NZBLOOD
Te Ratonga Toto O Aotearoa

National Haemovigilance Programme

Annual Report
2017

Written by the New Zealand Blood Service Haemovigilance Steering Group:

- Dr Krishna Badami, Transfusion Medicine Specialist
- Mr John Dagger, Technical Advisor
- Dr Deepak Sadani, Transfusion Medicine Specialist

Other contributors

- Dr Richard Charlewood, Transfusion Medicine Specialist
- Mr Christopher Corkery, Transfusion Nurse Specialist
- Dr Jim Faed, Transfusion Medicine Specialist
- Dr Peter Flanagan, National Medical Director

Acknowledgements

- Karen Martin, Executive Assistant
- Carolyn Jeffrey, Business Analyst, Information Services

Contact details

National Haemovigilance Office
New Zealand Blood Service
Private Bag 7904
Wellington 6242

Telephone:	64 4 380 2003
Facsimile:	64 4 389 5608
Email:	haemovigilance@nzblood.co.nz
NZBS website:	www.nzblood.co.nz

Disclaimer

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

- Any information that becomes known solely as the result of Haemovigilance is confidential; and
- Any documents brought into existence solely for the purposes of Haemovigilance are confidential; and
- The persons who engage in Haemovigilance in good faith are immune from civil liability.

Cover. Celebrating the 20 years since the establishment of New Zealand Blood Service in July 1998.

1 Contents

Abbreviations and Glossary

1

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
Prothrombinex®-VF	Coagulation Factors II, IX and X and low levels of Factor 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
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 thirteenth 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. Upon publication of the Annual Haemovigilance Report the paper records are destroyed and the unique patient identifier is then deleted from the database.

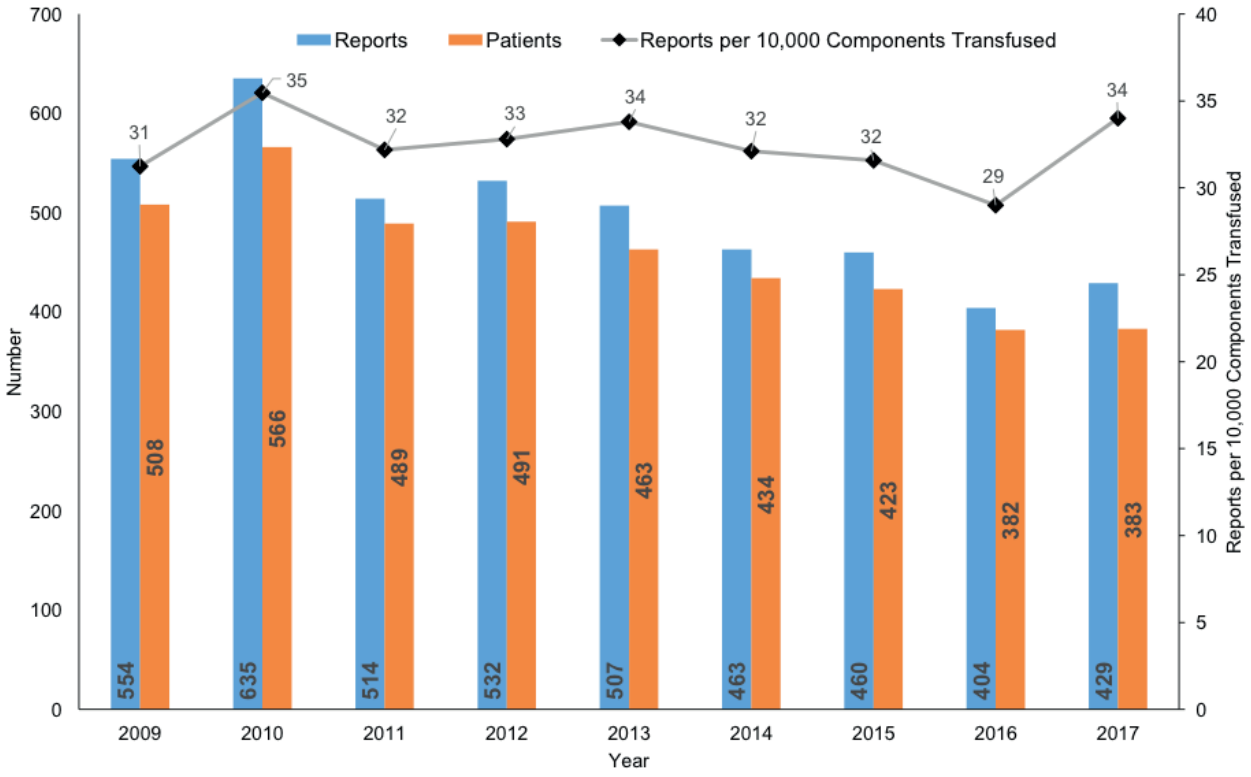
Reporting of TRAE to the National Haemovigilance Programme is voluntary. During 2017, there were 429 TRAE reported, involving 383 patients. Comparing 2017 to individual years from 2014 to 2016, the total number of reported events and the ratio of reports to number of components transfused shows no significant 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 2009 – 2017

