NZBLOOD
Te Ratonga Toto O Aotearoa

National Haemovigilance Programme

Annual Report 2010

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Cover photograph: Waitangi Day (February 6) Wellington Donor Centre decoration

Contents

1 Foreword

Publication of the 6th Annual Haemovigilance Report for New Zealand continues to demonstrate the success of the scheme and its acceptance by Healthcare Professionals and Hospitals across the country. The number of events reported to the National Haemovigilance Office in Wellington continues to increase. Hopefully this demonstrates increasing awareness of the value of the scheme in supporting quality improvements in the delivery of blood products to patients. Increased reporting rates will inevitably increase the workload for staff in the hospitals. The ongoing support of clinical and laboratory staff is very much appreciated. The Haemovigilance Office based in the Wellington Blood Centre, play an important role in ensuring the ongoing success of the programme. The support and enthusiasm of John Dagger, Technical Advisor to the scheme, and Dr Dorothy Dinesh, Lead Specialist for haemovigilance, deserve special mention.

Haemovigilance schemes internationally have contributed to increased recognition of Transfusion Related Acute Lung Injury (TRALI) as a leading cause of transfusion associated morbidity and mortality. Reduction of this risk has been a particular focus of New Zealand Blood Service over the last few years. This has been associated with a significant reduction in the number of reports of TRALI each year. Nonetheless three reports during 2010 suggest that there is more to be done. TRALI is normally associated with transfusion of blood components containing high volumes of plasma. The introduction of male only FFP in 2008 largely removed the risk from this product. Unfortunately similar approaches are not feasible for platelet components. NZBS is progressively moving to provision of platelets suspended in an artificial additive solution. International data indicates that this will further reduce the risk of both TRALI and allergic reactions associated with transfusion of platelet components. TRALI is normally associated with the presence of white cell antibodies in the donor. Plans are well advanced to introduce white cell antibody screening of platelet donors to further reduce the TRALI risk.

The safety profile of blood components compares well to other therapeutic modalities. Data from haemovigilance schemes increasingly demonstrates that the major risks posed to patients by transfusion reflect errors in the prescription, laboratory testing and administration of the components rather than the components themselves. This is evident by the significant number of reports falling in the incorrect blood component transfused (IBCT) category. Errors in pre-transfusion sample collection continue to be a concern and result in additional work for both clinical and laboratory staff. The NZBS Transfusion Nurse Specialist Team play an important role in raising awareness of these issues as well as responsibility for managing incidents as they occur. Technologies are now becoming available to reduce risks in this area and are already being introduced widely in the United Kingdom and elsewhere.

The haemovigilance report provides an opportunity for all involved in transfusion to gain an improved understanding of risks associated with transfusion. I hope that you will find the report informative and look forward to your ongoing support of the programme.

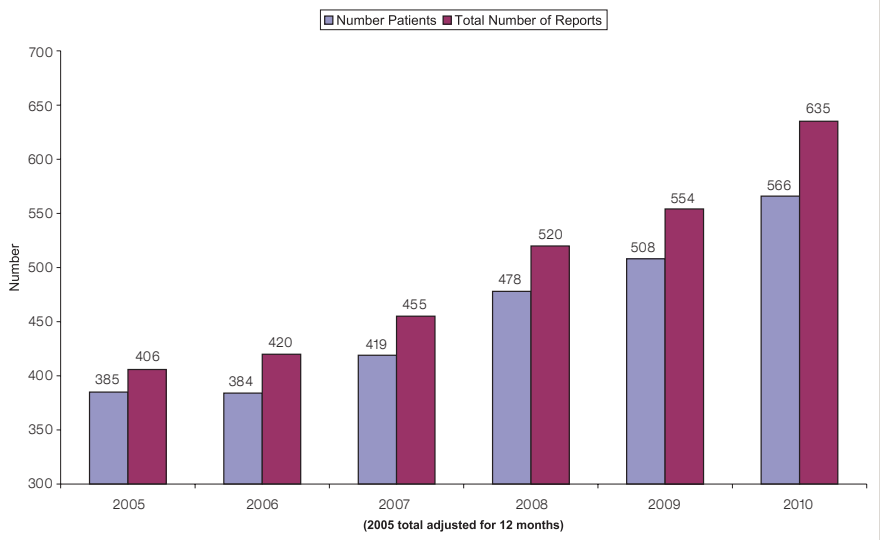
Dr Peter Flanagan
NZBS National Medical Director

2 Introduction

Haemovigilance is the surveillance of adverse or unexpected events or reactions in blood donors and blood product recipients. It includes the epidemiological assessment of infections in donors, full traceability of each individual unit to its final destination, device defects and reporting of post-transfusion infections.

The New Zealand National Haemovigilance Programme was established in 2005. This is the sixth annual haemovigilance report for New Zealand. The number of total reports per annum continues to increase as shown in Figure 1.

Figure 1. Reports Received by Haemovigilance Programme 2005 – 2010



The New Zealand Blood Service (NZBS) has overall responsibility for many aspects of the transfusion process and includes the following processes:

- recruitment of voluntary blood donors
- donor health check by registered nurse
- collection of whole blood or apheresis donations
- processing of blood and sending plasma for fractionation
- screening for infectious diseases
- red cell serologic tests
- storage and distribution of blood products
- maintaining a national inventory
- pre-transfusion testing and issuing blood products (operates six hospital blood banks)
- surveillance of untoward events related to transfusion
- clinical oversight over blood banks and transfusion practice

2 Introduction continued

The European Directorate for the Quality of Medicines and Healthcare (EDQM) defines the standards for haemovigilance and acknowledges that it is a shared responsibility of the professionals in the field and the competent national authorities for blood safety. Data on untoward events associated with transfusion must be shared with health professionals who prescribe and administer blood products so that they can continue to deliver the good without unintended negative consequences.

The Haemovigilance Office receives reports from Blood Bank Scientists and Transfusion Nurse Specialists from around New Zealand. The reporting form (Appendix I) includes a severity score, an imputability score and definitions of reporting categories, which are based on the definitions agreed upon by the International Haemovigilance Network (IHN).

All reports are reviewed by a team of Transfusion Medicine Specialists and a Senior Scientist. The data is entered into a secure database and does not include any clinician or patient names. The paper reports are destroyed on publication of the annual report.

Haemovigilance is a tool for quality improvement and plays a vital role in improving the safety of blood transfusion. It provides us with a mechanism to identify hazards and trends associated with transfusion as well as measure the impact of change within the vein to vein chain.

3 Blood Component Transfusion in New Zealand

All blood donations are collected from voluntary non-remunerated donors to minimize the risk of transfusion-transmitted infection. Donors can donate whole blood which is separated into various components such as red cells, platelets and plasma; or they can donate plasma or platelet concentrates by apheresis. Apheresis procedures involve a cell separator machine at the donor bedside. During apheresis donation the donor's red blood cells are returned to the donor. These types of donations take longer than whole blood donation however the donor can donate more frequently.

Platelet concentrates are produced by two methods:

1. pooling of 4 buffy coats of identical ABO group, suspended in plasma
2. apheresis procedure which can collect platelet rich plasma, usually 2 adult doses

Both methods produce leucodepleted platelet concentrates which are considered to be equivalent in terms of yield (>2.4 x 10^{11}) and efficacy. NZBS is in the process of validating procedures to manufacture platelets in additive solution. In some sites platelets suspended in additive solution have replaced pooled platelets in plasma. It will be interesting to note whether this will affect the rate of adverse reactions in the future.

Cryoprecipitate is produced from plasmapheresis donations collected from donors with suitable fibrinogen levels (>2.4g/L). Fresh frozen plasma (FFP) is produced from plasmapheresis donations that have been collected from males who have never been transfused.

Table 1 shows the total blood components transfused per year in New Zealand since 2007. Overall there has been a 4% increase since 2007.

Table 1. Total Annual Transfused Blood Components 2007 - 2010

Component	2007	2008	2009	2010	2007 - 2010 Percentage Change
Red cells	118,751	121,231	124,004	124,661	5%
Platelets -apheresis	6,762	7,942	7,571	8,165	21%
Platelets -pooled	4,749	5,157	5,326	5,451	15%
Fresh frozen plasma	19,956	18,962	20,006	17,873	-10%
Cryoprecipitate	1,991	2,372	2,869	2,951	48%
Cryodepleted plasma	927	524	517	486	-48%
Total	**153,136**	**156,188**	**160,293**	**159,587**	**4%**

4 Recipients of Blood Components

Table 2 shows the gender, age and transfusion profiles of recipients who received blood components during 2010.

Table 2. Blood Component Recipients 2010

		Red Cells	Platelets	FFP
Gender of Recipients	Female	16,228	1,367	1,745
	Male	11,857	2,334	2,569
	Unknown	45	2	3
	Total	**28,130**	**3,703**	**4,317**
Age of Recipients (years)	Mean	69	52	61
	Median	63	60	66
	Maximum	108	97	96
	Minimum	<1	<1	<1
Units Transfused per Recipient Total during 2010	Mean	4	4	4
	Median	2	2	2
	Maximum	193	109	574
	Minimum	1	1	1

5 Summary of Reported Events for 2010

During 2010 there were 635 reported events, of which 555 were included in the analysis. In 2010 12.6% of reports involved events that were attributed to causes other than transfusion (Table 3). The 80 events that were excluded from analysis involved symptoms that could be explained by the patient's underlying condition or febrile reactions which did not meet the definition criteria for FNHTR i.e. the temperature rise was <1°C or the temperature did not increase above 38°C, with no other symptoms.

