NZBLOOD
Te Ratonga Toto O Aotearoa

National Haemovigilance Programme

Annual Report
2018

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1 Contents

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Abbreviations and Glossary

AHTR	Acute Haemolytic Transfusion Reaction
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 45 – 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
Platelets Pooled	Platelets in Plasma
Prothrombinex®-VF	Coagulation Factors II, IX and X and low levels of Factor 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
RiaSTAP®	Coagulation Factor I (Fibrinogen) concentrate
TACO	Transfusion-Associated Circulatory Overload
TAD	Transfusion-Associated Dyspnoea
TMS	Transfusion Medicine Specialist
TNS	Transfusion Nurse 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 fourteenth annual 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 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.

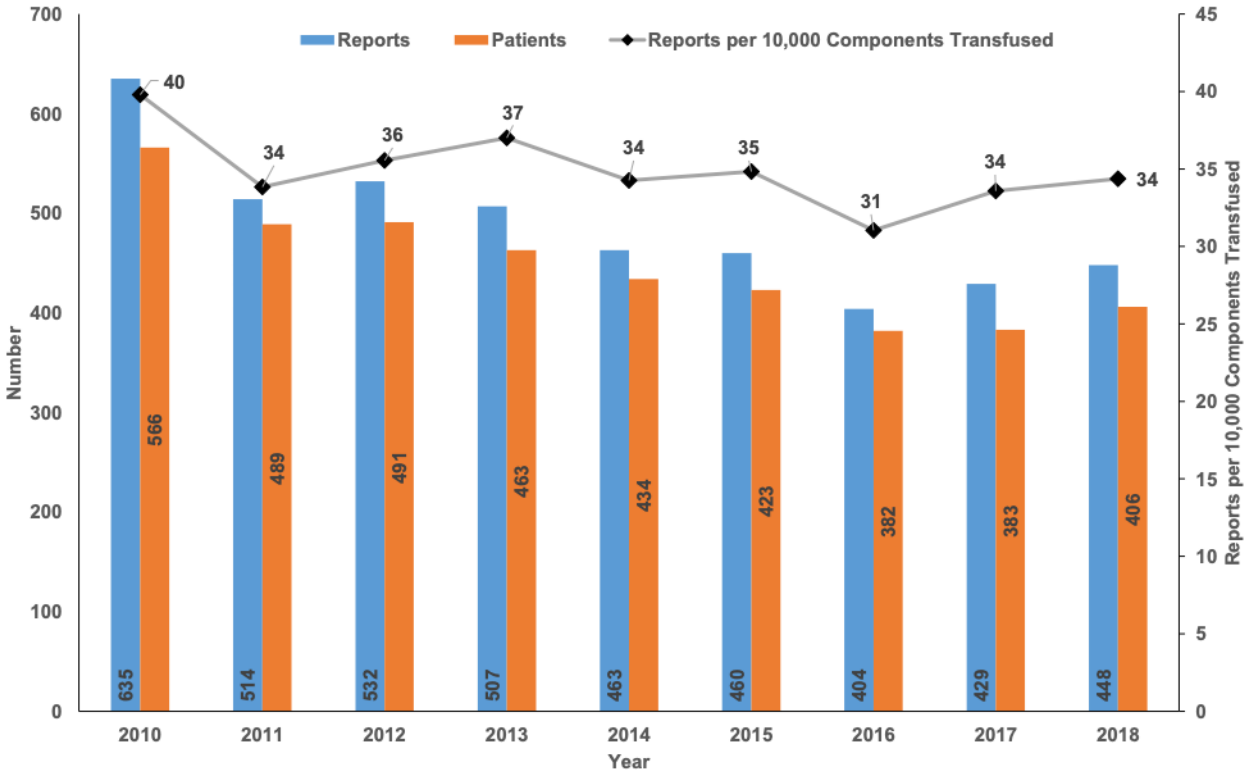
Reporting of TRAE to the National Comparing Haemovigilance Programme is voluntary. During 2018, there were 448 TRAE reported, involving 406 patients. Comparlng 2018 to individual years from 2014 to 2017, the total number of reported events and the ratio of reports to number of components transfused shows no significant difference (Table 2.1). The year-on-year number of events and patients is shown in Figure 2.1.

TABLE 2.1 HAEMOVIGILANCE REPORTS : COMPONENTS TRANSFUSED 2010 – 2018

	2010	2011	2012	2013	2014	2015	2016	2017	2018
Total Components Transfused	159,568	151,919	149,668	136,995	135,135	132,060	130,185	127,765	130,361
Number Haemovigilance Reports Received	635	514	532	507	463	460	404	429	448
Percentage Change From Previous Year									
Components Transfused	-1.9%	-4.8%	-1.5%	-8.5%	-1.4%	-2.3%	-1.4%	-1.9%	2.0%
Haemovigilance Reports	14.6%	-19.1%	3.5%	-4.7%	-8.7%	-0.6%	-12.2%	6.2%	4.4%
Reports : Components Transfused	**1:251**	**1:296**	**1:281**	**1:270**	**1:292**	**1:287**	**1:322**	**1:298**	**1:291**

Introduction continued

FIGURE 2.1 ANNUAL NUMBER OF TRANSFUSION-RELATED ADVERSE EVENTS 2010 – 2018



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 2018 to the number transfused in 2012, there has been a 15.6% reduction.

For the years 2013 to 2017 an average of 4,300 units of cryroprecipitate were transfused each year, there was a 27% increase in the use of cryoprecipitate in 2018 compared to usage in 2017.

The decrease in use of Cryodepleted plasma is related to the increased use of Albumex® 4 in plasma exchanges.

TABLE 3.1 ANNUAL NUMBER OF BLOOD COMPONENTS TRANSFUSED 2012 – 2018

Blood Component	2012	2013	2014	2015	2016	2017	2018	% Change 2018 compared to 2012
Red Cells	113,014	103,565	102,718	99,915	98,535	95,979	95,438	
Red Cells Neo	1,732	1,664	1,553	1,260	1,327	1,466	1,412	
Total Red Cells	**114,746**	**105,229**	**104,271**	**101,175**	**99,862**	**97,445**	**96,850**	**-15.6%**
Platelets - APH	2,117	487	523	411	530	548	502	
Platelets - Pooled	614	0	0	0	0	0	0	
Platelets - APH PAS	5,354	5,627	4,033	3,818	3,813	3,622	3,666	
Platelets - Pooled PAS	5,037	6,457	7,429	7,683	8,447	8,945	9,746	
Platelets - Neo	661	817	616	621	624	685	601	
Total Platelets	**13,783**	**13,388**	**12,601**	**12,533**	**13,414**	**13,800**	**14,515**	**5.3%**
Fresh Frozen Plasma	16,524	13,528	13,400	13,172	11,821	12,141	13,346	
Fresh Frozen Plasma Neo	200	175	151	162	161	131	196	
Total Fresh Frozen Plasma	**16,724**	**13,703**	**13,551**	**13,334**	**11,982**	**12,272**	**13,542**	**-19.0%**
Cryoprecipitate	3,745	4,167	4,198	4,482	4,463	4,147	5,279	41.0%
Cryodepleted Plasma	670	508	514	536	464	101	175	-73.9%
Total Components	**149,668**	**136,995**	**135,135**	**132,060**	**130,185**	**127,765**	**130361**	**-12.9%**

Trends in Blood Component Transfusion in New Zealand continued

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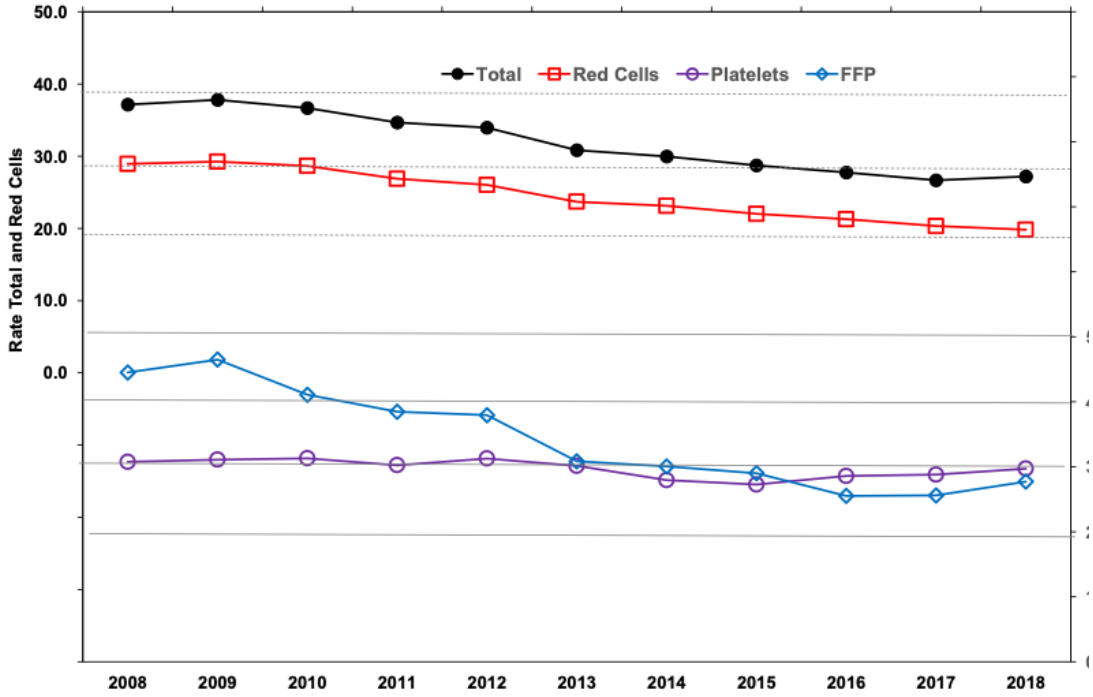
The annual blood component transfusion rates per 1,000 of the New Zealand population for the period 2012 to 2018 are shown in Figure 3.1. When comparing all components transfused in 2012 with those transfused in 2018 there is a 21.5% in rate of components transfused per 1,000 population.

FIGURE 3.1 ANNUAL RATE OF BLOOD COMPONENTS TRANSFUSED PER 1,000 NEW ZEALAND POPULATION 2008 – 2018



Compared to 2012, in 2018 there has been a 15.5% reduction in the number of recipients of red cells, 33.7% decrease in fresh frozen plasma and 9.7% decrease in the transfusion of platelets (Table 3.2).

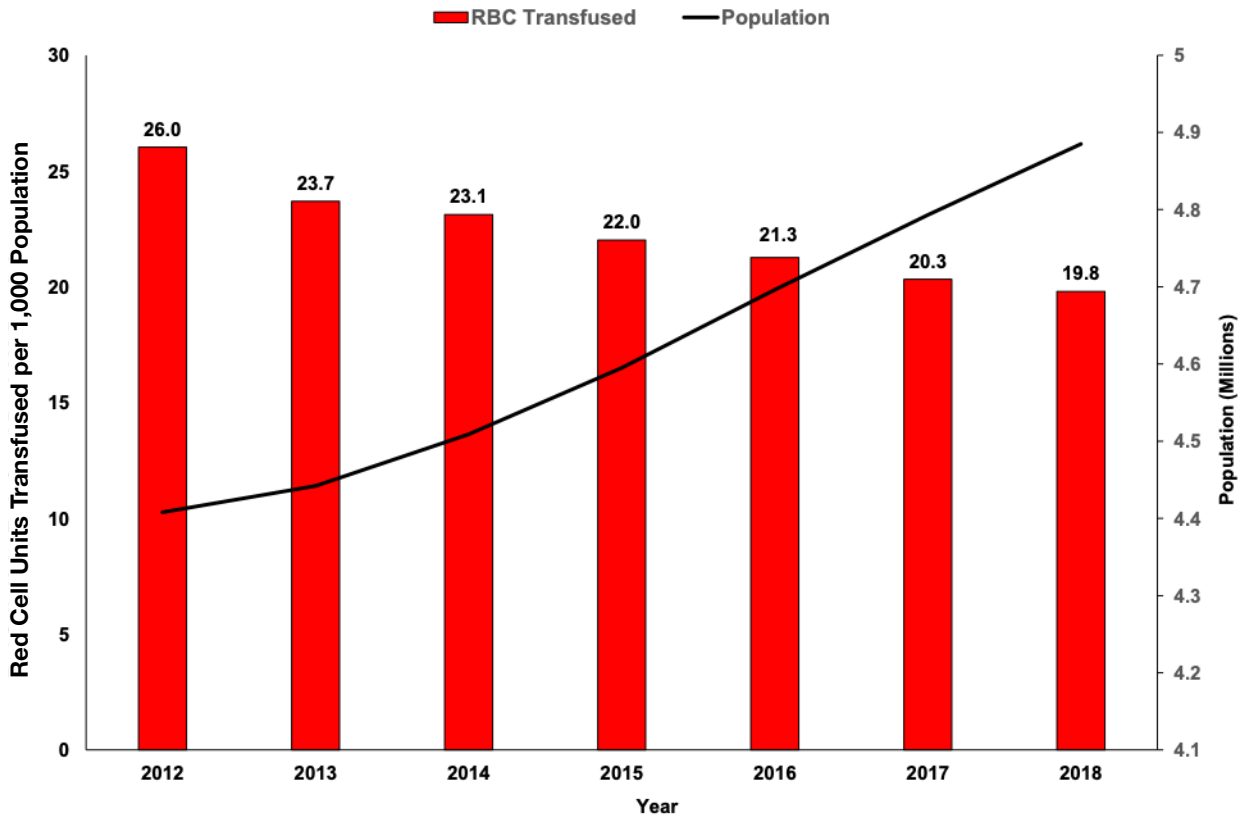
TABLE 3.2 ANNUAL NUMBER OF RED CELL, PLATELET AND FRESH FROZEN PLASMA RECIPIENTS 2012 – 2018

Component	Number of Recipients (Percentage Change from Previous Year)							% Change 2018 from 2012
	2012	2013	2014	2015	2016	2017	2018	
Red Cells	26,673 (-1.6%)	24,978 (-6.4%)	24,349 (-2.5%)	23,437 (-3.7%)	22,620 (-3.5%)	22,884 (1.2%)	22,534 (-1.5%)	-15.5%
Fresh Frozen Plasma	3,749 (-2.6%)	3,172 (-15.4%)	2,898 (-8.6%)	2,764 (-4.6%)	2,551 (-7.7%)	2,399 (-6.0%)	2,487 (3.7%)	-33.7%
Platelets	3,531 (-2.5%)	3,272 (-7.3%)	3,190 (-2.5%)	3,198 (0.3%)	3,154 (-1.4%)	3,104 (-1.6%)	3,187 (2.7%)	-9.7%

New Zealand is continuing with a more restrictive transfusion practice as is occurring internationally. The result is a decline in overall red cell usage of 15.5% since 2012 despite population increases of 10.8% (Figure 3.2).

3 Trends in Blood Component Transfusion in New Zealand continued

FIGURE 3.2 RATE RED CELL UNITS TRANSFUSED PER 1,000 POPULATION 2012 - 2018



Trends in Blood Component Transfusion in New Zealand continued

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Table 3.4 shows the number of blood components transfused and the transfusion rate for all New Zealand District Health Boards in 2018

TABLE 3.3 BLOOD COMPONENT TRANSFUSION RATES BY DISTRICT HEALTH BOARD 2018

District Health Board	Population	Number Components Transfused		Transfusion Rate per 10,000 Population	
		All Components	Red Cells	All Components	Red Cells
Waitemata DHB	620,300	8,210	7,144	132	115
Canterbury DHB	563,200	15,523	11,838	276	210
Counties Manukau DHB	558,200	11,030	8,886	198	159
Auckland DHB	536,800	32,347	19,513	603	364
Waikato DHB	416,400	12,436	9,171	299	220
Southern DHB	330,100	8,123	5,922	246	179
Capital and Coast DHB	317,500	13,323	8,831	420	278
Bay of Plenty DHB	237,000	4,620	4,078	195	172
MidCentral DHB	179,300	4,326	3,349	241	187
Northland DHB	179,100	3,398	2,877	190	161
Hawke's Bay DHB	165,800	3,826	3,127	231	189
Nelson Marlborough DHB	150,600	2,919	2,707	194	180
Hutt Valley DHB	149,500	1,716	1,593	115	107
Taranaki DHB	119,800	2,233	1,982	186	165
Lakes DHB	109,700	1,551	1,381	141	126
Whanganui DHB	64,900	1,049	1,009	162	155
South Canterbury DHB	59,900	1,454	1,339	243	224
Tairawhiti DHB	49,100	868	800	177	163
Wairarapa DHB	45,500	955	881	210	194
West Coast DHB	32,600	454	422	139	129
Grand Total	**4,885,300**	**130,361**	**96,850**	**267**	**198**

4 Recipients of Blood Components

Table 4.1 below provides information on the number of individual recipients (multiple transfusions to the same recipient are counted as one) of red cell, platelet and fresh frozen plasma components transfused during 2018.

TABLE 4.1 RECIPIENTS OF BLOOD COMPONENTS 2018

		Blood Component		
		Red Cells	Platelets	FFP
Recipient Gender (number)	Female	12,589	1,261	1,017
	Male	9,937	1,924	1,468
	Unknown	8	2	2
	Total	**22,534**	**3,187**	**2,487**
Recipient Age (years)	Mean	61	53	52
	Median	68	61	56
	Maximum	104	101	97
	Minimum	0	0	0
Units Transfused per Recipient	Mean	4	5	5
	Median	2	2	2
	Maximum	128	145	210
	Minimum	1	1	1

Further detail on the recipients of blood components and the type of blood components transfused during 2018 is shown in Table 4.2.

