NZBLOOD
Te Ratonga Toto O Aotearoa

National Haemovigilance Programme

Annual Report 2011

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DISCLAIMER

Haemovigilance has been declared a protected quality assurance activity under Section 54 of the Health Practitioners Competency Assurance Act 2003 as notified by the Health Practitioners Notice 2006, published in the New Zealand Gazette on 6 April 2006. The effect of this declaration is that subject to certain circumstances:

- 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

COVER PHOTOGRAPHS

A male neonate receiving a top-up red cell transfusion in Wellington Hospital, taken by Alastair Neill.

Contents

1 Foreword

This is the Annual Haemovigilance Report for New Zealand. The scheme continues to be successful due largely to the on-going support of health care professionals in hospitals across the country. Particular thanks go to Dr Dorothy Dinesh and John Dagger in Wellington who manage the scheme and who are largely responsible for production of the annual report. Dorothy will be leaving NZBS in December 2012 to continue her career in internal medicine. She has played a pivotal role in developing the scheme and will be greatly missed.

The information generated in the report is valuable to NZBS as it sets its priorities for assuring a safe blood supply. During 2012 NZBS has introduced further measures to reduce the risk associated with Transfusion Related Acute Lung Injury (TRALI). These involve the introduction of HLA antibody screening for female plateletpheresis donors and completion of the introduction of platelets suspended in platelet additive solution. The three TRALI reports contained in this report demonstrate the importance of on-going vigilance in this area.

Internationally concerns continue in relation to bacterial contamination of platelet components with many countries reinforcing measures to reduce the risk associated with this. During the last 2 years we have seen a number of probable or definite reports of sepsis following transfusion of platelet components. Currently just over 80% of platelet components are cultured prior to release. This proportion has not changed in recent years. NZBS is now actively investigating ways to move to 100% pre-release testing. The challenge will be to achieve this without increasing expiry rates for the short shelf life component.

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

2 Introduction

The New Zealand National Haemovigilance Programme was established in 2005. The purpose of the scheme is:

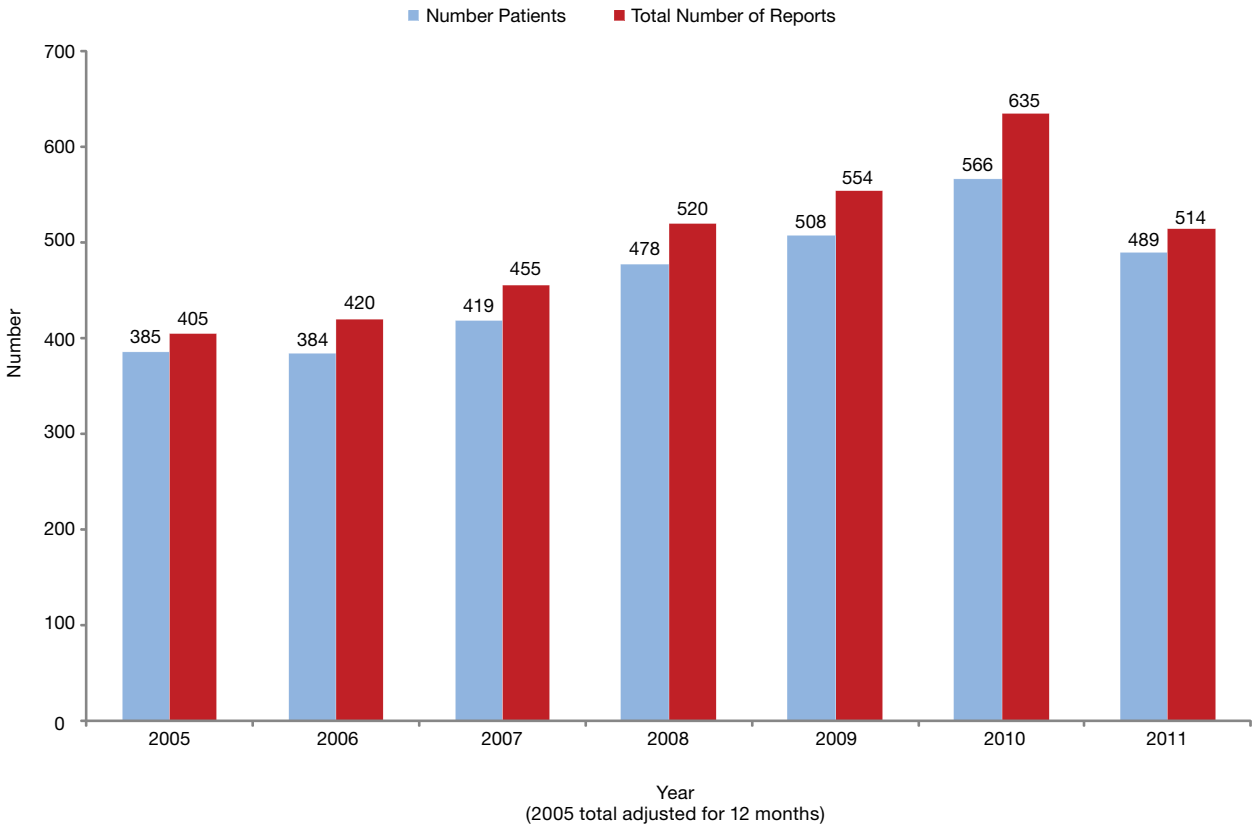
1. to collate and analyse reports of unexpected events or reactions in blood donors and blood product recipients,
2. to assess the rate of infections in blood donors and
3. to analyse incidents and errors that may impact on the safety of blood products.

The Haemovigilance Office receives reports of transfusion related adverse events from Blood Bank Scientists, Transfusion Nurse Specialists and Clinicians from all regions within New Zealand. The reporting form (Appendix 1) includes a severity score, an imputability score and definitions of reporting categories, which are those agreed upon by the International Haemovigilance Network. All reports are reviewed by a team of Transfusion Medicine Specialists and a Senior Scientist. The data is entered into a secure database and does not include any patient or clinician names.

Haemovigilance is a useful tool for quality improvement and continues to play a vital role in improving the safety of blood transfusion. Haemovigilance data allows us to quantify the risks associated with transfusion, measure the impact of changes in the transfusion chain and may alert us to emerging hazards of transfusion. In New Zealand reporting of events is voluntary and reports of any severity are reportable, to minimise under-reporting of transfusion-related events.

During 2011 there were 514 reports received, these involved 489 recipients. There were fewer reports than the previous year (Figure 1). Prior to 2011 there was a steady increase in reports received.

FIGURE 1. REPORTS RECEIVED BY HAEMOVIGILANCE PROGRAMME 2005 – 2011



3 Cumulative Haemovigilance Data (2008 - 2011)

Imputability scores were incorporated into the haemovigilance reporting form (Appendix 1) in 2008. There have been 1932 events with an imputability score of 3 or higher (i.e. possible, probable or certain) since 2008. Exclusion of events with low imputability (a score of 2 or lower) from the analysis improves the quality of the data.

Table 1 shows reported events by type for the 4 year period from 2008 to 2011. Febrile non-haemolytic transfusion reactions are the largest category (40.3%) followed by allergic transfusion reactions (34.4%).

TABLE 1. CUMULATIVE HAEMOVIGILANCE DATA 2008 – 2011 (IMPUTABILITY ≥ 3)

Event	Number of Reports	Percentage
FNHTR	779	40.3%
Allergic	665	34.4%
UCT	128	6.6%
IBCT	110	5.7%
TACO	76	3.9%
DSTR	47	2.4%
Hypotension	44	2.3%
TAD	35	1.8%
DHTR	13	0.7%
TRALI	10	0.5%
Acute	8	0.4%
TTI	8	0.4%
Near miss	7	0.4%
Component related	2	0.1%
Total	**1,932**	

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

4 Trends in Blood Component Transfusion in New Zealand

Blood donations are collected from voluntary non-remunerated donors around New Zealand. Whole blood donations are separated into red cells, platelets (buffy coats) and plasma. Apheresis donations involve cell separator machines at the donor bedside; the red cells are returned to the donor, resulting in a collection of plasma or platelet concentrate. Apheresis enables larger volumes to be collected and more frequent donations, in comparison to whole blood donation.

Platelet concentrates are produced either by apheresis or by pooling of 4 buffy coats of identical ABO group. During 2011 platelets suspended in platelet additive solution (PAS) were introduced in New Zealand. This involves replacing of two thirds of the plasma in each platelet concentrate, with PAS. Progressively all blood processing sites will produce platelets suspended in additive solution but this has not been approved for neonatal platelet transfusion in New Zealand.

All blood components have been leucodepleted in New Zealand since 2001. Fresh Frozen Plasma (FFP) is produced from male donors with no prior history of blood transfusion. This has resulted in reduced reports of TRALI (transfusion-related acute lung injury) since being implemented in 2008.

Table 2 shows the total number of blood components transfused per year in New Zealand since 2007. Overall there has been a reduction in total blood component transfusion since 2009, predominantly due to a reduction in red cells and FFP transfused. There was a 5.5% reduction in red cell transfusion from 2010 to 2011.

TABLE 2. TOTAL ANNUAL TRANSFUSED BLOOD COMPONENTS 2007 – 2011

Blood Component	2007	2008	2009	2010	2011	2007 - 2011 Percentage Change
Red cells	118,751	121,231	124,004	124,661	117,848	-0.8%
– Platelets - apheresis	6,762	7,942	7,571	8,165	7,146	5.7%
– Platelets - pooled	4,749	5,157	5,326	5,451	2,349	-50.5%
– Platelets - apheresis PAS					774	
– Platelets - pooled PAS					2,988	
Total Platelets	**11,511**	**13,099**	**12,897**	**13,616**	**13,257**	**15.2%**
Fresh frozen plasma	19,956	18,962	20,006	17,873	16,894	-15.3%
Cryoprecipitate	1,991	2,372	2,869	2,951	3,228	62.1%
Cryodepleted plasma	927	524	517	486	751	-19.0%
Total Components	**153,136**	**156,188**	**160,293**	**159,587**	**151,978**	**-0.8%**

5 Recipients of Blood Components

Table 3 shows the gender and age range of blood component recipients for 2011.