Table 3. Imputability Score Definitions and Percentage of Reports with Low Imputability

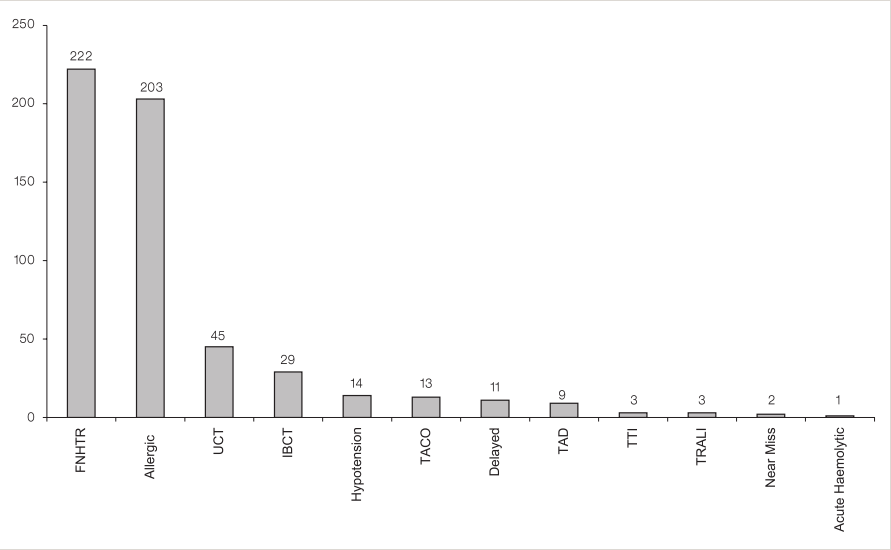
Imputability Score Definitions		
NA	**Not assessable**	When there is insufficient data for imputability assessment
1	**Excluded**	When there is conclusive evidence beyond reasonable doubt for attributing the event to alternative causes
2	**Unlikely**	When the evidence is clearly in favour of attributing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

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

5 Summary of Reported Events for 2010 continued

Figures 2 and 3 show the breakdown of the 555 reports by category. The pattern is similar to previous years with febrile non-haemolytic transfusion reactions (FNHTR) and allergic reactions comprising the majority of events (77%).

Figure 2. Reported Events by Category 2010 (n=555)

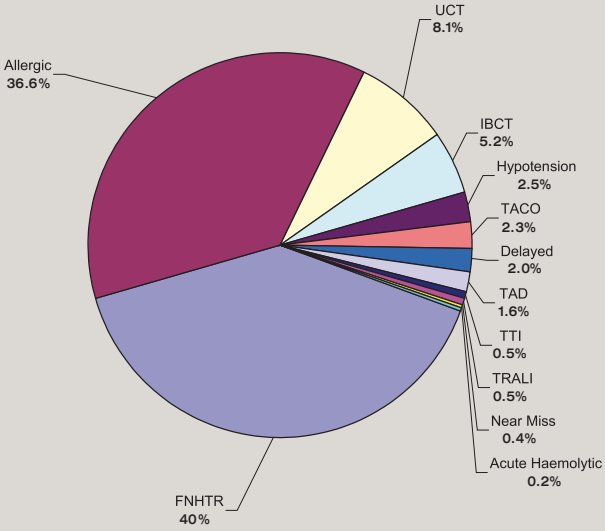


Key:

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

5 Summary of Reported Events for 2010 continued

Figure 3. Reports as Percentage of Total Reports (n=555)



During 2010 there were 53 patients for whom multiple transfusion-related events were reported (Table 4), with one patient having 5 reported events; this patient had relapsed acute myeloid leukaemia and had one febrile reaction and four allergic reactions associated with transfusion of red cells (2) and platelets (3).

Table 4. Number of Reported Events per Patient 2010

		Haemovigilance Reports				
	Total	1 Report	2 Reports	3 Reports	4 Reports	5 Reports
Number of Patients	566	513	41	9	2	1

6 Reports Involving Paediatric Recipients

During 2010 48 haemovigilance reports involved recipients aged 15 years or younger. Of these 42 (88%) had an imputability score of 3 or higher and were included in the analysis. These events involved 28 male and 14 female paediatric recipients. Allergic reactions were the most frequent type (27) followed by FNHTR (9). There were 4 IBCT and 2 TACO.

7 Imputability Scores

Lower imputability scores were associated with febrile reactions, unclassifiable complications of transfusion and hypotensive reactions (Table 5).

Table 5. Imputability Scores for Reported Events 2010

Event Type	Imputability Score						
	1	2	3	4	5	Total	Total ≥3
FNHTR	21	23	162	55	5	266	222
Allergic	2	3	78	112	13	208	203
UCT	9	10	37	8		64	45
IBCT	3				29	32	29
Hypotension	4	1	11	3		19	14
TACO			7	5	1	13	13
TAD		3	7	2		12	9
Delayed serological reaction	1				9	10	9
TTI			2		1	3	3
TRALI			1	2		3	3
Near Miss					2	2	2
Delayed haemolytic reaction			1	1		2	2
Acute haemolytic reaction			1			1	1
TOTAL	**40**	**40**	**307**	**188**	**60**	**635**	**555**
Percent All Reports	6.30%	6.30%	48.35%	29.61%	9.45%		
Percent Imputability ≥3			55.32%	33.87%	10.81%		

8 Severity of Events

The severity score definitions and scores for each event type are shown in Table 6.

Table 6. Severity Score Definitions and Severity Scores for Haemovigilance Reports 2010

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

Event Type	Severity Score				
	Grade 1	Grade 2	Grade 3	Grade 4	Total
FNHTR	218	4			222
Allergic	157	41	5		203
UCT	42	2	1		45
IBCT	29				29
Hypotension	12	1	1		14
TACO	8	3	2		13
Delayed serologic reaction	9				9
TAD	7	2			9
TRALI		1	1	1	3
TTI	2	1			3
Delayed haemolytic reaction	1	1			2
Near miss	2				2
Acute haemolytic		1			1
TOTAL	**498**	**60**	**11**	**1**	**555**
Percentage	89.73%	10.81%	1.98%	0.18%	

Most reactions were non-severe (90%). During 2010 there was one death attributable to transfusion. This was a case of TRALI (Patient A, page 22).

9 Reported Events by Type of Blood Component

As seen in previous years, reactions are most frequently reported with platelet transfusion, compared to other blood components. The overall rate of reported events in 2010 was 1 in 288 units (35 per 10,000 units transfused). Table 7 shows the rate by blood component type and Table 8 shows the number of reports of each type of adverse event, per blood component. Interestingly the rate of reported events is higher with pooled platelets compared to apheresis platelets (p = 0.028) whereas in the past the reverse has been observed.

Table 7. Reported Events 2010 by Type of Blood Component

Component	Number of Events*	Number Transfused	Frequency	Rate /10,000 Units Transfused (95%CI)
Red Cells	400	124,661	1:312	32.1 (29.1 – 35.4)
Platelets - apheresis	61	8,165	1:134	74.7 (58.1 – 96.0)
Platelets - pooled	58	5,451	1:94	106.4 (82.2 – 137.5)
Fresh frozen plasma	47	17,873	1:380	26.3 (19.7 – 35.0)
Cryoprecipitate	7	2,951	1:422	23.7 (10.4 – 50.0)
Cryodepleted plasma	4	486	1:122	82.3 (24.1 – 217.6)

** includes events where multiple components transfused*

9 Reported Events by Type of Blood Component continued

Table 8. Type of Adverse Event by Blood Component 2010

	Red Cells	Fresh Frozen Plasma	Platelets Apheresis	Platelets Pooled	Cryoprecipitate	Cryodepleted Plasma	Other*	Multiple Components
FNHTR	199	2	6	11		1	1	2
Allergic	28	37	81	38	1	2	1	15
UCT	41	1	1	2				
IBCT	12	1	3				11	2
Hypotension	14							
TACO	8		1		1	1		2
Delayed	11							
TAD	7			1				1
TTI	2		1					
TRALI	2							1
Near miss	1						1	
Acute haemolytic			1					
Total (n=555)	**325**	**41**	**94**	**52**	**2**	**4**	**14**	**23**

** Includes events associated with fractionated plasma products (10), allogeneic bone (1), granulocytes (1), autologous serum eye drops (1) and salvaged autologous blood (1).*

10 Events Associated with Other Components

During 2010 there was one report involving **allogeneic bone.** A femoral head was issued to one patient and grafted into a different patient. This was classified as an IBCT. Although there were no reported ill effects to the patient, this event compromised the traceability of human tissue.

There was one report of a reaction to **autologous blood.** This involved a patient who was transfused 200mL of blood collected from a wound drain following total knee joint replacement. The patient experienced rigors and the event was classified as a FNHTR.

There was one report of an allergic reaction following transfusion of a **granulocyte concentrate** (apheresis).

