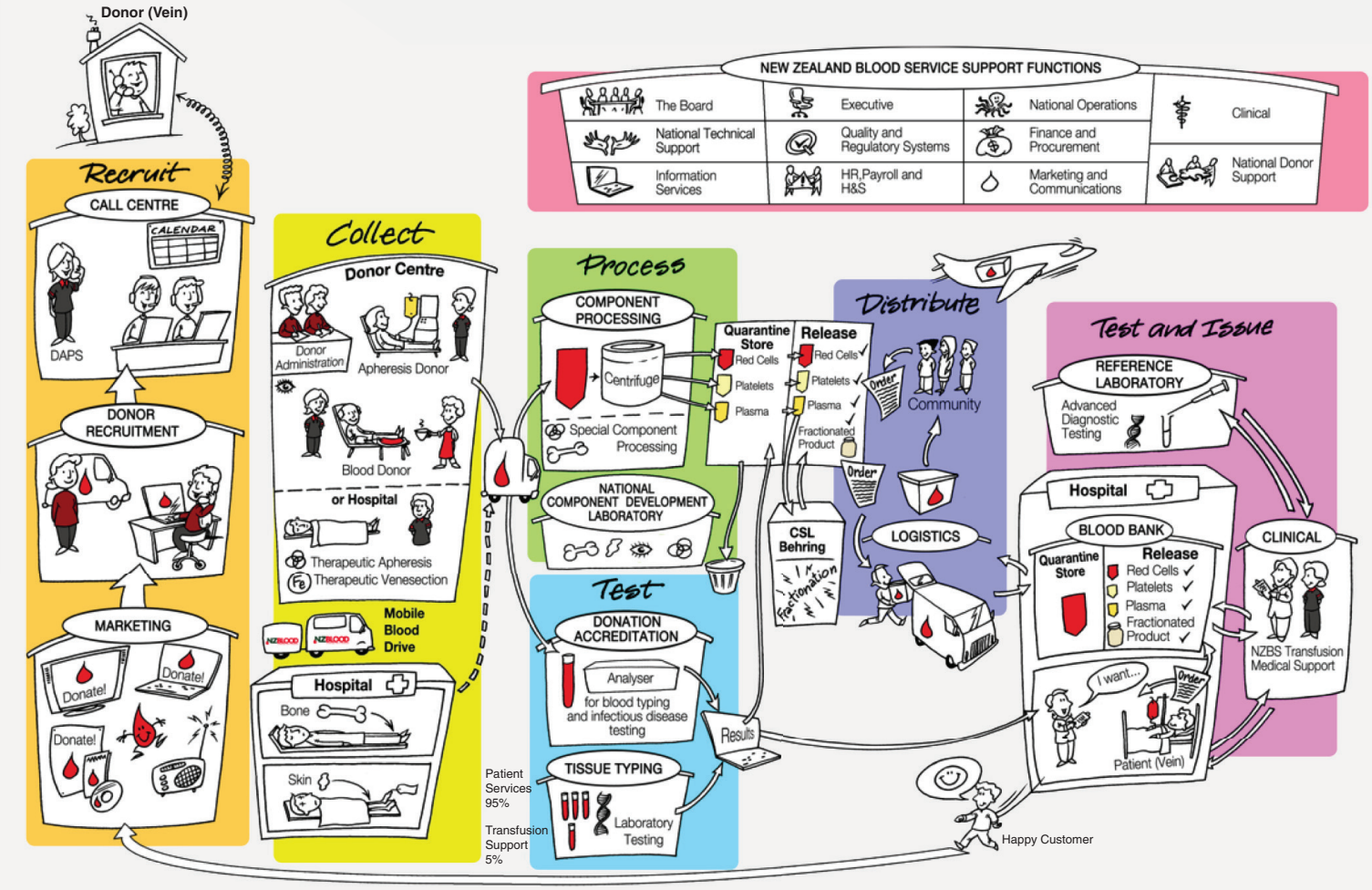
NZBLOOD
Te Ratonga Toto O Aotearoa

National Haemovigilance Programme

VEIN TO VEIN



Annual Report

2015

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Disclaimer

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Foreword

This is the 11th Annual Haemovigilance Report for New Zealand. Support for the programme remains strong. I would like to thank everyone contributing to the completion and submission of adverse event forms, particularly those of you providing additional clinical information when required for accurate event classification.

I would like to acknowledge the dedication of Mr John Dagger to the programme. In addition to his role as Head of the Haemovigilance Office in Wellington, he has once again collated the data and played a major role in drafting the Annual Report. His contribution to the programme throughout the year is greatly appreciated.

Patient blood management guidelines, applied to a growing spectrum of clinical settings, continue to reflect an increasingly restrictive red cell transfusion policy. This has lead to a gradual reduction in mean pretransfusion haemoglobin value to 75.6g/L in the recipients of red cells reported to NZ Haemovigilance in 2015. The change in local clinical practice has contributed to a 19% decline in the number of annual red cell transfusions in NZ since 2010, with a further 3% drop in annual red cell transfusions since 2014. A similar trend is seen for the use of platelet and fresh frozen plasma components, contributing to an overall 17% reduction in the annual total blood component use in NZ since 2010.

Largely as a result of these changing demand-patterns for fresh blood components, the annual number of reported transfusion events has declined by 24% since 2010. The frequency of one transfusion-related adverse event (TRAE) reported for every 285 components transfused has however remained stable over this period. Reporting to the National Haemovigilance Programme is voluntary, yet 20% of reports are classified with a low imputability score. This is encouraging indirect evidence that clinicians are likely to be over- rather than under-reporting adverse events to blood transfusion.

The difficulty in both assessing transfusion reactions at the bedside and subsequently classifying events is evidenced by the diversity and overlap of symptoms and signs accompanying classical features of the various TRAE. This is exemplified by the transfusion reactions with predominant respiratory features (TRRF) including transfusion-associated circulatory overload (TACO), transfusion-related acute lung injury (TRALI), some allergic reactions, and the heterogeneous group of transfusion-associated dyspnoea (TAD). Due to the occasional severe nature of these events, accurate classification of this group of reactions is important. Due to a concerted effort since 2013, the annual numbers of TRRF reactions remaining classified as TAD has significantly reduced.

The annual use of fractionated plasma products, predominantly intravenous immunoglobulin (IVIg), continues to rise in New Zealand. A similar trend is occurring internationally, as there is an increasing spectrum of conditions where IVIg-immunomodulation may be beneficial. Local demand for IVIg has contributed to the steady increase in plasmapheresis collections. Since 2010, the number of plasmapheresis donations has risen by 260%.

NZ Haemovigilance has since its inception in 2005 recorded donation-related adverse events and continues to actively monitor both apheresis and whole blood donations. Apheresis procedures are associated with a high frequency of adverse events and among these are events related to changes in circulating blood volume. In November 2015, modifications made to the plasmapheresis donor nomogram were introduced at Donor sites, with the aim of maximising total plasma volume collected while, at the same time, protecting vulnerable donors. Haemovigilance activity for the periods prior to and following this change identify early signs of up to an 80% reduction in donation-related adverse events for first time plasmapheresis donors.

I hope you will find the report informative and look forward to your on-going support of the programme.

Dr Daren Buhrkuhl
Transfusion Medicine Specialist
NZBS Wellington

Abbreviations and Glossary

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Albumex® 20	20% albumin solution for intravenous infusion
Albumex® 4	4% albumin solution for intravenous infusion
APH	Apheresis
Biostate®	Coagulation factor VIII and von Willebrand factor complex
Blood Components	Portions of a unit of whole blood – red cells, fresh frozen plasma, platelets, cryoprecipitate prepared by NZBS for transfusion
BNP	Brain (or B-type) Natriuretic Peptide
CAG	Clinical Advisory Group
DAT	Direct Antiglobulin Test
DHB	District Health Board
DHTR	Delayed Haemolytic Transfusion Reaction
DSTR	Delayed Serological Transfusion Reaction
Evogam®	Normal Immunoglobulin solution for subcutaneous administration
FFP	Fresh Frozen Plasma
FNHTR	Febrile Non-Haemolytic Transfusion Reaction
Fresh Frozen Plasma Neo	Fresh Frozen Plasma for neonatal transfusions, volume 46 – 90 mL
Hb	Haemoglobin
HBV	Hepatitis B Virus
HCV	Hepatitis C Virus
HIV	Human Immunodeficiency Virus
IAT	Indirect Antiglobulin Test
IBCT	Incorrect Blood Component Transfused
Intragam®P	Normal Immunoglobulin solution for intravenous infusion
LDH	Lactate Dehydrogenase
NAT	Nucleic Acid Amplification Test
NHI	National Health Index
NZBS	New Zealand Blood Service
PAS	Platelet Additive Solution
Platelets APH	Platelets prepared by apheresis suspended in plasma
Platelets APH PAS	Platelets prepared by apheresis suspended in PAS, introduced 2012
Platelets Neo	Platelets for neonatal transfusions, volume 30 – 60 mL
Platelets Pooled PAS	Pool of platelets from buffy coats suspended in PAS, introduced 2011
Prothrombinex®-VF	Coagulation factors II, IX and X and low levels of factors V and VII
Red Cells Neo	Red cells for neonatal transfusions, volume 55 – 85 mL
RhD Immunoglobulin-VF	Human Anti-D Immunoglobulin solution for intramuscular injection
TACO	Transfusion-Associated Circulatory Overload
TAD	Transfusion-Associated Dyspnoea
TMS	Transfusion Medicine Specialist
TRAE	Transfusion-Related Adverse Events
TRALI	Transfusion-Related Acute Lung Injury
TTI	Transfusion-Transmitted Infection
UCT	Unclassifiable Complication of Transfusion
Zoster Immunoglobulin-VF	Zoster Immunoglobulin solution for intramuscular injection

2 Introduction

Council of Europe Definition of Haemovigilance

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

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

The National Haemovigilance Office receives reports from Blood Bank Scientists and Transfusion Nurse Specialists from hospitals within New Zealand. The reporting form (Appendix I) includes a severity scale, an imputability scale and definitions of transfusion-related adverse events (TRAE) based upon those agreed by the International Society of Blood Transfusion's Working Party on Haemovigilance in collaboration with the International Haemovigilance Network (ISBT/IHN).

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

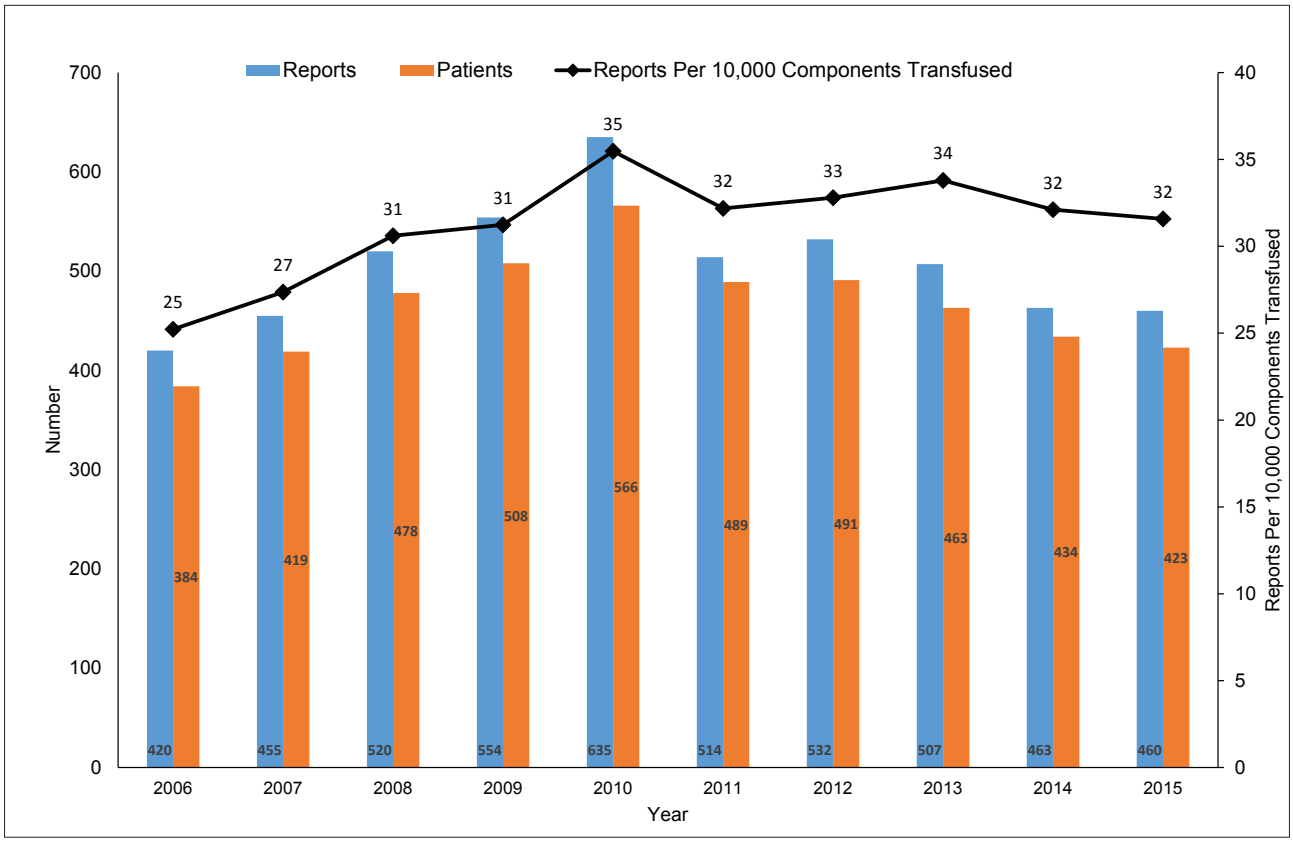
The reporting of TRAE to the National Haemovigilance Programme is voluntary. During 2015, there were 460 TRAE reported, involving 423 patients. Compared to 2014, both the total number of reported events and the ratio of reports to number of components transfused have remained relatively stable (Table 2.1). The year on year number of events and patients is shown in Figure 2.1.

TABLE 2.1 COMPARISON HAEMOVIGILANCE REPORTS : COMPONENTS TRANSFUSED 2007 – 2015

	Year								
	2007	**2008**	**2009**	**2010**	**2011**	**2012**	**2013**	**2014**	**2015**
Total Components Transfused	155,673	158,181	162,587	159,568	151,919	149,668	136,995	135,135	132,060
Number Haemovigilance Reports Received	455	520	554	635	514	532	507	463	460
Percentage Change From Previous Year									
Components Transfused		1.6%	2.8%	-1.9%	-4.8%	-1.5%	-8.5%	-1.4%	-2.3%
Haemovigilance Reports		14.3%	6.5%	14.6%	-19.1%	3.5%	-4.7%	-8.7%	-0.6%
Reports : Components Transfused	**1:342**	**1:304**	**1:293**	**1:251**	**1:296**	**1:281**	**1:270**	**1:292**	**1:287**

Introduction continued

FIGURE 2.1 ANNUAL NUMBER OF TRANSFUSION-RELATED ADVERSE EVENTS 2006 – 2015



3 Trends in Blood Component Transfusion in New Zealand

Table 3.1 shows the annual number of blood components transfused. Comparing the number of red cell units transfused in 2015 to the number transfused in 2010, there has been a 18.8% reduction. For platelets and fresh frozen plasma, the corresponding figures are reductions of 8.0% and 25.4%, respectively. The majority of the fall in use of these blood components was seen from 2010 to 2013, with a subsequent slower decline.

There has however been a 51.9% increase in the number of units of cryoprecipitate transfused which likely reflects the introduction of massive transfusion protocols in a number of hospitals and the use in cardiovascular surgery.

TABLE 3.1 ANNUAL NUMBER OF BLOOD COMPONENTS TRANSFUSED 2010 – 2015

Blood Component	2010	2011	2012	2013	2014	2015	% Change 2015 compared to 2010
Red Cells	122,745	116,071	113,014	103,565	102,718	99,915	
Red Cells Neo	1,898	1,749	1,732	1,664	1,553	1,260	
Total Red Cells	**124,643**	**117,820**	**114,746**	**105,229**	**104,271**	**101,175**	**-18.8%**
Platelets - APH	7,576	6,661	2,117	487	523	411	
Platelets - Pooled	5,403	2,349	614	0	0	0	
Platelets - APH PAS		774	5,354	5,627	4,033	3,818	
Platelets - Pooled PAS	48	2,988	5,037	6,457	7,429	7,683	
Platelets - Neo	589	485	661	817	616	621	
Total Platelets	**13,616**	**13,257**	**13,783**	**13,388**	**12,601**	**12,533**	**-8.0%**
Fresh Frozen Plasma	17,685	16,736	16,524	13,528	13,400	13,172	
Fresh Frozen Plasma Neo	187	127	200	175	151	162	
Total Fresh Frozen Plasma	**17,872**	**16,863**	**16,724**	**13,703**	**13,551**	**13,334**	**-25.4%**
Cryoprecipitate	2,951	3,228	3,745	4,167	4,198	4,482	51.9%
Cryodepleted Plasma	486	751	670	508	514	536	10.3%
Total Components	**159,568**	**151,919**	**149,668**	**136,995**	**135,135**	**132,060**	**-17.2%**

The annual blood component transfusion rates per 1,000 of the New Zealand population for the period 2010 to 2015 are shown in Table 3.2.

TABLE 3.2 ANNUAL RATE OF BLOOD COMPONENTS TRANSFUSED PER 1,000 NEW ZEALAND POPULATION 2010 – 2015

	Components Transfused per 1,000 Population					
	2010	2011	2012	2013	2014	2015
Red Cells	28.6	26.9	26.0	23.7	23.1	22.0
Platelets	3.1	3.0	3.1	3.0	2.8	2.7
Fresh Frozen Plasma	4.1	3.8	3.8	3.1	3.0	2.9
Cryoprecipitate	0.7	0.7	0.8	0.9	0.9	1.0
All Components	**36.7**	**34.7**	**34.0**	**30.8**	**30.0**	**28.7**
Population Estimate*	4,350,700	4,384,000	4,408,100	4,442,100	4,509,700	4,595,700

** www.stats.govt.nz*

Trends in Blood Component Transfusion in New Zealand continued

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The decrease in the number of red cell, platelet and FFP units transfused is reflected by a similar decrease in the number of recipients of these components (Table 3.3). Compared to 2010, there has been a 16.7% reduction in the number of recipients of red cells.

TABLE 3.3 ANNUAL NUMBER OF RED CELL, PLATELET AND FRESH FROZEN PLASMA RECIPIENTS 2010 – 2015

Component	Number of Recipients (Percentage Change from Previous Year)						% Change 2015 from 2010
	2010	2011	2012	2013	2014	2015	
Red Cells	28,130	27,101 (-3.7%)	26,673 (-1.6%)	24,978 (-6.4%)	24,349 (-2.5%)	23,437 (-3.7%)	-16.7%
Platelets	4,317	3,850 (-10.8%)	3,749 (-2.6%)	3,172 (-15.4%)	2,898 (-8.6%)	2,764 (-4.6%)	-36.0%
Fresh Frozen Plasma	3,703	3,623 (-2.2%)	3,531 (-2.5%)	3,272 (-7.3%)	3,190 (-2.5%)	3,198 (0.3%)	-13.6%

Table 3.4 shows the number of blood components transfused and the transfusion rate for all New Zealand District Health Boards in 2015.

TABLE 3.4 BLOOD COMPONENT TRANSFUSION RATES BY DISTRICT HEALTH BOARD 2015

District Health Board	Population*	Number Components Transfused		Transfusion Rate Per 10,000 Population	
		All Components	Red Cells	All Components	Red Cells
Waitemata DHB	575,600	9,894	8,654	172	150
Canterbury DHB	526,100	15,355	11,727	292	223
Counties Manukau DHB	521,700	13,535	11,463	259	220
Auckland DHB	490,000	29,401	18,952	600	387
Waikato DHB	390,600	13,531	9,722	346	249
Southern DHB	314,000	6,531	4,990	208	159
Capital and Coast DHB	301,100	12,047	8,259	400	274
Bay of Plenty DHB	221,500	5,479	4,836	247	218
MidCentral DHB	172,100	4,665	3,752	271	218
Northland DHB	168,300	3,344	2,746	199	163
Hawkes Bay DHB	160,500	4,178	3,164	260	197
Nelson Marlborough DHB	144,800	3,591	3,244	248	224
Hutt Valley DHB	144,000	2,299	2,102	160	146
Taranaki DHB	115,900	2,043	1,902	176	164
Lakes DHB	104,800	1,687	1,515	161	145
Whanganui DHB	62,600	925	851	148	136
South Canterbury DHB	58,600	1,209	1,100	206	188
Tairawhiti DHB	47,400	821	740	173	156
Wairarapa DHB	43,200	858	828	199	192
West Coast DHB	32,700	669	628	205	192

**http://nzdotstat.stats.govt.nz (Estimates published 30 June 2015)*

4 Recipients of Blood Components

Table 4.1 below provides information on the recipients of red cell, platelet and FFP components transfused during 2015.

TABLE 4.1 RECIPIENTS OF BLOOD COMPONENTS 2015

		Blood Component		
		Red Cells	Platelets	FFP
Recipient Gender (number)	Female	13,237	1,242	1,121
	Male	10,166	1,951	1,641
	Unknown	34	5	2
	Total	**23,437**	**3,198**	**2,764**
Recipient Age (years)	Mean	62	55	58
	Median	68	62	64
	Maximum	105	99	100
	Minimum	0	0	0
Units Transfused per Recipient	Mean	4	4	5
	Median	2	2	2
	Maximum	156	86	413
	Minimum	1	1	1

Table 4.2 and Figure 4.1 show the yearly mean pretransfusion haemoglobin from 2006 to 2015 for recipients of red cells where an adverse event was reported. There has been a significant decrease (p=<0.001) from 2006 (81.5g/L) to 2015 (75.2g/L).