	2009	2010	2011	2012	2013	2014	2015	2016	2017
Total Components Transfused	162,587	159,568	151,919	149,668	136,995	135,135	132,060	130,185	127,765
Number Haemovigilance Reports Received	554	635	514	532	507	463	460	404	429
Percentage Change From Previous Year									
Components Transfused		-1.9%	-4.8%	-1.5%	-8.5%	-1.4%	-2.3%	-1.4%	-1.9%
Haemovigilance Reports		14.6%	-19.1%	3.5%	-4.7%	-8.7%	-0.6%	-12.2%	6.2%
Reports : Components Transfused	**1:293**	**1:251**	**1:296**	**1:281**	**1:270**	**1:292**	**1:287**	**1:322**	**1:298**

Introduction continued

FIGURE 2.1 ANNUAL NUMBER OF TRANSFUSION-RELATED ADVERSE EVENTS 2009 – 2017



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 2017 to the number transfused in 2011, there has been a 16.3% reduction. Fresh frozen plasma use has stabilised with a small increase in use in 2017 compared to usage in 2016.

Cryoprecipitate usage shows a small decrease in the number of units transfused in 2017 compared to the number transfused in 2016.

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 2011 – 2017

Blood Component	2011	2012	2013	2014	2015	2016	2017	% Change 2017 compared to 2011
Red Cells	116,071	113,014	103,565	102,718	99,915	98,535	95,979	
Red Cells Neo	1,749	1,732	1,664	1,553	1,260	1,327	1,466	
Total Red Cells	**117,820**	**114,746**	**105,229**	**104,271**	**101,175**	**99,862**	**97,445**	**-17.3%**
Platelets - APH	6,661	2,117	487	523	411	530	548	
Platelets - Pooled	2,349	614	0	0	0	0	0	
Platelets - APH PAS	774	5,354	5,627	4,033	3,818	3,813	3,622	
Platelets - Pooled PAS	2,988	5,037	6,457	7,429	7,683	8,447	8,945	
Platelets - Neo	485	661	817	616	621	624	685	
Total Platelets	**13,257**	**13,783**	**13,388**	**12,601**	**12,533**	**13,414**	**13,800**	**4.1%**
Fresh Frozen Plasma	16,736	16,524	13,528	13,400	13,172	11,821	12,141	
Fresh Frozen Plasma Neo	127	200	175	151	162	161	131	
Total Fresh Frozen Plasma	**16,863**	**16,724**	**13,703**	**13,551**	**13,334**	**11,982**	**12,272**	**-27.2%**
Cryoprecipitate	3,228	3,745	4,167	4,198	4,482	4,463	4,147	28.5%
Cryodepleted Plasma	751	670	508	514	536	464	101	-86.6%
Total Components	**151,919**	**149,668**	**136,995**	**135,135**	**132,060**	**130,185**	**127,765**	**-15.9%**

Trends in Blood Component Transfusion in New Zealand continued

3

The annual blood component transfusion rates per 1,000 of the New Zealand population for the period 2011 to 2017 are shown in Table 3.2.

