NZBLOOD
Te Ratonga Toto O Aotearoa

National Haemovigilance Programme

Annual Report 2009

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Cover photograph: View of Wellington City from Mt Kau Kau

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1. Foreword

Publication of the fifth annual Haemovigilance report for New Zealand confirms the ongoing success of the scheme. The number of reports received by the National Haemovigilance office in Wellington continues to increase. This continued support of clinical and laboratory staff from across the health sector in New Zealand is a major contributor to the success of the scheme. NZBS is very appreciative of this ongoing support. Thanks are also due to the tremendous work undertaken by the national haemovigilance team, based in the Wellington Blood Centre. In particular the ongoing effort and support given by Dr Dorothy Dinesh and John Dagger is highly appreciated.

There is an increasing drive to standardise the definitions used to classify adverse events associated with transfusion. This work is largely undertaken by two organisations. The International Society of Blood Transfusion (ISBT) Haemovigilance working party and the International Haemovigilance Network (IHN). These two groups work collaboratively to set and review definitions. NZBS is involved in this process and utilises the agreed international definitions as they develop. This approach will facilitate future benchmarking activities. Initial attempts in this area have unfortunately raised more questions than answers and suggests that further work will be required before meaningful international benchmarking can occur.

Local New Zealand data continues to support improvement to NZBS' internal systems and provide useful information to monitor the impact of product developments such as the planned introduction of platelets suspended in platelet additive solution and changes to donor eligibility criteria aimed at reducing the risk of Transfusion Related Acute Lung Injury (TRALI). Near miss event reporting during the last two years has highlighted issues associated with irradiation of blood components. NZBS has reviewed the procedures involved in irradiation of blood components and introduced educational initiatives for staff involved in the process. The level of identified events appears to have reduced as a consequence. This is a good example of how NZBS can use haemovigilance data to improve overall safety of the components and products that we provide.

I hope that you will find the report informative and look forward to your ongoing support of the programme.

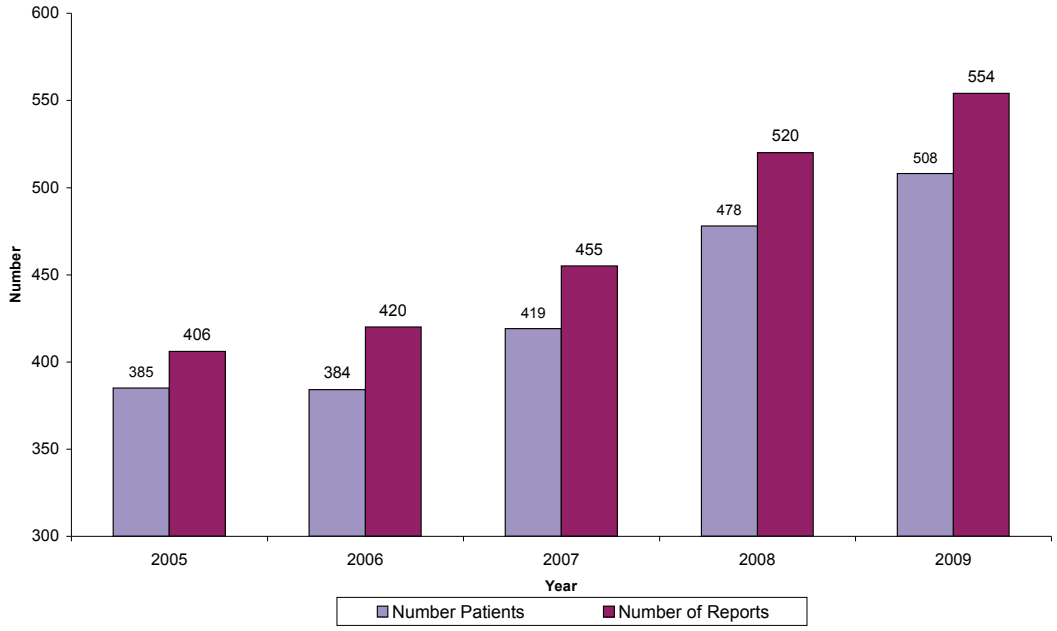
Dr Peter Flanagan
NZBS National Medical Director

2. Introduction

The National Haemovigilance Programme which has now been in existence for five years, has received over 2000 reports of transfusion related adverse events.

Reporting to the programme is voluntary and year on year the number of reports is increasing (Figure 1). We continue to emphasize the importance of reporting as the data provide useful information about the current risks associated with blood transfusion in New Zealand.

Figure 1. Reports Received by Haemovigilance Programme 2005 – 2009



(2005 total adjusted for 12 months)

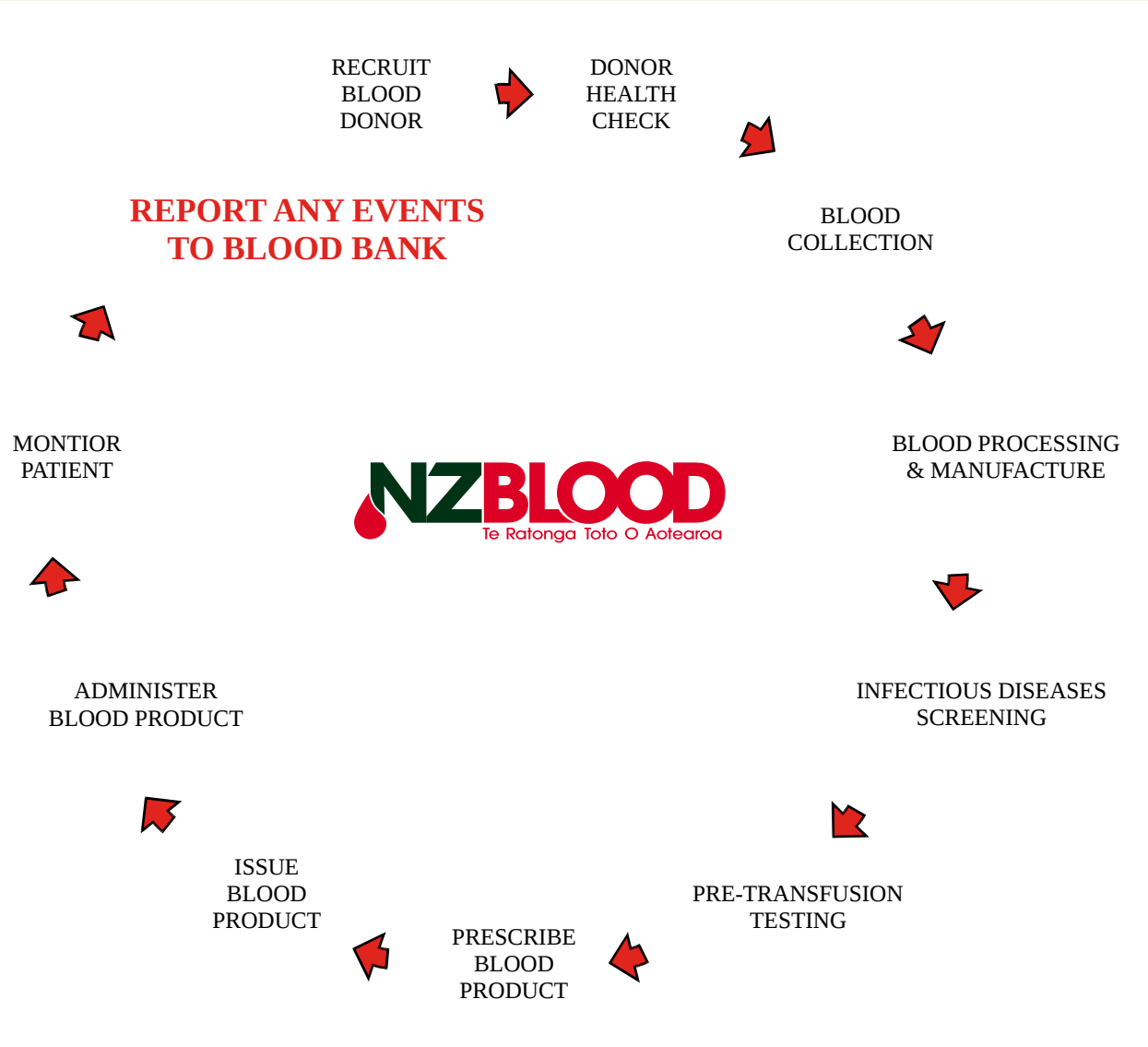
The New Zealand Blood Service (NZBS) is responsible for all aspects of the transfusion process: from the collection of blood from volunteer donors to the transfusion of blood products within the hospital environment - a "vein to vein" system. Haemovigilance, by definition (European Committee on Blood Transfusion), encompasses untoward events in both blood donors and recipients, i.e. events occurring at any point of the transfusion chain (Figure 2).

The Haemovigilance Office receives reports from Blood Bank Scientists or Transfusion Nurse Specialists from the 21 District Health Boards (DHBs) located around New Zealand. During 2009 a revised reporting form (Appendix I) was distributed. Major changes include:

1. respiratory rate and oxygen saturation at baseline and during the reaction
2. severity score
3. results of transfusion reaction investigation and
4. definitions of adverse events.

2. Introduction continued

Figure 2. The Transfusion Chain



All reports are reviewed by a team of Transfusion Medicine Specialists and a Senior Scientist and are entered into a secure database. Adverse events are categorised according to the International Haemovigilance Network (IHN) definitions (Appendix II). No identifying clinician or patient details are entered into the Haemovigilance database. The reports are stored in a secure database and destroyed on publication of the annual report.

The Haemovigilance Programme is recognised as a protected quality assurance activity and plays a vital role in transfusion safety by providing a mechanism for identifying hazards and trends associated with transfusion. Haemovigilance allows us to measure the impact of changes in transfusion practice. An example is the reduction in the number of cases of transfusion related acute lung injury (TRALI) reported since the introduction of male donor fresh frozen plasma 2 years ago.

3. Blood Component Transfusion in New Zealand

All blood donations are collected from voluntary non-remunerated donors in New Zealand. This ensures that the risk of transfusion transmitted infection remains very low. Donors can donate whole blood (which is separated into various components such as red cells, buffy coat and plasma) or they can donate plasma or platelet concentrates by apheresis. In this procedure the cells are separated and reinfused at the bedside, leaving platelets suspended in plasma or just plasma. Apheresis procedures take longer than whole blood donation but can be performed more frequently than whole blood donation.

Platelet components are produced by pooling 4 buffy coats or by plateletpheresis procedures. Cryoprecipitate is produced from plasmapheresis donations collected from donors with suitable fibrinogen levels. Fresh frozen plasma is produced from plasmapheresis donations by male donors who have never been transfused.

All blood components are leucodepleted by filtration within 24 hours of collection. This has several advantages: reduction in the risk of febrile transfusion reactions and cytomegalovirus transmission, less HLA alloimmunization and possible reduction in the risk of transmission of variant Creutzfeldt-Jakob disease.

Table 1 shows the total number of units of each blood component transfused per year for the previous 4 years.

Table 1. Total Annual Transfused Blood Components 2006 – 2009

Component	2006	2007	2008	2009	2006 – 2009 Percentage Change
Red cells	117,688	118,751	121,231	**124,004**	5%
Platelets - apheresis	6,758	6,762	7,942	**7,571**	12%
Platelets -pooled	4,657	4,749	5,157	**5,326**	14%
Fresh frozen plasma	20,619	19,956	18,962	**20,006**	-3%
Cryoprecipitate	1,847	1,991	2,372	**2,869**	55%
Cryodepleted plasma	690	927	524	**517**	-25%
Total	**152,259**	**153,136**	**156,188**	**160,293**	**5.0%**

A total of 40,240 individuals received a blood product in New Zealand during 2009. This represents approximately 1% of the population of New Zealand. Details of the gender, age and transfusion profile of blood component recipients are shown in Table 2.

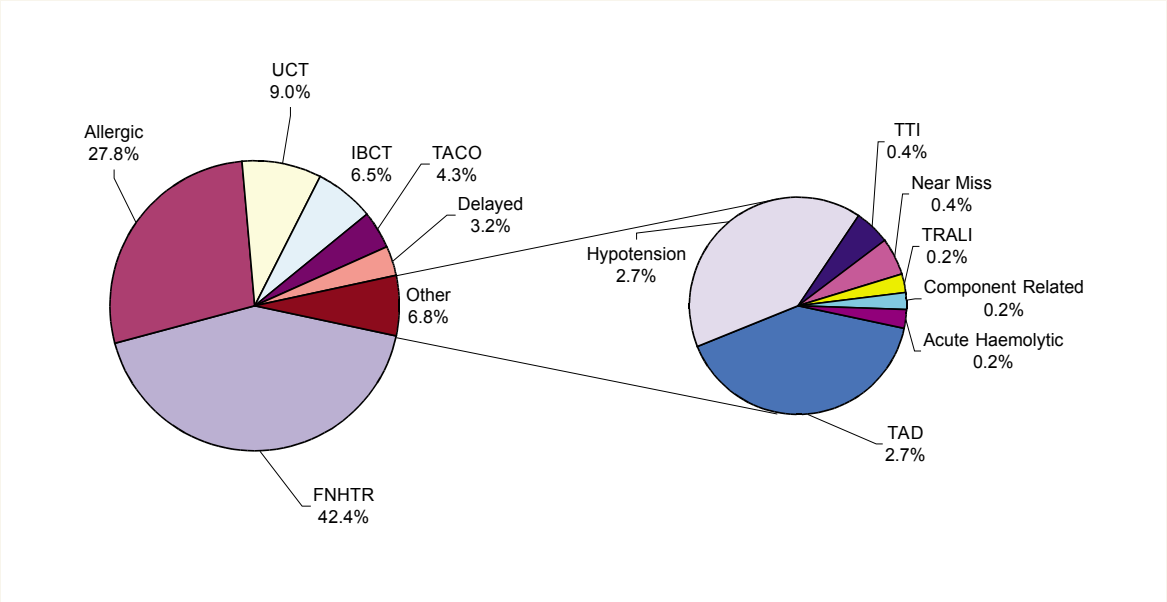
Table 2. Blood Component Recipients 2009

		Red cells	Platelets	FFP
Gender of recipients	Female	16,069	1,386	2,035
	Male	11,994	2,146	2,895
	Unknown	55	3	11
	Total	**28,118**	**3,535**	**4,941**
Age of recipients (years)	Mean	63	55	61
	Median	69	62	67
	Minimum	<1	<1	<1
	Maximum	109	109	109
Units transfused per recipient (total during 2009)	Mean	2	4	4
	Median	2	2	2
	Minimum	1	1	1
	Maximum	141	110	173

4. Summary of Reported Events for 2009

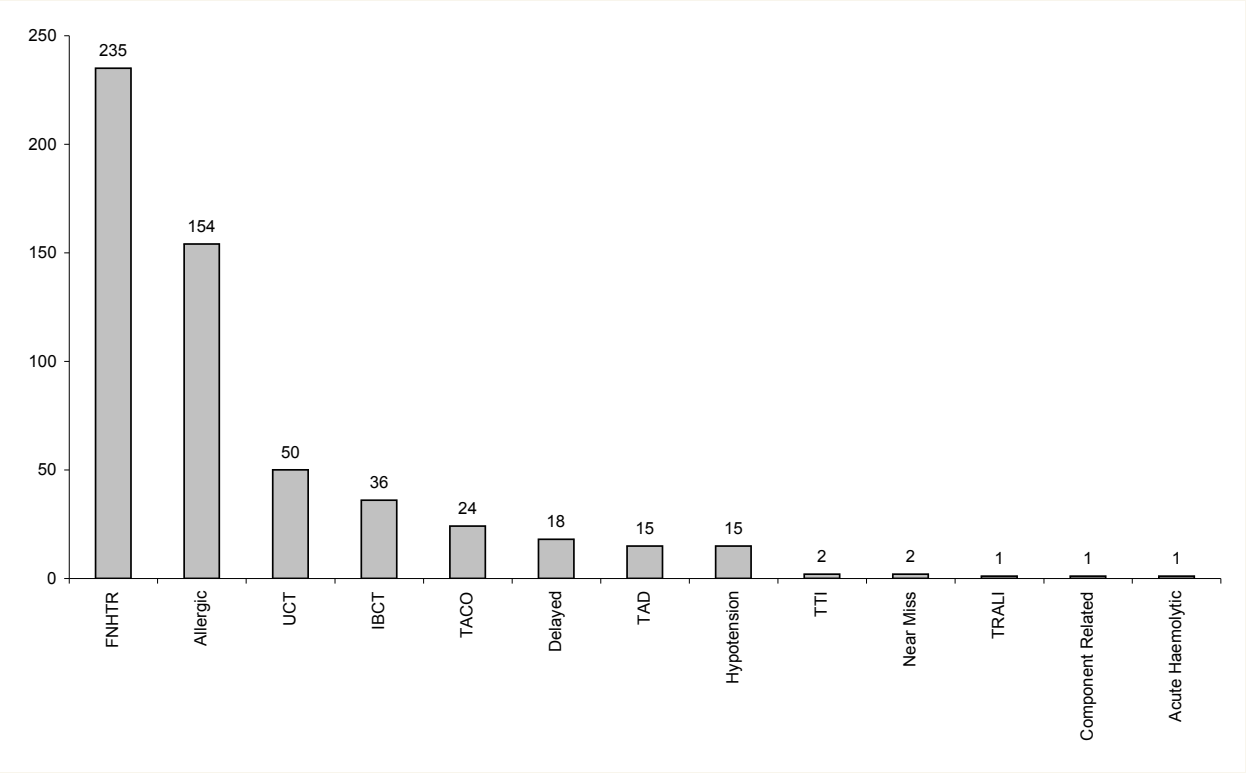
A total of 554 events involving 508 patients were reported to the National Haemovigilance Programme during 2009. Figures 3 and 4 show the breakdown of reports by category. As in previous years, febrile non-haemolytic and allergic reactions are the most frequently reported events.