TABLE 4.2 ANNUAL MEAN PRETRANSFUSION HAEMOGLOBIN CONCENTRATION 2006 – 2015

Year	Number	Mean Hb g/L	SD
2006	255	81.5	14.8
2007	290	80.4	13.5
2008	322	79.9	11.5
2009	357	79.0	11.5
2010	404	78.4	11.1
2011	306	79.5	11.2
2012	347	77.9	12.4
2013	351	77.7	11.2
2014	241	76.3	11.2
2015	306	75.7	10.2

Recipients of Blood Components
continued

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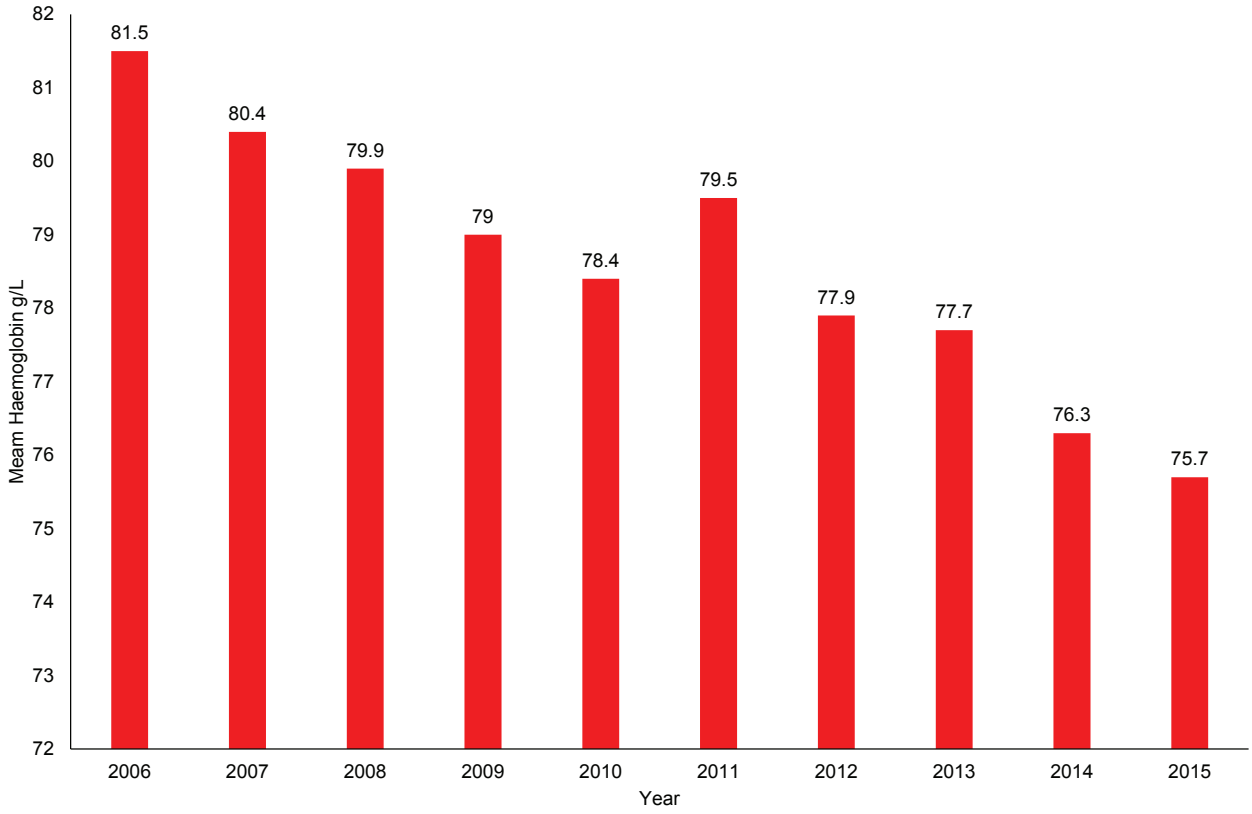
FIGURE 4.1 ANNUAL MEAN PRETRANSFUSION HAEMOGLOBIN CONCENTRATION 2006 – 2015

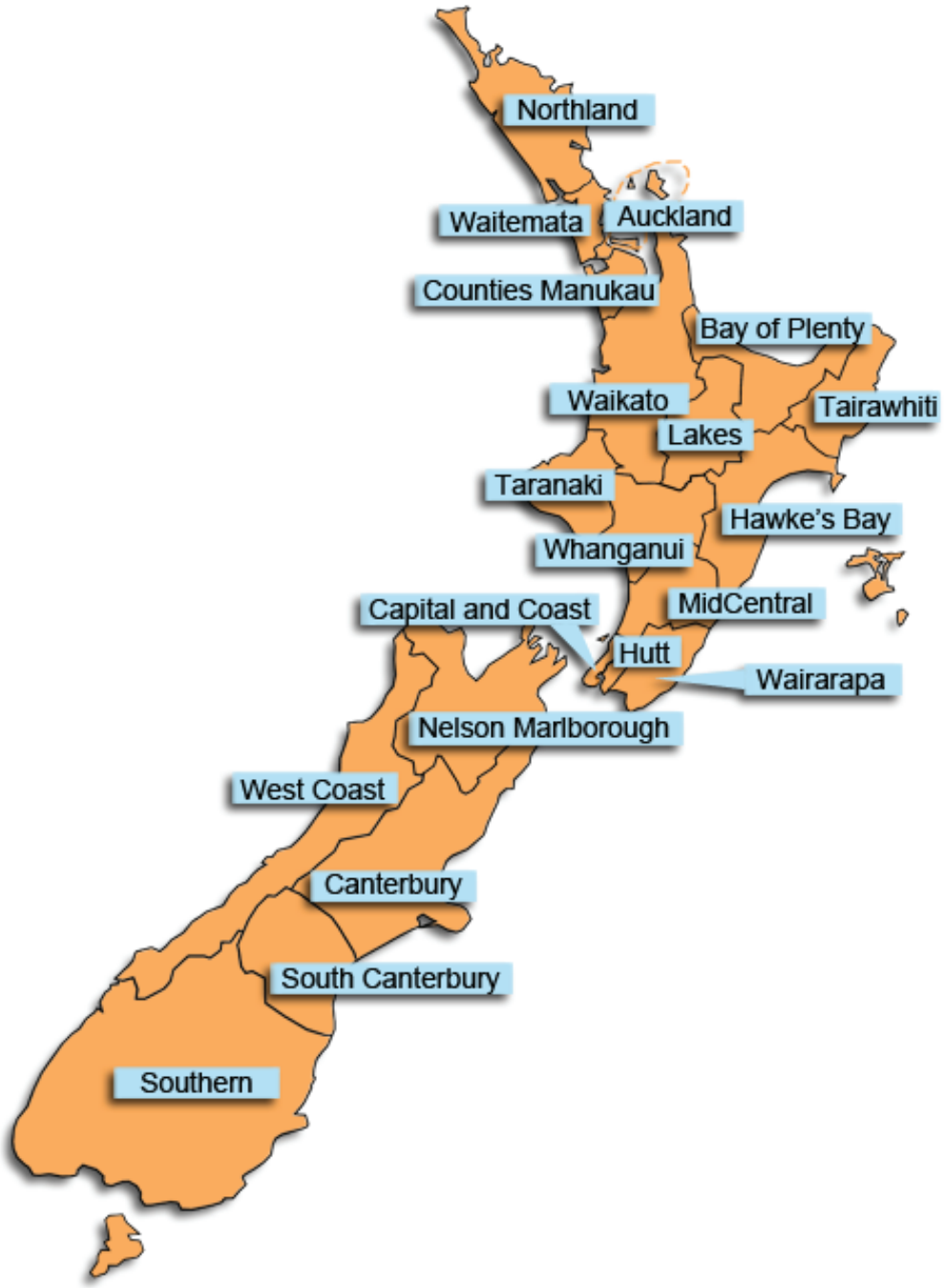


5 Transfusion-Related Adverse Events: Reporting District Health Boards

During 2015, transfusion-related adverse events (TRAE) were reported from all New Zealand District Health Boards except Whanganui and the West Coast DHBs. The number of events of imputability ≥3 per District Health Board and the event rate per 10,000 component units transfused are shown in Table 5.1 and Figure 5.2. The 2015 national TRAE rate was 27.5 per 10,000 component units transfused compared to 26.4 per 10,000 components transfused in 2014.

FIGURE 5.1 DISTRICT HEALTH BOARD BOUNDARIES

(www.health.govt.nz/new-zealand-health-system)



Transfusion-Related Adverse Events: Reporting District Health Boards continued

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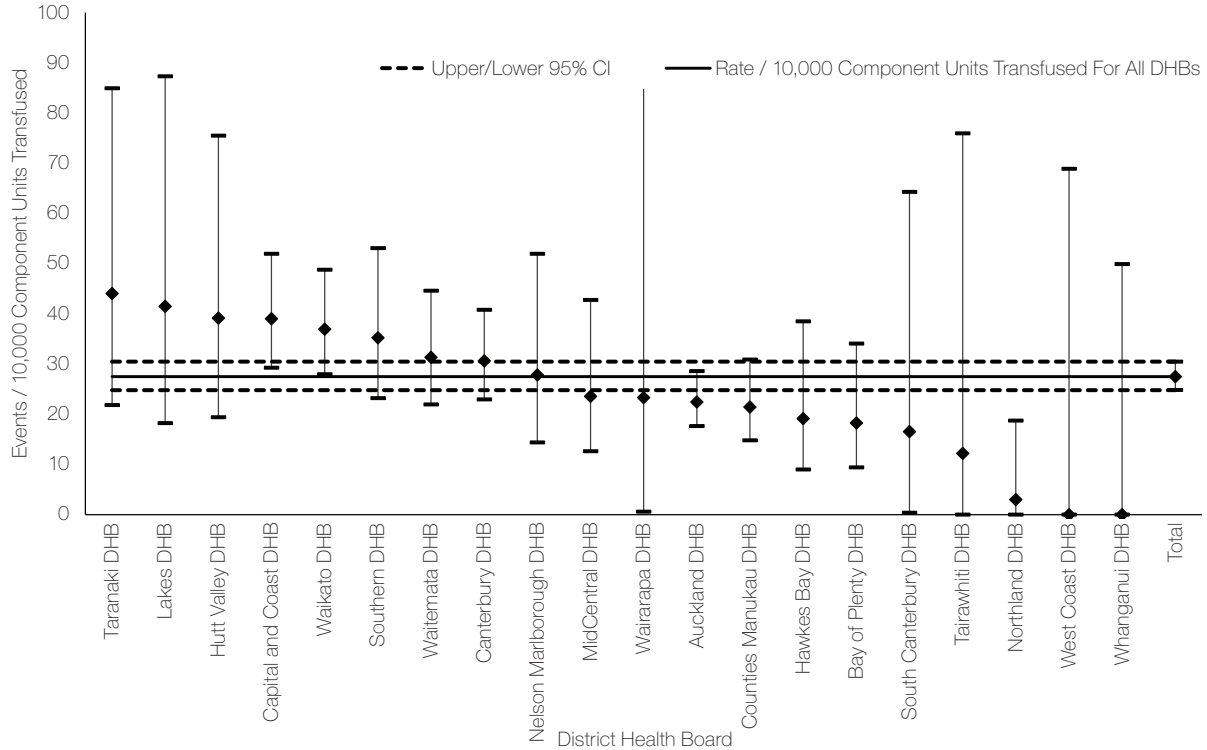
TABLE 5.1 TRANSFUSION-RELATED ADVERSE EVENTS (IMPUTABILITY ≥3) 2015 BY REPORTING DISTRICT HEALTH BOARD

District Health Board	Events	Units Transfused	Frequency	Rate / 10,000 Units Transfused (95%CI)
Taranaki DHB	9	2,043	1:227	44.1 (21.8 to 84.9)
Lakes DHB	7	1,687	1:241	41.5 (18.2 to 87.3)
Hutt Valley DHB	9	2,299	1:255	39.1 (19.4 to 75.5)
Capital and Coast DHB	47	12,047	1:256	39.0 (29.2 to 51.9)
Waikato DHB	50	13,531	1:271	37.0 (27.9 to 48.8)
Southern DHB	23	6,531	1:284	35.2 (23.2 to 53.1)
Waitemata DHB	31	9,894	1:319	31.3 (21.9 to 44.6)
Canterbury DHB	47	15,355	1:327	30.6 (22.9 to 40.8)
Nelson Marlborough DHB	10	3,591	1:359	27.8 (14.4 to 52.0)
MidCentral DHB	11	4,665	1:424	23.6 (12.6 to 42.7)
Wairarapa DHB	2	858	1:429	23.3 (0.6 to 90.4)
Auckland DHB	66	29,401	1:445	22.4 (17.6 to 28.6)
Counties Manukau DHB	29	13,535	1:467	21.4 (14.8 to 30.9)
Hawkes Bay DHB	8	4,178	1:522	19.1 (9.0 to 38.5)
Bay of Plenty DHB	10	5,479	1:548	18.3 (9.4 to 34.1)
South Canterbury DHB	2	1,209	1:605	16.5 (0.4 to 64.3)
Tairawhiti DHB	1	821	1:821	12.2 (0 to 75.9)
Northland DHB	1	3,344	1:3,344	3.0 (0 to 18.7)
West Coast DHB		669		
Whanganui DHB		925		
Total	**363**	**132,062**	**1:364**	**27.5 (24.8 to 30.5)**

FIGURE 5.2 TRANSFUSION-RELATED ADVERSE EVENTS (IMPUTABILITY ≥3) 2015 BY REPORTING DISTRICT HEALTH BOARD



6 Transfusion-Related Adverse Events: Imputability

During 2015, a total of 460 TRAE were reported to the National Haemovigilance programme. A total of 97 (21.1%) had a low ≤2 imputability score and were excluded from the analysis since they were unlikely to be attributable to transfusion. Excluded events were predominantly reported as either febrile non-haemolytic transfusion reactions (FNHTR) or unclassifiable complications of transfusion (UCT). Imputability score definitions (ISBT/IHN) are provided in Table 6.1.

TABLE 6.1 IMPUTABILITY SCORE DEFINITIONS

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

The number of reported events excluded due to low ≤2 imputability per year from 2009 to 2015 are shown in Table 6.2 and Table 6.3. As a proportion of all TRAE, the number with low ≤2 imputability has doubled since 2009 and, in 2015, comprised more than one fifth of all TRAE. These events are predominantly FNHTR (69%) and UCT (13%). This trend may be due to both increased reporting of mild rises in temperature that do meet criteria for FNHTR and an improvement in classifying adverse reactions; the latter being aided by an increasing awareness of clinicians in the value of providing complete clinical information and, where necessary, a concerted effort by the Haemovigilance Steering Committee to obtain additional detail for accurate event classification.

TABLE 6.2 TRANSFUSION-RELATED ADVERSE EVENTS OF LOW ≤2 IMPUTABILITY 2009 – 2015

	2009	2010	2011	2012	2013	2014	2015
Total Events	554	635	514	532	507	463	460
Number of Imputability ≤2	66	80	72	90	71	106	97
Percentage	11.9%	12.6%	14.0%	16.9%	14.0%	23.0%	21.1%

Transfusion-Related Adverse Events: Imputability continued

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TABLE 6.3 TRANSFUSION-RELATED ADVERSE EVENTS OF LOW ≤2 IMPUTABILITY 2009 – 2015 BY EVENT TYPE

	Percentage of Annual Total Reports of Low Imputability ≤2							
	2009	2010	2011	2012	2013	2014	2015	Total
FNHTR	34.3%	55.0%	72.6%	53.3%	70.4%	64.2%	69.1%	60.4%
UCT	34.3%	23.8%	16.4%	16.7%	23.9%	26.4%	13.4%	21.7%
Allergic	9.0%	6.3%	2.7%	14.4%	1.4%	1.9%	2.1%	5.3%
DSTR	3.0%	1.3%	2.7%	4.4%	0.0%	0.0%	8.2%	2.9%
Hypotension	3.0%	6.3%	2.7%	2.2%	0.0%	2.8%	3.1%	2.9%
IBCT	10.4%	3.8%	2.7%	0.0%	0.0%	0.9%	0.0%	2.2%
TAD	3.0%	3.8%	0.0%	4.4%	2.8%	0.9%	1.0%	2.2%
TACO	0.0%	0.0%	0.0%	2.2%	1.4%	0.0%	2.1%	0.9%
Acute Haemolytic	0.0%	0.0%	0.0%	1.1%	0.0%	0.9%	1.0%	0.5%
TRALI	0.0%	0.0%	0.0%	0.0%	0.0%	1.9%	0.0%	0.3%
DHTR	0.0%	0.0%	0.0%	1.1%	0.0%	0.0%	0.0%	0.2%
Pain	1.5%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.2%
TTI	1.5%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.2%
Total Reports Imputability ≤2	**67**	**80**	**73**	**90**	**71**	**106**	**97**	**584**

6 Transfusion-Related Adverse Events: Imputability continued

Table 6.4 shows all reported events in 2015 by event type and imputability score.

TABLE 6.4 TRANSFUSION-RELATED ADVERSE EVENTS 2015 BY EVENT TYPE AND IMPUTABILITY SCORE

	Imputability Score						
Event Type	**1**	**2**	**3**	**4**	**5**	**Total**	**Total ≥3**
FNHTR	39	28	131	54	4	256	189
Allergic		2	42	52	6	102	100
UCT	6	7	10	1	2	26	13
DSTR	8		3	2	7	20	12
TACO		2	7	7	2	18	16
IBCT			1		11	12	12
Hypotension	3		4		1	8	5
AHTR	1		3	1	1	6	5
DHTR			4		1	5	5
TAD	1		1		1	3	2
Component related				1		1	1
Near Miss					1	1	1
TRALI					1	1	1
TTI					1	1	1
Total	**58**	**39**	**206**	**118**	**39**	**460**	**363**
Percentage Events	12.6%	8.5%	44.8%	25.7%	8.5%		78.9%

Data analysed and included in the remainder of the Annual Haemovigilance Report is restricted to the 363 events of imputability ≥3. Figure 6.1 and 6.2 show the distribution of these events by event type. Febrile non-haemolytic and allergic transfusion reactions are the most frequently reported events.

Transfusion-Related Adverse Events: Imputability continued

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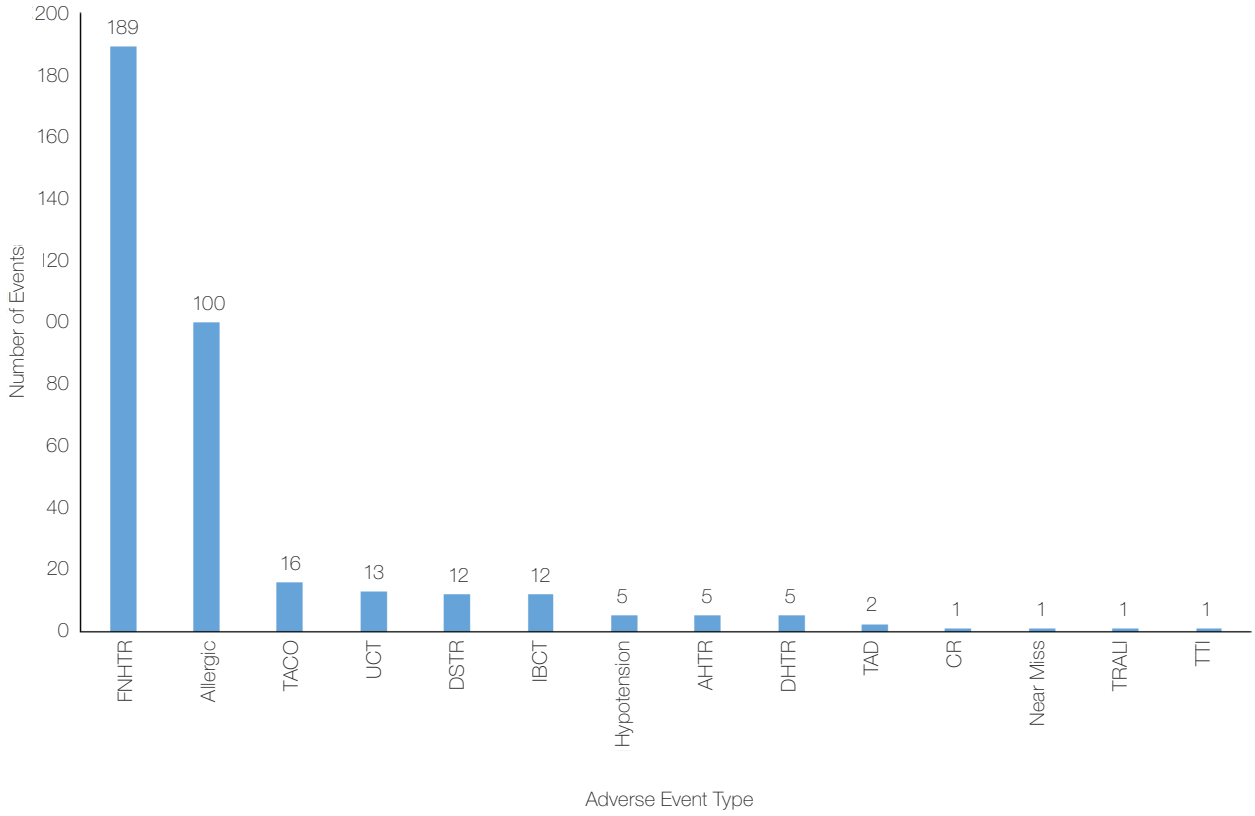
FIGURE 6.1 TRANSFUSION-RELATED ADVERSE EVENTS (IMPUTABILITY ≥3) 2015 BY EVENT TYPE

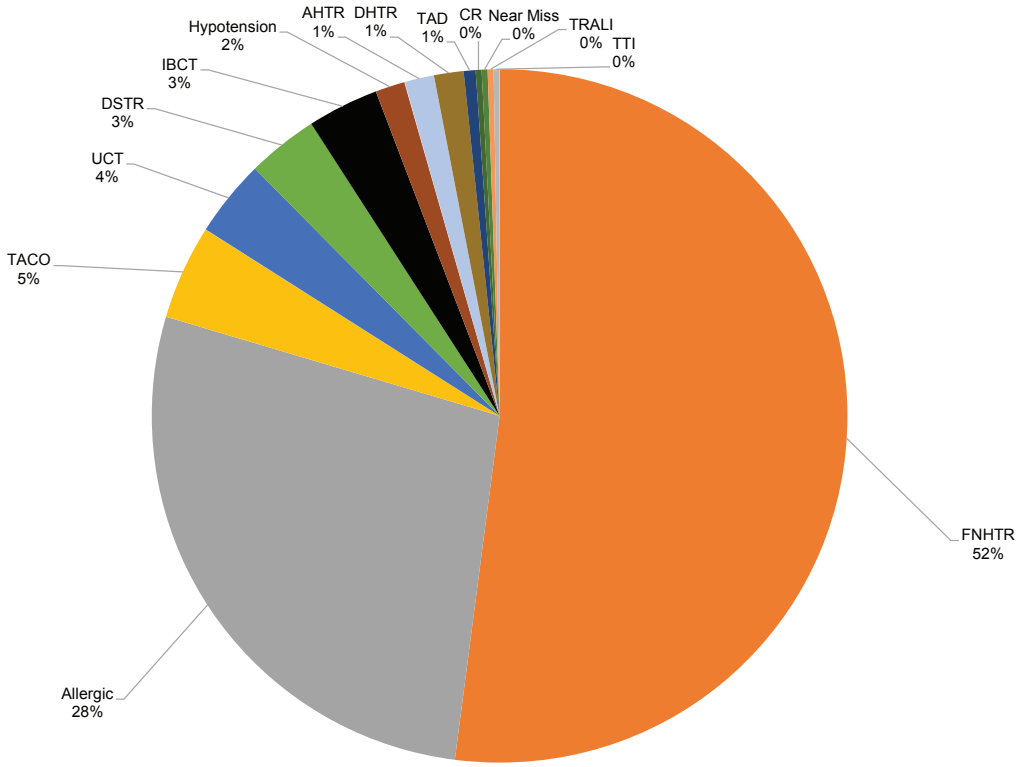


Key:

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

6 Transfusion-Related Adverse Events: Imputability continued

FIGURE 6.2 TRANSFUSION-RELATED ADVERSE EVENTS (IMPUTABILITY ≥3) 2015 BY EVENT TYPE



There were 328 transfusion recipients associated with the 363 reported events included in the analysis. Table 6.5 shows the events by recipient gender along with data on recipient age.