TABLE 3. BLOOD COMPONENT RECIPIENTS 2011

		Red Cells	Platelets	FFP
Gender of Recipients	Female	15,440	1,414	1,614
	Male	11,623	2,208	2,234
	Unknown	38	1	2
	Total	**27,101**	**3,623**	**3,850**
Age of Recipients (years)	Mean	63	53	61
	Median	69	61	66
	Maximum	104	98	101
	Minimum	<1	<1	<1
Units Transfused per Recipient Total during 2011	Mean	4	4	4
	Median	2	2	2
	Maximum	105	112	304
	Minimum	1	1	1

6 Summary of Reported Events for 2011

During 2011 there were 514 events reported to the National Haemovigilance Programme. 14% of reports had a low imputability score (≤2) and were excluded from the analysis. Imputability score definitions and the number of reports excluded per year are shown in Table 4.

TABLE 4. IMPUTABILITY SCORE DEFINITIONS AND PERCENTAGE OF REPORTS WITH LOW IMPUTABILITY

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

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

6 Summary of Reported Events for 2011 continued

As noted previously, febrile non-haemolytic transfusion reactions and allergic transfusion reactions are the most frequently reported events. Figures 2 and 3 show the 2011 reported events by category.

FIGURE 2. REPORTED EVENTS BY CATEGORY 2011 (n = 442)

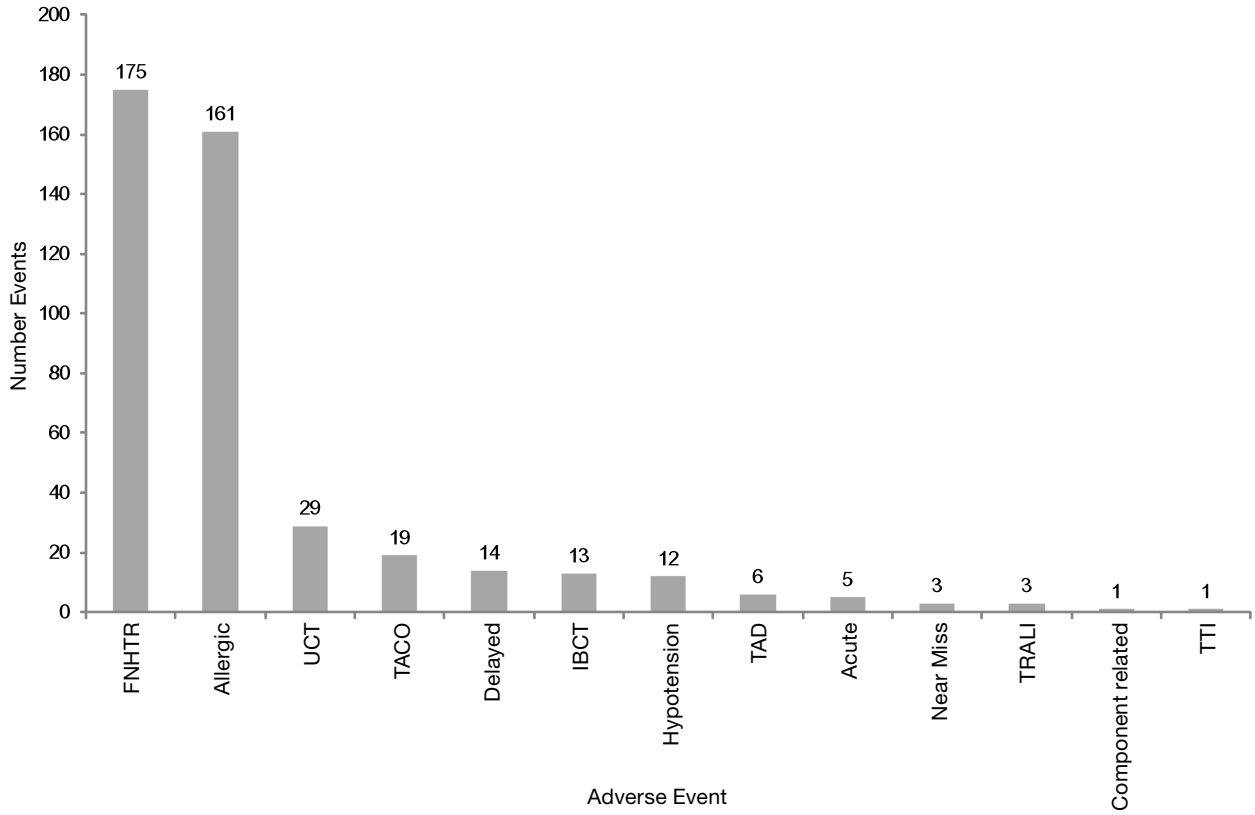
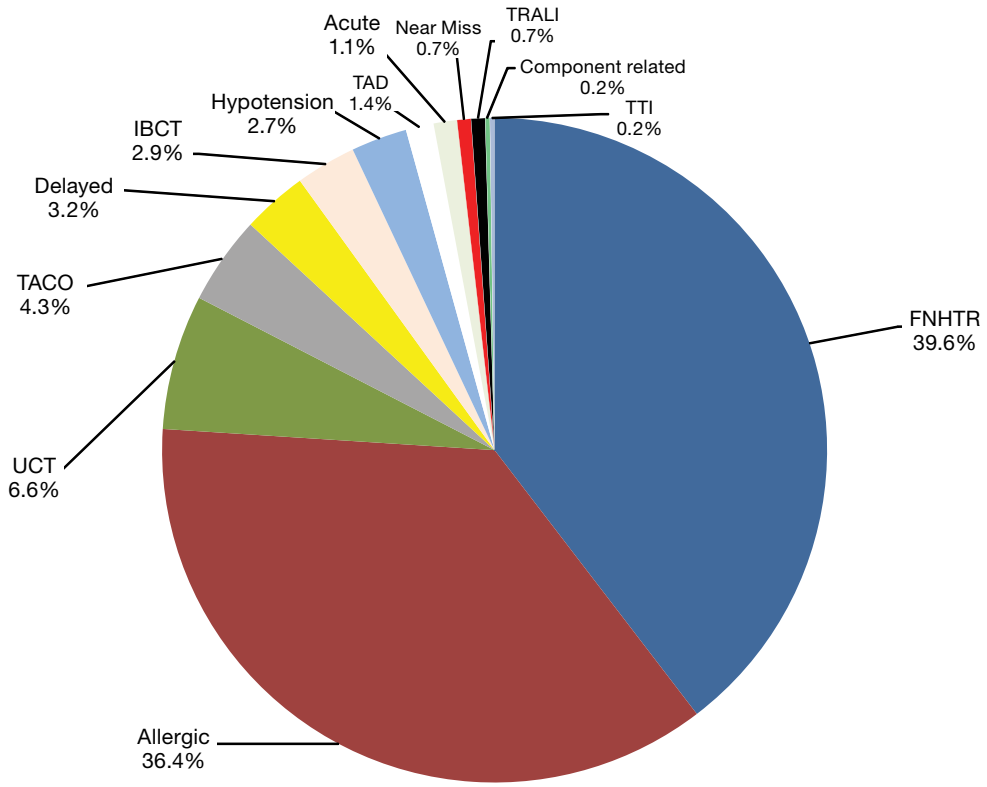


FIGURE 3. REPORTS AS PERCENTAGE OF TOTAL REPORTS 2011 (n = 442)



There were 411 transfusion recipients associated with the 442 events included in the analysis. Table 5 shows the age and gender of recipients with reported events.

TABLE 5. AGE AND GENDER OF PATIENTS WITH REPORTED ADVERSE EVENTS (IMPUTABILITY ≥3) 2011

	Number	Age (years)			
		Mean	Median	Minimum	Maximum
Female	233	58	63	2 days	98
Male	209	54	63	14 days	98
All	**442**	**56**	**62**	**2 days**	**98**

Multiple transfusion-related events were reported in 23 recipients (Table 6). The patient with five reports had allergic transfusion reactions associated with FFP and cryoprecipitate during therapeutic plasma exchange.

TABLE 6. REPORTED EVENTS PER PATIENT 2011

		Haemovigilance Reports (Imputability ≥3)				
	Total	1 Report	2 Reports	3 Reports	4 Reports	5 Reports
Number of Patients	411	388	17	5	0	1

7 Reports Involving Paediatric Recipients

During 2011 there were 34 reports (7%) involving recipients aged 15 years or younger. Two thirds of these events were allergic transfusion reactions and 26% were severe (Tables 7 and 10).

TABLE 7. REPORTS INVOLVING RECIPIENTS ≤15 YEARS AGE (2011)

Event Type	Female	Male	Total
Acute	1		1
Allergic	5	17	22
FNHTR	2	3	5
IBCT		1	1
TACO	1	1	2
UCT		3	3
Total	**9**	**25**	**34**

8 Imputability Scores

Lower imputability scores (<3) were excluded from the analysis. They were mainly associated with febrile non-haemolytic transfusion reactions and unclassifiable complications (Table 8).

TABLE 8. IMPUTABILITY SCORES BY TYPE OF EVENT 2011

Event Type	Imputability Score						
	1	2	3	4	5	Total	Total ≥3
FNHTR	26	26	105	65	5	227	175
Allergic	2		45	98	18	163	161
UCT	2	10	22	4	3	41	29
TACO			9	9	1	19	19
IBCT	2		1	1	11	15	13
DSTR	2		1		11	14	12
Hypotension	1	1	6	5	1	14	12
TAD			4	2		6	6
Acute			1	2	2	5	5
Near miss					3	3	3
TRALI			1	2		3	3
DHTR					2	2	2
Component related			1			1	1
TTI				1		1	1
Total	**35**	**37**	**196**	**189**	**57**	**514**	**442**
Percentage Reports	6.8%	7.2%	38.1%	36.8%	11.1%		86.0%

9 Severity of Reported Events

The severity score definitions and scores for reported events are shown in Table 9. 85% of events reported were non-severe (Grade 1). There were no reported transfusion related deaths in 2011.

TABLE 9. SEVERITY SCORE DEFINITIONS AND SEVERITY SCORES FOR EVENTS REPORTED DURING 2011

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.