Figure 3. Reports for 2009 as Percentage of Total (n = 554)



4. Summary of Reported Events for 2009 continued

Figure 4. Events Reported by Category 2009



Key:

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

Imputability scores are recorded for each report. The definitions are listed in Section G of the notification form (Appendix I). Table 3 summarizes the imputability scores by category for reported events in 2009. 12% of reports were excluded or unlikely to be attributable to transfusion, 49% of reports had high imputability scores (probable or certain).

All haemovigilance reports are graded for severity. The definitions of the severity scores (based on International Haemovigilance Network) are shown in Table 4.

4. Summary of Reported Events for 2009 continued

Table 3. Imputability Scores for Reported Events in 2009

Event Type	Imputability					
	Excluded	Unlikely	Possible	Likely/ Probable	Certain	Total
Acute haemolytic					1	1
Allergic	2	4	23	114	11	154
Component related					1	1
Delayed haemolytic reaction					3	3
Delayed serological reaction	2		1		12	15
Hypotension	2		8	5		15
IBCT	6	1	1		28	36
Near Miss					2	2
FNHTR	2	21	145	65	2	235
UCT	7	16	22	5		50
TACO			6	16	2	24
TAD	2		10	3		15
TRALI				1		1
TTI		1	1			2
TOTAL	**23**	**43**	**217**	**209**	**62**	**554**
Percentage	4%	8%	39%	38%	11%	

Table 4. Definitions of Severity

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.*

4. Summary of Reported Events for 2009 continued

Table 5 shows the severity scores for events reported to the Haemovigilance Programme in 2009. The majority of events (84%) are non-severe. There was one death reported in 2009 that was a direct consequence of blood transfusion. This was a case of Transfusion Related Acute Lung Injury (TRALI) involving a patient who was transfused fresh frozen plasma and platelets.

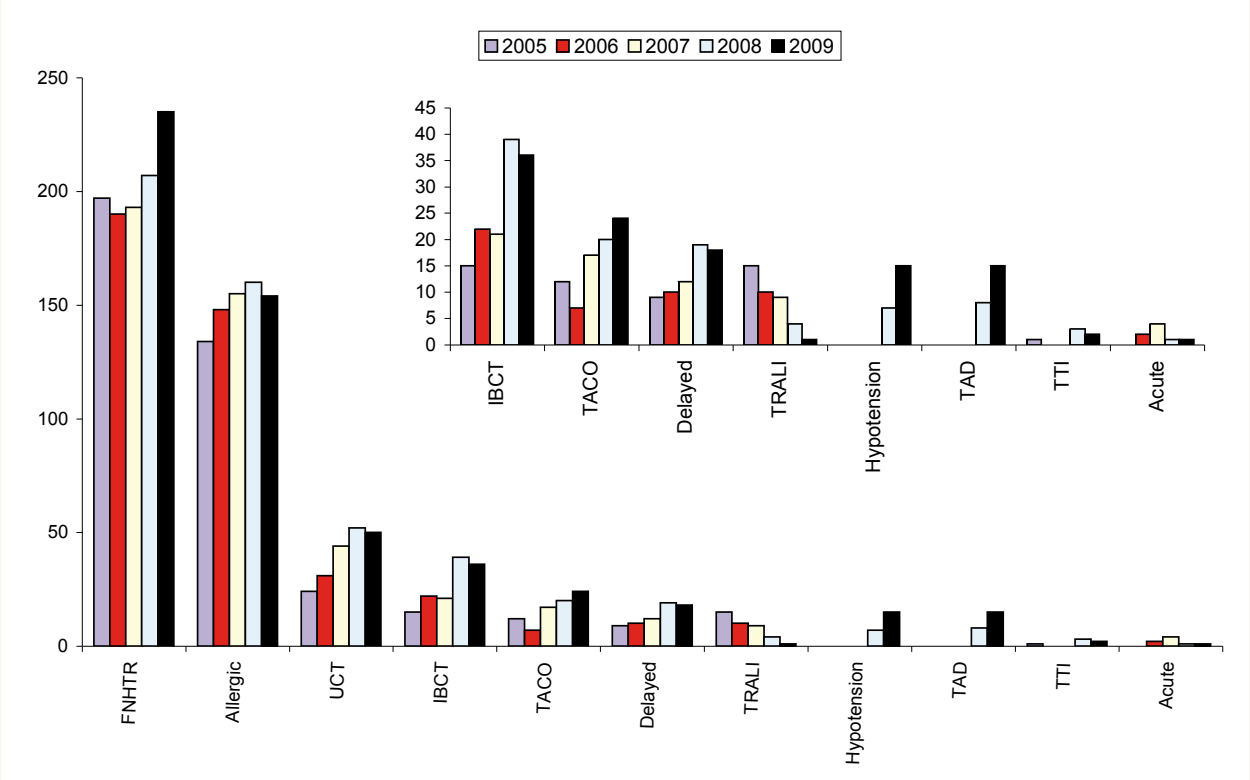
Table 5. Severity Scores for Reported Events 2009

Event Type	Severity Score				
	Grade 1	Grade 2	Grade 3	Grade 4	Total
Acute haemolytic reaction		1			1
Allergic	113	35	6		154
UCT	41	4	5		50
Delayed haemolytic transfusion reaction	3				3
Delayed serological transfusion reaction	15				15
Hypotension	5	8	2		15
IBCT	36				36
Near miss	2				2
FNHTR	232	3			235
TACO	6	16	2		24
TAD	11	2	2		15
TRALI				1	1
TTI (bacterial, viral, parasitic)		1	1		2
Component related	1				1
Total	**465**	**70**	**18**	**1**	**554**
Percentage	84%	13%	3%	0.2%	

5. Trends in Haemovigilance Reports 2005 – 2009

Figure 5 shows the total number of reports per year by category, since the scheme commenced. The 2005 data spans 8 months and has been corrected for a twelve month period, to allow comparison. The number of cases of reported TRALI has declined over the past 5 years.

Figure 5. Total Annual Reports 2005 – 2009



6. Haemovigilance Reports by Region

There are 21 District Health Boards (DHBs) in New Zealand that are responsible for providing health care services in specific geographic regions. Some DHBs have several hospitals within their region. Table 6 shows the origin of reported events for 2009 by DHB and the rate of events per 10,000 blood components transfused, in descending order of frequency. During 2009 20 DHBs submitted haemovigilance notifications.

Table 6. Origin of Haemovigilance Notifications 2009

District Health Board	Reported Adverse Events 2009 (n=554)	Components Transfused*	Events / 10,000 Components Transfused
Wairarapa	10	1,363	73
Waikato	97	15,839	61
Otago	38	6,642	57
Hutt Valley	17	3,362	51
South Canterbury	8	1,668	48
Lakes	10	2,092	48
Taranaki	15	3,190	47
MidCentral	34	7,339	46
Canterbury	73	16,816	43
Waitemata	42	10,769	39
Tairawhiti	6	1,603	37
Auckland	95	34,558	27
Bay of Plenty	19	7,101	27
Northland	11	4,171	26
Nelson Marlborough	8	3,833	21
Whanganui	3	1,486	20
Counties Manukau	28	13,965	20
Capital and Coast	32	16,058	20
Southland	3	2,883	10
Hawkes Bay	5	4,957	10
West Coast	0	598	0
Total	**554**	**160,293**	**35**

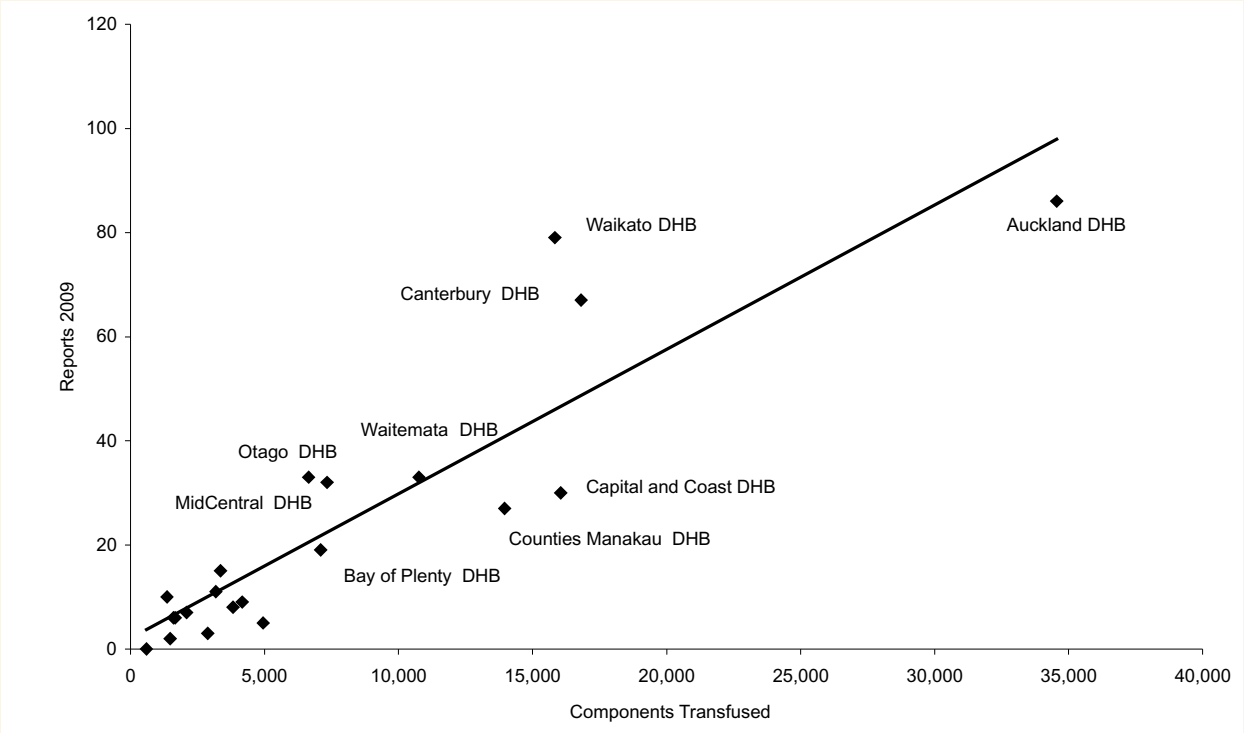
** Red cells, Platelets, FFP, Cryodepleted plasma, Cryoprecipitate*

The total number of reports received from each DHB in 2009, excluding reports which were unlikely to be related to transfusion (i.e. reports where the imputability was possible, probable or certain), is shown in Figure 6. The overall rate of reported events is approximately 1 in 330 units transfused.

6. Haemovigilance Reports by Region

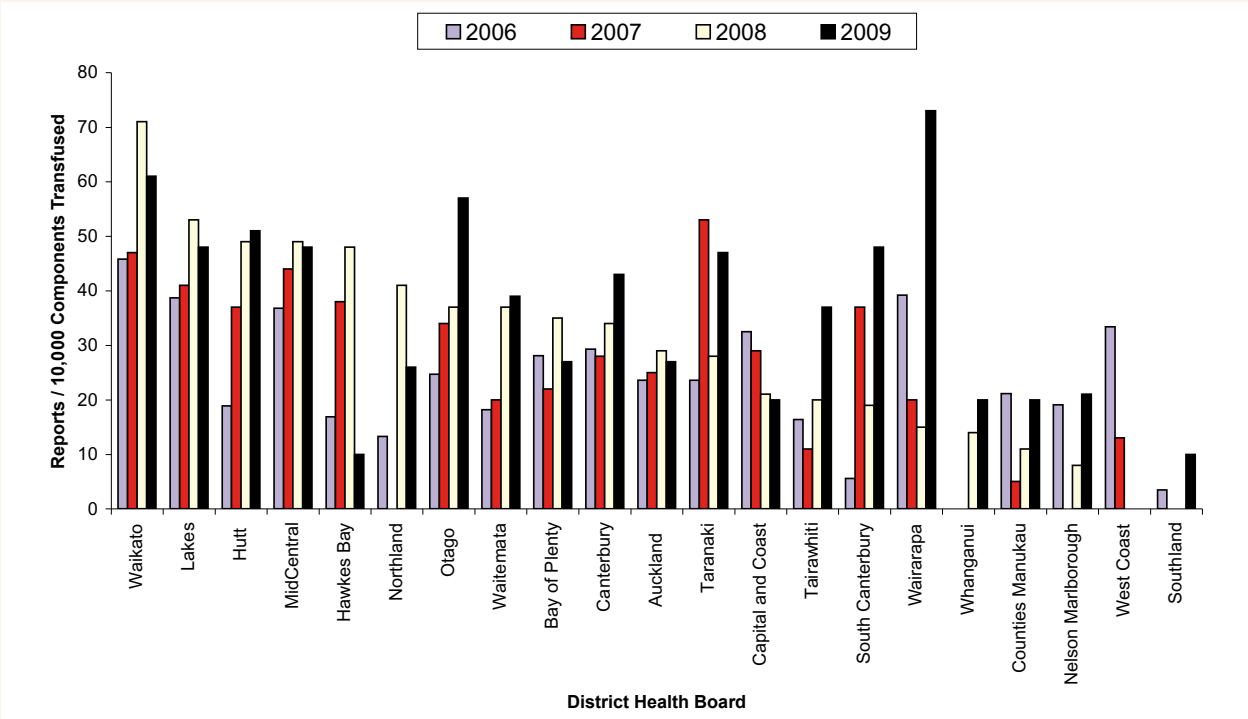
continued

Figure 6. Reports per DHB for 2009 vs Blood Components Transfused



The trend of events reported annually by each DHB since 2006 is shown in Figure 7. The data may be useful to monitor changes within individual DHBs, e.g. reporting trends may be influenced by regional changes in staffing, reporting procedures/policies, education etc.

Figure 7. Reported Events per Annum 2006 – 2009 by DHB



7. Reported Events by Type of Blood Component

In New Zealand reactions are consistently more frequently reported in association with transfusion of platelet components, compared to other blood components (excluding cryodepleted plasma, as the numbers are very small). Table 7 shows the frequency of reported reactions by type of blood component.

Table 7. Reported Events 2009 by Type of Blood Component

Component	Number Transfused	Number Events*	Frequency	Per 10,000 Units Transfused
Red Cells	124,004	420	1:295	34
Platelets - apheresis	7,571	54	1:140	71
Platelets - pooled	5,326	32	1:166	60
Fresh frozen plasma	20,006	68	1:294	34
Cryoprecipitate	2,869	6	1:478	21
Cryodepleted plasma	517	5	1:103	97

**includes events where multiple components transfused*

Overall, 71% reports were associated with red cell transfusion, 10% were associated with platelet transfusion and 10% were associated with plasma (FFP, cryoprecipitate and cryodepleted plasma). The type of reported event per type of blood component transfused is shown in Table 8.

