLE 2.3 TOTAL ANNUAL TRANSFUSED BLOOD COMPONENTS 2007 - 2012

Blood Component	Year					
	2007	2008	2009	2010	2011	2012
Red Cells - Leucodepleted	118,747	121,262	123,979	122,745	116,071	113,014
Red Cells Neonatal	1,928	1,961	1,840	1,898	1,749	1,732
Total Red Cells	**120,675**	**123,223**	**125,819**	**124,643**	**117,820**	**114,746**
Platelets - Apheresis	6,766	7,283	7,571	7,576	6,661	2,117
Platelets - Pooled	4,749	5,157	5,325	5,403	2,349	614
Platelets - Apheresis PAS					774	5,354
Platelets - Pooled PAS				48	2,988	5,037
Platelets - Neonatal	610	660	485	589	485	661
Total Platelets	**12,125**	**13,100**	**13,381**	**13,616**	**13,257**	**13,783**
Fresh Frozen Plasma	19,813	18,831	19,874	17,685	16,736	16,524
Fresh Frozen Plasma Neonatal	142	131	127	187	127	200
Total Fresh Frozen Plasma	**19,955**	**18,962**	**20,001**	**17,872**	**16,863**	**16,724**
Cryoprecipitate	1,991	2,372	2,869	2,951	3,228	3,745
Cryodepleted Plasma	927	524	517	486	751	670
Total Components	**155,673**	**158,181**	**162,587**	**159,568**	**151,919**	**149,668**

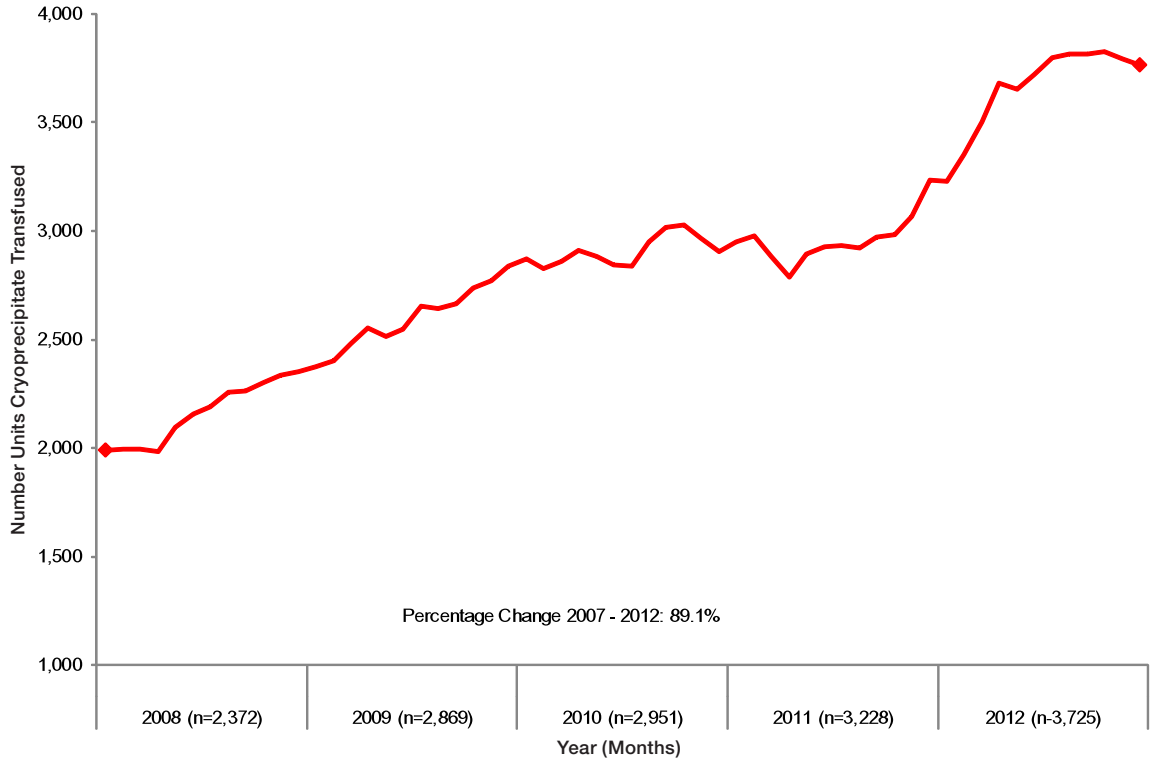
FIGURE 2.3 MOVING ANNUAL TOTAL PLATELET UNITS TRANSFUSED 2008 – 2012



Trends in Blood Component Transfusion in New Zealand continued

Transfusion rates of cryoprecipitate have increased progressively over the period with a more marked increase during the last two years (Figure 2.4). The initial increase reflects a response to the audit of cryoprecipitate use by NZBS in 2005. This showed significant under-dosing in a number of hospitals. The more recent increase likely reflects the introduction of massive transfusion protocols (MTPs) in a number of hospitals.

FIGURE 2.4 MOVING ANNUAL TOTAL CRYOPRECIPITATE UNITS TRANSFUSED 2008 - 2012



MTPs incorporate early use of cryoprecipitate as a source of fibrinogen to achieve haemostasis and a consequent reduction in overall transfusion requirements.

The changing pattern of blood component use is a good indicator that clinical transfusion practice is responding appropriately to the emergence of new evidence and good practice guidelines.

3 Recipients of Blood Components

Table 3.1 below provides information on the number of recipients of blood components during 2012.

TABLE 3.1 BLOOD COMPONENT RECIPIENTS 2012

		Red Cells	Platelets	FFP
Gender of Recipients	Female	15,138	1,384	1,457
	Male	11,482	2,146	2,287
	Unknown	53	1	5
	Total	**26,673**	**3,531**	**3,749**
Age of Recipients (years)	Mean	63	53	60
	Median	69	61	67
	Maximum	106	101	101
	Minimum	0	0	0
Units Transfused per Recipient Total During 2012	Mean	4	4	4
	Median	2	2	2
	Maximum	113	143	296
	Minimum	1	1	1

4 Summary of Reported Events for 2012

During 2012 a total of 532 events were reported to the National Haemovigilance Programme. A total of 90 (16.9%) had a low imputability score (≤2) and were excluded from the analysis since they were unlikely to be attributable to transfusion. Imputability score definitions (ISBT/IHN) and the number of reports excluded per year due to low imputability are shown in Table 4.1 and 4.2.

TABLE 4.1 IMPUTABILITY SCORE DEFINITIONS

Imputability Score Definitions		
NA	**Not assessable**	When there is insufficient data for imputability assessment
1	**Excluded**	When there is conclusive evidence beyond reasonable doubt for attributing the event to alternative causes
2	**Unlikely**	When the evidence is clearly in favour of attributing the event to causes other than transfusion
3	**Possible**	When the evidence is indeterminate for attributing the event either to the transfusion or alternative causes
4	**Likely, probable**	When the evidence is clearly in favour of attributing the event to the transfusion
5	**Certain**	When there is conclusive evidence beyond reasonable doubt for attributing the event to the transfusion

TABLE 4.2 NUMBER OF REPORTS WITH LOW IMPUTABILITY 2008 – 2012

	2008	2009	2010	2011	2012
Total Reports	520	554	635	514	532
Imputability ≤2	73	66	80	72	90
Percent Imputability ≤2	14.0%	11.9%	12.6%	14.0%	16.9%

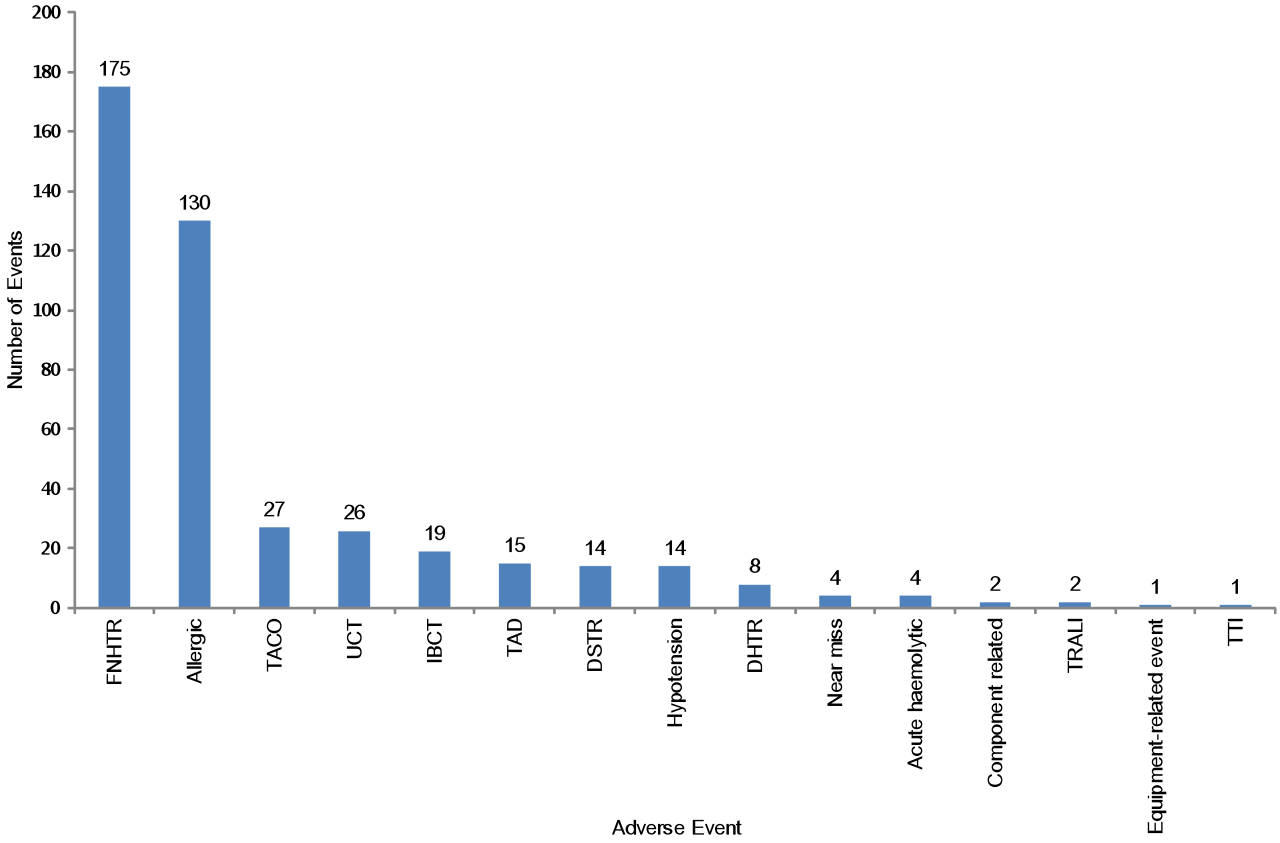
Summary of Reported Events for 2012

continued

The types of adverse events with an imputability score of ≥3 are detailed in Figures 4.1 and 4.2.

Febrile non-haemolytic and allergic transfusion reactions continue to be the most frequently reported events. Figure 4.1 and 4.2 show the overall pattern of reported events by category.

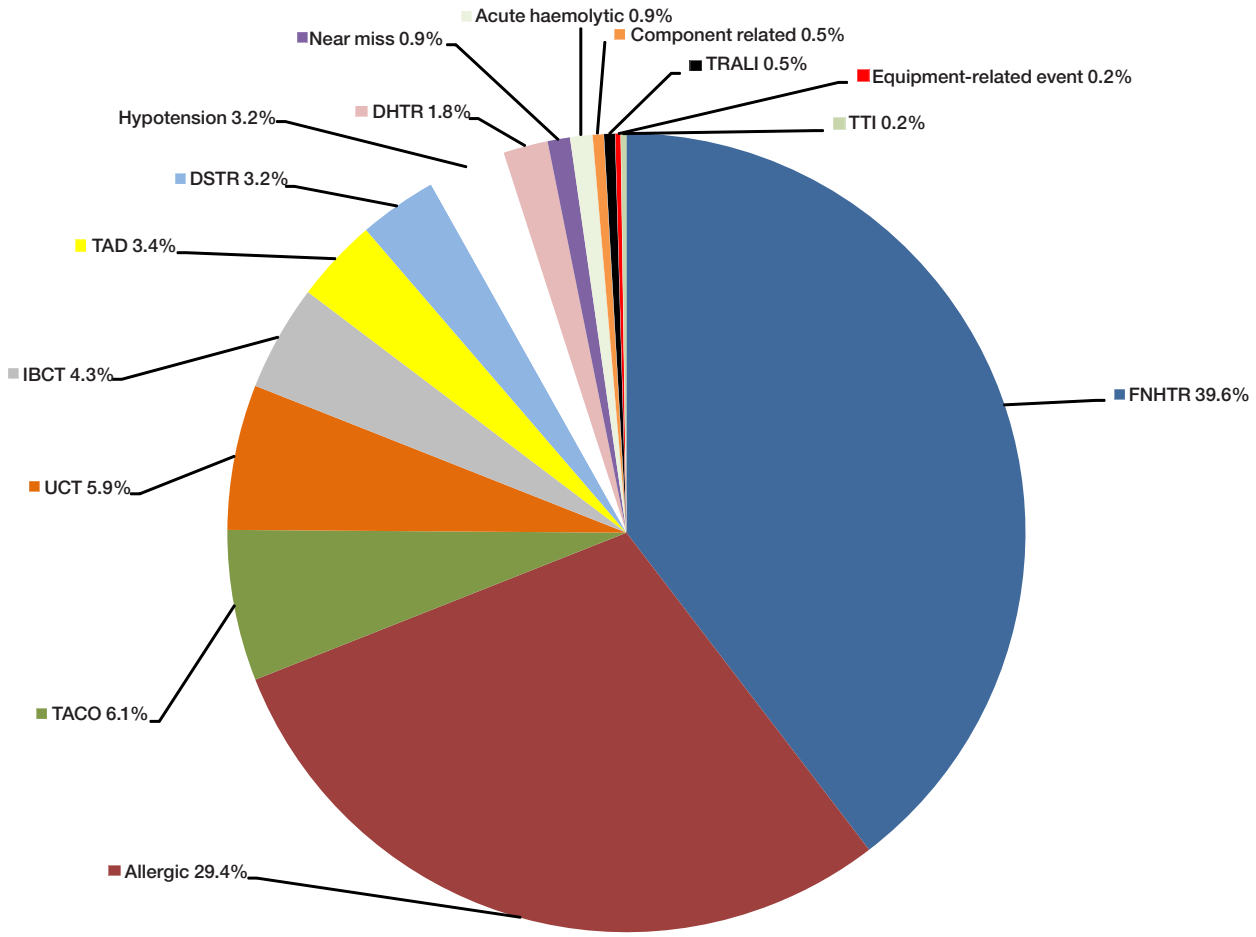
FIGURE 4.1 REPORTED EVENTS BY CATEGORY (IMPUTABILITY ≥3) 2012 (n = 442)



Key:

FNHTR	Febrile non-haemolytic transfusion reaction
Allergic	Allergic transfusion reaction
TACO	Transfusion-associated circulatory overload
IBCT	Incorrect blood component transfused
UCT	Unclassifiable complication of transfusion
TAD	Transfusion-associated dyspnoea
DSTR	Delayed serologic transfusion reaction
DHTR	Delayed haemolytic transfusion reaction
Acute	Acute haemolytic reaction
TRALI	Transfusion-related acute lung injury
TTI	Transfusion-transmitted infection

FIGURE 4.2 REPORTS AS A PERCENTAGE OF TOTAL REPORTS (IMPUTABILITY ≥3) 2012 (n=442)



There were 413 transfusion recipients associated with the 442 reports included in the analysis. Table 4.3 shows the age and gender of the recipients with reported events with an imputability score ≥3.

TABLE 4.3 AGE AND GENDER OF PATIENTS WITH REPORTED ADVERSE EVENTS (IMPUTABILITY ≥3) 2012

	Number	Age (years)			
		Mean	Median	Minimum	Maximum
Female	226	52	52	11 days	98
Male	216	58	65	18 days	97
All	**442**	**55**	**60**	**11 days**	**98**

4 Summary of Reported Events for 2012

continued

Multiple transfusion-related adverse events were reported in 25 patients (see Table 4.4).

TABLE 4.4 REPORTED EVENTS PER PATIENT 2012

	Haemovigilance Reports (Imputability ≥3)				
	Total	1 Report	2 Reports	3 Reports	4 Reports
Number of Patients	413	388	22	2	1

Table 4.5 summarises the imputability scores by event category for reported events in 2012. Lower imputability scores were associated with FNHTR, allergic and unclassifiable complications of transfusion.

TABLE 4.5 IMPUTABILITY SCORES BY TYPE OF EVENT 2012

Event Type	Imputability Score						
	1	2	3	4	5	Total	Total ≥3
FNHTR	19	29	135	38	2	223	175
Allergic	8	5	56	67	7	143	130
TACO	1	1	14	12	1	29	27
UCT	4	11	19	5	2	41	26
IBCT					19	19	19
TAD		4	14	1		19	15
DSTR	4		3	5	6	18	14
Hypotension		2	10	4		16	14
DHTR	1		3	3	2	9	8
Near miss					4	4	4
Acute haemolytic	1		1	2	1	5	4
Component related			1		1	2	2
TRALI			1	1		2	2
Equipment-related event				1		1	1
TTI			1			1	1
Total	**38**	**52**	**258**	**139**	**45**	**532**	**442**
Percentage Reports	7.1%	9.8%	48.5%	26.1%	8.5%		83.1%

5 Severity Of Reported Events

The severity score definitions for reported events developed by ISBT/IHN are shown in Table 5.1. 86% of reported events included within the analysis (i.e. imputability score ≥3) were assessed as non-severe (grade 1). Allergic and TACO events accounted for 60% of the severe (grade 2) and 88% of the life threatening adverse reactions reported in 2012 (Table 5.2). There were no reported transfusion related deaths in the year.