Event Type	Severity Score (for reports where imputability score ≥3)			
	Grade 1	Grade 2	Grade 3	Total
FNHTR	169	6		175
Allergic	125	34	2	161
UCT	29			29
TACO	9	9	1	19
IBCT	13			13
DSTR	11	1		12
Hypotension	8	3	1	12
TAD	5		1	6
Acute	1	4		5
Near miss	3			3
TRALI		2	1	3
DHTR	1	1		2
Component related	1			1
TTI		1		1
Total	**375**	**61**	**6**	**442**
Percentage of reports	84.8%	13.8%	1.4%	

TABLE 10. SEVERITY SCORES FOR EVENTS INVOLVING RECIPIENTS ≤15 YEARS AGE (2011)

Event	Severity Score		
	Grade 1	Grade 2	Total
Acute		1	1
Allergic	16	6	22
FNHTR	5		5
IBCT	1		1
TACO		2	2
UCT	3		3
Total	**25**	**9**	**34**

10 Reported Events by Type of Blood Component

The overall rate of reported events in 2011 was 1 in 344 units transfused (29 per 10,000 units transfused, 95% CI 27 to 32). Adverse reactions are reported more frequently with platelet transfusion compared to other blood components. Tables 11 and 12 show the rates and types of event by blood component. The reported rate of events for platelets suspended in plasma was 87 per 10,000 units and for platelets suspended in additive solution was 53 per 10,000 units (p = 0.02). Events associated with platelet transfusion are largely allergic in nature (Table 12).

TABLE 11. REPORTED EVENTS 2011 BY TYPE OF BLOOD COMPONENT TRANSFUSED (IMPUTABILITY SCORE ≥3)

	Number of Events*	Number Transfused	Frequency	Rate /10,000 Units Transfused (95%CI)
Platelets -pooled	25	2,349	1:94	106.4 (71.4 to 157.4)
Platelets - apheresis	58	7,146	1:123	81.2 (62.7 to 104.9)
Platelets - pooled PAS	18	2,988	1:166	60.2 (37.4 to 95.7)
Platelets - apheresis PAS	2	774	1:387	25.8 (0.6 to 100.2)
Cryodepleted plasma	5	751	1:150	66.6 (23.7 to 159.7)
Fresh frozen plasma	57	16,894	1:296	33.7 (26.0 to 43.8)
Red cells	311	117,848	1:379	26.4 (23.6 to 29.5)
Cryoprecipitate	5	3,228	1:646	15.5 (5.5 to 37.4)

**Includes events where multiple component types transfused*

TABLE 12. TYPE OF ADVERSE EVENT BY BLOOD COMPONENT 2011 (IMPUTABILITY SCORE ≥3)

	Red Cells	Fresh Frozen Plasma	Platelets Apheresis	Platelets Pooled	PAS platelets Apheresis	PAS Platelets Pooled	Cryoprecipitate	Cryodepleted Plasma	Other*	Multiple Components
FNHTR	152	4	9	3		2				5
Allergic	61	30	25	15	2	8		4		16
UCT	18	2	5			1			1	2
TACO	13					1				5
Hypotension	10		2							
IBCT	7	1							4	1
DSTR	11									1
TAD	5									1
Acute	3		2							
Near miss	2								1	
TRALI	1									2
DHTR	2									
Component related	1									
TTI			1							
Total (n=442)	**286**	**37**	**44**	**18**	**2**	**12**	**0**	**4**	**6**	**33**

**Events associated with fractionated plasma products (5) and salvaged autologous blood (1)*

11 Haemovigilance Reports by Region

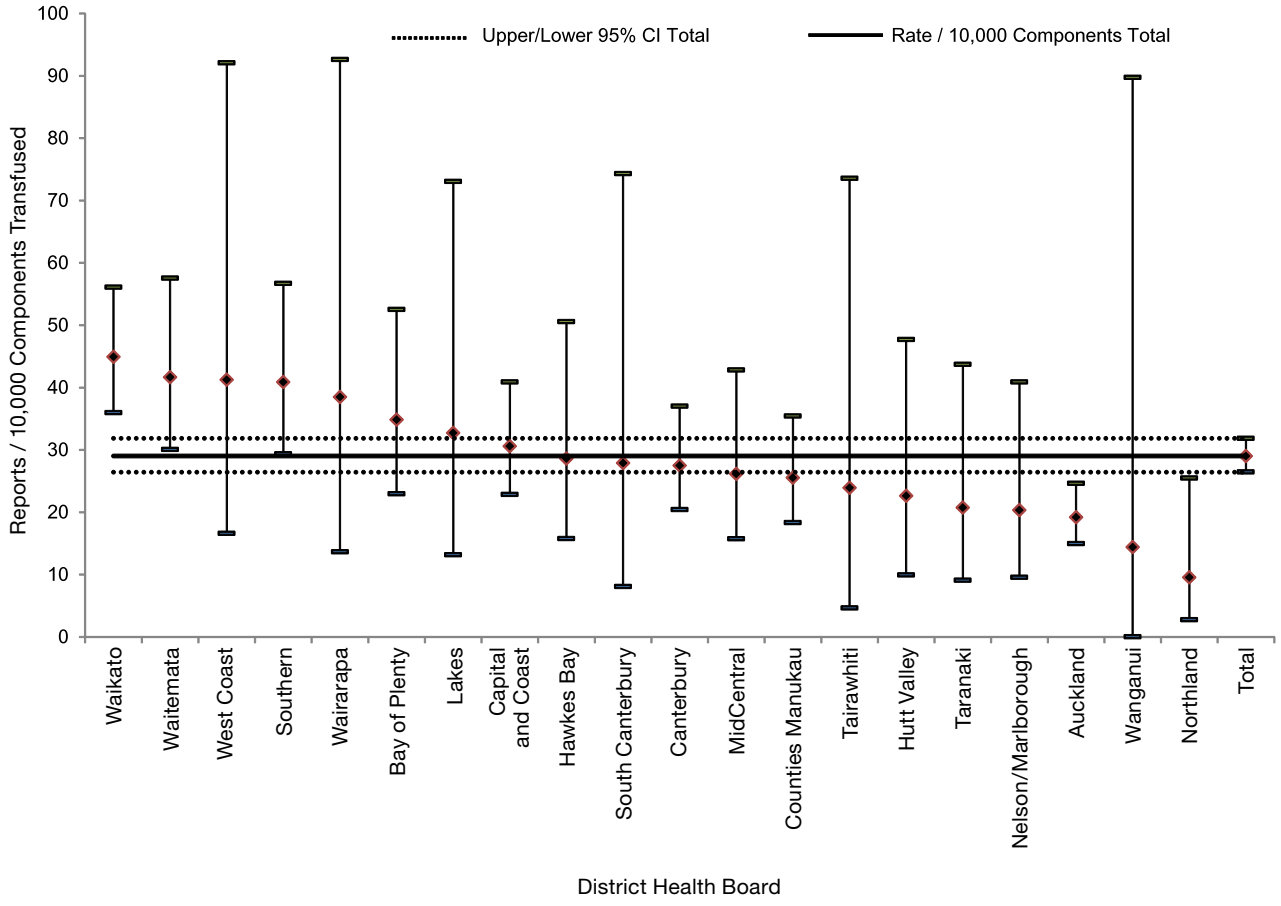
During 2011 events were reported from all 20 District Health Boards (DHBs) in New Zealand. The number of reported events per DHB and per 10,000 units transfused is shown in Table 13. It is useful for DHBs to compare their reporting rates with each other. The overall rate is similar to that in previous years.

TABLE 13. ORIGIN OF HAEMOVIGILANCE NOTIFICATIONS 2011 (IMPUTABILITY SCORE ≥3)

District Health Board	Reported Events	Components Transfused	Frequency	Rate /10,000 Components Transfused (95%CI)
Waikato	78	17,367	1:223	44.9 (35.9 to 56.1)
Waitemata	37	8,883	1:240	41.7 (30.1 to 57.5)
West Coast	6	1,454	1:242	41.3 (16.6 to 92.1)
Southern	36	8,809	1:245	40.9 (29.4 to 56.7)
Wairarapa	5	1,299	1:260	38.5 (13.6 to 92.6)
Bay of Plenty	24	6,602	1:275	36.4 (4.2 to 54.3)
Lakes	6	1,834	1:306	32.7 (13.1 to 73.0)
Capital and Coast	46	15,037	1:327	30.6 (22.9 to 40.9)
Hawke's Bay	12	4,193	1:349	28.6 (15.8 to 50.6)
South Canterbury	4	1,434	1:359	27.9 (8.1 to 74.3)
Canterbury	44	15,995	1:364	27.5 (20.4 to 37.0)
MidCentral	16	6,118	1:382	26.2 (15.7 to 42.8)
Counties Manukau	36	14,106	1:392	25.5 (18.3 to 35.4)
Tairawhiti	3	1,255	1:418	23.9 (4.6 to 73.6)
Hutt Valley	7	3,092	1:442	22.6 (9.9 to 47.7)
Taranaki	7	3,375	1:482	20.7 (9.1 to 43.7)
Nelson/Marlborough	8	3,931	1:491	20.4 (9.5 to 40.9)
Auckland	62	32,308	1:521	19.2 (14.9 to 24.6)
Wanganui	1	694	1:694	14.4 (.0 to 89.8)
Northland	4	4,192	1:1,048	9.5 (2.8 to 25.5)
Total	**442**	**151,978**	**1:344**	**29.1 (26.4 to 31.9)**

Figure 4 shows the reporting rate per DHB as a graph. Smaller DHBs that transfuse less have wider confidence intervals around the rate of reporting.

FIGURE 4. REPORTS PER 10,000 COMPONENTS TRANSFUSED (♦), 95% CONFIDENCE INTERVALS (2011)



12 Febrile Non-Haemolytic Transfusion Reactions (FNHTRs)

Febrile reactions are the most frequently reported type of transfusion reaction (40%). They are usually non-severe (severity grade 1 = 97%). The average increase in temperature was 1.7°C (Table 14).

TABLE 14. AGE AND GENDER OF PATIENTS WITH REPORTED FNHTRS 2011

	Number	Age (years)				Average Temp Rise
		Mean	Median	Minimum	Maximum	
Female	94	64	69	8	96	1.5
Male	81	59	64	1	97	1.8
All	**175**	**62**	**68**	**1**	**97**	**1.7**

In addition to fever, chills and rigors, other symptoms and signs are associated with FNHTRs. These are summarised in Table 15. Hypertension occurs in 26% of patients that are reported to have febrile transfusion reactions.

TABLE 15. OTHER SIGNS AND SYMPTOMS ASSOCIATED WITH FNHTRS 2011

	Number			% FNHTR Events
	Female	Male	Total	
Chills/rigors	52	50	102	58.3%
Hypertension	27	19	46	26.3%
Tachycardia	17	14	31	17.7%
Restless/anxiety	15	14	29	16.6%
Dyspnoea	14	12	26	14.9%
Flushing	12	8	20	11.4%

13 Allergic Transfusion Reactions

During 2011 36% of reported events were allergic reactions. 78% were non-severe and 22% severe or life-threatening. Table 16 shows the age and sex of recipients with reported allergic reactions during 2011.