Table 8. Type of Adverse Event by Blood Component Type 2009

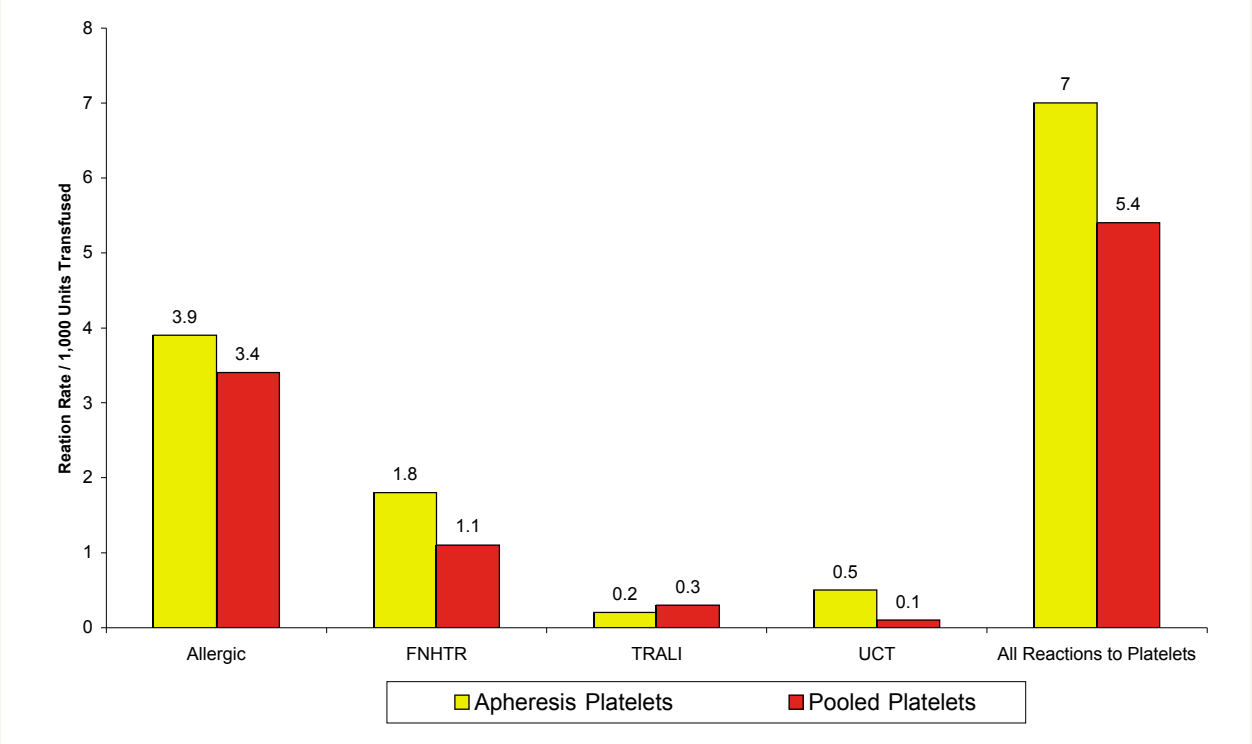
	Red cells	Fresh frozen plasma	Platelets apheresis	Platelets pooled	Cryoprecipitate	Crypdepleted plasma	Other*	Multiple components
Acute haemolytic	1							
Allergic	63	34	21	14	1	5		16
Component related	1							
Delayed haemolytic	3							
Delayed serological	15							
Hypotension	9	1	3	1				1
IBCT	13	8	2				13	
Near Miss	2							
FNHTR	211	1	10	3	1			9
UCT	43	1	2				2	2
TACO	19	2						3
TAD	11	2		1				1
TRALI								1
TTI	1			1				
Total (n=554)	**392**	**49**	**38**	**20**	**2**	**5**	**15**	**33**

**includes events associated with fractionated plasma products*

7. Reported Events by Type of Blood Component continued

Since data collection began five years ago the rate of reported events is observed to be more frequently associated with apheresis platelet transfusion compared to pooled platelet transfusion. Analysis of cumulative data from 2006 to 2009 show a statistically significant difference (p = 0.01) between the total reported reactions for apheresis platelets and pooled platelets. The reason for this is unclear. The data is shown in Figure 8.

Figure 8. Adverse Events Associated with Platelet Transfusion 2006 - 2009



	Apheresis PLTs	Pooled PLTs	p value
Allergic reactions	113	67	0.175
FNHTRs	52	22	0.027
TRALI	7	5	0.466
UCT	14	1	0.002
All reactions to PLTs	203	107	0.013

8. Recipient Related Data for Reported Events

The age and sex distribution of recipients with reported events in 2009 (Figure 9) is similar to that from previous years. Adverse events were more frequently reported in recipients of platelets (Table 9).

Overall 1 in 68 blood component recipients had an adverse event reported in 2009. Again febrile and allergic reactions were the most frequently reported reactions amongst blood component recipients (Table 10).

Figure 9. Age and Sex of Recipients of Adverse Events 2009

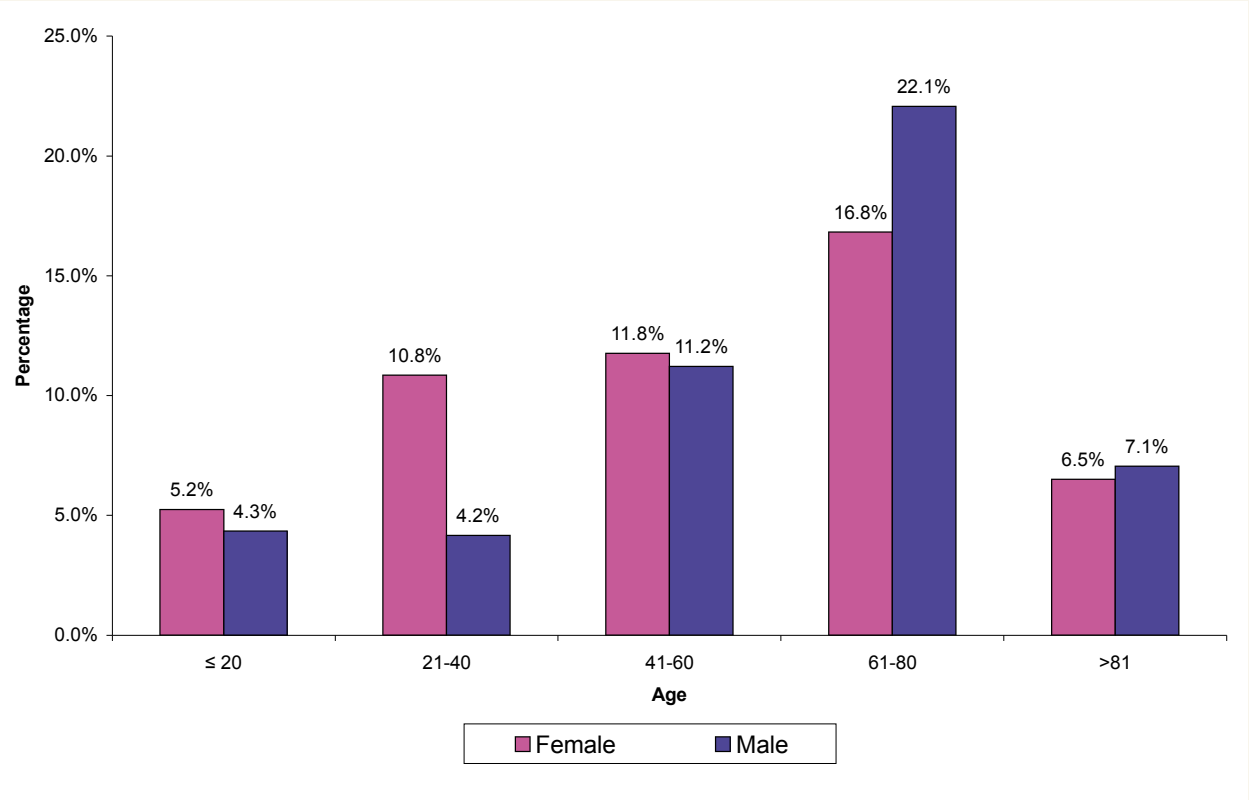


Table 9. Adverse Event by Blood Component per Recipient 2009

	Recipients	Number Events	Frequency	Per 1,000 Recipients
Red cells	28,118	420	1:67	15
Platelets	3,535	86	1:41	24
Fresh frozen plasma	4,941	68	1:73	14

8. Recipient Related Data for Reported Events continued

Table 10. Types of Adverse Reactions Reported in Recipients 2009

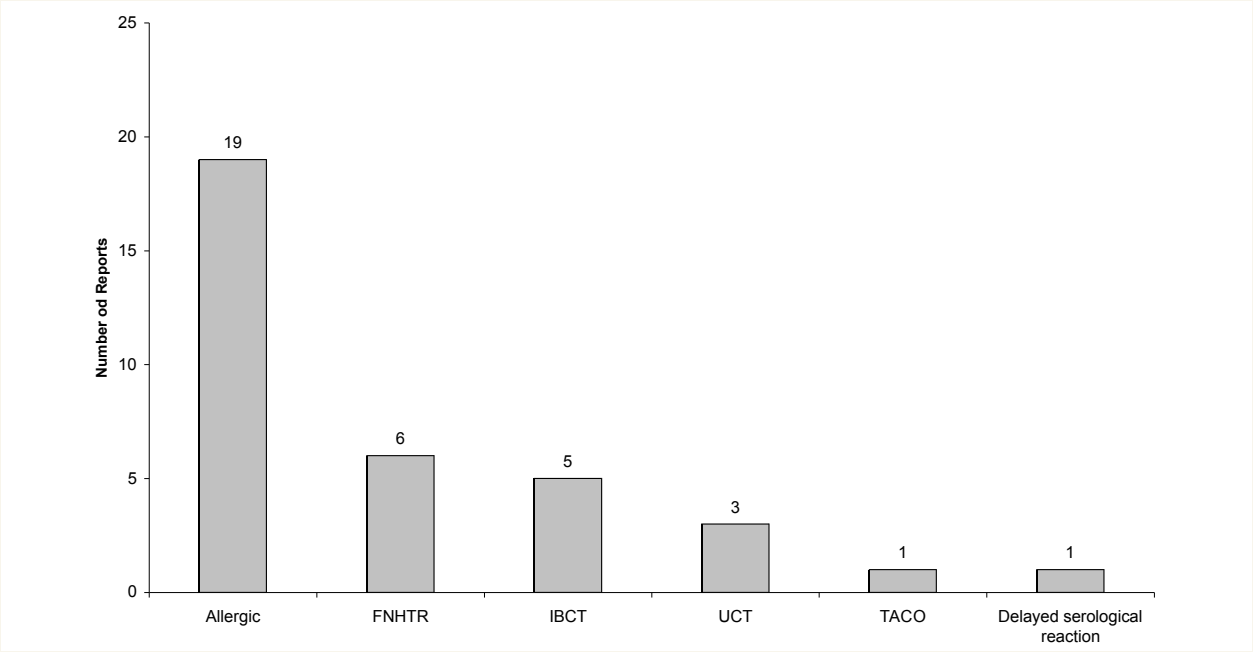
Event	Number	Frequency
FNHTR	235	1:156
Allergic	154	1:238
UCT*	48	1:762
TACO	24	1:1,525
IBCT*	23	1:1,591
Delayed serological reaction	15	1:2,240
Hypotension	15	1:2,440
TAD	15	1:,2440
Delayed haemolytic reaction	3	1:12,198
Near miss	2	1:18,297
TTI (bacterial, viral, parasitic)	2	1:18.297
Acute haemolytic	1	1:36,594
Component related	1	1:36,594
TRALI	1	1:36,594
All	**539**	**1:68**

** Excludes adverse events associated with fractionated products*

The pre-transfusion haemoglobin level was reported in 90% of events associated with red cell transfusion. The mean pre-transfusion haemoglobin was 79g/L.

During 2009 35 (6%) reports involved recipients under the age of 15 years (14 male, 21 female). Allergic reactions were the most frequently reported type of event (Figure 10).

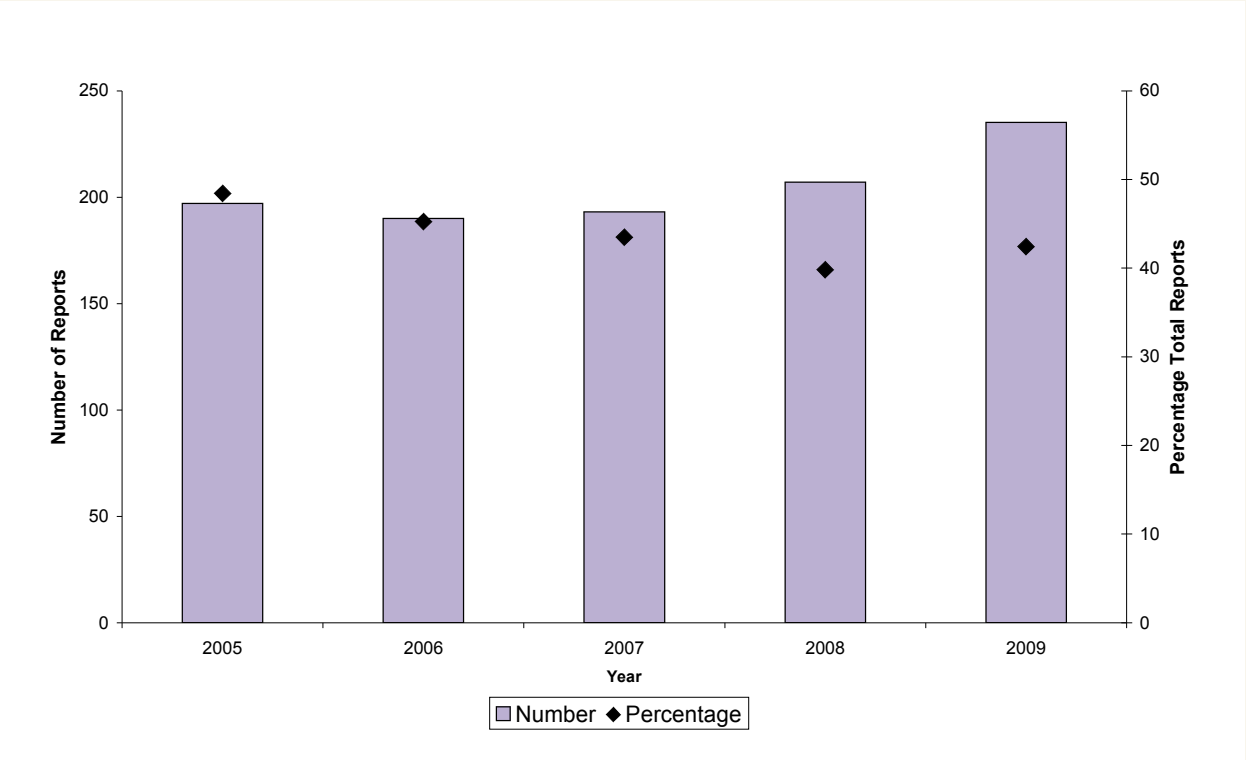
Figure 10. Reported Events in Paediatric Recipients 2009



9. Febrile Non-Haemolytic Transfusion Reactions (FNHTRs)

Febrile reactions are the most frequently reported type of transfusion reaction overall (42%). The total number for FNHTRs reported during 2009 increased by 28 from 2008 (Figure 11). Most (99%) of the febrile reactions were mild i.e. severity grade I (Table 5).

Figure 11. Total Annual FNHTRs Reported 2005 – 2009



The International Society of Blood Transfusion (ISBT) working party on haemovigilance recommends (2006) that for the purpose of international comparisons, only the most severe cases of FNHTR be reported; i.e. fever ≥ 39°C and change of ≥ 2°C from pre-transfusion value and chills/rigors. During 2009 84 reports of FNHTR were associated with a temperature rise of ≥ 2°C and 35 reports included fever ≥ 39°C.

There were similar numbers of males and females with reported febrile reactions, with a mean age of 60 years (Table 11).

Table 11. Age and Sex of Patients with Reported FNHTRs 2009

	Number	Age (years)			
		Mean	Median	Minimum	Maximum
Female	112	57	62	2	97
Male	123	61	64	14	94
All	**235**	**60**	**64**	**2**	**97**

10% of reports classified as FNHTRs were considered to be unlikely to be attributable to transfusion or a transfusion cause excluded. Imputability scores are shown in Table 3.

Each year a number of FNHTR reports include other symptoms and signs. Tachycardia, hypertension and dyspnoea are the most frequently reported other signs/symptoms associated with febrile reactions. These are listed in Table 12.