TABLE 6.5 TRANSFUSION-RELATED ADVERSE EVENTS (IMPUTABILITY ≥3) 2015 BY RECIPIENT GENDER

		Age (years)		
	Number	Mean	Minimum	Maximum
Female	201	52	2 month	94
Male	162	55	1 day	95
Total	**363**	**54**	**1 day**	**95**

Multiple TRAE were reported in 27 patients (Table 6.6).

TABLE 6.6 NUMBER OF RECIPIENTS HAVING MULTIPLE TRANSFUSION-RELATED ADVERSE EVENTS (IMPUTABILITY ≥3) 2015

		Events			
	Total	1 Event	2 Events	3 Events	8 Events
Recipient Number	328	301	24	2	1

For the one recipient where 8 TRAE were reported, all 8 were recorded as FNHTR. For two recipients where 3 events were reported, in one recipient all were recorded as FNHTR, the second recipient's TRAE were recorded as two FNHTR and one TAD.

Transfusion-Related Adverse Events: Severity

7

The severity score definitions for TRAE developed by ISBT/IHN are shown in Table 7.1. Of the reported events with imputability score ≥3, 89% were assessed as non-severe (grade 1). Severe (grade ≥2) events were 9% of all events and 75% of these were either allergic or TACO in nature (Table 7.2). There was one AHTR, due to an ABO incompatible red cell transfusion, and one TAD event implicated in the deaths (grade 4) of two patients in 2015 (Table 7.2).

TABLE 7.1 SEVERITY SCORE DEFINITIONS FOR TRANSFUSION-RELATED ADVERSE EVENTS 2015

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 hospitalisation or prolongation of hospitalisation directly attributable to the event; and/or the adverse event resulted in persistent or significant disability or incapacity; or the event necessitated medical or surgical intervention to preclude permanent damage or impairment of a body function.
Grade 3 (life-threatening)	The recipient required major intervention following the transfusion (e.g., vasopressors, intubation, transfer to intensive care) to prevent death.
Grade 4 (death)	The recipient died following an adverse transfusion reaction. Grade 4 should only be used if death is probably or definitely related to transfusion. If the patient died of another cause, the severity should be graded as 1, 2 or 3.

TABLE 7.2 TRANSFUSION-RELATED ADVERSE EVENTS (IMPUTABILITY ≥3) 2015 BY EVENT TYPE AND SEVERITY

Event Type	Severity				
	Grade 1	Grade 2	Grade 3	Grade 4	Total
FNHTR	187	2			189
Allergic	82	15	3		100
TACO	6	9	1		16
UCT	13				13
DSTR	12				12
IBCT	11	1			12
AHTR	2	2		1	5
DHTR	4	1			5
Hypotension	4	1			5
TAD	1			1	2
Component related	1				1
Near Miss	1				1
TRALI			1		1
TTI		1			1
Total	**324**	**32**	**5**	**2**	**363**
Percentage Events	89.3%	8.8%	1.4%	0.6%	

8 Transfusion-Related Adverse Events: Implicated Blood Components

A total of 132,060 blood component units were transfused in 2015. Of these, 378 units were implicated in the 363 reported adverse events. The overall adverse event rate in 2015 was 1 in 349 units transfused (28.6 per 10,000 units transfused, 95% CI 25.9 to 31.7). Table 8.1 shows the adverse event rates for the individual blood component types in 2015.

TABLE 8.1 TRANSFUSION-RELATED ADVERSE EVENTS (IMPUTABILITY ≥3) 2015 BY BLOOD COMPONENT TYPE

Component	Units Implicated in TRAE[1]	Units Transfused	Frequency	Rate / 10,000 Units Transfused (95%CI)
Platelets Apheresis PAS	23	3,818	1:166	60.2 (39.7 to 90.7)
Platelets Pooled PAS	44	7,683	1:175	57.3 (42.5 to 77.0)
Cryodepleted Plasma	3	536	1:179	56.0 (11.0 to 171.3)
Fresh Frozen Plasma	37	13,334	1:360	27.7 (20.0 to 38.3)
Red Cells	262	101,175	1:386	25.9 (22.9 to 29.2)
Cryoprecipitate	8	4,482	1:560	17.8 (8.4 to 35.9)
Platelets Apheresis Plasma[2]	1	1,032	1:1,032	9.7 (0 to 60.5)
Total	**378**	**132,060**	**1:349**	**28.6 (25.9 to 31.7)**

[1] *Includes TRAE where multiple component types transfused.*

[2] *Includes 621 units Platelets - Neonatal.*

Transfusion-Related Adverse Events: Implicated Blood Components continued

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Table 8.2 provides detail on TRAE by the event type and type of blood component involved.

TABLE 8.2 TRANSFUSION-RELATED ADVERSE EVENTS (IMPUTABILITY SCORE ≥3) 2015 BY EVENT TYPE AND BLOOD COMPONENT TYPE

	Red Cells	Fresh Frozen Plasma	Platelets Apheresis	PAS Platelets Apheresis	PAS Platelets Pooled	Cryoprecipitate	Cryodepleted Plasma	Fractionated Plasma Products[1]	Multiple Components	Other[2]
Number Units Transfused	**101,175**	**13,334**	**1,032**	**3,818**	**7,683**	**4,482**	**536**			
FNHTR	163			11	15				1	
Allergic	33	24	1	8	30	1	2		11	
TACO	13						1		2	
DSTR	12									
UCT	8				1				1	2
AHTR	5									
DHTR	5									
Hypotension	4	1								
IBCT	3	1						8		
TAD	2									
Near Miss	1									
Component related									1	
TRALI									1	
TTI					1					
Total	**249**	**26**	**1**	**19**	**47**	**1**	**3**	**8**	**17**	**2**

[1] *Events, other than ICBT and near miss, associated with fractionated plasma products are detailed in Chapter 18.*

[2] *Events associated with transfusion of stem cells and allogenic serum eye drops.*

9 Febrile Non-Haemolytic Transfusion Reactions (FNHTR)

Definition

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 any other cause such as haemolytic transfusion reaction, bacterial contamination or underlying condition.

Febrile reactions were the most frequently reported type of TRAE (52%). A total of 256 reports of FNHTR were received; 189 were of imputability ≥3 and included in the analysis. Of the reported events, 28 were of low ≤2 imputability and probably due to the patient's underlying medical condition. An additional 39 submitted reports of febrile reactions did not meet criteria for FNHTR and thus were excluded by the Haemovigilance Programme. Table 9.1 shows FNHTR events by recipient gender along with data on recipient age.

TABLE 9.1 FNHTR EVENTS (IMPUTABILITY ≥3) 2015 BY RECIPIENT GENDER

	Number	Age (years)		
		Mean	Minimum	Maximum
Female	97	57	3	94
Male	92	58	1 day	92
All	**189**	**59**	**1 day**	**94**

In addition to fever and chills/rigors, other clinical features associated with FNHTR are summarised in Table 9.2. An increase in blood pressure, restlessness or anxiety, dyspnoea, flushing and chest pain are not uncommon symptoms in transfusion recipients with FNHTR.

TABLE 9.2 FNHTR EVENTS (IMPUTABILITY ≥3) 2015 BY ASSOCIATED SIGNS AND SYMPTOMS

Symptom	Number			% Events		
	Female (n=97)	Male (n=92)	Total (n=189)	Female	Male	Total
Chills / Rigors	53	39	92	36.6%	36.4%	36.5%
Increase in blood pressure	21	12	33	14.5%	11.2%	13.1%
Restlessness / Anxiety	19	7	26	13.1%	6.5%	10.3%
Dyspnoea	11	14	25	7.6%	13.1%	9.9%
Tachycardia	12	2	14	8.3%	1.9%	5.6%
Hypoxaemia	6	6	12	4.1%	5.6%	4.8%
Chest pain	4	7	11	2.8%	6.5%	4.4%
Abdominal pain	3	3	6	2.1%	2.8%	2.4%
Cough	3	3	6	2.1%	2.8%	2.4%
Flushing	3	3	6	2.1%	2.8%	2.4%
Stridor / Wheeze	2	4	6	1.4%	3.7%	2.4%
Nausea	2	3	5	1.4%	2.8%	2.0%
Loin pain	2	2	4	1.4%	1.9%	1.6%
Urticaria	1	1	2	0.7%	0.9%	0.8%
Non-urticarial rash	2	0	2	1.4%	0.0%	0.8%
Fall in blood pressure	1	1	2	0.7%	0.9%	0.8%
Mean temperature rise	1.6°C	1.6°C	1.6°C			

Febrile Non-Haemolytic Transfusion Reactions (FNHTR) continued

9

Of the reported FNHTR events, 11 met ISBT criteria for serious FNHTR. The ISBT Working Party on Haemovigilance (July 2011) defines FNHTR as serious when accompanied by:

Fever ≥39°C oral (or equivalent) and a change of ≥2°C from pre-transfusion value, and chills/rigors.

Table 9.3 shows serious FNHTR events by recipient gender along with data on change in temperature and recipient age.

TABLE 9.3 SERIOUS FNHTR EVENTS (IMPUTABILITY ≥3) 2015 BY RECIPIENT GENDER

	Number	Temperature Rise (°C)			Age (Years)		
		Mean	Min	Max	Mean	Min	Max
Female	5	2.8	2.2	3.5	60	17	72
Male	6	2.4	2.0	3.0	51	23	67
Total	**11**	**2.6**	**2.0**	**3.5**	**55**	**17**	**72**

10 Allergic Transfusion Reactions

Definition

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 throat tightness, dysphagia, dysphonia, hoarseness, stridor. Pulmonary symptoms include dyspnoea, cough, wheeze/bronchospasm, hypoxaemia. Cardiovascular symptoms include hypotension, syncope.*

Allergic reactions are frequently reported after blood transfusions. They are most often mild reactions but may cause significant distress to recipients of blood transfusions and occasionally even significant morbidity.

During 2015, there were 100 (28%) events classified as allergic in nature. Of these, 82 (82%) were non-severe and the remaining 18 (18%) were severe or life-threatening. Table 10.1 shows allergic events by recipient gender along with data on recipient age.

TABLE 10.1 ALLERGIC EVENTS (IMPUTABILITY ≥3) 2015 BY RECIPIENT GENDER

	Number	Age (years)		
		Mean	Minimum	Maximum
Female	55	40	1	83
Male	45	45	2	95
All	**100**	**42**	**2**	**95**

Table 10.2 provides information on signs and symptoms associated with non-severe (grade 1) allergic events compared to severe and life threatening (grade 2 and 3) events reported in 2015.

TABLE 10.2 ALLERGIC EVENTS (IMPUTABILITY ≥3) 2015 BY ASSOCIATED SIGNS AND SYMPTOMS

Symptom	Allergic Events					
	Grade 1 (n=82)			Grade 2 & 3 (n=18)		
	Number	% Symptoms	% Grade 1 Events	Number	% Symptoms	% Grade 2 & 3 Events
Urticaria	61	47.7%	74.4%	11	19.0%	61.1%
Restlessness / Anxiety	15	11.7%	18.3%	8	13.8%	44.4%
Non-urticarial	11	8.6%	13.4%	2	3.4%	11.1%
Chills / Rigors	9	7.0%	11.0%	4	6.9%	22.2%
Tachycardia	7	5.5%	8.5%	5	8.6%	27.8%
Dyspnoea	7	5.5%	8.5%	5	8.6%	27.8%
Increase in blood pressure	5	3.9%	6.1%	2	3.4%	11.1%
Fall in blood pressure	3	2.3%	3.7%	6	10.3%	33.3%
Stridor / Wheeze	3	2.3%	3.7%	7	12.1%	38.9%
Chest pain	3	2.3%	3.7%	2	3.4%	11.1%
Cough	3	2.3%	3.7%	3	5.2%	16.7%
Loin pain	1	0.8%	1.2%	0	0.0%	0.0%
Hypoxaemia	0	0.0%	0.0%	3	5.2%	16.7%

Allergic Transfusion Reactions continued

The frequency of allergic events and, for those events where a single blood component was implicated, the rate per 10,000 component units transfused is shown in Table 10.3.

TABLE 10.3 ALLERGIC EVENTS (IMPUTABILITY ≥3) 2015 BY BLOOD COMPONENT TYPE

Component	Number Events	Number Units Transfused	Frequency	Rate / 10,000 Units Transfused (95%CI)
Cryodepleted Plasma	2	536	1:268	37.3 (1.0 to 144.3)
Platelets Pooled PAS	20	7,683	1:384	26.0 (16.6 to 40.4)
Platelets Apheresis PAS	8	3,818	1:477	21.0 (9.8 to 42.1)
Fresh Frozen Plasma	24	13,334	1:556	18.0 (12.0 to 26.9)
Platelets Apheresis Plasma[1]	1	1,032	1:1,032	9.7 (0 to 60.5)
Red Cells	32	101,175	1:3,162	3.2 (2.2 to 4.5)
Cryoprecipitate	1	4,482	1:4,482	2.2 (0 to 14.0)
Total	**88**	**132,060**	**1:1,501**	**6.7 (5.4 to 8.2)**

[1] *Includes Platelets - Neonatal.*

11 Acute Haemolytic Transfusion Reactions (AHTR)

Definition

A reaction in which symptoms and clinical or laboratory signs of increased red cell destruction occur at any time up to 24 hours following the transfusion of blood or a blood component.

Acute haemolytic transfusion reactions occur following the transfusion of immunologically incompatible red cells or due to mechanical red cell destruction.

Features of a haemolytic transfusion reaction include:

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

During 2015, there were five reported events classified as acute haemolytic transfusion reactions. The details of four of the events are provided below.

CASE A

A 1 day old group A RhD positive male baby, weighing 1.6 kg and with haemoglobin 86 g/L, received two units of group O RhD positive neonatal red cells. The baby had been delivered at 29 weeks gestation by emergency caesarean section for non-immune foetal hydrops and due to respiratory distress the infant was intubated and admitted to the neonatal intensive care unit.

The transfusion was uncomplicated however, 5 hours following the second unit, the baby was noted to have dark coloured urine and the serum bilirubin rose significantly reaching a peak of 354 µmol/L, necessitating phototherapy and followed by exchange transfusion 3 days later. Samples received by the blood bank following exchange transfusion revealed no serological anomalies. Due to abdominal distension and feed intolerance with delayed gastric emptying, a laparotomy was performed revealing malrotation, midgut volvulus and ischaemia causing extensive necrotic bowel. The baby subsequently died. The small bowel volvulus was deemed to have occurred antenatally.

The event was recorded as an acute haemolytic transfusion reaction, of grade 2 severity and possible imputability. Resorption of blood from the ischaemic bowel was considered a likely alternative mechanism leading to hyperbilirubinemia and the urine changes.

Acute Haemolytic Transfusion Reactions (AHTR) continued

11

CASE B

A 87 year old male, with metastatic prostate cancer causing transfusion-dependent anaemia and haemoglobin 80 g/L, received 100 mL of red cells before becoming breathless and anxious accompanied by chills, rigors and loin pain. He developed a tachycardia 117/min, mild hypertension 150/70 mmHg and pulse oximetry revealed an oxygen saturation of 92% on 4L of supplemental oxygen. Pretransfusion, the temperature was 37.8°C and this remained stable. The C-reactive protein was 286 mg/L. The chest xray was reported to be unremarkable. The serum bilirubin rose from 6 µmol/L the day prior to transfusion, up to 21 µmol/L and subsequently returned to baseline over the next 4 days. Over the same time period, the haemoglobin fell from 85 g/L to 71 g/L before prompting a further transfusion. No change in reticulocyte count or haptoglobin level was observed.

Pretransfusion, the red cell antibody screen (RCAS) on two occasions was negative. On a post-transfusion sample the RCAS and DAT were negative. A serological crossmatch was however incompatible, with anti-Wra, an antibody to a low incidence antigen, identified in the patient's serum. The unit was Wra positive.

The event was recorded as an acute haemolytic transfusion reaction due to anti-Wra, of grade 1 severity and possible imputability. Anti-Wra is a recognised but uncommon cause of acute haemolytic transfusion reactions. Anti-Wra reacts with a low frequency blood group antigen, Wra, which has a population frequency of less than 1:1,000 and anti-Wra will not be identified by routine blood group antibody screening.

11 Acute Haemolytic Transfusion Reactions (AHTR) continued

CASE C

A 90 year old female, weighing 37 kg, was admitted to a base hospital, transferred from a satellite hospital following a fractured neck of femur. A pretransfusion sample was tested by the laboratory and the patient grouped as group B RhD positive, red cell antibody screen negative. No previous blood group results were available in eProgesa.

Day 1 post-surgery, a unit of red cells was requested and transfused. The transfusion was aborted after half the unit of red cells had been transfused, as the patient complained of abdominal pain and started passing discoloured urine. The patient was hypothermic 34.9 – 35.5°C, had a raised respiratory rate from 14/min pretransfusion to 30/min post-transfusion, a drop in oxygen saturation from 95% on 2L/min to 89 – 93% on 3L/min supplemental oxygen. A second group B RhD positive unit was requested and transfused.

Day 2 post-surgery, a new pretransfusion sample was received by the blood bank. The ABO blood group on this sample was mixed-field group B and group O. The DAT was positive for both IgG and C3d. A further blood sample was requested and the mixed field reaction was confirmed. A pretransfusion haematology sample was obtained and grouped as group O RhD positive.

Subsequently, the patient became oliguric and died. A review of the patient's test results showed the following features:

	Pretransfusion	Post-transfusion
Blood group	B RhD positive	Mixed field (O and B cells)
Haemoglobin (g/L)	80	109
Bilirubin (µmol/L)	8	39
LDH (U/L)		1032
Haptoglobin (g/L)		0.12
Urine		Haemoglobinuria

The original pretransfusion sample was retrospectively tested and confirmed as group B RhD positive. This pretransfusion sample was received from the satellite hospital and was rejected as it did not meet the labelling acceptance criteria. The request form was only labelled with the family name and NHI number.

The completed investigation indicated that the patient was group O RhD positive and that the pretransfusion sample received was a wrong blood in tube (WBIT) from a group B RhD positive patient, resulting in two units of group B RhD positive red cells being transfused.

Subsequent investigations were carried out to establish which patient the incorrect sample was taken from. Another patient in the same room was identified as being group B RhD positive and an extended red cell phenotype from this individual matched the phenotype of the incorrectly labelled sample, indicating the likely source of the WBIT sample.

The event was recorded as an acute haemolytic transfusion reaction, of grade 4 severity and certain imputability.

Acute Haemolytic Transfusion Reactions (AHTR) continued

11

CASE D

A 71 year old female, with transfusion-dependent myelodysplastic syndrome and on treatment with lenolidamide and erythropoietin, received 3 units of red cells over 3 hours through the day unit for a haemoglobin 86 g/L. During completion of the third unit the patient developed chills, a rise in temperature from 36.8 to 40°C and hypotension with the blood pressure falling from 129/66 to 92/54 mmHg. The urine was noted to be red. No chest xray changes were seen and blood cultures were negative after 5 days incubation.

The immediate post-transfusion increment was poor and was followed by a gradual decline in haemoglobin concentration over the subsequent week. A further 3 unit red cell transfusion was given uneventfully 13 days later.

The haemoglobin, bilirubin, LDH and haptoglobin results following the transfusion are detailed in the table below.