TABLE 16. AGE AND SEX OF PATIENTS WITH REPORTED ALLERGIC REACTIONS 2011

	Number	Age (years)			
		Mean	Median	Minimum	Maximum
Female	71	45	46	9	85
Male	90	46	50	1	92
All	**161**	**45**	**47**	**1**	**92**

Clinical features of reported allergic transfusion reactions are summarised in Table 17.

TABLE 17. SIGNS AND SYMPTOMS ASSOCIATED WITH ALLERGIC REACTIONS 2011

	Number			% Allergic Events
	Female	Male	Total	
Urticaria	57	68	125	77.6%
Restless / Anxiety	14	24	38	23.6%
Stridor / Wheeze	7	17	24	14.9%
Non-urticarial rash	8	12	20	12.4%
Dyspnoea	5	15	20	12.4%
Facial oedema	12	7	19	11.8%
Chills / rigors	8	10	18	11.2%
Hypotension	5	12	17	10.6%
Flushing	6	11	17	10.6%
Tachycardia	3	13	16	9.9%
Hypertension	4	6	10	6.2%
Fall in O_2 saturation	1	7	8	5.0%
Chest pain	2	6	8	5.0%

14 Transfusion Associated Circulatory Overload (TACO)

During 2011 there were 19 events categorised as TACO. Nine were non-severe, nine were severe and one was life-threatening. The age and sex of the recipients is shown in Table 18. Table 19 shows the clinical features of reported TACOs during 2011.

TABLE 18. AGE AND SEX OF PATIENTS WITH REPORTED TACO 2011

	Number	Age (years)			
		Mean	Median	Minimum	Maximum
Female	14	64	70	2 days	98
Male	5	53	80	13 days	85
All	**19**	**61**	**74**	**2 days**	**98**

TABLE 19. CLINICAL FEATURES OF TACO 2011

	Number			
	Female	Male	Total	% TACO Events
Dyspnoea	13	2	15	75.0%
Pulmonary oedema	9	3	12	60.0%
Stridor / Wheeze	9	2	11	55.0%
Hypertension	6	3	9	45.0%
Hypoxaemia	6	2	8	40.0%
Restless / Anxiety	4	2	6	30.0%
Fall in O_2 saturation	3	1	4	20.0%
Tachycardia	1	2	3	15.0%
Chills / rigors	2	0	2	10.0%
Chest pain	2	0	2	10.0%

Transfusion Associated Circulatory Overload (TACO) continued

A chest xray was performed in 12 patients, not performed in 2 patients and not stated in 5 reports. A brain natriuretic peptide (BNP) level was provided in one report. It was markedly elevated at 2517pmol/L.

Two noteworthy TACO case reports from 2011 are summarised below. The names are not real.

Baby George, a pre-term infant in the neonatal unit, weighed 1000g. He was transfused one neonatal red cell unit (67mL). After completing the transfusion, respiratory distress, increased oxygen requirements and bilateral pitting leg oedema was noted. A chest xray showed bilateral diffuse opacification. He was given 2 doses of frusemide. Haemoglobin levels were not provided. 67mL exceeds the recommended dose of 10-20mL/kg for top-up red cell transfusion in children and neonates.

The dose of red cells for paediatric patients should always be prescribed in mL.

Mrs Green had a history of colon cancer. She was admitted with a haemoglobin level of 63g/L. Four units of red cells were prescribed, to be administered over 2 days. After the first 2 units she developed mild fluid overload which responded to frusemide. After the 4th unit she became flushed, dyspnoeic and wheezy, with accompanying tachycardia and hypertension. The post-transfusion haemoglobin was 172g/L, indicating overtransfusion.

For stable patients having top-up red cell transfusion, clinical reassessment for the need for further units should be undertaken.

15 Transfusion Related Acute Lung Injury (TRALI)

During 2011 there were three reports of TRALI in New Zealand. The cases are summarised below.

1. A 27 year old female developed sudden respiratory distress following transfusion of 4 units of FFP. She had a history of inflammatory bowel disease, with recent lower gastrointestinal bleeding, combined variable immunodeficiency and severe metabolic acidosis. She developed bilateral pulmonary infiltrates on chest xray and did not respond to diuretic therapy. She became progressively hypoxic and required intubation. Several hours later she died following VF arrest. All four FFP donors were males with no history of transfusion.

2. An 82 year old female with pancreatic cancer was administered 2 units of FFP to correct a prolonged INR of 2.5, prior to ERCP, percutaneous transhepatic cholangiogram (PTC) and biliary stenting. She developed dyspnoea, severe hypoxaemia, pulmonary oedema and bilateral pleural effusions confirmed on chest xray. She continued to deteriorate and died several days later. Both donors were male and negative for HNA antibodies. One donor had a negative HLA antibody screen and the other was positive for Class II antibodies. He was retired from donating fresh blood components.

3. A 68 year old female was having therapeutic plasma exchange (TPE) for haemolytic uraemic syndrome (HUS). She was transfused with 6 units of cryodepleted plasma and 1 pooled platelet concentrate. 40 minutes after the procedure she reported sudden onset of cough and dyspnoea, accompanied by oxygen desaturation. Pulmonary oedema was confirmed on a chest xray. She was treated with high flow oxygen, Phenergan and hydrocortisone. She recovered over 3 days. Four female and two male donors were investigated. All six donors had negative HNA antibody screens. One female donor had multiple strongly reacting HLA class I antibodies with specificities against the patient's HLA antigens (anti-A11, anti-B56). The implicated donor was retired.

A number of measures to reduce the risk of TRALI have been implemented. These include production of FFP from males with no history of blood transfusion (2008) and screening female plateletpheresis donors for HLA antibodies (2012). NZBS is assessing the feasiblility of extending HLA antibody screening to cryoprecipitate and cryosupernatant plasma donors.

16 Transfusion Associated Dyspnoea (TAD)

During 2011 there were six reports of TAD, five involved male recipients and one female recipient.

The mean age was 72 years (range 19 – 92). The clinical features of the reported cases are summarised in Table 20. Three patients had a chest xray, one did not have a chest xray and two reports did not mention whether a chest xray was done. It is useful to include radiological findings when reporting reactions with predominantly respiratory symptoms, as it may help to diagnose TACO or TRALI if new pulmonary infiltrates are identified.

TABLE 20. CLINICAL FEATURES OF TAD 2011

Clinical Signs and Symptoms	Number
Dyspnoea	6
Chills / rigors	3
Tachycardia	3
Fall in oxygen saturation	3
Restless / Anxiety	3
Hypertension	1
Hypotension	1
Stridor / Wheeze	1
Chest pain	1
Pulmonary oedema	1
Hypoxaemia	1

17 Hypotensive Transfusion Reactions

During 2011, 12 reports of hypotension were included in the analysis. These included 8 females and 4 males, age range 58 – 98 years (mean age 77 years). Seven patients were surgical with three events occurring intra-operatively.

18 Acute Haemolytic Transfusion Reactions (AHTRs)

During 2011 there were 5 reports categorised as AHTRs. These are summarised in Table 21. Two were caused by the transfusion of haemolysin in group O platelet concentrates, two were due to Kidd antibodies and one was due to an antibody to a low incidence antigen.

TABLE 21. ACUTE HAEMOLYTIC TRANSFUSION REACTIONS 2011

Patient Details	Product Transfused	Signs & Symptoms	Results
88 year old female: Myelodysplasia, hip replacement, ischaemic heart disease	1 unit RBC	Fever, vomiting, rigors, chest tightness, jaundice post-transfusion	Negative RCAS Positive IAT crossmatch on the pre- and post-transfusion samples, interpreted as antibody to low incidence antigen.
76 year old female: #femur, NSTEMI, transfused 1 unit RBCs 6 days earlier	1 unit RBC	Fever, chest pain, jaw pain, hypertension	Antibody of undetermined specificity later confirmed as anti-Jka after transfusion. DAT weakly positive (C3d and IgG), bilirubin 26 → 123µmol/L, LDH 746U/L, haptoglobin < 0.03g/L.
8 year old female: Newly diagnosed ALL Group B	Group O platelets*	Fever, tachycardia, hypertension, rigors, tachypnoea, oxygen desaturation, severe agitation, abdominal pain, no changes on chest x-ray	Hb 55 → 39g/L Platelets 24→65 x 10^9/L Pre-DAT negative Post-DAT 3+, IgG 3+, C3d 0.5 Eluate anti-B Patient & unit cultures negative.
70 year old female: Myelofibrosis, GI bleeding, known anti-Jk3	4 units RBC (Jka negative)	No clinical details provided. Incompatible units approved by Medical Officer for emergency transfusion	Hb 72→ 44g/L LDH 1,619IU/L Haptoglobin < 0.03g/L Bilirubin 5→ 53 µmol/L DAT 2+, IgG 2+, C3d weak.
16 year old male: Relapsed ALL, febrile neutropenia, cerebral aspergillosis Group A	Group O platelets*	Fever, rigors, hypertension, tachycardia, oxygen desaturation, chest pain	Hb 83→ 58g/L Bilirubin 25→54 µmol/L Unit IgG anti-IgA titre 512 No sample sent for DAT.

RCAS red cell antibody screen, IAT indirect antiglobulin test, NSTEMI non-ST elevation myocardial infarction, DAT direct antiglobulin test, ALL acute lymphoblastic leukaemia

**apheresis platelets suspended in plasma*

19 Delayed Haemolytic/Serologic Transfusion Reactions

Delayed haemolytic transfusion reactions (DHTRs) occur 1 – 28 days after red cell transfusion. These are usually identified by the blood bank when repeat testing identifies a new red cell alloantibody and a positive direct antiglobulin test (DAT) in the recipient. Red cell alloantibodies are formed following pregnancy or transfusion, although they can also be naturally occurring. Haemolysis is suggested by a poor haemoglobin increment, jaundice, raised LDH and low haptoglobin. If results for haemolysis markers are unavailable, or are not supportive of haemolysis, the reaction is classified as a delayed serologic transfusion reaction (DSTR).

During 2011 there were 2 DHTRs and 12 DSTRs reported to the Haemovigilance Programme. The specificities of the red cell antibodies are shown in Table 22. Two new antibodies were identified in 4 patients. Antibodies to Rh and Kidd antigens are the most frequently identified antibodies in the reactions. Cumulative data on antibody specificities from haemovigilance reports since 2006 are shown in Table 23 and Figure 5. Over half (59%) of the recipients were female and 83% were over the age of 50 years (Table 24).