TABLE 5.1 SEVERITY SCORE DEFINITIONS AND SEVERITY SCORES FOR EVENTS REPORTED DURING 2012

Grade 1	The recipient may have required treatment but lack of such would not have resulted in permanent damage or impairment of a body function.
Grade 2 (severe)	The recipient required hospitalization or prolongation of hospitalization directly attributable to the event; and/or the adverse event resulted in persistent or significant disability or incapacity; or the event necessitated medical or surgical intervention to preclude permanent damage or impairment of a body function.
Grade 3 (life-threatening)	The recipient required major intervention following the transfusion (e.g. vasopressors, intubation, transfer to intensive care) to prevent death.
Grade 4 (death)	The recipient died following an adverse transfusion reaction. Grade 4 should only be used if death is probably or definitely related to transfusion. If the patient died of another cause, the severity should be graded as 1, 2 or 3.

TABLE 5.2 SEVERITY GRADES BY EVENTS 2012. NUMBER OF EVENTS

Event Type	Severity Grade (for reports where imputability score ≥3)			
	Grade 1	Grade 2	Grade 3	Total
FNHTR	173	2		175
Allergic	105	21	4	130
TACO	12	12	3	27
UCT	26			26
IBCT	19			19
TAD	9	6		15
DSTR	14			14
Hypotension	5	9		14
DHTR	7	1		8
Near miss	4			4
Acute haemolytic	2	2		4
Component related	1	1		2
TRALI		1	1	2
Equipment-related event	1			1
TTI	1			1
Total	**379**	**55**	**8**	**442**
Percentage of reports	86%	12%	2%	

6 Reports Involving Paediatric Patients

During 2012 there were 35 reports (8%) involving recipients aged 15 years or younger. During the same period 2,126 recipients (6.3% of total) fell within this age range. 14% of reactions were recorded as severity grade 2 or higher. This is the same percentage as seen in all age groups. Allergic reactions were the most frequent adverse event reported in this age group (60%) and 19% of the reported allergic reactions were either severe, grade 2, or life-threatening, grade 3 (Table 6.1).

TABLE 6.1 REPORTS INVOLVING RECIPIENTS ≤15 YEARS AGE AND SEVERITY SCORE 2012

Event Type	Total Reports	Gender		Severity Score		
		Female	Male	1	2	3
Allergic	21	10	11	17	2	2
FNHTR	9	5	4	9		
IBCT	2		2	2		
Component related	1	1			1	
Equipment-related event	1		1	1		
UCT	1		1	1		
Total	**35**	**16**	**19**	**30**	**3**	**2**

7 Reported Events by Type of Component

A total of 149,668 blood components were transfused in 2012, 442 adverse events with an imputability score of ≥3 were reported. The overall rate of reported adverse events in 2012 was 1 in 339 units transfused (29 per 10,000 units transfused, 95% CI 27 to 32). Tables 7.1 and 7.2 show the rates and types of event by blood component.

TABLE 7.1 REPORTED EVENTS 2012 BY TYPE OF BLOOD COMPONENT TRANSFUSED (IMPUTABILITY SCORE ≥3)

	Number of Events*	Number Transfused	Frequency	Rate / 10,000 Units Transfused (95%CI)
Cryodepleted Plasma	3	670	1:223	44.8 (8.7 to 137.3)
Platelets - Apheresis PAS[$]	25	6,015	1:241	41.6 (27.9 to 61.6)
Platelets - Pooled PAS	13	5,037	1:387	25.8 (14.6 to 44.6)
Platelets - Apheresis	5	2,117	1:423	18.0 (6.4 to 43.4)
Platelets - Pooled	1	614	1:614	23.6 (8.4 to 56.9)
Red Cells	289	114,746	1:397	25.2 (22.4 to 28.3)
Fresh Frozen Plasma	26	16,724	1:643	15.5 (10.5 to 22.9)
Cryoprecipitate	4	3,745	1:936	10.7 (3.1 to 28.5)

**Includes events where multiple component types transfused*

[$] Includes 661 units Platelets - Neonatal

7 Reported Events by Type of Component

continued

TABLE 7.2 TYPE OF ADVERSE EVENT BY BLOOD COMPONENT 2012 (IMPUTABILITY SCORE ≥3)

	Red Cells	Fresh Frozen Plasma	Platelets Apheresis	Platelets Pooled	PAS Platelets Apheresis	PAS Platelets Pooled	Cryoprecipitate	Cryodepleted Plasma	Other*	Multiple Components
Number Components Transfused	114,746	16,724	2,778	614	5,354	5,037	3,745	670		
FNHTR	154	3	1		4	4				9
Allergic	65	26	8	2	10	5	2	2	1	9
TACO	22	1			1	1				2
UCT	20	1	1		4					
IBCT	3	1			2		1		11	1
TAD	11					1		1		2
DSTR	14									
Hypotension	10	1			2					1
DHTR	7									1
Near miss	2								2	
Acute haemolytic	4									
Component related	2									
TRALI				1						1
Equipment-related event	1									
TTI	0			1						
Total (n=442)	**315**	**33**	**10**	**4**	**23**	**11**	**3**	**3**	**14**	**26**

**Events associated with fractionated plasma products (11), WBIT (2) and allogeneic frozen cord HPC (1)*

8 Haemovigilance Reports by District Health Board

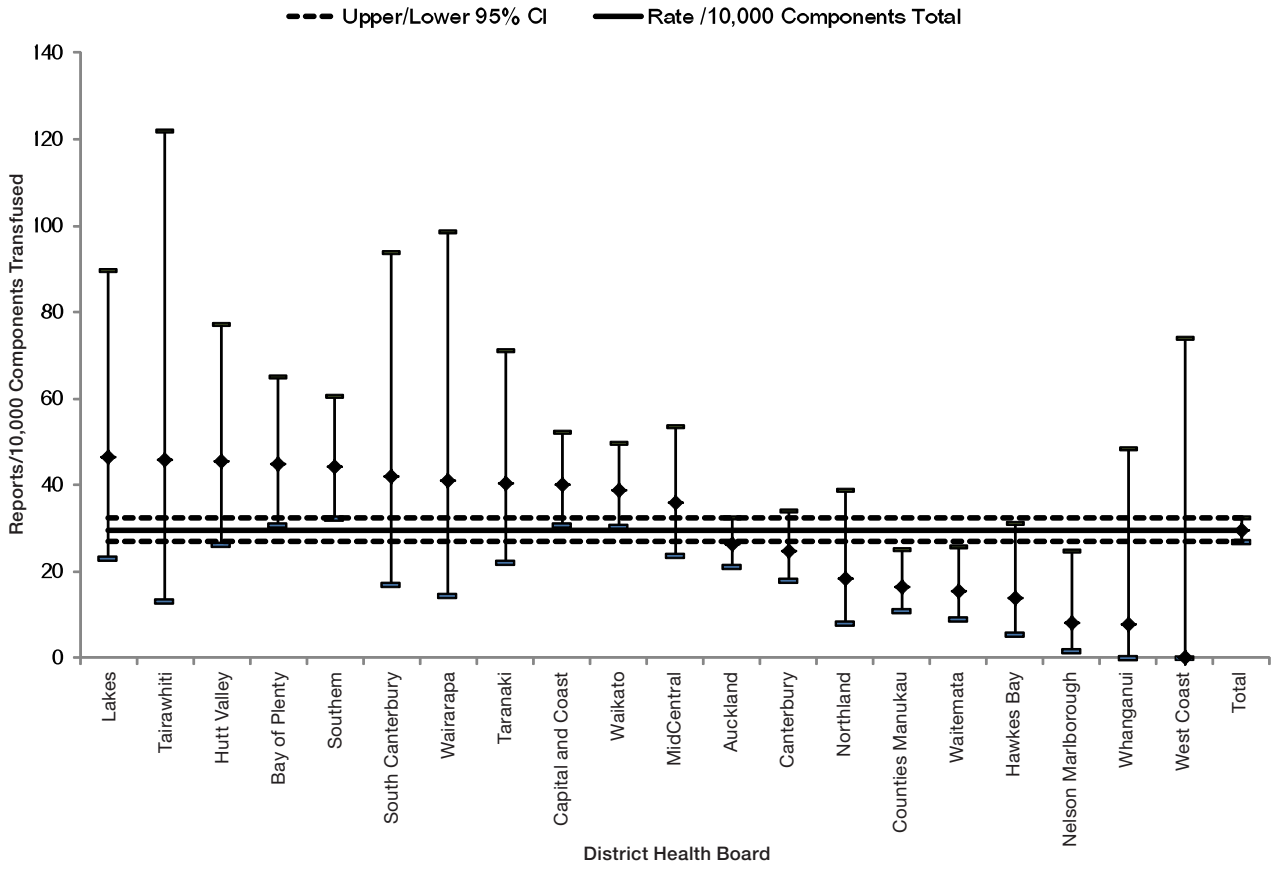
During 2012 events were reported from all 20 District Health Boards in New Zealand. Reports with an imputability ≥3 were received from 19 of the 20 District Health Boards. The number of reported events (imputability ≥3) per District Health Board and the rate of events per 10,000 components transfused are shown in Table 8.1. Figure 8.1 compares the reporting rate per 10,000 components transfused with each other. The national rate is similar to that reported in 2011 (29.1 per 10,000 components transfused).

TABLE 8.1 ORIGIN OF HAEMOVIGILANCE NOTIFICATIONS 2012 (IMPUTABILITY SCORE ≥3)

District Health Board	Reported Events	Components Transfused	Frequency	Rate / 10,000 Components Transfused (95%CI)
Lakes DHB	9	1,938	1:215	46.4 (23.0 to 89.5)
Tairawhiti DHB	4	871	1:218	45.9 (13.3 to 122.0)
Hutt Valley DHB	14	3,067	1:219	45.6 (26.4 to 77.2)
Bay of Plenty DHB	28	6,256	1:223	44.8 (30.7 to 64.9)
Southern	40	9,031	1:226	44.3 (32.4 to 60.4)
South Canterbury DHB	6	1,428	1:238	42.0 (16.9 to 93.7)
Wairarapa DHB	5	1,218	1:244	41.1 (14.6 to 98.7)
Taranaki DHB	12	2,977	1:248	40.3 (22.2 to 71.2)
Capital and Coast DHB	56	13,929	1:249	40.2 (30.9 to 52.3)
Waikato DHB	66	16,956	1:257	38.9 (30.5 to 49.6)
MidCentral DHB	24	6,711	1:280	35.8 (23.8 to 53.4)
Auckland DHB	84	32,088	1:382	26.2 (21.1 to 32.4)
Canterbury DHB	39	15,736	1:403	24.8 (18.0 to 34.0)
Northland DHB	7	3,811	1:544	18.4 (8.1 to 38.7)
Counties Manukau DHB	23	13,950	1:607	16.5 (10.9 to 24.9)
Waitemata DHB	15	9,708	1:647	15.5 (9.1 to 25.7)
Hawkes Bay DHB	6	4,316	1:719	3.9 (5.6 to 31.1)
Nelson Marlborough DHB	3	3,762	1:1254	8.0 (1.5 to 24.6)
Whanganui DHB	1	1,291	1:1291	7.7 (0 to 48.4)
West Coast DHB	0	624		
Total	**442**	**149,668**	**1:339**	**29.5 (26.9 to 32.4)**

8 Haemovigilance Reports by District Health Board continued

FIGURE 8.1 REPORTS PER 10,000 COMPONENTS TRANSFUSED (♦), 95% CONFIDENCE INTERVALS (2012)



9 Febrile Non-Haemolytic Transfusion Reactions

Febrile reactions were the most frequently reported type of transfusion reaction (40%). A total of 223 reports of FNHTR reports were received, 19 (8.5%) of the reports were excluded as they did not meet the criteria for a FNHTR event and 29 (13%) were classified as unlikely due to the patient's underlying condition (i.e. low imputability). The average increase in temperature reported was 1.7°C (Table 8.1).

TABLE 8.1 AGE AND GENDER OF PATIENTS WITH REPORTED FNHTRS 2012

	Number	Age (years)				Average Temp Rise (°C)
		Mean	Median	Minimum	Maximum	
Female	82	56	59	2	98	1.6
Male	93	62	68	73 days	93	1.7
All	**175**	**59**	**63**	**73 days**	**98**	**1.7**

In addition to fever, chills and rigors, other symptoms and signs associated with FNHTRs were documented. These are summarised in Table 8.2. An increase in blood pressure, hypertension, was noted in 20% of patients that are reported to have had a febrile non-haemolytic transfusion reaction.

TABLE 8.2 OTHER SIGNS AND SYMPTOMS ASSOCIATED WITH FNHTRS 2012

	Number			% FNHTR Events
	Female	Male	Total	
Chills / Rigors	55	46	101	57.7%
Increase in blood pressure	19	16	35	20.0%
Restlessness / Anxiety	18	16	34	19.4%
Dyspnoea	10	16	26	14.9%
Flushing	10	11	21	12.0%
Tachycardia	3	10	13	7.4%
Stridor / Wheeze	5	4	9	5.1%
Cough	3	4	7	4.0%
Fall in blood pressure	1	5	6	3.4%
Chest pain	3	1	4	2.3%
Hypoxaemia	2	2	4	2.3%

10 Allergic Transfusion Reactions

During 2012, 130 (29% of total) reported events were classified as allergic in nature. 105 (81%) of the allergic reactions were non-severe and the remaining 25 (19%) were severe or life-threatening. Table 10.1 shows the age and sex of recipients with reported reactions during 2012.

TABLE 10.1 AGE AND SEX OF PATIENTS WITH REPORTED ALLERGIC REACTIONS 2012

	Number	Age (years)			
		Mean	Median	Minimum	Maximum
Female	72	43	41	76 days	89
Male	58	43	43	18 days	89
All	**130**	**43**	**41**	**18 days**	**89**

Clinical features of reported allergic transfusion reactions are summarised in Table 10.2.

TABLE 10.2 SIGNS AND SYMPTOMS ASSOCIATED WITH ALLERGIC REACTIONS 2012

	Number			% Allergic Events
	Female	Male	Total	
Urticaria	48	53	101	77.7%
Restlessness	15	10	25	19.2%
Stridor / Wheeze	13	9	22	16.9%
Flushing	10	7	17	13.1%
Non-urticarial rash	12	2	14	10.8%
Dyspnoea	11	3	14	10.8%
Fall in blood pressure	7	6	13	10.0%
Facial oedema	8	4	12	9.2%
Chills / Rigors	5	3	8	6.2%
Cough	4	2	6	4.6%
Increase in blood pressure	2	3	5	3.8%

Table 10.3 below provides information on signs and symptoms associated with allergic type reactions by severity grade. Data for non-severe reactions (grade 1) are compared to those for severe and life threatening (grades 2 and 3). Stridor/wheeze and a fall in blood pressure were the key indicators of more severe type reactions.

TABLE 10.3 COMPARISON OF SIGNS AND SYMPTOMS AND SEVERITY GRADE IMPUTABILITY ≥3

	Severity Grade				p Value
	Grade 1 (n = 105)		Grade 2 and 3 (n = 26)		
	Number	Percentage	Number	Percentage	
Urticaria	84	50.0%	17	24.6%	0.001
Restlessness	17	10.1%	8	11.6%	NS
Stridor / Wheeze	11	6.5%	11	15.9%	0.01
Flushing	10	6.0%	7	10.1%	NS
Non-urticarial rash	13	7.7%	1	1.4%	0.02
Dyspnoea	8	4.8%	6	8.7%	NS
Fall in blood pressure	4	2.4%	9	13.0%	0.001
Facial oedema	6	3.6%	6	8.7%	NS
Chills / Rigors	6	3.6%	2	2.9%	NS
Cough	4	2.4%	2	2.9%	NS
Increase in blood pressure	5	3.0%	0		
Total	**168**		**69**		

Multiple allergic events were reported in 7 patients, (Table 10.4). The implicated products transfused and the diagnosis of those 7 patients with multiple allergic events is detailed in Table 10.5.

TABLE 10.4 ALLERGIC EVENTS IMPUTABILITY ≥3

		Number of Reports		
	Total Reports	1 Report	2 Reports	3 Reports
Number of Patients	130	114	5	2

TABLE 10.5 REPEAT ALLERGIC REACTIONS EVENTS IMPUTABILITY ≥3

	Number Reports	Implicated Components	Diagnosis
Patient 1	2	Cryodepleted plasma	Plasma exchange
Patient 2	2	Fresh frozen plasma	Acute cholecystitis
Patient 3	2	Apheresis PAS platelets	AML
Patient 4	2	Red cells	AML
Patient 5	2	Allogeneic frozen cord HPCs, Red cell	Eosinophilic leukaemia
Patient 6	3	Apheresis PAS platelets x 2, Red cell	MDS
Patient 7	3	Apheresis platelets	Aplastic anaemia

Allergic reactions are frequently reported after blood and blood product transfusions. Usually, they are not serious reactions but cause significant morbidity and distress to recipients of blood transfusions. The frequency of allergic events and the rate per 1,000 components transfused for those events where a single component was implicated in 2012 were analysed (Table 10.6).

TABLE 10.6 ALLERGIC EVENTS BY BLOOD COMPONENT TRANSFUSED 2012

Component	Allergic Events	Number Components Transfused	Frequency	Rate/1,000 Components Transfused (95%CI)
Red Cells	65	114,746	1:1,765	0.6 (0.4 to 0.7)
FFP	26	16,724	1:643	1.6 (1.1 to 2.3)
Platelets Apheresis - Plasma	8	2,778	1:347	2.9 (1.4 to 5.8)
Platelets Pooled - Plasma	2	614	1:307	3.3 (0.1 to 12.6)
Platelets Apheresis PAS	10	5,354	1:535	1.9 (1.0 to 3.5)
Platelets Pooled PAS	5	5,037	1:1,007	1.0 (0.4 to 2.4)
Cryoprecipitate	2	3,745	1:1,873	0.5 (0.0 to 2.1)
Cryodepleted Plasma	2	670	1:335	3.0 (0.1 to 11.6)

NZBS commenced introduction of pooled platelets suspended in Platelet Additive Solution (PAS) in late 2010 and apheresis PAS platelets in 2011. This significant change in production method was made with the specific purpose of reducing the amount of plasma in platelets. The dual benefits of recovering more plasma for fractionation and reducing the allergic reactions of platelets were envisaged and the haemovigilance data indicates that this latter goal has been achieved. Table 10.7 compares the number of allergic events associated with platelet components between 2007 and 2012. There is a significant reduction ($p = 0.001$) in the rate of allergic events with platelets suspended in PAS compared to platelets suspended in plasma. There is no significant difference ($p = 0.46$) in the rate of allergic events with apheresis or pooled platelets suspended in PAS.