		Days Post Transfusion				
	Pre Transfusion	Day 1	Day 2	Day 4	Day 5	Day 7
Haemoglobin (g/L)	86	101	90	82	85	83
Bilirubin (µmol/L)	10	36	31	27	21	18
LDH (U/L)		1709	1361	1017	917	830
Haptoglobin (g/L)		<0.05				

On a post-transfusion sample there were no blood group anomalies. The pre- and post-transfusion DAT were negative, as was the antibody screen.

The event was recorded as an acute haemolytic transfusion reaction, of grade 2 severity and possible imputability. There was a clear temporal relation to the transfusion however, without evidence of serological incompatibility, the pathophysiology underlying the haemolysis is unclear.

12 Transfusion-Related Acute Lung Injury (TRALI)

Definition

New acute lung injury (ALI): acute onset during or within 6 hours of completion of transfusion, hypoxaemia (PaO_2/FiO_2 <300 mmHg, oxygen saturation <90% on room air, or other clinical evidence), bilateral infiltrates on frontal chest radiograph, no left atrial hypertension or other evidence of circulatory overload, no temporal relationship to an alternative risk factor for ALI.

During 2015, there was one reported event of TRALI in New Zealand. The case is summarised below:

CASE E

A 56 year old male, with chronic hepatitis C and portal hypertension from liver cirrhosis, underwent elective banding of gastric varices. One week later, he was admitted acutely for variceal bleeding and required several emergency gastroscopies for variceal banding, various other bleeding control measures including insertion of Sengstaken-Blakemore tube, and blood transfusions. On day 9 of the admission, following a third episode of bleeding, the local massive transfusion protocol (MTP) was activated. General anaesthesia and endotracheal intubation were required to facilitate further banding and insertion of Sengstaken-Blakemore tube. During this procedure, ventilation became difficult with high peak airway pressures and deteriorating oxygen saturation. Continuous suction down the endotracheal tube showed no evidence of pulmonary oedema fluid. Between initiating the MTP and the onset of respiratory failure, 14 units each of red cells and fresh frozen plasma, 6 units of cryoprecipitate and a unit of platelets were administered. A transjugular intrahepatic portosystemic shunt (TIPS) procedure was performed, following which no further bleeding occurred. In the intensive care unit respiratory failure continued and the chest xray revealed new patchy bilateral lung opacities in the upper and midzones, as well as progression of bi-basal collapse/consolidation since the previous examination. Echocardiography was not performed. Oxygen requirements gradually reduced over the next 48 hours, chest xray appearances improved and he was extubated four days after admission to ICU.

Retrospectively, it was noted an acute and transient drop in leucocyte and neutrophil counts in relation to the respiratory event, both returning to baseline approximately 13 hours after the event. TRALI investigations were performed on blood samples from the patient and those female donors of blood components transfused in the 6 hours prior to the event. These included 7 red cell units and a pooled platelet unit, the latter made from buffy coats from 4 female whole blood donors. One female donor of red cells had demonstrable antibody with strong mean fluorescent intensity (MFI) against HLA-B7 that the patient was positive for. No other donor showed antibodies to human leucocyte antigens (HLA) or human neutrophil antigens (HNA).

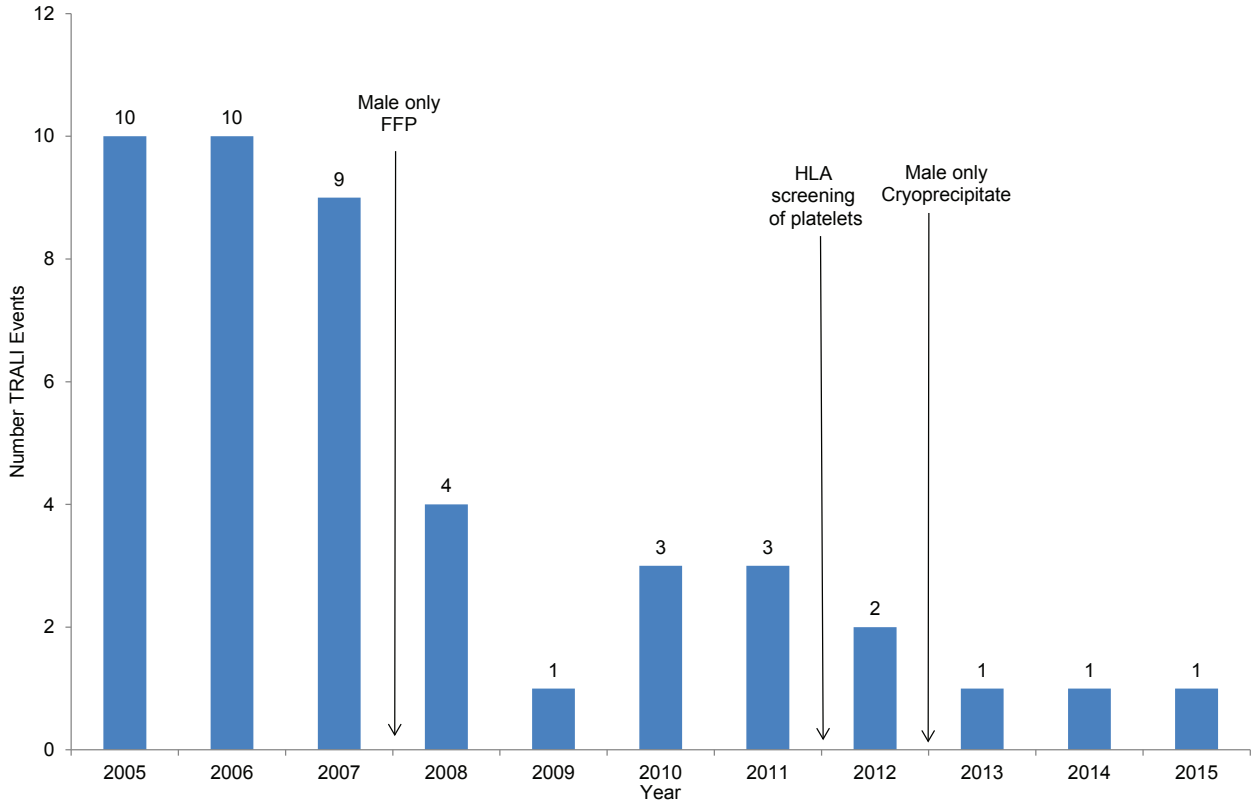
The event was recorded as TRALI, of grade 3 severity and certain imputability. The donor of the implicated red cell unit has been permanently deferred.

Transfusion-Related Acute Lung Injury (TRALI) continued

12

Figure 12.1 shows the number of TRALI events reported each year since 2005. Overall, the number of reported events has declined. NZBS has implemented a number of measures to reduce the risk of TRALI. Production of clinical FFP from male-only donors was implemented in 2008 and thereafter HLA-antibody screening of female plateletpheresis donors in July 2012. The male-only policy was extended in 2013 to include cryoprecipitate and cryo-depleted plasma. Work is currently underway to further extend the policy to include whole blood for allogeneic transfusion.

FIGURE 12.1 ANNUAL NUMBER OF TRALI EVENTS 2005 – 2015



12 Transfusion-Related Acute Lung Injury (TRALI) continued

The components implicated yearly in TRALI events between 2005 and 2015 are detailed in Table 12.1.

TABLE 12.1 COMPONENTS IMPLICATED IN TRALI EVENTS 2005 – 2015

Year	Number TRALI Reports	Implicated Components (multiple components implicated in a number of events)							
		Red Cells	Fresh Frozen Plasma	Apheresis Platelets Plasma	Pooled Platelets Plasma	Apheresis platelets PAS	Pooled Platelets PAS	Cryoprecipitate	Cryodepleted Plasma
2005	10	7	5	3	1			1	1
2006	10	4	5	5	2			1	
2007	9	4	6						
2008	4	2		1	1				
2009	1	1							
2010	3	2		1					
2011	3		2		1				
2012	2		1			1	2		
2013	1	1							
2014	1	1							
2015	1	1	1				1	1	
Total	**45**	**23**	**20**	**10**	**5**	**1**	**3**	**3**	**1**
Percentage		35%	30%	15%	8%	2%	4%	4%	2%

Transfusion-Associated Circulatory Overload (TACO)

13

Definition

Any 4 of the following occurring within 6 hours of completion of transfusion: acute respiratory distress, tachycardia, increased blood pressure, acute or worsening pulmonary oedema on frontal chest radiograph, evidence of positive fluid balance. An elevated BNP may be supportive of TACO.

During 2015, there were 16 reported TACO events (4.4% of total events). Six (37%) were non-severe, 9 (56%) were of grade 2 severity and 1 was of grade 3 life-threatening severity. Table 13.1 shows the TACO events by recipient gender, along with data on recipient age.

TABLE 13.1 TACO EVENTS (IMPUTABILITY ≥3) 2015 BY RECIPIENT GENDER

	Number	Age (Years)		
		Mean	Minimum	Maximum
Female	11	64	2 months	91
Male	5	81	75	86
All	**16**	**69**	**2 months**	**91**

Table 13.2 shows the recorded clinical features of the TACO events reported during 2015.

TABLE 13.2 TACO EVENTS (IMPUTABILITY ≥3) 2015 BY ASSOCIATED SIGNS AND SYMPTOMS

Symptom	Number			% TACO Events
	Female	Male	Total	
Dyspnoea	9	3	12	75%
Increase in blood pressure	7	1	8	50%
Stridor / Wheeze	4	3	7	44%
Raised JVP	3	4	7	44%
Pulmonary oedema	3	3	6	38%
Fall in O_2 saturation	2	3	5	31%
Tachycardia	2	2	4	25%
Restlessness / Anxiety	3	1	4	25%
Chills / Rigors	2	1	3	19%
Chest pain	0	2	2	13%

13 Transfusion-Associated Circulatory Overload (TACO)

Table 13.3 shows the blood components implicated in TACO events reported each year from 2007 to 2015.

TABLE 13.3 COMPONENTS IMPLICATED IN TACO EVENTS (IMPUTABILITY ≥3) 2007 – 2015

Year	Number TACO Reports	Implicated Components (multiple components implicated in a number of events)									
		Red Cells	Fresh Frozen Plasma	Pooled Platelets Plasma	Cryoprecipitate	Apheresis Platelets PAS	Pooled Platelets PAS	Apheresis Platelets Plasma	Fractionated Products	Cryodepleted Plasma	Granulocytes
2007	14	10	2	2					1		
2008	20	17	5	3					1		
2009	24	21	4					2			
2010	13	10	2	2	2			2		1	
2011	19	18	4	1	1		2				
2012	27	24	2			1	2	1	1		
2013	16	13	4		3	4	2				1
2014	12	12									
2015	16	14	2		1	1				1	
Total	**161**	**139**	**25**	**8**	**7**	**6**	**6**	**5**	**3**	**2**	**1**
Percentage		86.3%	15.5%	5.0%	4.3%	3.7%	3.7%	3.1%	1.9%	1.2%	0.6%

Table 13.4 shows the number of TACO events reported each year from 2010 to 2015.

TABLE 13.4 ANNUAL NUMBER OF TACO EVENTS (IMPUTABILITY ≥3) 2010 – 2015

Year	Reported TACO Events	Total Component Units Transfused	Frequency	Rate / 100,000 Units Transfused (95%CI)
2010	13	159,568	1:12,274	8.1 (4.6 to 14.1)
2011	19	151,919	1:7,996	12.5 (7.9 to 19.7)
2012	27	149,668	1:5,543	18.0 (12.3 to 26.4)
2013	16	136,995	1:8,562	11.7 (7.0 to 19.1)
2014	12	135,135	1:11,261	8.9 (4.9 to 15.7)
2015	16	132,060	1:8,254	12.1 (7.3 to 19.9)
Total	**103**	**865,345**	**1:8,401**	**11.9 (9.8 to 14.4)**

Transfusion-Associated Circulatory Overload (TACO) continued

13

From 2010 to 2015, four percent of all reported events were classified as TACO, however they were responsible for 20% of events graded with a severity score ≥2 (Table 13.5).

TABLE 13.5 SEVERE TACO EVENTS (IMPUTABILITY ≥3) 2010 – 2015

		Severity Grade			Total
		Grade 2 (Severe)	Grade 3 (Life Threatening)	Grade 4 (Death)	
All Adverse Events	Number	254	37	5	293
TACO Events	Number	49	8	2	59
	Percentage of Grade	19%	22%	40%	20%

TACO occurs predominantly in older recipients in whom careful consideration of total volume and rate of transfusion is particularly important along with judicious use of diuretics to avoid fluid overload.

CASE F

An 86 year old female, with a background of essential hypertension, hyperlipidaemia, non-insulin-dependent diabetes mellitus and severe infra-renal aortic stenosis, was awaiting imminent intervention under the vascular surgical team. She was admitted with constipation and vomiting, having started opioid analgesics 4 days earlier for leg claudication. A small amount of fresh rectal bleeding was noted after attempts at defecation. At the request of the vascular team, who had a transfusion threshold of 90 g/L prior to interventional procedures, one unit of red cells was administered for Hb 92 g/L. Towards the end of the transfusion, the patient became breathless and wheezy. The blood pressure increased from 150/70 to 212/90 mmHg, respiratory rate from 16 to 40/minute and oxygen saturations fell from 93 to 70% on room air. The jugular venous pressure was elevated. A new systolic heart murmur was noted. Crepitations were auscultated over the lung fields bilaterally consistent with pulmonary oedema. B-type natriuretic peptide (BNP) taken following the event was elevated at 650 ng/L. No baseline value was available. Treatment with diuretic was administered and the patient discharged home the following day with a plan for outpatient echocardiography. Post-transfusion Hb 107 g/L.

The event was recorded as TACO, of grade 2 severity and probable imputability.

CASE G

A 70 year old female, with a background of gastric banding for obesity, was admitted with diarrhoea and vomiting. Investigations revealed acute renal failure and evidence of microangiopathic haemolysis with serum creatinine 587 mmol/L, anaemia Hb 98 g/L and thrombocytopenia 13 x 10^9/L. Bilirubin 43 mmol/L and lactate dehydrogenase 5970 U/L were elevated. Routine coagulation testing was normal. A disorder on the spectrum of haemolytic uraemic syndrome (HUS) - thrombotic thrombocytopenic purpura (TTP) was suspected. Therapy with plasma exchange and prednisone 80mg daily was initiated.

Following transfusion of 3 units of fresh frozen plasma and one unit of platelets, the patient suddenly became breathless with tachypnoea 36/min, severe hypoxia, sinus tachycardia with pulse rising from 80 to 150/min, rise in blood pressure from 160/80 to 185/115 mmHg and chest xray evidence of worsening pulmonary oedema. NT-proBNP levels both pre- and post-transfusion were elevated >4000 ng/L. The patient required intubation and ventilation in the intensive care unit.

The event was recorded as TACO, of grade 3 severity and probable imputability.

14 Transfusion-Associated Dyspnoea (TAD)

Definition

Respiratory distress within 24 hours of transfusion that does not meet the criteria of TRALI, TACO, or allergic reaction and is not explained by the patient's underlying condition.

During 2015, there were 2 events classified as TAD. Both reports involved male recipients. One recipient was 54 years old and the second 75 years old. One of the events was classified as non-severe (grade 1) and one was classified as grade 4 and implicated in the death of the patient.

Table 14.1 shows the number of TAD events reported each year from 2008 to 2015.

TABLE 14.1 ANNUAL NUMBER OF TAD EVENTS (IMPUTABILITY ≥3) 2008 – 2015

Year	TAD Events	Total Component Units Transfused	Frequency	Rate / 100,000 Units Transfused (95%CI)
2008	8	158,181	1:19,773	5.1 (2.4 to 10.2)
2009	13	162,587	1:12,507	8.0 (4.5 to 13.8)
2010	9	159,568	1:17,730	5.6 (2.8 to 10.9)
2011	6	151,919	1:25,320	3.9 (1.6 to 8.8)
2012	15	149,668	1:9,978	10.0 (5.9 to 16.7)
2013	26	136,995	1:5,269	19.0 (12.8 to 27.9)
2014	4	135,135	1:33,784	3.0 (0.9 to 7.9)
2015	2	132,060	1:66,030	1.5 (0 to 5.9)
Total	**83**	**1,186,113**	**1:14,291**	**7.0 (5.6 to 8.7)**

CASE H

A 75 year old male, with transfusion-dependent myelodysplastic syndrome (MDS) of subtype refractory cytopenia with multilineage dysplasia, presented to hospital with acute severe respiratory distress and fever the day following a routine 2 unit red cell transfusion for Hb 61 g/L. CXR showed bilateral infiltrates and echocardiography demonstrated a reduced left ventricular ejection fraction of 40% and septal hypokinesia. Non-invasive ventilatory support for 24 hours in the intensive care unit was given for suspected acute coronary syndrome complicated by cardiogenic pulmonary oedema.

During the following week, while on a cardiology ward, further episodes of transient deterioration in respiratory function occurred, accompanied by spiking fevers. Inflammatory markers were raised. These episodes were temporally related to blood transfusions. Anuric renal failure developed; urinalysis suggesting acute tubular necrosis. Chest CT showed diffuse ground glass abnormality with minor septal thickening. Broad spectrum antibiotics were administered. Blood and sputum cultures were negative. Screening tests for evidence of vasculitis were negative.

One week after initial hospital admission, during a further blood transfusion, severe hypoxia and cardiac arrest occurred. Cardiopulmonary resuscitation was successful. The patient was intubated and remained stable for the subsequent 48 hours. While transfusion-associated circulatory overload (TACO) with cumulative myocardial injury was considered a differential diagnosis, the possibility of immunologically-mediated reactions to blood transfusion was discussed with NZBS. On this basis, two units of washed red cells were provided for the ongoing severe anaemia. Transfusion precipitated another severe respiratory deterioration. In consultation with relatives, active treatment was withdrawn and the patient later died.

The event was recorded as TAD, of grade 4 severity and certain imputability.

Hypotensive Transfusion Reactions

15

Definition

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 conditions that could explain hypotension.

During 2015, there were five events classified as hypotensive transfusion reactions. Red cell units transfused were implicated in four events and fresh frozen plasma in the other. The severity grade of the reaction with fresh frozen plasma was severe (grade 2) while the other four events with allogeneic red cells were non-severe (grade 1).

Table 15.1 show the components implicated in hypotensive events reported each year from 2009 to 2015.

TABLE 15.1 COMPONENTS IMPLICATED IN HYPOTENSIVE EVENTS (IMPUTABILITY ≥3) 2009 – 2015

Year	Total Hypotensive Events	Implicated Components					
		Red Cells	Apheresis Platelets Plasma	Apheresis Platelets PAS	Fresh Frozen Plasma	Pooled Platelets Plasma	Autologous Salvaged Red Cells
2009	13	9	3		1	2	
2010	14	14					
2011	12	10	2				
2012	14	10	1	3	1		
2013	2	1		1			
2014	3	2					1
2015	5	4			1		
Total	**63**	**50**	**6**	**4**	**3**	**2**	**1**
Percentage		79.4%	9.5%	6.3%	4.8%	3.2%	1.6%

16 Delayed Haemolytic / Serologic Transfusion Reactions (DHTR / DSTR)

Definition

A delayed haemolytic transfusion reaction is one in which symptoms and clinical or laboratory signs of increased red cell destruction occur between 24 hours and 28 days following the transfusion of blood or a blood component. If markers of increased red cell destruction are unavailable or not supportive of a haemolytic process, the event is classified as a delayed serological transfusion reaction.

These events are normally identified by the blood bank when repeat testing identifies a new blood group antibody and a positive DAT in a patient recently transfused. Haemolysis is suggested by a poor post-transfusion haemoglobin increment, clinical jaundice or a raised serum bilirubin, raised LDH and low/undetectable serum haptoglobin levels.

During 2015, there were five reports of DHTR and 12 reports of DSTR of imputability ≥3. Table 16.1 shows these events by recipient gender along with data on recipient age. Table 16.2 details the specificities of the blood group antibodies implicated in the DHTR and DSTR events.

TABLE 16.1 DELAYED TRANSFUSION REACTIONS (IMPUTABILITY ≥3) 2015 BY EVENT TYPE AND RECIPIENT GENDER

		Number	Age (years)		
			Mean	Minimum	Maximum
DHTR	Female	3	45	32	68
	Male	3	80	69	91
DSTR	Female	12	60	24	88
	Male	0			

Delayed Haemolytic / Serologic Transfusion Reactions (DHTR / DSTR)

16

continued

TABLE 16.2 DELAYED TRANSFUSION REACTIONS (IMPUTABILITY ≥3) 2015 BY SPECIFICITY OF RED CELL ANTIBODY

Antibody Specificity	Number (Percentage)		
	Delayed Haemolytic	Delayed Serological	Total
Anti-Jk^{b}	2 (40%)	2 (17%)	4 (23.5%)
Anti-Jk^{a}	1 (20%)	2 (17%)	3 (17.6%)
Anti-Jk^{3}	1 (20%)		1 (5.9%)
Antibody to low frequency antigen	1 (20%)		1 (5.9%)
Anti-Fy^{a}		1 (8%)	1 (5.9%)
Anti-K		1 (8%)	1 (5.9%)
Anti-C+e+Jk^{a}		1 (8%)	1 (5.9%)
Anti-E		3 (25%)	3 (17.6%)
Anti-e		1 (8%)	1 (5.9%)
Anti-M		1 (8%)	1 (5.9%)
Total	**5**	**12**	**17**
Blood Group System			
Kidd	4 (80%)	4 (33.3%)	8 (47.1%)
Rh		4 (33.3%)	4 (23.5%)
Duffy		1 (8.3%)	1 (5.9%)
Kell		1 (8.3%)	1 (5.9%)
MNSs		1 (8.3%)	1 (5.9%)
Multiple		1 (8.3%)	1 (5.9%)
Low frequency antigen	1 (20%)		1 (5.9%)

CASE I

A 35 year old female, with end-stage renal failure, was transfused with two units of red cells in the Cook Islands. The patient was transferred to New Zealand for dialysis. Five days post-transfusion, the red cell antibody screen was negative. Day 9 post-transfusion, anti-Jk^{3} was identified, the direct antiglobulin test was IgG weak and anti-Jk^{3} was eluted.