TABLE 22. SPECIFICITIES OF RED CELL ANTIBODIES IN DELAYED REACTIONS 2011

	Antibody	Number
Delayed Haemolytic Transfusion Reactions	Fy^b	1
	K	1
Delayed Serologic Transfusion Reactions	Jk^a	2
	C+e	2
	Fy^a	2
	E	1
	Lu^a	1
	E + K	1
	K	1
	Jk^b	1
	C + K	1

TABLE 23. ANTIBODY SPECIFICITIES FOR DELAYED REACTIONS 2006 – 2011

Antibody Specificity	Number	Percentage
Jk^a	21	20.2%
E	20	19.2%
Fy^a	12	11.5%
K	12	11.5%
Jk^b	8	7.7%
c	8	7.7%
C	8	7.7%
e	7	6.7%
S	2	1.9%
s	2	1.9%
Fy^b	1	1.0%
Lu^a	1	1.0%
M	1	1.0%
Vel	1	1.0%
Total	**104**	

FIGURE 5. BLOOD GROUP ANTIBODIES RESPONSIBLE FOR DELAYED REACTIONS 2006 - 2011

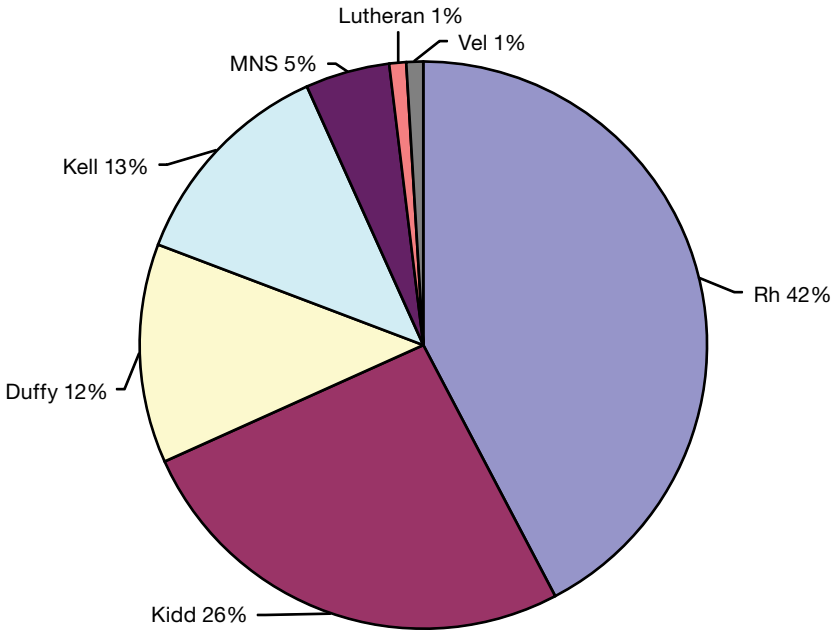


TABLE 24. AGE AND GENDER OF RECIPIENTS WITH DELAYED REACTIONS 2005 – 2011

	Age Group (Years)									
	10-19	20-29	30-39	40-49	50-59	60-69	70-79	80-89	90-100	Total
Female	1	1	3	5	11	11	8	13	2	55
Male	1	1	2	2	7	8	6	8	4	39
Total	**2**	**2**	**5**	**7**	**18**	**19**	**14**	**21**	**6**	**94**

20 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 requirements. During 2011 there were 13 IBCT events, which is less than half the number included in the analysis from the previous year (29). Although the reduction involved all types, there were fewer IBCT events involving Rh D immunoglobulin compared to the previous years.

Four events involved errors made by the blood bank, three were inappropriately prescribed by a doctor, two were inappropriately prescribed by a midwife and the origin of the error was not evident in 4 reports. The 2011 IBCT events are summarised in Table 25.

TABLE 25. IBCT EVENTS 2011 (TOTAL = 13)

IBCT Event Type of Product	Description
Inappropriate transfusion RBC (2), Rh D Ig (2), FFP (1)	4 units RBC transfused based on point of care haemoglobin test result of 73g/L. Post-transfusion Hb 152g/L, retrospective test indicated that pre-transfusion Hb was actually 99g/L
	8 units RBC given to a patient with GI bleeding, pre-transfusion Hb was 103g/L and post-transfusion Hb was 177g/L
	FFP requested and transfused to a patient instead of platelets
	Rh D Ig given to a Rh D negative mother following birth of an Rh D negative infant because the midwife had checked the Rh D type of a previous infant who was Rh D positive
	An Rh D negative mother with immune anti-D was given Rh D immunoglobulin post-partum
Issue of incorrect product or dose RBC (1), Biostate (2), Rh D Ig (1)	A group A patient was issued and transfused a haemolysin positive (group O) unit of RBCs, no sequelae reported
	A patient with von Willebrand disease was prescribed 1500IU of Biostate however only 500IU was issued
	Biostate was issued to a 9 month old infant with Haemophilia A instead of recombinant FVIII which was requested
	250IU dose of Rh D Ig was given to an Rh D negative patient with antepartum haemorrhage at 35/40 gestation, instead of 625IU; the request form did not specify the dose and the laboratory did not check with the midwife
Non-irradiated units transfused RBC (2)	3 units RBCs were transfused to a patient in a small hospital not linked to the National Blood Management System (BMS) because the transfusion protocol for irradiated cells was not apparent when the units were issued, no sequelae
	1 unit of RBC was transfused during a computer outage
Labelling error RBC (1)	2 units RBC were transfused to a patient, the first name on the unit labels differed from that on the request form (it was the same patient)
Expired unit transfused RBC (1)	1 unit of RBC was transfused to a post-operative patient one day after it's expiry, the unit had been sent to the small hospital one day before the expiry date

21 Near Miss Events

A near miss event is an error that is discovered before the start of the transfusion. The event could have led to an IBCT if not identified. During 2011 there were 3 near miss events reported to the Haemovigilance Programme. Table 26 summarises near miss events recorded during 2011. Most of the events (31) were obtained directly from the NZBS incident management database and involve NZBS Blood Banks or blood processing laboratories.

TABLE 26. NEAR MISS EVENTS 2011

Error	Site of Error			Total Errors
	Blood Bank	Blood Processing	Clinical	
Wrong product issued (including wrong product, dose or to wrong patient)	7			7
Red cells almost transfused to wrong patient			1	1
Irradiation labelling errors	1	11		12
Data entry, transcription errors or other laboratory errors	3			3
Labelling errors	8			8
Provision of red cells that did not meet protocol requirements	1			1
Pre-transfusion specimen validity errors	1			1
Wrong blood in tube (identified at DHB blood bank)			1	1
Total	**21**	**11**	**2**	**34**

22 Component Related Events

During 2011 there was one component related event reported to the Haemovigilance Programme. This involved a unit of whole blood which was used to prime the cardiac bypass circuit for a one year old patient. Calcium was administered to prevent a citrate reaction. The blood in the circuit clotted before the procedure started.

23 Transfusion Transmitted Infections (TTIs)

During 2011 there was one TTI. This involved a unit of apheresis platelets which was transfused to a 67 year old female patient with multiple myeloma. She had received chemotherapy and had a platelet count of <10 x 10^9/L. Following the platelet transfusion she reported rigors and neck pain. She became febrile (38.3°C) and tachycardic. Cultures from the unit and the patient were positive for *Staphylococcus lugdunensis*. The unit was five days old and had not been sampled for bacterial contamination on Day 2.

24 Unclassifiable Complications of Transfusion (UCT)

During 2011 there were 42 reported events which could not be classified into a specific category. 13 of these were excluded from the analysis as the events appeared to be due to causes other than transfusion. The remaining 29 reports are summarised in Table 27. Pain was the predominant symptom in ten reports, with chest pain in seven reports, abdominal pain in two reports and pain at the infusion site in one report.

TABLE 27. UNCLASSIFIABLE COMPLICATIONS OF TRANSFUSION (IMPUTABILITY ≥3) 2011

Reaction	Number of Reports
Pain	10
Hypertension	4
Flushing	5
Cough	2
Nausea	2
Rh D immunisation with PAS platelets	2
Tachycardia	2
Dyspnoea/rigors*	1
Anxiety	1
Total	**29**

**30 minutes following the reinfusion of 550mL autologous blood from a knee joint replacement drain*

25 Bacterial Monitoring of Platelet Concentrates

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 a 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 are withdrawn if a positive culture signal is obtained.

Testing for platelet bacterial contamination started in 2003. All NZBS sites are now involved in the scheme. Currently it operates as a quality monitoring system and there is no formal requirement for all platelet components to be tested. The proportion of components tested has increased progressively over the last few years. In 2011 approximately 84% of all apheresis collections and 81% of platelets pools were tested. These rates are similar to those in previous years. Data on the proportion of platelet components tested by site during 2011 is shown in Table 28.

There is no clear consensus on the optimal system for bacterial culture. A number of variables can affect sensitivity. These include the volume of initial inoculum, the timing of culture (day one or two post-collection) and using an aerobic bottle only versus both aerobic and anaerobic bottles. International practice is highly variable.

TABLE 28. PROPORTION OF PLATELET COMPONENTS TESTED FOR BACTERIAL CONTAMINATION IN 2011

	Apheresis Platelets			Pooled Platelets		
	Collections	Components Tested	% Tested	Produced	Tested	% Tested
Auckland	2,174	1,806	83	3,887	2,859	74
Waikato	1,211	1,043	86	2,043	1,886	92
Wellington	854	709	83	1,268	1,027	81
Christchurch	1,028	795	77	558	519	93
Manawatu	419	364	87			
Otago	334	323	97			
Total	**6,020**	**5,040**	**84**	**7,756**	**6,291**	**81**

Results of testing during 2011 are shown in Table 29. The data indicates that NZBS systems compare well with published data. The Council of Europe Guide to the Preparation Use and Quality Assurance of Blood Components (16th Edition) identifies a contamination rate of 0.2 to 0.4%.

TABLE 29. RESULTS OF DAY 2 TESTING OF PLATELET COMPONENTS DURING 2011

	Total Components Sampled	Number Reactive	% Reactive	Frequency of Reactives
Total reactive on BacT Alert	11,331	17	0.15	1:667
Total confirmed reactive	11,331	3	0.03	1:3,777

There is increasing evidence 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 in 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 30. Nonetheless some Blood Services, including the English National Health Service Blood and Transplant (NHSBT) have extended the shelf life of platelet concentrates to seven days when routine bacterial culture has been implemented arguing that that the slow growing organisms identified towards the end of the component shelf life are unlikely to be of clinical significance.