There was one report where expired **autologous serum eye drops** were dispensed to a patient 15 days after the expiry date. However no adverse effects were reported from the patient.

11 Haemovigilance Reports by Region

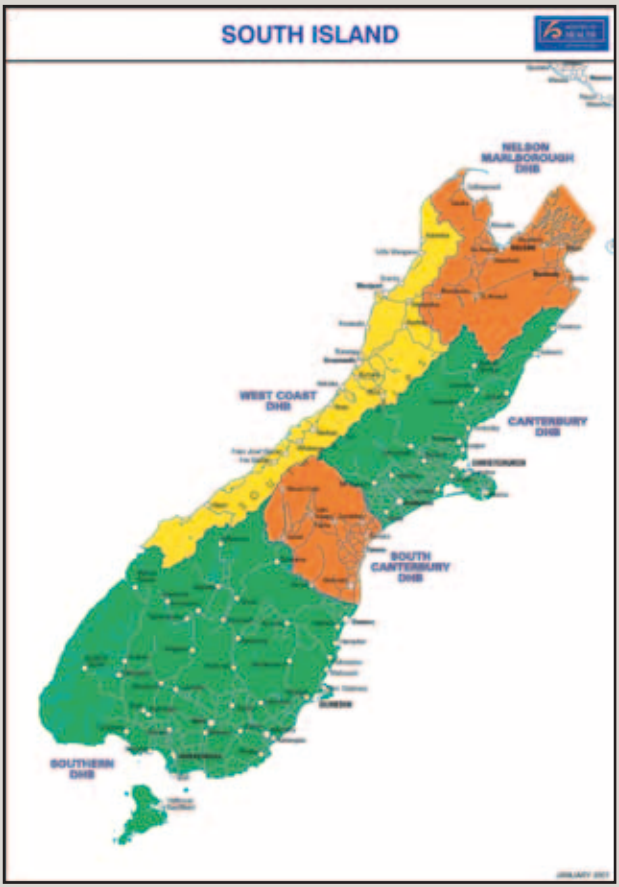
District Health Boards (DHBs) are responsible for providing, or funding the provision of, health and disability services in their district. There are 20 DHBs in New Zealand that are responsible for providing health care services in specific geographic regions. These are shown in Figures 4 and 5. Previously there were 21 DHBs however Southland and Otago are now known as Southern DHB.

Figure 4. DHB Districts in the North Island

Source: http://www.moh.govt.nz/dhbmaps

11 Haemovigilance Reports by Region continued

Figure 5. DHB Districts in the South Island



Source: http://www.moh.govt.nz/dhbmaps

11 Haemovigilance Reports by Region continued

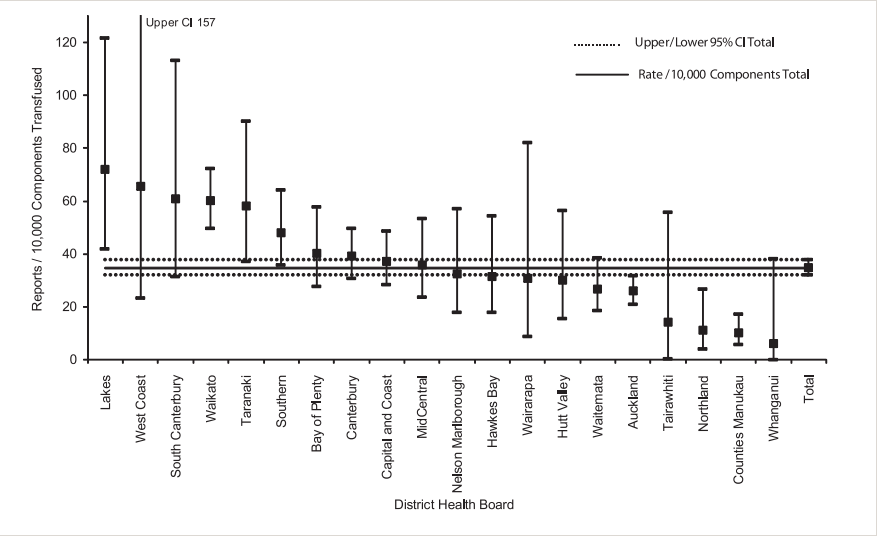
Table 9 shows the Haemovigilance Notifications by DHB that comprised the reports analysed for 2010. Figure 6 shows the variability in reporting by DHBs, including 95% confidence intervals.

Table 9. Origin of Haemovigilance Notifications 2010 (Imputability score ≥3)

District Health Board	Reported Events	Components Transfused	Frequency	Rate /10,000 Components Transfused (95%CI)
Lakes	14	1,942	1:139	72.1 (41.8 – 121.8)
West Coast	5	763	1:153	65.5 (23.3 – 157.2)
South Canterbury	10	1,643	1:164	60.9 (31.4 – 113.3)
Waikato	109	18,155	1:167	60.0 (49.8 – 72.4)
Taranaki	20	3,435	1:172	58.2 (37.1 – 90.3)
Southern	45	9,372	1:208	48.0 (35.8 – 64.3)
Bay of Plenty	29	7,236	1:250	40.1 (27.7 – 57.7)
Canterbury	66	16,858	1:255	39.2 (30.7 – 49.8)
Capital and Coast	54	14,464	1:268	37.3 (28.5 – 48.8)
MidCentral	24	6,727	1:280	35.7 (23.7 – 53.3)
Nelson Marlborough	12	3,716	1:310	32.3 (17.8 – 57.0)
Hawkes Bay	13	4,115	1:317	31.6 (17.9 – 54.6)
Wairarapa	4	1,298	1:325	30.8 (8.9 – 82.0)
Hutt Valley	10	3,312	1:331	30.2 (15.6 – 56.3)
Waitemata	29	10,807	1:373	26.8 (18.5 – 38.7)
Auckland	89	34,373	1:386	25.9 (21.0 – 31.9)
Tairawhiti	2	1,395	1:698	14.3 (0.3 – 55.7)
Northland	5	4,507	1:901	11.1 (3.9 – 26.8)
Counties Manukau	14	13,837	1:988	10.1 (5.9 – 17.1)
Whanganui	1	1,632	1:1,632	6.1 (-2.6 – 38.3)
Total	**555**	**159,587**	**1:288**	**34.8 (32.0 – 37.8)**

11 Haemovigilance Reports by Region continued

Figure 6. Reports per 10,000 Components Transfused (■), 95% Confidence Intervals



12 Febrile Non-Haemolytic Transfusion Reactions (FNHTRs)

Febrile reactions are the most frequently reported type of transfusion reaction overall (40%). Although they can be distressing, they are not harmful, with 98% classified as non-severe (Table 6). A total of 266 reports were classified as FNHTRs in 2010, of these 44 (16.5%) were excluded from the analysis because the event did not meet the definition criteria, i.e. rise in temperature was <1°C, the temperature did not increase above 38°C or the features could be explained by the patient's underlying condition(s). 43 (19%) reports were associated with a temperature rise of >2°C. Table 10 summarizes the age, sex and average temperature increment for the reported FNHTRs during 2010.

Table 10. Age and Sex of Patients with Reported FNHTRs 2010

	Number	Age (years)				Average Temp Rise
		Mean	Median	Minimum	Maximum	
Female	87	60	65	1	90	1.4
Male	135	61	66	1	90	1.9
All	**222**	**61**	**66**	**1**	**90**	**1.7**

A number of other symptoms are reported to occur during FNHTRs. These are summarised in Table 11. Hypertension was reported in 18.5% and tachycardia in 10.8% of FNHTRs.

Table 11. Other Signs and Symptoms Associated with FNHTRs 2010

	Number			% FNHTR Events
	Female	Male	Total	
Hypertension	20	21	41	18.5%
Tachycardia	7	17	24	10.8%
Restless / Anxiety	9	12	21	9.5%
Dyspnoea	9	9	18	8.1%
GI symptoms	7	10	17	7.7%
Chest pain	3	7	10	4.5%
Hypotension	3	3	6	2.7%

13 Allergic Transfusion Reactions

A total of 203 reactions were classified as allergic transfusion reactions during 2010. Table 12 shows the age and sex of recipients with reported allergic reactions during 2010. Urticarial rash was noted in 70.9% of allergic reactions (Table 13). 41 (20%) of reported allergic reactions were severe and 5 (3%) were life-threatening (Table 6).

Table 12. Age and Sex of Recipients with Reported Allergic Reactions 2010

	Number	Age (years)			
		Mean	Median	Minimum	Maximum
Female	92	46	43	3	96
Male	111	43	51	1	89
All	**203**	**45**	**45**	**1**	**96**

Table 13. Clinical Features of Reported Allergic Reactions 2010

Symptoms	Number	Percentage
Urticaria	144	70.9%
Restlessness / Anxiety	41	20.2%
Stridor / Wheeze	29	14.3%
Non-urticarial rash	24	11.8%
Dyspnoea	22	10.8%
Hypotension	20	9.9%
Tachycardia	18	8.9%

14 Transfusion Associated Circulatory Overload (TACO)

During 2010 there were 13 reports classified as TACO. Eight cases were non-severe (grade 1). Most cases (62%) were associated with red cell transfusion, similar to previous years. Table 14 shows the age and sex of recipients with reported TACO. Table 15 lists the clinical features of events reported as TACO during 2010. Chest x-ray findings to support the diagnosis of TACO were noted in 7 of the 13 reports of TACO, 6 reports did not contain any information about chest x-ray changes. Only one report listed a BNP (brain natriuretic peptide) result, which was elevated. Two reports involved patients with an elevated troponin, which may be indicative of acute myocardial injury or strain.