TABLE 10.7 ALLERGIC EVENTS ASSOCIATED WITH THE TRANSFUSION OF A SINGLE PLATELET COMPONENT 2007 - 2012

Platelet Component Type	Number Allergic Events	Number Units Transfused	Frequency Events	Rate / 1,000 Transfusions (95%CI)
Apheresis Plasma*	154	41,464	1:269	3.7 (3.2 to 4.3)
Pooled Plasma	89	23,597	1:265	3.8 (3.1 to 4.6)
Apheresis PAS	11	6,128	1:557	1.8 (1.0 to 3.3)
Pooled PAS	14	8,073	1:577	1.7 (1.0 to 2.9)
All Plasma Platelets	243	65,061	1:268	3.7 (3.3 to 4.2)
All PAS Platelets	25	14,201	1:568	1.8 (1.2 to 2.6)
Total	**268**	**79,262**	**1:296**	**3.4 (3.0 to 3.8)**

** includes Neonatal Platelets*

11 Transfusion Associated Circulatory Overload (TACO)

During 2012 there were 27 events categorised as TACO. 12 (44%) were non-severe, 12 (44%) were severe and 3 (12%) were life-threating. The age and sex of the recipients is shown in Table 11.1. Table 11.2 shows the clinical features of reported TACO during 2012.

TABLE 11.1 AGE AND SEX OF PATIENTS WITH REPORTED TACO REACTIONS 2012

	Number	Age (years)			
		Mean	Median	Minimum	Maximum
Female	13	69	66	42	90
Male	14	70	72	26	97
All	**27**	**69**	**69**	**26**	**97**

TABLE 11.2 CLINICAL FEATURES OF TACO 2012

	Number			% TACO Events
	Female	Male	Total	
Dyspnoea	9	13	22	81%
Increase in blood pressure	9	7	16	59%
Stridor / Wheeze	6	6	12	44%
Fall in O_2 saturation	4	5	9	33%
Restlessness / Anxiety	5	4	9	33%
Chills / Rigors	4	4	8	30%
Tachycardia	5	3	8	30%
Hypoxaemia	3	3	6	22%
Pulmonary oedema	3	2	5	19%
Chest pain	1	2	3	11%
Urticaria	2	0	2	7%

11 Transfusion Associated Circulatory Overload (TACO) continued

Table 11.3 shows the number of TACO events reported by year for the period 2007 - 2012. The number of events is higher in 2012 compared to 2007 ($p<0.05$) but no statistical trend is apparent over the period. Overall TACO constituted 6% of reports but was responsible for 24% of severe and life threatening events. These events occur predominantly in older recipients in whom careful consideration of total volume and rate of transfusion is particularly important along with judicious use of diuretics to avoid fluid overload.

TABLE 11.3 TACO EVENTS 2007 – 2012, IMPUTABILITY ≥3

Year	Reported TACO Events	Total Components Transfused	Frequency	Rate / 100,000 Components Transfused (95%CI)
2007	17	155,673	1:9,157	10.9 (6.7 to 17.6)
2008	20	158,181	1:7,909	12.6 (8.1 to 19.7)
2009	24	162,587	1:6,774	14.8 (9.8 to 22.1)
2010	13	159,568	1:12,274	8.1 (4.6 to 14.1)
2011	19	151,919	1:7,996	12.5 (7.9 to 19.7)
2012	27	149,668	1:5,543	18.0 (12.3 to 26.4)
Total	**120**	**937,596**	**1:7,813**	**12.8 (10.7 to 15.3)**

12 Transfusion Related Acute Lung Injury (TRALI)

During 2012 there were two reports of TRALI in New Zealand. The cases are summarised below:

CASE 1

A 74 year old female having elective high risk surgery, re-do Aortic Valve Replacement plus Mitral Valve Replacement became unstable after coming off cardiopulmonary bypass. The patient required vasopressor (BP60/20), inotropic and respiratory support. Copious frothy secretions were seen in the bypass circuit. Bilateral pulmonary oedema was confirmed on chest x-ray (new changes). This was thought to be a primary lung problem as the heart had been functioning satisfactorily. Patient was not overloaded clinically, had 1L fluid + bypass volume.

The patient had been transfused with one unit of apheresis platelets, one unit of pooled platelets (both platelet components suspended in platelet additive solution) and 2 units of fresh frozen plasma. The fresh frozen plasma and pooled platelets were all from un-transfused males and the apheresis platelet component from an HLA antibody negative female. The imputability score was classified as possible and the severity grade as 3 (life-threatening).

CASE 2

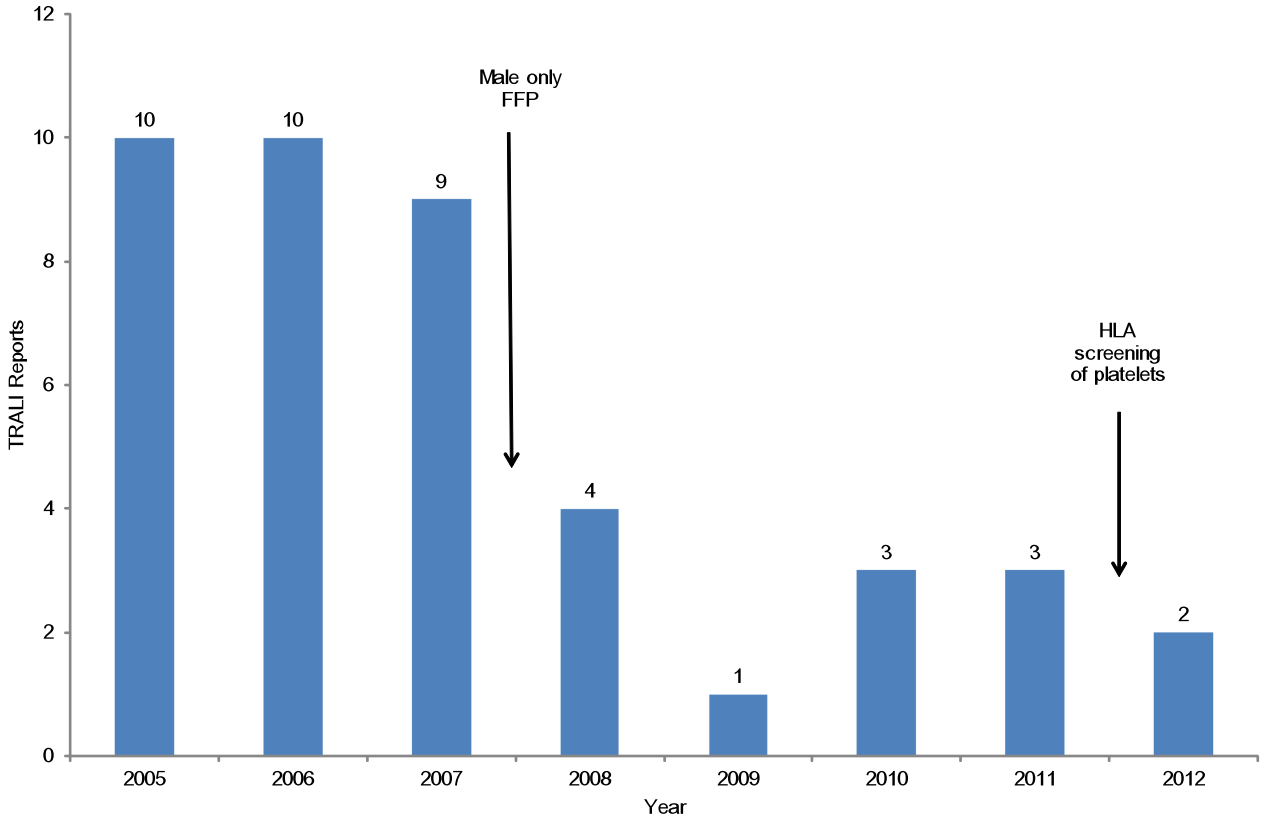
A 21 year old female newly diagnosed with AML, platelet count 29 x 109/L. Platelet transfusion was given prior to injection of intrathecal cytabarine. Three hours after the commencement of the transfusion she reported dyspnoea, cough and chest tightness accompanied by oxygen desaturation (96% to 80%). Blood pressure and heart rate remained normal. Chest x-ray showed slight opacity left side and CT scan showed ground glass alveolar to bilateral upper lobes and also lower lobe of the left lung. Repeat chest x-ray 24 hours later showed resolution of the patchy changes seen on the left side.

The patient received one unit of pooled platelets suspended in platelet additive solution. The pooled platelet unit was collected from three female blood donors and one un-transfused male donor. Request for samples for the investigation of the female donors for HLA and HNA antibodies are still pending.

12 Transfusion Related Acute Lung Injury (TRALI) continued

Figure 12.1 shows the number of cases of TRALI received each year since 2005. Overall the number of reports has reduced. NZBS has implemented a number of measures to reduce the risk. Production of clinical FFP from only male donors was implemented in 2008 and HLA antibody screening of female plateletpheresis donors in July 2012. Plans are well advanced to further reduce the risk by extending the male only policy to include cryoprecipitate and cryodepleted plasma by the end of 2013. The two reports from 2012 reinforce that occasional reports of TRALI will likely continue despite these measures.

FIGURE 12.1 TRALI REPORTS 2005 - 2012



13 Transfusion Associated Dyspnoea (TAD)

TAD is defined as 'respiratory distress occurring within 24 hours of transfusion that do not meet the criteria for TRALI, TACO or an allergic reaction and which is not explained by the patient's underlying condition'.

During 2012 there were 15 reports classified as TAD, 9 involving female recipients and 6 male recipients. The mean age was 63 years (range 33 – 89). 9 (60%) of the reports were classified as non–severe and 6 (40%) as severe. No life threatening reports were received. The clinical features are summarised in Table 13.1.

TABLE 13.1 CLINICAL FEATURES OF TAD 2012

	Number	% TAD Events
Dyspnoea	12	80.0%
Stridor / Wheeze	5	33.3%
Increase in blood pressure	4	26.7%
Hypoxaemia	4	26.7%
Chills / Rigors	3	20.0%
Flushing	3	20.0%
Tachycardia	2	13.3%
Fall in O_2 saturation	2	13.3%
Restlessness	2	13.3%
Pulmonary oedema	2	13.3%
Arrhythmia	2	13.3%
Shortness of breath	2	13.3%

TABLE 13.2 TAD EVENTS 2008 – 2012, IMPUTABILITY ≥3

Year	Reported TAD Events	Total Components Transfused	Frequency	Rate / 100,000 Components Transfused (95%CI)
2008	8	158,181	1:19,773	5.1 (2.4 to 10.2)
2009	13	162,587	1:12,507	8.0 (4.5 to 13.8)
2010	9	159,568	1:17,730	5.6 (2.8 to 10.9)
2011	6	151,919	1:25,320	3.9 (1.6 to 8.8)
2012	15	149,668	1:9,978	10.0 (5.9 to 16.7)
Total	**51**	**781,923**	**1:15,332**	**6.5 (4.9 to 8.6)**

14 Acute Haemolytic and Other Severe Acute Transfusion Reactions

An acute transfusion reaction is defined as a 'reaction occurring at any time up to 24 hours following a transfusion of blood or a blood component'. The major concern in evaluating these acute reactions is exclusion of bacterial contamination of a blood component or haemolysis due to the transfusion of incompatible red cells.

Features of a haemolytic transfusion reaction include:

- Fever, tachycardia, change in blood pressure, flank or back pain
- Inadequate rise in haemoglobin after the transfusion or a drop in haemoglobin
- Rise in LDH, bilirubin
- Haemoglobinura
- Decrease in haptoglobin

There were four reports that were classified as an acute haemolytic or other severe acute reaction in 2012. One report was of an ABO incompatible transfusion. The details of the reports are provided below:

PATIENT A. ABO INCOMPATIBLE RED CELL TRANSFUSION. IMPUTABILITY – CERTAIN, SEVERITY GRADE 2 (SEVERE)

A 78 year old woman was three days post-operative following abdomino-perineal resection for cancer of the rectum. The patient, group O RhD negative, was transfused with 300mL of group A RhD positive red cells over 2 hours. The patient's temperature remained stable however her blood pressure increased from 138/70 to 175/75mmHg) and she complained of loin pain. She also had signs and symptoms of hypoxaemia, arrhythmia, tachycardia and slight haematuria.

Three hours after the transfusion the patients bilirubin was 42µmol/L, (reference range 2–20), LDH 529IU/L, (reference range 110–220). The pretransfusion haemoglobin was 80g/L, 93g/L 3 hours after the commencement of the transfusion and fell to 81g/L 16 hours post commencement of the transfusion.

The blood bank investigated the reported reaction and reported:

– Pre-transfusion sample: group O RhD negative, red cell antibody screen negative, DAT negative
– Post-transfusion sample: group O RhD negative, red cell antibody screen negative, DAT positive
– Red cell unit transfused: group A RhD positive, DAT negative, incompatible by saline room temperature testing with pre and post transfusion patient sample.

An analysis of the event was undertaken to establish what happened, why, and identify contributing factors and formulate recommendations.

Investigation of Cause

In a bed beside Patient A in the High Dependency Unit was Patient X. Doctor Y felt it was clinically indicated that Patient A receive a blood transfusion. Dr Y prescribed 2 units of red cells to be transfused over 2 hours each and completed a "blood product transfusion record" form but labelled it with Patient X's details who also had red cells reserved for transfusion. The blood bank released the first unit of red cells that were labelled for Patient X, group A RhD positive. Two Registered Nurses (S and W) checked the unit of red cells against the "blood product transfusion record" in the drug room. Patient details on the red cell unit matched those of the transfusion request form. Nurse S took the unit of red cells to the bedside of Patient A and did not cross check that the patient details on the red cell unit matched those of the patient identification band or question Patient A for her name and date of birth. The transfusion commenced at 1200hrs.

The error was identified when Nurse S and Nurse M were checking prior to the transfusion of the second unit of red cells.

Comment: This incident demonstrates the importance of **bedside checking** of patient details attached to the red cell components with those on the patient's identification wrist band.

PATIENT B. IMPUTABILITY- LIKELY / PROBABLE, SEVERITY SCORE GRADE 1

An 87 year old female with lymphoplasmacytic lymphoma was transfused two units of leucodepleted red cells. She developed a non-urticarial rash, hypertension, nausea, vomiting, diarrhoea and chest pain 2 hours following the commencement of the transfusion.

Four hours following the transfusion the patient's bilirubin had increased from 20 to 75 µmol/L and the AST from 18 to 96U/L (reference range <40IU/L). The post transfusion sample was slightly haemolysed. Seven days post transfusion the bilirubin was 16µmol/L and AST 16IU/L

The blood bank investigated the reported reaction and reported;

- Pre-transfusion sample: group AB RhD negative, red cell antibody screen negative, DAT positive. Known cold agglutinins
- Post-transfusion sample: group AB RhD negative, red cell antibody screen negative, DAT positive,
- Red cell unit transfused; group A RhD negative, DAT negative. Red cells transfused were issued on a negative saline room temperature test. No organisms were seen in the gram stain and the culture of the units was negative.

Compatibility testing by the indirect antiglobulin test (IAT) with the pre and post-transfusion samples was positive. Samples were referred to the National Red Cell Reference Laboratory and an antibody to the Rh antigen VS (Rh20) was identified. The VS antigen has a low frequency (<1%) in the White population but is more common in the Black population

Antibodies to low incidence antigens will not be detected by current standard pre-transfusion testing protocols. A transfusion protocol has been added to patient B's e-Progesa record to require a full anti-globulin cross-match to be carried out before any future red cell transfusions.

PATIENT C. IMPUTABILITY- LIKELY / PROBABLE, SEVERITY SCORE GRADE 2 (SEVERE)

A 65 year old male with sepsis and multi-organ failure, known to have anti-Chido, was transfused with 2 units of red cells.

Eight hours following the commencement of this transfusion the patient displayed symptoms of dyspnoea, tachycardia and an erythematous rash was observed on the torso. The patient's pre-transfusion haemoglobin was 76g/L, bilirubin 13mol/L. Twelve hours after the reported reaction samples taken from the patient were noted to be haemolysed, haemoglobin 104g/L, bilirubin 55µmol/L, LDH 1692 U/L (reference range 120 – 250U/L) and the blood film showed the presence of spherocytes. Two days after the reaction the haemoglobin was 79g/L, bilirubin 15µmol/L and LDH 654U/L. Six days post transfusion the patient's haemoglobin was 87g/L, bilirubin 11µmol/L, LDH 408U/L.

Samples were referred to the local blood bank for investigation of the adverse transfusion related event. The patient was known to have anti-Chido and an antibody of undetermined specificity. The patient also had a positive Direct Antiglobulin Test (DAT). An eluate prepared showed the presence of an unidentified antibody by the anti-human globulin (AHG) technique. The laboratory was advised to issue ABO and RhD compatible red cell components on the basis of a negative indirect anti-globulin cross match.

Anti-Chido is not associated with haemolytic transfusion reactions. A retrospective analysis of the antibody identification panel suggested the possibility that the antibody of undetermined specificity could possibly be anti-Fya. The patient was determined to be Fya negative by DNA genotyping and the two units transfused were Fya positive.

PATIENT D. IMPUTABILITY – LIKELY / PROBABLE, SEVERITY SCORE GRADE 1

A 38 year old female bleeding following a miscarriage had a haemoglobin of 74g/L. Two units of leucodepleted red cells were requested for transfusion.

The patient was group B RhD positive, and the red cell antibody screen was negative. Samples taken 8 months and 2 years previously also had negative antibody screens. Two units of group B RhD positive red cell units were tested for compatibility by a room temperature immediate spin technique and gave negative results. These components were reserved for the patient. The transfusion of the first unit commenced at 1545 hours and the transfusion was completed at 1755 hours. The second unit was started at 1912 hours when the patient experienced a reaction.

The patient complained of chills, rigors, chest, loin and abdominal pain. Her blood pressure increased from 90/65 to 135/88 and dyspnoea. The symptoms gradually lessened once the transfusion was stopped. The patient was taken to the Intensive Care Unit and treated for a possible gram negative sepsis.