TABLE 30. RESULTS OF TESTING OF EXPIRED PLATELETS DURING 2011

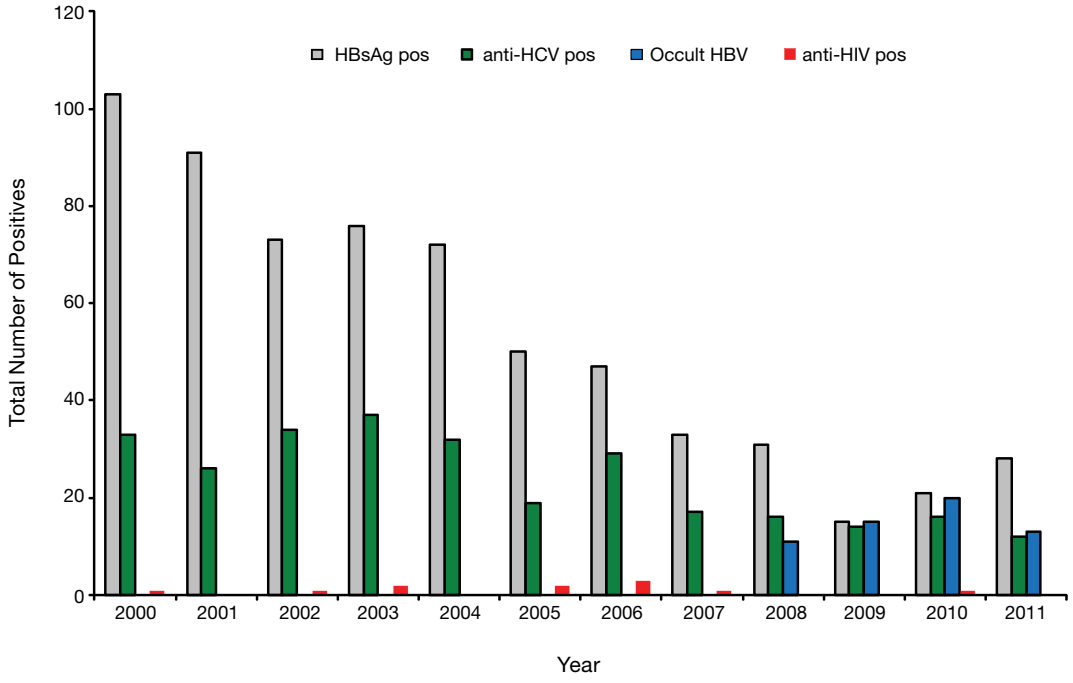
	Total Components Sampled	Number Reactive	% Reactive	Frequency of Reactives
Total BacT Alert reactive	3,360	1	0.03	1:3,360
Total confirmed reactive	3,360	0	0	0:3,360

NZBS is currently assessing the feasibility of extending testing to include all manufactured platelet components. This will bring NZBS in line with established international practice. In doing so care will be taken to avoid any increase in the overall expiry rates for the component and will also include an evaluation of the appropriateness of extending the shelf life of the component to seven days.

26 Donor Infectious Diseases Screening

In New Zealand all blood donations are screening 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 tested for anti-HTLV I & II. Additional testing is performed on selected donations e.g. CMV IgG for fetal and neonatal transfusions, Chagas and malarial tests in donors who may pose a risk. Figure 6 shows the trend of confirmed positive infectious disease testing in donors over the past 12 years. Occult HBV is defined as infection with detectable Hepatitis B DNA and undetectable surface antigen (HBsAg) in the donor's (or patient's) blood. HBV DNA screening of blood donations was implemented in New Zealand in 2007.

FIGURE 6. DONOR EPIDEMIOLOGIC DATA 2000 – 2011



During 2011 there were 182,470 donations collected from 92,829 donors. 81% were repeat donors and 19% were new donors (previously untested).

Table 31 shows the number of donors with confirmed positive serology during 2011. There were 28 donors who were confirmed positive for HBsAg, all were first time donors. Twelve donors were confirmed positive for HCV and one donor for HTLV.

Table 32 shows the frequency of confirmed HBsAg, HCV and HIV in new and repeat donors per year for the previous 5 years.

TABLE 31. DONORS WITH CONFIRMED POSITIVE SEROLOGY 2011

		HBV (HBsAg Positive)	HCV	HIV	Syphilis	HBV Occult	HTLV I/II
Number	New donor (n = 17,515)	28	9		6	1	1
	Repeat donor (n = 75,314)	0	3		3	12	0
	Total (n = 92,829)	28	12	0	9	13	1
% positive donations		0.015%	0.007%		0.005%	0.007%	0.0005%
Frequency of positive donation	Repeat donor		1:54,985		1:54,985	1:13,746	
	New donor	1:626	1:1,946		1:2,919	1:17,515	1:17,515
	All donors	1:3,315	1:7,736		1:10,314	1:7,141	1:92,829

TABLE 32. DONORS WITH CONFIRMED POSITIVE SEROLOGY 2007 – 2011

		2007	2008	2009	2010	2011
HBsAg positive	New donor	1:677	1:725	1:1,294	1:896	1:626
	Repeat donor	1:7,841	1:78,090	1:75,204		
HCV positive	New donor	1:1,400	1:1,451	1:1,294	1:1,255	1: 946
	Repeat donor	1:78,090	1:78,090		1:75,345	1:54,985
HIV positive	New donor	1:21,000			1:18,822	
	Repeat donor					

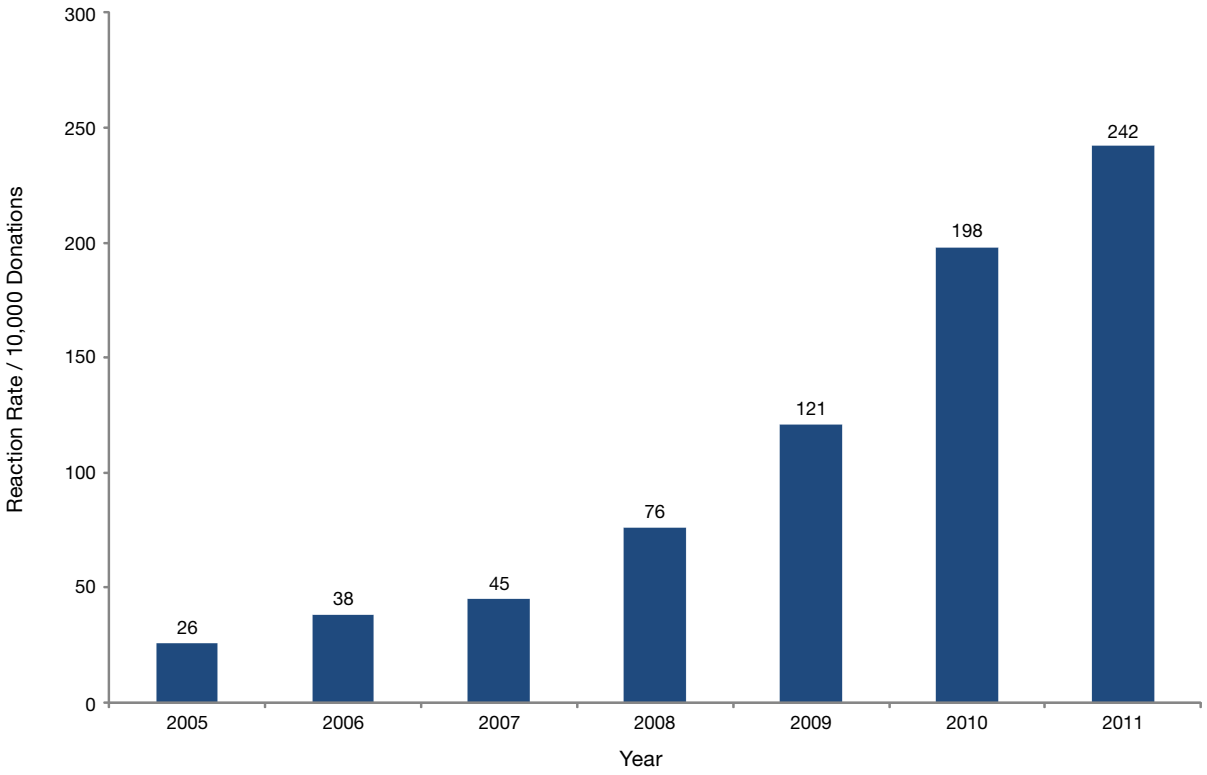
27 Adverse Events Associated With Blood Donation

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

The definitions of donor complications are those of the Working Group on Complications Related to Blood Donation, International Society of Blood Transfusion Working Party on Haemovigilance Standard for Surveillance of Complications Related to Blood Donation (2008). A standardized national form is used by all collection sites to record the information for each donor incident (Appendix II).

In New Zealand during 2011 there were 182,470 donations (147,093 whole blood, 28,886 plasmapheresis and 6,491 plateletpheresis donations). Adverse events were reported for 4,413 donations, involving 4,354 donors. 59 donors had more than one such event reported. The overall rate of a donation-related adverse event was 1:41. The reported rate per 10,000 donations appears to be increasing (Figure 7). However, this may be explained by improved reporting as there have been considerable efforts to increase the reporting of all donor adverse events.

FIGURE 7. ANNUAL TREND OF DONOR ADVERSE EVENTS PER 10,000 DONATIONS



Adverse events are more frequently reported with apheresis procedures than whole blood donations (Table 33).

TABLE 33. DONOR ADVERSE EVENT PER PROCEDURE 2011

Procedure	Donors	Donations with Events	Total Donations	Frequency	Rate / 10,000 Donations (95% CI)
Whole blood donation	3,288	3,300	147,093	1:45	224 (217 to 232)
Plasmapheresis	697	722	28,886	1:40	250 (233 to 269)
Plateletpheresis	369	391	6,491	1:17	602 (547 to 663)
All apheresis procedures	**1,066**	**1,113**	**35,377**	**1:32**	**315 (297 to 333)**
Total Procedures	**4,354**	**4,413**	**182,470**	**1:41**	**242 (235 to 249)**

Immediate vasovagal reactions and bruising/haematoma are the most frequently reported complications associated with donation (Table 34). The most frequently reported complication associated with whole blood donation is immediate vasovagal reaction (60.6%) and with apheresis procedures is bruising/haematoma (59.7%). These are shown in Table 35.