TABLE 3.2 ANNUAL RATE OF BLOOD COMPONENTS TRANSFUSED PER 1,000 NEW ZEALAND POPULATION 2011 – 2017

	Components Transfused per 1,000 Population						
	2011	2012	2013	2014	2015	2016	2017
Population Estimate*	4,384,000	4,408,100	4,442,100	4,509,700	4,595,700	4,696,500	4,793,600
Red Cells	28.6	26.9	26.0	23.7	23.1	22.0	21.3
Platelets	3.1	3.0	3.1	3.0	2.8	2.7	2.9
Fresh Frozen Plasma	4.1	3.8	3.8	3.1	3.0	2.9	2.6
Cryoprecipitate	0.7	0.7	0.8	0.9	0.9	1.0	1.0
Cryodepleted Plasma	0.1	0.2	0.2	0.1	0.1	0.1	0.1
All Components	**36.7**	**34.7**	**34.0**	**30.8**	**30.0**	**28.7**	**27.7**

** www.stats.govt.nz*

The decrease in the number of red cell, platelet and FFP units transfused is reflected by a similar decrease in the number of recipients of these components (Table 3.3). Compared to 2011, there has been a 15.6% reduction in the number of recipients of red cells, 37.7% decrease in fresh frozen plasma and 14.3% decrease in the transfusion of platelets.

TABLE 3.3 ANNUAL NUMBER OF RED CELL, PLATELET AND FRESH FROZEN PLASMA RECIPIENTS 2011 – 2017

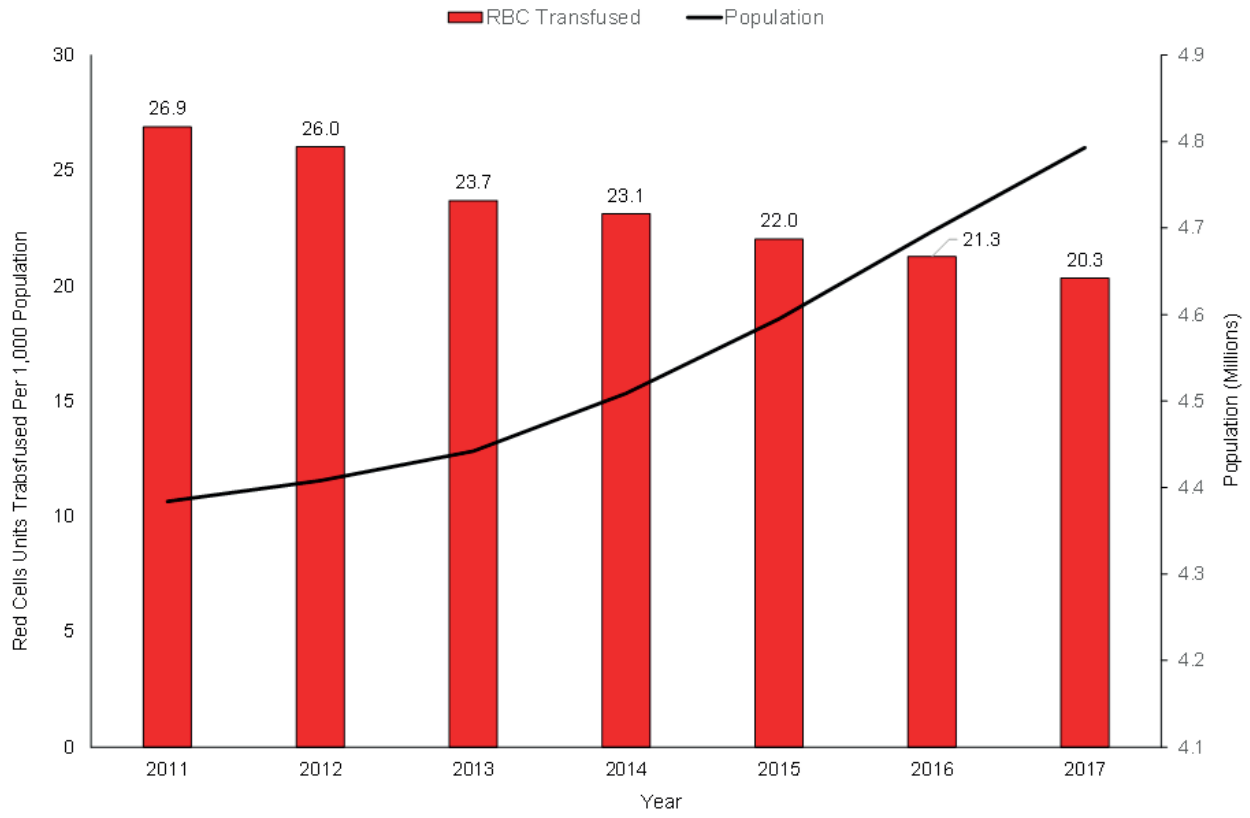
Component	Number of Recipients (Percentage Change from Previous Year)							% Change 2017 from 2011
	2011	2012	2013	2014	2015	2016	2017	
Red Cells	27,101	26,673 (-1.6%)	24,978 (-6.4%)	24,349 (-2.5%)	23,437 (-3.7%)	22,620 (-3.5%)	22,884 (1.2%)	-15.6%
Fresh Frozen Plasma	3,850	3,749 (-2.6%)	3,172 (-15.4%)	2,898 (-8.6%)	2,764 (-4.6%)	2,551 (-7.7%)	2,399 (-6.0%)	-37.7%
Platelets	3,623	3,531 (-2.5%)	3,272 (-7.3%)	3,190 (-2.5%)	3,198 (0.3%)	3,154 (-1.4%)	3,104 (-1.6%)	-14.3%