Table 14. Age and Sex of Recipients with Reported TACO 2010

	Number	Age (years)			
		Mean	Median	Minimum	Maximum
Female	6	56	68	4	86
Male	7	67	87	6	89
All	**13**	**62**	**79**	**4**	**89**

Table 15. Clinical Features of TACO 2010

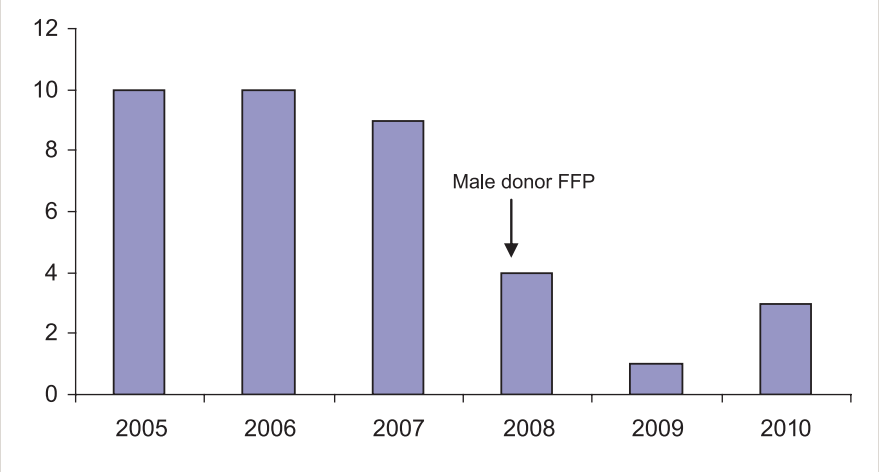
Clinical Signs and Symptoms	Number
Pulmonary oedema	7
Hypertension	7
Dyspnoea	7
Wheeze	6
Restlessness / Anxiety	4
Tachycardia	3
Rigors / Chills	2
Raised JVP	3
Flushing	3
Hypoxaemia	2
Vomiting	1
Extensive urticaria	1
Loin pain	1
Hypotension	1
Chest pain	1

Six of the 13 patients had pre-existing cardiac disease or renal impairment. Some reports contained very little clinical information. One case of TACO was the result of a transfusion prescribing error where 2 red cell units were transfused to a child. The prescription did not state that the units should have been paediatric red cell units nor the dose in millilitres (mLs). The child's haemoglobin increased from 66 to 197g/L.

15 Transfusion Related Acute Lung Injury (TRALI)

Approximately 80% of TRALI is associated with the transfusion of donor white cell antibodies (anti-HLA or anti-HNA) and historically these reactions occur during the transfusion of plasma-containing blood components, usually produced from donations from multiparous female donors. In February 2008 NZBS began restricting the production of fresh frozen plasma to male donors with no history of transfusion and this strategy did reduce the number of TRALI cases reported per annum (Figure 7).

Figure 7. TRALI Reports per Annum



During 2010 there were 3 reports categorised as TRALI. Two cases were associated with red cell transfusion and one case with both red cells and platelets. These cases are summarised below:

Patient A *is a 45 year old female with ALL (acute lymphoblastic leukaemia) who was admitted to hospital with neutropenia and thrombocytopenia. She developed abdominal pain which was thought to be due to psoas muscle haemorrhage. Red cells and platelets were transfused. During platelet transfusion she became hypotensive and hypoxaemic. She was intubated, sedated and ventilated. Radiological imaging did not demonstrate a cause for the abdominal pain however did show bilateral pulmonary infiltrates and acute pulmonary oedema. She initially required high amounts of oxygen and PEEP (positive end expiratory pressure) however her lungs improved over the next 48 hours. Subsequently she developed renal failure and required inotropic support. She failed to wake after the sedative was stopped. Brain imaging showed diffuse white matter changes. She continued to deteriorate and died several days later. Investigation of the associated donors showed that one female donor (buffy coat in pooled platelet concentrate) had anti-HLA B62. The patient was typed and confirmed to express class I HLA B62 antigen. The donor was subsequently retired from donating. Imputability score = 4 (probable).*

15 Transfusion Related Acute Lung Injury (TRALI) continued

Patient B *is a 62 year old female with upper gastrointestinal bleeding who was transfused one unit red cells. Within half an hour she became febrile (temperature 37.5➔38.4°C), tachypnoeac, hypotensive (120/62➔98/50mmHg), and hypoxaemic (SaO_2 96➔88%). She reported chills, stridor, cough, restlessness, abdominal pain and diarrhoea. Her heart rate increased from 78 to 90 beats per minute. There was no peripheral oedema and the jugular venous pressure (JVP) was not elevated. Echocardiogram and BNP were normal. The chest x-ray showed infiltrates, blood culture and a haemolytic screen were negative. IgA level was 2.5g/L (normal). She was treated with high flow oxygen and recovered over 2 days. The red cell unit was collected from a female blood donor however it appears that no further testing occurred. Imputability score = 4 (probable).*

Patient C *is a 61 year old male who underwent re-do coronary artery bypass grafting following the occlusion of his coronary stents. He was transfused 4 units of red cells during the operation. He was on cardiopulmonary bypass for over 2½ hours. There were no signs of circulatory overload however he developed a massive pleural effusion during the operation, which was seen on transoesophageal echocardiogram (TOE). The pleural space was opened and several litres of straw coloured fluid emerged. At the same time a large volume of fluid came up the endotracheal tube "like a garden hose". The fluid was serous and came up at a very high pressure, described by the anaesthetist as very dramatic, shooting 10m across the room. The team were unable to keep up with the torrential volume loss due to "an extraordinary transpulmonary leak into both the pleura and the bronchial tree". The patient died on the operating table. The post-mortem report listed the principle pathological findings as pulmonary oedema, pleural effusion and severe coronary atherosclerosis with stents within vessels. The blood bank was notified 3 months later following a coroner's meeting. Two of the 4 blood donors were female and were tested for anti-HNA and anti-HLA. Both were negative for HNA antibodies, one donor had a positive Class I HLA antibody screen however the PRA was 0% and no antibody identification was performed; the other donor had a negative Class I HLA antibody screen. Imputability score = 3 (possible TRALI).*

16 Transfusion Associated Dyspnoea (TAD)

During 2010 there were 9 reports of TAD, five involved female recipients and four male recipients. Seven events were graded as mild and two were graded as severe (Table 6). Other symptoms and signs associated with these events are listed in Table 16. Only one report commented that a chest x-ray had been done. In general these events are associated with multiple symptoms and are difficult to categorise.

Table 16. Clinical Features of TAD 2010

Clinical Signs and Symptoms	Number
Dyspnoea	9
Restlessness / Anxiety	4
Wheeze	3
Rigors / Chills	3
Hypoxaemia	3
Hypertension	2
Loin pain	2
Tachycardia	1
Flushing	1
Chest pain	1

17 Hypotensive Transfusion Reactions

There were 14 reports of Hypotensive Transfusion Reaction included in the 2010 analysis. These involved 9 females and 5 males, age range 52 – 82 years, mean age 70 years. The mean decrease in systolic blood pressure was 60mmHg (maximum decrease 144mmHg). Most reactions were non-severe and had low imputability (Tables 5 and 6).

18 Acute Haemolytic Transfusion Reaction (AHTR)

There was one AHTR reported during 2010. This case involved the transfusion of a group O platelet concentrate to a group A recipient. The case is summarised below:

Patient D *is a 17 year old male on regular transfusions because of pancytopenia due to myelodysplasia. His medical history includes Kartagener syndrome, bronchiectasis, bronchiolitis obliterans, portal hypertension and ongoing gastrointestinal blood loss. Immediately following transfusion of one apheresis platelet unit he reported chills, dyspnoea, chest tightness and severe pains in his legs and head which required morphine. His temperature increased from 36.7➔37.7°C, heart rate increased from 68➔102 beats per minute, blood pressure decreased slightly from 111/51➔94/48 mmHg, and oxygen saturation decreased from 97➔86%. He was treated with salbutamol, paracetamol and hydrocortisone. His platelet count increased from 13➔31 x 109/L however the haemoglobin decreased from 60g/L to 48g/L. Investigations showed a weakly positive direct antiglobulin test (DAT) on a post-transfusion sample. Further testing using monospecific reagents showed that the anti-C3d was positive and anti-IgG was negative. The pre-transfusion sample had a negative DAT. Although all donations are screened for haemolysin, these reactions which are caused by the transfusion of passive anti-A and/or anti-B, are still observed approximately once per year in New Zealand.*

19 Delayed Reactions

Delayed haemolytic transfusion reactions (DHTR) occur 24 hours – 28 days following red cell transfusion and are characterized by anaemia, jaundice and detectable red cell antibodies. Patients can form antibodies following previous transfusion or pregnancy and red cell transfusion can stimulate an anamnestic response with an increase in antibody concentration. Reports for delayed reactions where there are no clinical or laboratory signs of haemolysis are sub-categorised as delayed serologic transfusion reactions (DSTR).