9. Febrile Non-Haemolytic Transfusion Reactions (FNHTRs) continued

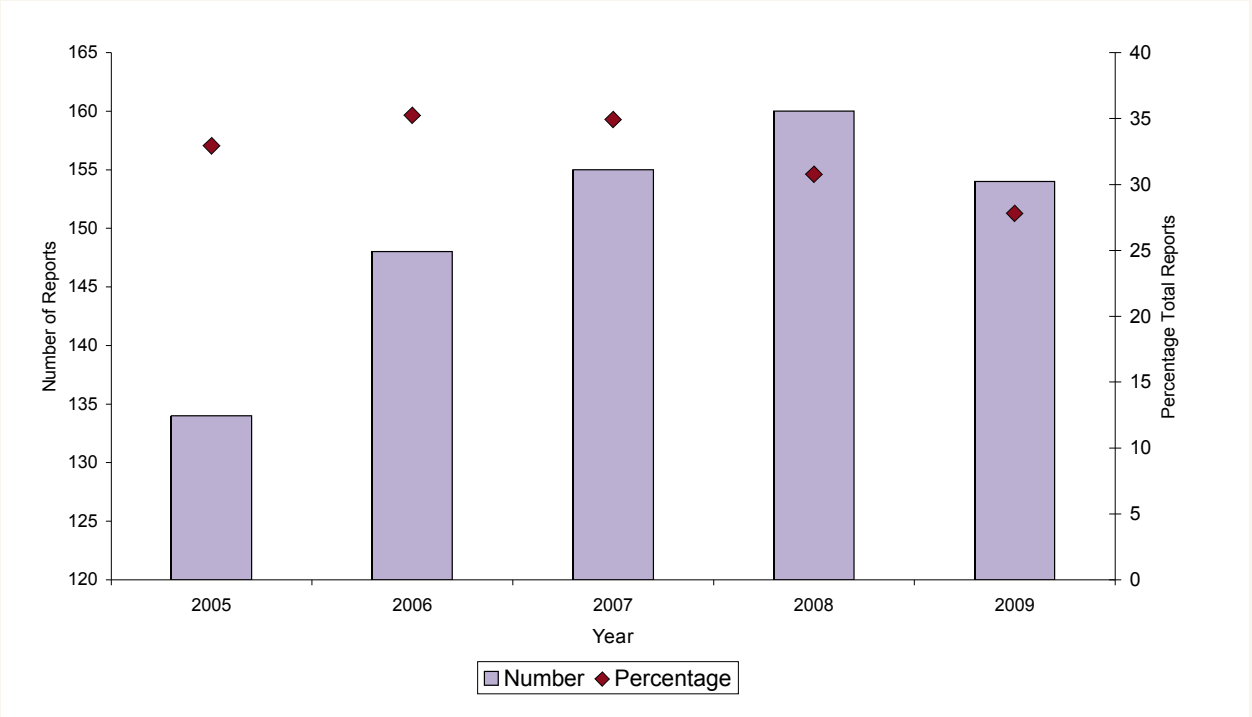
Table 12. Other Signs & Symptoms Associated With FNHTRs 2009

Sign/symptom	Number
Hypertension	44
Hypotension	11
Tachycardia	50
Dyspnoea	23
Chest pain	8
Nausea/vomiting	5
Stridor/wheeze	5

10. Allergic Reactions

Allergic reactions comprised 28% of overall reports in 2009 and was the most frequent type of reaction reported in paediatric recipients (Figure 10). The total annual reported allergic reactions for 2005 to 2009 are shown in Figure 12. During 2009 73% of the total reported allergic reactions were mild and 27% were severe or life-threatening (Table 5). 4% reports were excluded or unlikely to be related to the transfusion and 81% reports were probably or definitely caused by the transfusion (Table 3).

Figure 12. Total Annual Allergic Reactions 2005 – 2009



10. Allergic Reactions continued

There were 154 reported allergic reactions in 2009. These occurred with similar frequency between male and female recipients. The mean recipient age was 49 years and the recipient age range was 0 – 88 years (Table 13).

Table 13. Age & Sex of Recipients with Reported Allergic Reactions 2009

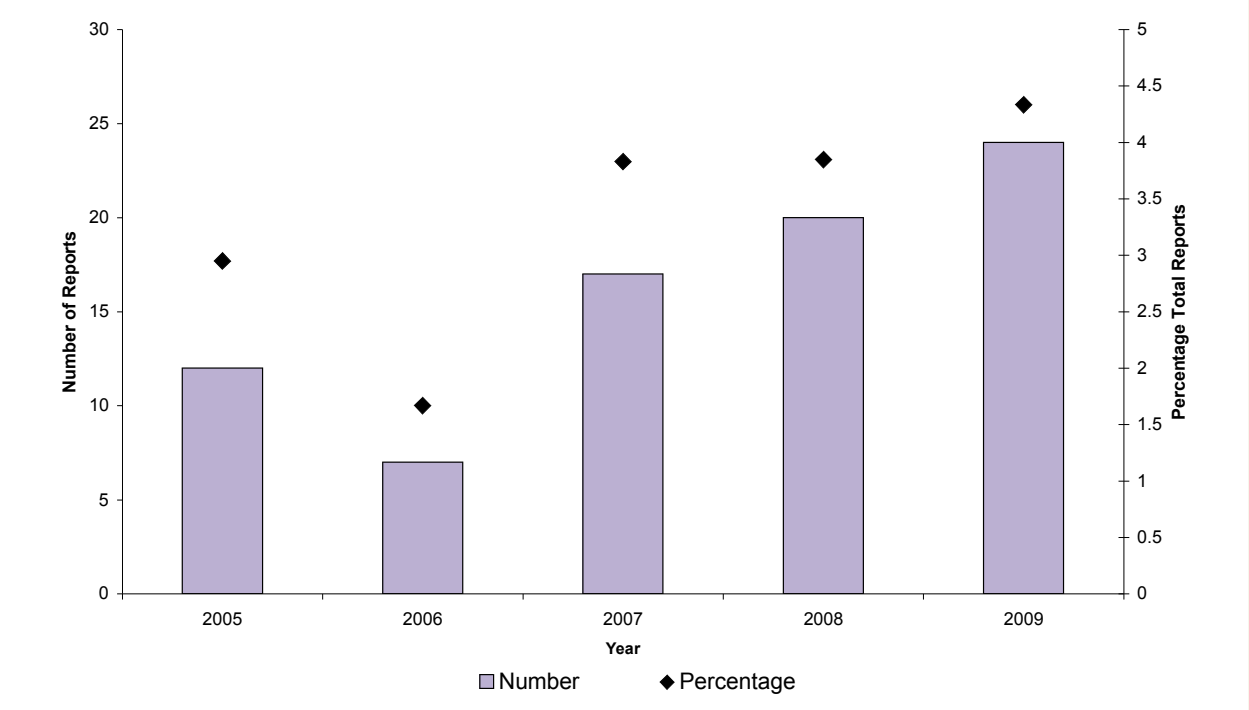
	Number	Age (years)			
		Mean	Median	Minimum	Maximum
Female	81	46	45	<1	88
Male	73	53	59	4	82
All	**154**	**49**	**52**	**<1**	**88**

74% of reported allergic reactions had urticaria and 23% had a non-urticarial rash. Other reported features include hypertension (6%), hypotension (10%), tachycardia (18%), dyspnoea (18%), stridor/wheeze (12%), fall in O_2 saturation (8%), periorbital oedema (5%), gastrointestinal symptoms (3%), pruritus (2%), lip/tongue swelling (2%) flushing (3%) and headache (one report).

11. Transfusion Associated Circulatory Overload (TACO)

There were 24 reports of TACO during 2009, involving 10 female and 14 male recipients. The mean recipient age was 65 years and the age range was 1 – 93 years (Table 14). Figure 13 shows the total annual reports for TACO from 2005 to 2009. Most of the reported cases of TACO (79%) were associated with the transfusion of red blood cells (Table 8).

Figure 13. Total Annual Report of TACO 2005 – 2009



11. Transfusion Associated Circulatory Overload (TACO) continued

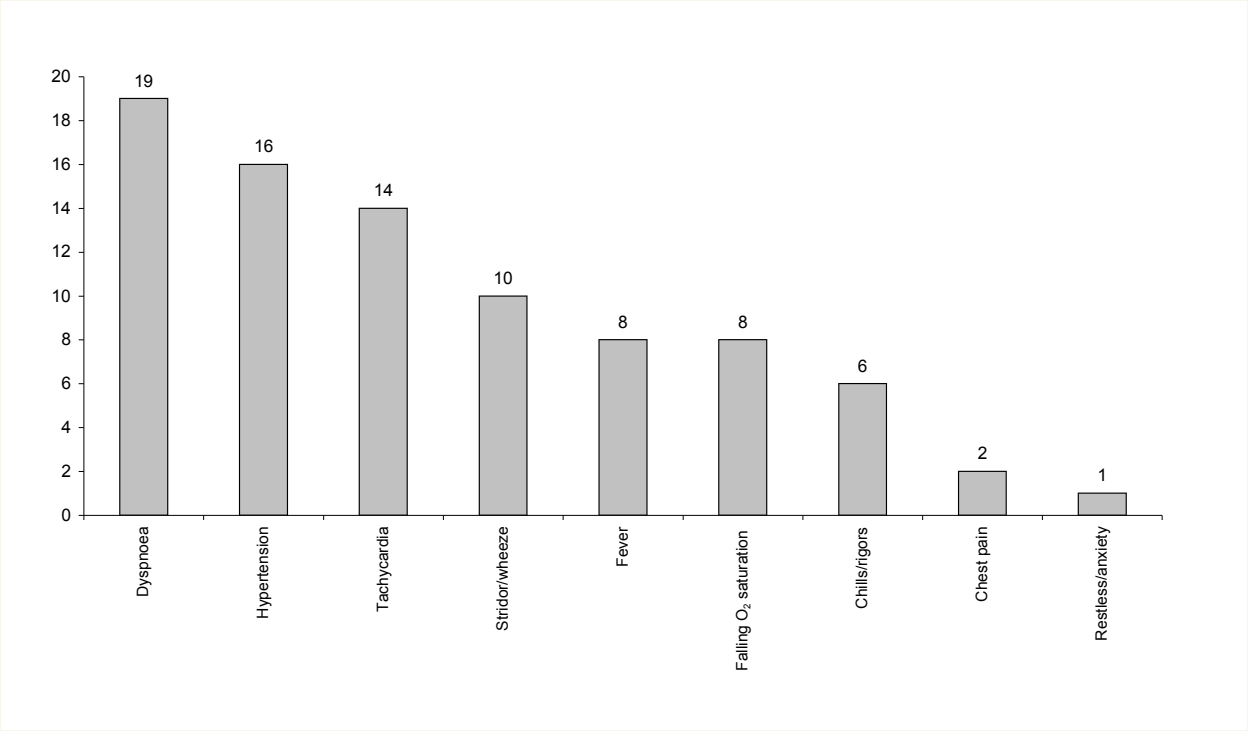
Table 14. Age & Sex of Recipients With Reported TACO 2009

	Number	Age (years)			
		Mean	Median	Minimum	Maximum
Female	10	61	65	18	93
Male	14	68	77	1	87
All	**24**	**65**	**75**	**1**	**93**

Imputability scores for reported TACO are shown in Table 3. 75% reports were probably or definitely caused by transfusion and 25% reports were possibly attributable to transfusion.

25% of reported TACO cases were not severe and 75% were severe or life-threatening (Table 5). Dyspnoea, hypertension and tachycardia were the most prominent features of TACO (Figure 14). Eight patients had a history of a cardiac condition and/or congestive cardiac failure, 5 patients had cancer and 5 patients had a history of renal failure.

Figure 14. Clinical Features of TACO 2009



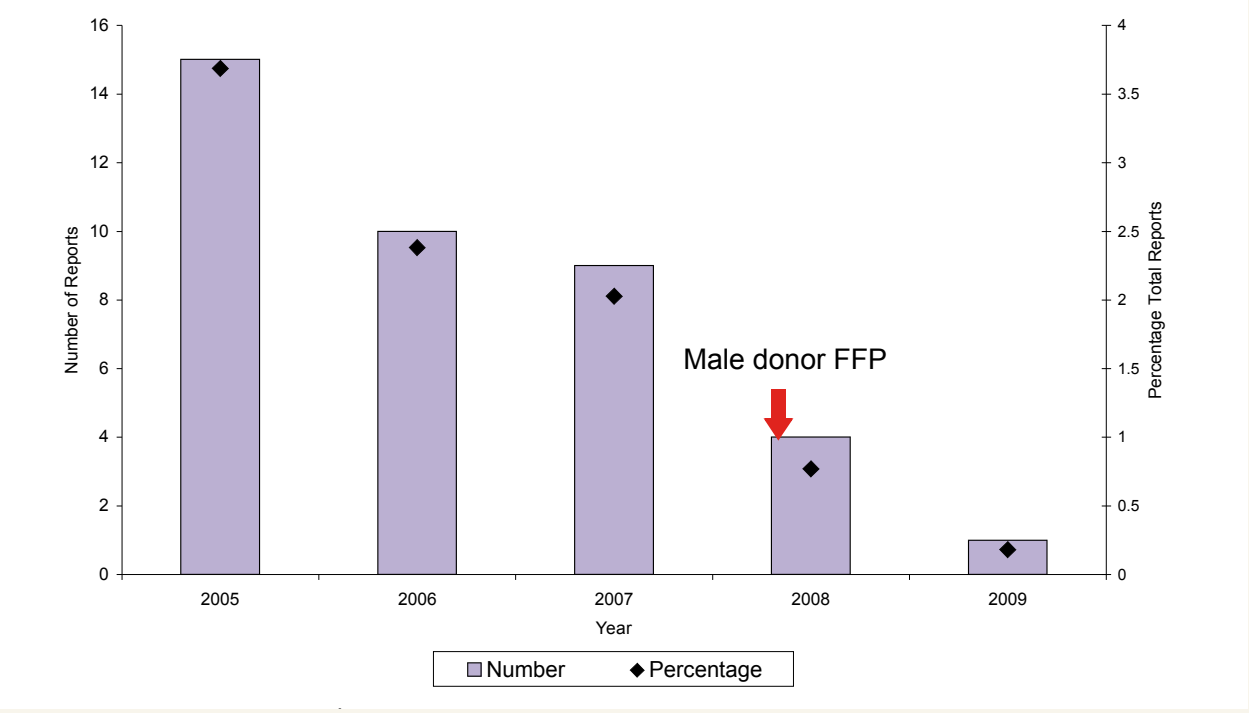
12. Transfusion Related Acute Lung Injury (TRALI)

The pathogenesis of TRALI in many cases can be explained by white cell antibodies in donor plasma reacting with recipient neutrophils, leading to damage to pulmonary vascular endothelium and protein-rich oedema fluid in the alveoli. TRALI cases occur more frequently with transfusion of plasma-containing blood components. White cell antibodies may be detectable in donors who are multiparous or have previously been transfused. There has been a significant reduction in the reports of TRALI in New Zealand since the implementation of male donor plasma early in 2008 (Table 15 & Figure 15).

Table 15. TRALI Reports by Time Period

Time Period	TRALI reports	p value
2006 - 2007	19	0.002
2008 - 2009	5	

Figure 15. Total Annual Reports of TRALI 2005 – 2009



(2005 corrected for 12 month period)

During 2009 there was one haemovigilance notification of TRALI. The case is summarized below.

A 75 year old man with a prior history (5 months earlier) of septic arthritis (*Staphylococcus aureus)*, developed endocarditis involving the aortic valve. He initially responded well to antibiotic therapy however became unwell with aortic regurgitation and congestive heart failure. He was readmitted to hospital for aortic valve replacement. The procedure was carried out without any problems. He had detectable anti-c and auto-reactive red cell antibodies. Compatible red cell units were available and 3 units of red cells were transfused. He was transferred post-operatively to the Intensive Care Unit and remained stable for several hours. However he had approximately 1000mL blood loss from his chest drains and was transfused 2 units of FFP and 1 pooled platelet concentrate. One wheal was noted on his shoulder. Within 20 minutes he became unstable and the following findings were noted:

- profuse amount of pulmonary oedema coming out of the endotracheal tube, bilateral pulmonary oedema seen on chest xray
- mean arterial pressure decreased from 65 → 45 mmHg, increased inotropic support and oxygen required
- a transthoracic echocardiogram showed highly inflated lungs on both sides and the heart could not be seen
- a transoesophageal echocardiogram showed a very contractile left ventricle with a well-functioning aortic valve
- no cardiac tamponade

12. Transfusion Related Acute Lung Injury (TRALI) continued

Although there was no clear surgically rectifiable situation he was taken back to the operating theatre and re-opened because he was very unstable. There was some blood in front of the heart and about 500mL in the right chest. The lungs were highly inflated and continued to distend. The heart was relatively empty. The lung inflation pressures increased to 70 – 80 mmHg which was a lot higher than the aortic systolic pressure (50 – 60 mmHg). His blood pressure rapidly decreased and internal cardiac massage was instituted along with boluses of adrenaline. Both lungs continued to distend and the patient was declared deceased after approximately 25 minutes. After discussion with the coroner a decision was made to issue a death certificate with the cause of death as a reaction to a blood product.

The report was classified as probable TRALI, severity grade IV (death).

Investigation of donors

Both units of FFP were produced from male donors with no history of transfusion. The pooled platelet concentrate was produced from buffy coats from 3 male donors plus one buffy coat and plasma from a female donor. The female donor had detectable Class I & II HLA antibodies and was retired from donating.

It is interesting to note that the 2 reports of probable TRALI in 2008 were associated with the transfusion of platelets and in both cases, female donors with detectable white cell antibodies were implicated. The other 2 cases of TRALI in 2008 had lower imputability scores. The New Zealand Blood Service has commenced testing female platelet donors for white cell antibodies. The results of this study will influence whether further strategies need to be employed to further reduce the residual risk of TRALI in New Zealand.

13. Transfusion Associated Dyspnoea (TAD)

During 2009 there were 15 reports of TAD. Ten involved female recipients and five male recipients. The mean age was 64 years with a range of 20 – 84 years. Two cases were excluded (Table 3) and most (73%) were mild in severity (Table 5). Three patients had sepsis, five patients had recent surgery and seven patients had cancer. In most cases the symptoms may have been attributable to the transfusion or an alternative cause.