TABLE 34. FREQUENCY OF DONOR ADVERSE EVENTS BY CATEGORY 2011

	All Donations (total =182,470)			
	Adverse Events	Percentage Reactions	Frequency	Rate / 10,000 Donations
Immediate vasovagal	2,222	54.2%	1:82	122 (117 to 127)
Haematoma	1,352	33.0%	1:135	74 (70 to 78)
Painful arm	168	4.1%	1:1,086	9 (8 to 11)
Delayed vasovagal	143	3.5%	1:1,276	8 (7 to 9)
Nerve irritation	105	2.6%	1:1,738	6 (5 to 7)
Other	40	1.0%	1:4,562	2 (2 to 3)
Delayed bleeding	23	0.6%	1:7,933	1 (1 to 2)
Nerve injury	20	0.5%	1:9,124	1 (1 to 2)
Arterial puncture	9	0.2%	1:20,274	0 (0 to 1)
Allergy	7	0.2%	1:26,067	0 (0 to 1)
Thrombophlebitis	7	0.2%	1:26,067	0 (0 to 1)
Tendon damage	2	<0.1%	1:91,235	0 (0 to 0)

TABLE 35. ADVERSE EVENTS BY DONATION TYPE, CATEGORY AND FREQUENCY 2011

	Type of Donation							
	Whole Blood (Total Collections = 147,093)				Apheresis (Total Collections = 35,377)			
	Events	% Reaction	Freq.	Rate / 10,000 donations (95% CI)	Events	% Reaction	Freq.	Rate / 10,000 donations (95% CI)
Immediate vasovagal	2,046	60.6%	1:72	139 (133 to 145)	176	24.5%	1:201	50 (43 to 58)
Haematoma	923	27.3%	1:159	63 (59 to 67)	429	59.7%	1:82	121 (110 to 133)
Painful arm	122	3.6%	1:1,206	8 (7 to 10)	46	6.4%	1:769	13 (10 to 17)
Delayed vasovagal	124	3.7%	1:1,186	8 (7 to 10)	19	2.6%	1:1862	5 (3 to 8)
Nerve irritation	87	2.6%	1:1,691	5 (5 to 7)	18	2.5%	1:1,965	5 (3 to 8)
Other	29	0.9%	1:5,072	2 (1 to 3)	11	1.5%	1:3,216	3 (2 to 6)
Nerve injury	15	0.4%	1:9,806	1 (1 to 2)	5	0.7%	1:7,075	1 (0 to 3)
Delayed bleeding	16	0.5%	1:9,193	1 (1 to 2)	7	1.0%	1:5,054	2 (1 to 4)
Arterial puncture	7	0.2%	1:21,013		2	0.3%	1:17,689	
Thrombophlebitis	5	0.1%	1:29,419		2	0.3%	1:17,689	
Allergy	4	0.1%	1:36,773		3	0.4%	1:11,792	
Tendon damage	1	<0.1%	1:147,093		1	0.1%	1:35,377	
Total	**3,379**		**1:44**	**229 (222 to 237)**	**719**		**1:49**	**203 (189 to 218)**

	Apheresis Only Complications			
	Events	% Reaction	Freq.	Rate / 10,000 donations (95% CI)
RBC not returned	485	66.5%	1:73	137 (125 to 150)
Citrate toxicity	241	33.1%	1:147	68 (60 to 77)
Haemolysis	3	0.4%	1:11,792	1 (0 to 3)
Total apheresis events	**729**		**1:49**	**206 (192 to 221)**

Table 36 shows the severity of donor adverse events. During 2011 there were 19 adverse events that were classified as severe, 17 were associated with whole blood donations and two with apheresis procedures. Severe donor events are defined by any of the following:

- Hospitalisation: if it was attributable to the complication
- Intervention: to prevent permanent damage or impairment of a body function or 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

Moderate and severe donor adverse event rates are shown in Table 37.

TABLE 36. DONOR ADVERSE EVENTS BY SEVERITY 2011

			Rate per 10,000 Donations					
			Whole Blood (n=147,093)		Plasmapheresis (n=28,886)		Plateletpheresis (n=6,491)	
			Events	Rate	Events	Rate	Events	Rate
Complications mainly characterised by blood outside blood vessels	Haematoma	Mild	854	58	310	107	91	140
		Moderate	65	4	21	7	6	9
		Severe	4	0.3	1	0.3		
	Arterial puncture	Mild	7	0.5	1	0.3	1	2
	Delayed bleeding	Mild	12	0.8	5	2		
		Moderate	3	0.2	2	0.7		
		Severe	1	0.1				
Pain	Nerve irritation	Mild	81	6	14	5		
		Moderate	6	0.4	2	0.7	2	3
	Nerve injury	Mild	12	0.8	2	0.7	1	2
		Moderate	3	0.2	1	0.3	1	2
	Tendon damage	Mild	1	0.1	1	0.3		
	Painful arm	Mild	104	7	29	10	11	17
		Moderate	18	1	5	2	1	2
Other complications with local symptoms	Thrombophlebitis	Mild	2	0.1	1	0.3	1	2
		Moderate	3	0.2				
	Allergy (local)	Mild	4	0.3	1	0.3		
		Moderate			2	0.7		
Immediate vasovagal reaction	Without injury	Mild	1,781	121	108	37	30	46
		Moderate	242	17	25	9	7	11
		Severe	8	0.5	1	0.3		
	With injury	Mild	10	0.7	5	2		
		Moderate	4	0.3				
		Severe	1	0.1				
Delayed vasovagal reaction	Without injury	Mild	87	6	8	3	5	8
		Moderate	20	1	1	0.3		
		Severe	3	0.2				
	With injury	Mild	7	0.5			5	8
		Moderate	7	0.5				
Other			29	2	8	3	3	5
Complications related to apheresis	Citrate reaction				45	16	196	302
	Haemolysis				2	0.7	1	2
	RBC not returned				358	124	127	196

TABLE 37. MODERATE AND SEVERE DONOR ADVERSE EVENTS 2011

Procedure	Total Donations	Severity	Number of Events	Frequency	Rate / 10,000 Donations
Whole blood donation	147,093	Moderate	371	1:396	25 (23 to 28)
		Severe	17	1:8,653	1 (1 to 2)
Apheresis donation	35,377	Moderate	76	1:465	21 (17 to 27)
		Severe	2	1:17,689	1 (0 to 2)
All donations	182,470	Moderate	447	1:408	24 (22 to 27)
		Severe	19	1:9,604	1.0 (0.7 to 1.6)

The frequency of adverse events is higher in younger blood donors, especially those under the age of 20 years (odds ratio 2.79). The rate of adverse events for whole blood donations, by age group, is shown in Table 38. A similar trend (odds ratio 3.47) is noted for vasovagal reactions (Table 39).

TABLE 38. DONOR ADVERSE EVENTS BY AGE GROUP FOR WHOLE BLOOD DONATION 2011

Age group	Number of Events	Total Donors in Age Group	Frequency	Rate /1,000 Donations (95% CI)	Odds Ratio (95%CI)
16 - 19 Years	901	14,658	1:16	61.5 (57.7 to 65.5)	2.79 (2.58 to 3.00)
20 - 29 Years	960	26,855	1:28	35.7 (33.6 to 38.0)	1.58 (1.47 to 1.70)
30 - 39 Years	450	22,411	1:50	20.1 (18.3 to 22.0)	1.54 (1.43 to 1.66)
40 - 49 Years	432	30,215	1:70	14.3 (13.0 to 15.7)	0.62 (0.56 to 0.68)
50 - 59 Years	429	33,516	1:78	12.8 (11.6 to 14.1)	0.55 (0.50 to 0.61)
≥60 Years	207	19,438	1:94	10.6 (9.3 to 12.2)	0.46 (0.40 to 0.53)
All	**3,379**	**147,093**	**1:44**	**23.0 (22.2 to 23.8)**	**1.00 (0.95 to 1.05)**

TABLE 39. VASOVAGAL REACTIONS BY AGE GROUP FOR WHOLE BLOOD DONATION 2011

Age Group	Number of Events	Total Donors in Age Group	Frequency	Rate /1,000 Donations (95% CI)	Odds Ratio (95%CI)
16 - 19 Years	725	14,658	1:20	49.5 (46.1 to 53.1)	3.47 (3.18 to 3.78)
20 - 29 Years	664	26,855	1:40	24.7 (22.9 to 26.7)	1.69 (1.55 to 1.85)
30 - 39 Years	273	22,411	1:82	12.2 (10.8 to 13.7)	0.82 (0.72 to 0.93)
40 - 49 Years	201	30,215	1:150	6.7 (5.8 to 7.6)	0.45 (0.39 to 0.52)
50 - 59 Years	215	33,516	1:156	6.4 (5.6 to 7.3)	0.43 (0.37 to 0.50)
≥60 Years	92	19,438	1:211	4.7 (3.9 to 5.8)	0.32 (0.26 to 0.39)
Total	**2,170**	**147,093**	**1:68**	**14.8 (14.1 to 15.4)**	

28 Adverse Events Associated With Fractionated Plasma Products

Adverse events involving fractionated plasma products have a separate reporting procedure from those associated with fresh blood components. (See notification form in Appendix III). During 2011 there were 27 notifications of adverse events with fractionated plasma products. 23 described reactions and 4 an incorrect product or dose administered. The latter are described in the IBCT section of the report.

Table 40 summarises the 27 notifications during 2011. The Intragam P reactions are described further in Table 41. Pyrexia and allergic reactions were the commonest type of event associated with fractionated plasma products.

TABLE 40. REPORTED EVENTS FOR FRACTIONATED PLASMA PRODUCTS 2011

Plasma Product	Type of Event	Number of Reports
Intragam P	Various (12) - see Table 41	12
Prothrombinex-VF	Thrombotic (1), allergic (3)	4
Albumex 20	Pyrexia (3)	3
RhD Immunoglobulin	Allergic (1), IBCT (2)	3
Albumex 4	Allergic (1), pyrexia (1)	2
Biostate	IBCT (2)	2
Next Gen. 16% Immunoglobulin	Infection	1
Total		**27**

TABLE 41. REACTIONS REPORTED WITH INTRAGAM P 2011

Type of Reaction	Causality				Total
	Unlikely	Possible	Likely / Probable	Highly Probable	
Allergic / inflammatory				2	2
Febrile		1		1	2
Weakness, incoordination and flu-like symptoms			2*		2
Acute neurological symptoms		1			1
Dyspnoea		1			1
Febrile and general malaise				1	1
Haemolytic				1	1
Nausea and vomiting	1				1
Neuromuscular				1	1
Total	**1**	**3**	**2**	**6**	**12**

**same patient*

22 events were classified as not severe, three as severe and one incident (involving Biostate) was escalated (requiring a national response).