During 2010 there were 2 DHTR reports and 9 DSTR reports analysed. These occurred in 8 female and 3 male recipients. The specificity of the red cell antibodies are shown in Table 17.

Table 17. Specificity of Red Cell Antibodies in Delayed Reactions 2010

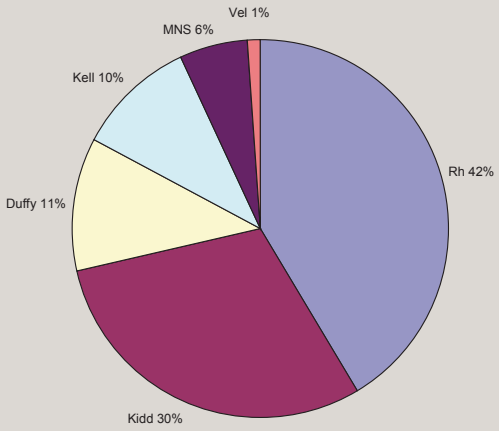
	Antibody	Number
Delayed haemolytic transfusion reactions	Jk^a	1
	Fy^a	1
Delayed serologic transfusion reactions	c + E	2
	Jk^a	2
	Jk^b	1
	Fy^a	1
	C	1
	E	1
	M	1

A total of 70 delayed reactions have been reported to the haemovigilance programme to date, since 2006. In total, 87 new red cell antibodies have been identified in amongst the 70 transfusion recipients. The most frequently identified red cell antibodies were anti-Jka and anti-E (Table 18 and Figure 8).

Table 18. Antibody Specificities for Delayed Reactions 2006 - 2010

Antibody Specificity	Number	Percentage
E	18	20.7%
Jk^a	18	20.7%
Fy^a	9	10.3%
K	9	10.3%
Jk^b	8	9.2%
c	7	8.0%
C	6	6.9%
e	5	5.7%
S	2	2.3%
s	2	2.3%
Fy^b	1	1.1%
M	1	1.1%
Vel	1	1.1%
Total	**87**	

Figure 8. Blood Groups Antibodies Responsible for Delayed Reactions 2006 – 2010



20 Transfusion Transmitted Infections (TTIs)

During 2010 there were 3 reports of suspected bacterial TTI. However, only one case was confirmed by positive cultures obtained in both the unit transfused and in the patient. This was a case of a contaminated 20 day old unit of resuspended red cells that was transfused to a patient with anaemia secondary to a drug reaction. *Yersinia enterocolitica* was cultured from the unit and the patient. Presumably the donor had asymptomatic bacteraemia although no further information was received from the Donor Centre. The 3 reported cases are summarised in Table 19. The other 2 cases were not confirmed because one patient was on antibiotics and had a negative blood culture and the other patient was transfused platelets that may have become contaminated after stopping the transfusion (3 organisms cultured from the unit). There were no reported viral or parasitic TTIs during 2010.

Table 19. Transfusion Transmitted Infections Reported During 2010

Clinical Details	Blood Component	Patient Culture Result	Unit Culture Result	Imputability	Severity Grade
45 year old male, lymphoma, pancytopenia and neutropenic sepsis. Temperature rise 2.2°C and chills 15 minutes after starting transfusion. *Patient on IV antibiotics	Resuspended red cells	No growth* (culture 4 days later)	Proprionibacterium species	Possible	Grade 1
64 year old male, AML, pancytopenia. Flushing, fever (38.2°C) and isolated urticaria around the neck, 50 minutes after starting transfusion	Apheresis platelets	Coagulase negative Staphylococcus	Coagulase negative Staphylococcus + Bacillus species	Possible	Grade 1
45 year old female, anaemia. Temperature rise 2.4°C, rigors, flushing, hypoxaemia, chest pain and hypotension, 20 minutes after starting transfusion	Resuspended red cells	Yersinia enterocolitica	Yersinia enterocolitica	Certain	Grade 2 (severe)

21 Unclassifiable Complications of Transfusion (UCT)

During 2010 there were 64 reports of transfusion related events which could not be classified into a specific category. Of these 19 were excluded from the analysis on the basis that the event was attributable to a cause other than transfusion. The 45 reports analysed involved 33 female and 12 male adult recipients. These reports are summarised in Table 20. There were 15 reports of acute pain associated with transfusion of red cells. Seven reports were of chest pain, 2 had abdominal pain, 2 had loin pain, 2 had pain at the infusion site and 2 had arm pain.

Table 20. UCT Events Possibly or Probably Related to Transfusion 2010

Reaction	Number Reports	Component Transfused
Hypertension	11	Red cells (11)
Pain	15	Red cells (14), platelets (1)
Tachycardia	8	Red cells (8)
Other	5	Red cells (5)
Flushing	3	Red cells (3)
Anxiety	3	Red cells (1), platelets (2)
Phlebitis	2	Red cells (2)
Citrate toxicity	1	Fresh frozen plasma (1)
Stridor	1	Red cells (1)
Total	**45**	

22 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. These types of errors do not always result in harm to the patient however it is important to identify and prevent them from recurring.

During 2010 there were 32 reports categorised as IBCT, 3 of which were excluded (one was a neonatal transfusion that spanned over 5 hours and 2 were reports of "overtransfusion" of red cells with no features of circulatory overload). The 29 reported events included in the analysis originated from a wide range of hospitals. Four events involved patients who should have received irradiated red cells.

There were 11 events (38%) that originated in the laboratory. These are summarized in Table 21. Wrong products issued and transfused included a wrong dose of Rh D Immunoglobulin, plasma volume reduced platelets issued to the wrong neonate, the incorrect brand of recombinant FVIII issued, recombinant FVIIa instead of Prothrombinex (verbal request from the Emergency Department) and red cells issued instead of cryoprecipitate.

Table 22 summarizes the errors that occurred relating to the decision to transfuse, the prescription or the request of blood products, made by doctors. Half of these were due to using an incorrect laboratory result to determine whether to transfuse the patient.

Other errors involved failure to follow blood administration procedures and carry out the necessary pre-transfusion checks (Tables 23 and 24).

Table 21. Errors Made by Laboratory Scientists 2010

Error	Number
Wrong blood product issued and transfused	5
Expired product issued (autologous serum eye drops)	1
Transcription error in typing resulting in Rh D positive red cell transfusion to Rh D negative female	2
Red cells that had been out of the fridge for >1 hour were returned, re-issued and transfused	1
Irradiation protocol not followed (one event during a computer outage and one when issuing "least incompatible" red cells to a patient with red cell autoantibodies)	2
Total	**11**

22 Incorrect Blood Component Transfused (IBCT) continued

Table 22. Errors Made by Doctors 2010

Error	Number
Red cell transfusion based on incorrect haemoglobin result (dilute sample from drip arm)	3
Not stating red cell dose in mL for paediatric transfusion	1
Platelet transfusion based on incorrect low platelet count due to clumping	1
Known Rh D positive patient administered Rh D Immunoglobulin	2
A Jehovah's witness patient was prescribed and administered red cell transfusion while delirious, the error was identified and the transfusion stopped after 80mL had been infused	1
Patients who had been treated with fludarabine were transfused with non-irradiated red cells	2
Total	**10**

Table 23. Administration Errors Made by Nurses 2010

Error	Number
Group B platelets administered to wrong patient (group O), ABO incompatible	1
2 units FFP administered to wrong patient, ABO compatible	1
Red cells issued to a mother were transfused to her baby in an emergency (both A positive)	1
Femoral head issued for Patient A given to patient B	1
Total	**4**

Table 24. Errors Made by Midwives 2010

Error	Number
Prescribed and administered the incorrect dose of Rh D Immunoglobulin	2
Wrong patient details on prescription	1
Administered Rh D Immunoglobulin instead of Hepatitis B Immunoglobulin to a newborn (baby Rh D positive)	1
Total	**4**

22 Incorrect Blood Component Transfused (IBCT) continued

Prescriptions for paediatric transfusions should state the volume to be transfused in mLs. The case of Miss L below demonstrates how prescribing errors can lead to iatrogenic polycythaemia in small recipients.

Case: Miss L

Miss L was a 3 year old female with a history of microcephaly, developmental delay, epilepsy and percutaneous endoscopic gastrostomy (PEG) tube feeding. She weighed 17kg and underwent bilateral femoral osteotomies and adductor release for the treatment of bilateral hip dislocation. On Day 1 post-surgery her haemoglobin was 66g/L and 2 units of red cells were prescribed. Over the next 5 hours she was transfused 2 adult units of resuspended red cells (468mL in total). A repeat blood test showed a high haemoglobin of 197g/L and haematocrit increase from 0.2 to 0.55. She showed signs of fluid overload and was treated with intravenous frusemide.

23 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. Near miss events are usually reported to local incident management systems (within a DHB) so that appropriate investigation is undertaken and the necessary education and preventive actions are implemented. During 2010 there were two near miss events formally reported to the Haemovigilance Programme and 36 events recorded in the NZBS incident management system. These events are summarized in Table 25.