TABLE 4.2 PERCENTAGE RECIPIENTS OF BLOOD COMPONENTS 2018 BY AGE GROUP AND BLOOD COMPONENT TYPE

Component	Age Group (years)									
	0-4	5-14	15-24	25-34	35-44	45-54	55-64	65-74	75-84	85+
Red cells	4.1%	1.4%	4.2%	7.7%	6.5%	8.3%	12.6%	19.5%	21.0%	14.6%
FFP	6.0%	1.6%	4.7%	7.6%	7.5%	10.5%	17.4%	21.3%	18.0%	5.4%
Cryoprecipitate	13.4%	5.0%	2.1%	8.8%	8.6%	11.3%	16.1%	18.7%	13.3%	2.7%
Platelets	10.0%	4.1%	3.8%	4.7%	5.4%	11.0%	18.4%	23.7%	15.9%	3.1%
CryoDepleted plasma	0.0%	0.0%	14.3%	0.0%	28.6%	14.3%	28.6%	14.3%	0.0%	0.0%
All components	**5.3%**	**1.9%**	**4.1%**	**7.4%**	**6.6%**	**8.9%**	**13.8%**	**20.1%**	**19.9%**	**12.0%**

Tables 4.3 and Figure 4.1 show the age distribution of recipients of blood components compared to that of the New Zealand population in 2018. Greater than 60% of the recipients of red cells, fresh frozen plasma, platelet and all blood components transfused were ≥55 years old. In contrast, 27% of the New Zealand population were ≥55 years old.

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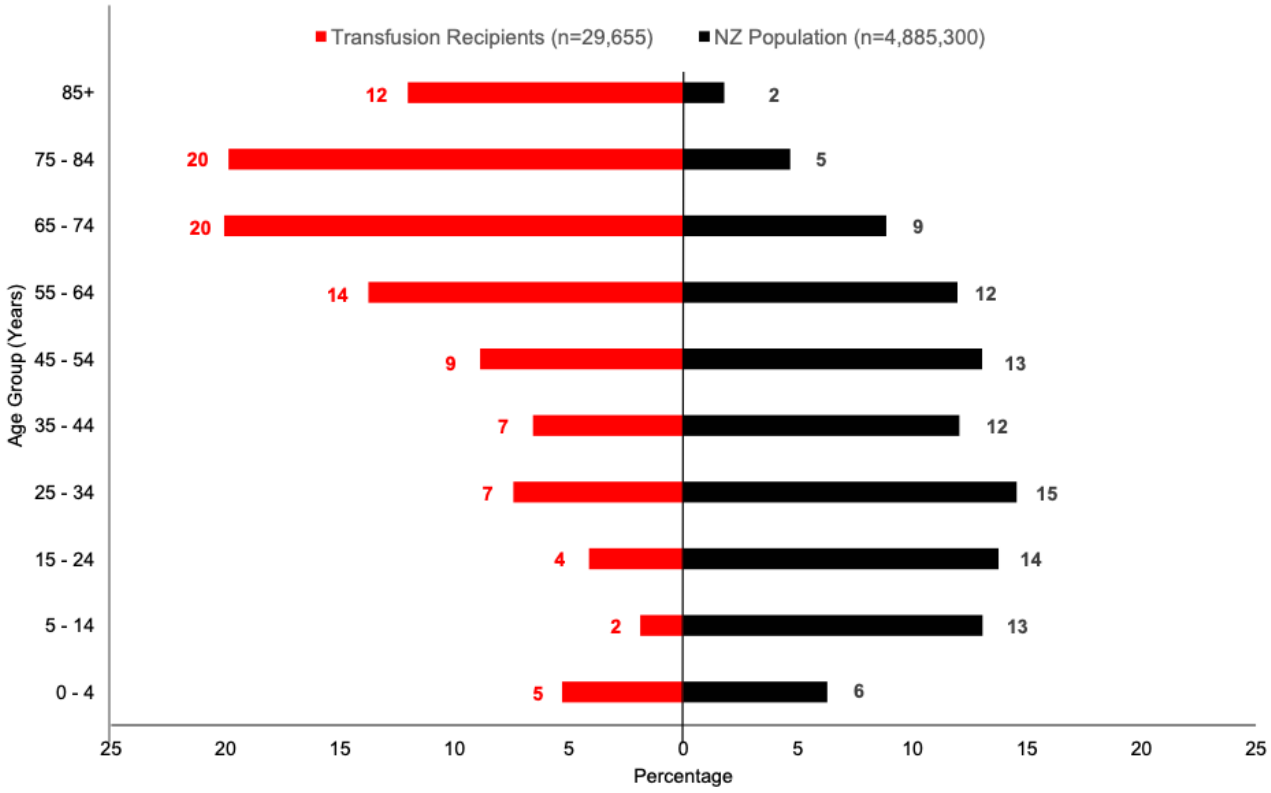
Recipients of Blood Components continued

TABLE 4.3 RECIPIENTS OF BLOOD COMPONENTS 2018 BY AGE GROUP AND COMPARED TO THE NEW ZEALAND POPULATION

	Age Group (years)									
	0-4	5-14	15-24	25-34	35-44	45-54	55-64	65-74	75-84	85+
Transfusion Recipients (n=29,655)	5.3%	1.9%	4.1%	7.4%	6.6%	8.9%	13.8%	20.1%	19.9%	12.0%
NZ Population (n=4,885,300)	6.3%	13.1%	13.8%	14.5%	12.1%	13.0%	12.0%	8.9%	4.7%	1.8%

FIGURE 4.1 RECIPIENTS OF BLOOD COMPONENTS 2018 BY AGE GROUP AND COMPARED TO THE NEW ZEALAND POPULATION



5 Transfusion-Related Adverse Events: Reporting District Health Boards

During 2018, transfusion-related adverse events (TRAE) with an imputability score of ≥3 were reported from all New Zealand District Health Boards (DHB) except the Whanganui DHB. The number of events with 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 2018 national TRAE rate was 24.5 per 10,000 component units transfused compared to 23.6 per 10,000 components transfused in 2017.

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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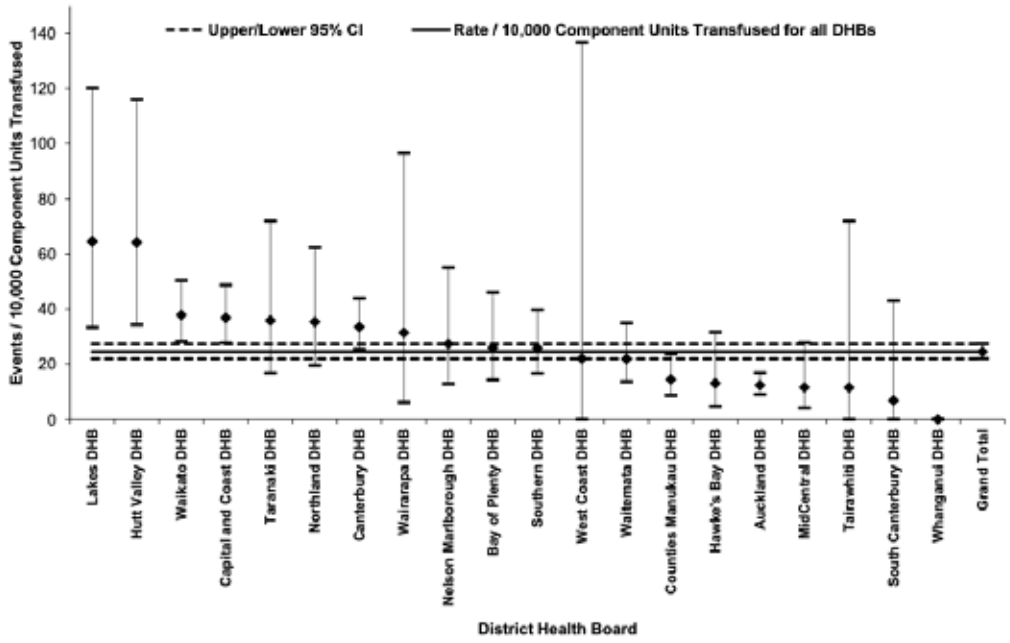
TABLE 5.1 TRANSFUSION-RELATED ADVERSE EVENTS (IMPUTABILITY ≥3) 2018 BY REPORTING DISTRICT HEALTH BOARD

District Health Board	Events	Units Transfused	Frequency	Rate / 10,000 Units Transfused (95%CI)
Lakes DHB	10	1,551	1:155	64.5 (33.3 to 120.0)
Hutt Valley DHB	11	1,716	1:156	64.1 (34.3 to 115.9)
Waikato DHB	47	12,436	1:265	37.8 (28.3 to 50.3)
Capital and Coast DHB	49	13,323	1:272	36.8 (27.7 to 48.7)
Taranaki DHB	8	2,233	1:279	35.8 (16.8 to 71.9)
Northland DHB	12	3,398	1:283	35.3 (19.5 to 62.4)
Canterbury DHB	52	15,523	1:299	33.5 (25.5 to 44.0)
Wairarapa DHB	3	955	1:318	31.4 (6.1 to 96.5)
Nelson Marlborough DHB	8	2,919	1:365	27.4 (12.9 to 55.0)
Bay of Plenty DHB	12	4,620	1:385	26.0 (14.3 to 45.9)
Southern DHB	21	8,123	1:387	25.9 (16.7 to 39.7)
West Coast DHB	1	454	1:454	22.0 (-9.1 to 136.7)
Waitemata DHB	18	8,210	1:456	21.9 (13.6 to 34.9)
Counties Manukau DHB	16	11,030	1:689	14.5 (8.7 to 23.8)
Hawke's Bay DHB	5	3,826	1:765	13.1 (4.6 to 31.5)
Auckland DHB	40	32,347	1:809	12.4 (9.0 to 16.9)
MidCentral DHB	5	4,326	1:865	11.6 (4.1 to 27.9)
Tairawhiti DHB	1	868	1:868	11.5 (-4.9 to 71.9)
South Canterbury DHB	1	1,454	1:1454	6.9 (-2.9 to 43.0)
Whanganui DHB	0	1,049		
National Total	**320**	**130,361**	**1:407**	**24.5 (22.0 to 27.4)**

FIGURE 5.2 TRANSFUSION-RELATED ADVERSE EVENTS (IMPUTABILITY ≥3) 2018 BY REPORTING DISTRICT HEALTH BOARD



6 Transfusion-Related Adverse Events: Imputability

During 2018, a total of 448 TRAE were reported to the National Haemovigilance programme. A total of 128 (28.6%) had a low (≤2) imputability score and were excluded from the analysis as 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

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 2010 to 2018 is shown in Table 6.2 and Table 6.3. As a proportion of all TRAE, compared to 2010 the number with low (≤2) imputability has increased 60% in 2018. These events are predominantly FNHTR (80%) and UCT (8%). 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 2010 – 2018

	2010	2011	2012	2013	2014	2015	2016	2017	2018
Total Events	635	514	532	507	463	460	404	429	448
Number Imputability ≤2	80	72	90	71	106	97	78	127	128
Percentage	12.6%	14.0%	16.9%	14.0%	23.0%	21.1%	19.3%	29.6%	28.6%

Transfusion-Related Adverse Events: Imputability continued

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TABLE 6.3 TRANSFUSION-RELATED ADVERSE EVENTS OF LOW (≤2) IMPUTABILITY 2010 – 2018 BY EVENT TYPE

	Percentage of Annual Total Reports of Low Imputability ≤2								
	2010	**2011**	**2012**	**2013**	**2014**	**2015**	**2016**	**2017**	**2018**
FNHTR	55.0%	72.6%	53.3%	70.4%	64.2%	69.1%	60.8%	73.2%	**80.5%**
UCT	23.8%	16.4%	16.7%	23.9%	26.4%	13.4%	16.5%	9.4%	**7.8%**
Allergic	6.3%	2.7%	14.4%	1.4%	1.9%	2.1%	2.5%	1.6%	**0.8%**
DSTR	1.3%	2.7%	4.4%	0%	0%	8.2%	7.6%	5.5%	**1.6%**
Hypotension	6.3%	2.7%	2.2%	0%	2.8%	3.1%	3.8%	2.4%	**7.0%**
IBCT	3.8%	2.7%	0%	0%	0.9%	0%	2.5%	1.6%	**0%**
TAD	3.8%	0%	4.4%	2.8%	0.9%	1.0%	0%	0%	**0.8%**
TACO	0%	0%	2.2%	1.4%	0%	2.1%	3.8%	6.3%	**1.6%**
AHTR	0%	0%	1.1%	0%	0.9%	1.0%	1.3%	0%	**0%**
TRALI	0%	0%	0%	0%	1.9%	0%	1.3%	0%	**0%**
DHTR	0%	0%	1.1%	0%	0%	0%	0%	0%	**0%**
Pain	0%	0%	0%	0%	0%	0%	0%	0%	**0%**
TTI	0%	0%	0%	0%	0%	0%	0%	0%	**0%**
Total Reports Imputablity ≤2	**80**	**72**	**90**	**71**	**106**	**97**	**78**	**127**	**128**

Table 6.4 shows all reported events in 2018 by event type and imputability score.

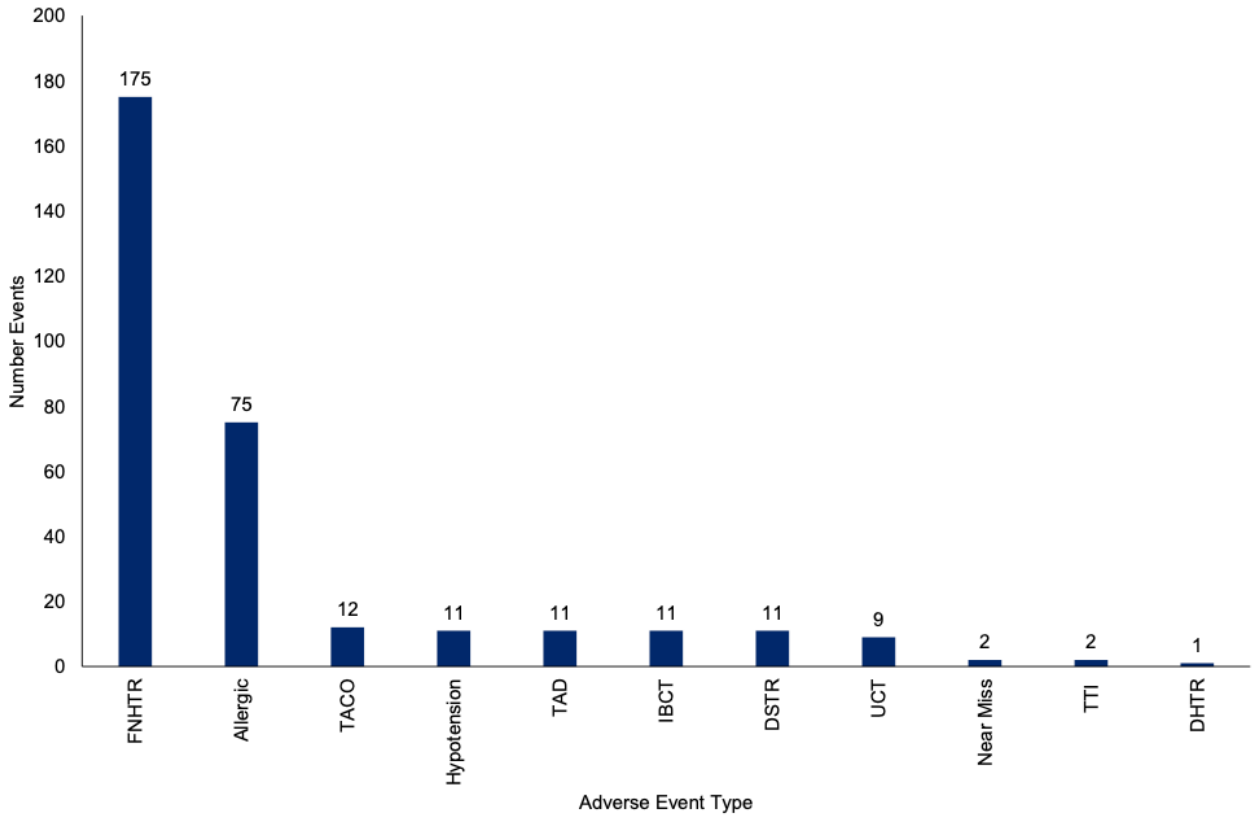
TABLE 6.4 TRANSFUSION-RELATED ADVERSE EVENTS 2018 BY EVENT TYPE AND IMPUTABILITY SCORE

Event Type	**Imputability Score**						
	1	**2**	**3**	**4**	**5**	**Total**	**Total ≥3**
FNHTR	47	56	131	42	2	278	175
Allergic		1	21	42	12	76	75
Hypotension	9		9		2	20	11
UCT	7	3	9			19	9
TACO	2		9	3		14	12
DSTR	2		1		10	13	11
TAD	1		8	3		12	11
IBCT			1	1	9	11	11
Near Miss					2	2	2
TTI			1	1		2	2
DHTR					1	1	1
Grand Total	**68**	**60**	**190**	**92**	**38**	**448**	**320**
Percentage Events	15.2%	13.4%	42.4%	20.5%	8.5%		

Data analysed and included in the remainder of the Annual Haemovigilance Report is restricted to the 320 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.