Post-transfusion laboratory results are detailed below.

	Days Post-Transfusion of the Incompatible Red Cell Unit			
	Day 6	Day 7	Day 8	Day 10
Haemoglobin (g/L)	94	90	73	65
Reticulocytes (x10^{9}/L)				121
Bilirubin (µmol/L)				9
Haptoglobin (g/L)				1.39
LDH (U/L)				552
Blood Film comments			RBC fragments	RBC fragments

The event was recorded as DHTR, of grade 1 severity and possible imputability.

17 Unclassifiable Complications of Transfusion (UCT)

Definition

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.

During 2015, there were 26 reports received of adverse events which could not be classified into a definitive category. Thirteen of these were excluded from the analysis on the basis that the event could be attributable to a cause other than the transfusion. The remaining 13 events, included in the analysis, involved 6 female and 7 male recipients. Nine events involved only red cell components and one each involved PAS pooled platelets; thawed haemopoietic stem cells; allogeneic serum eye drops. One event involved multiple red cell and PAS pooled platelet components. The predominant clinical features of these UCT events are summarised in Table 17.1.

TABLE 17.1 UCT EVENTS (IMPUTABILITY ≥3) 2015 BY ASSOCIATED SIGNS AND SYMPTOMS

Symptom	Number of Events
Nausea	4
Cough	3
Chest pain	1
Increase in blood pressure	1
Light headedness	1
Sore eyes	1
Infusion pain	1
Tachycardia	1
Total	**13**

18 Reports Involving Paediatric Patients

During 2015, there were 32 events (8.8% of all events) involving recipients aged 15 years or younger. Allergic reactions were the most frequent adverse event reported in this age group (63%). Table 18.1 details the event type and severity of adverse events occurring in paediatric patients.

TABLE 18.1 ADVERSE EVENTS (IMPUTABILITY ≥3) 2015 IN RECIPENTS ≤15 YEARS AGE BY EVENT TYPE

Event Type	Number	Percentage of Events	Gender		Severity Score		
			Female	Male	1	2	3
Allergic	20	63%	13	7	16	4	
FNHTR	9	28%	2	7	9		
IBCT	1	3%		1	1		
TACO	1	3%	1			1	
AHTR	1	3%		1		1	
Total	**32**		**16**	**16**	**26**	**6**	

Transfusion Transmitted Infections (TTIs)

19

During 2015, there was one TTI reported and this was recorded as grade 2 in severity and of certain imputability.

The adverse event involved the transfusion of a unit of pooled platelets suspended in PAS, prepared from the buffy coats from four whole blood donors and issued at day four post-collection.

The platelet unit was transfused to a 41 year old female with metastatic breast cancer receiving palliative chemotherapy and having a platelet count of 10 x 10^9/L.

Within 15 minutes of starting the transfusion, the patient had an acute onset febrile reaction; the temperature rose from 36.8 to 40.4°C, with associated rigors, nausea, dyspnoea and sinus tachycardia of 169/min.

Visual checks of the platelet unit at the time of issue were normal and upon receipt of the returned unit to the blood bank. Gram stain of the returned platelet unit demonstrated large numbers of gram positive cocci and cultures grew Staphylococcus aureus. BacT/Alert monitoring of the platelet unit sampled at day 2 post-collection did not alarm out to day 7. Gram stain and culture of the BacT/Alert sample were negative. Gram stain and culture of the four red cell units and the four plasma units related to the platelet pool were negative.

The normal visual appearance of the platelet unit involved is unusual. Equally unusual is the absence of a pretransfusion BactT/Alarm and the negative cultures of the donor red cells and plasma components.

NZBS has implemented a number of strategies that will likely increase the sensitivity of the monitoring of platelet components for bacterial contamination. The key changes include an increase in the volume of the BactT/Alarm inoculum to a minimum of 7.5mL (up to 10mL) and the use of a two (aerobic and anaerobic) bottle system, as opposed to the system of three single aerobic culture bottles that was established practice at the time of this adverse event.

Lookbacks

All cases of potential transfusion transmitted infections are investigated by the NZBS Central Lookback Office. Lookbacks are carried out when:

- Investigation of a donor, who has previously tested negative, is repeat reactive on the current donation and with a confirmed positive HIV, HBV, HCV or HTLV infection. All previous donations in the preceding 24 months are documented, and the fate of previous donations shall be undertaken and where appropriate the clinicians responsible for the recipient's care are notified and arrangements made to inform and counsel the recipient and arrange for testing of the recipient.
- When NZBS is informed that a recipient of blood components or products has developed laboratory test results and/or disease symptoms indicating that a blood component or product may have been infectious for hepatitis B, hepatitis C, HIV, HTLV, CJD, a bacterial infection or any other infection that may be transmitted through blood transfusion. Archived samples of these donations are retested and confirmatory testing shall be carried out by an external reference laboratory. Implicated donors are traced and asked to provide samples for retesting if they have not donated or have not been retested since their implicated donation.
- If a donor or healthcare provider notifies NZBS that a donor has developed signs or symptoms of an infection after a donation indicating that his/her donation may have been infectious.

During 2015, thirteen lookbacks were undertaken. Eleven lookbacks involved repeat reactive donors who had previously tested negative and two lookbacks involved recipients of blood that subsequently developed laboratory test results and/or disease symptoms indicating that a transfused blood component or product may have been infectious. The lookbacks are summarised below.

A. Donors Previously Tested Negative, Current Donation Repeat Reactive

Ten investigations involved possible occult HBV infection (Ultrio Plus reactive but non-discriminating; anti-HBc positive). One donor, previously negative for HCV, showed evidence of seroconversion with anti-HCV detected on samples from a donation in 2015; HCV NAT reactive.

The 11 lookbacks involved 35 recipients of blood. Of the 35 recipients, 14 (40%) were deceased and for the remaining 21 recipients a request for testing was sent to the patient's General Practitioner or Hospital Consultant. Test results were received on 8 patients (38%) and in all these cases were negative for evidence of transfusion-transmitted infection (Table 19.1).

19 Transfusion Transmitted Infections (TTIs) continued

TABLE 19.1 REPEAT REACTIVE DONOR LOOKBACK INVESTIGATIONS 2015 BY INFECTION TYPE

Infectious Disease	Number Lookbacks	Recipients Identified	Deceased Recipients	Requests for Recipient Testing	Lookback Outcome
Occult HBV	10	32	14	18	HBV negative (7)
HCV	1	3	0	3	HCV negative (1)
Total	**11**	**35**	**14**	**21**	**Negative (8)**

B. Reports of Possible Transfusion-Transmitted Infection

There were two possible transfusion-transmitted infections, one involving HCV and one HBV.

CASE J – HCV

A 50 year old female patient, with a history of alcoholic liver disease and duodenal ulcer disease, was diagnosed in 2015 with chronic hepatitis C infection. A negative hepatitis C test result was available from May 2012. No obvious risk factors for HCV acquisition were identified.

The patient was transfused with two units of red cells in April 2012. The two donors of the red cells were identified and investigated.

Donor 1 has made a total of 17 blood donations, the last donation was in 2014. The donor made a further six donations following that which was transfused to the patient. All 17 donations have tested negative for anti-HCV and for HCV RNA.

Donor 2 has made a total of 18 blood donations, the last donation was in 2015. The donor made a further eight donations following that which was transfused to the patient. All 19 donations have tested negative for anti-HCV and for HCV RNA.

CASE K – HBV

A 66 year old female patient was initially diagnosed with myeloma in 2012. She underwent an autologous haemopoietic progenitor cell (HPC) transplant in October 2014. She was transfused a number of blood components with the last of the red cells in January 2015. On a routine follow-up visit, she was noted to have markedly deranged liver functions in June 2015 and serology for Hepatitis B showed acute infection or reactivation. Virology screen for Hepatitis A and Hepatitis C were negative.

As part of the investigation for the cause of transmission of hepatitis B, NZBS was notified and performed a thorough review of her transfusion history and a lookback on the donors. Prior to the transplant the patient had been transfused with 7 units of red cells. Post-transplant the patient received 19 units of red cells, 2 units of fresh frozen plasma and 6 units of platelets. The components transfused came from 40 blood donors. All the donors were HBsAg negative and HBV DNA non-reactive. Thirty of the donors made a subsequent donation and these donations were also HBsAg negative and HBV DNA non-reactive.

Retention samples from all the donors were tested for anti-HBs and anti-HBc. Six donors were found to be anti-HBc positive and HBV DNA non-reactive by a reference laboratory. Retrospective testing of samples taken immediately prior to the HPC transplant found the patient to be anti-HBc positive.

Six donors who had not made a further donation and whose anti-HBs was less than 100 IU/L were identified and a request for complimentary HBV testing was sent to five, the sixth donor had moved and the current address was unknown. Samples were received from four of the donors, all of which were HBV DNA non-reactive.

This was a long and complex logistic exercise with no clear indication that blood transfusion was directly responsible for the transmission of hepatitis B in this patient. It could have been a reactivation of a past infection or reinfection. She was started on Lamivudine and her liver functions have since returned back to normal.

Adverse Events Associated with Fractionated Plasma Products

20

Adverse events associated with fractionated plasma products have a separate reporting procedure from those associated with fresh blood components (Appendix II). NZBS receives reports from clinicians and these are forwarded to the manufacturer, CSL Behring (Australia) Pty Ltd. Periodic reports are provided to the Centre for Adverse Reaction Monitoring (CARM).

During 2015, there were reports of 40 adverse events associated with fractionated plasma products. Of the 40 events, 35 involved adverse reactions and the remaining 5 reports involved administration using an incorrect product or dose. The events associated with an incorrect product or dose are described in Chapter 21: Incorrect Blood Components Transfused (IBCT).

Table 20.1 shows the 40 adverse events by fractionated plasma product type. Additional information on events associated specifically with administration of Intragam®P is provided in Table 20.2.

TABLE 20.1 TRANSFUSION-RELATED ADVERSE EVENTS (ANY CAUSALITY) 2015 ASSOCIATED WITH FRACTIONATED PLASMA PRODUCTS

Product Type	Event Type	Number of Reports
Intragam®P	Various, see Table 19.2	20
RhD Immunoglobulin-VF	Wrong blood product (3), wrong dose (2)	5
Evogam® (IV immunoglobulin)	Allergic (3), failure of effect (1)	4
Albumex® 4	Allergic (1), febrile (1), hypotensive (1)	3
Privigen® (IV immunoglobulin)	Allergic (2), aseptic meningitis (1)	3
Albumex® 20	Tachypnoea (1), chest pain (1)	2
Prothrombinex®-VF	Allergic	1
Berinert® (C1-esterase inhibitor)	Patient not considered to have C1-esterase inhibitor deficiency.	1
Biostate®	Allergic	1
Total		**40**

TABLE 20.2 TRANSFUSION-RELATED ADVERSE EVENTS (ANY CAUSALITY) 2015 ASSOCIATED WITH INTRAGAM®P

Type of Reaction	Total	Causality					Severity	
		Excluded	Unlikely	Possible	Probable	Highly probable	Non-severe	Severe
Allergic	11			2	3	6	10	1
Haemolytic	3					3	3	
Hypotension and pyrexia	1		1				1	
Headache	2					2	2	
Nausea and vomiting	1		1				1	
Neuropsychiatric symptoms	1	1					1	
Tachycardia	1			1			1	
Total	**20**	**1**	**2**	**3**	**3**	**11**	**19**	**1**

20 Adverse Events Associated with Fractionated Plasma Products continued

All but three of the adverse events to fractionated products were classified as non-severe. Severe events were associated with the infusion of Intragam®P, Evogam® and Prothrombinex®-VF and were classified with a causality of possible or probable.

CASE L – Severe Event Involving Prothrombinex®-VF

A male patient commenced a 2500 IU dose of Prothrombinex-VF at 3mL/min for reversal of warfarin. Vitamin K had also been administered intravenously. After 15 minutes he developed a full body rash, hypotension with blood pressure 180/90 falling to 88/45 mmHg, tachycardia with heart rate 62 rising to 104/min, and hypoxia with oxygen saturation 99% falling to 76% on air. The infusion was terminated after 1500 IU Prothrombinex-VF had been infused. He was given oxygen 15 L/min, 100 mg hydrocortisone intravenously and Loratadine 10mg orally with good effect. Adrenaline was not required and vital signs returned to pre-treatment levels. The rash was resolving but still faintly present 8 hours after the Prothrombinex-VF infusion. The pre-treatment INR 2.2 had fallen to 1.3 following the dose of Prothrombinex-VF. The patient underwent acute surgery for an incarcerated inguinal hernia later in the day. Causation is probable.

CASE M – Severe Event Involving Evogam®

A female patient with myasthenia gravis was receiving Evogam® due to extreme difficulty with venous access, including previous superior vena caval thrombosis requiring dilatation. She developed a myasthenic relapse in association with a lower respiratory infection. The efficacy of Evogam® when administered in small weekly doses was questioned. There has subsequently been a change in the patient's other immunosuppressive medications in attempt to achieve control of her myasthenia gravis. Causation is possible.

CASE N – Severe Allergic Event Involving Intragam®P

A male patient received a third infusion of Intragam®P for secondary hypogammaglobulinaemia. Two days later he awoke with a red, blotchy, itchy rash on the upper chest and forehead. He started antihistamine (Loratadine) with no improvement after several days. Two days later he had a general anaesthetic at a private hospital for resection of a scalp lesion and was started on Cefaclor antibiotic prophylaxis. On the following day the rash was present on his entire face and upper body, his eyes were swollen and he complained of visual disturbance. He developed mouth ulcers and a raw feeling inside the nostrils. The Cefaclor was stopped and he was commenced on four days treatment with prednisone 60 mg/day. Following the steroid he was much improved but the rash later returned and extended down his arms, legs and back. Prednisone 60 mg/day was recommenced and the rash slowly settled. No adverse events have occurred following previous Intragam®P doses and Cefaclor treatment in 2014 was without complication. Medications administered for the perioperative anaesthesia and analgesia were Propofol, Midazolam, Fentanyl, Remifentanil and Paracetamol. The patient has subsequently died from a rapidly progressive malignancy. Causation is possible.

Incorrect Blood Component Transfused (IBCT)

21

Definition

IBCT is the transfusion of a blood component or product that was intended for another patient or one that did not meet the patient's requirements.

During 2015, there were 12 IBCT events reported. This compares to 20 IBCT events reported in 2014. The IBCT events for 2015 are detailed in Table 21.1.

TABLE 21.1 IBCT EVENTS 2015

IBCT Event Type of Product	Description	Site of Error
Incorrect product/dose Red cells (2) Intragam®P (1)	Group A fresh frozen plasma transfused to a group AB patient without the required authorisation. Stock group AB plasma was available for use.	Laboratory
	Red cell unit with haemoglobin content below the manufacturing discard level was transfused to a patient. No clinical consequences occurred.	Laboratory
	Prescription for Intragam®P was ambiguous. Patient transfused with 2g/kg of Intragam®P daily for three days instead of 2g/kg divided over three days.	Clinical
Non-irradiated components transfused Red cells (1)	Patient required irradiated components; non-irradiated red cells issued and transfused. Two-person check did not identify the error.	Laboratory
Inappropriate transfusion RhD Immunoglobulin (7) Red cells (1)	RhD Immunoglobulin-VF issued and administered to RhD negative patient previously sensitised to RhD.	Laboratory
	RhD Immunoglobulin-VF issued for patient KM but administered to patient ER. Both patients RhD negative.	Clinical
	RhD Immunoglobulin-VF administered to RhD positive woman. Five previous records available in the laboratory detailing the patient's RhD group as RhD positive.	Laboratory
	RhD group of cord blood sample transcribed incorrectly as RhD positive. RhD Immunoglobulin-VF administered unnecessarily to RhD negative mother after birth of RhD negative baby. (2 events)	Laboratory
	Midwife knew patient was RhD positive; patient insisted she was RhD negative and this was reiterated by the patient's mother in Egypt. Patient insisted on receiving RhD Immunoglobulin-VF. RhD group of patient confirmed to be RhD positive.	Clinical
	RhD Immunoglobulin (Rhophylac®) instructed to be administered intravenously but administered intramuscularly.	Clinical
	Two emergency group O RhD negative units transfused, pre- and post-transfusion haemoglobin values were 117g/L and 144g/L respectively.	Clinical

22 Near Miss Events

Definition

A near miss event is an error or deviation from standard procedure or policy that is discovered before the transfusion and that, if not discovered, would have led to an inappropriate transfusion and has potential for an adverse reaction in the recipient.

Near miss events are usually reported to a local incident management system (within a DHB) so that appropriate investigations are undertaken and the necessary education and preventive actions are implemented. During 2015, there were eight events identified from the NZBS incident management system and one report from a DHB Blood Bank detailing a WBIT event. These events are summarised in Table 22.1.

TABLE 22.1 NEAR MISS EVENTS 2015 BY ERROR TYPE AND SITE

Error	Site of Error			
	Blood Bank	Processing	Clinical	Total
Wrong product/component issued (including wrong dose or wrong patient)				
RBC 5	3		2	5
Other blood products 1				
Irradiation errors		2		2
WBIT			1	1
Expiry of blood components	1			1
Total	**4**	**2**	**3**	**9**

CASE O

The laboratory was contacted by a Junior Medical Officer (JMO) regarding Patient A. There was no valid sample available for a planned transfusion so the JMO offered to collect a sample. About 1 hour later a sample was received for Patient B. Both form and sample were accepted according to the standard acceptance criteria. There was no form and sample received for Patient A. The sample for Patient B grouped as O RhD negative. Historically, this patient had been grouped several times as A RhD positive. The JMO was contacted and asked which patient she had collected a sample from. The reply was Patient A, however the form and sample were labelled as Patient B.

From further discussion it appears that:

1. The form had not been printed first and taken to the bedside.
2. The sample was not labelled at the bedside.
3. The JMO had taken the unlabelled sample to the office before printing a label for the form.
4. The wrong patient label was generated and the wrong patient's details were written on the sample.

CASE P

Three red cell components were irradiated but not transformed prior to sending to the blood bank. The blood bank staff noticed at group checking that the units were not transformed and therefore the expiry date had not been amended to 14 days post-irradiation. They called the donor centre and arranged for the units to be sent back and transformed.

Near Miss Events continued

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CASE Q

A Duty Nurse Manager collected a red cell unit from the after-hours refrigerator but failed to check it correctly before leaving blood bank. The Duty Nurse Manager took the red cell unit to the ward and performed the checks there only to find that the incorrect unit had been selected; one cross-matched for another patient with a similar name. The red cell unit was immediately returned to the blood bank and a request made for red cells to be cross-matched for the patient.

CASE R

A clinical area requested 2 x 100mL bottles of 20% human albumin solution. The blood bank provided 2 x 500mL bottles of 4% human albumin solution. The product was returned to the blood bank and the correct albumin issued, causing unnecessary delay in transfusion. The blood bank staff member was unable to explain the error except to note that it had been a very busy time with multiple requests for that patient and that the patient had previously been issued 4% albumin.

CASE S

A blood collection form for Patient C (group A RhD positive) was received and 1 unit of group A RhD positive red cells issued to the ward. The ward phoned the blood bank 15min later to say the request for blood had been sent for the wrong patient. The request was supposed to be for Patient D (group O RhD positive) but accidentally a sticker for Patient C had been used on the blood collection form. Ward staff realised the error as the line was being primed to transfuse to Patient D. The patients were in neighbouring beds and the red cell unit was almost transfused to the wrong patient.

CASE T

A red cell unit expiring at midnight that evening was reserved for a patient. The red cell unit did not leave the Blood Bank and remained on the issue shelf of the blood bank refrigerator. Nightshift did not notice that the unit had expired and failed to remove it from the refrigerator. At 1008 hrs the next morning the unit was sent up to the ward for transfusion. A nurse noticed that the unit had expired and it was returned to blood bank.

23 NZBS Wrong Blood in Tube (WBIT) Events

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

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

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

Rather than relying on voluntary Haemovigilance reporting of near miss events, the NZBS incident management system collects accurate WBIT data from the six NZBS Blood Banks. In 2015, historic ABO RhD blood groups were available in eProgesa for 66.3% (range 61.6% to 70%) of all pretransfusion samples submitted to NZBS Blood Banks. There were 21 WBIT errors identified. In three cases, the historic result was assumed to be incorrect. Table 23.1 shows the corrected WBIT rate for the 18 current WBIT events reported by the NZBS Blood Banks in 2015. The overall corrected WBIT rate was 3.2 per 10,000 samples (1:3,170).

TABLE 23.1 NZBS WBIT EVENTS 2015 BY BLOOD BANK SITE

	WBIT Events	Historic Groups	WBIT Frequency[1]	Rate / 10,000 Specimens (95% CI)[1]
Palmerston North	2	5,571	1:1,741	5.7 (1.2 to 17.1)
Dunedin	2	6,180	1:1,931	5.2 (1.1 to 15.5)
Christchurch	4	14,280	1:2,231	4.5 (1.9 to 9.8)
Wellington	3	14,989	1:3,123	3.2 (1.1 to 7.9)
Auckland	6	32,626	1:3,399	2.9 (1.5 to 5.6)
Waikato	1	17,652	1:11,033	0.9 (-0.1 to 4.1)
NZBS Total	**18**	**91,298**	**1:3,170**	**3.2 (2.2 to 4.6)**

[1] *Corrected to account for silent errors.*

Table 23.2 shows the cumulative number of WBIT errors for the six NZBS Blood Banks over an eight year period from 2007 to 2015. The overall corrected WBIT rate was 2.6 per 10,000 samples (1:3,900). An international study (Dzik et al. Vox Sanguinis 2003: 85; 40-47) involving 10 countries reported an approximate median WBIT rate of 5 per 10,000 samples (1:2,000).