Table 25. Near Miss Events 2010

Error	Site of Error			Total Errors
	Blood Bank	Blood Processing	Clinical	
Wrong blood product issued by the blood bank: includes wrong product, wrong dose or wrong patient	9		1	10
Data entry or transcription errors or other laboratory errors	13			13
Irradiation labelling errors		10		10
Expired red cells received in blood bank from processing site		1		1
Pretransfusion specimen validity errors	2			2
Component labelling error		1		1
Provision of red cells that did not meet protocol requirements	1			1
Total	**25**	**12**	**1**	**38**

24 Bacterial Monitoring of Platelet Concentrates

Bacterial contamination of blood products is now considered the most frequent infectious risk of transfusion. Platelet concentrates are stored at warmer temperatures than red cells and are therefore more likely to allow replication of bacteria if contamination has occurred. There are several possible sources of contamination: bacteria on the skin entering the unit at the time of collection, bacteraemia of the donor or contamination during collection or blood processing procedures. Strategies to minimize these events include careful donor assessment and selection, optimal skin disinfection of the venepuncture site, diversion of the first aliquot of the donation and using processing procedures that maintain a closed sterile system. Sterility testing allows us to assess the effectiveness of these strategies.

NZBS commenced a pilot study to assess the frequency of bacterial contamination during October 2003. The scheme was progressively rolled out such that by the end of 2007 all sites within NZBS that manufacture platelets were participating. The proportion of components tested for aerobic bacteria has increased progressively over the last two years. During 2010 approximately 84% of all apheresis platelet concentrates and 81% of platelet pools were tested (Table 26). These rates are similar to those seen in previous years. Apheresis collections are normally split into two components (doses) soon after production. Currently only one of the 2 apheresis components is tested.

Table 26. Proportion of Platelet Components Sterility Tested at Day 2 in 2010

	Apheresis Platelets			Pooled Platelets		
	Collections	Components Tested	% Tested	Produced	Tested	% Tested
Auckland	2,331	1,970	85	4,065	3,113	77
Waikato	1,177	979	83	1,823	1,546	85
Wellington	869	775	89	1,423	1,234	87
Christchurch	1,062	756	71	776	680	88
Manawatu	468	443	95			
Otago	347	333	96			
Total	**6,254**	**5,256**	**84**	**8,087**	**6,573**	**81**

The NZBS protocol for bacterial monitoring involves sampling 6mL from a platelet unit at day 2 and culturing in aerobic conditions. Platelet concentrates that are not transfused are cultured again after expiry on day 8. Results of the day 2 and day 8 testing of platelet concentrates are shown in Table 27.

24 Bacterial Monitoring of Platelet Concentrates continued

Table 27. Results of Sterility Testing of Platelet Components During 2010

	BacTalert Positive	Confirmed Culture Positive	% Positive	Frequency of Positives
Day 2 sampling (total 11,829)	26	6	0.05	1:1,972
Expired platelets sampled (total 3,401)	4	2	0.06	1:1,701

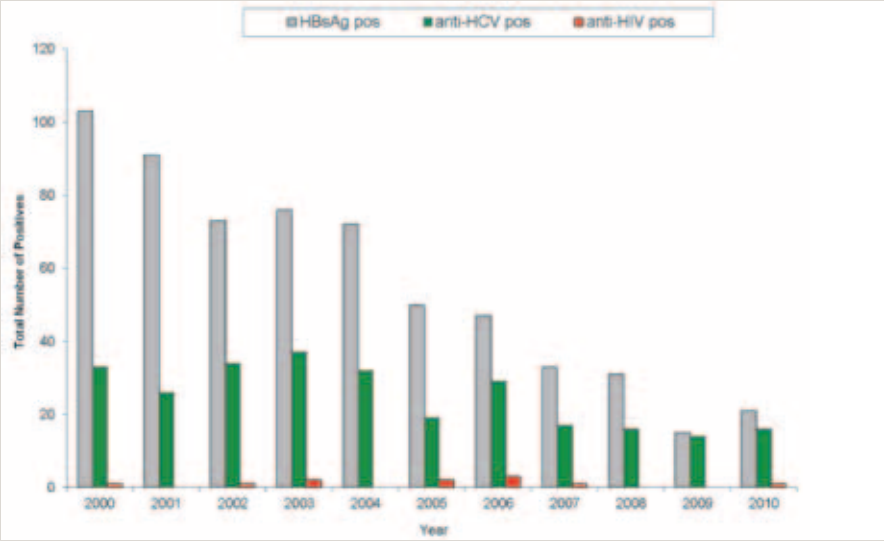
Cumulative results for the past 4 years (2007–2010) of day 2 sterility testing of platelet concentrates indicate that over 42,000 platelet units have been tested and the overall rate of a confirmed positive unit is 1:3,281.

NZBS plans to continue to utilise the bacterial monitoring programme as a quality assurance tool. Aseptic sampling techniques are important to minimize the risk of false positive cultures due to contamination at the time of sampling or inoculation in culture. All instances of a positive culture need to be promptly investigated.

25 Donor Infectious Diseases Screening

In New Zealand all blood 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. Red cells for fetal and neonatal transfusion are produced from donations that are negative for CMV IgG. Donors who have travelled overseas may be at risk of malaria or Chagas disease and selected donations are also screened for these diseases. Figure 9 shows the trend in the number of donors with confirmed positive serology for HBV, HCV and HIV for the previous 11 years.

Figure 9. Donor Epidemiologic Data 2000 - 2010



During 2010 there were 177,785 donations collected from 94,167 donors. 80% were repeat donors and 20% were new donors (previously untested).

HBV DNA donation screening was introduced in New Zealand in 2007. This has allowed us to identify occult HBV infection, i.e. when there is detectable HBV DNA and undetectable HBsAg. During 2010 there were 20 donors who were found to have occult HBV infection. Of these 85% were repeat donors and 15% were new donors.

Table 28 shows the number of donors with confirmed positive serology during 2010. There were 21 donors who were confirmed positive for HBsAg, 16 donors confirmed positive for HCV, one donor confirmed positive for HIV and one with anti-HTLV. Table 29 shows the frequency of confirmed positive HBsAg, HCV and HIV in new and repeat donors per year for the previous 4 years.

25 Donor Infectious Diseases Screening continued

Table 28. Donors with Confirmed Positive Serology 2010

		HBV (HBsAg Positive)	HCV	HIV	Syphilis	HBV Occult	HTLV I/II
Number	New donor (n = 18,822)	21	15	1	8	3	1
	Repeat donor (n = 75,345)		1		4	17	
	Total (n = 94,167)	21	16	1	12	20	1
% Positive donations		0.022%	0.017%	0.001%	0.013%	0.021%	0.001%
Frequency of positive donation	Repeat Donor		1:75,345		1:18,836	1:4,432	
	New Donor	1:896	1:1,255	1:18,822	1:2,353	1:6,274	1:18,822
Overall frequency		1:4,484	1:5,885	1:94,167	1:7,847	1:4,708	1:94,167

Table 29. Donors with Confirmed Positive Serology 2007 – 2010

		2007	2008	2009	2010
HBsAg positive	New donor	1:677	1:725	1:1,294	1:896
	Repeat donor	1:7,841	1:78,090	1:75,204	
HCV positive	New donor	1:1,400	1:1,451	1:1,294	1:1,255
	Repeat donor	1:7,841	1:78,090		1:75,345
HIV positive	New donor	1:21,001			1:18,822
	Repeat donor				

26 Residual Risk of Virus Transmission via Transfusion

The utilisation of highly sensitive screening methods and nucleic acid amplification testing minimises the risk of transmission of HBV, HCV and HIV through transfusion. The calculated residual risk of viral infection is summarized in Table 30. The data is similar to 2009. The denominator used for HCV and HIV is based on data from the past 9 years; the denominator used for the HBV residual risk estimate is based on data from the past 4 years (since the implementation of deferring donors who have been vaccinated for HBV within 7 days, because this is included in the confirmed positive serology data).

Table 30. Residual Risk Estimates for Viral TTI in New Zealand

Virus	Frequency (95% CI)	Risk per Million Donations (95% CI)
HBV	1:284,170 (88,639 - 911,033)	3.5 (1.1 - 11.3)
HCV	1:2,150,480 (305,067 - 15,159,221)	0.5 (0.1 - 3.3)
HIV	1:5,145,855 (358,547 - 73,853,322)	0.2 (0.0 - 2.8)
HTLV	1:2,658,321 (28,391 - 248,912,795)	0.4 (0.0 - 35.2)

27 Adverse Events Associated with Blood Donation

All donors undergo a health check by a registered nurse prior to proceeding with collection of whole blood or an apheresis collection. Adverse events can occur during or after donation. Delayed complications are defined as those that occur after the donor has left the donation site. During 2010 3,525 donations involving 3,409 donors were associated with an adverse event (a number of donors had more than one donation associated with an adverse event). In total there were 177,785 donations, comprised of 153,043 whole blood donations, 18,243 plasmapheresis and 6,499 plateletpheresis donations. The overall rate of a donation related adverse event was 1:50. This appears to be increasing (Figure 10) however is likely to be explained by improved reporting rates.