14. Hypotensive Transfusion Reactions

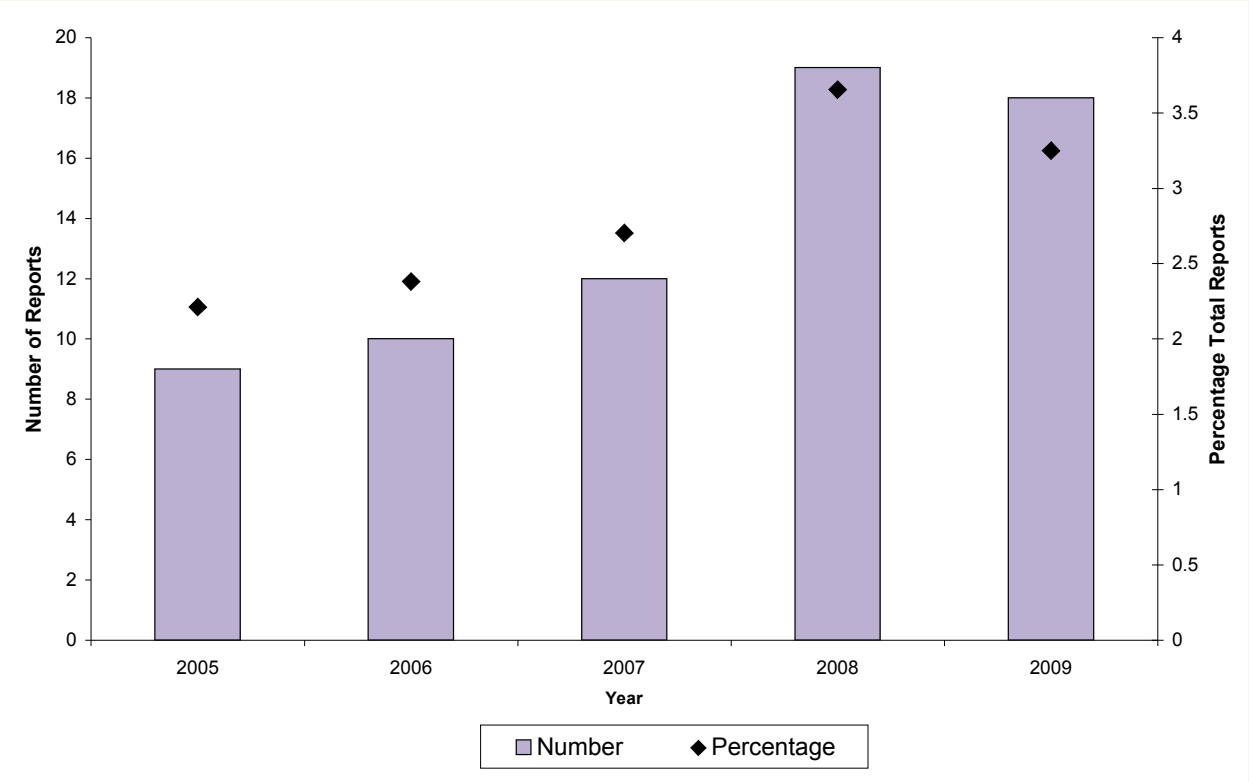
During 2009 there were 15 reports of hypotension associated with transfusion (involving 7 female and 8 male recipients). The mean age was 66 years and the range was 19 – 89 years. Two reports were excluded (Table 3) and 67% were classified as severe (Table 5). Five patients were under general anaesthesia and 2 patients had a non-urticarial rash. Eight patients had surgery, three involved cardiopulmonary bypass.

15. Delayed Haemolytic Transfusion Reactions (DHTRs)

Delayed haemolytic transfusion reactions are often identified and reported by blood banks when red cells are requested for a patient who has been recently transfused, and a new red cell antibody is identified in the pre-transfusion (crossmatch) sample, which was not detectable prior to the recent transfusion. These patients may have formed the red cell antibodies following previous pregnancy or transfusion and the recent red cell transfusion stimulated an anamnestic response with an increase in the antibody concentration. These antibodies generally cause extravascular haemolysis. Alloantibody production may be stimulated without evidence of haemolysis. Reports are sub-categorised as delayed serologic transfusion reactions (DSTRs) when there are no clinical or laboratory signs of accelerated destruction of red cells.

During 2009 there were 3 DHTRs and 15 DSTRs reported to the Haemovigilance programme. These involved 8 female and 10 male recipients. Figure 16 shows the total annual delayed reactions from 2005 – 2009.

Figure 16. Total Annual Delayed Reactions 2005 – 2009



Three patients had two new red cell antibodies. Table 16 shows the specificity of the red cell antibodies for the reported DHTRs and DSTRs during 2009. Rh antibodies were the most common specificity (56%), followed by Kidd (anti-Jka 22%).

15. Delayed Haemolytic Transfusion Reactions (DHTRs) continued

Table 16. Specificity of Red Cell Antibodies in Delayed Reactions 2009

	Antibody	Number
Delayed haemolytic transfusion reactions	C + e	1
	c	1
	Fy^a	1
Delayed serological transfusion reactions	E	5
	Jk^a	4
	C + e	2
	K	2
	c	1
	S	1

From 2006 to 2009, 59 delayed reactions were reported. These include 74 new red cell antibodies identified in 59 transfusion recipients. The most frequent alloantibodies identified were anti-Jk^a and anti-E (20% each) followed by anti-K (12%). Cumulative data (2006 – 2009) for red cell antibody specificities are shown in Figure 17 and by blood group is shown in Figure 18.

Figure 17. Antibody Specificities for Delayed Reactions 2006 – 2009

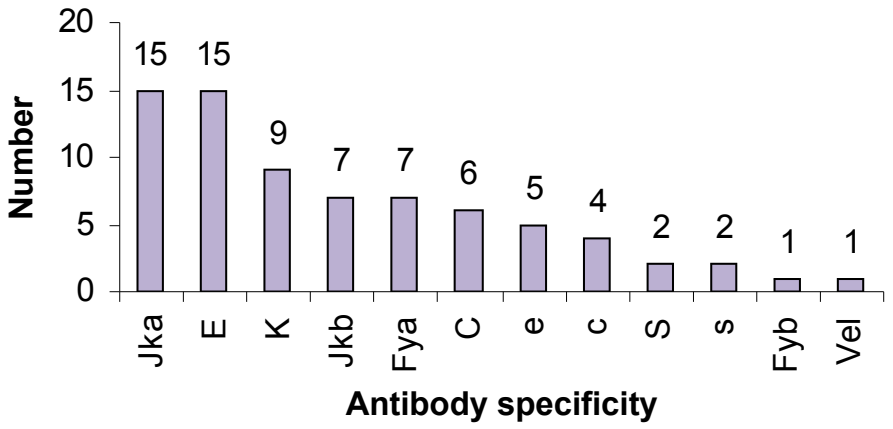
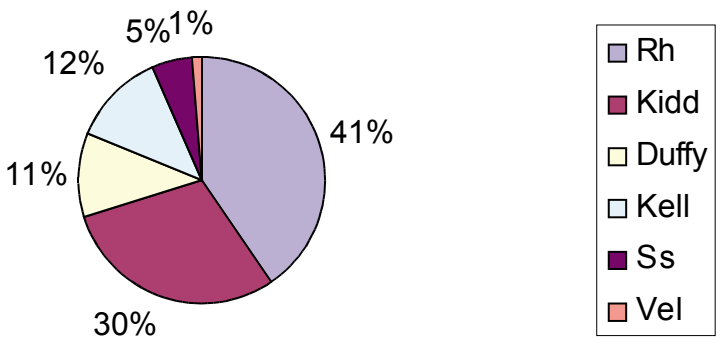


Figure 18. Antibody Blood Groups for Delayed Reactions 2006 – 2009



16. Acute Haemolytic Transfusion Reactions (AHTRs)

There was one report of an AHTR reported to the Haemovigilance Programme during 2009. The report was received 6 weeks after the incident and involved a 70 year old female (Mrs A) with a history of acute epistaxis, anaemia (haemoglobin 71g/L), chronic renal failure and hypertension. The patient's pre-transfusion sample was tested using an automated method but the analyser was not interfaced with the blood bank computer. A manual reading of the patient's blood group was done from a printout. Two printouts were misread as group "AB" on the printout. Two units of group AB red cells were issued to Mrs A. After 100mL was transfused she developed chills, rigors, dyspnoea, loin pain, vomiting, haemoglobinuria, anxiety and hypertension (blood pressure increased from 157/76 to 186/90 mmHg). There was no change in temperature or heart rate. The scientist realized that the correct blood group on the printout was group A and that incompatible units had been issued. No serological investigations were performed. Mrs A recovered after approximately 6 hours.

Although there was no laboratory evidence of acute haemolysis, the clinical features in the context of ABO incompatible transfusion was deemed sufficient to classify the event as an AHTR, severity grade II.

Learning points

- Errors can occur in the laboratory. Always be vigilant about clerical checking procedures and monitoring for reactions.
- Manual entry of blood group results should be verified by a second blind entry, which wherever possible should be carried out by a second operator.
- The laboratory should have excluded incompatibility between Mrs A and the donor units using crossmatching techniques such as immediate spin or IAT crossmatch.
- Electronic crossmatching (selection and issue of units without serological testing) is only permissible where a completely automated system for ABO/D testing exists, i.e. there is no manual step or clerical input into the process from the entry of the sample for testing into the laboratory system, until the final result is obtained and downloaded into the laboratory computer record.[1,2.]
- Robust procedures and strict adherence to protocols are essential to ensure safe practice. This event should have been fully investigated and notified promptly.

1. BCSH guidelines "The specification and use of Information Technology (IT) systems in Blood Transfusion Practice" (2006). www.bschguidelines.com
2. ANZSBT Guidelines for Pretransfusion Laboratory Practice (2007). www.anzsbt.org.au

17. Unclassifiable Complications of Transfusion (UCT)

During 2009 there were 50 reports received by the Haemovigilance Programme which could not be classified according to an already defined event. Previously these were categorised as “other notifications”. Of the 50 reports, 46% were unlikely to be attributable to the transfusion or excluded. 22 events were possibly related to the transfusion and 5 events were probably related to the transfusion (Table 3). These 27 events are summarized in Table 17.

During 2009 there were 17 reports of pain associated with transfusion, 6 of which were excluded from analysis. In 2008 there were 14 reports of pain notified to the Haemovigilance Programme. Pain at IV infusion sites is likely to be related to potassium which increases in stored and/or irradiated red cell units and is irritant to the veins. Two patients had their transfusion stopped, with resolution of pain and recurrence when the transfusion was resumed either via the same line (after flushing with saline) or at a new IV site. The explanation for other acute pain transfusion reactions in the absence of haemolysis, is yet to be elucidated.

Table 17. UCT Events Possibly or Probably Related to Transfusion 2009

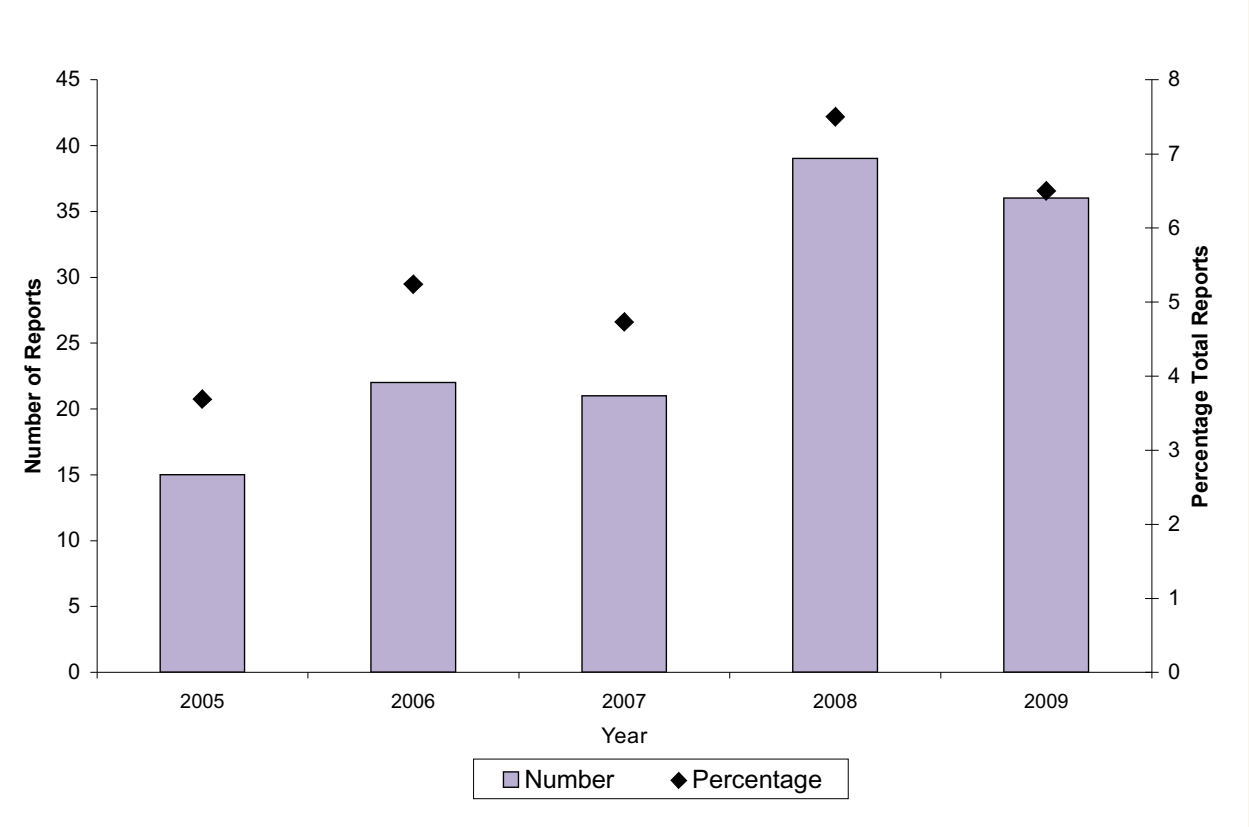
Reaction		Number of reports	Component transfused
Tachycardia		5	RBCs
Hypertension		5	RBCs
Pain	Chest pain	5	RBCs
	Abdominal pain	1	RBCs
	Headache	1	RBCs
	Upper resp tract	1	Platelets
	Infusion site	3	RBCs
Generalised paraesthesiae		1	RBCs
Nausea		1	RBCs
Jaundice		1	RBCs
Cardiorespiratory arrest		1	RBCs
Syncope		1	Platelets
Anaphylaxis		1	Bone graft*
TOTAL		27	

*1st report of reaction to allogeneic bone graft to Haemovigilance Programme

18. Incorrect Blood Component Transfused (IBCT)

IBCT is defined as a transfusion where the blood product was intended for another patient or did not meet the appropriate requirements. During 2009 36 reports were classified as IBCT, and seven reports were excluded from analysis. These 7 reports came from one hospital (submitted by the Transfusion Nurse Specialist) and comprised 4 reports of "underdosing" of FFP, 2 reports of inappropriate use of FFP and 1 report of inappropriate use of red cells. Figure 19 shows the total annual reports of IBCT from 2005 to 2009.

Figure 19. Incorrect Blood Component Transfused (IBCT) 2005 – 2009



Of the 29 events analysed, 59% were laboratory errors, 17% prescribing errors and 24% occurred during the administration of the blood product. Seven reports related to Rh D immunoglobulin (Rh D Ig) and three involved ABO incompatible transfusions.

18. Incorrect Blood Component Transfused (IBCT) continued

Table 18 shows the breakdown of errors that originated in the blood bank. A number of these involved the blood bank computer system, e.g. blood components required during an outage therefore specific transfusion protocols were not observed.

Table 18. Blood Bank Errors 2009

Event	Number
Pre-transfusion sample validity expired, red cells issued & transfused	3
Expired product issued & transfused (Tetanus Ig)	1
Wrong ABO group product issued & transfused 1. 2 units group O FFP to a group A patient inadvertently 2. Group O platelets to a stem cell transplant recipient, where group A indicated	2
Wrong blood product issued 1. Factor IX requested for a child, MonoFIX (plasma product) issued & transfused instead of BeneFIX (recombinant) 2. 4 vials MonoFIX (2000IU) issued & transfused instead of Prothrombinex, for warfarin reversal 3. Red cells issued & transfused instead of FFP	3
Wrong dose issued (250IU Rh D Ig instead of 625IU)	1
Failure to follow protocol 1. Irradiation of red cells indicated 2. Compatibility testing (phenotyping & IAT crossmatch) 3. Ordinary platelets issued & transfused instead of 2 units of reserved HLA matched platelets	4 2 1
Total	**17**

The prescribing errors are shown in table 19. Four of five prescribing errors were related to Rh D Ig.

Table 19. Prescribing Errors 2009

Event	Number
4000IU Prothrombinex prescribed for a bleeding patient, INR 1.0, patient not on warfarin, 3500IU (7 vials) transfused	1
250IU Rh D Ig requested for a patient at 16/40 gestation, error identified and additional 625IU Rh D Ig issued	1
Rh D Ig given to Rh D positive recipient	3
Total	**5**

18. Incorrect Blood Component Transfused (IBCT) continued

Current ANZSBT Guidelines require that two members of staff shall be responsible for carrying out the identity check of the patient and the blood component at the patient's bedside prior to transfusion. In addition the patient's consent and the prescription must also be checked. Wrong blood transfusions show that these checking procedures are not universally followed. There were 7 reports where the wrong patient was transfused in 2009 (Table 20). Two of these involved Rh D Ig.