6 Transfusion-Related Adverse Events: Imputability continued

FIGURE 6.1 TRANSFUSION-RELATED ADVERSE EVENTS (IMPUTABILITY ≥3) 2018 BY EVENT TYPE



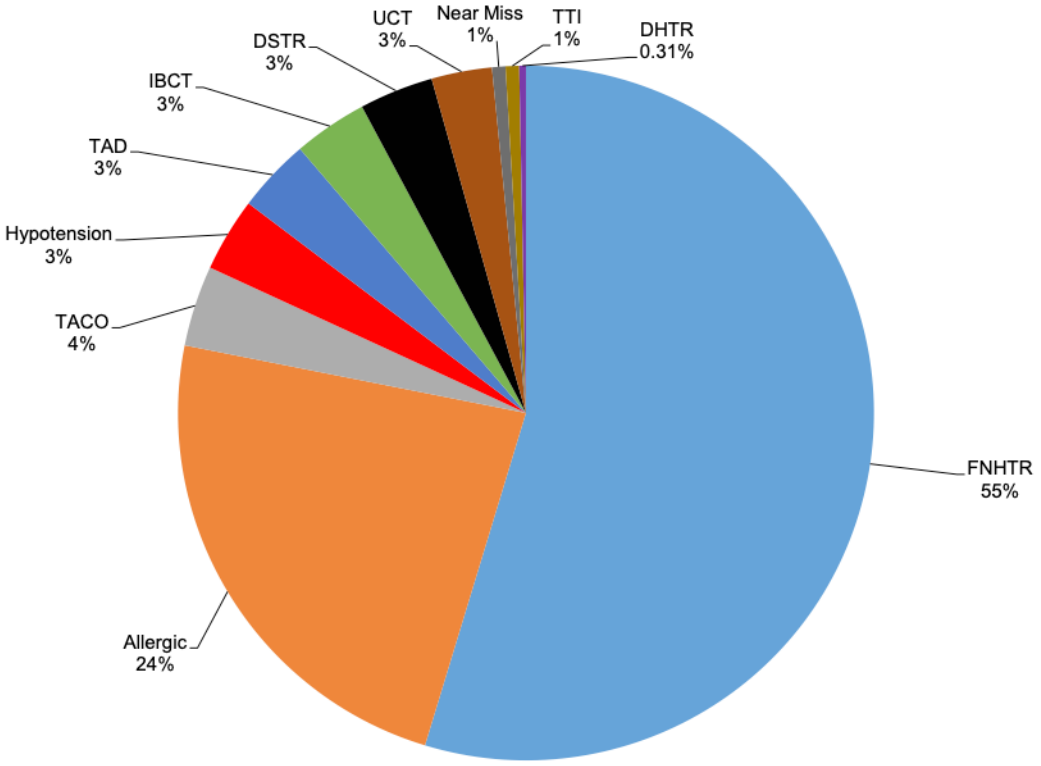
Key:

FNHTR	Febrile non-haemolytic transfusion reaction
Allergic	Allergic transfusion reaction
TACO	Transfusion-associated circulatory overload
Hypotension	
TAD	Transfusion-associated dyspnoea
IBCT	Incorrect blood component transfused
DSTR	Delayed serologic transfusion reaction
UCT	Unclassifiable complication of transfusion
Near Miss	
TTI	Transfusion transmitted infection
DHTR	Delayed haemolytic transfusion reaction

6

Transfusion-Related Adverse Events: Imputability continued

FIGURE 6.2 TRANSFUSION-RELATED ADVERSE EVENTS (IMPUTABILITY ≥3) 2018 BY EVENT TYPE



There were 286 transfusion recipients associated with the 320 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) 2018 BY RECIPIENT GENDER

		Age (years)		
	Number	Mean	Minimum	Maximum
Female	145	55	12	88
Male	141	59	14 days	94
Total	**286**	**57**	**14 days**	**94**

Multiple TRAE were reported in 28 patients (Table 6.6). The five adverse events reported by the one recipient were allergic associated with the transfusion of platelets, one apheresis and 4 pooled platelets.

TABLE 6.6 NUMBER OF RECIPIENTS HAVING MULTIPLE TRANSFUSION-RELATED ADVERSE EVENTS (IMPUTABILITY ≥3) 2018

		Events				
	Total	1 Event	2 Events	3 Events	4 Events	5 Events
Recipient Numbers	286	258	25	1	1	1

7 Transfusion-Related Adverse Events: Severity

The severity score definitions for TRAE developed by ISBT/IHN are shown in Table 7.1. Of the reported events with imputability score ≥3, 92.5% were assessed as non-severe (grade 1). Severe (grade ≥2) events were 7.5% of all events and 46% of these were either allergic or TACO in nature. The two grade 4 (death) adverse events were classified as TACO (Table 7.2).

TABLE 7.1 SEVERITY SCORE DEFINITIONS FOR TRANSFUSION-RELATED ADVERSE EVENTS 2018

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.
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) 2018 BY EVENT TYPE AND SEVERITY

Event Type	Severity				
	Grade 1	Grade 2	Grade 3	Grade 4	Total
FNHTR	172	3			175
Allergic	72	3			75
TACO	4	5	1	2	12
Hypotension	7	2	2		11
TAD	9	1	1		11
IBCT	11				11
DSTR	11				11
UCT	8	1			9
Near Miss	2				2
TTI		2			2
DHTR		1			1
Total	**296**	**18**	**4**	**2**	**320**
Percentage Events	92.5%	5.6%	1.3%	0.6%	

8 Transfusion-Related Adverse Events: Implicated Blood Components

A total of 130,361 blood component units were transfused in 2018. Of these, 325 units were implicated in the 320 reported adverse events. The overall adverse event rate in 2018 was 1 in 401 units transfused (24.9 per 10,000 units transfused, 95% CI 22.4 to 27.8). Table 8.1 shows the adverse event rates for the individual blood component types in 2018.

TABLE 8.1 TRANSFUSION-RELATED ADVERSE EVENTS (IMPUTABILITY ≥3) 2018 BY BLOOD COMPONENT TYPE

Component	Units Implicated in TRAE[1]	Units Transfused	Frequency	Rate / 10,000 Units Transfused (95%CI)
Cryodepleted Plasma	1	175	1:175	57.1 (-22.4 to 349.1)
Platelets Apheresis PAS	17	3,666	1:216	46.4 (28.4 to 74.7)
Platelets Pooled PAS	40	9,746	1:244	41.0 (30.0 to 56.0)
Platelets (Apheresis) [2]	4	1,103	1:276	36.3 (10.5 to 96.5)
Red Cells	237	96,850	1:409	24.5 (21.5 to 27.8)
Fresh Frozen Plasma	25	13,542	1:542	18.5 (12.4 to 27.4)
Cryoprecipitate	1	5,279	1:5279	1.9 (0 to 11.9)
Total	**325**	**130,361**	**1:401**	**24.9 (22.4 to 27.8)**

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

[2] *Platelets suspended in plasma Includes 601 units Platelets - Neonatal.*

8 Transfusion-Related Adverse Events: Implicated Blood Components continued

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) 2018 BY EVENT TYPE AND BLOOD COMPONENT TYPE

	Frequency Adverse Event (Components Transfused/Number Adverse Events)							Number Adverse Events	
	Red Cells	Fresh Frozen Plasma	Platelets Apheresis	Platelets Apheresis PAS	Platelets Pooled PAS	Cryoprecipitate	Cryodepleted Plasma	Multiple Components	Other[1]
Number Units Transfused	**96,850**	**13,542**	**1,103**	**3,666**	**9,746**	**5,279**	**175**		
FNHTR	1:633			1:611	1:750			3	
Allergic	1:3,725	1:713	1:552	1:917	1:541		1:175	5	
DSTR	1:8,805								
TACO	1:9,685							2	
TAD	1:9,685							1	
UCT	1:12,106				1:9,746				
Hypotension	1:13,836			1:3,666	1:3,249				
IBCT	1:96,850	1:4,514		1:3,666					1
DHTR	1:96,850								
TTI	1:96,850			1:3,666					
Near Miss									2
Total	**1:425**	**1:616**	**1:552**	**1:282**	**1:278**		**1:175**	**11**	**3**

[1] *Other Events : IBCT - Autologous serum eye drops*
Near Miss - Two wrong blood in tube events reported by Non-NZBS Blood Bank

Febrile Non-Haemolytic Transfusion Reactions (FNHTR) 9

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 non-haemolytic reactions were the most frequently reported type of TRAE, 54% of those TRAEs with an imputability ≥3. A total of 278 reports of FNHTR were received; 175 were of imputability ≥3 and included in the analysis. Of the reported events, 56 were of low ≤2 imputability and probably due to the patient's underlying medical condition. An additional 47 submitted reports of FNHTR did not meet criteria of a fever ≥38°C or a temperature change of ≥1°C and thus were excluded in this Haemovigilance Report. Table 9.1 shows FNHTR events by recipient gender along with data on recipient age.

TABLE 9.1 FNHTR EVENTS (IMPUTABILITY ≥3) 2018 BY RECIPIENT GENDER

	Number	Age (years)		
		Mean	Minimum	Maximum
Female	93	59	12	85
Male	82	65	6	94
All	**175**	**61**	**6**	**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 is not an uncommon symptom in transfusion recipients with FNHTR.

TABLE 9.2 FNHTR EVENTS (IMPUTABILITY ≥3) 2018 BY ASSOCIATED SIGNS AND SYMPTOMS

Symptom	Number			% Events		
	Female (n=93)	Male (n=82)	Total (n=175)	Female	Male	Total
Chills / Rigors	42	37	79	45%	45%	45%
Increase in blood pressure	26	9	35	28%	11%	20%
Dyspnoea	8	6	14	9%	7%	8%
Restlessness / Anxiety	10	4	14	11%	5%	8%
Tachycardia	7	4	11	8%	5%	6%
Nausea	8	1	9	9%	1%	5%
Stridor / Wheeze	6	1	7	6%	1%	4%
Cough	5	2	7	5%	2%	4%
Vomiting	4	1	5	4%	1%	3%
Abdominal pain	4	1	5	4%	1%	3%
Fall in blood pressure	1	1	2	1%	1%	1%
Chest pain	2	0	2	2%		1%

9 Febrile Non-Haemolytic Transfusion Reactions (FNHTR) continued

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) 2018 BY RECIPIENT GENDER

	Number	Temperature Rise (°C)			Age (Years)		
		Mean	Min	Max	Mean	Min	Max
Female	7	2.2	2.0	2.5	66	54	76
Male	4	2.4	2.0	2.6	45	7	68
Total	**11**	**2.3**	**2.0**	**2.6**	**58**	**7**	**76**

Allergic Transfusion Reactions

10

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. Severe reactions may include laryngeal symptoms including 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 2018, there were 75, 23% of the TRAEs with an imputability of ≥3, classified as allergic in nature. Of these, 72 (96%) were non-severe and the remaining 3 (4%) were classified as severe (Grade 2) . Table 10.1 shows allergic events by recipient gender along with data on recipient age.

TABLE 10.1 ALLERGIC EVENTS (IMPUTABILITY ≥3) 2018 BY RECIPIENT GENDER

	Number	Age (years)		
		Mean	Minimum	Maximum
Female	35	47	13	84
Male	40	47	1 month	93
All	**75**	**47**	**1 month**	**93**

10 Allergic Transfusion Reactions
continued

Table 10.2 provides information on signs and symptoms associated with all allergic events reported in 2018.

TABLE 10.2 ALLERGIC EVENTS (IMPUTABILITY ≥3) 2018 BY ASSOCIATED SIGNS AND SYMPTOMS

Symptom	Allergic Events					
	Number			% Allergic Events		
	Female (n=35)	Male (n=40)	Total (n=75)	Female	Male	Total
Urticaria	30	28	58	86%	70%	77%
Fall in blood pressure	4	4	8	11%	10%	11%
Dyspnoea	4	4	8	11%	10%	11%
Non-urticarial Rash	2	6	8	6%	15%	11%
Restlessness / Anxiety	2	4	6	6%	10%	8%
Generalised Itchiness	3	3	6	9%	8%	8%
Tachycardia	4	1	5	11%	3%	7%
Chills / Rigors	3	1	4	9%	3%	5%
Stridor / Wheeze	1	3	4	3%	8%	5%
Hypoxaemia	2	2	4	6%	5%	5%
Increase in blood pressure	1	2	3	3%	5%	4%
Chest pain	2		2	6%		3%

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) 2018 BY A SINGLE BLOOD COMPONENT TYPE

Component	Number Events	Number Units Transfused	Frequency	Rate / 10,000 Units Transfused (95%CI)
Cryodepleted Plasma	1	175	1:175	57.1 (-22.4 to 349.1)
Platelets Pooled PAS	18	9,746	1:541	18.5 (11.5 to 29.4)
Platelets Apheresis Plasma[1]	2	1,103	1:552	18.1 (0.4 to 70.4)
Fresh Frozen Plasma	19	13,542	1:713	14.0 (8.8 to 22.1)
Platelets Apheresis PAS	4	3,666	1:917	10.9 (3.1 to 29.1)
Red Cells	26	96,850	1:3,725	2.7 (1.8 to 4.0)
Cryoprecipitate	0	5,279		0 (0 to 8.8)
Total	**70**	**130,361**	**1:1,862**	**5.4 (4.2 to 6.8)**

[1] *Includes Platelets – Neonatal*

11

Transfusion-Related Acute Lung Injury (TRALI)

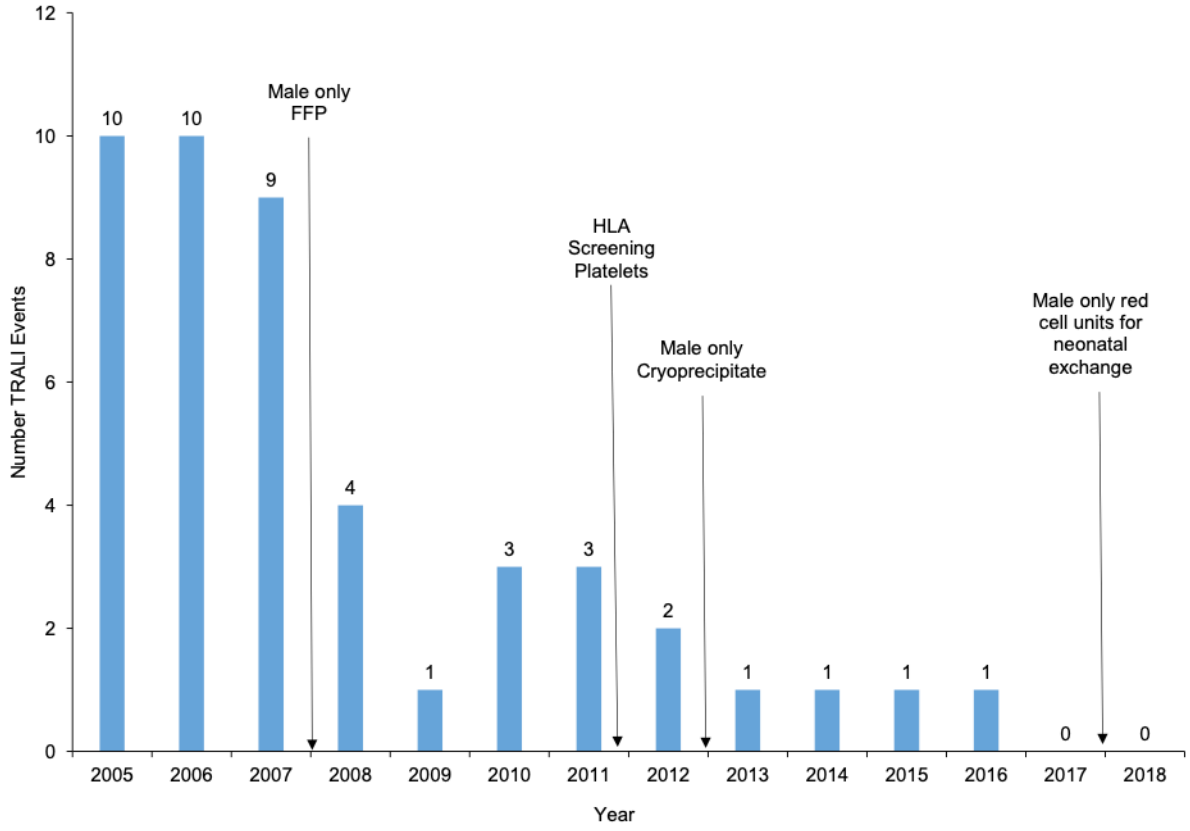
Definition:

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 2018 there was no reported event of TRALI in New Zealand.

Figure 11.1 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 cryodepleted plasma and in 2018 to include red cell units for neonatal exchange.

FIGURE 11.1 ANNUAL NUMBER OF TRALI EVENTS 2005 – 2018



The components implicated yearly in TRALI events between 2005 and 2018 are detailed in Table 11.1.

11 Transfusion-Related Acute Lung Injury (TRALI) continued

TABLE 11.1 COMPONENTS IMPLICATED IN TRALI EVENTS 2005 – 2018

Year	Implicated Components (multiple components implicated in a number of events)								
	Number TRALI Reports	Red Cells	Fresh Frozen Plasma	Platelets APH	Platelets Pooled	Platelets APH PAS	Platelets Pooled 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	
2016	1						1		
2017	0								
2018	0								
Total	**46**	**23**	**20**	**10**	**5**	**1**	**4**	**3**	**1**
Percentage		50%	43%	22%	11%	2%	9%	7%	2%

12 Transfusion-Associated Circulatory Overload (TACO)

Definition:

Any four of the following occurring within six 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 2018, there were 12 reported TACO events (3.7% of total events). Four were non-severe, five were grade 2 (severe), one was grade 3 (life-threatening) and two grade 4 (death). Table 12.1 shows the TACO events by recipient gender, along with data on recipient age.