Figure 10. Donation Associated Adverse Event per 10,000 Donations 2005 - 2010

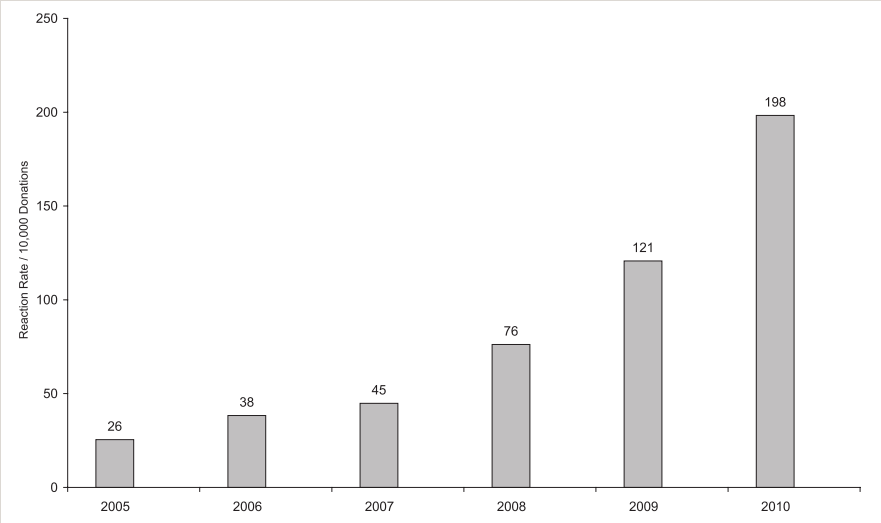


Table 31 shows the rate of adverse event by donation procedure and the rate per 10,000 donations.

Table 31. Donor Adverse Event per Procedure 2010

Procedure	Total Donations	Donations with Events	Frequency	Rate / 10,000 Donations (95% CI)
Whole Blood	153,043	2,950	1:52	193 (186 – 200)
Plasmapheresis	18,243	381	1:48	209 (189 – 231)
Plateletpheresis	6,499	194	1:34	299 (260 – 343)
All apheresis procedures	24,742	575	1:43	232 (214 – 253)
Total procedures	**177,785**	**3,525**	**1:50**	**198 (192 – 205)**

27 Adverse Events Associated with Blood Donation continued

Vasovagal reactions and bruising/haematoma are the most frequent complications associated with donation. Some donors experienced more than one complication per donation, in total there were 3,886 donor events reported during 2010. These are shown in Table 32. Apheresis donations are associated with a higher rate of adverse events compared to whole blood donation.

Table 32. Donation Associated Events by Category and Frequency for 2010

Donor Event	Number	% Total Events	Frequency	Rate / 10,000 Donations (95% CI)
Immediate vasovagal	1,789	46.0%	1:99	101 (96 – 105)
Haematoma	1,241	31.9%	1:143	70 (67 – 74)
Apheresis procedures	354	9.1%	1:70*	143 (129 – 159)
Painful arm	143	3.7%	1:1,243	8 (7 – 10)
Delayed vasovagal	113	2.9%	1:1,573	6 (5 – 8)
Nerve irritation	90	2.3%	1:1,975	5 (4 – 6)
Other	66	1.7%	1:2,694	4 (3 – 5)
Nerve Injury	56	1.4%	1:3,175	3 (2 – 4)
Delayed bleeding	16	0.4%	1:11,112	1 (0.6 – 2)
Arterial puncture	7	0.2%	1:25,398	0.4 (0.2 – 0.8)
Allergy	6	0.2%	1:29,631	0.3 (0.2 – 0.7)
Tendon damage	3	0.1%	1:59,262	0.2 (0.1 – 0.5)
Thrombophlebitis	2	0.1%	1:88,893	0.1 (0 – 0.4)
Total	**3,886**		**1:46**	**219 (212 – 225)**

** calculated on apheresis donations only*

Severe complications related to blood donation are defined as events resulting in any of the following:

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

During 2010 there were 5 donation associated adverse events classified as severe - all were vasovagal reactions following whole blood donation (Table 33). There were no donation associated deaths reported during 2010.

27 Adverse Events Associated with Blood Donation continued

Table 33. Donor Complication Rate by Severity Score per 10,000 Donations 2010

			Rate per 10,000 Donations		
			Whole Blood (n= 153,043)	Plasma-pheresis (n = 18,243)	Platelet-pheresis (n= 6,499)
Complications mainly characterised by blood outside blood vessels	Haematoma	Mild	58	84	162
		Moderate	5	7	17
	Arterial puncture	Mild	0.4		
		Moderate	0.1		
	Delayed bleeding	Mild	2	2	
		Moderate	0.2		
Pain/soft tissue injury	Nerve irritation	Mild	5	4	3
		Moderate	0.5	3	
	Nerve injury	Mild	3	3	6
		Moderate	0.4		
	Tendon damage	Mild	0.1		
		Moderate	0.1		
	Painful arm	Mild	6.5	7	8
		Moderate	1.3	1	6
Other complications with local symptoms	Thrombophlebitis	Mild	0.1		
		Moderate		0.5	
	Allergy (local)	Mild	0.3	0.5	
		Moderate	0.1		
Immediate vasovagal reaction	Without injury	Mild	91	35	31
		Moderate	18	7	6
		Severe	0.2		
	With injury	Mild	1	0.5	
		Moderate	0.3		
Delayed vasovagal reaction	Without injury	Mild	4	3	2
		Moderate	3		
		Severe	0.1		
	With injury	Mild	0.1		
		Moderate	0.2	0.5	
Complications related to apheresis	Citrate reaction			3	19
	Haemolysis			0.5	
	RBC not returned			116	191

The frequency of donation associated adverse events is higher in younger blood donors, in particular donors under the age of 20 years (odds ratio 2.0). This trend is observed for vasovagal reactions and for all complications associated with whole blood donation (Figures 11 and 12).

27 Adverse Events Associated with Blood Donation continued

Figure 11. Odds Ratio For All Complications Associated with Whole Blood Donation 2010

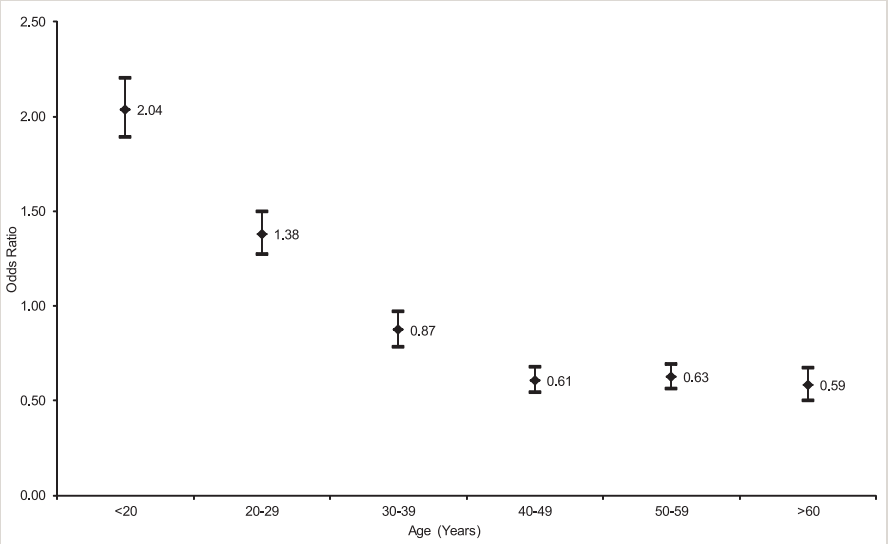
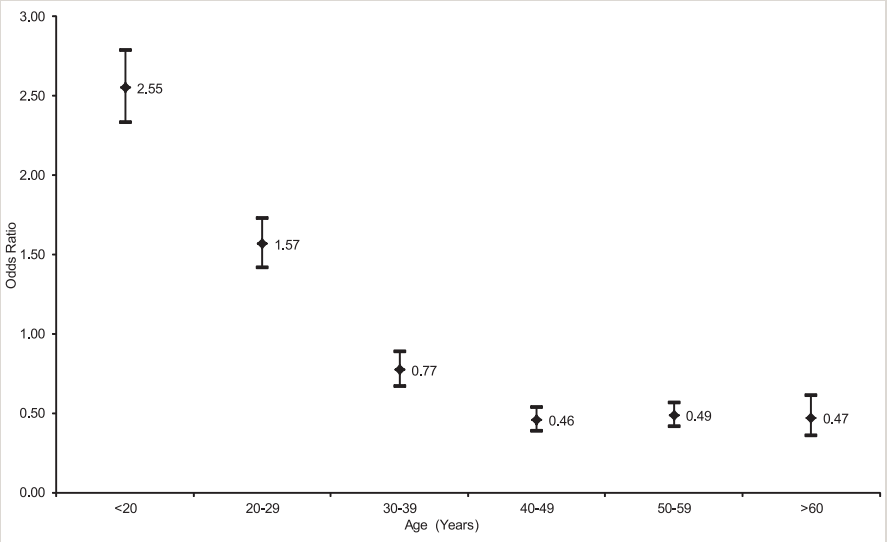


Figure 12. Odds Ratio For Vasovagal Reactions Associated With Whole Blood Donation 2010



28 Adverse Events Associated With Fractionated Plasma Products

Adverse events associated with fractionated plasma products have a separate reporting procedure to that for blood components. The majority of plasma products used in New Zealand are manufactured from New Zealand donor plasma by CSL (Australia).