NZBS Wrong Blood in Tube (WBIT) Events continued

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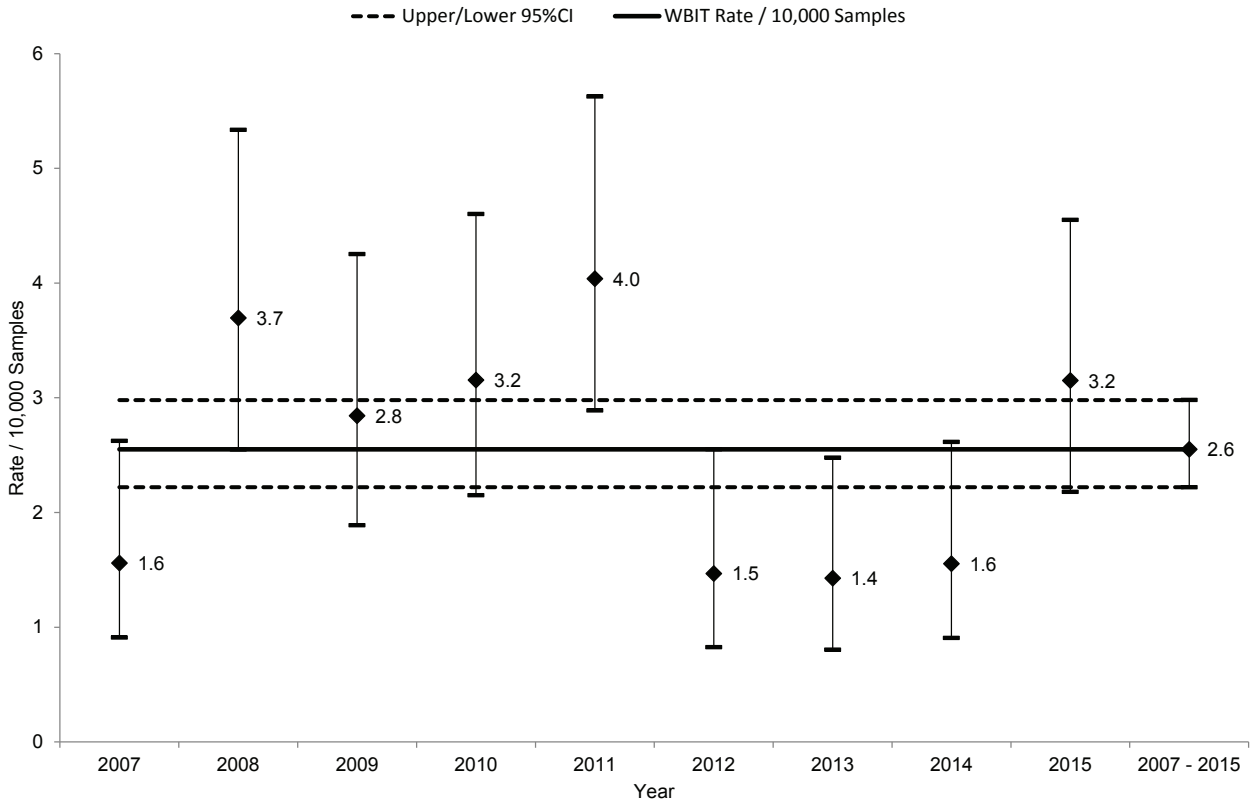
TABLE 23.2 NZBS WBIT EVENTS 2007 – 2015 BY BLOOD BANK SITE

	WBIT Events	Historic Groups	WBIT Frequency[1]	Rate / 10,000 Samples (95% CI)[1]
Wellington	39	117,699	1:1,886	5.3 (4.1 to 6.8)
Palmerston North	9	50,867	1:3,532	2.8 (1.7 to 4.8)
Auckland	40	272,638	1:4,260	2.3 (1.8 to 3.0)
Dunedin	7	55,487	1:4,954	2.0 (1.1 to 3.6)
Christchurch	15	134,166	1:5,590	1.8 (1.2 to 2.7)
Waikato	16	158,273	1:6,183	1.6 (1.1 to 2.4)
NZBS Total	**126**	**789,130**	**1:3,914**	**2.6 (2.2 to 2.9)**

[1] *Corrected to account for silent errors.*

The annual NZBS WBIT event rate per 10,000 (95% CI) samples from 2007 to 2015 is shown in Figure 23.1.

FIGURE 23.1 ANNUAL NZBS WBIT EVENT RATE 2007 – 2015



24 Bacterial Monitoring of Platelet Concentrates

Bacterial contamination in platelets can result in sepsis with the associated morbidity occasionally leading to death and as such continues to be a serious risk of transfusion. Bacteria will either enter the component at the time of venepuncture or more rarely arises due to an occult infection in the donor but can also enter due to a breach of the closed system during processing. The warm storage temperature of 22 ± 2°C combined with the platelet component itself is an ideal medium for some, though not all, bacteria to flourish. The likelihood of detecting bacteria in platelet components and the consequent risk of clinical sepsis in the recipient increases with the cumulative age of the platelet.

International Haemovigilance programmes report the rate of septic reactions to bacterially contaminated platelets as 0.001 to 0.002% (1 in 100,000 to 1 in 50,000) and the risk of death from a contaminated platelet as 0.0002 to 0.0004% (1 in 500,000 to 1 in 250,000). The Serious Hazards of Transfusion (SHOT: the UK Haemovigilance system) 2009 report identified approximately 1 septic reaction per 75,000 platelets issued and 1 death per 273,000 platelets issued. Similar data has been reported by both the USA and French Haemovigilance where septic reactions are 1 in 83,000 and 1 in 50,000 respectively. The rate of fatal reactions reported by the USA is approximately 1 in 500,000 while France reports 1 in 300,000. These risks will however have reduced significantly as a consequence of the introduction of specific measures designed to both reduce the likelihood of contamination occurring and to detect the presence of contamination prior to the component being transfused.

Five cases of bacterial infection attributable to transfusion of contaminated platelets have been reported to the NZBS haemovigilance office during the last ten years, one in each of 2008, 2009, 2010, 2011 and 2015. No cases were reported in either 2012 or 2013. All five patients developed fever temporally linked to the platelet transfusion but with no significant clinical sequelae. Two of the cases (2009 and 2010) involved platelet components that had been cultured on day 2. In both instances an alternative source for the infection in the patient was identified. A third case reported in 2015 appears to have been a 'true false negative' with Staph. aureus grown from both the patient and component but no growth in the sample taken at day 2. The remaining two cases in 2008 and 2011 involved platelet components that had not been cultured.

Blood service organisations, including the New Zealand Blood Service (NZBS) have introduced initiatives aimed at reducing the incidence of bacterial contamination in blood components including improved skin disinfection at the venepuncture site and diversion of the first 30-50mL of the donation in order to avoid skin commensals contaminating the donation. These measures are widely accepted to reduce the risk of contamination by 60-70%.

In early 2014 NZBS made a submission to Medsafe to extend the platelet shelf-life to 7 days with the implementation of a mandatory system for bacterial culture of the platelets. The proposed culture system is identical to that used by the NHSBT in England. Medsafe gave approval in principle with the initiative in January 2015. A pilot system went live in Auckland in June 2015. The results of this were carefully monitored and was followed by a national rollout in December 2015. The system involves the use of a larger sample volume, both aerobic and anaerobic culture bottles and supports an extended seven day shelf life of the platelet component.

The frequency of reactive results has increased with the introduction of the new system. This is shown in Table 24.1. Data for the Auckland site, which acted as the pilot site, is provided for the period January to September 2015 when the original single bottle aerobic culture system was in place and for the period October to December 2015 when both aerobic and anaerobic bottles were used with a larger inoculum volume.

TABLE 24.1 COMPARISON OF TWO DIFFERENT CULTURE SYSTEMS

	Number components tested	Number reactive(%)	Number confirmed positive(%)
January to September 2015	4,243	9 (0.21%)	1 (0.02%)
October to December 2015	1,488	18 (1.21%)	1 (0.07%)

The high rate of unconfirmed reactive results seen in the period October to December 2015 is a concern. This is currently being investigated. Interestingly this is not evident at two of the other three processing sites which have been using the new system since December 14 2015. A similar variation in initial reactive rate by site and machine is reported from other blood services internationally.

No clinical reports suggestive of bacterial contamination of platelet components has been received since the new system went live. Clinicians are informed in the event that a reactive culture signal is obtained for a platelet component that has been transfused.

Donor Infectious Disease Screening and Transfusion-Transmitted Infections (TTI)

25

In New Zealand, all blood donations are screened for hepatitis B surface antigen (HBsAg), HBV DNA, anti-HCV, HCV RNA, anti-HIV-1/2, HIV RNA and syphilis antibody. All new donors are also tested for anti-HTLV-I/II. Additional testing is performed on selected donations, e.g., CMV IgG for fetal and neonatal transfusions, Trypanasoma cruzi (Chagas) and malarial antibody tests in donors who may pose a risk due to residence and/or travel to affected areas.

During 2015, there were 169,914 donations collected from 82,859 donors. Of these donors, 81% were repeat donors and 19% were previously untested new donors.

Table 25.1 shows the number of donors with confirmed positive serology in 2015. There were 28 donors confirmed positive for HBV and 8 confirmed positive for HCV.

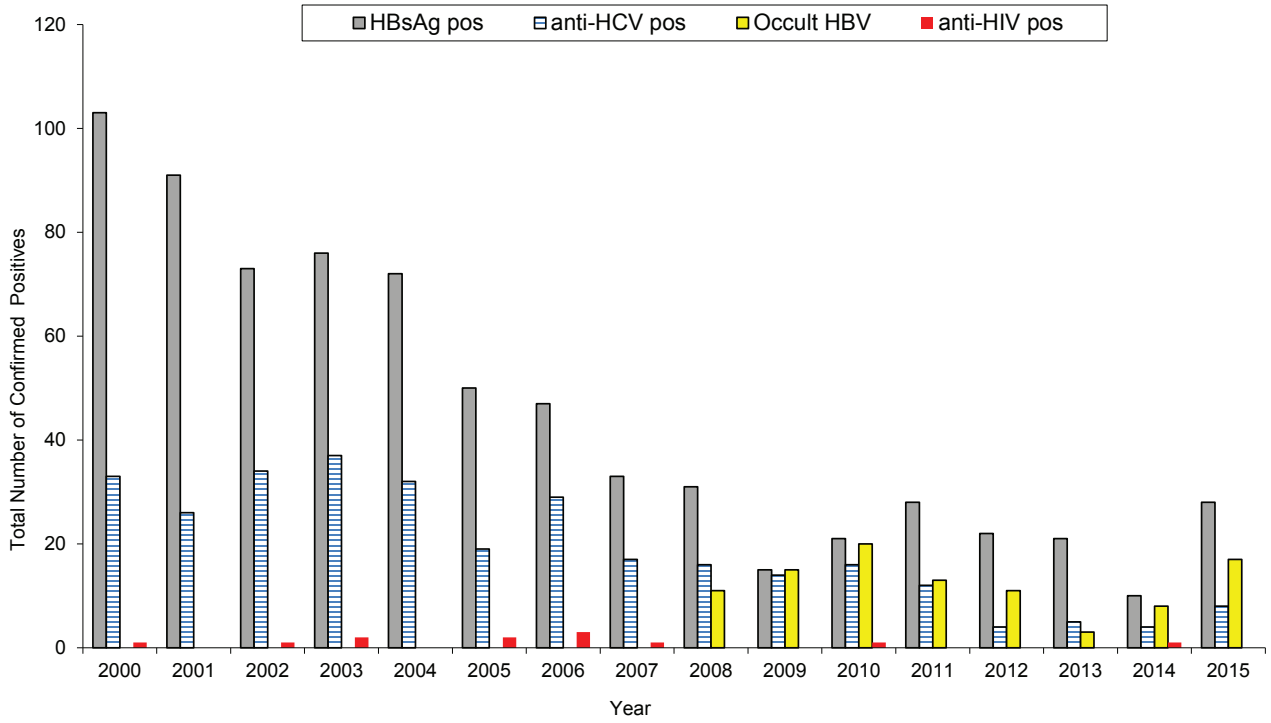
TABLE 25.1 DONORS WITH CONFIRMED POSITIVE INFECTIOUS DISEASE SEROLOGY 2015

		HBV	HCV	HIV	Syphilis	HBV Occult	HTLV I/II
Number	New Donors (n = 15,468)	26	8	0	4	4	0
	Repeat Donor (n = 67,391)	2	0	0	2	13	0
	Total Donors (n = 82,859)	28	8	0	6	17	0
Rate Per 100,000 Donations	New Donors	168.1	51.7	0	25.9	25.9	0
	Repeat Donors	3.0	0	0	3.0	19.3	0
	All Donations	33.8	9.7	0	7.2	20.5	0
Frequency of Positive Donors	New Donors	1:595	1:1,934		1:3,867	1:3,867	
	Repeat Donors	1:33,696			1:33,696	1:5,184	
	Overall Donor Frequency	1:2,959	1:10,357		1:3,810	1:4,874	

25 Donor Infectious Disease Screening and Transfusion-Transmitted Infections (TTI) continued

Figure 25.1 shows the number of confirmed positive results each year from 2000 to 2015. Occult hepatitis B infection is defined as 'the presence of HBV DNA in donor plasma without detectable HBsAg, outside the window period'. Detection of these donors only became possible following the implementation of HBV DNA testing in 2007.

FIGURE 25.1 ANNUAL NUMBER OF DONORS WITH CONFIRMED POSITIVE INFECTIOUS DISEASE SEROLOGY 2000 – 2015



Adverse Events Associated with Blood Donation

26

The year on year number of annual blood donations by donation type is shown in Table 26.1. The decline in plateletpheresis donations since 2012 is due to a change at a number of NZBS sites from a 60:40 to 40:60 ratio of apheresis to platelet pools for the production of platelet components.

TABLE 26.1 ANNUAL NUMBER OF BLOOD DONATIONS 2005 – 2015 BY DONATION TYPE

Year	Number							
	Whole Blood		Plasmapheresis		Plateletpheresis		Total	
	Donors	Donations	Donors	Donations	Donors	Donations	Donors	Donations
2005	95,382	156,684	1,227	6,479	979	5,098	97,588	168,261
2006	91,929	151,934	2,647	12,880	957	5,148	95,533	169,962
2007	88,584	150,308	4,064	23,514	957	5,493	93,605	179,315
2008	90,364	152,760	4,190	26,985	1,009	5,998	95,563	185,743
2009	89,159	151,689	3,012	18,106	1,143	6,578	93,314	176,373
2010	89,623	153,044	3,407	18,243	1,136	6,499	94,166	177,786
2011	86,986	147,093	4,723	28,886	1,119	6,491	92,828	182,470
2012	83,040	139,845	5,037	30,179	1,138	6,527	89,215	176,551
2013	75,069	125,684	5,078	29,585	830	4,942	80,977	160,211
2014	72,754	120,668	5,910	38,099	595	3,570	79,259	162,337
2015	71,511	119,554	7,586	46,983	555	3,377	79,652	169,914

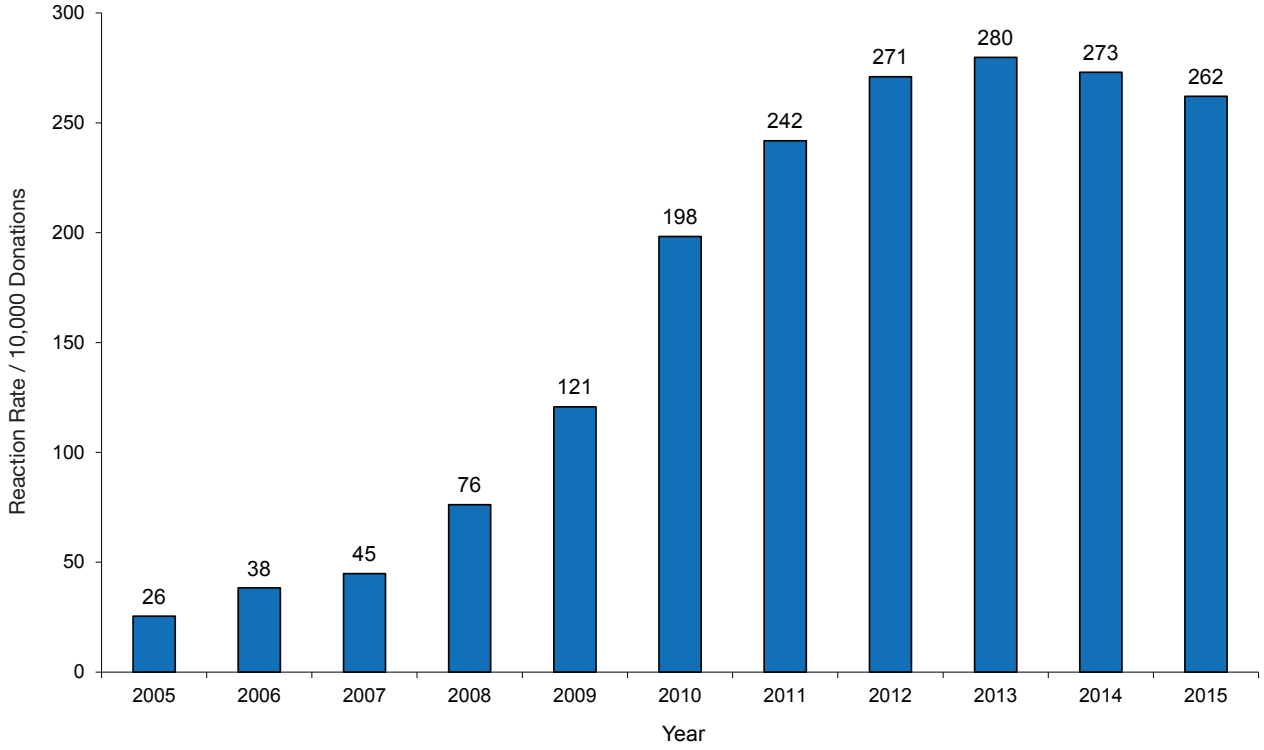
Adverse events associated with blood donation can occur during or after collection of the donation. Delayed complications are defined as a complication which has occurred after the donor has left the donation site. Delayed complications are notified either by a telephone call, personal visit, email or letter.

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

The annual reported donation-related adverse event rate per 10,000 donations has remained similar for the last three years (Figure 26.1). Prior to this, the increase seen likely reflected efforts within NZBS to improve consistency of reporting across the sites.

26 Adverse Events Associated with Blood Donation continued

FIGURE 26.1 ANNUAL DONATION-RELATED ADVERSE EVENT RATE PER 10,000 DONATIONS 2005 – 2015



During 2015, there were 169,914 donations (119,554 whole blood, 46,983 plasmapheresis and 3,377 plateletpheresis donations) collected. Adverse events were reported in relation to 4,453 of the donations and involving 4,083 donors. The overall frequency of reported donation-related adverse events was 1:38. Adverse events are more frequently reported with apheresis procedures, particularly plateletpheresis, than whole blood donations (Table 26.2).

TABLE 26.2 DONATION-RELATED ADVERSE EVENTS 2015 BY COLLECTION METHOD

Procedure	Donors	Donations with Events	Total Donations	Frequency	Rate / 10,000 Donations (95%CI)
Whole blood donation	2,836	2,923	119,554	1:41	244.5 (235.9 to 253.4)
Plasmapheresis	1,007	1,187	46,983	1:40	252.6 (238.8 to 267.2)
Plateletpheresis	240	343	3,377	1:10	1,015.7 (918.2 to 1,122.3)
All apheresis procedures	1,247	1,530	50,360	1:33	303.8 (289.2 to 319.2)
Total procedures	**4,083**	**4,453**	**169,914**	**1:38**	**262.1 (254.6 to 269.8)**

Adverse Events Associated with Blood Donation continued

26

A number of donors experienced more than one adverse event with a single donation so, in total, there were 4,856 reported events with 2,974 involving whole blood donations and 1,882 involving apheresis procedures. Immediate vasovagal reactions and bruising/haematoma were the most common events associated with donation. For whole blood donation, the most common event (63.5%) was an immediate vasovagal reaction. For apheresis procedures, the most common event (60.6%) was bruising/haematoma. Donation-related adverse events by reaction type and collection method are shown in Table 26.3 and Table 26.4.