TABLE 12.1 TACO EVENTS (IMPUTABILITY ≥3) 2018 BY RECIPIENT GENDER

		Age (Years)		
	Number	Mean	Minimum	Maximum
Female	4	71	69	73
Male	8	79	62	90
All	**12**	**76**	**62**	**90**

Table 12.2 shows the recorded clinical features of the TACO events reported during 2018

TABLE 12.2 TACO EVENTS (IMPUTABILITY ≥3) 2018 BY ASSOCIATED SIGNS AND SYMPTOMS

Symptom	Number			% TACO Events
	Female	Male	Total	
Dyspnoea	3	6	9	75.0%
Hypoxaemia	3	5	8	66.7%
Fall in O_2 saturation	3	5	8	66.7%
Increase in blood pressure	3	4	7	58.3%
Pulmonary oedema	1	4	5	41.7%
Chills / Rigors	2	1	3	25.0%
Tachycardia	2	1	3	25.0%
Stridor / Wheeze	2	1	3	25.0%
Restlessness / Anxiety	1	1	2	16.7%
Loin pain	1	0	1	8.3%
Chest pain	0	1	1	8.3%
Raised Jugular venous pressure (JVP)	0	1	1	8.3%

12 Transfusion-Associated Circulatory Overload (TACO) continued

Table 12.3 shows the blood components implicated in TACO events reported each year from 2007 to 2018.

TABLE 12.3 COMPONENTS IMPLICATED IN TACO EVENTS (IMPUTABILITY ≥3) 2007 – 2018

Year	Implicated Components (multiple components implicated in a number of events)							
	Number TACO Reports	Red Cells	Fresh Frozen Plasma	Cryoprecipitate	Platelets	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	4		1	
2011	19	18	4	1	3			
2012	27	24	2		4	1		
2013	16	13	4	3	6			1
2014	12	12						
2015	16	14	2	1	1		1	
2016	11	11	1		1			
2017	9	8	1		1			
2018	12	11			1			
Total	**193**	**169**	**27**	**7**	**28**	**3**	**2**	**1**
Percentage		87.6%	14.0%	3.6%	14.5%	1.6%	1.0%	0.5%

Table 12.4 shows the number of TACO events reported each year from 2010 to 2017.

TABLE 12.4 ANNUAL NUMBER OF TACO EVENTS (IMPUTABILITY ≥3) 2010 – 2018

Year	Reported TACO Events	Total Component Units Transfused	Frequency	Rate / 100,000 Units Transfused (95%CI)
2010	13	159,568	1:12,274	0.8 (0.5 to 1.4)
2011	19	151,919	1:7,996	1.3 (0.8 to 2.0)
2012	27	149,668	1:5,543	1.8 (1.2 to 2.6)
2013	16	136,995	1:8,562	1.2 (0.7 to 1.9)
2014	12	135,135	1:11,261	0.9 (0.5 to 1.6)
2015	16	132,060	1:8,254	1.2 (0.7 to 2.0)
2016	11	130,185	1:11,835	0.8 (0.5 to 1.5)
2017	9	127,765	1:14,196	0.7 (0.3 to 1.4)
2018	12	130,361	1:10,863	9.2 (5.1 to 16.3)
Total	**135**	**1,253,656**	**1:9,286**	**10.8 (9.1 to 12.8)**

Transfusion-Associated Circulatory Overload (TACO) continued

12

From 2010 to 2018, 4% of all reported events were classified as TACO, however they were responsible for 33% of events graded with a severity score ≥2 (Table 12.5).

TABLE 12.5 SEVERE TACO EVENTS (IMPUTABILITY ≥3) 2010 – 2018

		Severity Grade			
		Grade 2 (Severe)	Grade 3 (Life Threatening)	Grade 4 (Death)	Total
All Adverse Events	Number	312	47	8	367
TACO Events	Number	62	12	5	79
	Percentage of Grade	19.9%	25.6%	62.5%	21.5%

Details of the two grade 4 (death) TACO adverse event are described (Case A and Case B).

CASE A

An 81 year old man with multiple past medical problems (diabetes, alcoholic cardiomyopathy, hypertension, atrial fibrillation, chronic obstructive pulmonary disease, sleep apnoea, biventricular heart failure, CLL with possible autoimmune haemolytic anaemia, hiatus hernia, and diverticular disease) presented to an emergency department with shortness of breath likely secondary to anaemia possibly related to his underlying disorders and an acute lower gastrointestinal bleed. His Hb was 59 g / L, and his INR 3.1. He was on multiple medications including Rivaroxaban, beta-blockers, bronchodilators, oral anti-diabetic agents, a proton pump inhibitor, Allopurinol, and Salazopyrin. He was admitted, given a dose of Tranexamic acid, 4000 units of prothrombin complex concentrate, and two units of RBC. Pre-transfusion, his heart rate was 54 bpm, BP 77 / 52 mm Hg, respiratory rate 34 / min, and O_2 saturation 85%. About two hours in to the transfusion, during the transfusion of the second unit, he developed a cough, and his breathlessness worsened. At this time his heart rate was 37 bpm, BP 50 / 40 mm Hg, respiratory rate 14 / min, and O_2 saturation was unchanged at 84%. His chest x-ray showed 'overload'; and an enlarged heart. We do not have intake / output readings, but it is noted that normally he weighs 85 – 86 kg, at admission on this occasion, he weighed 91 kg. BNP results were not available. He was treated with oxygen, and pressor agents but died about two and a half hours after the transfusion was started. The event was classified as transfusion-associated circulatory overload (TACO), grade 4, imputability; certain.

12 Transfusion-Associated Circulatory Overload (TACO) continued

CASE B

A previously well, 72 year old woman presented to tertiary care with what later transpired to be AML in blast crisis (likely monocytic), was noted on examination to have no abnormalities other than oral mucosal bleeds. She was reported to have a recent history of fever, tachycardia, dry cough, slightly slurred speech and possible mild cognitive impairment. Her white cell count was 362 x 10^9/L, of which blasts were 353 x 10^9/L, the Hb was 54 g / L, and platelets were 29 x 10^9/L. Clotting screen showed a borderline high INR, but normal APTT, and fibrinogen. Recent therapies included hydroxyurea, IV saline, and IV potassium for a previous hypokalaemia (K^+ 2.4 mmoL / L) although K^+ at this presentation was 7.4 mmoL / L. The diagnosis at the tertiary care centre was hyperleukocytosis with tumour lysis syndrome. The treatment plan was to start leukapheresis with supportive therapy for tumour lysis. She was transfused one unit of platelets prior to central line insertion of the central line. She became acutely unwell with breathlessness, wheeze, stridor, tachycardia (HR 142 / min), and hypertension (BP 169 / 116 mm Hg) during the transfusion. ECG showed changes suggestive of acute cardiac ischaemia, there was a significant Troponin T rise (123 to 163 ng / L) and the BNP went up from 387 pre-transfusion to 775 pmol / L post-event. A chest x-ray showed new bilateral interstitial oedema, but no airspace shadowing or cardiomegaly. She was treated with diuretics and bronchodilators. About two hours after this event, a unit of RBC was transfused. Thirty minutes after starting the RBC transfusion, she suffered a cardiac arrest and died despite resuscitation attempts.

There are a number of possible causes for the acute deterioration in this case:

- Raised whole blood viscosity secondary to hyperleukocytosis, which was exacerbated by the red cell transfusion.
- Transfusion-associated circulatory overload (TACO) secondary to transfusion with additional crystalloid fluid overload during therapy for for tumour lysis syndrome.
- An acute myocardial infarction, with secondary acute pulmonary oedema resulting in the sudden deterioration during the initial platelet transfusion.
- A potential, although unlikely, cause may have been transfusion-related acute lung injury (TRALI).
- Female donors.

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.

Transfusion-Associated Dyspnoea (TAD)

13

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 2018, there were 11 events classified as TAD. There were six reports involving female patients and five reports involving male recipients. Nine were classified as non-severe (grade 1), one severe (grade 2) and one life-treatening (grade 3).

Table 13.1 shows the number of TAD events reported each year from 2008 to 2018

TABLE 13.1 ANNUAL NUMBER OF TAD EVENTS (IMPUTABILITY ≥3) 2008 – 2018

Year	TAD Events	Total Component Units Transfused	Frequency	Rate / 100,000 Units Transfused (95%CI)
2008	8	158,101	1:19,763	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 (0.0 to 5.9)
2016	8	130,185	1:16,273	6.1 (2.9 to 12.4)
2017	14	127,765	1:9,126	11.0 (6.3 to 18.6)
2018	11	130,361	1:11,851	8.4 (4.5 to 15.3)
Total	**116**	**1,574,344**	**1:13,572**	**7.4 (6.1 to 8.8)**

14 Hypotensive Transfusion Reactions

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 2018, there were 11 events classified as hypotensive transfusion reactions. Red cell units transfused were implicated in seven of the TRAEs, platelets pooled in PAS in two and platelets apheresis in PAS in two events. Of the 11 reports, seven were classified as non-severe (grade 1), two reports as severe (grade 2) and two reports as life-threatening (grade 3).

Table 14.1 shows the components implicated in hypotensive events reported each year from 2009 to 2018.

TABLE 14.1 COMPONENTS IMPLICATED IN HYPOTENSIVE EVENTS (IMPUTABILITY ≥3) 2009 – 2018

Year	Total Hypotensive Events	Implicated Components							
		Red Cells	Platelets APH	Platelets APH PAS	Fresh Frozen Plasma	Platelets Pooled PAS	Platelets Pooled	Multiple Components	Autologous Salvaged Red Cells
2009	13	8	3				1	1	
2010	14	14							
2011	12	10	2						
2012	14	10		2	1			1	
2013	2	1		1					
2014	3	2							1
2015	5	4			1				
2016	11	11							
2017	10	9			1				
2018	11	7		2		2			
Total	**95**	**76**	**5**	**5**	**3**	**2**	**1**	**2**	**1**
Percentage	80.0%	5.3%	5.3%	3.2%	2.1%	1.1%	2.1%	1.1%	

15

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 and pain along the vein
- Inadequate rise in haemoglobin after the transfusion or a drop in haemoglobin
- Rise in LDH, bilirubin
- Haemoglobinuria
- Decrease in haptoglobin

During 2018, there were no reported events classified as an acute haemolytic transfusion reaction.

16 Delayed Haemolytic / Serological 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 2018, there was one report of DHTR and 11 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) 2018 BY EVENT TYPE AND RECIPIENT GENDER

		Number	Age (years)		
			Mean	Minimum	Maximum
DHTR	Female	1	40		
DSTR	Female	6	75	38	88
	Male	5	54	32	70

TABLE 16.2 DELAYED TRANSFUSION REACTIONS (IMPUTABILITY ≥3) 2018 BY SPECIFICITY OF RED CELL ANTIBODY

Antibody Specificity	Number (Percentage)		
	Delayed Haemolytic	Delayed Serological	Total
Anti-E	1 (100%)		1 (8%)
Anti-K		5 (45%)	5 (42%)
Anti-Jk^3		2 (18%)	2 (17%)
Anti-JS		2 (18%)	2 (17%)
Anti-c		1 (9%)	1 (8%)
Anti-Fy^a		1 (9%)	1 (98%)
Total	**1**	**11**	**12**

Delayed Haemolytic / Serological Transfusion Reactions (DHTR / DSTR) continued

16

CASE C - DELAYED HAEMOLYTIC TRANSFUSION REACTION

A 40 year old male, day sixteen post-transfusion, Anti-E was identified, the direct antiglobulin test was anti-IgG 1+ve, anti- C3d Negative and Anti-E was eluted.

Post-transfusion laboratory results are detailed below.

	Days Post-Transfusion							
	Day 0	**Day 16**	**Day 17**	**Day 18**	**Day 19**	**Day 20**	**Day 21**	**Day 22**
RBC Antibody Screen	Negative	Positive					Positive	
RBC Units Transfused	3	2			2		1	
DAT		IgG 1+ve						
Antibody Identification		Anti-E						Anti-E
Eluate		Anti-E						
Haemoglobin (g / L)	111	65	80	80	71		71	81
Reticulocytes ($x10^9$ / L)		141						
Bilirubin (µmol / L)	12	17	51	51	39	18		
Haptoglobin (g / L)		<0.01						
LD (120 – 250 U / L)		1690			2076			
Blood Film		Spherocytes Acanthocytes Fragments Haemolysis						
The event was recorded as DHTR, of grade 2 severity and certain 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 2018, there were 19 reports of adverse events which could not be classified into a definitive category. Ten were excluded from analysis on the basis that the event could be attributable to a cause other than the transfusion. The remaining nine included in the analysis, involved four female and five male recipients. Eight events involved only red cell components, one involved Platelets Pooled PAS.

TABLE 17.1 UCT EVENTS (IMPUTABILITY ≥3) 2018 BY ASSOCIATED SIGNS AND SYMPTOMS

Symptom	Number of Events
Other	2
Increased blood pressure	2
Pain	2
Vasovagal event	1
Dizziness	1
Vomitting	1
Total	**9**

18 Reports Involving Paediatric Patients

During 2018, there were 16 events (5% of all events) involving recipients aged 15 years or younger. Allergic reactions were the most frequent adverse event reported in this age group (50%), whereas in all recipients allergic reactions were the second most common reported adverse event (23%). Table 18.1 details the event type and severity of adverse events occurring in paediatric patients.

TABLE 18.1 ADVERSE EVENTS (IMPUTABILITY ≥3) 2018 IN RECIPIENTS ≤15 YEARS AGE BY EVENT TYPE

Event Type	Number	Percentage of Events	Gender		Severity Score		
			Female	Male	1	2	3
Allergic	8	50%	1	7	8		
FNHTR	5	31%	1	4	5		
IBCT	2	13%		1	2		
TAD	1	6%	1	1			1
Total	**16**		**3**	**13**	**15**		**1**

The components or blood product being transfused at the time of the TRAE is detailed in Table 18.2

TABLE 18.2 ADVERSE EVENTS (IMPUTABILITY ≥3) 2018 IN RECIPIENTS ≤15 YEARS AGE COMPONENT / PRODUCT

Event Type	Implicated Component / Product (Number)		
	Red Cells	Platelets Pooled PAS	Blood Product
Allergic	4	3	
FNHTR	5	1	
IBCT			2
TAD	1		
Total	**10**	**4**	**2**

19 Transfusion Transmitted Infections (TTIs) and Lookbacks

During 2018, there were two reports of bacterial TTI. The two reported cases are summarised in Table 29.1

Table 19.1 TRANSFUSION TRANSMITTED INFECTIONS NOTIFICATIONS 2018

Clinical Details	Blood Component	Patient Culture Result	Unit Culture Result	Imputability	Severity Grade
66 year old male with red cell aplasia. Re-admiited 10 days post transfusion, Yersina enterocolitica identified	Red Cells Transfused day 17 post collection	Yersinia enterocolitica	Donor plasma only available, culture negative	3	Grade 2
69 year old female, myelodysplastic syndrome Temperature rise 1.5°C, chills, rigors and rise in blood pressure 5 hours post transfusion	Platelets APH PAS Transfused day 5 post collection	Staphylococcus epidermidis	Staphylococcus epidermidis	4	Grade 2

Lookbacks

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

- A donor, who has previously tested negative, is repeat reactive on the current donation and with a confirmed positive HIV, HBV or HCV infection. All previous donations in the preceding 24 months are traced and the fate of previous donations determined. 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.
- NZBS is informed that a recipient of blood components or products has developed a reactive laboratory test results and/or disease symptoms indicating that a blood component or product may have been infectious for HBV, HCV, 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 is 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.
- 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 2018 six lookbacks were undertaken. All the lookbacks involved repeat reactive donors who had previously tested negative.

Transfusion Transmitted Infections (TTIs) and Lookbacks continued

19

Donors Previously Tested Negative, Current Donation Repeat Reactive

Four investigations involved possible occult HBV and two for syphilis.

Three of the lookbacks involved five recipients, four were deceased and one an overseas visitor that contact details for his country of origin were not available. One lookback involved a plasmapheresis donor only and the fractionator was informed. There were no recipients within the previous two years for the two syphilis seroconversion donors.

TABLE 19.2 REPEAT REACTIVE DONOR LOOKBACK INVESTIGATIONS 2018 BY INFECTION TYPE

Case	Infection	Recipients Identified	Deceased Recipients	Requests for Recipient Testing	Lookback Outcome
1	Occult HBV	0	Plasmapheresis donor, fractionator notified		
2	Occult HBV	2	2		
3	Occult HBV	2	2		
4	Occult HBV	1	Overseas visitor, contact details not available		
5	Syphilis	0			
6	Syphilis	0			

20 Incorrect Blood Component Transfused (IBCT)

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 2018, there were 11 IBCT events reported. This compares to 14 IBCT events reported in 2017. The IBCT events for 2018 are detailed in Table 20.1.