During 2010 there were a total of 46 reported events associated with plasma products. Two thirds of these were reactions and one third were errors with no associated harm to the patient. Table 34 shows that 57% of adverse events were associated with Intragam P. The reactions associated with Intragam P are shown in Table 35. Two reactions (autoimmune haemolytic anaemia and allergic/inflammatory) were deemed to be unlikely to be related to the plasma product (Intragam P in both cases). One reaction with highly probable causality was recorded as serious, this was an allergic/inflammatory reaction associated with Intragam P.

Table 34. Reported Adverse Events per Fractionated Plasma Product 2010

Plasma Product	Adverse Events
Intragam P	26
Rh D Immunoglobulin	10
Albumex 4	3
MonoFIX-VF	2
Prothrombinex-VF	2
Biostate	2
Tetanus Immunoglobulin	1
Total	**46**

Table 35. Reactions Reported with Intragam P 2010

Type of Reaction	Number of Events
Allergic/inflammatory	15
Pyrexia	6
Haemolytic	2
Aseptic meningitis	1
Autoimmune haemolytic anaemia	1
Hypotension & dyspnoea	1
Total	**26**

The reactions associated with other products are summarised in Table 36. All were categorised as not severe.

28 Adverse Events Associated With Fractionated Plasma Products continued

Table 36. Reactions Reported with Other Plasma Products 2010

Plasma Product	Type of Reaction	Number
Prothrombinex-VF	Pain	1
WinRho-SDF	Allergic/inflammatory	1
Albumex 4	Volume overload Pyrexia	2 * 1
Total		**5**

**same patient*

Errors involving plasma products are summarized earlier (page 30) and include wrong product issued and transfused, expired product dispensed, wrong patient given product, wrong dose and inappropriate use of a product. These events involved MonoFIX-VF, Tetanus Immunoglobulin, Biostate, Rh D Immunoglobulin and Prothrombinex-VF.

29 Request Form and Sample Labelling Errors

The collection of a blood sample for pre-transfusion testing from the correct patient is a vital step in the process of a safe transfusion. Errors that occur during labelling of a pre-transfusion sample can lead to the transfusion of ABO incompatible red cells for the intended recipient. ABO incompatible red cell transfusions can cause significant morbidity and even be fatal.

PRE-TRANSFUSION SAMPLES MUST BE LABELLED AT THE BEDSIDE IMMEDIATELY FOLLOWING COLLECTION AND PATIENT IDENTITY MUST BE CONFIRMED EITHER VERBALLY WITH THE PATIENT OR VIA A LABEL ATTACHED TO THE PATIENT.

Pre-transfusion samples must be hand-labelled. This requirement was introduced by NZBS in 2004. Samples that are received with a pre-printed addressograph label are discarded. Over the past 5 years, the six NZBS Blood Banks (Auckland, Waikato, Manawatu, Wellington, Christchurch and Dunedin) have been recording errors and corrective actions associated with pre-transfusion samples. Data is entered into a Microsoft Access™ database at each site and then analysed. Reports are reviewed by Hospital Transfusion Committees and by the NZBS Clinical Advisory Group.

The minimum requirements for pre-transfusion request forms and sample labelling (for NZBS Blood Banks) are outlined in Table 37.

Table 37. Pre-transfusion Request Form and Sample Labelling Requirements (NZBS)

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

During 2010 a total of 138,666 pre-transfusion samples were received by the six NZBS Blood Banks. Errors were identified in 3,254 samples/forms. The overall error rate for the six NZBS Blood Banks for 2010 is 23.5 per 1,000 samples received which is equivalent to a rate of 1:43. Table 38 shows the error rate per 1,000 samples for each of the six NZBS Blood Banks in 2010.

29 Request Form and Sample Labelling Errors continued

Table 38. Sample Error Rates per NZBS Blood Bank 2010

Blood Bank	Errors	Total Samples	Error Rate	Rate / 1,000 Samples (95% CI)
Auckland	851	48,595	1:57	17.5 (16.4 – 18.7)
Christchurch	677	23,487	1:35	28.8 (26.8 – 31.0)
Dunedin	352	10,273	1:29	34.3 (30.9 – 38.0)
Manawatu	411	8,641	1:21	47.6 (43.3 – 52.3)
Waikato	518	27,521	1:53	18.8 (17.3 – 20.5)
Wellington	445	20,149	1:45	22.1 (20.1 – 24.2)
NZBS	**3,254**	**138,666**	**1:43**	**23.5 (22.7 - 24.3)**

The most frequent error (24%) was “declaration not signed” followed by “evidence of pre-printed addressograph label on tube” (19%). The error types and actions are summarised in Table 39. When corrections are allowable, they must be carried out by the collector, at the Blood Bank (unless the collector is directly involved in critical patient care). If the collector is not available a new sample must be collected.

Some requisitions/samples were received with more than one type of error (total number of errors 3,435). Wrong blood in tube (WBIT) errors are discussed separately.

29 Request Form and Sample Labelling Errors continued

Table 39. Sample and Request Form Errors and Action Required 2010

Error type	Number	% Total	Frequency	Rate / 1,000 Samples	Action Required
Declaration not signed	809	23.6%	1:171	5.8	Corrected by collector or recollect
Pre-printed ID label (or evidence of removal)	654	19.0%	1:212	4.7	Recollect
Missing patient details (moderate error)	520	15.1%	1:267	3.8	Correction by collector
Sample not signed	483	14.1%	1:287	3.5	Correction by collector
Missing patient details (major error)	326	9.5%	1:425	2.4	Recollection
Other clerical error	158	4.6%	1:878	1.1	Consult Team Leader
Signature on sample and declaration differ	157	4.6%	1:883	1.1	Recollect
Technical	123	3.6%	1:1,127	0.9	Recollect
Unlabelled sample	120	3.5%	1:1,156	0.9	Recollect
Original details overwritten	85	2.5%	1:1,631	0.6	Recollect
Total	**3,435**				

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

30 Sample Recollection Rates

The overall rate of requests for recollection of pre-transfusion samples, by NZBS Blood Banks, was 13.8 per 1,000 samples during 2010. Table 40 summarizes the recollection rates for each NZBS Blood Bank in 2010. Overall 59% of errors resulted in a request for recollection of the pre-transfusion sample.

Table 40. Recollection Rate per Blood Bank 2010

Blood Bank	Recollection Requests	Total Number of Samples	Frequency	% Errors	Rate / 1,000 Samples (95% CI)
Auckland	531	48,595	1:92	62%	10.9 (10.0 – 11.9)
Christchurch	399	23,487	1:59	59%	17.0 (15.4 – 18.7)
Dunedin	133	10,273	1:77	38%	12.9 (10.98 – 15.3)
Manawatu	258	8,641	1:33	63%	29.9 (26.5 – 33.7)
Waikato	266	27,521	1:103	51%	9.7 (8.6 – 10.9)
Wellington	325	20,149	1:62	73%	16.1 (14.5 – 18.0)
NZBS	**1,912**	**138,666**	**1:73**	**59%**	**13.8 (13.2 – 14.4)**

31 Wrong Blood in Tube (WBIT) Errors

A "wrong blood in tube" error is when the pre-transfusion sample was collected from the wrong patient or the sample was labelled with the details of another patient. These types of errors are usually identified when ABO testing shows a different blood group from the historic results. Some countries refer to these as "wrong name on tube" (WNOT) errors. A current WBIT is where the sample received is proven to be incorrectly collected or labelled and an historic WBIT is where the historic result was likely to be based on a sampling or labelling error. Silent errors can occur when the wrong patient is bled, however has the same ABO group as the intended patient. The corrected WBIT rate is calculated using the following equation:

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

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

31 Wrong Blood in Tube (WBIT) Errors continued

During 2010 historic blood groups were available for 62% of all pre-transfusion samples submitted to NZBS Blood Banks. There were 20 WBIT errors identified by NZBS Blood Banks. In three cases the historic result was assumed to be incorrect. Table 41 shows the corrected WBIT rate for the 17 current WBITs reported by the NZBS Blood Banks in 2010.

Table 41. Corrected WBIT Error Rate per NZBS Blood Bank 2010

Blood Bank	WBIT Errors	Historic Groups	WBIT Frequency*
Auckland	2	30,419	1:9,506
Christchurch	5	14,971	1:1,871
Dunedin	0	6,144	
Manawatu	3	5,247	1:1,093
Waikato	1	17,252	1:10,783
Wellington	6	12,219	1:1,273
NZBS	**17**	**86,252**	**1:3,171**

** corrected to account for silent errors*

The overall rate of a WBIT error is approximately 1:3,100 pre-transfusion samples. Table 42 shows cumulative data for the past 3 years.

Table 42. Corrected WBIT Error Rate 2008 - 2010

Blood Bank	WBIT Errors	WBIT Frequency*
Auckland	17	1:3,153
Christchurch	7	1:4,179
Dunedin	4	1:2,764
Manawatu	4	1:2,273
Waikato	7	1:4,460
Wellington	11	1:1,923
NZBS	**50**	**1:3,108**

** corrected to account for silent errors*

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

National Haemovigilance Programme 111F04208

Page 1 of 4

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.

New Zealand Government