TABLE 26.3 DONATION-RELATED ADVERSE EVENTS 2015 BY REACTION TYPE

Adverse Event	All Blood Donations (Total Collections 169,914)			
	Number Events[1]	Percentage	Frequency	Rate / 10,000 Donations (95% CI)
Immediate Vasovagal	2,147	52.7%	1:79	126 (121 to 132)
Haematoma	1,402	34.4%	1:121	83 (78 to 87)
Painful arm	156	3.8%	1:1,089	9 (8 to 11)
Nerve Irritation / Injury	142	3.5%	1:1,197	8 (7 to 10)
Delayed Vasovagal	120	2.9%	1:1,416	7 (6 to 8)
Other	51	1.3%	1:3,332	3 (2 to 4)
Re-bleeding	33	0.8%	1:5,149	2 (1 to 3)
Arterial Puncture	8	0.2%	1:21,239	<1 (0 to 1)
Local Allergic Reaction	6	0.1%	1:28,319	<1 (0 to 1)
Thrombophlebitis	4	0.1%	1:42,479	<1 (0 to 1)
Cellulitis	2	0.05%	1:84,957	<1 (0 to 1)
Other Serious Complications	2	0.05%	1:84,957	<1 (0 to 1)
Total	**4,073**		**1:42**	**240 (233 to 247)**

[1] *Apheresis-specific complications excluded, i.e., citrate reactions and red cell return failures.*

26 Adverse Events Associated with Blood Donation continued

TABLE 26.4 DONATION-RELATED ADVERSE EVENTS 2015 BY REACTION TYPE AND COLLECTION METHOD

Adverse Event	Type of Blood Donation					
	Whole Blood (Total Collections = 119,554)			Apheresis (Total Collections = 50,360)		
	% All Events	Freq.	Rate / 10,000 Donations (95% CI)	% All Events	Freq.	Rate / 10,000 Donations (95% CI)
Immediate Vasovagal	63.5%	1:63	160 (153 to 167)	20.9%	1:212	47 (42 to 54)
Haematoma	23.6%	1:168	59 (55 to 64)	60.6%	1:73	137 (127 to 148)
Painful arm	3.8%	1:1,040	10 (8 to 12)	8.7%	1:509	20 (16 to 24)
Delayed Vasovagal	3.4%	1:1,161	9 (7 to 10)	1.6%	1:2,798	4 (2 to 6)
Nerve Irritation / Injury	3.3%	1:1,208	8 (7 to 10)	3.8%	1:1,171	9 (6 to 12)
Re-bleeding	1.0%	1:3,857	3 (2 to 4)	0.6%	1:7,194	1 (1 to 3)
Other	0.8%	1:4,782	2 (1 to 3)	3.5%	1:1,259	8 (6 to 11)
Arterial Puncture	0.3%	1:14,944	1 (0 to 1)			
Local Allergic Reaction	0.2%	1:2,3911	<1 (0 to 1)	0.1%	1:50,360	<1 (0 to 1)
Thrombophlebitis	0.1%	1:59,777	<1 (0 to 1)	0.2%	1:25,180	<1 (0 to 2)
Cellulitis				0.1%	1:50,360	<1 (0 to 1)
Other Serious Complications				0.1%	1:50,360	<1 (0 to 1)
Generalised Allergic Reaction				0.6%	1:7,194	1 (1 to 3)
Total		**1:40**	**252 (243 to 261)**		**1:44**	**227 (214 to 240)**

	Apheresis-only Complications		
	% Reaction	Freq.	Rate / 10,000 Donations (95% CI)
RBC not returned	63.1%	1:102	98 (90 to 107)
Citrate toxicity	36.9%	1:174	57 (51 to 64)
Total Apheresis-specific Events		**1:64**	**155 (145 to 167)**

Adverse Events Associated with Blood Donation continued

26

During 2015, there were 119,554 whole blood donations with 91% of these collected from repeat donors. Except for re-bleeding, the frequency of all donation-related adverse events was higher in first-time donors compared to repeat donors. The distribution of event types within the two groups was similar with vasovagal reactions and haematoma events predominating (Table 26.5).

TABLE 26.5 WHOLE BLOOD DONATION-RELATED ADVERSE EVENTS 2015 BY REACTION TYPE FOR NEW AND REPEAT DONORS

Adverse Event	New Donors (n=10,598)			Repeat Donors (n=108,956)		
	% Reactions	Freq.	Rate Per 1,000 Donations	% Reactions	Freq.	Rate Per 1,000 Donations
Immediate Vasovagal	79.8%	1:15	68.07	55.1%	1:98	10.21
Haematoma	12.6%	1:93	10.72	29.2%	1:185	5.42
Delayed Vasovagal	2.7%	1:427	2.34	3.8%	1:1,435	0.70
Nerve Irritation / Injury	1.8%	1:664	1.51	4.1%	1:1,329	0.75
Painful arm	1.7%	1:703	1.42	4.9%	1:1,098	0.91
Other	0.8%	1:1,493	0.67	0.9%	1:6,330	0.16
Local Allergic Reaction	0.4%	1:2,986	0.33	0.1%	1:107,611	0.01
Re-bleeding	0.1%	1:11,943	0.08	1.5%	1:3,587	0.28
Arterial Puncture	0.1%	1:11,943	0.08	0.4%	1:15,373	0.07
Cellulitis	0.1%	1:11,943	0.08	0.1%	1:107,611	0.01
Thrombophlebitis				0.1%	1:107,611	0.01
Other Serious Complications				0.1%	1:107,611	0.01
Total	**1,019**	**1:12**	**85.32**	**1,994**	**1:54**	**18.5**

The frequency of donation-related adverse events in whole blood donors is inversely related to age, and is highest in donors under the age of 20 years. In this youngest group of donors, aged 16 to 19 years, the adverse event rate is 1:15 donations and the odds ratio is 2.86 (Table 26.6).

TABLE 26.6 WHOLE BLOOD DONATION-RELATED ADVERSE EVENTS 2015 BY DONOR AGE GROUP

Age Group	Number Adverse Events	Total Donors in Age Group	Frequency	Rate / 1,000 Donations (95%CI)	Odds Ratio (95%CI)
16 - 19 Years	728	10,831	1:15	67.2 (62.6 to 72.1)	2.86 (2.63 to 3.11)
20 - 24 Years	592	13,742	1:23	43.1 (39.8 to 46.6)	1.79 (1.63 to 1.95)
25 - 29 Years	399	11,385	1:29	35.0 (31.8 to 38.6)	1.44 (1.29 to 1.60)
30 - 34 Years	212	8,830	1:42	24.0 (21.0 to 27.4)	0.98 (0.85 to 1.12)
35 - 39 Years	192	8,859	1:46	21.7 (18.8 to 24.9)	0.88 (0.76 to 1.02)
40 - 44 Years	155	10,787	1:70	14.4 (12.3 to 16.8)	0.58 (0.49 to 0.68)
45 - 49 Years	152	11,041	1:73	13.8 (11.7 to 16.1)	0.55 (0.47 to 0.65)
50 - 54 Years	145	12,513	1:86	11.6 (9.9 to 13.6)	0.46 (0.39 to 0.55)
55 - 59 Years	133	12,215	1:92	10.9 (9.2 to 12.9)	0.44 (0.37 to 0.52)
≥60 Years	215	18,636	1:87	11.5 (10.1 to 13.2)	0.46 (0.40 to 0.53)
All	**2,923**	**118,839**	**1:41**	**24.6 (23.7 to 25.5)**	

26 Adverse Events Associated with Blood Donation continued

Vasovagal reactions are the most common whole blood donation-related adverse event. Table 26.7 shows that the higher rate of vasovagal reactions in new donors versus repeat donors is seen across all age groups. There is a steady reduction in the likelihood of a vasovagal reaction with increasing age.

TABLE 26.7 WHOLE BLOOD VASOVAGAL EVENTS 2015 BY DONOR AGE GROUP FOR NEW DONORS AND REPEAT DONORS

		New Donors (n = 10,598)		Repeat Donors (n = 108,956)	
Age Group	Gender	Frequency	Rate / 1,000 Donations (95%CI)	Frequency	Rate / 1,000 Donations (95%CI)
16 - 19	Female	1:10	102.0 (91.1 to 114.0)	1:25	40.4 (34.3 to 47.5)
	Male	1:17	57.9 (49.4 to 67.9)	1:36	28.0 (21.9 to 35.8)
20 - 24	Female	1:10	103.1 (85.7 to 123.6)	1:34	29.4 (25.8 to 33.6)
	Male	1:18	55.0 (42.7 to 70.5)	1:57	17.4 (14.0 to 21.8)
25 - 29	Female	1:10	97.3 (77.0 to 122.3)	1:40	25.1 (21.3 to 29.5)
	Male	1:20	49.9 (36.2 to 68.1)	1:74	13.5 (10.4 to 17.4)
30 - 34	Female	1:19	52.0 (33.8 to 78.6)	1:62	16.1 (12.6 to 20.5)
	Male	1:17	60.0 (41.8 to 85.2)	1:113	8.8 (6.3 to 12.3)
35 - 39	Female	1:16	63.7 (41.1 to 96.8)	1:74	13.6 (10.5 to 17.5)
	Male	1:27	36.9 (21.1 to 62.8)	1:126	7.9 (5.5 to 11.2)
40 - 44	Female	1:21	48.4 (28.9 to 78.9)	1:139	7.2 (5.3 to 9.8)
	Male	1:23	42.9 (23.9 to 74.2)	1:332	3.0 (1.7 to 5.1)
45 - 49	Female	1:20	49.8 (27.0 to 87.9)	1:137	7.3 (5.4 to 9.9)
	Male	1:26	39.0 (18.7 to 76.4)	1:313	3.2 (1.9 to 5.2)
50 - 54	Female	1:19	52.1 (27.4 to 94.4)	1:157	6.4 (4.7 to 8.7)
	Male	1:47	21.4 (6.4 to 55.6)	1:449	2.2 (1.3 to 3.8)
55 - 59	Female	1:13	74.8 (36.4 to 142.6)	1:134	7.5 (5.6 to 10.1)
	Male	1:38	26.5 (5.7 to 78.5)	1:765	1.3 (0.6 to 2.6)
≥60	Female	1:20	50.6 (16.0 to 126.9)	1:144	7.0 (5.4 to 8.9)
	Male	1:26	38.5 (8.6 to 111.6)	1:607	1.6 (1.0 to 2.7)
Total	Female	1:11	88.8 (81.8 to 96.3)	1:67	14.9 (13.9 to 15.9)
	Male	1:19	52.0 (46.6 to 57.9)	1:152	6.6 (5.9 to 7.3)
	Total	**1:14**	**70.4 (66.0 to 75.1)**	**1:91**	**11.0 (10.4 to 11.6)**

In line with international practice, NZBS has introduced measures to reduce the frequency of adverse reactions in younger donors. Current guidance contained in the Council of Europe Guide to the Preparation, Use and Quality Assurance of Blood Components identifies that a standard whole blood donation can be undertaken from a donor weighing at least 50kg. In addition, in younger donors, an estimate of total blood volume is made based on donor weight and height. Donors with an estimated blood volume of less than 3,500mL are deferred from donating.

Adverse Events Associated with Blood Donation continued

26

Donation-related adverse events associated with citrate toxicity during plateletpheresis

A survey in 2012 of the six NZBS sites collecting platelets by apheresis showed that the rate of citrate-related adverse events was 83 per 1,000 procedures (range 3 to 161) and that there was variation in practice of offering donors calcium supplements to prevent hypocalcaemia associated with this procedure. The results of the survey lead to the implementation in 2014 of a national protocol for calcium supplementation for plateletpheresis donors.

All plateletpheresis donors now receive at the time of venesection 3 chewable Nestlé Quick-Eze antacid tablets each containing 800mg calcium carbonate followed by a further 3 tablets with the onset of symptoms of citrate toxicity, and repeated if necessary every 20-30 minutes to a maximum dose of 9 tablets. Comparing the national rate of citrate reactions reported in 2015 to that in 2013, a decrease of 40% has occurred (p=<0.001) (Table 26.8).

TABLE 26.8 DONATION-RELATED ADVERSE EVENTS ASSOCIATED WITH CITRATE TOXICITY DURING PLATELETPHERESIS 2013 – 2015

	Year				
	2013	2014	2015	% Change	P Value
Number Citrate Adverse Events	493	238	202		
Number Plateletpheresis Procedures	4,942	3,570	3,377		
Rate / 1,000 Procedures	100	67	60	-40%	<0.001

27 Request Form and Specimen Labelling Errors

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

International guidelines require that labels on pretransfusion specimens must be handwritten at the patient's bedside. A declaration must be signed by the collector at the time of collection of the specimen certifying that:

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

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

Over the past nine years, the six NZBS Blood Banks (Auckland, Waikato, Palmerston North, Wellington, Christchurch and Dunedin) have been recording errors and corrective actions associated with pretransfusion specimens. 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 pretransfusion request forms and specimen labelling (for NZBS Blood Banks) are outlined in Table 27.1.

TABLE 27.1 NZBS PRETRANSFUSION REQUEST FORM AND SPECIMEN LABELLING REQUIREMENTS

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

During 2015, a total of 137,946 pretransfusion specimens were received by the six NZBS Blood Banks. Errors were identified in 3,053 specimens/forms. The overall error rate for the six NZBS Blood Banks was 22.1 per 1,000 specimens received, which is equivalent to an error rate of 1:45 specimens. The error rate in 2015 was a 2.6% decrease from that reported in 2014 (22.7 per 1,000 specimens or 1:41). Table 27.2 details the error rate per 1,000 specimens for the six NZBS Blood Banks in 2015.

Request Form and Specimen Labelling Errors continued

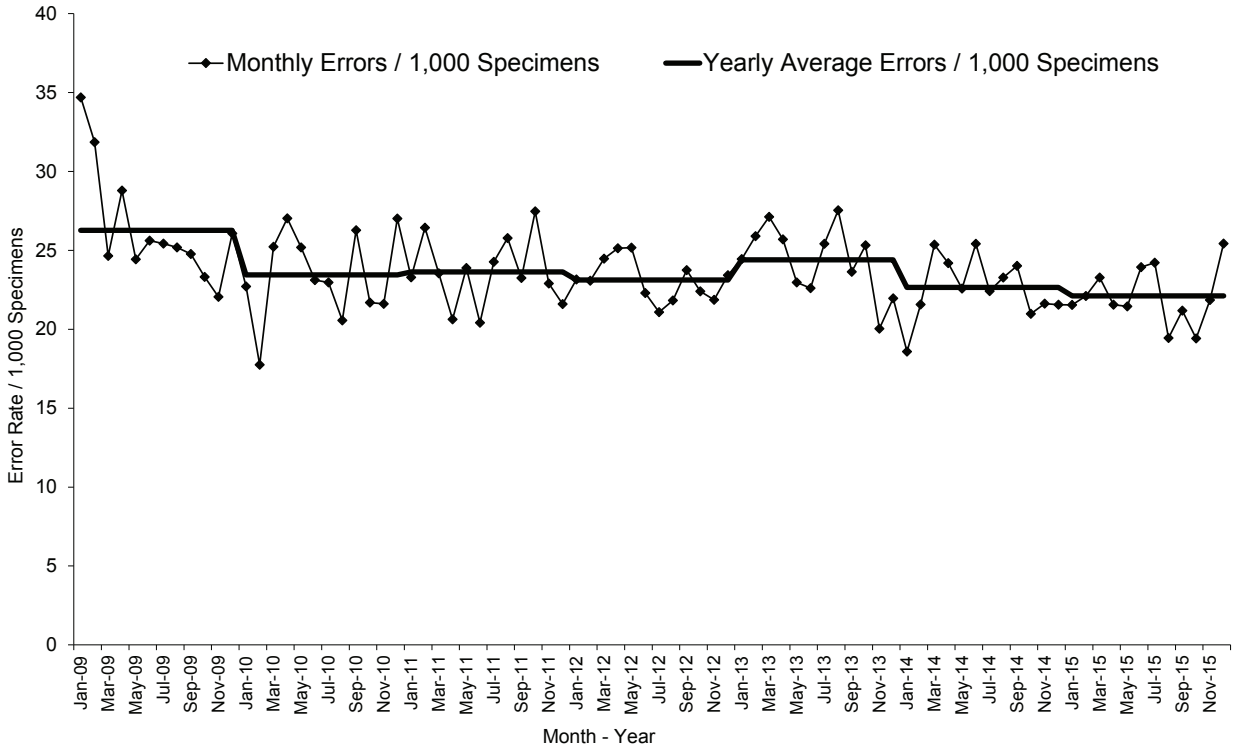
27

TABLE 27.2 PRETRANSFUSION REQUEST FORM AND SPECIMEN LABELLING ERRORS 2015 BY NZBS BLOOD BANK SITE

Blood Bank	Errors	Total Specimens	Error Rate	Rate / 1,000 Specimens (95% CI)
Palmerston North	270	8,415	1:31	32.1 (28.5 to 36.1)
Christchurch	618	22,286	1:36	27.7 (25.7 to 30.0)
Wellington	544	22,414	1:41	24.3 (22.3 to 26.4)
Waikato	615	25,956	1:42	23.7 (21.9 to 25.6)
Dunedin	214	9,904	1:46	21.6 (18.9 to 24.7)
Auckland	792	48,971	1:62	16.2 (15.1 to 17.3)
NZBS Total	**3,053**	**137,946**	**1:45**	**22.1 (21.4 to 22.9)**

The monthly and yearly mean error rate per 1,000 pretransfusion specimens received by the NZBS Blood Banks from 2009 to 2015 is detailed in Figure 27.1.

FIGURE 27.1 PRETRANSFUSION REQUEST FORM AND SPECIMEN LABELLING ERROR RATE PER 1,000 SPECIMENS 2009 – 2015



27 Request Form and Specimen Labelling Errors continued

The types of errors and the corrective actions taken are summarised in Table 27.3. Some request forms and specimens received had more than one type of error present. The total number of errors was 3,079. The most frequent type of error (20%) was "Declaration not signed (specimen signed)" followed by "Specimen not signed (declaration signed)". The most common error resulting in a request for recollection (15.8%) was "Missing / incomplete / incorrect patient details (major error)".

When corrections are allowable they must be carried out by the collector within the Blood Bank, unless the collector is directly involved in critical patient care. If the collector is not available, a new pretransfusion specimen must be collected. The collector must sign a declaration stating that "I have re-checked and verified the identity of the patient from whom this specimen originated and I accept full responsibility for the accurate completion of this form / specimen".

TABLE 27.3 PRETRANSFUSION REQUEST FORM AND SPECIMEN LABELLING ERRORS 2015 BY ERROR TYPE

Error	Number	% Total	Frequency	Rate / 1,000 Specimens	Action Required
Declaration not signed (sample is signed)	605	19.6%	1:228	4.4	Correction by collector or Recollect
Sample not signed (declaration is signed)	455	14.8%	1:303	3.3	Correction by collector or Recollect
Missing Patient Details (Major Error)	455	14.8%	1:303	3.3	Recollect
Adhesive remaining, indicating label removed	298	9.7%	1:463	2.2	Recollect
Pre-printed patient ID label on sample	283	9.2%	1:487	2.1	Recollect
Moderate error on sample	239	7.8%	1:577	1.7	Correction by collector or Recollect
Technical[1]	228	7.4%	1:605	1.7	Recollect
Signature On Sample And Declaration Differ	148	4.8%	1:932	1.1	Recollect
Moderate error on form	114	3.7%	1:1,210	0.8	Correction by collector or Recollect
Unlabelled Sample	89	2.9%	1:1,550	0.6	Recollect
Declaration and sample not signed	71	2.3%	1:1,943	0.5	Recollect
Presence of partial pre-printed label	49	1.6%	1:2,815	0.4	Recollect
Original Details Overwritten	40	1.3%	1:3,449	0.3	Recollect
Other Clerical Error	5	0.2%	1:27,589	0.1	Correction by collector or Recollect
Total	**3,079**				

[1] *Technical errors include incorrect blood collection tube type, insufficient specimen, haemolysed and leaking/broken specimens.*

Request Form and Specimen Labelling Errors continued

27

The overall rate of request for recollection of pretransfusion specimens by NZBS Blood Banks for 2015 was 14.7 per 1,000 specimens received. Table 27.4 summarises the recollection rates for each NZBS Blood Bank in 2015. Overall, 66% of errors resulted in a request for recollection of the pretransfusion specimen.

TABLE 27.4 PRETRANSFUSION SAMPLE RECOLLECTION REQUESTS 2015 BY NZBS BLOOD BANK SITE

	Recollection Requests	Total Number of Specimens	Frequency	% Errors Requiring Re-collection	Rate / 1,000 Specimens (95% CI)
Palmerston North	161	8,415	1:52	60%	19.1 (16.4 to 22.3)
Christchurch	407	22,286	1:55	66%	18.3 (16.6 to 20.1)
Wellington	371	22,414	1:60	68%	16.6 (15.0 to 18.3)
Waikato	415	25,956	1:63	67%	16.0 (14.5 to 17.6)
Dunedin	154	9,904	1:64	72%	15.5 (13.3 to 18.2)
Auckland	520	48,971	1:94	66%	10.6 (9.7 to 11.6)
NZBS	**2,028**	**137,946**	**1:68**	**66%**	**14.7 (14.1 to 15.4)**

Appendix I. Transfusion-Related Adverse Event Notification Form

NZBLOOD Te Ratonga Toto O Aotearoa

Transfusion Related Adverse Event Notification Form

A. Patient Details

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

B. Transfusion & Clinical Details

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

Event occurred during/ following transfusion with: (please circle)	Red Cells	Platelets	Fresh Frozen Plasma	Cryoprecipitate	Cryodepleted Plasma
	Other:				
	A Fractionated Product Reaction form (111F003) may be required.				
Donation number(s) of unit(s) transfused	Red Cells: Platelets: Fresh Frozen Plasma: Cryoprecipitate: Cryodepleted Plasma:				
Patient's diagnosis, reason for transfusion & other medical/surgical history					
Medications & treatment					

C. Signs and Symptoms

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

Please circle relevant symptoms & provide details:

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

Urticaria: Isolated / Extensive

Non-urticarial rash:

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

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

GI tract: Nausea / Vomiting / Diarrhoea

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

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

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

No symptoms

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

HV

For Haemovigilance Office Use Only

Appendix I. Transfusion-Related Adverse Event Notification Form continued

D. Severity score

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

E. Pretransfusion haematology

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

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

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

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

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

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

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

TMS informed: Yes / No

TMS name: .....

Date: .....

Time: .....

Blood Bank or Transfusion Nurse Specialist can notify TMS if necessary

G. Imputability Score

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

Reported by:

Contact Number:

Date:

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

HV | | | | | | |

For Haemovigilance Office Use Only

Appendix I. Transfusion-Related Adverse Event Notification Form continued

H. For Blood Bank/Transfusion Nurse Specialist Use Only

Transfusion History

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

Pages 1 & 2 completed Yes / No

Transfusion reaction investigation

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

Microbiology: Yes / No / Not tested

Unit / Patient / Both

Result:

Other:

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

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

Name:.....

Telephone: .....

Date:.....

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

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

I. For National Haemovigilance Office Only

Form received on.....

Acknowledgement sent.....