TABLE 20.1 IBCT EVENTS 2018

IBCT Event Type Product	Description	Site of Error
Incorrect product/dose Autologous serum eye drops Blood product Red cells	Lab error in dispensing Autologous eye drops dispensed to the wrong patient who used them.	Laboratory
	Recombinant Factor VIII requested but no stocks of the specific product were available. Human Factor VIII (Biostate) was substituted instead of recombinant FVIII. Patient had not consented for this human product.	Laboratory
	Patient presented with AIHA with no previous transfiusion history. Autoantibody and positive DAT identified. Phenotyped matched units approved for transfusion. Jk antigen typing done by incorrect technique i.e; IAT. Patient typed as Jk^a+ and a Jk^a+ unit transfused. Subsequent investigations by by serology and DNA testing showed patient was Jk^a-.	Laboratory
Inappropriate Transfusion Platelets Fresh frozen plasma x 3	Patient with thrombocytopenia was refractory to platelet transfusion NZBS informed the hospital clinicians to stop further platelet transfusions until HLA and HPA antibody investigations were done. The antibody investigations were not done and a further nine units of platelets were transfused before intravenous immunoglobulin was transfused to the patient.	Clinical
	Inappropriate transfusion of fresh frozen plasma (FFP) to a patient with a normal INR	Clinical
	Patient had a perforated colon for upcoming surgery also had thrombocytopenia and a normal coagulation screen, INR 1.2. Registrar was concerned patient was at risk of bleeding from low platelets and requested and transfused two units of fresh frozen plasma, patient also transfused with two units platelets.	Clinical
	Patient administered IV Clexane. FFP requested to reverse Clexane. Transfusion Medicine Specialist consulted and gave advice that FFP was not indicated. All coagulation normal. Contrary to advice given, patient was transfused with two units of FFP, no further coagulation tests done.	Clinical
RhD Immunoglobulin	Patient with allo Anti-D given 625 IU RhD Immunoglobulin	Clinical
	Female less than 55 years old received two units of RhD positive platelets without being given RhD Immunoglobulin . Red cell antibody screen three months after event found no Anti-D.	Clinical
	250 IU RhD Immunoglobulin given to a patient with allo Anti-D with a titre greater than 4096	Clinical
	A vial of RhD Immunoglobulin removed from a remote refrigerator by a midwife and administered to a patient. The RhD Immunoglobulin had expired one month prior to the administration of the product.	Clinical

Near Miss Events

21

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 2018, there were 22 events identified from the NZBS incident management system and two reports from a DHB Blood Bank detailing wrong blood in tube (WBIT) near miss events. These events are summarised in Table 21.1.

TABLE 21.1 NEAR MISS EVENTS 2018 BY ERROR TYPE AND SITE

Error	Site of Error			
	Blood Bank	Processing	Clinical	Total
Expiry of blood components	7		2	9
Wrong product/component issued (including wrong dose or wrong patient), three events involving red cells, one cryoprecipitate and three blood products	4	1	2	7
Labelling error	4			4
WBIT from two DHB Blood Banks			2	2
Irradiation errors		1		1
Data Entry	**1**			**1**
Total	**16**	**2**	**6**	**24**

CASE D (Two Events)

Incorrect IV Immunoglobulin product issued.

On two occasions Privigen® was approved and requested to be issued for a specific patient. The blood bank issued Intragam®P on both occasions. The process for issuing IV Immunoglobulin is for the blood bank staff to check in the patient's file for the IV Immunoglobulin approved for issue, this did not occur.

These errors were detected by the clinical staff prior to the transfusions, the incorrect product returned to the blood bank and the correct IV Immunoglobulin product issed.

CASE E (One Event)

A request for a specific Recombinant Factor VIII was made and a different Recombinant Factor VIII issued. Incorrect Recombinant Factor VIII issued

21 Near Miss Events continued

CASE F (Three Events)

The clinical area requested red cells for a specific patient and the blood bank issued red cells for another patient.

These errors were detected by the clinical staff prior to the transfusions, the red cells for the incorrect patient were returned to the blood bank and red cell units for the correct patient issued.

CASE G

Unit of platelet issued nine minutes before expiry

A platelet request for a patient was received at 23.40 hrs and a unit of platelets was issued with an expiry time of 23.59 hrs was issued at 23.50 hrs. A nurse contacted the blood bank at 00.00 hrs and was advised not to give the expired unit.

CASE H

Two units of group O RhD negative red cells, four days post expiry, were found labelled for emergency issue within the blood bank refrigerator.

CASE I

Two instances of blood components sent to a clinical area without compatibility labels attached to indicate which patient they have been issued for.

The components were returned to the blood bank, labelled and re-issued to the clinical area.

22

Donor Infectious Disease Screening

In New Zealand, all blood donations are screened for hepatitis B surface antigen (HBsAg), HBV DNA, anti-HCV, HCV RNA, anti-HIV-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 2018, there were 174,705 donations collected from 81,203 donors. Of these donors, 80% were repeat donors and 20% were previously untested new donors.

Table 22.1 shows the number of donors with confirmed positive serology in 2018. There were 14 donors confirmed positive for HBV and 11 confirmed positive for syphilis.

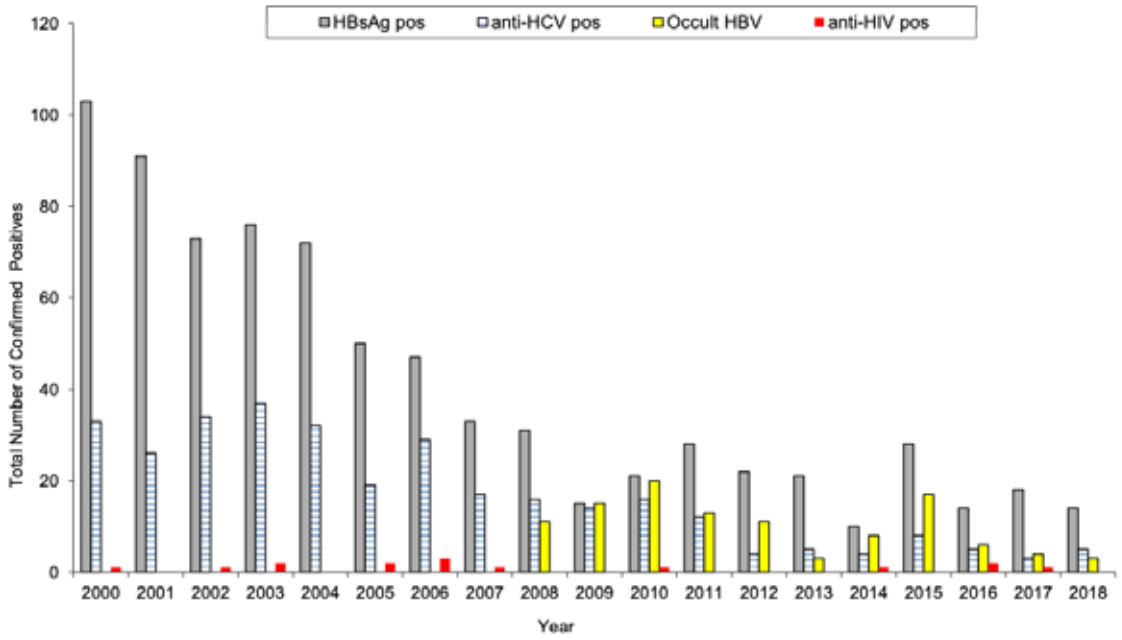
TABLE 22.1 DONORS WITH CONFIRMED POSITIVE INFECTIOUS DISEASE SEROLOGY 2018

		HBV	HCV	HIV	Syphilis	HBV Occult	HTLV I/II
Number	New Donors (n = 16,257)	13	5	0	3	1	0
	Repeat Donors (n =64,946)	1	0	0	8	3	0
	Total Donors (n = 81,203)	14	5	0	11	4	0
Rate per 10,000 Donations	New Donors	80.0	30.8	0	18.5	6.2	
	Repeat Donors	1.5	0	0	12.3	4.6	
	All Donations	17.2	6.2	0	13.5	4.9	0
Frequency of Positive Donor	New Donors	1:1,251	1:3,251		1:5,419	1:16,257	
	Repeat Donors	1:64,946			1:8,118	1:21,649	
	Overall Donor Frequency	1:5,800	1:16,241		1:7,382	1:20,301	

22 Donor Infectious Disease Screening continued

Figure 22.1 shows the number of confirmed positive results each year from 2000 to 2018. 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 22.1 ANNUAL NUMBER OF DONORS WITH CONFIRMED POSITIVE INFECTIOUS DISEASE SEROLOGY 2000 – 2018



23 Bacterial Testing Of Platelet Concentrates

NZBS undertakes pre-release sampling for bacterial culture on all platelet components. This was introduced in late 2015 and has been in place for over two years. Implementation of the system was associated with an extension of the platelet shelf life from five to seven days. The approach used by NZBS is based on the system used by the English National Blood Service (NHSBT).

Sampling of the component takes place a minimum of 36 hours following collection of the component which are then released to inventory for clinical issue. The system involves the use of both aerobic and anaerobic culture bottles with a minimum of 7mL of the component inoculated into each bottle. The sample is then cultured using the Bac-T Alert system until the end of the shelf-life of the component or the detection of a reactive result. All components linked to the implicated donations are discarded in the event of a reactive result and the clinician responsible for the patient informed if the component had already been transfused. The reactive Bac-T bottle and, where available, the remaining component are then sent to the local DHB microbiology laboratory for culture and identification.

The system involves testing of all platelet pools and of each apheresis collection (sampled prior to splitting into individual components). The number of tests is therefore lower than the number of platelet components available for transfusion. NZBS has adopted the classification produced by the AABB for interpretation of results. This is summarised in Table 23.1.

TABLE 23.1 DEFINITIONS USED TO CLASSIFY POSITIVE CULTURE RESULTS

Classification	Definition
Initial positive	Positive or abnormal (out of range) initial test
False positive	Positive on initial test & both the remainder of unit negative & recipient has no clinical or microbiological evidence of sepsis
Indeterminate	Positive on the initial test and either no confirmatory test was performed or results could not be interpreted
True positive	Positive on initial test and confirmatory test - the confirmatory test must be culture-based and be performed on a different sample than the culture bottle or other sample used for the initial test e.g. a sample source for the confirmatory test could be the original platelet component. A subculture of the initial positive culture is not an adequate sample for this purpose. If transfused: the remainder of component is positive or recipient has sepsis or positive blood culture with the same organism.

During 2018, 15,206 platelet components were tested. 98 (0.65%) of these gave an initial positive result. A breakdown of the results is provided in Table 23.2.

TABLE 23.2 RESULTS OF PLATELET BACTERIAL CULTURE PERFORMED IN 2018

Classification	Number (Percentage)		
	Apheresis Platelets N=2,539	Platelets Pooled N=12,569	Total N=15,108
Non reactive	2,522 (99.33%)	12,488 (99.36%)	15,100 (99.35%)
Initial positive	17 (0.7%)	81 (0.64%)	98 (0.65%)
False positive	9 (0.35%)	47 (0.37%)	56 (0.37%)
Indeterminate	4 (0.16%)	19 (0.15%)	23 (0.15%)
True positive	4 (0.16%)	15 (0.12%)	19 (0.13%)

23 Bacterial Testing Of Platelet Concentrates continued

The NZBS true positive rate in 2018 is slightly higher than that seen in 2107 (0.08). The difference is not statistically significant (p=0.146). The rate is similar to the 0.11% confirmed positive rate reported by the Australian Red Cross Blood Service in 2017 *(https://kirby.unsw.edu.au/sites/default/files/kirby/report/Transfusion-transmissible-infections-in-Australia-Surveillance-Report-2018.pdf)*

The bacterial species identified in the 19 true positive samples is shown in Table 23.3. This also identifies the number of culture positive platelet components that were transfused.

TABLE 23.3 BACTERIAL SPECIES IDENTIFIED IN CONFIRMED POSITIVE CASES

Species	Number		
	Total	Transfused	Not Transfused
Propionibacterium acnes	11	5	6
Staphylococcus saccharolyticus	1	0	1
Streptococcus viridans	1	0	1
Enterococcus faecalis	1	0	1
Gram positive cocci	3	0	3
Staphylococcus capitis	1	0	1
Staphylococcus epidermidis	1	0	1
Total	**19**	**5**	**14**

None of the five transfused patients exhibited any symptoms at the time of the transfusion. Four of the five were already on broad spectrum antibiotics at the time of the transfusion. One of the five died of unrelated causes some days following the transfusion.

In the three year period 2016-18 a total of fifteen platelet components with confirmed positive cultures were transfused to patients. Fourteen involved contamination with Propionibacterium acnes and one with Staphylococcus saccharolyticus. No adverse signs or symptoms were noted in fourteen of the patients with the remaining patient developing a fever of 38.5°C but no other symptoms.

The high proportion of P. acnes cases identified and subsequently transfused in 2018 is similar to that seen in 2016 and 2017. This organism grows very slowly and is therefore often detected after the component has been transfused. It is rarely associated with clinical complications.

Two cases of sepsis were reported to the haemovigilance office 2018. It is noteworthy that one of the reports related to a platelet transfusion that had a negative Bac-T culture at 36 hours. This is a timely reminder that the bacterial culture programme reduces but does not eliminate the risk of bacterial contamination.

24 Adverse Events Associated with Fractionated Plasma Products

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, reviews these reports and also forwards them to the manufacturer, CSL Behring (Australia) Pty Ltd, with recipient identifying details redacted. Periodic reports are provided to the Centre for Adverse Reaction Monitoring (CARM).

In 2018, 52 adverse reactions and product administration errors were reported and these broadly showed the same pattern and frequencies seen in recent years. The largest number of reports received involved events occurred to high-volume immunoglobulin products, Intragam®P, Privigen® (34 reactions); four reactions occurred to Albumex®, Prothrombinex-VF and Rh(D) Immunoglobulin-VF.

Table 24.1 shows the 52 events by fractionated plasma product type. Additional information on events associated specifically with administration of Privigen® are shown in Table 24.2 and with Intragam®P in Table 24.3.

TABLE 24.1 TRANSFUSION-RELATED ADVERSE EVENTS (ANY CAUSALITY) 2018 ASSOCIATED WITH FRACTIONATED PLASMA PRODUCTS

Product Type	Event Type	Number of Reports
Privigen®	Various (See Table 24.2)	23
Intragam®P	Various (See Table 24.3)	10
Albumex® 4	Allergic (2), febrile (2)	4
Prothrombinex-VF	Mixed symptoms and signs (2), allergic (2)	4
Rh(D) Immunoglobulin-VF	Inappropriate use (2), febrile, incorrect product	4
Albumex® 20	Allergic, hypotensive, febrile	3
Evogam®	Headache, lack of expected effect	2
Rhophylac®	Advised to administer IV, administered IM.	1
Biostate®	Infused without informed consent	1
Total		**52**

24 Adverse Events Associated with Fractionated Plasma Products continued

TABLE 24.2 TRANSFUSION-RELATED ADVERSE EVENTS (ANY CAUSALITY) 2018 ASSOCIATED WITH PRIVIGEN®

Type of Reaction	Total	Causality						Severity	
		Excluded	Unlikely	Possible	Probable	Highly probable	Certain	Non-severe	Severe
Allergic	9		2	1	5	1		7	2
Febrile	3			1		2		3	
Other	2		1	1				1	1
Aseptic meningitis	1					1		1	
Haemolytic	1					1			1
Headache	1					1		1	
Failure of effect on ITP	1			1				1	
SOB	1				1			1	
Neutropenia	1				1			1	
Systemic fatigue syndrome with cramps, fevers	1					1		1	
Pain	1					1		1	
Thrombotic	1			1					1
Total	**23**	**0**	**3**	**5**	**7**	**8**	**0**	**18**	**5**

TABLE 24.3 TRANSFUSION-RELATED ADVERSE EVENTS (ANY CAUSALITY) 2018 ASSOCIATED WITH INTRAGAM®P

Type of Reaction	Total	Causality						Severity	
		Excluded	Unlikely	Possible	Probable	Highly probable	Certaim	Non-severe	Severe
Allergic	4				1	3		4	
Febrile	1		1					1	
Haemolytic	1					1		1	
Other	1			1				1	
Nausea	1			1				1	
Phlebitis	1			1				1	
Thrombotic	1				1				1
Total	**10**		**1**	**3**	**2**	**4**		**9**	**1**

Six events were classified as serious, five involving Privigen® and one with the infusion of Intragam®P. The severity of the adverse events associated with different fractionated products is detailed in Table 24.4.

Adverse Events Associated with Fractionated Plasma Products continued

24

TABLE 24.4 SEVERITY OF ADVERSE EVENTS IN 2018 ASSOCIATED WITH FRACTIONATED PLASMA PRODUCTS

Product Type	Severity	
	Non-severe	Severe
Privigen®	18	5
Intragam®P	9	1
Albumex® 4	4	
Prothrombinex-VF	4	
Rh(D) Immunoglobulin-VF	4	
Albumex® 20	3	
Evogam®	2	
Rhophylac®	1	
Biostate®	1	
Total	**46**	**6**

Reactions classified as severe were those that required admission of the recipient to hospital or intervention to prevent a potentially serious complication.

The data for 2018 is consistent with the overall frequencies for the years 2007 - 2017.

24 Adverse Events Associated with Fractionated Plasma Products continued

Summary of Severe Adverse Reactions

Case J – Privigen® in a patient with Kawasaki disease: Haemolytic adverse event

This one year old boy which blood group A, presented with a six-day history of fevers, fluctuating rash over his body, tachycardia and lethargy. He had a systolic murmur and cardiac studies showed a vegetation on the mitral valve. He had a marked inflammatory state but two blood cultures were negative. He was diagnosed with possible Kawasaki disease and received standard treatment with an infusion of Privigen® 2g/kg on 17-Jan-2018; the dose was repeated two days later. Symptoms resolved after the second infusion. The child's haemoglobin level fell from 106g/L before treatment to 76g/L two days after the second treatment dose. He recovered from the haemolytic episode slowly and reached a normal haemoglobin level on 16-Mar-2018. Causality for the haemolytic reaction is highly probable.