The blood bank investigated the reaction and reported:

- The appearance of the pre-transfusion sample was normal, post-transfusion sample jaundiced.
- Pre and post-transfusion samples group B RhD positive, red cell antibody screens negative, DATs negative.
- Red cell unit group B RhD positive, DAT negative. No organisms were seen in the gram stain and the 5 day culture of the unit was negative.
- Patients pre and post transfusion samples incompatible with donor unit by IAT.
- Bilirubin 28µmol/L 90 minutes following reaction.

Patient samples were referred to the National Red Cell Reference Laboratory which reported an antibody to a low incidence antigen. The specificity of the low incidence antibody was not identified but anti-Bga, -Wra, -Vw, -MUT, -Mur and -Cob were excluded.

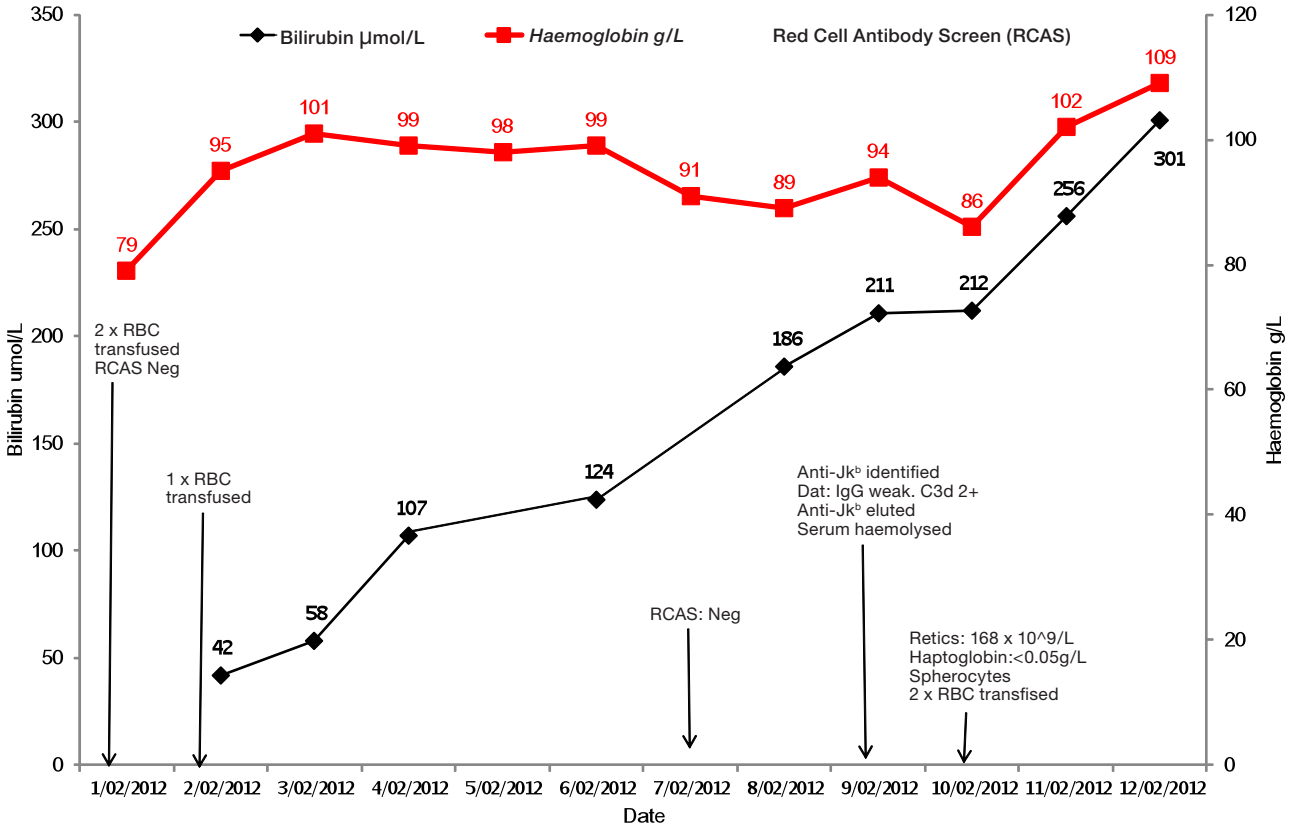
The antibody to the low frequency antigen was not detected by the current standard pre-transfusion testing protocols. A transfusion protocol has been added to this patient's e-Progesa record requiring a full indirect antiglobulin compatibility test to be carried out before any future red cell transfusions.

15 Delayed Haemolytic / Serologic Transfusion Reactions

Delayed haemolytic transfusion reactions (DHTRs) occur between 24 hours and 28 days after a red cell transfusion. These reactions are normally identified by the blood bank when repeat testing identifies a new blood group antibody and a positive DAT in the recipient. Haemolysis is usually suggested by a poor haemoglobin increment, clinical jaundice or a raised bilirubin, raised LDH and low haptoglobin. If the results for markers for increased red cell destruction are unavailable or not supportive of a haemolytic process, the reaction is classified as a delayed serological transfusion reaction (DSTR).

Figure 15.1 details a delayed haemolytic transfusion reaction reported in a 76 year old male due to anti-Jk^{b}.

FIGURE 15.1 DELAYED HAEMOLYTIC TRANSFUSION REACTION DUE TO ANTI-Jk^{b}



During 2012 there were 8 reports of DHTRs and 14 reports of DSTRs with imputability scores ≥3 reported to the Haemovigilance Programme. Table 15.1 shows the age and gender of the recipients and Table 15.2 the specificities of the blood group antibodies implicated in the DHTR and DSTR events. Antibodies to the Kidd blood group antigens accounted for 55% of the antibodies identified in the delayed reactions.

15 Delayed Haemolytic / Serologic Transfusion Reactions continued

TABLE 15.1 AGE AND SEX OF PATIENTS WITH DELAYED TRANSFUSION REACTIONS 2012

		Number	Age (years)		
			Median	Minimum	Maximum
DHTR	Female	3	56	43	67
	Male	5	63	40	83
	All	**8**	**61**	**40**	**83**
DSTR	Female	8	53	26	91
	Male	6	64	43	76
	All	**14**	**58**	**26**	**91**

TABLE 15.2 SPECIFICITIES OF RED CELL ANTIBODIES IN DELAYED REACTIONS 2012

	Antibody Specificity	Number
Delayed Haemolytic Transfusion Reaction	Jk^a	3
	K	2
	C	1
	Jk^b	1
	Low frequency antigen	1
Delayed Serologic Transfusion Reaction	Jk^a	4
	Jk^b	3
	E	2
	E + K	1
	C + E	1
	Jk^3	1
	Fy^a	1
	Fy^b	1

16 Hypotensive Transfusion Reaction

During 2012, 14 reports classified as hypotensive transfusion reactions were received. Red cells transfused were involved in 10 events, platelets in 3 and fresh frozen plasma in 1. 8 of the events involved females and 6 males. The ages ranged from 20 to 86 years (mean age 69 years). 6 of the events occurred intra-operatively. The mean decrease in systolic blood pressure was 51mmHg (maximum decrease was 75mmHg). The severity grade of 64% of the reactions was classified as severe (Table 5.2).

17 Unclassifiable Complications of Transfusion (UCT)

During 2012 there were 41 reports received of transfusion related events which could not be classified into a specific category. 15 of these were excluded from the analysis on the basis that the event could be attributable to a cause other than the transfusion. The remaining 26 reports were included in the analysis. Red cells were transfused in 20 events, platelets in 5 and fresh frozen plasma in 1. The 26 reports analysed involved 11 females and 15 male recipients. These reports are summarised in Table 17.1

TABLE 17.1 UNCLASSIFIABLE COMPLICATIONS OF TRANSFUSION (IMPUTABILITY ≥3) 2012

Reaction	Number of Reports
Flushing	9
Pain (5 x chest, 1 x abdominal)	6
Hypertension	5
Arrhythmia	2
Stridor	1
Wheeze	1
Anxiety	1
Other	1
Total	**26**

18 Adverse Events Associated With Fractionated Plasma Products

Adverse reactions involving fractionated plasma products have a separate reporting procedure from those associated with fresh blood components. During 2012, 33 adverse events associated with fractionated blood products were reported. Of the 33 reported events, 26 involved adverse reactions and the remaining 7 reports involved administration of an incorrect product or dose. The events associated with an incorrect product or dose are described in the section of this report on Incorrect Blood Components Transfused (IBCT).

All but one of the reported adverse reactions were classified as not serious. The exception was a report of cardiac overload associated with the transfusion of Albumex 20.

Table 18.1 summarises the 26 adverse reactions received during 2012. Additional information on reactions associated with administration of Intragam P is provided in Table 18.2

TABLE 18.1 REPORTED EVENTS FOR FRACTIONATED PLASMA PRODUCTS 2012

Fractionated Product	Type of Event	Number of Reports
Intragam P	Various (15) see Table 17.2	15
Albumex 20	Allergic (2), cardiac overload (1), probable chemical meningitis following rapid infusion (1)	4
RhD Immunoglobulin	Febrile (2), Allergic (1)	3
Albumex 4	Allergic (2)	2
Normal Immunoglobulin	Nausea	1
Prothrombinex-VF	Allergic	1
Total		**26**

TABLE 18.2 REACTIONS REPORTED WITH INTRAGAM P 2012

	Causality				
Type of Reaction	Unlikely	Possible	Likely/ Probable	Highly Probable	Total
Haemolytic				6	6
Allergic		1	1		2
Febrile	1	1			2
Failure to obtain complete protection against varicella infection			1		1
Malaise and headaches		1			1
Neutropenia				1	1
Pain, stiffness & headaches				1	1
Respiratory distress				1	1
Total	**1**	**3**	**2**	**9**	**15**

5 of the 6 reports of haemolytic transfusion reactions with Intragam P, the patients were group A and the remaining patient, group AB.

19 Incorrect Blood Component Transfused (IBCT)

IBCT is the transfusion of a blood component or product that was intended for another patient or one that did not meet the patient's requirement. During 2012 there were 19 IBCT events reported (Table 19.1), this compares to 13 IBCT events reported in 2011.

TABLE 19.1 IBCT EVENTS 2012

IBCT Event Type of Product	Description	Site of Error
Incorrect product or dose RBC (2) RhD Ig (2) FFP (1) Cryoprecipitate (1) Albumex 4 (2) Platelets (1) Intragam P (2)	Patient grouped as A RhD positive in 2005, transfused 4 RhD positive RBC units. Patient confirmed as A RhD negative in 2012 with anti-D+C+S.	Either wrong blood in tube event in 2005 or laboratory RhD grouping error.
	250 IU dose of RhD Ig given to an RhD negative patient at the end of the third trimester instead of 625IU; incorrect dose prescribed by House Surgeon.	Clinical
	RhD negative patient, 9 weeks gestation given 625IU RhD Ig, 250IU prescribed but wrong dose removed from storage refrigerator by a nurse.	Clinical
	Requested two units of FFP which were issued and transfused when the component prescribed was platelets.	Clinical
	2 units cryoprecipitate issued and transfused when the component requested was 2 units FFP.	Laboratory
	Bottle of Albumex 4 issued and labelled for patient A transfused to patient B. Two separate events.	Clinical
	Group O RBC units with haemolysins issued and transfused to a group B patient.	Laboratory
	Unit of matched platelets issued and transfused 1 day post expiry. Issue of the platelets occurred during National Blood Management System outage.	Laboratory
	Incorrect dose of Intragam P given to two patients with ITP. One patient of 110kg prescribed 1g Intragam P as opposed to 1g/kg, 10.5kg infant prescribed 0.2g/kg Intragam P.	Clinical
Non-irradiated components transfused RBC (1)	Blood Bank not informed patient receiving fludarabine and required irradiated blood components. Non-irradiated units transfused multiple times.	Clinical
Inappropriate transfusion RhD Ig (5) RBC (1)	RhD negative patient administered RhD Immunoglobulin though immune anti-D confirmed and reported. 3 events.	Clinical
	RhD Immunoglobulin administered to RhD positive woman.	Clinical
	RhD Immunoglobulin given to RhD negative woman following delivery of RhD negative baby.	Clinical
	Hb reported as 46g/L. One unit red cells transfused. Pre-transfusion sample determined to be diluted. Post transfusion Hb 113g/L.	Clinical
Sample validity RBC (1)	Sample drawn 27.01.2012 with 72 hour validity. Staff member misinterpreted validity date as 27.03.2012 and red cell unit issued and transfused. New sample obtained and red cell unit confirmed as compatible.	Laboratory

20 Near Miss Events

A near miss event is an error or deviation from standard procedures or policies that is discovered before the transfusion and that if not discovered would have led to an inappropriate transfusion or reaction in the recipient. Near miss events are usually reported to a local incident management system (within a DHB) so that appropriate investigations are undertaken and the necessary education and preventive actions are implemented. During 2012 there were 4 near miss events formally reported to the Haemovigilance Programme, two involving wrong blood in tube events. A further 32 near miss events were identified from the NZBS incident management system. These events are summarised in Table 20.1.

TABLE 20.1 NEAR MISS EVENTS 2012

Error	Site of Error			
	Blood Bank	Processing	Clinical	Total
Wrong Product Issued (including wrong product, dose or to wrong patient)				
RBC 9	12	1	1	14
Platelets 3				
RhD Ig 1				
Biostate 1				
Irradiation Errors	1	5		6
Labelling Errors	4	2		6
Failure to group confirm of RBC units	8			8
WBIT (identified at DHB Blood Bank)			2	2
Total	**25**	**8**	**3**	**36**

21 Events Involving RhD Immunoglobulin

RhD immunoglobulin is provided in two vial sizes, 250 IU and 600–625 IU. The 250 IU dose is recommended for use after potentially sensitising events occurring in the first trimester with the larger 600-625 IU dose recommended for all other indications (including first trimester events in multiple pregnancies). A Kleihauer test, or other test to estimate the size of a feto-maternal bleed, is also recommended for all events occurring after 20 weeks gestation to identify those women who may require a larger dose of RhD immunoglobulin.

A. IBCT EVENTS

Between May 2005 and December 2012 there has been 35 IBCT notifications reported to the Haemovigilance Office involving RhD immunoglobulin. Twenty two, (63%), of the reports involved inappropriate use of the product of which 10 involved the administration of the product to women who were RhD positive. There were 10 (28%) reports where the incorrect dose of RhD immunoglobulin was administered. The IBCT events are summarised in Table 21.1.

TABLE 21.1 IBCT EVENTS INVOLVING RhD IMMUNOGLOBULIN, MAY 2005 – DECEMBER 2012

Event Type (Percentage Events)	Description	Number of Reports
Inappropriate Use (63%)	• Baby RhD negative.	3
	• Given to wrong patient.	3
	• Mother had immune anti-D identified.	6
	• Mother RhD positive.	10
Failure to Administer RhD Immunoglobulin (6%)	• One patient subsequently formed anti-D.	2
Incorrect Dose RhD Immunoglobulin (28%)	• 250 IU removed and administered instead of 600–625 IU removed from refrigerator.	2
	• 600–625 IU requested, 250 IU issued by Blood Bank and administered.	2
	• 250 IU requested, 600–625 IU issued by Blood Bank and administered.	1
	• 250 IU charted, 600–625 IU administered.	1
	• 600–625 IU charted, 250 IU administered.	2
	• 250 IU issued instead of 600–625 IU, Blood Bank failure to follow protocols.	1
	• 600–625 IU issued instead of 250 IU. Blood Bank failure to follow protocols.	1
Incorrect RhD Typing of Baby (3%)	• RhD type of RhD negative baby incorrectly interpreted as RhD positive.	1

21 Events Involving RhD Immunoglobulin

continued

B. NEAR MISSES INVOLVING RhD IMMUNOGLOBULIN.

A total of 31 near miss events involving RhD immunoglobulin were recorded in the NZBS incident management system. In 16 events (52%) the NZBS Blood Management System (e-Progesa) identified that the woman was RhD positive when the requester thought the patient was RhD negative. Retesting was undertaken to confirm the RhD group of the patient and in all instances confirmed that the patient was RhD positive. Incidents of product labelling errors were detected by the clinical staff during the checking process before administration of the RhD immunoglobulin. The IBCT events are summarised in Table 21.2.

TABLE 21.2 NEAR MISS EVENTS INVOLVING RhD IMMUNOGLOBULIN, MAY 2005 – DECEMBER 2012

Event Type (Percentage Events)	Description	Number of Reports
Inappropriate Request (52%)	• Woman RhD positive.	16
Incorrect Dose Issued (6%)	• Incorrect IU vial size issued.	2
Incorrect Product Issued (26%)	• Blood Bank issued incorrect product e.g. Tetanus immunoglobulin instead of the RhD immunoglobulin requested.	6
	• RhD immunoglobulin expired.	2
Product Labelling Error (13%)	• RhD immunoglobulin labelled with incorrect patient name.	1
	• RhD immunoglobulin labelled by Blood Bank for correct patient but incorrect dose size.	3
Incorrect RhD Typing of Baby (3%)	• RhD group of mother entered into a hospital information system, RhD negative instead of RhD positive.	1

Between January 2007 and December 2012 approximately 53,000 vials of RhD immunoglobulin were issued by NZBS to Blood Banks within New Zealand. The number of reports of IBCT and near misses involving RhD immunoglobulin is small but there may be underreporting. The data shows however that a number of the errors are preventable.

22 Irradiated Red Cells

Four sites within NZBS are responsible for irradiation of blood components. Irradiation is used to prevent Transfusion Associated Graft versus Host Disease (TA-GvHD) in 'at risk' recipients. NZBS Manufacturing Standards, based on international standards, require red cell components to be irradiated within 14 days of collection and to be transfused within 14 days of irradiation. This reduction in shelf life aims to avoid issues associated with the increased leakage of potassium seen in stored irradiated red cell components.