Further information requested Yes / No

Appendix I. Transfusion-Related Adverse Event Notification Form continued

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

Appendix II. Notification of Adverse Reactions to Fractionated Blood Product

NZBLOOD Te Ratonga Toto O Aotearoa

NATIONAL
111F00307

NOTIFICATION OF SUSPECTED ADVERSE REACTION TO A FRACTIONATED BLOOD PRODUCT

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

BLOOD PRODUCTS ADMINISTERED * Asterisk implicated Blood Product

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

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

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

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

DESCRIPTION OF ADVERSE REACTION OR EVENT

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

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

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

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

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

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

NZBLOOD
Te Ratonga Toto O Aotearoa

NATIONAL
111F00307

NOTIFICATION OF SUSPECTED ADVERSE REACTION TO A FRACTIONATED BLOOD PRODUCT

Treatment of adverse reaction or event

Adverse Reaction Information

Seriousness

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

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

☐ Life-threatening ☐ Death _____ *date*
☐ Persistence of significant disability / incapacity
☐ Required intervention to prevent permanent impairment / damage
☐ Congenital anomaly / birth defect
☐ Required hospitalisation or hospitalisation was prolonged
☐ Suspected transfusion of an infectious agent

Case Outcome as at _____ dd/mmm/yyyy

☐ Recovered _____ dd/mmm/yyyy, Time _____
☐ Recovered with sequelae _____ (specify)
☐ Permanently disabled
☐ Death _____dd/mmm/yyyy, autopsy: date _____ *or* ☐ not done
☐ Not yet recovered ☐ Unknown

Did reaction abate after stopping blood product?

First batch: ☐ Yes ☐ No ☐ Not applicable
Second batch: ☐ Yes ☐ No ☐ Not applicable

Did reaction reappear after re-introduction?

First batch: ☐ Yes ☐ No ☐ Not applicable
Second batch: ☐ Yes ☐ No ☐ Not applicable

Previous therapy with suspected blood product?

1._____ ☐ Yes ☐ No ☐ Not applicable

2. ._____ ☐ Yes ☐ No ☐ Not applicable

Has suspected product been tolerated in the past?

1. ._____ ☐ Yes ☐ No ☐ Not applicable
2. ._____ ☐ Yes ☐ No ☐ Not applicable

If yes, dates: dd/mmm/yyyy

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

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

Report type (tick all that apply)

☐ Product used for a MedSafe-registered indication ☐ S29 Medicine ☐ Medication error ☐ Overdose / Underdose
☐ Unexpected therapeutic benefit ☐ Lack of effect ☐ Pregnancy ☐ Lactation occurring ☐ Off-label use ☐ Misuse
☐ Occupational exposure ☐ Incorrect product transfused ☐ Idiosyncratic effect ☐ Quality defect in product

REPORTER DETAILS

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

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

INSTRUCTIONS

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

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

Appendix III. Reporting Adverse Events Associated with Blood Donation

NATIONAL
107M00509

REPORTING OF ADVERSE EVENTS RELATED TO BLOOD DONATION

REASON FOR ISSUE: New definitions and grading based on IHN.

1. PURPOSE

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

2. SCOPE

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

3. KEY RESPONSIBILITIES

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

4. ITEMS REQUIRED

4.1. Related documents

107F005	Donor Adverse Event Report
107M016	Management of Complications of Phlebotomy for Standard Whole Blood and Apheresis Collections from Voluntary Donors
170P005	H&S Manual Section E: Incident/Injury Reporting & Management
170F007	Accident Report Form *(To be used only when NZBS Intranet or Q-Pulse not available)*

5. DEFINITIONS

5.1. Definitions and description of categories of adverse event.

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

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

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

Appendix III. Reporting Adverse Events Associated with Blood Donation continued

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REPORTING OF ADVERSE EVENTS RELATED TO BLOOD DONATION

A. Complications mainly with local symptoms.

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

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

Haematoma (Bruise)
Definition: A haematoma is an accumulation of blood in the tissues outside the vessels.
Mechanism: The symptoms are caused by blood flowing out of damaged vessels and accumulating in the soft tissues. For apheresis procedures, haematomas may also be caused by infiltration of the soft tissues by red cells during the return phase of the procedure. Large haematomas, particularly those in deeper layers of the forearm, put pressure on surrounding tissues and may contribute to other complications such as nerve irritation and injury and more rarely compartment syndrome. Bruises can be very extensive but without any measurable swelling, whereas when the name haematoma is used there would generally be swelling. However, as there is no physiological difference between bruises and haematomas except for the thickness, extensive skin discolouration can still be registered as a haematoma.
Haematoma is the second most common acute complication associated with blood donation.
Signs and Symptoms: Bruising, discolouration, swelling and local pain.

Bleeding may arise from:

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

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

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

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

Re-bleeding
Definition: Leakage of blood from the venepuncture site after the initial bleeding has stopped.
Mechanism: Re-bleeding may be related to pressure not being applied to the correct location or for an adequate duration, or premature removal.

Appendix III. Reporting Adverse Events Associated with Blood Donation continued

After the donor has left the donation site, re-bleeding may be related to heavy lifting or strain to the donor's arm. Donors on certain medications, such as autologous donors on anticoagulants, may be at higher risk to re-bleed.

A2. Complications mainly characterised by pain.

Nerve Injury/Irritation
Definition: Direct injury or indirect irritation of a nerve.
Mechanism: A nerve may be hit directly by the needle at insertion or withdrawal, or there may be pressure on a nerve due to a haematoma or inflammation of the soft tissues. Include all cases confirmed by a medical diagnosis, as well as cases reported on the basis of documented 'nerve' type symptoms.
Signs and Symptoms: Radiating, often 'electrical' sharp pain moving away from the venepuncture site, and/or paraesthesia's such as tingling, burning sensations in the hand, wrist or shoulder area but away from the venepuncture site. Symptoms may arise immediately when the needle is inserted or withdrawn. In cases associated with a haematoma, pain will not be apparent at the time and may start when the haematoma has reached a sufficient size, some time after the insertion of the needle. Symptoms may be worse in certain positions or with certain arm movements. Rarely weakness of the arm may develop.
Later, after the haematoma has been absorbed, some scar tissue can be left around the nerve and give rise to pain and paraesthesiae which can last for weeks or months. In order to avoid this complication, it is important to discontinue the donation immediately if the donor complains of paraesthesiae to minimize the volume of haematoma.
Symptoms resolving within a year will be classed as non-severe and those lasting more than a year will be classed as severe.

Other Painful arm

Definition: Pain in the arm is the primary symptom and not related to the characteristics of nerve injury or irritation or haematoma.
Mechanism: Pain is usually related to tissue injury, possibly due to haematoma in the deeper tissues or related to a tendon injury.
Signs and Symptoms: Pain in the arm used for the donation and arising during or within hours following donation, but without further details to permit classification in one of the already more specific categories mentioned above. Maybe described as an ache or heaviness in the arm, similar to that after vaccination. This does not include pain at venepuncture site that appears at time of insertion of needle and disappears after donation is completed.

A3. Localised Infection/inflammation

Definition: Inflammation along the course of a vein, which may progress to localised infection several days after phlebotomy. There may be clotting in the vein.
Mechanism: Tissue damage and introduction of surface bacteria into the deeper tissues with venepuncture. The superficial vein itself (thrombophlebitis) or surrounding subcutaneous tissue (cellulitis) may be predominantly affected.
Signs and Symptoms: Warmth, tenderness, local pain, redness and swelling at the site of phlebotomy. The site and the vein may feel tender, firm and warm to touch. Fever may be present. These may be divided into 2 categories;

Thrombophlebitis: The redness, swelling and tenderness extend along the course of the vein. Thrombophlebitis in a superficial vein gives rise to a subcutaneous red, hard and tender cord. Thrombophlebitis in a deep vein gives more severe symptoms and may be associated with fever.

Cellulitis: The redness, swelling and tenderness affect the soft tissues and are not localised to the course of the vein.

Appendix III. Reporting Adverse Events Associated with Blood Donation continued

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REPORTING OF ADVERSE EVENTS RELATED TO BLOOD DONATION

A4. Other major blood vessel injury.

These rare, serious conditions must always be medically diagnosed.

Deep vein Thrombosis (DVT)
Definition: Thrombosis of a deep vein in the donor's phlebotomy arm.
Mechanism: Superficial venous thrombosis may progress into the deeper veins of the donor's arm. DVT may also rarely occur without previous signs and symptoms of superficial thrombosis. An additional risk factor (use of oral pills) may be present in these donors.
Signs and Symptoms: Swelling and pain in the upper arm. May be accompanied by symptoms of superficial inflammation and thrombosis (as above).

Arteriovenous fistula
Definition: Acquired connection between the vein and artery due to venepuncture lacerations.
Mechanism: A channel forms between the lacerated vein and artery immediately post-venepuncture, or in the healing process. May be related to arterial puncture.
Signs and Symptoms: Pulsating mass with a palpable thrill and associated bruit. The affected area may be warm, and the distal part of the arm may be cool if significant shunting of blood is present. The distal veins may be dilated and may pulsate.

Compartment Syndrome:
Definition: Increased compartment pressure leading to muscle and soft tissue necrosis.
Mechanism: Blood may accumulate in the frontal deep areas of forearm, closing small blood vessels and resulting in muscle and tissue necrosis. May be related to arterial puncture.
Signs and Symptoms: Painful arm, particularly on movement, swelling, Paresthesias and partial paralysis.

Brachial artery pseudoaneurysm
Definition: Collection of blood outside an artery, contained by adventitia or surrounding tissues alone.
Mechanism: After a traumatic arterial puncture, blood may leak out of the artery and accumulate in the surrounding space. In time this collection of blood gets surrounded by adventitia and forms a "pseudoaneurysm".
Signs and Symptoms: Pulsating mass in the arm. May be accompanied pain and paraesthesia. May be preceded by a large haematoma following the arterial puncture.

B. Complications mainly with generalised symptoms: Vasovagal reaction

Definition: A vasovagal reaction is a general feeling of discomfort and weakness with anxiety, dizziness and nausea, which may progress to loss of consciousness (faint). It is the most common acute complication related to blood donation.
Mechanism: Both physiological and psychological factors are important. The reaction is generated by the autonomic nervous system and further stimulated by psychological factors and the volume of blood removed, relative to the donor's total blood volume.
Signs and Symptoms: Usually several of the following; discomfort, weakness, anxiety, light-headedness/dizziness, nausea, sweating, vomiting, pallor, hyperventilation, rapid or a slow pulse. Hypotension and loss of consciousness (LOC) may occur and can be accompanied by loss of bladder or bowel control or convulsive movements.
Reactions can occur before phlebotomy (rare), during phlebotomy or immediately after phlebotomy, when the donor stands up, or in the refreshment area, or after the donor has left the donor site, (delayed vasovagal reaction). Most reactions occur within 12 hours of phlebotomy. Reactions accompanied by LOC carry a risk of injury, particularly if they occur once the donor has left the donor site, (delayed vasovagal reaction).

Appendix III. Reporting Adverse Events Associated with Blood Donation continued

REPORTING OF ADVERSE EVENTS RELATED TO BLOOD DONATION

Vasovagal reactions are divided into two main groups:

Without loss of consciousness (LOC) – the donor does not faint.
With loss of consciousness (LOC) – the donor faints for a period.

Donors who faint (with LOC) are further subdivided into two categories depending on the length of faint and if they had other complications of convulsive movements, urinary or faecal incontinence. Thus

LOC<60 seconds – without other signs and symptoms
LOC>60seconds – or with complications of convulsive movements, urinary or faecal incontinence.

The second subdivision depends if the donor sustained any injury as a result of the vasovagal reaction.

Thus;

With Injury – Injury caused by falls or accidents in donors with a vasovagal reaction
Without Injury

And lastly subdivision is based on the location of reaction;

Immediate – Symptoms occurred before donor has left the donation site
Delayed – Symptoms occurred after the donor has left the donation site

C. Complications related to apheresis.

Citrate reaction.
Definition: Neuromuscular hyperactivity related to reduced ionized calcium levels.
Mechanism: Infusion of citrate anticoagulant during apheresis causes a fall in ionised calcium levels, leading to neuromuscular hyperactivity. If untreated, symptoms may progress to tetany and severe cardiac arrhythmias, including cardiac arrest. Operator error with mix up of saline and citrate bags may occur with some apheresis equipment, and lead to rapid citrate infusion.
Signs and Symptoms: Numbness or tingling of lips, feelings of vibrations, numbness or tingling in the fingers, muscle twitching, rapid or slow pulse, shortness of breath.
Symptoms may progress to carpopedal spasms and vomiting, and in severe reactions, to generalised muscle contractions (tetany), shock, irregular pulse and cardiac arrest.

Haemolysis.
Definition: Donor red cells may be damaged, releasing haemoglobin.
Mechanism: There may be malfunctioning valves, kinks or obstruction of the tubing, incorrect installation of equipment, or other equipment failures affecting the extracorporeal circuit. Incompatible replacement fluids such as dextrose may be used in error.
Signs and Symptoms: Pink or red plasma, blood in lines or filter may appear dark. The donor may notice pink or red urine after collection

Air embolism
Definition: Air bubble introduced into the donor's circulation.
Mechanism: Air may enter into the lines due to incomplete priming of lines, as a result of a machine malfunction or defective collection kits or through incorrect manipulation by staff. Air in the donor's pulmonary circulation may occlude the pulmonary arteries in the lung and cause cardiopulmonary symptoms. Air may pass to the arterial circulation through an atrial septal defect, and reduce blood flow to the brain.

Appendix III. Reporting Adverse Events Associated with Blood Donation continued

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REPORTING OF ADVERSE EVENTS RELATED TO BLOOD DONATION

Signs and symptoms: Bubbling sound or feeling at the venipuncture site. Cough, dyspnea, apprehension, sweating, chest pain, confusion, tachycardia, hypotension, nausea and vomiting.

D. Allergic Reactions.

Allergy (Local)
Definition: Red or irritated skin at the venepuncture site.
Mechanism: Reaction caused by allergens or irritants in solutions used for disinfection of the arm (such as chlorhexidine) or in manufacture of the collection set. Irritation may also occur due to application of the adhesive bandage (bandage adhesive dermatitis). An allergic reaction to latex that may be in supplies such as gloves may also occur.
Signs and Symptoms: Itching and redness at the venepuncture site, the bandage or adhesive site or the entire skin disinfection area. In a true allergic reaction there may be raised rash or hives in the in these areas that may expand to cover a larger area of the arm. The reaction may occur soon after donation or in hours to days post donation.

Generalised allergic reaction (anaphylactic reaction)
Definition: An anaphylactic type reaction usually starting soon after the procedure is begun and may progress rapidly to cardiac arrest.
Mechanism: Extremely rare reactions, attributed to donor sensitivity to ethylene oxide gas used to sterilise some collection bags.
Signs and Symptoms: Apprehension, anxiousness, flushing, swelling of eyes, lips or tongue, cyanosis, cough, wheezing, dyspnoea, chest tightness, cramps, nausea, vomiting, diarrhoea, tachycardia, hypotension and altered mentation.

E. Other serious complications related to blood donation

Major cardiovascular event (MCE)
Acute cardiac symptoms (other than myocardial infarct or cardiac arrest
Myocardial infarction
Cardiac arrest
Transient Ischemic arrest
Cerebrovascular accident
Death

F. Other complications

Other systemic reactions or complications that do not fit into any of the above, such as chest pain that was investigated as angina, but actually diagnosed as musculoskeletal or transmission of infection to a donor through erroneous re-use of equipment.

Grading of severity.

Life threatening complications and long-term disability are thankfully extremely rare after blood donation. The criteria for classification of a reaction as serious (severe) are:

- Hospitalisation: If it was attributable to the complication. The criterion of hospital admission is applicable if the donor is kept in hospital overnight. Cases where a donor is seen, examined, and in some cases given treatment (e.g. suturing, IV fluids, treatment of a fracture) but discharged home are not automatically classified as severe.
- Intervention: To preclude permanent damage or impairment of a body function or to prevent death (life threatening).
- Symptoms: Causing significant disability or incapacity following a complication of blood donation and persisted for more than a year after the donation (Long term morbidity).

Appendix III. Reporting Adverse Events Associated with Blood Donation continued

REPORTING OF ADVERSE EVENTS RELATED TO BLOOD DONATION

- Death: If it follows a complication of blood donation and the death was possibly, probably or definitely related to the donation.

6. PROCEDURE

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

6.2. Provide appropriate nursing care to donor immediately.

6.3. If the donor suffers harm as a direct consequence of the donation process, this is managed as a clinical event. As such record appropriate details of the adverse event/complication on the Donor Adverse Event Report form, 107F005.
Note: If the donor suffers harm due to factors other than the recognized complications of blood donation this is to be managed as a workplace injury - refer to 170P005 and complete an Accident and Investigation Report Form, using intranet or Q-Pulse reporting format, if the intranet or Q-Pulse is unavailable use 170F007.

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

- For "Type of Donation" indicate what type of donation was carried out (whole blood, plasma, platelets, autologous whole blood, stem cell collection etc). Also use the check boxes to indicate if the donor is a new donor or not. This form does not need to be filled in for therapeutic plasma exchange patients.
- For complications in A and B, tick **only one** of the grades of severity as is seen appropriate.
- Provide details of all care and advice given to donor in the section "Adverse Event Description and Action Taken".
- Indicate whether a follow up was carried out or not. If a follow up was done, provide details in the space provided. All follow ups should be completed within 10 working days.
- ALWAYS enter any comments or codes in donor's eProgesa record and indicate this in the space provided in page two. If no comments or codes have been entered write down 'NIL'.
- Ensure donor receives a copy of the appropriate information sheet (Haematoma or Bruising and Faints).
- Fill in the appropriate outcome for the donor using the four tick box options.
- **Complete form by filling in name and signing the document.**

6.4. If the adverse event is reported at a session, pass the completed form to the Clinical Nurse Leader/Session Coordinator or to the Medical Officer at the end of the session or immediately after follow up has been completed. If the adverse event is reported after the session, or no MO is present at the session, send the form to the appropriate Medical Officer/TMS immediately.

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

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

Appendix III. Reporting Adverse Events Associated with Blood Donation continued

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REPORTING OF ADVERSE EVENTS RELATED TO BLOOD DONATION

7. TRAINING REQUIREMENTS

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

Appendix IV. Donor Adverse Event Report Form

NZBLOOD Te Ratonga Toto O Aotearoa

NATIONAL
107F00511

DONOR ADVERSE EVENT REPORT

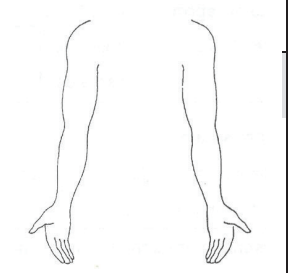
REASON FOR ISSUE: Add a space to record plasma target volume.

OFFICE USE ONLY: Database Record No:	

EVENT				
Date of Report:		**Type of Report:**	**Venue**	**Type of Donation**
Time of Report:		☐ At Session ☐ Phone call	☐ Static Site ☐ Mobile	☐ WB ☐ Plasma Target Volume:____gm
Date of Event:		☐ Personal Visit ☐ Email ☐ Letter	Location:	☐ Platelets ☐ PBSCH / Granulocyte New donor **Y** ☐ **N** ☐

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

ADVERSE EVENT DETAILS

Complication		**Grade**		
		Non-severe	**Severe**	
A. COMPLICATIONS MAINLY WITH LOCAL SYMPTOMS				
A1. Complications mainly characterised by the occurrence of blood outside blood vessels	Haematoma	☐	☐	 Right Left
	Arterial Puncture	☐	☐	
	Re-bleeding	☐	☐	
A2. Complications mainly characterised by pain	Nerve Irritation/ Injury	☐	☐	
	Other Painful Arm	☐	☐	
A3. Localised Inflammation/Infection	Thrombophlebitis	☐	☐	
	Cellulitis	☐	☐	
A4. Other major vessel injury				

B. COMPLICATIONS MAINLY WITH GENERALISED SYMPTOMS					
		Without LOC	**With LOC (loss of consciousness)**		**Severe**
			Without other signs/symptoms	With other signs/symptoms and/or >60 secs	
Immediate Vasovagal Reaction	Without Injury	☐	☐	☐	☐
	With Injury	☐	☐	☐	☐
Delayed Vasovagal Reaction	Without Injury	☐	☐	☐	☐
	With Injury	☐	☐	☐	☐

C. COMPLICATIONS RELATED TO APHERESIS		
Citrate Reaction		**RED CELLS RETURNED:**
Haemolysis		**Y** ☐ **N** ☐
Air Embolism		

D. ALLERGIC REACTIONS	
1. Local ☐	2. Generalised allergic reaction ☐

E. OTHER SERIOUS COMPLICATIONS RELATED TO BLOOD DONATION

F. OTHER COMPLICATIONS

Appendix IV. Donor Adverse Event Report Form
continued

NZBLOOD Te Ratonga Toto O Aotearoa

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DONOR ADVERSE EVENT REPORT

DESCRIPTION of ADVERSE EVENT and /or HARM and ACTION TAKEN				
Give details:				
Information Sheet e.g. Faints, Haematoma/Bruising given to donor (tick one) **YES** ☐ / **NO** ☐ / **NA** ☐				
Observations:		**Time**	**BP**	**Pulse**
	First:			
	Final:			
Names of Staff/Witnesses Involved:				
Deferral Code/Comments:			**Entered:**	**YES** ☐ / **NO** ☐
Outcome for Donor:	☐ No Action		☐ Return from apheresis to whole blood donation	
	☐ Deferred until / /		☐ Permanent Deferral	
Follow up required	**YES** ☐ / **NO** ☐ (If yes complete follow up then forward form to MO)			
Name of Staff (filling in form):	**Name:**		**Sign:**	**Date:**
FOLLOW UP DETAILS				
Name of Staff (conducting F/U):	**Name:**		**Sign:**	**Date:**

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

SAVE LIVES
GIVE BLOOD

New Zealand Government