Case K - Severe allergic event involving Privigen® in a person with idiopathic thrombocytopenia purpura (ITP)

This 78 year old foreign traveller was holidaying on a cruise ship in NZ waters. He had a past medical history of idiopathic thrombocytopenic purpura (ITP) and an acute myocardial infarct. He was found to have a very low platelet count indicating a relapse of the ITP and a low haemoglobin level due to acute gastrointestinal bleeding. He was taking several medicines, including prednisone (for ITP), clopidogrel (for thromboprophylaxis) and celebrix which are all likely to have contributed to the bleeding. He required emergency retrieval by helicopter to NZ. On admission to Hospital he was given standard treatment for ITP, i.e. IV immunoglobulin 1g/kg with Privigen®. During the infusion he became pyrexic, developed a rapid respiration rate with reduced oxygen saturation and wheeze throughout the lung fields. His pulse and blood pressure were both raised but his jugular venous pressure was not increased. The adverse event was treated with ondansetron 4mg, cyclizine 25mg, promethazine 10mg and hydrocortisone 100mg (all given IV) and nebulised salbutamol. On the following day he was given 75g of an alternative product, Intragam®P, without adverse symptoms. Causality for an acute severe allergic reaction caused by Privigen® was assessed as probable.

Adverse Events Associated with Fractionated Plasma Products continued

24

Case L - Severe event involving Privigen® in a patient treated for chronic inflammatory demyelinating polyneuropathy (CIPD).

This 67 year old female was diagnosed as having chronic inflammatory demyelinating polyneuropathy (CIPD) with complex features and had significant functional impairment in daily activities. She was prescribed high dose IV immunoglobulin (Privigen® 40g / d for five days) and received the infusions as an outpatient. During the first night after starting the infusions she experienced six episodes of diarrhoea together with headache and fatigue. She began vomiting on the following evening and was admitted to hospital to receive IV fluids, potassium replacement and anti-emetics. Observations showed her temperature was normal, cardiorespiratory and abdominal examination were initially normal and her chest X-ray was also clear. A urine sample had increased leucocytes but no bacteria were seen and the culture result was not available. Subsequently, an ECG showed fast atrial fibrillation with a heart rate of 160 / bpm and an increase in troponin (to 113) which was attributed to the fast atrial fibrillation. The atrial fibrillation later ceased spontaneously, she felt symptomatically improved and was discharged. The patient has since had three infusions of Intragam®P with no reported adverse reactions. Causality for Privigen® to be the cause of the signs and symptoms is possible, but other more likely causes exist.

Case M - Severe event involving Privigen® Guillain-Barré Syndrome (GBS)

This 66 year old patient was admitted to Hospital with developing Guillain-Barré Syndrome (GBS). He received Intragam®P over two days but due to impaired respiratory function was transferred to the Base Hospital where he received intermittent ventilator support. He had a severe form of GBS and his recovery was expected to be slow, and likely to be incomplete. He deteriorated further with increasing respiratory weakness and was given a second course of immunoglobulin, and on this occasion received Privigen® - 35g / day (total dose 175g). The dose was repeated two months later. On the second day of that treatment event he became acutely hypotensive - BP 110 / 60, falling to 50 / 30 with ECG changes suggestive of myocardial ischaemia. He was treated with metaraminol to manage his BP and 1000 mL IV fluids. He was given 300mg aspirin to manage the risk from myocardial ischaemia. His left ventricular function was later reported to be normal.

Possible diagnoses considered were: a delayed response to fentanyl but was discounted as he had been on regular morphine, a reaction to IV Immunoglobulin, or possible sepsis. It is reported that the patient has multiple risk factors for myocardial ischaemia, with known atherosclerotic disease, type II diabetes and hyperlipidaemia. Causality for Privigen® being the cause of the adverse event is possible, but other more likely causes exist.

24 Adverse Events Associated with Fractionated Plasma Products continued

Case N -Severe event involving Privigen® Thrombocytopenia possibly due to ITP, history of peptic ulcer

This 76 year old man was admitted to hospital with shortness of breath, fever and thrombocytopenia. He was started on IV antibiotics but continued to decline. He was transferred to the ICU where he was later intubated following hypoxaemic respiratory failure. A chest x-ray showed bilateral pulmonary infiltrates, but no clear bacterial or viral cause. Bone marrow biopsy suggested ITP and Privigen® 80g was given together with five units of platelets over two days. Echocardiography showed critical aortic stenosis and poor left ventricular function. Accordingly, a balloon aortic valvuloplasty was performed but the patient did not regain consciousness after the procedure. He had a marked increase in ALT to >4000 U/L and Pro BNP, and a continued fall of Albumin to 20g / L with a high and rising CRP to 200-300 mg/L. A brain CT showed a large left hemisphere ischaemic infarction. Palliative care was commenced and the patient died on 12-Jan-2018. The cause of death was recorded as ischaemic stroke secondary to severe aortic stenosis and atrial fibrillation. The causality for Privigen® being a contributory factor for a thrombotic ischaemic stroke is possible but other likely causes exist.

Case O - Severe event involving Intragam®P in a patient who has chronic inflammatory demyelinating polyneuropathy (CIDP)

This 65 year old patient has CIDP and is dependant on long term IV immunoglobulin therapy. Peripheral venous access had been difficult and a permanent implanted port was inserted to replace a PICC line which had been difficult to manage. Symptoms of thrombotic obstruction of the SVC were later recognised by the GP. The patient had developed shortness of breath overnight and this resolved with sitting up; she also complained of a painful, tight arm. The latter appeared to coincide with her last IVIg infusion and difficulty with flushing the infusion port. Problems with catheter blocking had occurred intermittently over the previous six months and Alteplase (+ PA) had been used to unblock the line. A chest CT confirmed brachiocephalic vein thrombus at tip of implanted port, located at the junction of the SVC. The thrombosis was managed with warfarin anticoagulation for six months. An SVC stent was not inserted due to the potential complications from re-thrombosis of a stent. Dabigatran was later substituted for warfarin due to venous access problems for INR testing. The patient was commenced on subcutaneous infusions of Evogam®, at a dose of 12.8g weekly, after ceasing anticoagulation. It was noted that she has a history of previous deep vein thromboses during both of her pregnancies. The causality for Intragam®P being a contributing factor to SVC thrombotic obstruction is probable but other contributory prothrombotic factors exist.

Adverse Events Associated with Fractionated Plasma Products continued

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Review of the frequency of events during 2007 – 2018, identified 497 events involving either an adverse event, or inappropriate exposure, to a blood product, see Table 24.5. High-volume immunoglobulin products were associated with 69% of the events, 12% were associated with Albumex® products, 6% with coagulation factor concentrates and 1% with various other normal or hyperimmune immunoglobulins. Rh(D) Immunoglobulin was associated with 9% of events and mostly involved either administration of the product when not indicated, or the supply of an incorrect dose.

TABLE 24.5 TRANSFUSION-RELATED ADVERSE EVENTS ASSOCIATED WITH FRACTIONATED PLASMA PRODUCTS 2007 – 2018

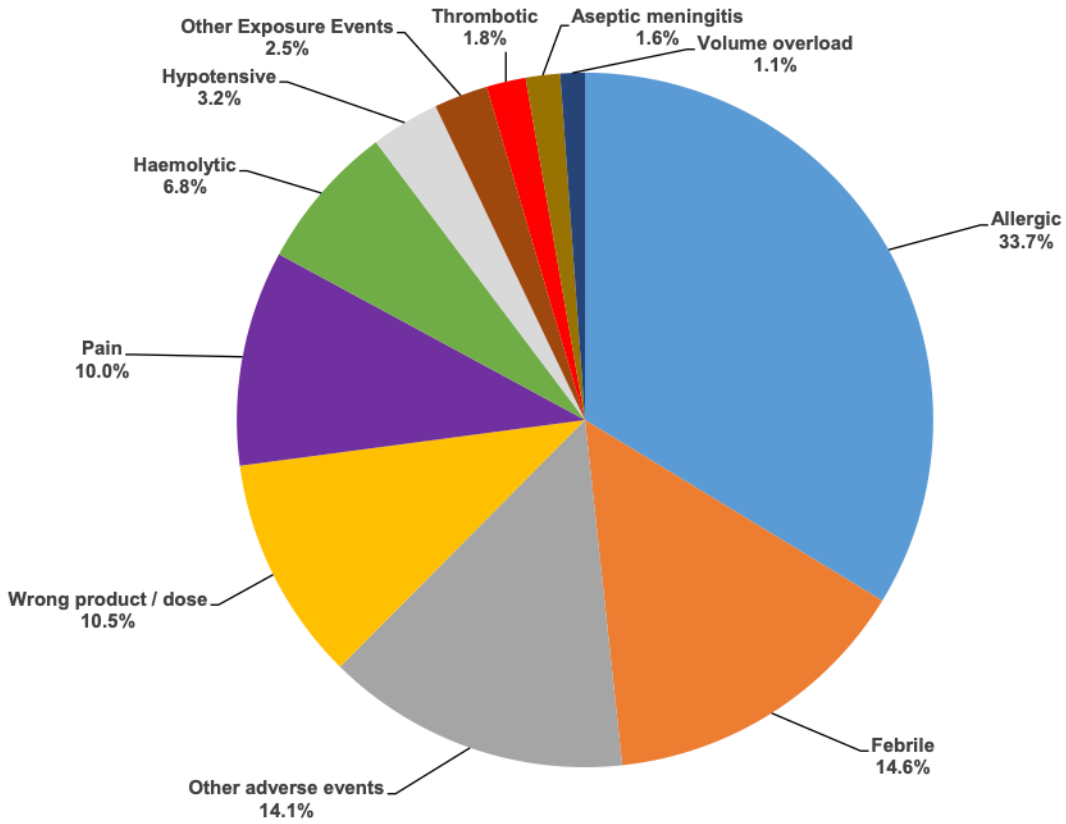
Year	Total Events	Percent
Intragam®P, Privigen®, NextGen® 16% Ig	342	68.8%
Rh(D) Immunoglobulin-VF / WinRho® / Rhophylac®	47	9.5%
Albumex®4	37	7.4%
Albumex®20	21	4.2%
Prothrombinex™-HT / Prothrombinex®-VF	21	4.2%
Biostate® / AHF-HP	11	2.2%
Evogam®	9	1.8%
MonoFIX®-VF	3	0.6%
Tetanus Immunoglobulin-VF	3	0.6%
Normal Immunoglobulin-VF	1	0.2%
Hepatitis B Immunoglobulin-VF	1	0.2%
Zoster Immunoglobulin-VF	1	0.2%
Total	**497**	

Data for the frequencies of different types of adverse event are provided in Figure 24.1. The data for 2018 is similar to the overall frequencies in the 12 year period, 2007- 2018. Review of data for the 12 year period shows that the most frequent types of adverse events were –

- Allergic reactions 34%
- Febrile reactions 15%
- Pain 10%
- Mixed or other adverse reactions 14%
- Supply of a wrong product or dose 10%
- Adverse events associated with thrombosis, hypotension, aseptic meningitis and volume overload were less frequent and occurred at approximately 2–3% of events for each type of reaction.

24 Adverse Events Associated with Fractionated Plasma Products continued

FIGURE 24.1 FREQUENCY OF ADVERSE EVENTS TO FRACTIONATED PLASMA PRODUCTS 2007 – 2018



25 Adverse Events Associated with Blood Donation

The year on year number of annual blood donations by donation type is shown in Table 25.1. 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 25.1 ANNUAL NUMBER OF BLOOD DONATIONS 2005 – 2018 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
2016	69,857	114,779	8,789	54,059	425	2,878	79,071	171,716
2017	66,871	111,188	9,121	54,125	415	2,766	76,407	168,079
2018	67,407	112,162	10,243	59,895	436	2,648	78,086	174,705

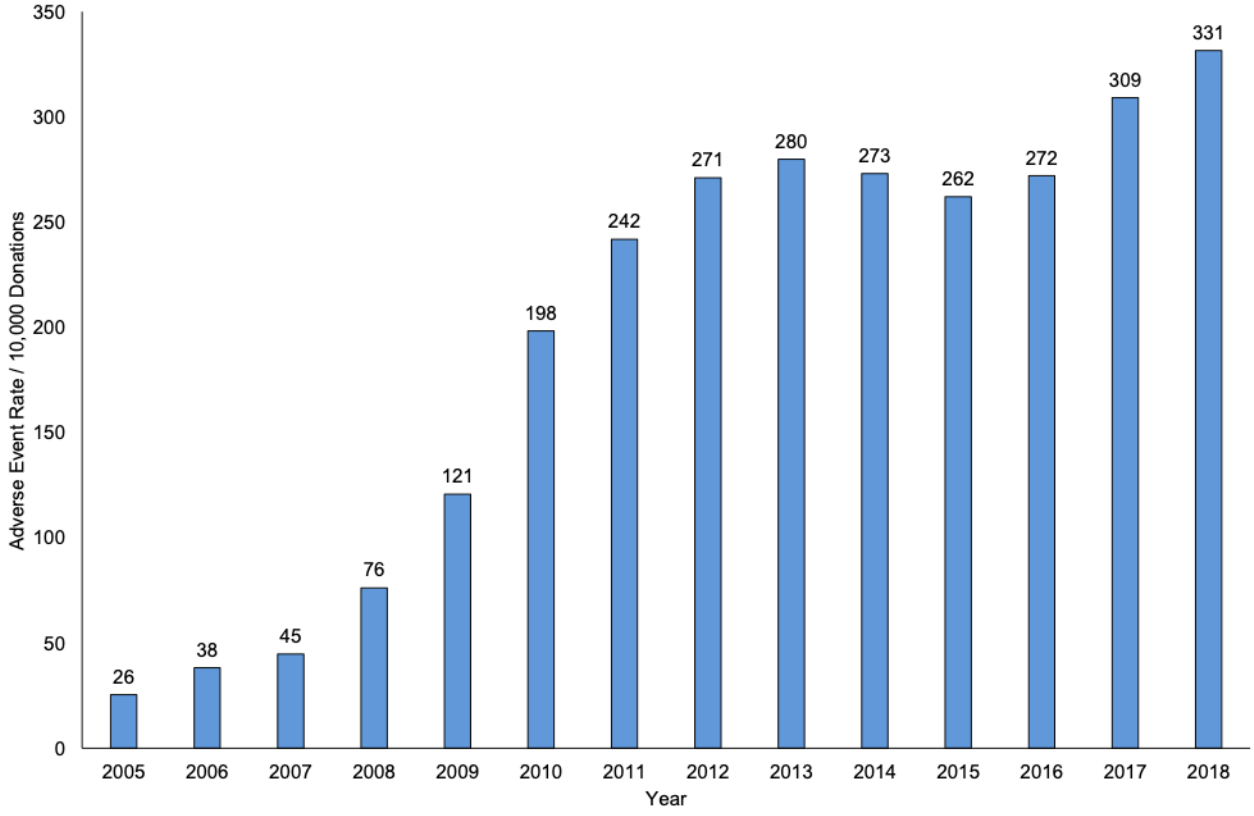
Adverse events associated with blood donation can occur during or after collection. Delayed complications are defined as an event which has occurred after the donor has left the donation site. Delayed complications are notified either by a telephone call, personal visit, email or letter.

NZBS utilises definitions for these adverse events contained in the Standard for Surveillance of Complications Related to Blood Donation (2014) developed by the Working Group on Donor Vigilance, 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 five years (Figure 25.1). Prior to this, the increase seen, likely reflected efforts within NZBS to improve consistency of reporting across the sites.

25 Adverse Events Associated with Blood Donation continued

FIGURE 25.1 ANNUAL DONATION-RELATED ADVERSE EVENT RATE PER 10,000 DONATIONS 2005 – 2018



Three donors experienced an adverse event that was classified as severe, two females and one male. Two experienced an immediate vasovagal event and one a haematoma. All donors were permanently deferred from further blood donations.

The criteria for classification of a reaction as severe include:

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

In 2018, following an adverse event, a total of 106 donors were permantly deferred from further donations; 15 plasma and 91 whole blood donors. 79% of the donors permanently deferred had a vasovagal adverse event.

25

Adverse Events Associated with Blood Donation continued

During 2018, there were 174,705 donations (112,162 whole blood, 59,895 plasmapheresis and 612 plateletpheresis donations) collected. Adverse events were reported in relation to 5,791 of the donations, involving 5,412 donors. The overall frequency of reported donation-related adverse events was 1:30. Adverse events are more frequently reported with plateletpheresis procedures, than whole blood donations or plasmapheresis procedures (Table 25.2).

TABLE 25.2 DONATION-RELATED ADVERSE EVENTS 2018 BY COLLECTION METHOD

Procedure	Donors	Donations with Events	Total Donations	Frequency	Rate / 10,000 Donations (95%CI)
Whole Blood Donation	3,805	3,922	112,162	1:29	35.0 (33.9 to 36.1)
Plasmapheresis	1,422	1,618	59,895	1:37	27.0 (25.7 to 28.3)
Plateletpheresis	185	251	2,648	1:11	94.8 (84.2 to 106.6)
All Apheresis Procedures	1,607	1,869	62,543	1:33	29.9 (28.6 to 31.2)
Total Procedures	**5,412**	**5,791**	**174,705**	**1:30**	**33.1 (32.3 to 34.0)**

A number of donors experienced more than one adverse event with a single donation, so in total, there were 5,791 reported events with 3,922 involving whole blood donations and 1,869 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 (58.1%) was an immediate vasovagal reaction. For apheresis procedures, the most common event (55.5%) was bruising/haematoma. Donation-related adverse events by reaction type and collection method are shown in Table 25.3 and Table 25.4.