In December 2012 an incident internally within NZBS was reported in which a number of red cell components had been irradiated greater than 14 days post collection. Investigation included an analysis of e-Progesa component records to identify all instances when red cells were irradiated greater than 14 days post-collection during 2012. The investigation documented that there were a total of 38 instances where the red cell components irradiated did not meet the specification of less than 14 days. The red cell components involved were Red Cells Resuspended (32) and Red Cells Resuspended Neonatal (6). No reports of adverse outcomes in patients have been identified. There were no instances of red cells used for exchange or intra-uterine transfusion being irradiated beyond the allowable time period.

The results of the investigation of red cells irradiated greater than 14 days is detailed in Table 22.1

TABLE 22.1 ANALYSIS OF RED CELL COMPONENTS IRRADIATED GREATER THAN 14 DAYS POST-COLLECTION

	Red Cells Component	
	Red Cells Resuspended	Red Cells Resuspended Neonatal
Number of units	32	6
Number units transfused	23	2
Range days post collection all units	15 to 34	15 - 31
Range days post collection units transfused	15 to 33	19 and 31 days

Procedures are in place to ensure that red cell components selected for irradiation meet the manufacturing standards. Staff have received further training in the procedures including provision of information on the changes that occur to red cell components post irradiation. Following the incident a new national daily report has been developed. This identifies any red cell components that have been irradiated beyond 14 days and leads to their removal from stock. The situation is being closely monitored and the feasibility of controlling the process more closely in e-Progesa is being investigated.

23 Bacterial Monitoring Of Platelet Concentrates

Bacterial transmission remains the major component of morbidity and mortality associated with transfusion transmitted infection. Cumulative data from SHOT, the United Kingdom Haemovigilance system, published in 2009 identified 38 reported cases involving 40 recipients over a 12 year period. 32 of the cases related to bacterial contamination of platelets with 5 deaths occurring in this group. Similar data has been reported from the French Haemovigilance system and from the USFDA.

Increasing concern relating to bacterial transmission of platelet concentrates has led a number of Blood Services to investigate methods to reduce the risk. Canada, the Netherlands and Hong Kong were the first countries to introduce a formal requirement for the use of pre-release bacterial detection systems for platelet concentrates. In recent years many other countries have followed. In particular the AABB introduced a formal requirement for screening of platelet components in 2004 and have required testing to utilise either FDA approved systems or systems shown to have equivalent sensitivity since 2011. The Australian Red Cross Blood Service (ARCBS) implemented a pre-release culture system across its sites in April 2008. This involves culture on day one post production with no quarantine of cultured platelets.

Unfortunately at this stage there is no clear international consensus on the definition of an optimal system for bacterial culture. A number of variables can significantly impact on overall system sensitivity. These include the volume of initial inoculum, the timing of culture (day one or two post-collection) and the use of a single aerobic bottle versus both aerobic and anaerobic detection. International practice is highly variable.

A number of systems are currently available to support bacterial detection in platelet concentrates. These can either be used to monitor the level of contamination, as required by the Council of Europe Guide, or to support release of platelets on a 'negative at release' basis. NZBS commenced a pilot study to assess the frequency of bacterial contamination during October 2003. The scheme has been progressively rolled out such that by the end of 2007 all sites within NZBS that manufacture platelets were participating. The proportion of components tested increased during the first few years but has remained reasonably stable over the last 2-3 years. During 2012 approximately 92% of all apheresis collections and 77% of platelet pools were tested. Apheresis collections are normally split into two components (doses) soon after production. Currently only one of the 2 components is tested. The detailed results of day 2 testing undertaken by individual sites during 2012 is shown in Table 23.1.

TABLE 23.1 PROPORTION OF PLATELET COMPONENTS BACTERIALLY CULTURED IN 2012

Site	Apheresis Platelets			Pooled Platelets		
	Collections	Components Tested	% Tested	Produced	Components Tested	% Tested
Auckland	2,313	2,139	92	3,495	2,079	60
Waikato	1,140	1,087	95	1,956	1,906	97
Wellington	909	828	91	1,050	936	89
Christchurch	1,094	951	87	591	551	93
Manawatu	447	427	96			
Otago	369	359	97			
TOTAL	**6,272**	**5,791**	**92**	**7,092**	**5,472**	**77**

23 Bacterial Monitoring Of Platelet Concentrates continued

The NZBS protocol for bacterial monitoring involves testing of platelets at day 2 of storage. A 6ml sample of the concentrate is used to inoculate the BacT alert aerobic culture bottle. The bottles are cultured until a positive signal is obtained or until the platelet concentrate has expired. The platelets are available for release immediately following sampling and will be withdrawn from inventory in the event that a positive culture signal is obtained. Results of testing undertaken during 2012 are shown in Table 23.2.

TABLE 23.2 RESULTS OF DAY 2 TESTING OF PLATELET COMPONENTS DURING 2012

	Total Components Sampled	Number Reactive	% Reactive	Frequency Of Reactives
National All reactives	11,263	15	0.13	1:750
National Confirmed reactives	11,263	1	0.01	1:11263

The data indicates that NZBS systems compare well with published data. The CoE Guide (17th Edition) identifies that reported rates of contamination can be as high as 0.4% although most reports identify rates of 0.2% or lower.

There is increasing data that demonstrates that bacterial culture of samples collected at day one of storage reduces but does not eliminate the risk of subsequent bacterial growth in platelet concentrates. Data from Ireland and the American Red Cross published during 2007 indicates that this testing might only detect 50% of contaminated platelet concentrates. This view is supported by the results of day 8 testing of expired platelet components undertaken by NZBS. This is shown in Table 23.3. The clinical significance of these late positives is unclear.

TABLE 23.3 RESULTS OF TESTING OF EXPIRED PLATELETS DURING 2012

	Total Components Sampled	Number Reactive	% Reactive	Frequency Of Reactives
National All reactives	2,627	0	0	0:2627
National Confirmed reactives	2,627	0	0	0:2627

NZBS is currently developing systems to support 100% culture of platelet components in order to bring us into line with international practice. Systems are being designed to ensure that this does not result in increased expiry and will also explore the feasibility of extending the platelet shelf life from five to seven days. These changes will require Medsafe approval.

24 Donor Infectious Disease Screening

In New Zealand all blood donations are screened for hepatitis B surface antigen (HBsAg), HBV DNA, anti-HCV, HCV RNA, anti-HIV I & II, HIV RNA and syphilis EIA. All new donors are also tested for anti-HTLV I & II. Additional testing is performed on selected donations e.g. CMV IgG for foetal and neonatal transfusions. Trypanasoma Cruzi, (Chagas), and malarial antibody tests are performed in donors who may pose a risk due to residence and/or travel to affected areas.

During 2012 176,551 donations were collected from 91,802 donors. 82% of the donors were repeat donors and 18% previously untested new donors.

Table 24.1 shows the number of donors with confirmed positive serology in 2012. There were 22 donors confirmed positive for HBV and 4 confirmed positive for HCV. No HIV confirmed positive donors were identified during the year.

TABLE 24.1 DONORS WITH CONFIRMED SEROLOGY 2012

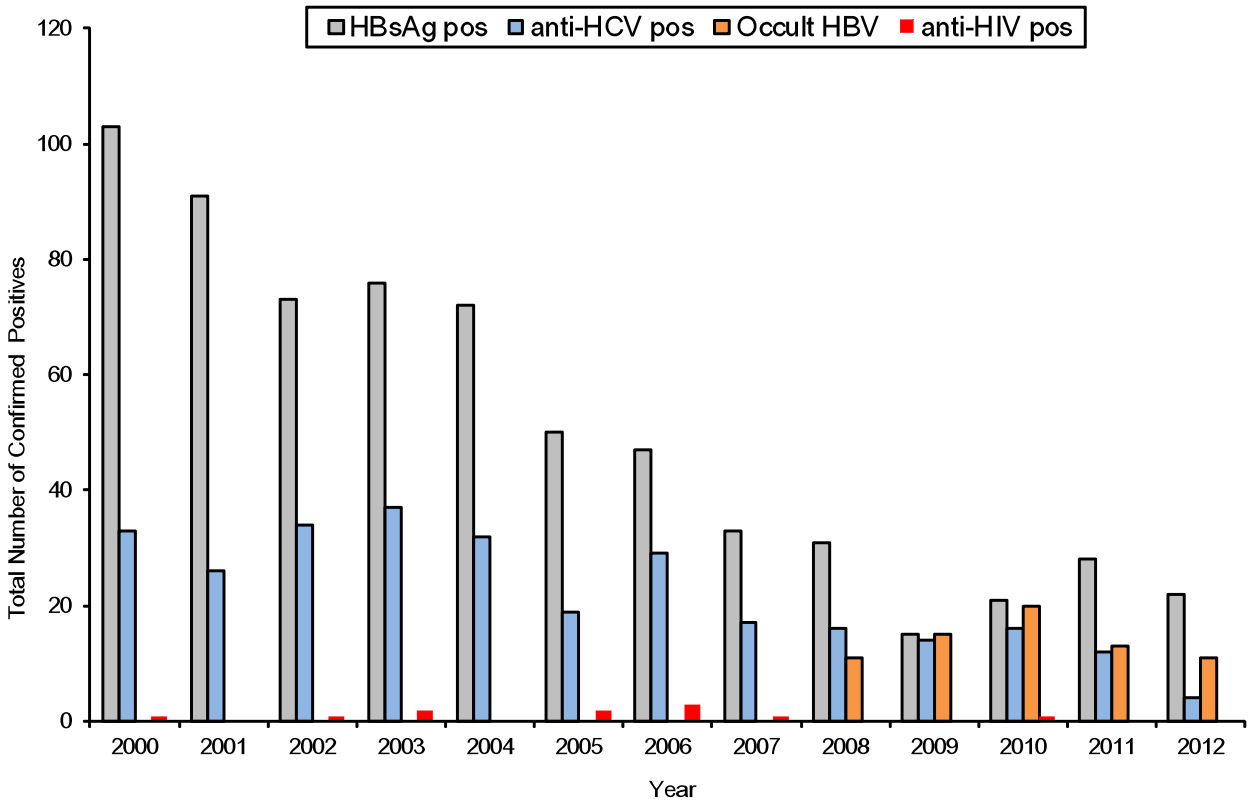
		HBV	HCV	HIV	Syphilis	HBV Occult	HTLV I/II
Number	New Donors (n = 16,202)	21	4	0	7	2	0
	Repeat Donor (n = 75,600)	1	0	0	2	9	0
	Total Donors (n = 91,802)	22	4	0	9	11	0
Rate per 100,000 Donations	New Donors	129.6	24.7	0.0	43.2	12.3	
	Repeat Donors	1.3	0	0	3.9	4.8	
	All Donations	24.0	4.4	0	9.8	12.0	
Frequency of Positive Donors	New Donors	1:772	1:4,051		137,800	1:8,400	
	Regular Donor	1:75,600			1:2,315	1:8,101	
	Overall Frequency	1:4,173	1:22,951		1:10,200	1:8,346	

24 Donor Infectious Disease Screening

continued

Figure 24.1 shows the frequency of confirmed positive results by year over the period 2000-2012. This shows a consistent reduction in detection rates for each of the main markers. Occult hepatitis B infection is defined as 'the presence of HBV DNA in donor plasma without detectable HBsAg outside the window period'. Detection of these donors only became possible following the implementation of HBV DNA testing in 2007.

FIGURE 24.1 DONOR EPIDEMIOLOGIC DATA 2000 – 2012



24 Donor Infectious Disease Screening

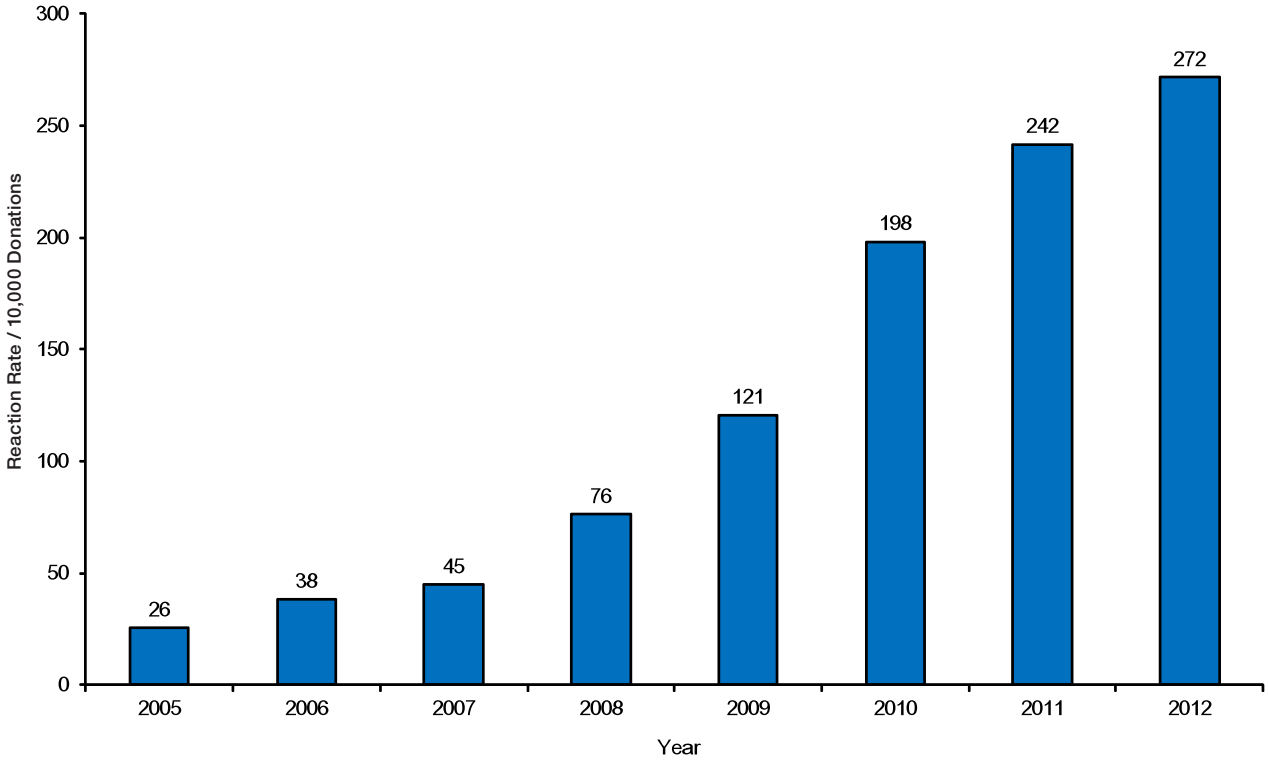
continued

Adverse events relating to blood donation can occur during or after donation. Delayed complications are defined as a complication which has occurred after the donor has left the donation site. Delayed complications are notified either by a telephone call, personal visit, e-mail or letter.

NZBS utilises definitions for these adverse events contained in the Standard for Surveillance of Complications Related to Blood Donation (2008) developed by the International Society of Blood Transfusion Working Party on Haemovigilance (Appendix III). A standardised national form is used by all collection sites to record the information for each donor adverse event (Appendix IV).

In New Zealand during 2012, 176,551 donations (139,845 whole blood, 30,179 plasmapheresis and 6,527 plateletpheresis donations) were collected. Adverse events were reported occurring in 4,795 of the donations, involving 4,418 donors. The overall frequency of reported donation related adverse events was 1:37. The yearly reported rate per 10,000 donations continues to increase (Figure 25.1). This likely reflects on-going efforts within NZBS to improve consistency of reporting across the sites.

FIGURE 25.1 DONATION ASSOCIATED ADVERSE EVENTS PER 10,000 DONATIONS 2005 - 2012



25 Adverse Events Associated With Blood Donation

Adverse events are more frequently reported with apheresis procedures than whole blood donations (Table 25.1).

TABLE 25.1 DONOR ADVERSE EVENT PER PROCEDURE 2012

Procedure	Donors	Donations with Events	Total Donations	Frequency	Rate / 10,000 Donations (95%CI)
Whole blood donation	**3,251**	**3,309**	**139,845**	**1:42**	**237 (225 to 241)**
Plasmapheresis	667	737	30,179	1:41	244 (205 to 238)
Plateletpheresis	508	758	6,527	1:9	1161 (716 to 846)
All apheresis procedures	**1,175**	**1,495**	**36,706**	**1:25**	**407 (303 to 339)**
Total procedures	**4,426**	**4,804**	**176,551**	**1:37**	**272 (244 to 258)**

Immediate vasovagal and bruising/haematoma were the most frequent complications associated with donation. The most common complication associated with whole blood donation was an immediate vasovagal reaction (57.2%). For apheresis procedures bruising/haematoma was the most frequent reported complication (61.7%). A number of donors experienced more than one complication during donation, in total there were 4,827 complications (3,379 whole blood and 1,448 apheresis). Table 25.3 shows the reported rate for whole blood and apheresis procedures. The frequency and rate per 10,000 donations for all procedures is detailed in Table 25.2.