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 17.3% since 2011 despite population increases of 9.3% (Figure 3.1). This is also reflected in a gradually decreasing pre-transfusion haemoglobin from 81.5g/L in 2006 to 74.4g/L in 2017 from recipients that had a reported adverse event to a blood component. The number of recipients has also declined by 15.6% over the same time period.

3 Trends in Blood Component Transfusion in New Zealand continued

The reduction in the use of fresh frozen plasma may be accounted for by the introduction in 2013 of revised warfarin reversal guidelines. Fresh frozen plasma should only be used to reverse warfarin anticoagulation in the presence of bleeding or prior to emergency surgery where a prothrombin complex concentrate is unavailable or deemed inappropriate.

FIGURE 3.1 RATE RED CELL UNITS TRANSFUSED PER 10,000 POPULATION 2011 – 2017



Trends in Blood Component Transfusion in New Zealand continued

3

Table 3.4 shows the number of blood components transfused and the transfusion rate for all New Zealand District Health Boards in 2017

TABLE 3.4 BLOOD COMPONENT TRANSFUSION RATES BY DISTRICT HEALTH BOARD 2017

District Health Board	Population	Number Components Transfused		Transfusion Rate Per 10,000 Population	
		All Components	Red Cells	All Components	Red Cells
Waitemata DHB	606,000	8,737	7,494	144	124
Canterbury DHB	551,400	13,971	11,163	253	202
Counties Manukau DHB	546,600	11,734	9,732	215	178
Auckland DHB	523,500	30,078	18,918	575	361
Waikato DHB	408,800	13,289	9,684	325	237
Southern DHB	324,300	6,880	5,509	212	170
Capital and Coast DHB	312,700	13,155	9,011	421	288
Bay of Plenty DHB	231,900	4,573	3,876	197	167
MidCentral DHB	176,600	5,089	4,110	288	233
Northland DHB	175,400	3,077	2,687	175	153
Hawkes Bay DHB	163,900	3,387	2,683	207	164
Nelson Marlborough DHB	148,800	3,229	2,953	217	198
Hutt Valley DHB	147,900	1,689	1,577	114	107
Taranaki DHB	118,100	2,089	1,900	177	161
Lakes DHB	108,500	1,694	1,483	156	137
Whanganui DHB	64,100	1,171	1,100	183	172
South Canterbury DHB	59,600	1,542	1,380	259	232
Tairawhiti DHB	48,500	862	756	178	156
Wairarapa DHB	44,500	1,052	992	236	223
West Coast DHB	32,500	467	437	144	134
Total	**4,793,600**	**127,765**	**97,445**	**267**	**203**

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 FFP components transfused during 2017.

TABLE 4.1 RECIPIENTS OF BLOOD COMPONENTS 2017

		Blood Component		
		Red Cells	Platelets	FFP
Recipient Gender (number)	Female	12,832	1,183	1,001
	Male	9,973	1,915	1,391
	Unknown	79	6	7
	Total	**22,884**	**3,104**	**2,399**
Recipient Age (years)	Mean	61	54	56
	Median	68	62	62
	Maximum	105	96	97
	Minimum	0	0	0
Units Transfused per Recipient	Mean	4	4	5
	Median	2	2	2
	Maximum	135	131	528
	Minimum	1	1	1

Table 4.2 and Figure 4.1 show the yearly mean pre-transfusion haemoglobin from 2006 to 2017 for recipients of red cells where an adverse event was reported. There has been a significant decrease (p=<0.001) from 2006 (81.5g/L) to 2017 (74.4g/L).