Table 20. Blood Products Administered to the Wrong Patient 2009

1	Biostate issued to Patient A administered to Patient B
2	Biostate issued to Patient B administered to Patient A, 1 vial found in the ward fridge after 1 year
3	Emergency O negative red cells issued to an unknown patient were transfused to another patient, both patients died (trauma)
4	FFP transfused to wrong patient (FFP = group A, patient = group B)
5	Red cells transfused to the wrong patient (group O red cells)
6	625IU Rh D Ig given to another patient with the same first name, in a shared room, recipient Rh D positive
7	Rh D Ig issued to Patient X given to Patient Y(Rh D negative), both patients having termination of pregnancy

19. Near Miss Events

A near miss event is an error or deviation from standard procedures or policies that is discovered before the start of the transfusion and that could have led to an inappropriate transfusion or reaction in the recipient. These events are usually reported to local incident management systems so that root cause analysis can be undertaken and preventive action and education can be implemented to reduce the risk of harm in transfusion recipients. There were 56 incidents involving near miss events recorded in the New Zealand Blood Service database representing incidents from 4 blood processing centres and 6 hospital blood banks, and two additional incidents formally reported to the Haemovigilance Programme. The 58 events are summarized in Table 21. Overall 64% of errors occurred in the laboratory (blood bank or blood processing laboratory).

Table 21. Near Miss Events 2009

Near miss event details	Number of cases
Wrong blood product issued by blood bank Includes wrong product, wrong dose or wrong patient	10
Data entry or transcription error by blood bank	5
Irradiation and labelling errors	18
Expired red cells in blood bank or ward fridge	3
Storage errors (platelets placed in refrigerator, red cells stored in wrong refrigerator, red cells packed in contact with ice ballast)	4
Wrong blood in tube	16
Patient identification incorrect	1
Wrong blood collected by after hours ward staff (for patient with same surname)	1
Total	**58**

20. Transfusion Transmitted Infections (TTIs)

During 2009 two reports of transfusion-transmitted bacterial infection were received by the Haemovigilance programme. These are summarized in Table 22. No reports of viral or parasitic TTIs were received.

Table 22. Transfusion Transmitted Infections 2009

Clinical details	Blood component	Patient culture result	Unit culture result	Imputability
38 year old male with AML, pancytopenia following chemotherapy, temperature rise 1.1°C & rigors 35 minutes after starting transfusion	Pooled platelet concentrate	Central line: 1. Coagulase negative Staphylococcus 2. Escherichia coli Peripheral blood: Escherichia coli	Coagulase negative Staphylococcus	Possible
86 year old male with AML, neutropenic sepsis; temperature rise of 2°C, 1 hour 25 minutes into 2nd unit transfusion	2 units resuspended red cells	Listeria monocytogenes	Not sent for culture, reaction reported to Haemovigilance Programme following review of case at morbidity meeting (3 months after transfusion)	Unlikely

21. 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 2010 identified 40 reported cases involving 43 recipients over a 13 year period. This included 11 deaths due to infection. 33 cases related to bacterial contamination of platelets. Similar data have 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 suit. In particular, the AABB introduced a formal requirement for screening of platelet components in 2004 and will require testing to use FDA approved systems by early 2011. The Australian Red Cross Blood Service (ARCBS) has completed implementation of a pre-release culture system across its sites in April 2008. The ARCBS system involves culture on day one post production with no quarantine of cultured platelets. Unfortunately at this stage there is no clear 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 collect) and the use of a single aerobic bottle versus both aerobic and anaerobic detection. Current 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 has increased progressively over the last two years. During 2009 approximately 85% of all apheresis collections and 81% 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 2009 is shown in Table 23.

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 BacTalert aerobic culture bottle. The bottles are cultured until a positive signal is obtained or until day 8 following collection. Platelets are available for release immediately following sampling and are withdrawn from inventory if a positive culture signal is obtained. Confirmatory testing is carried out on all samples and units where a BacTalert positive is detected. Results of testing during 2009 are shown in Table 24.

Table 23. Proportion of Platelet Components Subjected to Bacterial Culture

	APHERESIS PLATELETS			POOLED PLATELETS		
	Collections	Components tested	% Tested	Produced	Tested	% Tested
Auckland	2,318	2,113	91	4,388	3,364	77
Waikato	1,240	1,085	88	1,440	1,314	91
Wellington	860	645	75	1,528	1,237	81
Christchurch	1,217	877	72	793	726	92
Manawatu	436	418	96			
Otago	307	298	97			
TOTAL	**6,378**	**5,436**	**85**	**8,149**	**6,641**	**81**

21. Bacterial Monitoring of Platelet Concentrates continued

Table 24. Results of Day 2 Testing of Platelet Components

	TOTAL COMPONENTS SAMPLED	NUMBER POSITIVE	% POSITIVE	FREQUENCY OF POSITIVES
BacTalert positive	12,077	26	0.21	1:465
Confirmed culture positive	12,077	2	0.02	1:6,040

The data indicates that NZBS systems compare well with published data. The CoE Guide (13th Edition) identifies a confirmed positive rate of 0.2 to 0.4%.

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 25.

Table 25. Results of Testing of Expired Platelets

	TOTAL COMPONENTS SAMPLED	NUMBER POSITIVE	% POSITIVE	FREQUENCY OF POSITIVES
BacTalert positive	3,655	9	0.25	1:406
Confirmed culture positive	3,655	2	0.05	1:1,830

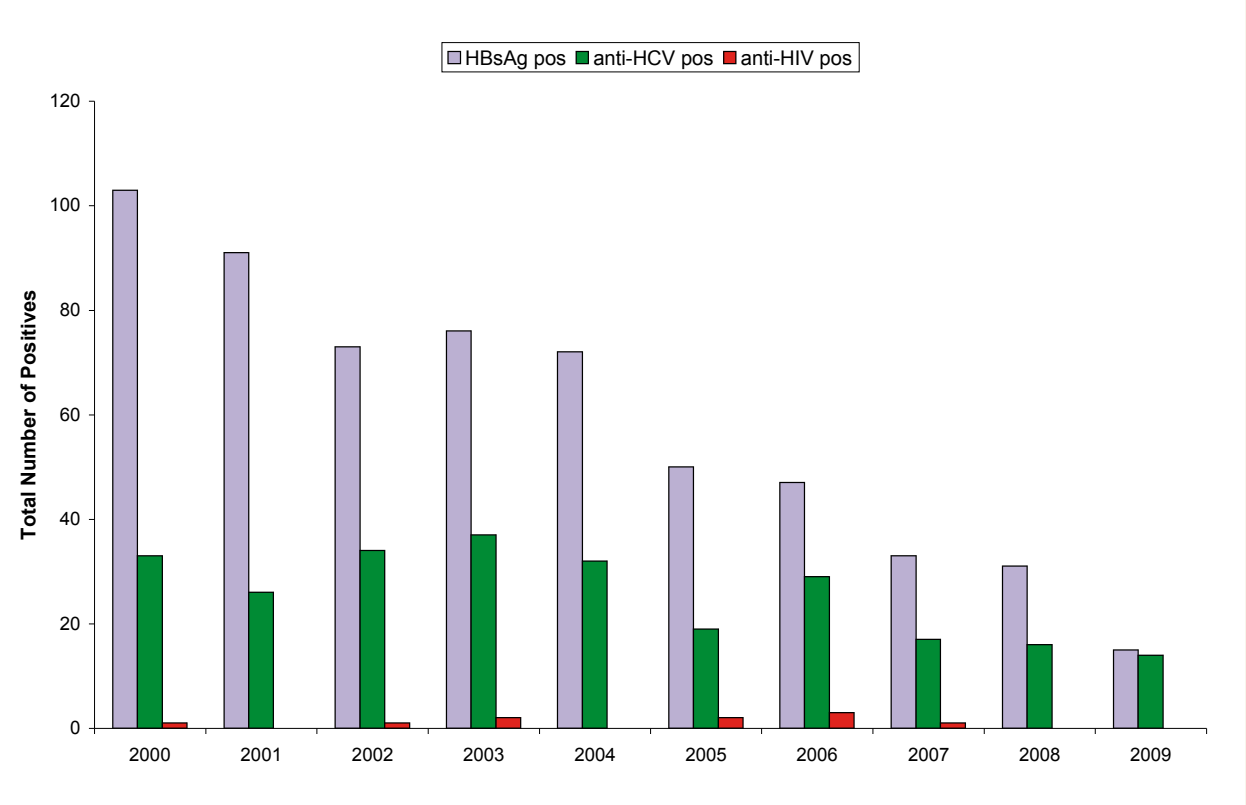
NZBS plans to continue the bacterial monitoring programme as a quality assurance tool. This is consistent with recommendations contained in the Council of Europe Guide. Current NZBS policy will be kept under review taking into account local results and clinical data, the Australian experience and any new data that suggests bacterial detection systems can be used to extend the shelf life of platelets to seven days.

22. Donor Infectious Diseases Screening

The New Zealand Blood Service has two Donation Accreditation laboratories, one is situated in the North Island (Auckland) and the other in the South Island (Christchurch). All donations are screened for hepatitis B surface antigen (HBsAg), hepatitis B DNA (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 performed on selected donations include CMV IgG, malaria and Trypanosoma cruzii antibodies.

There has been a steady decline in the number of donors with confirmed positive serology in New Zealand (Figure 20).

Figure 20. Donor Epidemiologic Data 2000 - 2009



During 2009 a total of 176,372 donations were collected from 93,316 donors. 81% of the 93,316 donors had been previously tested while 19% were previously untested (new) donors. Table 26 shows the number of donors who were confirmed positive on infectious disease testing. The confirmed positive hepatitis B cases do not include occult hepatitis B infections. There have been no confirmed HIV infections in New Zealand donors since 2007.

Occult hepatitis B infection is where there is detectable HBV DNA and undetectable HBsAg. A recent study of occult hepatitis B infection in New Zealand blood donors (n = 15) showed that 0.004% donations had occult hepatitis B infection and that 80% were repeat donors. In contrast, the majority (> 90%) of confirmed HBsAg positive donors are new donors.

During 2009 13 donors were identified to be HBV DNA positive and HBsAg negative. All donors lived in the North Island and most had donated previously.

22. Donor Infectious Diseases Screening continued

Table 26. Donors with Confirmed Positive Serology 2009

		HBV (HBsAg positive)	HCV	HIV	Syphilis	Anti-HTLV
Number		15 (14 new donors)	14 (all new donors)	0	5 (4 new donors)	2 (both new donors)
% Positive donations		0.009%	0.008%		0.003%	0.001%
Frequency of positive donation	New Donor	1:1,294	1:1,294		1:4,528	1:9,056
	Regular Donor	1:75,204			1:75,204	
Overall frequency		1:6,221	1:6,665		1:18,663	1:46,658

23. Residual Risk of Virus Transmission via Transfusion

Despite highly sensitive screening methods there is a small residual risk for blood product recipients, particularly if the donation is collected during the window period (time between infection and the first detectable viral marker). Analysis of the residual risk of viral infection from blood component transfusion in New Zealand, using mathematical modelling[1], was recently performed. Data from an eight year period including 1,307,764 donations from repeat donors and 105,726 donations from first-time donors were analysed. The residual risk estimates are shown in Table 27.

Table 27. Residual Risk Estimates for Viral TTI in New Zealand

Virus	Estimated risk per 10^6 donations (95% confidence interval)
HBV	3.4 (0.0 – 8.1)
HCV	0.4 (0.0 – 3.5)
HIV	0.2 (0.0 – 3.2)
HTLV	0.4 (0.0 – 7.8)

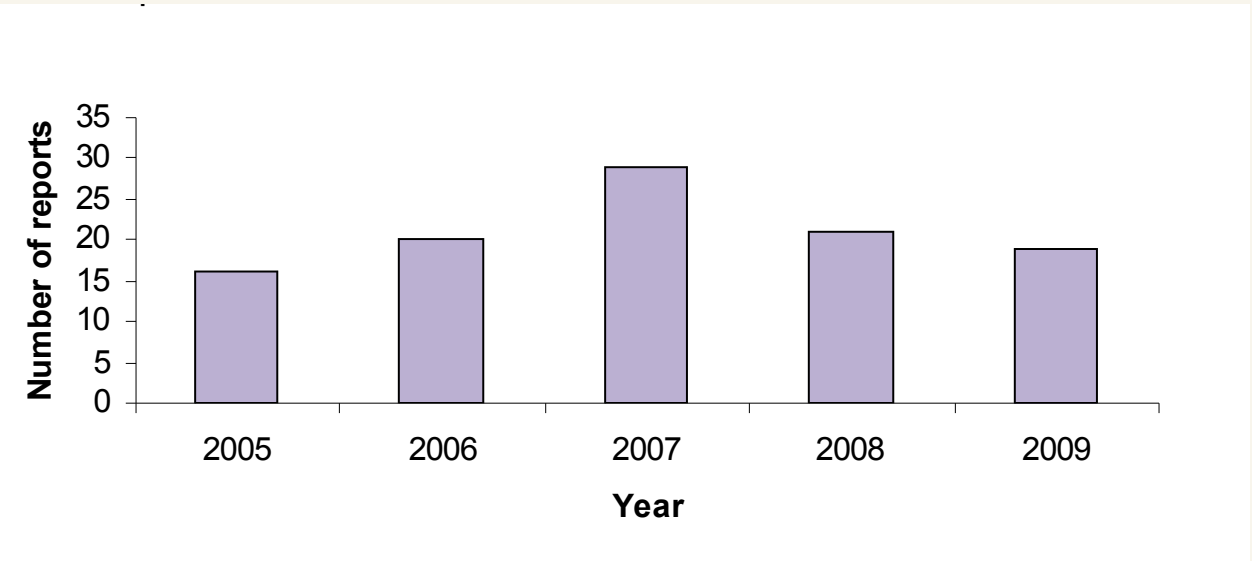
[1]Seed et al. Intern Med J 2005:35:592-598

24. Adverse Reactions to Fractionated Plasma Products

Plasma from New Zealand blood donors is pooled and fractionated into various blood products by CSL Bioplasma. These include Albumex (4% and 20%), Intragam P, Normal Immunoglobulin, Biostate, MonoFIX, Prothrombinex, Thrombotrol, Rh D Immunoglobulin, Hepatitis B Immunoglobulin and Tetanus Immunoglobulin. Zoster Immunoglobulin, WinRho SDF, Berinert P, Ceprotin, HyperHep B, Imogam Rabies, Fibrogammin and Haemocomplettan P are commercially sourced.

Adverse reactions to fractionated blood products are notified on a separate form (Appendix III). This is forwarded to the New Zealand Blood Service who collate and report data to CSL, the New Zealand Blood Service Clinical Advisory Group (NZBS CAG) and the Centre for Adverse Reactions Monitoring (CARM). This is a separate process outside the activity of the National Haemovigilance Programme and was established long before the Haemovigilance Programme commenced in 2005. The annual number of reports of reactions to fractionated products has remained low and relatively constant over the previous 5 years (Figure 21).

Figure 21. Reported Reactions to Fractionated Products 2005 - 2009



During 2009 there were 19 reported adverse reactions to fractionated products in New Zealand. These comprised 8 females (one recipient had 3 reactions) and 9 males. Most reactions (15) were associated with Intragam P, 2 with Albumex 4 and 2 with Prothrombinex. The majority of reactions (84%) were allergic in nature. Reactions to fractionated products are summarized in Table 28.