TABLE 25.2 ADVERSE EVENTS ALL DONATION PROCEDURES 2012

	All Blood Donations (Total Collections = 176,551)			
	Adverse Events	Percentage Reactions	Frequency	Rate / 10,000 Donations
Immediate Vasovagal	2,138	51.8%	1:83	121 (116 to 126)
Haematoma	1,455	35.2%	1:121	82 (78 to 87)
Painful Arm	176	4.3%	1:1,003	10 (9 to 12)
Delayed Vasovagal	131	3.2%	1:1,348	7 (6 to 9)
Nerve Irritation	105	2.5%	1:1,681	6 (5 to 7)
Other	55	1.3%	1:3,210	3 (2 to 4)
Nerve Injury	22	0.5%	1:8,025	1 (1 to 2)
Delayed Bleeding	19	0.5%	1:9,292	1 (1 to 2)
Tendon Damage	10	0.2%	1:17,655	1 (0 to 1)
Arterial Puncture	9	0.2%	1:19,617	1 (0 to 1)
Allergy	6	0.1%	1:29,425	0 (0 to 1)
Thrombophlebitis	3	0.1%	1:58,850	0 (0 to 1)
Total	**4,129**		**1:43**	**234 (227 to 241)**

Apheresis specific complications excluded

25 Adverse Events Associated With Blood Donation continued

TABLE 25.3 DONATION ASSOCIATED EVENTS BY DONATION TYPE, CATEGORY, FREQUENCY AND RATE 2012

	Type Of Blood Donation							
	Whole Blood (Total Collections = 139,845)				Apheresis (Total Collections = 36,707)			
	Events	% React.	Freq.	Rate / 10,000 Donations (95% CI)	Events	% React.	Freq.	Rate / 10,000 Donations (95% CI)
Immediate Vasovagal	1985	57.2%	1:70	142 (136 to 148)	153	21.4%	1:240	42 (36 to 49)
Haematoma	1014	29.2%	1:138	73 (68 to 77)	441	61.7%	1:83	120 (109 to 132)
Painful Arm	121	3.5%	1:1,156	9 (7 to 10)	55	7.7%	1:667	15 (11 to 20)
Delayed Vasovagal	118	3.4%	1:1,185	8 (7 to 10)	13	1.8%	1:2,824	4 (2 to 6)
Nerve Irritation	89	2.6%	1:1,571	6 (5 to 8)	16	2.2%	1:2,294	4 (3 to 7)
Other	31	0.9%	1:4,511	2 (2 to 3)	24	3.4%	1:1,529	7 (4 to 10)
Nerve Injury	19	0.5%	1:7,360	1 (1 to 2)	3	0.4%	1:12,235	1 (0 to 3)
Delayed Bleeding	13	0.4%	1:10,757	1 (1 to 2)	6	0.8%	1:6,118	2 (1 to 4)
Tendon Damage	8	0.2%	1:17,481	1 (0 to 1)	2	0.3%	1:18,353	1 (0 to 2)
Arterial Puncture	7	0.2%	1:19,978	1 (0 to 1)	2	0.3%	1:18,353	1 (0 to 2)
Allergy	6	0.2%	1:23,308		0			
Thrombophlebitis	3	0.1%	1:46,615		0			
Total	**3414**	**0.0%**	**1:41**	**244 (236 to 252)**	**715**		**1:51**	**195 (181 to 209)**

	Apheresis Only Complications			
	Events	% React.	Freq.	Rate / 10,000 Donations (95% CI)
Citrate toxicity	621	59.9%	1:59	169 (156 to 183)
RBC not returned	415	40.1%	1:88	113 (103 to 124)
Total Apheresis Specific Events	1,036		1:35	282 (266 to 300)

25 Adverse Events Associated With Blood Donation continued

Table 25.4 details the donor complications for each donation procedure and the severity for each reaction and the rate per 10,000 donations. In 2012 there were 6 donation associated events that were classified as severe, 5 whole blood donations and 1 apheresis donation. No deaths were reported as a result of blood donation. Severe complications are defined as events resulting in any of the following:

- Hospitalization, if it was attributable to the complication.
- Intervention, to preclude permanent damage or impairment of a body function or to prevent death (life-threatening).
- Symptoms, causing significant disability or incapacity following a complication of blood donation and persisting for more than a year after donation (long term morbidity).
- Death, if it follows a complication of blood donation and the death was possibly, probably or definitely related to donation.

TABLE 25.4 DONOR ADVERSE EVENTS AND RATE BY SEVERITY SCORE PER 10,000 DONATIONS 2012

			Rate per 10,000 Donations					
			Whole Blood (n=139,845)		Plasmapheresis (n=30,179)		Plateletpheresis (n-6,527)	
			Events	Rate	Events	Rate	Events	Rate
Complications mainly characterised by blood outside blood vessels	Haematoma	Mild	951	68	333	110	87	133
		Moderate	63	25	14	5	6	9
		Severe			1	0.3		
	Arterial puncture	Mild	6	0.4	2	0.7		
		Moderate	1	0.1				
	Delayed bleeding	Mild	11	0.8	3	1.0	3	5
		Moderate	2	0.1				
Pain	Nerve irritation	Mild	86	6	10	3	5	8
		Moderate	3	0.2			1	2
	Nerve injury	Mild	14	1	2	0.7	1	2
		Moderate	5	0.4				
	Tendon damage	Mild	7	0.5	1	0.3		
		Moderate	1	0.1	1	0.3		
	Painful arm	Mild	106	8	35	12	16	25
		Moderate	15	1	3	1.0	1	2
Other complications with local symptoms	Thrombophlebitis	Moderate	3	0.2				
	Allergy (local)	Mild	5	0.4				
		Moderate	1	0.1				
Immediate vasovagal reaction	Without injury	Mild	1,577	113	95	32	25	38
		Moderate	378	27	24	8	7	11
		Severe	5	0.4				
	With injury	Mild	17	1	2	0.7		
		Moderate	8	0.6				
Delayed vasovagal reaction	Without injury	Mild	85	6	9	3	1	2
		Moderate	26	2	3	1		
	With injury	Mild	2	0.1				
		Moderate	5	0.4				
Other	Citrate reaction		31	2	20	7	4	6.1
Complications related to apheresis	Citrate reaction				67	22	554	849
	RBC not returned				295	98	120	184

25 Adverse Events Associated With Blood Donation continued

The majority of adverse events were classified as non–severe. In 2012 of the total 4,129 reported events 572 were classified as moderate and only 6 as severe. 5 of these involved whole blood donations and 1 involved an apheresis donation. No deaths were reported as a result of blood donation (Table 25.5).

TABLE 25.5 DONOR MODERATE AND SEVERE REACTIONS 2012

Procedure	Total Donations	Severity	Number Events	Frequency	Rate / 10,000 Donations (95%CI)
Whole Blood Donation	139,845	Moderate	511	1:274	37 (34 to 40)
		Severe	5	1:27,969	0.4 (0 to 1)
Apheresis Donation	36,706	Moderate	61	1:602	17 (13 to 21)
		Severe	1	1:36,706	0.3 (0 to 2)
All Donations	176,551	Moderate	572	1:309	32 (30 to 35)
		Severe	6	1:29,425	0.3 (0 to 1)

There is a significant difference (p=<0.001) between the frequency of moderate reactions reported by whole blood donors and those in apheresis donors but no significant difference in the frequency of reported severe reactions.

The frequency of donation associated adverse events is higher in younger blood donors in particular donors under the age of 20 years (odds ratio 2.29). A similar trend is observed for vasovagal reactions to that of all complications associated with whole blood donation (Tables 25.6 and 25.7)

TABLE 25.6 DONOR ADVERSE EVENTS BY AGE GROUP FOR WHOLE BLOOD DONATION 2012

Age Group	Number Adverse Events	Total Donors in Age Group	Frequency	Rate / 1,000 Donations (95%CI)	Odds Ratio (95%CI)
16 - 19 Years	860	13,799	1:16	62.3 (58.4 to 66.5)	2.74 (2.54 to 2.96)
20 - 29 Years	1,055	25,802	1:24	40.9 (38.5 to 43.4)	1.76 (1.64 to 1.89)
30 - 39 Years	420	20,318	1:48	20.7 (18.8 to 22.7)	0.87 (0.79 to 0.97)
40 - 49 Years	374	27,781	1:74	13.5 (12.2 to 14.9)	0.56 (0.51 to 0.63)
50 - 59 Years	384	31,867	1:83	12.1 (10.9 to 13.3)	0.50 (0.45 to 0.56)
≥60 Years	216	20,278	1:94	10.7 (9.3 to 12.2)	0.44 (0.39 to 0.51)
All	**3,309**	**139,845**	**1:42**	**23.7 (22.9 to 24.5)**	

25 Adverse Events Associated With Blood Donation continued

TABLE 25.7 VASOVAGAL REACTIONS BY AGE GROUP FOR WHOLE BLOOD DONATION 2012

Age Group	Number Adverse Events	Total Donors in Age Group	Frequency	Rate / 1,000 Donations (95%CI)	Odds Ratio (95%CI)
16 - 19 Years	675	13,799	1:20	48.9 (45.4 to 52.6)	3.36 (3.08 to 3.68)
20 - 29 Years	742	25,802	1:35	28.8 (26.8 to 30.9)	1.94 (1.78 to 2.11)
30 - 39 Years	254	20,318	1:80	12.5 (11.1 to 14.1)	0.83 (0.73 to 0.94)
40 - 49 Years	156	27,781	1:178	5.6 (4.8 to 6.6)	0.37 (0.31 to 0.43)
50 - 59 Years	184	31,867	1:173	5.8 (5.0 to 6.7)	0.38 (0.33 to 0.44)
≥60 Years	95	20,278	1:213	4.7 (3.8 to 5.7)	0.31 (0.25 to 0.38)
Total	**2,106**	**139,845**	**1:66**	**15.1 (14.4 to 15.7)**	

In line with international practice NZBS is introducing measures to reduce the frequency of adverse reactions in younger donors. Current guidance contained in the Council of Europe Guide to the Preparation, Use and Quality Assurance of Blood Components identifies that a standard whole blood donation can be undertaken from a donor weighing at least 50kg. In younger donors in addition to this an estimate of total blood volume is made, based on donor weight and height, and donors with an estimated blood volume of less than 3,500ml are not allowed to donate.

26 Request Form and Sample Labelling Errors

The collection of a blood sample for pre-transfusion testing from the correct patient is vital for safe transfusion. Errors made in the collection of the pre-transfusion sample can lead to the transfusion of ABO incompatible red cells which can cause significant morbidity and death.

International guidelines require that labels on pre-transfusion samples must be handwritten at the patient's bedside. A declaration must be signed by the collector at the time of collection of the sample certifying that:

- The identity of the patient was made by direct enquiry and/or inspection of their wristband.
- Immediately upon the blood being drawn the specimen was labelled.

Samples received with a pre-printed addressograph label are not acceptable for pre-transfusion testing purposes and are discarded.

Over the past seven years, the six NZBS Blood Banks (Auckland, Waikato, Palmerston North, Wellington, Christchurch and Dunedin) have been recording errors and corrective actions associated with pre-transfusion samples. Data is entered into a Microsoft Access™ database at each site and then analysed. Reports are reviewed by Hospital Transfusion Committees and by the NZBS Clinical Advisory Group.

The minimum requirements for pre-transfusion request forms and sample labelling (for NZBS Blood Banks) are outlined in Table 26.1.

TABLE 26.1 PRE-TRANSFUSION REQUEST FORM AND SAMPLE LABELLING REQUIREMENTS

Request Form Hand-written or pre-printed label	Sample Must be hand-written
Full name	Family name and one or more given names (not abbreviated)
National Health Index (NHI) number and/or date of birth	NHI number and/or date of birth
Gender	Signature or initials of collector
Patient's location	
Details of request (group and screen, blood products etc.)	
Name or signature or other identifier of person completing the form	
Signed declaration by sample collector that • The patient was positively identified prior to collection • Sample labelled before leaving the patient	
Date and time of sample collection on sample or form	

26 Request Form and Sample Labelling Errors continued

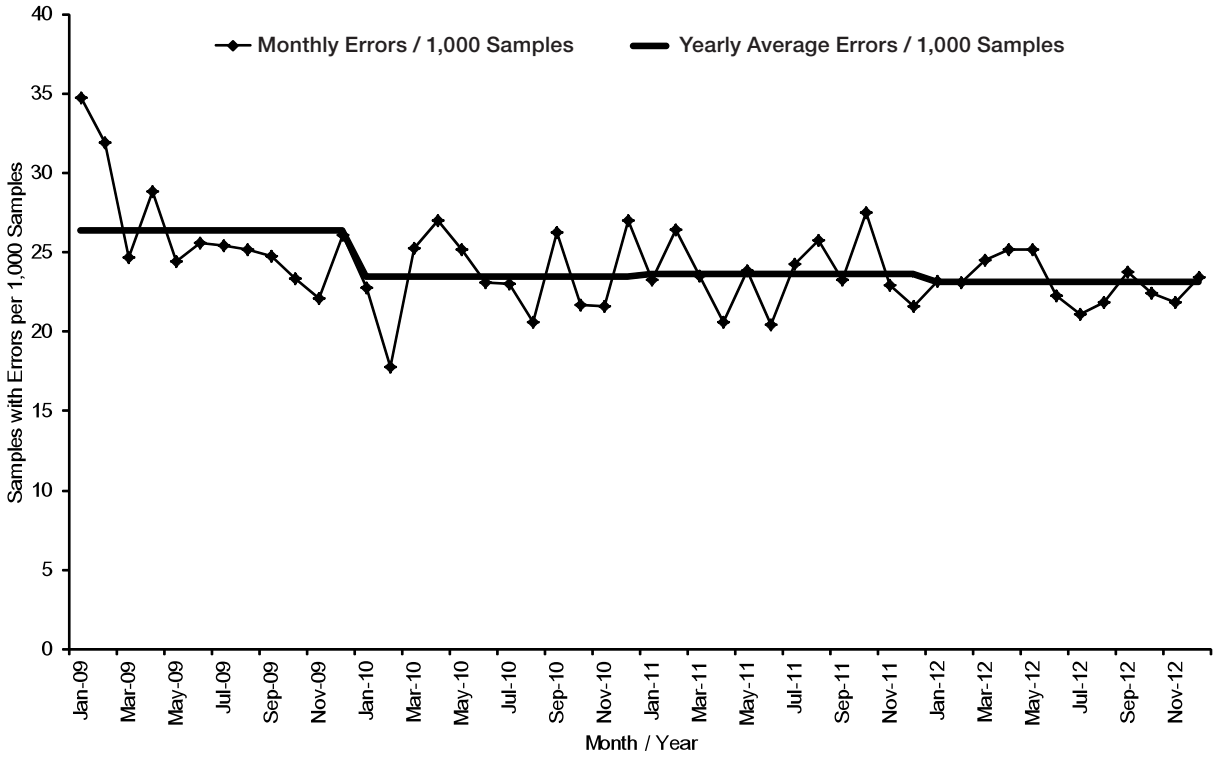
During 2012, a total of 140,974 pre-transfusion samples were received by the six NZBS Blood Banks. Errors were identified in 3,262 samples/forms. The overall error rate for the six NZBS Blood Banks for 2012 was 23.1 per 1,000 samples received which is equivalent to an error rate of 1:43 samples. This is similar to the error rate in 2011 (23.7 per 1,000 samples or 1:42). Table 26.2 details the error frequency and error rate per 1,000 samples for the six NZBS Blood Banks in 2012.

TABLE 26.2 SAMPLE ERROR RATES PER NZBS BLOOD BANK 2012

Blood Bank	Errors	Total Samples	Error Rate	Rate / 1,000 Specimens (95% CI)
Palmerston North	337	8,822	1:26	38.2 (34.4 to 42.4)
Christchurch	624	21,636	1:35	28.8 (26.7 to 31.2)
Dunedin	269	10,531	1:39	25.5 (22.7 to 28.7)
Waikato	690	28,954	1:42	23.8 (22.1 to 25.7)
Wellington	475	21,794	1:46	21.8 (19.9 to 23.8)
Auckland	867	49,237	1:57	17.6 (16.5 to 18.8)
NZBS	**3,262**	**140,974**	**1:43**	**23.1 (22.4 to 23.9)**

The error rate per 1,000 pretransfusion samples received by the NZBS Blood Banks has shown little variation between 2009 and 2012 (Figure 26.1).

FIGURE 26.1 NZBS ERROR RATE PER 1,000 SAMPLES 2009 - 2012



26 Request Form and Sample Labelling Errors continued

The types of errors and actions taken are summarised in Table 26.3. Some request forms/samples received had more than one type of error present. The total number of errors was 3,424. The most frequent type of error (20%) was "declaration not signed" followed by the tube being labelled with a pre-printed addressograph label or evidence that a pre-printed label had been removed (18%). When corrections are allowable, they must be carried out by the collector within the Blood Bank (unless the collector is directly involved in critical patient care). If the collector is not available a new pre-transfusion sample must be collected.

TABLE 26.3 TYPE OF SAMPLE AND REQUEST FORM ERRORS 2012

	Errors	% Total Errors	Frequency	Rate / 1,000 Samples	Action Required
Declaration not signed	671	19.6%	1:206	4.9	Correction by collector or Recollect
Pre-printed ID label (or evidence of removal)	622	18.2%	1:222	4.5	Recollect
Sample not signed	560	16.4%	1:247	4.1	Correction by collector or Recollect
Missing patient details (moderate error)	519	15.2%	1:266	3.8	Correction by collector or Recollect
Missing patient details (major error)	463	13.5%	1:298	3.4	Recollect
Technical*	161	4.7%	1:858	1.2	Recollect
Signature on sample and declaration differ	158	4.6%	1:874	1.1	Recollect
Other clerical errors	135	3.9%	1:1,023	1.0	Consult Team Leader
Unlabelled sample	83	2.4%	1:1,665	0.6	Recollect
Original details overwritten	52	1.5%	1:2,657	0.4	Recollect
Total	**3,424**				

** Technical errors include incorrect blood collection tube type, insufficient sample, haemolysed and leaking/broken samples.*

26 Request Form and Sample Labelling Errors continued

The overall rate of request for recollection of pre-transfusion sample by NZBS Blood Banks was 14.9 per 1,000 samples received during 2012. Table 26.4 summarises the recollection rates for each NZBS Blood Bank in 2012. Overall 64% of errors resulted in a request for recollection of the pre-transfusion sample.

TABLE 26.4 REQUESTS FOR RE-COLLECTION 2012

	Recollection Requests	Total Number of Samples	Frequency	% Errors Requiring Re-collection	Rate / 1,000 Specs (95% CI)
Palmerston North	191	8,822	1:46	57%	21.7 (18.8 to 24.9)
Christchurch	414	21,636	1:52	66%	19.1 (17.4 to 21.0)
Waikato	486	28,954	1:60	70%	16.8 (15.4 to 18.3)
Wellington	345	21,794	1:63	73%	15.8 (14.3 to 17.6)
Dunedin	118	10,531	1:89	44%	11.2 (9.4 to 13.4)
Auckland	545	49,237	1:90	63%	11.1 (10.2 to 12.0)
NZBS	**2,099**	**140,974**	**1:67**	**64%**	**14.9 (14.3 to 15.5)**

27 Wrong Blood in Tube (WBIT) Errors

A "wrong blood in tube", sometimes referred as "wrong name on tube "(WNOT), error is when the pre-transfusion sample was collected from the wrong patient or the sample was labelled with the details of another patient. These types of errors are normally identified when ABO and RhD testing show a different blood group from the historic results for the patient in e-Progesa. A current WBIT is where the sample received is proven to be incorrectly labelled; an historic WBIT is where the historic grouping result was likely based on a sampling or labelling error. Silent errors can occur when the wrong patient is bled but where the two patients have the same ABO and RhD groups. The corrected WBIT rate is calculated using the following equation:

$$\text{Corrected WBIT rate} = \frac{\text{Number of historical groups}}{\text{Number WBITs x 1.6}}$$

The correction factor 1.6 is based on New Zealand blood group frequencies and corrects reported rates to take into account silent WBIT events.