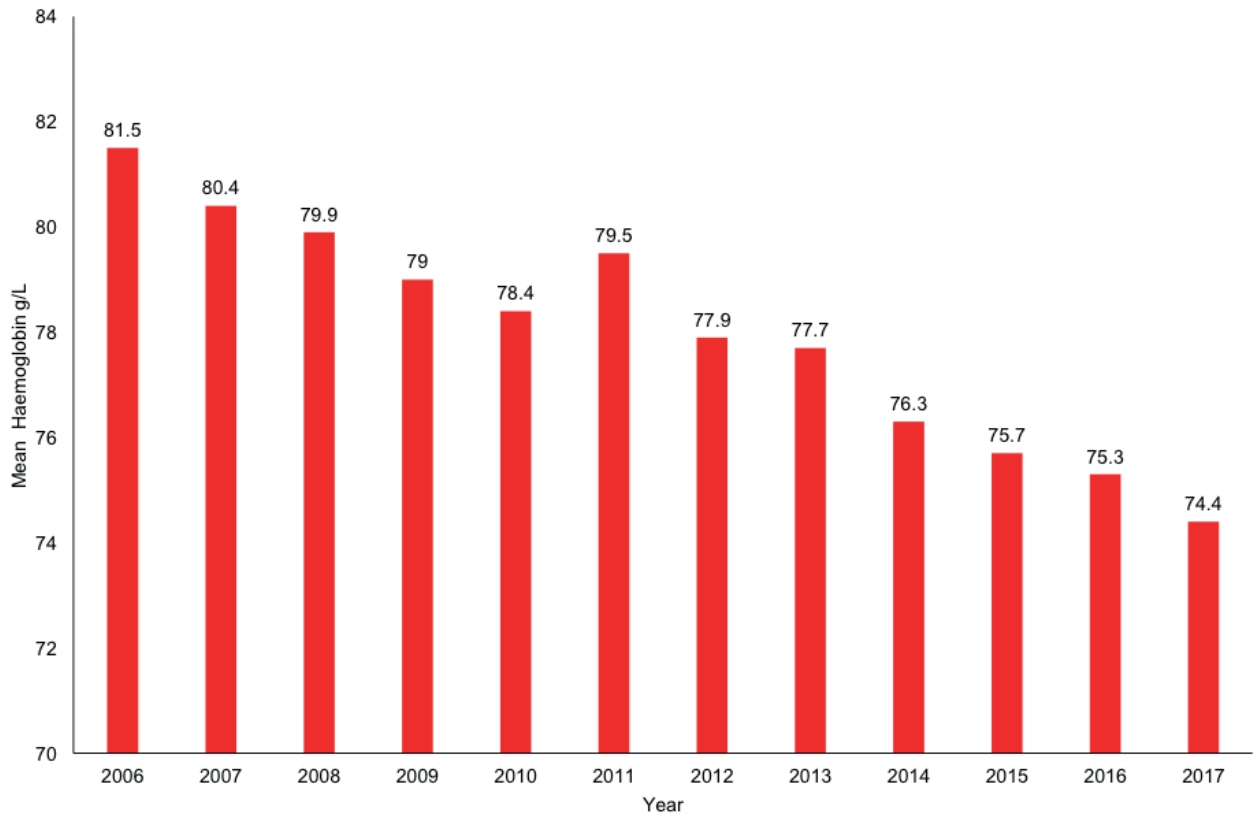
TABLE 4.2 ANNUAL MEAN PRE-TRANSFUSION HAEMOGLOBIN CONCENTRATION 2006 – 2017

Year	Number Recipients	Mean Hb g/L	SD
2006	255	81.5	14.8
2007	290	80.4	13.5
2008	322	79.9	11.5
2009	357	79.0	11.5
2010	404	78.4	11.1
2011	306	79.5	11.2
2012	347	77.9	12.4
2013	351	77.7	11.2
2014	241	76.3	11.2
2015	306	75.7	10.2
2016	257	75.3	11.1
2017	305	74.4	11.3

4

Recipients of Blood Components continued

FIGURE 4.1 ANNUAL MEAN PRE-TRANSFUSION HAEMOGLOBIN CONCENTRATION 2006 – 2017



5 Transfusion-Related Adverse Events: Reporting District Health Boards

During 2017, transfusion-related adverse events (TRAE) were reported from all New Zealand District Health Boards (DHB) except Tairawhiti, Whanganui and the West Coast DHBs. The number of events of imputability ≥3 per District Health Board and the event rate per 10,000 component units transfused are shown in Table 5.1 and Figure 5.2. The 2017 national TRAE rate was 23.6 per 10,000 component units transfused compared to 25.0 per 10,000 components transfused in 2016.