24. Adverse Reactions to Fractionated Plasma Products continued

Table 28. Adverse Reactions to Fractionated Products 2009

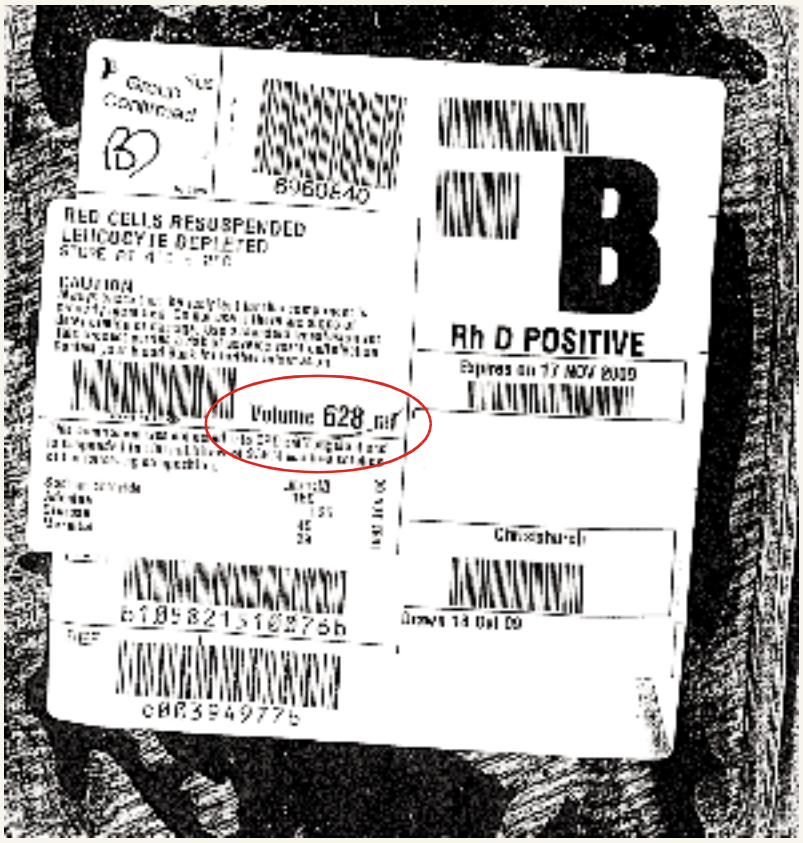
Age (years), Sex	Product	Reaction	Outcome	Causality	Seriousness
84, male	Prothrombinex	Allergic	Recovered	Highly probable	Not serious
60, female	Intragam P	Back ache, chest tightness, possibly allergic	Recovered	Highly probable	Not serious
31, female	Intragam P	Allergic	Recovered	Possible	Not serious
43, male	Intragam P	Pain, tingling & periorbital numbness	Recovered	Possible	Not serious
9, male	Intragam P	Rash & fever	Recovered	Possible	Not serious
59, female	Intragam P	Allergic	Recovered	Possible	Not serious
80, female	Intragam P	Shivering	Recovered	Possible	Not serious
41, male	Albumex 4	Allergic	Recovered	Possible	Not serious
39, female*	Intragam P	Inflammatory ? allergic	Recovered	Highly probable	Not serious
39, female*	Intragam P	Inflammatory ? allergic	Recovered	Highly probable	Not serious
39, female*	Intragam P	Inflammatory ? allergic	Recovered	Highly probable	Not serious
58, male	Intragam P	Allergic	Unknown	Highly probable	Not serious
48, female	Intragam P	Allergic	Unknown	Highly probable	Not serious
50, male	Albumex 4	Allergic/anaphylactoid	Recovered	Highly probable	Required intervention
16, female	Intragam P	Allergic	Recovered	Possible	Not serious
73, male	Intragam P	Allergic, type III hypersensitivity	Not yet recovered	Highly probable	Required intervention
51, female	Intragam P	Haemolysis & abnormal LFT	Not yet recovered	Highly probable	
81, male	Intragam P	Allergic/inflammatory	Not yet recovered	possible	
82, male	Prothrombinex	Loss of consciousness	Death	Possible	Death

*same patient

25. Component Related Events

There was one component related event notified during 2009. This involved red cell transfusion to a postpartum patient in a small hospital. The nurse collecting the unit commented on the volume (628mL) and asked the person issuing the unit if it was correct. She was told by the scientist that this was correct. The scientist was a rotating scientist who did not work very often in the blood bank. The unit was charted to be infused over 2 hours. After one hour the IVAC alarmed to signify the transfusion was complete i.e. 314 mL was transfused. Although the unit was transfused in half of the time than that intended, the patient had no ill effects. An image of the unit label is shown in Figure 22. The error on the unit label was notified to the supplying blood centre.

Figure 22. Red Cell Unit Label Showing Incorrect Volume



26. Adverse Events in Donors

An adverse event in a donor is an unintended reaction in a donor associated with the collection of blood or blood components. Events relating to the blood donation are either observed by the collection staff or reported by the donor after they have left the collection venue. Initial care and advice to the donor as well as follow-up of the reaction is provided by the collection staff and a Medical Officer reviews all adverse event forms and provides clinical advice and support if required.

The events are recorded in a secure database following Medical Officer review. The database includes information of:

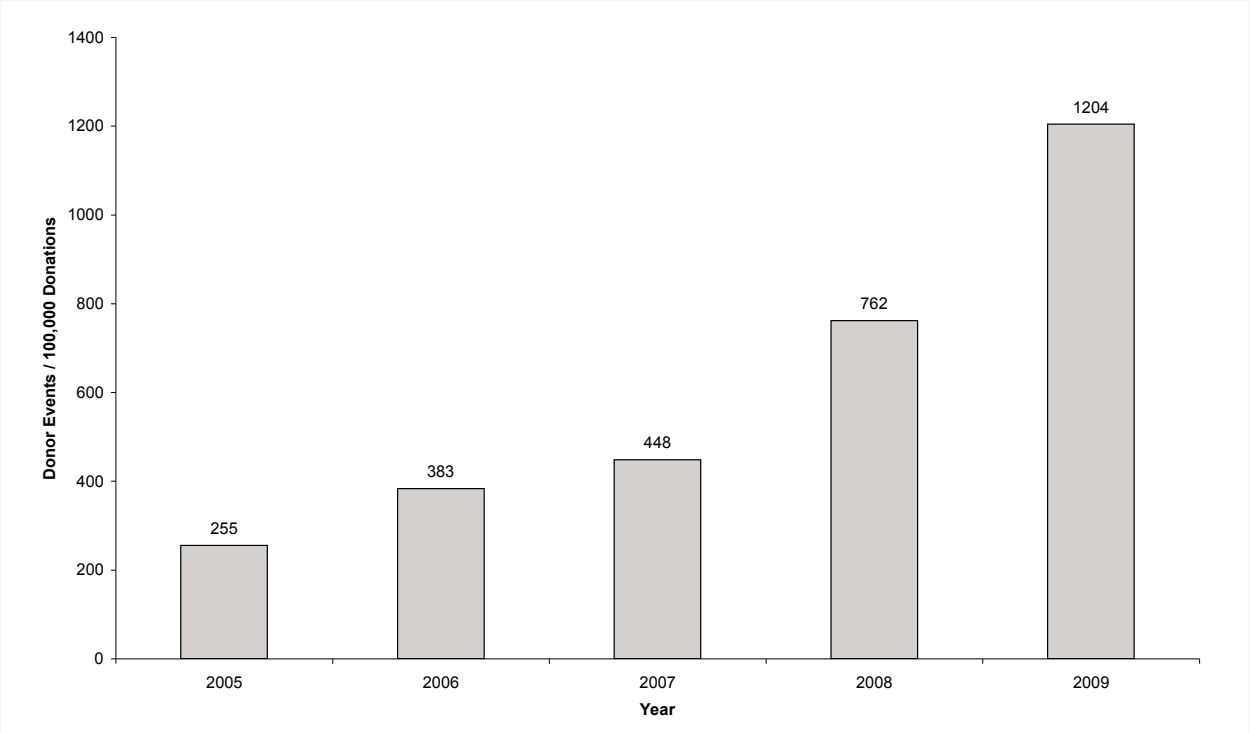
- Donor demographic details
- Donation information
- Type of blood component collected
- Donor outcome
- Type of reaction

The donor incident reporting form was revised in April 2010 (Appendix IV).

During 2009 176,371 blood components were collected by NZBS. This included 151,687 whole blood donations, 18,106 plasmapheresis donations and 6,578 plateletpheresis donations. Adverse events were reported in 1,894 volunteer donors and 14 therapeutic donors. 38 donors experienced adverse events involving two separate donations and 4 donors experienced adverse events involving three donations.

A total of 2,124 donor adverse events were reported during 2009. These involved 1,908 blood donations. The overall rate of donor adverse events is increasing (Figure 23) however this is likely to be attributable to improved reporting by collections staff.

Figure 23. Total Donor Adverse Events per 100,000 Donations 2005 - 2009



26. Adverse Events in Donors continued

Table 29 shows donor adverse events by procedure, Table 30 gives a detailed breakdown of the type of event by procedure and Table 31 shows the rate for each type of event. The overall rate of an adverse event is 1:83 donations. Vasovagal reactions remain the most frequent complication of blood donation (Figure 24).

Table 29. Donor Adverse Events per Procedure 2009

	Procedure			
	Whole Blood	Plateletpheresis	Plasmapheresis	**Total**
Procedures	151,687	6,578	18,106	**176,371**
Number of Complications	1,649	166	309	**2,124**
Frequency	1:92	1:40	1:59	**1:83**
Complications / 100,000 donations (95% CI)	1,087 (1,035 – ,140)	2,523 (2,172 – 2,931)	1,707 (1,906- 1,906)	**1,204 (1,154 – 1,256)**

Table 30. Breakdown of Donor Adverse Events 2009

		Plasmapheresis		Plateletpheresis		Whole Blood		Total Donations	
		No.	Rate /100,000 donations	No.	Rate /100,000 donations	No.	Rate /100,000 donations	No.	Rate /100,000 donations
Needle Insertion Site	Bruise	47	260	21	319	320	211	388	220
	Haematoma	62	342	33	502	206	136	301	171
	Arterial Puncture	0	0	0	0	6	4	6	3
Vasovagal Reactions	Without Faint	22	122	15	228	620	409	657	373
	Immediate Faint	8	44	3	46	344	227	355	201
	Delayed Faint	6	33	1	15	71	47	78	44
Nerve Damage	Needle	5	28	0	0	49	32	54	31
	Haematoma	3	17	1	15	7	5	11	6
	Cardiovascular	2	11	3	46	2	1	7	4
	Allergic	1	6	0	0	6	4	7	4
	Tendon Damage	0	0	0	0	7	5	7	4
	Other	1	1	2	30	11	7	14	8
Apheresis Only	Red Cells Not Returned	149	823	78	1,186		0	227	920
	Citrate Toxicity	3	17	9	137	0	0	12	49

26. Adverse Events in Donors continued

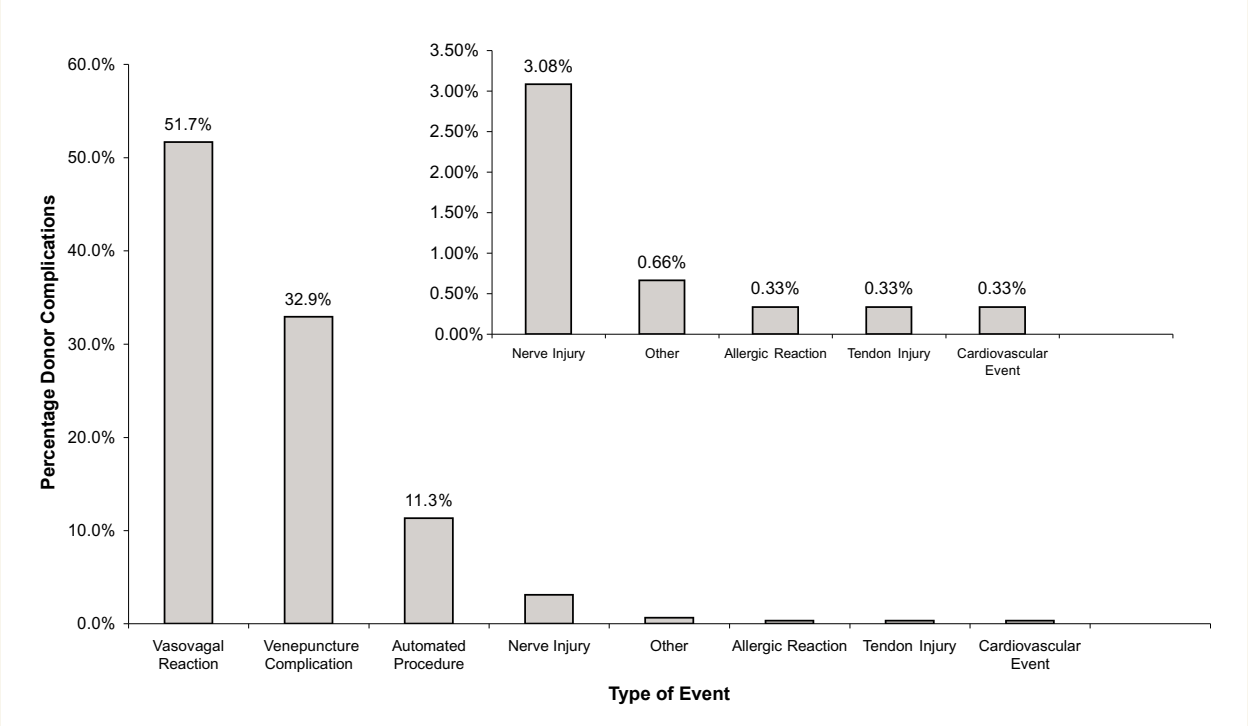
Table 31. Frequency of Donor Adverse Events 2009

	Number	Frequency	Per 100,000 donations
Vasovagal Reaction	1,090	1:162	618
Venepuncture Complication	695	1:254	394
Automated Procedure *	239	1:103	968
Nerve Injury	65	1:2,713	37
Other	14	1:12,598	8
Allergic Reaction	7	1:25,196	4
Tendon Injury	7	1:25,196	4
Cardiovascular Event	7	1:25,196	4
Total	**2,124**	**1:83**	**1,204**

*calculated on apheresis donations only

Vasovagal events occurred more frequently in donors <20 years old. Table 32 shows the vasovagal events by age group and Figure 25 shows the odds ratio of vasovagal reactions for whole blood donations by age group (the bars represent 95% confidence intervals).

Figure 24. Percentage of Donor Complications 2009



26. Adverse Events in Donors

Table 32. Vasovagal Donor Events By Age 2009

Age group (years)	Events (Percentage)
<20	329 (30.2%)
20 - 29	316 (29.0%)
30 - 39	129 (11.8%)
40 - 49	127 (11.7%)
50 - 59	117 (10.7%)
>60	72 (6.6%)
All	1,090

Overall 0.3% of donors were permanently deferred from donating following an adverse event. All of these occurred following whole blood donation (Table 33).

Figure 25. Odds Ratio of Vasovagal Events for Whole Blood Donations by Age (95% confidence interval)

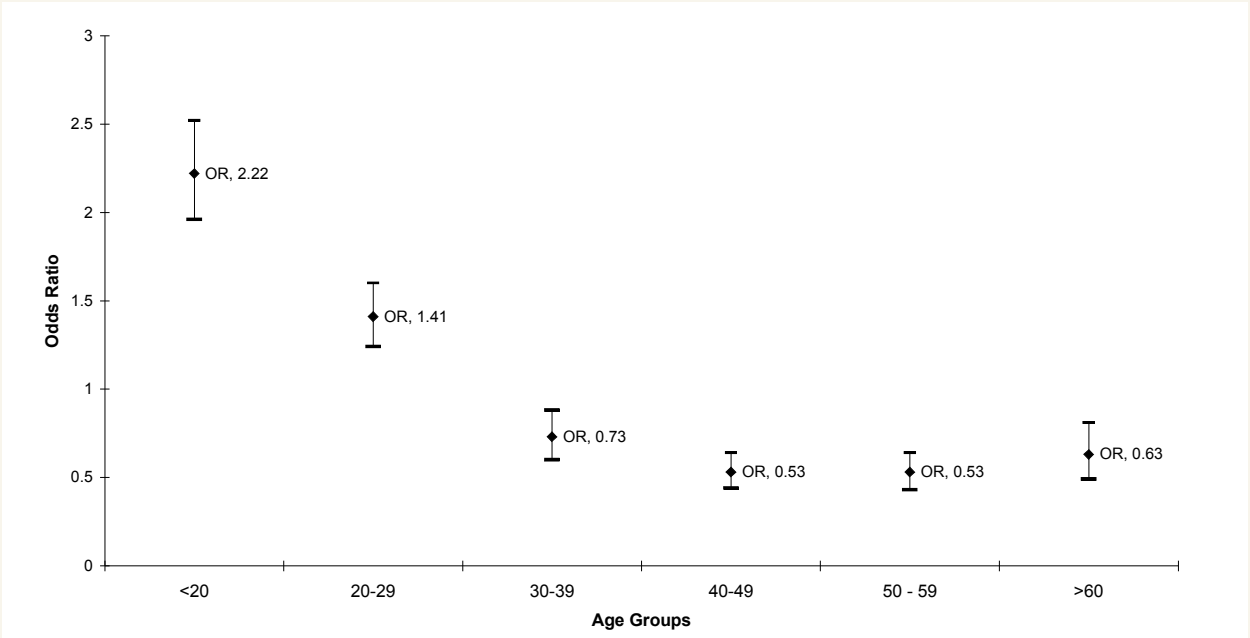


Table 33. Outcome for Donors Following Adverse Event

Procedure	No action	Temporary deferral	Converted to whole blood	Permanent deferral	Total donations
Plasmapheresis	60.7%	38.8%	0.5%		196
Plateletpheresis	62.3%	32.5%	5.3%		114
Whole Blood	89.5%	10.2%	0.0	0.3%	1,598
Total	**84.9%**	**14.5%**	**0.4%**	**0.3%**	**1,908**

27. Request Form and Sample Labelling Errors

Since May 2006 NZBS has collected standardised national data on errors involving blood samples and request forms at the six NZBS blood banks (Auckland, Waikato, Palmerston North, Wellington, Christchurch, Otago). Each of these records the errors and the corrective actions taken. Data is entered into a Microsoft Access™ database and then analysed. Reports are regularly reviewed by Hospital Transfusion Committees and the NZBS Clinical Advisory Group.