In 2012 historic ABO RhD blood groups were available in e-Progesa for 63.6% of all pre-transfusion samples submitted to NZBS Blood Banks. There were 9 WBIT errors identified. In one case the historic result was assumed to be incorrect. Table 27.1 shows the corrected WBIT rate for the 8 current WBITs reported by the NZBS Blood Banks in 2012. The overall corrected WBIT rate was 1.5 per 10,000 samples (1:6,812).

27 Wrong Blood in Tube (WBIT) Errors

TABLE 27.1 WBIT ERRORS IN NZBS BLOOD BANKS 2012

	WBIT Errors	Historic Groups	WBIT Frequency*	Rate / 10,000 (95% CI)*
Wellington	3	13,312	1:2,773	3.6 (1.2 to 8.9)
Waikato	2	17,167	1:5,365	1.9 (0.4 to 5.6)
Auckland	3	30,924	1:6,443	1.6 (0.5 to 3.8)
Christchurch	0	13,825		0
Dunedin	0	6,310		0
Palmerston North	0	5,653		0
NZBS	**8**	**87,191**	**1:6,812**	**1.5 (0.8 to 2.6)**

**Corrected to account for silent errors*

Table 27.2 shows the cumulative WBIT errors for the six NZBS Blood Banks over a six year period from 2007–2012. The overall corrected WBIT rate for the six year period was 2.8 per 10,000 samples (1:3,540). An international study (Dzik et al. Vox Sanguinis (2003) 85: 40 - 47) involving 10 countries reported an approximate median rate of WBIT of 5 per 10,000 samples (1:2,000).

TABLE 27.2 CUMULATIVE WBIT ERRORS FOR NZBS BLOOD BANKS 2007 - 2012

	WBIT Errors	Historic Groups	WBIT Frequency*	Rate / 10,000 (95% CI)*
Wellington	28	73,386	1:1,638	6.1 (4.5 to 8.2)
Palmerston North	7	34,106	1:3,045	3.3 (1.8 to 5.9)
Auckland	28	176,840	1:3,947	2.5 (1.9 to 3.4)
Dunedin	5	36,673	1:4,584	2.2 (1.0 to 4.4)
Waikato	13	101,899	1:4,899	2.0 (1.3 to 3.1)
Christchurch	10	92,466	1:5,779	1.7 (1.0 to 2.8)
NZBS	**91**	**515,370**	**1:3,540**	**2.8 (2.4 to 3.3)**

Appendix I
Transfusion Related Adverse Event Notification Form

NZBLOOD Te Ratonga Toto O Aotearoa

Transfusion Related Adverse Event Notification Form

A. Patient Details

NHI:	**Hospital:**
DOB: **Sex:** Male / Female	**Ward/clinical area:**

B. Transfusion & Clinical Details

Date of transfusion	/ /	Time reaction noticed	am / pm
Time transfusion started	am/pm	Volume transfused	mL

Event occurred during/ following transfusion with: (please circle)	Red Cells	Platelets	Fresh Frozen Plasma	Cryoprecipitate	Cryodepleted Plasma
	Other:				
	A Fractionated Product Reaction form (111F003) may be required.				

Donation number(s) of unit(s) transfused	Red Cells: Platelets: Fresh Frozen Plasma: Cryoprecipitate: Cryodepleted Plasma:
Patient's diagnosis, reason for transfusion & other medical/surgical history	
Medications & treatment	

C. Signs and Symptoms

Baseline observations pretransfusion:	Temp:	Pulse:	BP:	RR:	O_2 sat^n:
Observations at time of reaction:	Temp:	Pulse:	BP:	RR:	O_2 sat^n:

Please circle relevant symptoms & provide details:

Febrile: Chills / Rigors / Flushing Temperature rise: ˚C

Urticaria: Isolated / Extensive

Non-urticarial rash:

Respiratory: Dyspnoea / Wheeze / Stridor / Pulmonary oedema / Cough / Hypoxaemia

Circulatory: Pulmonary oedema / Arrhythmia / Hypotension / Hypertension / Tachycardia / Δ JVP

GI tract: Nausea / Vomiting / Diarrhoea

Pain: Chest / Loin / Abdominal / Infusion site / Other

Restlessness/Anxiety: **Red urine:** Yes / No / Unknown

Chest xray changes: **Patient under anaesthesia:** Yes / No

No symptoms

Other comments, signs, symptoms & laboratory results: (bilirubin, haptoglobin, BNP etc)

HV

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Appendix I
Transfusion Related Adverse Event Notification Form continued

D. Severity score

☐ **Grade 1:**	The recipient may have required treatment but lack of such would not have resulted in permanent damage or impairment of a body function.
☐ **Grade 2 (severe):**	The recipient required hospitalization or prolongation of hospitalization directly attributable to the event; and/or the adverse event resulted in persistent or significant disability or incapacity; or the adverse event necessitated medical or surgical intervention to preclude permanent damage or impairment of a body function.
☐ **Grade 3 (life-threatening):**	The recipient required major intervention following the transfusion (e.g. vasopressors, intubation, transfer to intensive care) to prevent death.
☐ **Grade 4 (death):**	The recipient died following an adverse transfusion reaction. *Grade 4 should only be used if death is possibly, probably or definitely related to transfusion. If the patient died of another cause, the severity should be graded as 1, 2 or 3.*

E. Pretransfusion haematology

If red cells transfused state pretransfusion haemoglobin: _____ Date: Time:

If platelets transfused state pretransfusion platelet count: _____ Date: Time:

If fresh frozen plasma transfused state pretransfusion INR: _____ Date: Time:

If cryoprecipitate transfused state pretransfusion fibrinogen: _____ Date: Time:

F. Nature of adverse event (definitions on back page)

- ☐ Allergic reaction
- ☐ Anaphylaxis
- ☐ Febrile non-haemolytic transfusion reaction
- ☐ Component or equipment related event
- ☐ Haemolytic transfusion reaction: acute / delayed
- ☐ Incorrect blood component/product transfused
- ☐ Near miss event
- ☐ Post-transfusion purpura (PTP)
- ☐ Transfusion associated circulatory overload (TACO)
- ☐ Transfusion associated graft vs host disease (TA-GVHD)
- ☐ Transfusion related acute lung injury (TRALI)
- ☐ Transfusion-transmitted infection (TTI)
- ☐ Other *(please specify)*

Notify a Transfusion Medicine Specialist (TMS) of all severe (Grade 2 – 4) reactions

TMS informed: Yes / No

TMS name: .....

Date: .....

Time: .....

Blood Bank or Transfusion Nurse Specialist can notify TMS if necessary

G. Imputability Score

NA	**Not assessable**	When there is insufficient data for imputability assessment	☐
1	**Excluded**	When there is conclusive evidence beyond reasonable doubt for attributing the event to alternative causes	☐
2	**Unlikely**	When the evidence is clearly in favour of attributing the event to causes other than the transfusion	☐
3	**Possible**	When the evidence is clearly indeterminate for attributing the event either to the transfusion or alternative causes	☐
4	**Likely, probable**	When the evidence is clearly in favour of attributing the event to the transfusion	☐
5	**Certain**	When there is conclusive evidence beyond reasonable doubt for attributing the event to the transfusion	☐

Reported by:

Contact Number:

Date:

Please note that patient identifiers will be removed for reporting to the National Haemovigilance Programme.

HV | | | | | | | |

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National Haemovigilance Programme 111F04208

Appendix I
Transfusion Related Adverse Event Notification Form continued

H. For Blood Bank/Transfusion Nurse Specialist Use Only

Transfusion History

☐ Yes < 3 months ☐ Yes > 3 months ☐ No ☐ Unknown

Pages 1 & 2 completed Yes / No

Transfusion reaction investigation

Red cell serology: Anomalies: Yes / No / Not tested

Microbiology: Yes / No / Not tested

Unit / Patient / Both

Result:

Other:

☐ **Check TMS has been notified if applicable (page 2)**

Notification form sent by: (if different from person completing pages 1 and 2)

Name:.....

Telephone: .....

Date:.....

Please retain a copy of pages 1 – 3 of this form for your records, send the original to the National Haemovigilance Office:

National Haemovigilance Office
New Zealand Blood Service
Private Bag 7904
Wellington 6242
Phone 04 380 2243
Fax 04 389 5608
Website www.nzblood.co.nz
Email haemovigilance@nzblood.co.nz

I. For National Haemovigilance Office Only

Form received on.....

Acknowledgement sent.....

Further information requested Yes / No

Appendix I
Transfusion Related Adverse Event Notification Form continued

Reporting categories for transfusion-related adverse events	
Allergic reaction	Mucocutaneous signs and symptoms during or within 4 hours of transfusion: morbilliform rash with pruritus, urticaria, localised angioedema, oedema of lips, tongue and uvula, periorbital pruritus, erythema and oedema, conjunctival oedema. **Anaphylactic reaction** is when, in addition to mucocutaneous symptoms, there is airway compromise or cardiovascular involvement. Laryngeal symptoms include tightness in throat, dysphagia, dysphonia, hoarseness, stridor. Pulmonary symptoms include dyspnoea, cough, wheeze/bronchospasm, hypoxaemia. Cardiovascular symptoms include hypotension, hypotonia, syncope.
Febrile non-haemolytic transfusion reaction (FNHTR)	Fever (≥38˚C and a change of ≥1˚C from pre-transfusion value) and/or chills/rigors occurring during or within 4 hours of transfusion without other cause such as haemolytic transfusion reaction, bacterial contamination or underlying condition.
Component-related event	An adverse event related to anticoagulant or use, misuse or defect of the bag or container occurring at some point from collection from the donor through to transfusion. Also includes use of an incorrect or inappropriate IV fluid with the component.
Equipment-related event	An adverse event resulting from use, misuse or malfunction of equipment involved in the transfusion e.g. filters, infusion pumps, blood warmers, pressure devices.
Haemolytic transfusion reaction	**Acute:** onset within 24 hours of transfusion. Clinical and laboratory features of haemolysis are present. May be due to red cell antibodies or non-immunological factors e.g. malfunction of a pump, blood warmer, use of hypotonic solutions etc. **Delayed:** Usually manifests between 24 hours and 28 days after a transfusion and signs of haemolysis are present. It may manifest as an inadequate rise of post-transfusion haemoglobin level or unexplained fall in haemoglobin. Blood group serology normally gives abnormal results confirming immunological origin.
Hypotensive transfusion reaction	Decrease in systolic and/or diastolic blood pressure of > 30 mmHg occurring during or within one hour of completing transfusion. All other categories of adverse reactions presenting with hypotension must have been excluded together with underlying condition that could explain hypotension.
Haemosiderosis	Ferritin level of ≥ 1000mcg/L, with or without organ dysfunction, in the setting of repeated RBC transfusions.
Hyperkalaemia	Any abnormally high potassium level (≥5mmol/L or ≥1.5 mmol/L net increase) within an hour of transfusion.
Incorrect blood component transfused (IBCT)	Patient was transfused with a blood product that did not meet the appropriate requirements or which was intended for another patient.
Near miss event	An error or deviation from standard procedures or policies that is discovered before the start of the transfusion and that could have led to a wrongful transfusion or a reaction in the recipient.
Post-transfusion Purpura (PTP)	Thrombocytopenia arising 5-12 days following transfusion of cellular blood components with findings of antibodies in the patient directed against the Human Platelet Antigen (HPA) system.
Transfusion associated circulatory overload (TACO)	Any 4 of the following: acute respiratory distress, tachycardia, increased blood pressure, acute or worsening pulmonary oedema on frontal chest radiograph, evidence of positive fluid balance. Occurring within 6 hours of completion of transfusion. An elevated BNP is supportive of TACO.
Transfusion associated dyspnoea (TAD)	Respiratory distress within 24 hours of transfusion that do not meet the criteria of TRALI, TACO, or allergic reaction. Not explained by the patient's underlying condition.
Transfusion associated graft versus host disease (TA-GVHD)	Clinical syndrome characterized by fever, rash, liver dysfunction, diarrhoea, pancytopenia and findings of characteristic histological appearances on biopsy occurring 1-6 weeks following transfusion with no other apparent cause. The diagnosis of TA-GVHD is further supported by the presence of chimerism.
Transfusion related acute lung injury (TRALI)	New acute lung injury (ALI): acute onset, hypoxaemia (PaO_2/FiO_2 < 300 mmHg, or oxygen saturation < 90% on room air, or other clinical evidence), bilateral infiltrates on frontal chest radiograph, no evidence of left atrial hypertension i.e. circulatory overload, no temporal relationship to an alternative risk factor for ALI. During or within 6 hours of completion of transfusion.
Transfusion transmitted infection (TTI)	Following investigation the recipient has evidence of infection post-transfusion, and there was no evidence of infection prior to transfusion and no evidence of an alternative source of infection.
Unclassifiable complication of transfusion (UCT)	Occurrence of an adverse effect or reaction temporally related to transfusion, which cannot be classified according to an already defined event with no risk factor other than transfusion.

Appendix II
Notification of Adverse Reactions to Fractionated Blood Products

NZBLOOD
Te Ratonga Toto O Aotearoa

NATIONAL
111F00307

NOTIFICATION OF SUSPECTED ADVERSE REACTION TO A FRACTIONATED BLOOD PRODUCT

RECIPIENT				
Family Name / First Names		National Health Index No. / Gender		NZBS Use
Address		Date of Birth dd/mmm/yyyy	Weight	Height
Relevant history: pre-existing conditions, diagnoses, pre-existing medical conditions, smoking, alcohol use, surgical procedure(s) with dates, Pregnancy with LMP, etc				Pregnant ☐Yes ☐ No ☐ Not applicable

BLOOD PRODUCTS ADMINISTERED * Asterisk implicated Blood Product

Blood Product(s)	Manufacturer	Batch Number	Expiry Date	Dose / Volume	Date administered (start / stop)	Indication(s) for Use
1.						
2.						
3.						

Previous administration of this / these product(s) if any. Indicate date of commencement and dates or frequency of administration

ALL OTHER MEDICINES IN USE (including Premedication/Anaesthetic agents, 'Over The Counter' and 'Alternative' Medicines) *Asterisk agents that may be implicated in reaction. *Add further medicines on separate page if necessary*

Medicine	Daily Dose (with units)	Batch number	Route	Date Started	Date Stopped	Indications for Use / Comments

DESCRIPTION OF ADVERSE REACTION OR EVENT

Transfusion started / Product administered: Date _____ Time _____ Route: ☐ IV ☐ IM ☐ Subcut ☐ Other
If the patient was receiving a course of treatment with daily / frequent doses, what were the intended **dates and doses(s)** of treatment: _____

Onset of Reaction: *date* _____ time _____. **End of reaction** *date* _____ *time* _____ *or* ☐ not yet settled.

For IV or Subcut Immunoglobulin: infusion rate at time of reaction _____, **dose given** on day_____.

For freeze dried products: concentration of solution infused: _____, solvent used for reconstitution _____.

Describe adverse reaction (signs, symptoms, diagnosis, course, relevant test results) *continue on separate page if necessary*

II Appendix II
Notification of Adverse Reactions to Fractionated Blood Products continued

NZBLOOD
Te Ratonga Toto O Aotearoa

NATIONAL
111F00307

NOTIFICATION OF SUSPECTED ADVERSE REACTION TO A FRACTIONATED BLOOD PRODUCT

Treatment of adverse reaction or event

Adverse Reaction Information

Seriousness

Is the event serious (treatment needed to preserve life)? ☐ Yes ☐ No

If yes, please tick at least one of the following boxes.

☐ Life-threatening ☐ Death _____ *date*

☐ Persistence of significant disability / incapacity

☐ Required intervention to prevent permanent impairment / damage

☐ Congenital anomaly / birth defect

☐ Required hospitalisation or hospitalisation was prolonged

☐ Suspected transfusion of an infectious agent

Case Outcome as at _____ dd/mmm/yyyy

☐ Recovered _____ dd/mmm/yyyy, Time _____

☐ Recovered with sequelae _____ (specify)

☐ Permanently disabled

☐ Death _____dd/mmm/yyyy, autopsy: date _____ *or* ☐ not done

☐ Not yet recovered ☐ Unknown

Did reaction abate after stopping blood product?

First batch: ☐ Yes ☐ No ☐ Not applicable

Second batch: ☐ Yes ☐ No ☐ Not applicable

Did reaction reappear after re-introduction?

First batch: ☐ Yes ☐ No ☐ Not applicable

Second batch: ☐ Yes ☐ No ☐ Not applicable

Previous therapy with suspected blood product?

1._____ ☐ Yes ☐ No ☐ Not applicable

2. ._____ ☐ Yes ☐ No ☐ Not applicable

Has suspected product been tolerated in the past?

1. ._____ ☐ Yes ☐ No ☐ Not applicable

2. ._____ ☐ Yes ☐ No ☐ Not applicable

If yes, dates: dd/mmm/yyyy

Causality assessment: ☐ Highly probable ☐ Possible ☐ Unlikely ☐ Unassessable

Other Conditions Present (tick all that apply): ☐ Renal Disease ☐ Hepatic Disease ☐ Cardiac Disease ☐ Allergy

☐ Respiratory Disease ☐ Other medical conditions (list):

Report type (tick all that apply)

☐ Product used for a MedSafe-registered indication ☐ S29 Medicine ☐ Medication error ☐ Overdose / Underdose

☐ Unexpected therapeutic benefit ☐ Lack of effect ☐ Pregnancy ☐ Lactation occurring ☐ Off-label use ☐ Misuse

☐ Occupational exposure ☐ Incorrect product transfused ☐ Idiosyncratic effect ☐ Quality defect in product

REPORTER DETAILS

This information will be used for follow up of the result by NZ Blood Service and will be retained only as long as needed for this review.