25 Adverse Events Associated with Blood Donation continued

TABLE 25.3 DONATION-RELATED ADVERSE EVENTS 2018 BY REACTION TYPE

Adverse Event	All Blood Donations (Total 174,705) Collections)			
	Number Events[1]	Percentage	Frequency	Rate / 10,000 Donations (95% CI)
Immediate Vasovagal	2,706	47.2%	1:65	155 (149 to 161)
Haematoma	2,009	35.1%	1:87	115 (110 to 120)
Painful Arm	464	8.1%	1:377	27 (24 to 29)
Re-bleeding	172	3.0%	1:1,016	10 (8 to 11)
Nerve Irritation / Injury	144	2.5%	1:1,213	8 (7 to 10)
Other Complications	131	2.3%	1:1,334	7 (6 to 9)
Delayed Vasovagal	67	1.2%	1:2,608	4 (3 to 5)
Local Allergic Reaction	19	0.3%	1:9,195	1 (1 to 2)
Arterial Puncture	6	0.1%	1:29,118	
Thrombophlebitis	3	0.1%	1:58,235	
Cellulitis	2	0.03%	1:87,353	
Other Serious Complications	2	0.03%	1:87,353	
Generalised Allergic Reaction	1	0.02%	1:174,705	
Other Major Vessel Injury	1	0.02%	1:174,705	
Total	**5,727**		**1:31**	**328 (320 to 336)**

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

Adverse Events Associated with Blood Donation continued

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TABLE 25.4 DONATION-RELATED ADVERSE EVENTS 2018 BY REACTION TYPE AND COLLECTION METHOD

Adverse Event	Type of Blood Donation					
	Whole Blood (Total Collections = 112,162)			Apheresis (Total Collections = 62,543)		
	% All Events	Freq.	Rate / 10,000 Donations (95% CI)	% All Events	Freq.	Rate / 10,000 Donations (95% CI)
Immediate Vasovagal	58.1%	1:47	212 (204 to 221)	20.0%	1:191	52 (47 to 58)
Haematoma	26.9%	1:102	98 (92 to 104)	55.5%	1:69	145 (136 to 155)
Painful Arm	6.3%	1:435	23 (20 to 26)	12.6%	1:304	33 (29 to 38)
Re-bleeding	2.86%	1:959	10 (9 to 13)	3.4%	1:1,137	9 (7 to 11)
Nerve Irritation / Injury	2.3%	1:1,181	8 (7 to 10)	3.0%	1:1,276	8 (6 to 10)
Other Complications	1.8%	1:1,536	7 (5 to 8)	3.5%	1:1,078	9 (7 to 12)
Delayed Vasovagal	1.3%	1:2,039	5 (4 to 6)	0.7%	1:5,212	2 (1 to 3)
Local Allergic Reaction	0.2%	1:14,020	1 (0 to 1)	0.7%	1:5,686	2 (1 to 3)
Arterial Puncture	0.05%	1:56,081		0.2%	1:15,636	1 (0 to 2)
Thrombophlebitis	0.05%	1:56,081		0.1%	1:62,543	
Cellulitis	0.02%	1:112,162		0.1%	1:62,543	
Other Serious Complications	0.02%	1:112,162		0.1%	1:62,543	
Generalised Allergic Reaction				0.1%	1:62,543	
Other Major Vessel Injury				0.06%	1:62,543	
Total			**365 (354 to 376)**		**1:270**	**37 (33 to 42)**

	Number Adverse Events	Apheresis-only Events		
		% Reaction	Freq.	Rate / 10,000 Donations (95% CI)
RBC not returned	511	68.6%	1:122	82 (75 to 89)
Citrate Toxicity	232	31.1%	1:270	37 (33 to 42)
Haemolysis	2	0.3%	1:31,272	
Total Apheresis-specific Events	**745**			**1:84**

25 Adverse Events Associated with Blood Donation continued

During 2018, 90% of the whole blood donations were collected from repeat donors. The distribution of event types within the two groups was similar with vasovagal reactions and haematoma events predominating (Table 25.5).

TABLE 25.5 WHOLE BLOOD DONATION-RELATED ADVERSE EVENTS 2018 BY REACTION TYPE FOR NEW AND REPEAT DONORS

Adverse Event	New Donors (n=10,693)			Repeat Donors (n=98,577)		
	% Reactions	Freq.	Rate / 1,000 Donations	% Reactions	Freq.	Rate / 1,000 Donations
Immediate Vasovagal	76.4%	1:10	98.8	50.3%	1:74	134.3
Haematoma	17.3%	1:45	22.4	32.9%	1:114	87.6
Painful Arm	3.7%	1:210	4.8	7.9%	1:476	21.0
Delayed Vasovagal	1.3%	1:594	1.7	1.6%	1:2,292	4.4
Nerve Irritation / Injury	0.8%	1:972	1.0	2.9%	1:1,280	7.8
Other Complications	0.4%	1:1,782	0.6	.		
Local Allergic Reaction	0.1%	1:10,693	0.1			
Generalised Allergic Reaction						
Arterial Puncture				0.04%	1:98,577	0.1
Cellulitis				0.04%	1:98,577	0.1
Other Serious Complications						
Thrombophlebitis				0.08%	1:49,289	0.2
Re-bleeding				4.2%	1:888	11.3
Total		**1:8**	**129.3**		**1:37**	**266.8**

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 the youngest group of donors, aged 16 to 19 years, the adverse event rate is 1:11 donations and the odds ratio is 4.50 (Table 25.6).

Adverse Events Associated with Blood Donation continued

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TABLE 25.6 WHOLE BLOOD DONATION-RELATED ADVERSE EVENTS 2018 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	938	10,107	1:11	92.8 (87.3 to 98.6)	4.50 (4.16 to 4.86)
20 - 24 Years	712	11,655	1:16	61.1 (56.9 to 65.6)	2.86 (2.62 to 3.11)
25 - 29 Years	532	11,989	1:23	44.4 (40.8 to 48.2)	2.04 (1.85 to 2.25)
30 - 34 Years	356	9,888	1:28	36.0 (32.5 to 39.9)	1.64 (1.47 to 1.84)
35 - 39 Years	276	8,940	1:32	30.9 (27.5 to 34.7)	1.40 (1.23 to 1.59)
40 - 44 Years	190	9,354	1:49	20.3 (17.6 to 23.4)	0.91 (0.78 to 1.06)
45 - 49 Years	186	10,374	1:56	17.9 (15.5 to 20.7)	0.80 (0.69 to 0.93)
50 - 54 Years	199	10,005	1:50	19.9 (17.3 to 22.8)	0.89 (0.77 to 1.03)
55 - 59 Years	203	10,963	1:54	18.5 (16.2 to 21.2)	0.83 (0.72 to 0.96)
≥60 Years	330	17,962	1:54	18.4 (16.5 to 20.4)	0.82 (0.73 to 0.92)
All	**3922**	**111,237**	**1:28**	**35.3 (34.2 to 36.4)**	

Vasovagal reactions are the most common whole blood donation-related adverse event. Table 25.7 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.

25 Adverse Events Associated with Blood Donation continued

TABLE 25.7 WHOLE BLOOD VASOVAGAL EVENTS 2018 BY DONOR AGE GROUP FOR NEW DONORS AND REPEAT DONORS

Age Group	Gender	New Donors (n = 10,693)		Repeat Donors (n = 98,577)	
		Frequency	Rate / 1,000 Donations (95%CI)	Frequency	Rate / 1,000 Donations (95%CI)
16 – 19	Female	1:7	135.7 (122.8 to 149.7)	1:19	53.7 (46.6 to 61.9)
	Male	1:12	85.8 (74.3 to 98.9)	1:32	31.7 (24.8 to 40.5)
20 – 24	Female	1:8	121.1 (103.3 to 141.3)	1:28	36.1 (31.8 to 41.0)
	Male	1:7	140.7 (109.5 to 178.8)	1:37	27.3 (22.2 to 33.5)
25 – 29	Female	1:9	110.1 (91.2 to 132.3)	1:40	25.3 (21.7 to 29.5)
	Male	1:7	153.4 (118.7 to 195.8)	1:71	14.1 (10.8 to 18.2)
30 – 34	Female	1:16	62.8 (45.9 to 85.2)	1:51	19.7 (16.1 to 24.1)
	Male	1:7	134.2 (99.9 to 177.9)	1:69	14.5 (11.2 to 18.7)
35 – 39	Female	1:16	60.7 (41.5 to 87.8)	1:61	16.4 (13.0 to 20.6)
	Male	1:12	87.0 (55.0 to 134.0)	1:102	9.8 (7.1 to 13.6)
40 – 44	Female	1:22	45.0 (28.2 to 70.4)	1:122	8.2 (6.0 to 11.2)
	Male	1:28	35.5 (14.7 to 77.0)	1:252	4.0 (2.3 to 6.6)
45 – 49	Female	1:26	38.8 (22.2 to 65.9)	1:175	5.7 (4.0 to 8.1)
	Male	1:22	44.6 (20.1 to 90.8)	1:218	4.6 (2.9 to 7.1)
50 – 54	Female	1:16	61.8 (37.7 to 98.7)	1:112	8.9 (6.7 to 11.9)
	Male	1:20	49.5 (18.5 to 113.5)	1:309	3.2 (1.9 to 5.5)
55 – 59	Female	1:19	51.8 (27.2 to 93.9)	1:105	9.5 (7.3 to 12.4)
	Male	1:26	39.0 (8.7 to 113.0)	1:451	2.2 (1.2 to 4.0)
≥60	Female	1:13	79.1 (43.4 to 137.5)	1:111	9.0 (7.2 to 11.3)
	Male	1:17	60.0 (14.4 to 168.4)	1:542	1.8 (1.1 to 3.0)
Total	Female	1:10	102.7 (95.8 to 110.1)	1:56	18.0 (16.9 to 19.1)
	Male	1:11	95.2 (86.2 to 105.0)	1:115	8.7 (7.9 to 9.6)
	Total	**1:10**	**100.1 (94.5 to 105.9)**	**1:72**	**13.9 (13.2 to 14.6)**

In line with international practice, NZBS has introduced measures to reduce the frequency of adverse events 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 3,500 mL are deferred from donating.

25

Adverse Events Associated with Blood Donation continued

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 three chewable Nestlé Quick-Eze antacid tablets each containing 800mg calcium carbonate followed by a further three tablets with the onset of symptoms of citrate toxicity, and repeated if necessary every 20-30 minutes to a maximum dose of nine tablets. Comparing the national rate of citrate reactions reported in 2018 to that in 2013, a decrease of 48% has occurred (p=<0.001) (Table 25.8).

TABLE 25.8 DONATION-RELATED ADVERSE EVENTS ASSOCIATED WITH CITRATE TOXICITY DURING PLATELETPHERESIS 2013 – 2018

	Year						% Change 2013 to 2018
	2013	2014	2015	2016	2017	2018	
Number Citrate Adverse Events	493	238	202	166	164	138	
Number Plateletpheresis Procedures	4,942	3,570	3,377	2,878	2,766	2,648	
Rate / 1,000 Procedures	100	67	60	58	59	52	-48%

26 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 thirteen years, the six NZBS Blood Banks (Auckland, Hamilton, Palmerston North, Wellington, Christchurch and Dunedin) have been recording errors and corrective actions associated with pretransfusion specimens. Since September 2017 data is entered via the NZBS blood bank computer system, eTraceline, 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 26.1.

TABLE 26.1 NZBS PRETRANSFUSION REQUEST FORM AND SPECIMEN LABELLING REQUIREMENTS

Request Form Handwritten or Pre-printed Label	Specimen Must be Handwritten
Full name	Family name and one or more given names (not abbreviated)
National Health Index (NHI) number and/or date of birth	NHI number and/or date of birth
Gender	Signature or initials of collector
Patient's location	
Details of request (group and screen, blood products etc.)	
Name or signature or other identifier of person completing the form	
Signed declaration by 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 2018, a total of 140,888 pre-transfusion specimens were received by the six NZBS Blood Banks. Errors were identified in 4,632 specimens/forms. The overall error rate for the six NZBS Blood Banks was 32.9 per 1,000 specimens received, which is equivalent to an error rate of 1:30 specimens. Table 26.2 details the error rate per 1,000 specimens for the six NZBS Blood Banks in 2018.

Request Form and Specimen Labelling Errors continued

26

TABLE 26.2 PRETRANSFUSION REQUEST FORM AND SPECIMEN LABELLING ERRORS 2018 BY NZBS BLOOD BANK SITE

Blood Bank	Errors	Total Specimens	Error Rate	Rate / 1,000 Specimens (95% CI)
Waikato	1,422	25,143	1:18	56.6 (53.8 to 59.5)
Dunedin	409	10,400	1:25	39.3 (35.8 to 43.2)
Palmerston North	315	8,403	1:27	37.5 (33.6 to 41.8)
Wellington	790	22,645	1:29	34.9 (32.6 to 37.4)
Christchurch	682	22,981	1:34	29.7 (27.6 to 32.0)
Auckland	1,014	51,316	1:51	19.8 (18.6 to 21.0)
NZBS	**4,632**	**140,888**	**1:30**	**32.9 (32.0 to 33.8)**

The types of errors and the corrective actions taken are summarised in Table 26.3. Some request forms and specimens received had more than one type of error present. The total number of errors was 4,683. The most frequent type of error (19%) was “Minor Error” followed by the “Missing Patient Details (Major discrepancy)” and Sample not signed (Declaration signed)”.

When corrections are allowable they must be carried out by the collector in 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”.

26 Request Form and Specimen Labelling Errors continued

TABLE 26.3 PPRETRANSFUSION REQUEST FORM AND SPECIMEN LABELLING ERRORS 2018 BY ERROR TYPE

Error	Number Specimens With Error	% Total	Frequency	Error Rate / 10,000	Action Required
Minor Error	1,128	24.1%	1:125	80.1	Correction by collector or recollect
Missing Patient Details (Major discrepancy)	775	16.5%	1:182	55.0	Recollection
Specimen not signed (Declaration signed)	450	9.6%	1:313	31.9	Correction by collector or recollect
Declaration not signed (specimen is signed)	426	9.1%	1:331	30.2	Correction by collector or recollect
Adhesive on tube (indication label removal)	403	8.6%	1:350	28.6	Recollection
Pre-printed patient ID label on specimen	381	8.1%	1:370	27.0	Recollection
Moderate error on specimen	329	7.0%	1:428	23.4	Correction by collector or recollect
Technical problem[1]	245	5.2%	1:575	17.4	Recollection
Signatures on specimen and declaration differ	179	3.8%	1:787	12.7	Recollection
Presence of partial pre-printed label	91	1.9%	1:1,548	6.5	Recollection
Unlabelled specimen	83	1.8%	1:1,697	5.9	Recollection
Moderate error on form	57	1.2%	1:2,472	4.0	Correction by collector or recollect
Haemolysed specimen	55	1.2%	1:2,562	3.9	Recollection
Original details overwritten	43	0.9%	1:3,276	3.1	Recollection
Declaration and specimen not signed	38	0.8%	1:3,708	2.7	Recollection
Total	**4683**		**1:30**	**332.4**	

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

Request Form and Specimen Labelling Errors continued

26

The overall rate of requests for recollection of pretransfusion specimens by NZBS Blood Banks for 2018 was 21.1 per 1,000 specimens received. Table 26.4 summarises the recollection rates for each NZBS Blood Bank in 2018. Overall, 64% of the specimen with an error resulted in a request for recollection of the pretransfusion specimen.

TABLE 26.4 PRETRANSFUSION SPECIMEN RECOLLECTION REQUESTS 2018 BY NZBS BLOOD BANK SITE

	Number Recollection Requests	Total Number of Specimens	Frequency	% Errors Requiring Re-collection	Rate / 1,000 Specimens (95% CI)
Dunedin	318	10,400	1:33	78%	30.6 (27.4 to 34.1)
Palmerston North	217	8,403	1:39	69%	25.8 (22.6 to 29.4)
Waikato	569	25,143	1:44	40%	22.6 (20.9 to 24.5)
Wellington	506	22,645	1:45	64%	22.3 (20.5 to 24.4)
Christchurch	450	22,981	1:51	66%	19.6 (17.9 to 21.5)
Auckland	906	51,316	1:57	89%	17.7 (16.6 to 18.8)
NZBS	**2,966**	**140,888**	**1:48**	**64%**	**21.1 (20.3 to 21.8)**

27 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 specimen was collected from the wrong patient or the specimen 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 eTraceline. A current WBIT is where the specimen received is proven to be incorrectly labelled. A historic WBIT is where the historic grouping result was likely based on a specimen 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 2018, historic ABO RhD blood groups were available in eTraceline for 72% (range for the six NZBS Blood Banks 66% to 74%) of all pretransfusion specimen submitted to NZBS Blood Banks. There were 12 WBIT errors identified. In one case, the historic result was assumed to be incorrect. Table 27.1 shows the corrected WBIT rate for the 11 current WBIT events reported by the NZBS Blood Banks in 2018. The overall corrected WBIT rate was 1.7 per 10,000 samples (1:5,729).