In January 2009, minor changes were made to the database categories. Categories where no action needed to be taken were removed. This change has coincided with the reduction in the overall error rate.

The rule around the requirements for labelling of pre-transfusion test request forms and samples are there to ensure that blood for transfusion is as safe as possible. Establishing the identity of every patient by verbal enquiry or sighting the wristband is crucial in providing the right blood product to the right patient. Minimum requirements for pre-transfusion request forms and sample labelling (for NZBS blood banks) are outlined in Table 34.

Table 34. Pre-transfusion Request Form & Sample Labelling Requirements

Request form **Hand-written or pre-printed label**	**Sample** **Must be hand-written**
Full name	Family name + one or more given names (not abbreviated)
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 (G & S, blood product etc)	
Name or signature or other identifier (e.g. pager number) of person completing form	
Signed declaration by sample collector that • Patient positively identified during collection • Sample labelled before leaving patient	
Date & time of sample collection on sample **OR** form	

There should be a local policy for identifying patients who are unconscious, irrational or unable to respond to direct questioning and are without an identification wristband.

In 2009 a total of 138,763 samples were received by the six NZBS blood banks. Of these, errors were found in 3,645 samples/forms (equivalent to 1:38) however the total number of errors amounted to 3,823. The overall error rate for the six NZBS blood banks for 2009 was 2.6% compared to 3.5% in 2008. Figure 26 shows the monthly error rate for the total and individual six blood banks for 2009.

Table 35 shows a breakdown of sample and request form errors recorded by the six blood banks in 2009. The most frequent errors were: pre-printed label on sample, missing patient details, declaration not signed and sample not signed.

27. Request Form and Sample Labelling Errors continued

Figure 26. Errors per 1,000 Requests for 2009

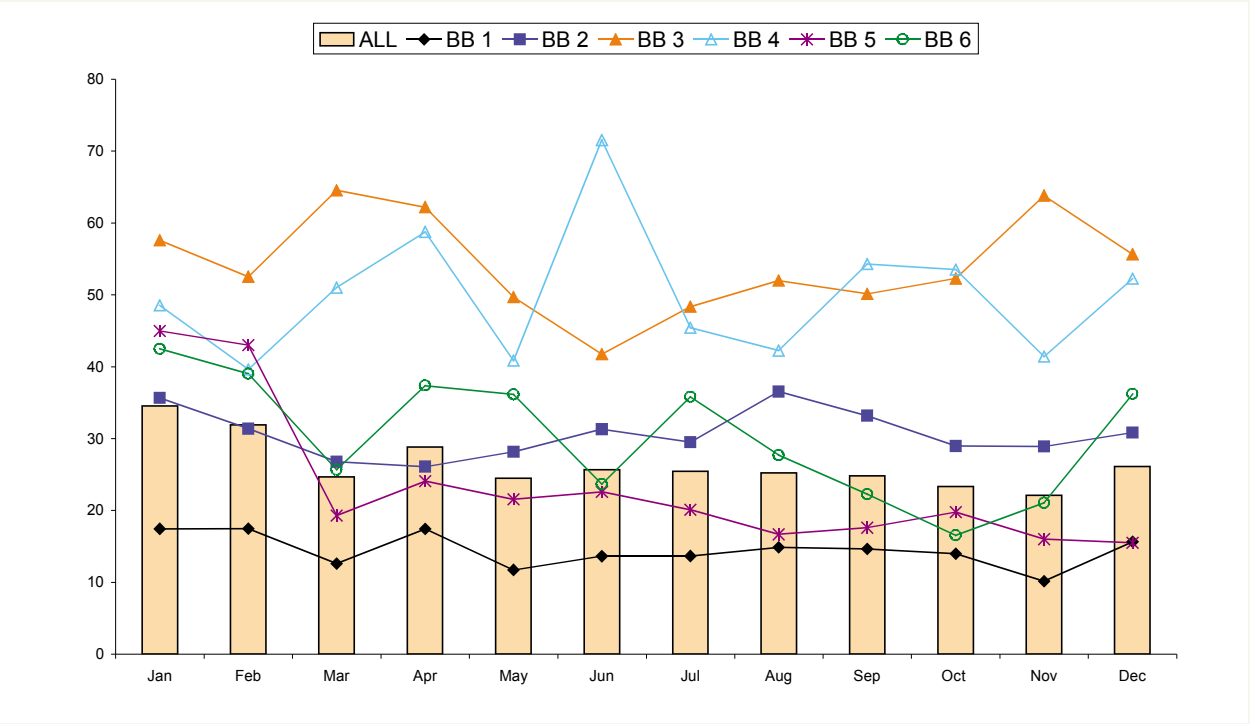


Table 35. Sample and Request Form Errors 2009

Error type	Number	Percentage
Declaration not signed	673	17.6%
Missing patient details (major error)	334	8.7%
Missing patient details (moderate error)	743	19.4%
Original details overwritten	116	3.0%
Other errors	146	3.8%
Person completing request form not identifiable	34	0.9%
Pre-printed ID label (or evidence of removal)	761	19.9%
Sample not signed	582	15.2%
Signature on sample and declaration differ	176	4.6%
Technical	127	3.3%
Unlabelled sample	115	3.0%
WBIT* - current sample	15	0.4%
WBIT* - historical sample	1	0.03%
Total	**3,823**	

*wrong blood in tube

27. Request Form and Sample Labelling Errors continued

Technical errors include wrong blood collection tube type, insufficient sample, haemolysed sample and leaking/broken samples. A new sample was requested in the majority of instances for these technical errors.

The actions taken when samples are received with an error include:

- Request for re-collection
- Correction by collector (person making correction must sign declaration taking full responsibility)
- Correct details obtained via telephone

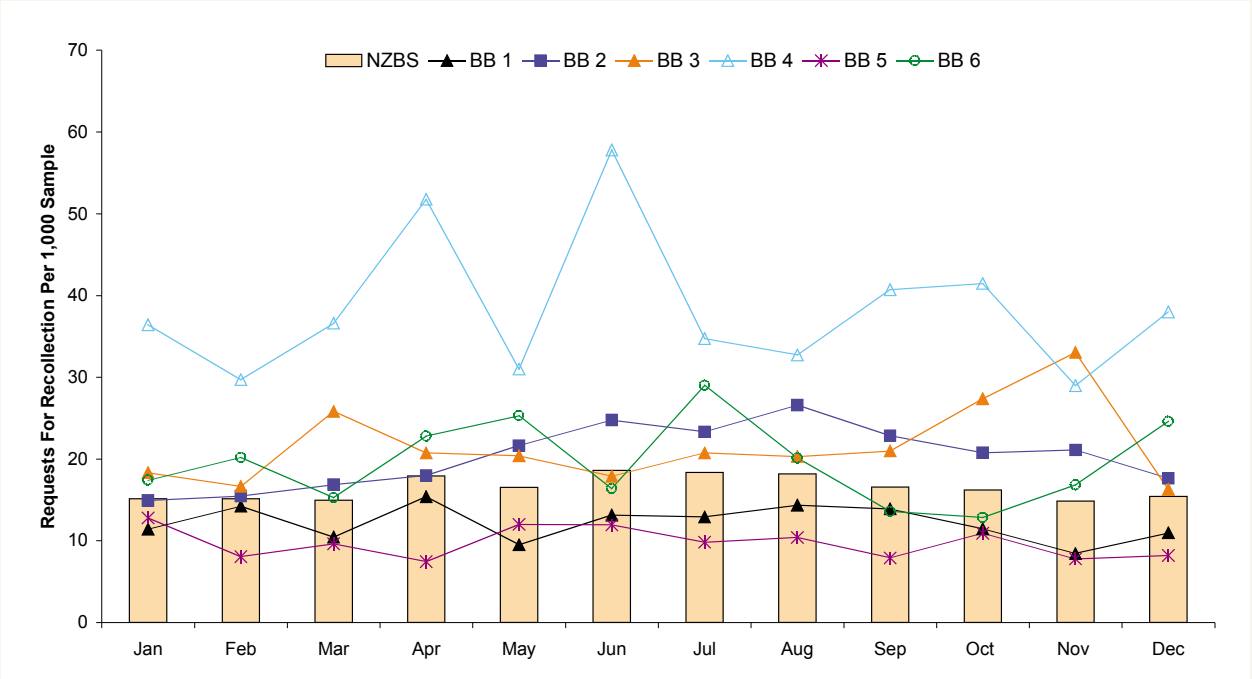
Table 36 summarises the actions taken in response to the errors identified within the blood banks.

Table 36. Summary of Actions Taken in Response to Errors

Action taken	Number
Sample discarded	94
Recollect requested	2,290
Labelling corrected by collector	1,290
Correct details obtained by telephone/facsimile	33
Other (specify In comments)	9
Total	**3,716**

Overall 63% of errors resulted in a request for re-collection of a new sample from the patient. Requests for re-collection were also made in those instances where corrections were permissible but the person responsible for the error could not be contacted or not available. Re-collection of pre-transfusion samples impacts on staff time, resources, patient discomfort and delays in cross-matching. The average re-collection rate for the six blood banks was 17 per 1,000 samples received (Figure 27).

Figure 27. Monthly Requests for Recollection Per 1,000 Samples for 2009



28. Wrong Blood in Tube (WBIT) Errors

A “wrong blood in tube” event involves miscollection and is identified when a pre-transfusion sample is tested and found to have an ABO Rh D group that is different from that in the historic record. It occurs as a result of collecting blood from the wrong patient or labelling the sample and request form with different patient details. Historic blood groups were available for 62% of the samples submitted to the six NZBS blood banks in 2009.

There were 16 WBIT errors identified by NZBS blood banks in 2009. In one case the historic result was assumed to be incorrect. One blood bank identified a WBIT error and requested a repeat sample, however the repeat sample showed the same blood group as the first sample and it became evident that repeat sample was collected from the incorrect patient for a second time. Table 37 shows the frequency of WBIT errors for 2009. Silent errors can occur when the wrong patient bled has the same ABO blood group as the intended patient. To correct for this the rate is multiplied by a correction factor. The overall frequency of WBIT errors was 1;3,518 in 2009. This is comparable to the rate of 1:3,377 in 2008.

Table 37. Frequency of WBIT 2009

	Historic groups	WBIT	Frequency*
BB 1	29,041	10	1:1,815
BB 2	16,257	0	
BB 3	5,889	0	
BB 4	5,069	0	
BB 5	16,952	4	1:2,649
BB 6	11,220	1	1:7,013
Total	**84,428**	**15**	**1:3,518**

*Corrected to account for silent errors. Corrected WBIT rate= No. historical groups / No WBIT * correction factor. The correction factor 1.6, is based on New Zealand blood group frequencies.

Appendix I

Transfusion Related Adverse Event Notification Form page 1

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

For Haemovigilance Office Use Only

Appendix I

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

For Haemovigilance Office Use Only

Appendix I

Transfusion Related Adverse Event Notification Form page 3

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 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.

Appendix II

Reporting Categories for Transfusion Related Adverse Events

page 1

<table>
<tr><th>Type of event</th><th colspan="3">Definition</th></tr>
<tr><td rowspan="2">Acute haemolytic transfusion reaction (AHTR)</td><td colspan="3">Onset within 24 hours of transfusion
Clinical and laboratory features of haemolysis are present. AHTR may also be due to red cell autoantibodies or non-immunological factors e.g. malfunction of a pump, blood warmer, use of hypotonic solutions etc.</td></tr>
<tr><td colspan="2">Signs/symptoms of AHTR:
• Fever
• Chills/rigors
• Facial flushing
• Chest pain
• Abdominal pain
• Back/flank pain
• Nausea/vomiting
• Diarrhoea
• Hypotension
• Pallor
• Jaundice
• Oligouria/anuria
• Diffuse bleeding
• Dark urine</td><td>Laboratory features:
• Haemoglobinaemia
• Haemoglobinuria
• Decreased serum haptoglobin
• Unconjugated hyperbilirubinaemia
• Increased LDH and AST levels
• Decreased haemoglobin levels
• Positive DAT
• Red cell antibody/evidence of incompatibility</td></tr>
<tr><td rowspan="3">Allergic reaction</td><td colspan="3">Mucocutaneous signs and symptoms during or within 4 hours of transfusion:
• Morbilliform rash with pruritus
• Urticaria (hives)
• Localised angioedema
• Oedema of lips, tongue and uvula
• Periorbital pruritus, erythema and oedema
• Conjunctival oedema

Grade 1 = non-severe

Anaphylactic reaction is when, in addition to mucocutaneous symptoms, there is airway compromise or cardiovascular involvement.</td></tr>
<tr><td>Laryngeal symptoms include:
• Tightness in throat
• Dysphagia
• Dysphonia
• Hoarseness
• Stridor</td><td>Pulmonary symptoms include:
• Dyspnoea
• Cough
• Wheeze/bronchospasm
• Hypoxaemia</td><td>Cardiovascular symptoms include:
• Hypotension
• Hypotonia
• Syncope</td></tr>
<tr><td colspan="3">Grade 2 = severe
Grade 3 = life-threatening
Grade 4 = death</td></tr>
</table>

Appendix II

Reporting Categories for Transfusion Related Adverse Events

page 2

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.
Delayed haemolytic transfusion reaction (DHTR)	Usually manifests between 24 hours and 28 days after a transfusion and signs of haemolysis are present. Signs/symptoms are similar to AHTR but are usually less severe. 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.
Delayed serologic transfusion reaction (DSTR)	Synonymous with alloimmunization. After a transfusion, there is demonstration of clinically significant red cell antibodies which were previously absent and no clinical or laboratory signs of haemolysis.
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.
Febrile non-haemolytic transfuson reaction (FNHTR)	One or both of: • Fever (≥38°C and a change of ≥1°C from pre-transfusion value) • Chills/rigors Occurring during or within 4 hours of transfusion without other cause such as haemolytic transfusion reaction, bacterial contamination or underlying condition.
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. May be associated with other symptoms such as facial flushing, dyspnoea, abdominal cramps.

Appendix II

Reporting Categories for Transfusion Related Adverse Events

page 3

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.

Appendix II

Reporting Categories for Transfusion Related Adverse Events

page 4

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. Alternative risk factors for ALI: • Direct lung injury: aspiration, pneumonia, toxic inhalation, lung contusion, near drowning • Indirect lung injury: severe sepsis, shock, multiple trauma, burn injury, acute pancreatitis, cardiopulmonary bypass, drug overdose
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. The donor may have evidence of the same transmissible infection or the component transfused may be shown to contain the infectious agent.
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 III

Notification of Suspected Adverse Reaction to a Fractionated Blood Product page 1

NZBLOOD
Te Ratonga Toto O Aotearoa

NATIONAL
111F00304

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/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

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*

Author: Jim Faed
Authoriser: Peter Flanagan
QA Approver: Meredith Smith

Effective Date: 24/08/2009

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Previous ID: 111F00303

Appendix III

Notification of Suspected Adverse Reaction to a Fractionated Blood Product page 2

NZBLOOD
Te Ratonga Toto O Aotearoa

NATIONAL
111F00304

NOTIFICATION OF SUSPECTED ADVERSE REACTION TO A FRACTIONATED BLOOD PRODUCT

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/mm/yyyy

☐ Recovered _____ dd/mm/yyyy. Time _____
☐ Recovered with sequelae _____ (specify)
☐ Permanently disabled
☐ Death _____ dd/mm/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/mm/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 8556	06 350 8557	Dunedin Hospital Blood Bank	03 470 9369	03 470 9513

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Appendix IV

Donor Incident Report page 1

NZBLOOD
Te Ratonga Toto O Aotearoa

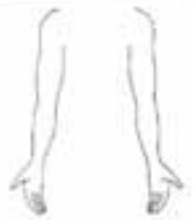
NATIONAL
107F00505

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		**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 ...					

Author: Anup Chand
Authoriser: Peter Flanagan
QA Approver: Meredith Smith

Effective Date: 12/04/2010

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Previous ID: 107F00504
Refer to document(s): 107M005

Appendix IV
Donor Incident Report page 2

NZBLOOD
Te Ratonga Toto O Aotearoa

NATIONAL
107F00505

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

Follow Up Required:	**YES / NO**		
NZBS Accident Form Required (17GF007)	**YES / NO**		
Names of Staff/Witnesses Involved:			
Name of Staff (filling in form)	**Name:**	**Sign:**	**Date:**

FOLLOW UP			
Give details:			
Outcome for Donor:	☐ No Action ☐ Return from apheresis to whole blood donation		
	☐ Deferred until / /		
	☐ Permanent Deferral		
Deferral Code/Comments:		**Entered:**	**YES / NO**
Name of Staff (conducting F/U)	**Name:**	**Sign:**	**Date:**

OFFICE USE ONLY			
	Responsible	**Sign**	**Date**
Review	TMS/MO		
Review and Database Entry	QSA/Delegate		

Page 2 of 2

SAVE LIVES
GIVE BLOOD

New Zealand Government