29 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. An error at this stage can potentially lead to the transfusion of ABO incompatible red cells, which can cause significant morbidity and death.

Labels on pre-transfusion samples must be handwritten at the patient's bedside. Use of pre-printed addressograph labels can lead to mislabelling and samples labelled with these are discarded. A declaration on the accompanying request form must be signed by the collector at the time of sample certifying that:

- The blood specimen(s) accompanying this request was drawn from the named patient
- The identity of the patient was established by direct enquiry and/or inspection of their wristband
- Immediately upon the blood being drawn the sample tube was hand labelled and signed at the bedside

Over the past six 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 42.

TABLE 42. NZBS PRE-TRANSFUSION REQUEST FORM AND SAMPLE LABELLING REQUIREMENTS

Request Form Handwritten or Pre-printed Label	Sample Must be Handwritten
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	

In 2011, 138,156 pre-transfusion samples were received by the six NZBS Blood Banks. Errors were identified in 3,268 samples/forms. The overall error rate for the six NZBS Blood Banks for 2011 is 23.7 per 1,000 samples received or 1:42 samples. This is similar to the error rate in 2010 (23.5 per 1,000 samples or 1:43). Table 43 shows the error rate per 1,000 samples for the six NZBS Blood Banks in 2011.

TABLE 43. SAMPLE ERROR RATES PER NZBS BLOOD BANK 2011

Blood Bank	Samples with Error(s)	Total Samples	Error Rate	Rate / 1,000 Samples (95% CI)
Palmerston North	312	8,942	1:29	34.9 (31.3 to 38.9)
Dunedin	342	10,587	1:31	32.3 (29.1 to 35.8)
Christchurch	690	21,759	1:32	31.7 (29.5 to 34.1)
Wellington	443	21,002	1:47	21.1 (19.2 to 23.1)
Waikato	569	27,039	1:48	21.0 (19.4 to 22.8)
Auckland	912	48,827	1:54	18.7 (17.5 to 19.9)
NZBS	**3,268**	**138,156**	**1:42**	**23.7 (22.9 to 24.5)**

Types of error and the actions taken are summarised in Table 44. Some request forms/samples received had more than one type of error present. The total number of errors was 3,456. The most frequent type of error (21%) 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 (20%). 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 44. SAMPLE AND REQUEST FORM ERRORS 2011

	Errors	% Total	Frequency	Rate / 1,000 Samples	Action Required
Declaration not signed	734	21.2%	1:188	5.3	Correction by collector or recollect
Pre-printed ID label (or evidence of removal)	676	19.6%	1:204	4.9	Recollect
Sample not signed	561	16.2%	1:246	4.1	Correction by collector or recollect
Missing patient details (moderate error)	531	15.4%	1:260	3.8	Correction by collector or recollect
Missing patient details (major error)	378	10.9%	1:365	2.7	Recollect
Other clerical errors	170	4.9%	1:813	1.2	Consult Team Leader
Signature on sample & declaration differ	141	4.1%	1:980	1.0	Recollect
Technical*	108	3.1%	1:1,279	0.8	Recollect
Unlabelled sample	82	2.4%	1:1,685	0.6	Recollect
Original details overwritten	75	2.2%	1:1,842	0.5	Recollect
Total	**3,456**				

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

The overall rate of request for recollection of pre-transfusion sample by NZBS Blood Banks was 14.9 per 1,000 samples received during 2011. Table 45 shows the recollection rate for each NZBS Blood Bank in 2011. Overall 63% of errors resulted in a request for recollection of the pre-transfusion sample.

TABLE 45. REQUESTS FOR RE-COLLECTION PER BLOOD BANK 2011

	Recollection Requests	Total Number of Samples	Frequency	% Errors	Rate / 1,000 Samples (95% CI)
Palmerston North	190	8,942	1:47	61%	21.2 (18.5 to 24.5)
Christchurch	446	21,759	1:49	65%	20.5 (18.7 to 22.5)
Wellington	321	21,002	1:65	72%	15.3 (13.7 to 17.0)
Waikato	384	27,039	1:70	67%	14.2 (12.9 to 15.7)
Dunedin	147	10,587	1:72	43%	13.9 (11.8 to 16.3)
Auckland	564	48,827	1:87	62%	11.6 (10.6 to 12.5)
NZBS	**2,052**	**138,156**	**1:67**	**63%**	**14.9 (14.2 to 15.5)**

30 Wrong Blood in Tube (WBIT) Errors

A "wrong blood in tube", also referred to as "wrong name on tube" (WNOT) is where a pre-transfusion sample is collected from the wrong patient, or the sample is labelled with the details of another patient. These errors are usually identified when ABO or Rh D typing shows a different result from the historic results. A current WBIT is where the recently collected sample 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 the patient bled has the same ABO Rh D group as the one who should have been bled. The corrected WBIT rate can be calculated using the following equation:

$$\text{Corrected WBIT rate} = \frac{\text{Number of historic groups}}{\text{Number WBITs} \times 1.6}$$

The correction factor of 1.6 is based on New Zealand blood group frequencies.

In 2011 historic ABO Rh D results were available for 63% of all pre-transfusion samples submitted to NZBS Blood Banks. There were 23 WBIT errors identified in 2011. In one, the historic result was assumed to be incorrect. Table 46 shows the corrected WBIT rate for the 22 current WBITs reported by the NZBS Blood Banks in 2011. The overall rate was 4 per 10,000 samples (1:2,477).

TABLE 46. WBIT ERRORS IN NZBS BLOOD BANKS 2011

	WBIT Errors	Historic Groups	WBIT Frequency*	Rate / 10,000 (95% CI)*
Wellington	11	13,312	1:756	13.2 (8.2 to 21.2)
Waikato	4	17,162	1:2,682	3.7 (1.6 to 8.1)
Palmerston North	1	5,653	1:3,533	2.8 (-0.3 to 12.7)
Dunedin	1	6,310	1:3,944	2.5 (-0.2 to 11.4)
Christchurch	2	13,824	1:4,320	2.3 (0.5 to 6.9)
Auckland	3	30,923	1:6,442	1.6 (0.5 to 3.8)
NZBS	**22**	**87,184**	**1:2,477**	**4.0 (2.9 to 5.6)**

** Corrected to account for silent errors*

Table 47 shows the cumulative WBIT errors for the six NZBS Blood Banks over the five year period from 2007 – 2011. The overall corrected WBIT rate for the five year period was 3 per 10,000 samples (1:3,304).

TABLE 47. CUMULATIVE WBIT ERRORS FOR NZBS BLOOD BANKS 2007 - 2011

	WBIT Errors	Historic Groups	WBIT Frequency*	Rate / 10,000 (95% CI)*
Wellington	25	60,074	1:1,502	6.7 (4.9 to 9.1)
Palmerston North	7	28,453	1:2,540	3.9 (2.1 to 7.1)
Auckland	25	145,916	1:3,648	2.7 (2.0 to 3.7)
Dunedin	5	30,363	1:3,795	2.6 (1.2 to 5.3)
Waikato	11	84,732	1:4,814	2.1 (1.3 to 3.3)
Christchurch	10	78,641	1:4,915	2.0 (1.2 to 3.3)
NZBS	**83**	**428,179**	**1:3,224**	**3.1 (2.6 to 3.7)**

** Corrected to account for silent error*

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 1
Transfusion Related Adverse Event Notification Form – page 2

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

Page 2 of 4

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

HV | | | | | | |
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Appendix 1
Transfusion Related Adverse Event Notification Form – page 4

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.

NZBLOOD
Te Ratonga Toto O Aotearoa

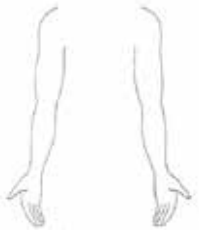
NATIONAL
107F00507

DONOR INCIDENT REPORT

OFFICE USE ONLY: Database Record No:	

INCIDENT				
Date of Report:		**Type of Report:**	**Venue**	**Type of Donation**
Time of Report:		☐ At Session ☐ Phone call	☐ Static Site ☐ Mobile	☐ WB ☐ Plasma
Date of Incident:		☐ Personal Visit ☐ Email ☐ Letter	Location:	☐ Platelets Other:

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

INCIDENT 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
Give details …

NZBLOOD
Te Ratonga Toto O Aotearoa

NATIONAL
107F00507

DONOR INCIDENT REPORT

INCIDENT DESCRIPTION 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		
NZBS Accident Form Required (170F007)	**YES/NO**		
Name of Staff (filling in form):	**Name:**	**Sign:**	**Date:**

FOLLOW UP REQUIRED: YES/NO			
Give 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:*

Appendix 3
Notification of suspected adverse reaction to a fractionated blood product – page 1

NZBLOOD Te Ratonga Toto O Aotearoa

NOTIFICATION OF SUSPECTED ADVERSE REACTION TO A FRACTIONATED BLOOD PRODUCT

NATIONAL 111F00306
NZBS use

RECIPIENT

Family Name	First Names	National Health Index No.	Gender	Reporting date

Address	Date of Birth dd/mm/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 ☐ SC ☐ Other
Transfusion finished / terminated: *date* _____ *time* _____. **Treatment location:** ☐ Hospital/clinic ☐ Home/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 reactions during infusion of Intragam P: 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*

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Refer to Document(s): 111M003

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Treatment of adverse reaction or event

Adverse Reaction Information

Seriousness

Is the event serious? ☐ 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

Blood Group ABO/D (if relevant)

Direct antiglobulin test (if relevant)

Causality assessment

☐ Highly probable ☐ Possible ☐ Unlikely ☐ Unassessable

OTHER CONDITIONS PRESENT

☐ Renal Disease ☐ Hepatic Disease ☐ Cardiac Disease ☐ Respiratory Disease ☐ Allergy ☐ Other medical conditions: ☐ Chemical Exposure:

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		Telephone	Fax
Auckland Hospital Blood Bank	09 307 2834	09 307 2823	Wellington Hospital Blood Bank	04 9186961	04 385 5982
Waikato Hospital Blood Bank	07 839 8919	07 858 0988	Christchurch Hospital Blood Bank	03 364 0314	03 364 0159
Palmerston North Hospital Blood Bank	06 350 8558	06 357 2854	Dunedin Hospital Blood Bank	03 470 9369	03 470 9513

SAVE LIVES
GIVE BLOOD

New Zealand Government