Person Reporting the event	**Details of Treating Specialist/GP/Midwife if different from notifier**
Name & Role/Occupation:	**Name:**
If the reporter is the patient, has consent been given to contact the Treater to follow up the adverse reaction? ☐ Yes ☐ No **Organisation / Address:**	**Organisation / Address:**
	Phone: **Fax:**
Phone: **Fax:**	**Email:**
Email:	**Registrar** (if relevant): **Pager contact:**

INSTRUCTIONS

1. **If the reaction or event is serious, telephone the Transfusion Medicine Specialist via a Blood Bank listed below.**
2. All adverse reactions to blood products must be notified to NZ Blood Service and should be reported on this form.
3. Please fill in all sections relevant to you, your patient and the clinician responsible for treating the patient.
4. Use pre-printed identification labels for patient information, if available. Use only standard abbreviations
5. Record all medicines in use. Continue report on a separate page, if necessary, so that full information is provided.
6. Return the completed form to the Blood Bank as soon as possible. The form will then be forwarded to the NZBS National Reporting Centre. Relevant information will be forwarded to the manufacturer of the product. A non-identifying summary report may be forwarded to Medsafe and CARM.

Blood Bank	Telephone	Fax	Blood Bank	Telephone	Fax	Blood Bank	Telephone	Fax
Auckland	09 307 2834	09 307 2823	Palmerston N'th	06 350 2854	06 350 8557	Christchurch	03 364 0314	03 364 0159
Waikato	07 839 8919	07 858 0988	Wellington	04 9186961	04 385 5982	Dunedin	03 470 9369	03 470 9513

Appendix III
Reporting Adverse Events Relating to Blood Donation

NATIONAL
107M00508

REPORTING OF ADVERSE EVENTS RELATED TO BLOOD DONATION

REASON FOR ISSUE: To clarify Scope. To reference new procedure for management of Accident Report Forms.

1. PURPOSE

To ensure that adverse events related to blood donations and therapeutic procedures are appropriately identified, recorded and reviewed so that donor health issues are managed appropriately. To provide a database of donor related adverse events to assist in improving the management of such events.

2. SCOPE

This procedure should be followed for all incidents in which a donor experiences any adverse event or suffers any harm as a direct consequence of the donation process – this includes fainting, nerve irritation.
Any harm caused to the donor by factors other than the donation process is classified as a workplace injury and managed through another process.

3. KEY RESPONSIBILITIES

- All staff to identify and document any donor adverse event.
- Nursing staff to provide initial care and follow up.
- Medical Staff to review the event, and follow up when and where appropriate.
- Delegated individuals to record the relevant information in the donor adverse event database, and provide reports for review.
- Senior operations staff members may review data to identify trends.

4. ITEMS REQUIRED

4.1. Related documents

107F005	Donor Adverse Event Report
107M016	Management of Complications of Phlebotomy for Standard Whole Blood and Apheresis Collections from Voluntary Donors
170P005	H&S Manual Section E: Incident/Injury Reporting and Management
170F007	Accident and Investigation Report Form

5. DEFINITIONS

5.1. Definitions and description of categories of adverse event.

A. Complications mainly with local symptoms.

These complications are directly caused by the insertion of the needle. Some of these are mainly characterised by visible swelling from bleeding into tissues, whereas others are mainly characterised by pain.

A1. Complications mainly characterized by the occurrence of blood outside vessels.

Haematoma
A haematoma is an accumulation of blood in the tissues outside the vessels. Bruises can be very extensive but without any measurable swelling, whereas when the name haematoma is used there would generally be swelling. However, as there is no physiological difference between bruises and haematomas except for the thickness, extensive skin discolouration can still be registered as a haematoma.
Haematoma is the second most common acute complication associated with blood donation. Symptoms are bruising, discolouration, swelling and local pain.

Bleeding may arise from:

- Incomplete insertion of the bevel of the needle into a vein or movement that dislodges the needle partly or completely from the vein: a haematoma typically forms over the vein and is usually visible and obvious except with deeply located veins;
- The needle penetrates the back of the vein: the haematoma forms under the vein and may not be visibly obvious.

In both instances blood may accumulate locally producing swelling or may track through tissues, depending on the location. Pain typically increases progressively over a few minutes as inflammation starts and generates pain-producing kinins, prostaglandins and other mediators of inflammation.

Pressure will develop locally, depending on size of the swelling and softness of the surrounding tissue. Pressure on nerves will result in neurological symptoms like pain radiating down in forearm and hand, and of peripheral tingling. If blood accumulates in the frontal deep layers of the forearm between muscles and tendons swelling is hard to recognize, but the pressure increases very easily. Therefore, complications like injury of a nerve and even a compartment syndrome occurs more often related to a haematoma with this localisation.

Note: *If haematoma is large and/or exhibits other neurological/vascular signs, e.g. numbness of fingers in venesected arm or weak pulse, this warrants urgent medical attention.*

Arterial puncture
Arterial puncture is a puncture of the brachial artery or of one of its branches by the needle used for bleeding of donor.
Symptoms: variable pain which is usually localized to the elbow region. Objectively a lighter red colour than usual of the collected blood can be seen and perhaps some movements of the needle caused by arterial pulsation; the bag fills very quickly. In uncomplicated cases there may be no haematoma.
Complications: The risk of a large haematoma is increased and thereby risks such as Compartment Syndrome in the forearm, brachial artery pseudo aneurysm and arterio-venous fistula.

Delayed bleeding
Delayed bleeding is spontaneous recommencement of bleeding from the venepuncture site, which occurs **after donor has left the donation site.**

A2. Complications mainly characterised by pain.

Nerve irritation
Irritation of a nerve by pressure from a haematoma:
Symptoms are nerve type as radiating pain and/or paraesthesiae in association with a haematoma. The haematoma may not always be apparent at the time.
Symptoms do not occur immediately on insertion of the needle but start when the haematoma has reached a sufficient size, some time after insertion of the needle.

Note:
The category “Irritation of a nerve by pressure from a haematoma” has been included to draw special attention to a specific complication where a haematoma causes neurological symptoms such as paraesthesiae. When the haematoma increases in size, especially if blood has collected in the restricted soft tissue space behind the vein and beneath tendons (where it is difficult to detect) it may put pressure on the nerve causing paraesthesiae in the lower arm and hand.
Later, after the haematoma has been absorbed, some scar tissue can be left around the nerve and give rise to pain and paraesthesiae which can last for weeks or months .In order to avoid this complication, it is important to discontinue the donation immediately the donor complains of paraesthesiae to minimize the volume of haematoma.

Nerve injury
Injury of a nerve by the needle at insertion or withdrawal.
Symptoms are pain often associated with paraesthesiae. The pain is severe and radiating. It arises immediately when the needle is inserted or withdrawn.

Injury of a tendon by the needle.
Symptoms are very severe local non-radiating pain initiating immediately when the needle is inserted.

Painful arm
Cases characterised mainly by severe local and radiating pain in the arm used for the donation and arising during or within hours following donation, but without further details to permit classification in one of the already more specific categories mentioned above.

A3. Other kinds of categories with local symptoms.

Thrombophlebitis
Inflammation in a vein associated with a thrombus.
Symptoms are warmth, tenderness, local pain, redness and swelling.
Thrombophlebitis in a superficial vein gives rise to a subcutaneous red, hard and tender cord.
Thrombophlebitis in a deep vein gives more severe symptoms and may be associated with fever.

Allergy (local)
Allergic type skin reaction at the venepuncture site caused by allergens in solutions used for disinfection of the arm or from the needle or dressing.
Symptoms are rash, swelling and itching at venepuncture site.

B. Complications mainly with generalised symptoms.

Vasovagal reaction
A vasovagal reaction is a general feeling of discomfort and weakness with anxiety, dizziness and nausea, which may progress to loss of consciousness (faint). Most give only minor symptoms, but a few have a more severe course with symptoms like loss of consciousness and convulsions or incontinence, or may show persisting postural hypotension for several hours.
Symptoms are discomfort, weakness, anxiety, dizziness, nausea, sweating, vomiting, pallor, hyperventilation, convulsions, and loss of consciousness.
The reaction is generated by the autonomic nervous system and further stimulated by psychological factors, and the volume of blood removed relative to the donor's total blood volume.
It is the most common acute complication related to blood donation.
Some of the most severe complications seen in relation to blood donation are accidents in donors who lose consciousness after leaving the donation site. In order to register these properly the vasovagal reactions have been grouped in:

- Immediate Vasovagal reaction
  Symptoms occur before donor has left the donation site

- Immediate Vasovagal Reaction with injury
  Injury caused by falls or accidents in donors with a vasovagal reaction and unconsciousness before donor has left the donation site

- Delayed Vasovagal Reaction
  Symptoms occur after donor has left the donation site.
- Delayed Vasovagal Reaction with injury
  Injury caused by falls or accidents in donors with a vasovagal reaction after donor has left the donation site.

C. Complications related to apheresis.
- **Citrate reaction**. Donors who show ANY reaction (no matter how mild) to citrate toxicity should be reported using the Donor Adverse Event form, irrespective of whether they have been given prophylactic calcium prior to the procedure.
- **Haemolysis.**
- **Generalised allergic reaction.**
- **Air embolism.**

D. Other complications related to blood donation.

Any other complication not described in the above categories will need to be documented in this section.

5.2. Description of Grades of Severity.

Severity is graded in two main levels severe and non-severe, based on requirements for treatment and on outcome, in a way which corresponds to other systems in use internationally (i.e. ISBT for grading of adverse reactions to blood transfusion, European Commission for grading of transfusion reactions, FDA for grading of drug adverse events). The non-severe grade is further divided into mild and moderate, hence there are three grades of severity for complications in categories A and B.

Severe complications
Conditions which define a case as severe are:

- Hospitalisation: If it was attributable to the complication.
- Intervention: To preclude permanent damage or impairment of a body function or to prevent death (life threatening)
- Symptoms: Causing significant disability or incapacity following a complication of blood donation and persisted for more than a year after the donation (Long term morbidity)
- Death: If it follows a complication of blood donation and the death was possibly, probably or definitely related to the donation.

Non-severe complications
The non-severe complications are complications which do not satisfy any of the requirements for being severe. The non-severe level may be subdivided into mild and moderate complications as for instance for the following categories.

Haematoma:
- Mild: Local discomfort during phlebotomy only minor pain or functional impairment, visible bruising
- Moderate: As for mild but with discomfort during normal activities

Arterial puncture:
- Mild: No symptoms or local discomfort during phlebotomy and/or haematoma
- Moderate: Local discomfort continuing after the collection was terminated

Delayed bleeding:
- Mild: Any bleeding occurring after the donor leaves the collection site where cleaning of the donor skin or clothes is required and no other symptoms
- Moderate: As for mild but with other symptoms (less than severe).

Painful arm/nerve irritation or injury/tendon injury:
- Mild: Symptoms for less than two weeks
- Moderate: Symptoms for more than two weeks but less than 1 year

Thrombophlebitis:
- Mild: Local symptoms within approximately 5 cm of the venepuncture site.
- Moderate: Symptoms extending into upper arm and systemic symptoms such as fever.

Allergy:
- Mild: localised rash
- Moderate: Rash with blistering and, or weeping lesions

Vasovagal reaction:
- Mild: Subjective symptoms perceived by donor only. Examples: discomfort, weakness, anxiety, dizziness, nausea,
- Moderate: Objective symptoms as noted by others. Examples: sweating, loss of consciousness, convulsions, incontinence, vomiting, pallor, hyperventilation.

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REPORTING OF ADVERSE EVENTS RELATED TO BLOOD DONATION

5.3. Other Definitions

Donation site is the area within which staff can observe donor and be responsible for care of donors with complications. This includes the reception area, registration, collection, refreshment area and also the designated toilet area for donors.

Complications related to blood donation are adverse reactions and adverse events with a temporal relation to a blood donation.

An immediate complication is a complication which occurs before donor has left the donation site.

A delayed complication is a complication which occurs after donor has left the donation site. The relation of a delayed complication to the actual blood donation should be critically assessed

6. PROCEDURE

6.1. Identify the complication. This may be at a session or reported later.

6.2. Provide appropriate nursing care to donor immediately.

6.3. If the donor suffers harm as a direct consequence of the donation process, this is managed as a clinical event. As such record appropriate details of the adverse event/complication on the Donor Adverse Event Report form, 107F005.

Note: If the donor suffers harm due to factors other than the recognized complications of blood donation this is to be managed as a workplace injury - refer to 170P005 and complete an Accident and Investigation Report Form 170F007.

6.3.1 In the first instance, appropriate action and follow up of donor should be done by the staff involved or the team leader. **ALL parts of the document need to be completed.**
Note:

- For “Type of Donation” indicate what type of donation was carried out (whole blood, plasma, platelets, autologous whole blood, stem cell collection etc). Also circle one of YES/NO to indicate if the donor is a new donor or not.
- For complications in A and B, tick **only one** of the three grades of severity as is seen appropriate.
- In D: provide details about any other complication that may have happened but is not available in the form as a tick box option.
- Provide details of all care and advice given to donor in the section “Adverse Event Description and Action Taken”.
- Indicate whether a follow up was carried out or not. If a follow up was done, provide details in the space provided. All follow ups should be completed within 10 working days.
- ALWAYS enter any comments or codes in donor’s eProgesa record and indicate this in the space provided in page two. If no comments or codes have been entered write down ‘NIL’.
- Ensure donor receives a copy of the appropriate information sheet (Haematoma or Bruising and Faints).
- Fill in the appropriate outcome for the donor using the four tick box options.
- **Complete form by filling in name and signing the document.**

6.4. If the adverse event is reported at a session, pass the completed form to the Session Team Leader or to the Medical Officer.

6.4.1 If the adverse event is reported after the session, or no MO is present at the session, send the form to the appropriate Medical Officer/TMS.

Appendix III
Reporting Adverse Events Relating to Blood Donation continued

6.5. The Medical Officer reviews the adverse event and action taken. If required, further action and follow up is carried out by the Medical Officer. The form is then sent to the local delegated individual.

6.6. The delegated person logs the form, assigns a number, updates the Donor Adverse Event database and files the form.

6.7. Senior operations staff may review the data for any trends.

7. TRAINING REQUIREMENTS

☒	Complete Document Sign-Off Sheet (108F060). • Read specified sections: Sections: *(2, 4.1, 6.3)*
☐	Complete Document Sign-Off Sheet (108F060). • Read and understand whole document
☐	Complete Document Sign-Off Sheet (108F060). • Formal training required
☐	Complete Training Module *(enter name of module)*
☐	No training required. Specify reason:

IV Appendix IV
Donor Adverse Event Report Form

NZBLOOD
Te Ratonga Toto O Aotearoa

NATIONAL
107F00509

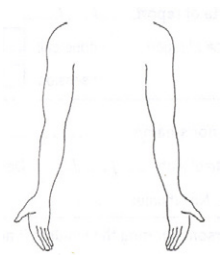
DONOR ADVERSE EVENT REPORT

REASON FOR ISSUE: Removal of accident form reference, addition of new donation type.

OFFICE USE ONLY: Database Record No:	

EVENT				
Date of Report:		**Type of Report:**	**Venue**	**Type of Donation**
Time of Report:		☐ At Session ☐ Phone call	☐ Static Site ☐ Mobile	☐ WB ☐ Plasma
Date of Event:		☐ Personal Visit ☐ Email ☐ Letter	Location:	☐ Platelets ☐ PBSCH/ Granulocyte New donor **YES/NO**

DONOR DETAILS					
Donor's Name:				**Other person reporting the event** (i.e. not donor or NZBS staff):	
Donor Number:					
Date of Birth:		**Gender:**	**M / F**	**Name:**	
Telephone No:	**(Home)**			**Relationship to Donor:**	
	(Work)				

ADVERSE EVENT DETAILS					
Complication		**Grade**			
		Mild	**Moderate**	**Severe**	
A. COMPLICATIONS MAINLY WITH LOCAL SYMPTOMS					
A1. Complications mainly characterised by the occurrence of blood outside blood vessels	Haematoma	☐	☐	☐	 Right Left
	Arterial Puncture	☐	☐	☐	
	Delayed Bleeding	☐	☐	☐	
A2. Complications mainly characterised by pain	Nerve Irritation	☐	☐	☐	
	Nerve Injury	☐	☐	☐	
	Tendon Injury	☐	☐	☐	
	Painful Arm	☐	☐	☐	
A3. Other complications with local symptoms	Thrombophlebitis	☐	☐	☐	
	Allergy (Local)	☐	☐	☐	
B. COMPLICATIONS MAINLY WITH GENERALISED SYMPTOMS					
Immediate Vasovagal Reaction	Without Injury	☐	☐	☐	
	With Injury	☐	☐	☐	
Delayed Vasovagal Reaction	Without Injury	☐	☐	☐	
	With Injury	☐	☐	☐	

C. COMPLICATIONS RELATED TO APHERESIS		
Citrate Reaction		
Haemolysis		
Generalised allergic reaction		
RED CELLS RETURNED:	**YES / NO**	

D. OTHER DONATION COMPLICATIONS(Not related to A, B or C)
Give details …

IV Appendix IV
Donor Adverse Event Report Form continued

NZBLOOD
Te Ratonga Toto O Aotearoa

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DONOR ADVERSE EVENT REPORT

DESCRIPTION of ADVERSE EVENT and /or HARM and ACTION TAKEN
Give details:
Information Sheet e.g. Faints, Haematoma/Bruising given to donor (circle one) **YES / NO / NA**

		Time	**BP**	**Pulse**
Observations:	**First:**			
	Final:			

Names of Staff/Witnesses Involved:			
Deferral Code/Comments:		**Entered:**	**YES/NO**
Outcome for Donor:	☐ No Action	☐ Return from apheresis to whole blood donation	
	☐ Deferred until / /	☐ Permanent Deferral	
Follow up required	**YES/NO** (If yes complete follow up then forward form to MO)		
Name of Staff (filling in form):	**Name:**	**Sign:**	**Date:**

FOLLOW UP DETAILS			
Name of Staff (conducting F/U):	**Name:**	**Sign:**	**Date:**

OFFICE USE ONLY			
Review – TMS/MO	*Name:*	*Signature:*	*Date:*
Database Entry carried out by:	*Name:*	*Signature:*	*Date:*

New Zealand Government