TABLE 27.1 NZBS WBIT EVENTS 2018 BY BLOOD BANK SITE

	WBIT Events	Historic Groups	WBIT Frequency[1]	Rate / 10,000 Specimens (95% CI)[1]
Auckland	8	37,384	1:2,921	3.4 (1.9 to 5.9)
Hamilton	2	18,548	1:5,796	1.7 (0.4 to 5.2)
Wellington	1	16,508	1:10,318	1.0 0 to 4.4)
Christchurch	0	15,247	0	0 (0 to 3.0)
Dunedin	0	7,136	0	0 (0 to 6.5)
Palmerston North	0	6,003	0	0 (0 to 7.7)
NZBS Total	**11**	**100,826**	**1:5,729**	**1.7 (1.1 to 2.8)**

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

Table 27.2 shows the cumulative number of WBIT errors for the six NZBS Blood Banks over a twelve year period from 2007 to 2018. The overall corrected WBIT rate was 2.5 per 10,000 samples (1:4,022). An international study (Dzik et al. Vox Sanguinis 2003: 85; 40-47) involving ten countries reported an approximate median WBIT rate of 5 per 10,000 specimen (1:2,000).

NZBS Wrong Blood in Tube (WBIT) Events continued

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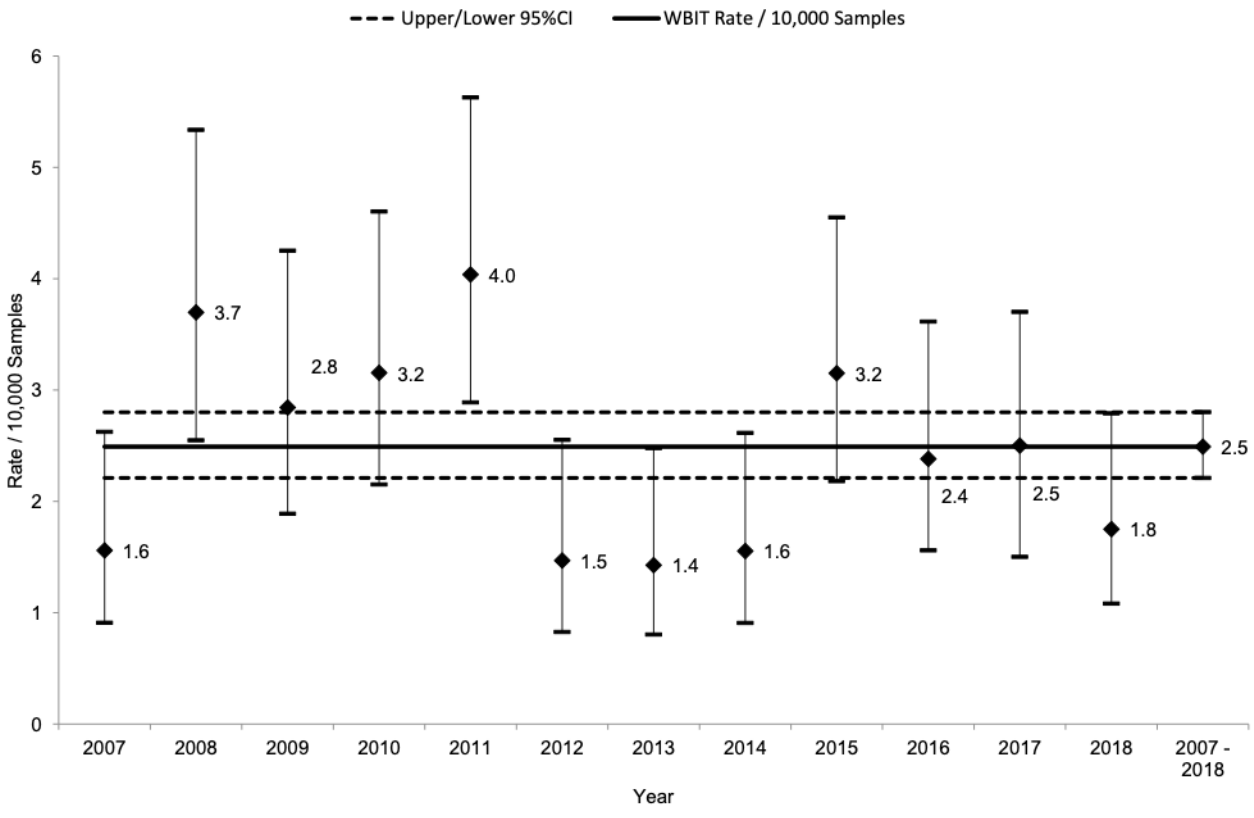
TABLE 27.2 NZBS WBIT EVENTS 2007 – 2018 BY BLOOD BANK SITE

	WBIT Events	Historic Groups	WBIT Frequency[1]	Rate/10,000 Specimen (95% CI)[1]
Wellington	45	166,800	1:2,317	4.3 (3.4 to 5.4)
Palmerston North	13	69,328	1:3,333	3.0 (1.9 to 4.6)
Auckland	58	378,927	1:4,083	2.4 (2.0 to 3.0)
Christchurch	24	178,479	1:4,648	2.2 (1.6 to 3.0)
Dunedin	8	75,096	1:5,867	1.7 (1.0 to 3.0)
Hamilton	20	212,416	1:6,638	1.5 (1.1 to 2.1)
NZBS Totall	**168**	**1,081,046**	**1:4,022**	**2.5 (2.2 to 2.8)**

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

The annual NZBS WBIT event rate per 10,000 (95% CI) specimen from 2007 to 2018 is shown in Figure 27.1.

FIGURE 27.1 FIGURE 27.1 ANNUAL NZBS WBIT EVENT RATE 2007 – 2018



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 ☐☐☐☐☐☐☐
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National Haemovigilance Programme 111F04208

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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 Events to Fractionated Blood Products

NZBS Use Only:

NZBLOOD Te Ratonga Toto O Aotearoa

FRACTIONATED BLOOD PRODUCT - ADVERSE EVENT NOTIFICATION

Recipient Details (pre-printed label may be used)				
Family Name / First Names		National Health Index No.	Weight (kg)	Height (cm)
Address		Date of Birth (dd/mm/yyyy)	Gender ☐Male ☐Female	Pregnant ☐Yes ☐No or N/A

Diagnosis and Indication for Fractionated Blood Product (include relevant medical history/allergies/surgery/LMP if pregnant):

Suspected or Implicated Fractionated Blood Product(s) - *add a separate page if necessary*

Blood Product(s)	Dose / Volume Prescribed	Route	Date Given	Start time	Dose/Volume Administered	Stop time (infusions only)	Batch Number(s)

If an IV or SC product: Infusion Rate - *at start:* _____ *mL/hr* Infusion Rate - *at time of reaction:* _____ *mL/hr*

If a freeze dried product: The solvent used to reconstitute: ☐ As supplied ☐ Other: (specify)

Description of Adverse Reaction or Event (signs, symptoms, relevant test results) – *add separate page if necessary*

Date adverse event detected: / / 20

Details:

Treatment of Adverse Reaction or Event (include any medicines given, with dose/route)

Other Medicines in Use (include any premedications, anaesthetic agents and 'over the counter' products) – *add a separate page if necessary*

Medicine	Daily Dose (with units)	Route	Date Started *or* >3 months	Date Stopped *or* Ongoing	Indication(s) for Use

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

NZBS Use Only:

FRACTIONATED BLOOD PRODUCT - ADVERSE EVENT NOTIFICATION

Assessment and Imputability of Adverse Event	
Previous therapy with suspected blood product? *(summary only)* ▪ *Product Name:* ▪ *Date Started:* ▪ *Frequency:*	☐ Yes ☐ No ☐ Not applicable
Has the suspected blood product been tolerated in the past?	☐ Yes ☐ No ☐ Not applicable
After stopping suspected blood product, did the reaction abate?	☐ Yes ☐ No ☐ Not applicable
If the blood product was re-introduced, did the reaction reoccur?	☐ Yes ☐ No ☐ Not applicable

Was the event classified as serious? *(Was treatment needed to preserve life?)*	**Causality Assessment:**
☐ **Yes** ☐ **No** ***If yes,*** *please tick at least one of the following outcome boxes:* ☐ Life-threatening ☐ Persistence of significant disability / incapacity ☐ Required intervention to prevent permanent impairment / damage ☐ Congenital anomaly / birth defect ☐ Required hospitalisation or hospitalisation was prolonged ☐ Suspected infusion of an infectious agent ***If no,*** *did the patient require hospitalisation or was hospitalisation prolonged?* ☐ Yes ☐ No ☐ N/A	*Likely correlation to blood product* ☐ Highly probable ☐ Possible ☐ Unlikely ☐ Unassessable ☐ Unrelated

Case Outcome: *(on the day of reporting this event)*
☐ Recovered: Date _____ Time _____ *or* ☐ Not yet recovered
☐ Recovered with sequelae (specify):
☐ Permanently disabled
☐ Death: Date _____ Autopsy: Date _____ *or* ☐ not undertaken

Report type: *(please tick all that apply)*

☐ Product used for a MedSafe-registered indication	☐ Section 29 Medicine	☐ Medication error
☐ Incorrect product transfused	☐ Overdose	☐ Under-dose
☐ Pregnancy	☐ Lactation occurring	☐ Quality defect in product
☐ Lack of effect	☐ Idiosyncratic effect	☐ Unexpected therapeutic benefit
☐ Occupational exposure	☐ Off-label use	☐ Misuse

Adverse Event Reported by: (essential)	**Treating Specialist/GP/Midwife: (essential)**
Name/Role: Organisation and Address: Phone: EMAIL: (essential) **DATE:**	Name/Role: Organisation and Address: Phone: EMAIL: (essential)
If the reporter is the patient, has consent been given by the patient to contact the treating specialist to follow-up the adverse event ☐ Yes ☐ No	**Registrar name and email:** *(if relevant)*

Return the completed form to the Blood Bank as soon as possible.
If the adverse event is serious, please contact a Transfusion Medicine Specialist, via your local Blood Bank.

Blood Bank	Telephone	Fax	Blood Bank	Telephone	Fax	Blood Bank	Telephone	Fax
Auckland	09 307 2834	09 307 2823	Palmerston North	06 350 8558	06 357 2854	Christchurch	03 364 0310	03 364 0159
Waikato	07 839 8919	07 858 0988	Wellington	04 918 6961	04 385 5982	Dunedin	03 470 9369	03 470 9513

The Blood Bank on receipt will forward this form to the NZBS National Reporting Centre via:
Adverse.Reaction@nzblood.co.nz (preferred) **or Fax (03) 470-9513** (if no facility to email)
The NZBS National Reporting Centre will notify the manufacturer, and if indicated, MedSafe and CARM.

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Appendix III. Reporting Adverse Events Associated with Blood Donation

NATIONAL
107M00510

REPORTING OF ADVERSE EVENTS RELATED TO BLOOD DONATION

REASON FOR ISSUE: To include instructions for registered nurses to check forms for completion prior to forwarding to MO/TMS. To refer to completion of the revised Donor Adverse Event form.

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.
- Collections 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 donors 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.

Appendix III. Reporting Adverse Events Associated with Blood Donation continued

NATIONAL
107M00510

REPORTING OF ADVERSE EVENTS RELATED TO BLOOD DONATION

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

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.

Appendix III. Reporting Adverse Events Associated with Blood Donation continued

Mechanism: Re-bleeding may be related to pressure not being applied to the correct location or for an adequate duration, or premature removal.
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, sometime 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

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

Appendix III. Reporting Adverse Events Associated with Blood Donation continued

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REPORTING OF ADVERSE EVENTS RELATED TO BLOOD DONATION

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

Appendix III. Reporting Adverse Events Associated with Blood Donation continued

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REPORTING OF ADVERSE EVENTS RELATED TO BLOOD 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 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, session coordinator or the Clinical Nurse 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.
- Tick all boxes that apply for the Adverse Event Details sections on page 1 of 107F005.
- Provide details of all care and advice given to donor
- 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 on 107F005. 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).
- For complications in A and B, tick **only one** of the grades of severity as is seen appropriate.
- **Complete form by filling in name and signing the document.**

6.4. Once the Donor Adverse Event Report has been completed, pass the form to the Clinical Nurse Leader/Session Coordinator at the end of the session or immediately after follow up has been completed.

6.4.1. A designated Registered Nurse must check the form to ensure all necessary actions are completed prior to forwarding to the appropriate MO/TMS for final review and sign off.

6.5. The Medical Officer/TMS reviews the adverse event and action taken. If required, further action and follow up is carried out by the Medical Officer/TMS. 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: (6)
☐	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 Rahonga Toto O Aotearoa

NATIONAL
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DONOR ADVERSE EVENT REPORT

				OFFICE USE ONLY Database Record No:	
EVENT DETAILS					
Venue:	☐ Static Site ☐ Mobile	**Site:**		**Event Date:**	
				Event Time:	
Type of Report:	☐ At Session	☐ Phone Call	☐ Personal Visit	☐ Email	☐ Letter
Type of Donation:	☐ Whole Blood ☐ TV Patient (Type 11)	☐ Plasma Target Volume - _____ g		☐ Platelets	☐ HPC / Granulocyte
New Donor:	☐ Yes ☐ No	**Red Cells Returned:**		☐ Yes ☐ No ☐ N/A	
Time of report:		**Date of report:**		**Completed by:**	
DONOR DETAILS					
Full Name:					
DOB:		**Gender:**	M ☐ F ☐	**Phone No:**	
eProgesa ID:		**Donation Number:**			

ADVERSE EVENT DETAILS		
Vasovagal / Citrate (Circle One)		**Needle related** ☐ Left arm ☐ Right arm
☐ Pallor, pale skin/lips	☐ Hyperventilation	☐ Haematoma / Bruising
☐ Lightheaded/dizziness	☐ Tingling/Numbness - lips/fingers	☐ Re-bleeding
☐ General discomfort/weakness	☐ Muscle cramping	☐ Swelling of arm
☐ Sweaty/Clammy	☐ Twitching	☐ Pain at needle site
☐ Nausea/Vomiting	☐ Convulsion	☐ Pain shooting down arm
☐ Fainted/LOC (< 60 sec)	☐ Loss of bladder/bowel control	☐ Numbness/tingling of finger, hand or arm
☐ Fainted/LOC (≥ 60 sec)		☐ Possible arterial puncture
☐ Other (specify in comments below)		☐ Pain localised in elbow area
Allergic Reactions		
☐ Redness at needle site	☐ Wheezing	☐ Scratchy feeling in throat
☐ Rash/hives/itching at needle site	☐ Difficulty breathing	☐ Swollen face/tongue/eyes/throat
☐ Generalised rash/hives/itching	☐ Anxiety/restlessness	
Interventions/Management		
☐ Needle removed	☐ After care discussed	☐ Oxygen administered: L/min
☐ Fan used	☐ Hydration discussed	☐ Calcium supplement given:
☐ Fluids offered/given	☐ Diet discussed	Time given ……..
☐ Cool compress applied	☐ Changeover performed	Time given ……..
☐ Placed in recovery position	☐ MO informed/Consulted	☐ Faints/Syncope leaflet given
☐ Legs elevated	☐ Rang 111	☐ Haematoma leaflet given
☐ Ice pack applied	☐ Transported to hospital	☐ Follow up offered:
☐ Pressure bandage applied	☐ Other, specify:	☐ Accepted ☐ Refused
☐ Advised to take slow/deep breaths		☐ Return from apheresis to WB donation
Outcome of procedure:	☐ Donation Completed	☐ Donation Discontinued
Comments e.g. haematoma size/description:		

Author: Robyn Millett
Authoriser: Maree Clarkin/Jim Faed
QA Approver: Jacqueline Hoole

Effective Date: 26/10/2018

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Previous ID: 107F00512
Refer to document(s):107M005

Appendix IV. Donor Adverse Event Report Form continued

NZBLOOD Te Ratonga Toto O Aotearoa

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DONOR ADVERSE EVENT REPORT

DONOR MONITORING					
	Time	BP	Pulse	Position (circle one) Reclining	Sitting
Pre-donation					
Observations					
Discharge					
Was Donor Hospitalised?		☐ Yes ☐ No		Comments/outcome	

☐ No action required ☐ Follow up required (If yes complete follow up then forward form to MO)
☐ DRM entry completed ☐ Deferral Code/Comments entered Deferred until / ☐ Permanent deferral

DONOR FOLLOW UP (if required)			
☐ Phone	☐ Message left	☐ No contact	☐ DRM entry completed
Comments including Deferral Instructions if any:			
Follow-up completed by:		Signature:	Date:

ADVERSE EVENT REVIEW DETAILS			
A. COMPLICATIONS MAINLY WITH LOCAL SYMPTOMS		Non-severe	Severe
A1. Complications mainly characterised by the occurrence of blood outside blood vessels	Haematoma	☐	☐
	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) Without other signs/symptoms	With other signs/symptoms and/or >60 secs	Severe
Immediate Vasovagal Reaction	Without Injury	☐	☐	☐	☐
	With Injury	☐	☐	☐	☐
Delayed Vasovagal Reaction	Without Injury	☐	☐	☐	☐
	With Injury	☐	☐	☐	☐

C. COMPLICATIONS RELATED TO APHERESIS		D. ALLERGIC REACTIONS	
Citrate Reaction		1. Local	☐
Haemolysis		2. Generalised allergic reaction	☐
Air Embolism			

E. OTHER SERIOUS COMPLICATIONS RELATED TO BLOOD DONATION

F. OTHER COMPLICATIONS

Signature:		Date:	

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

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SAVE LIVES
GIVE BLOOD

New Zealand Government