FIGURE 5.1 DISTRICT HEALTH BOARD BOUNDARIES

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

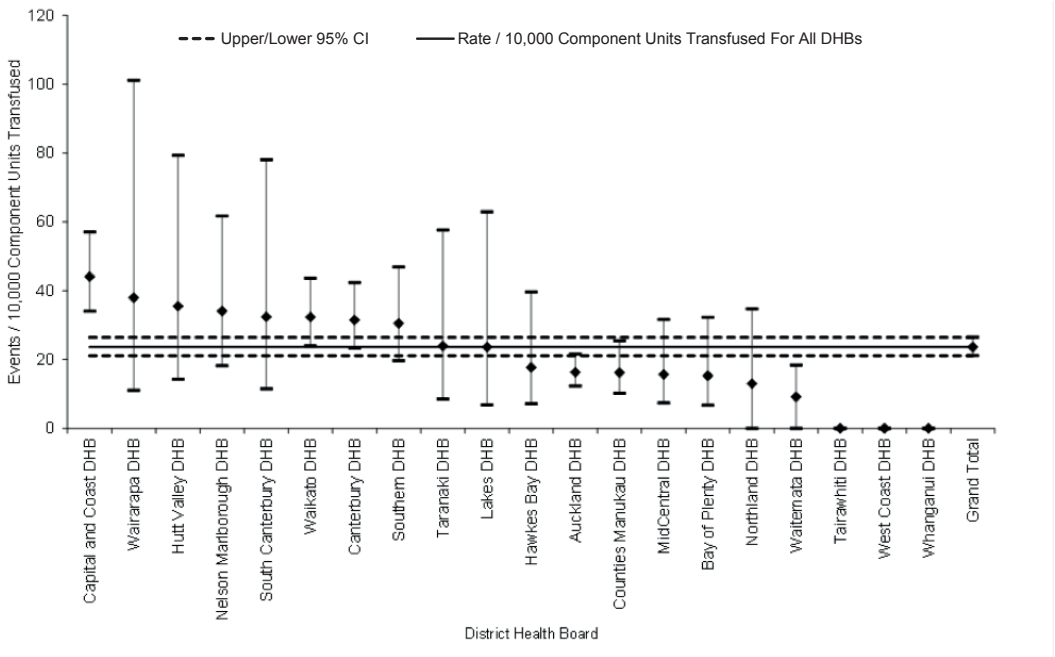
Transfusion-Related Adverse Events: Reporting District Health Boards continued

5

TABLE 5.1 TRANSFUSION-RELATED ADVERSE EVENTS (IMPUTABILITY ≥3) 2017 BY REPORTING DISTRICT HEALTH BOARD

District Health Board	Events	Units Transfused	Frequency	Rate / 10,000 Units Transfused (95%CI)
Capital and Coast DHB	58	13,155	1:227	44.1 (34.0 to 57.0)
Wairarapa DHB	4	1,052	1:263	38.0 (11.0 to 101.1)
Hutt Valley DHB	6	1,689	1:282	35.5 (14.3 to 79.3)
Nelson Marlborough DHB	11	3,229	1:294	34.1 (18.2 to 61.7)
South Canterbury DHB	5	1,542	1:308	32.4 (11.5 to 78.1)
Waikato DHB	43	13,289	1:309	32.4 (23.9 to 43.7)
Canterbury DHB	44	13,971	1:318	31.5 (23.4 to 42.3)
Southern DHB	21	6,880	1:328	30.5 (19.7 to 46.9)
Taranaki DHB	5	2,089	1:418	23.9 (8.5 to 57.7)
Lakes DHB	4	1,694	1:424	23.6 (6.8 to 62.9)
Hawkes Bay DHB	6	3,387	1:565	17.7 (7.1 to 39.6)
Auckland DHB	49	30,078	1:614	16.3 (12.3 to 21.6)
Counties Manukau DHB	19	11,734	1:618	16.2 (10.2 to 25.5)
MidCentral DHB	8	5,089	1:636	15.7 (7.4 to 31.6)
Bay of Plenty DHB	7	4,573	1:653	15.3 (6.7 to 32.3)
Northland DHB	4	3,077	1:769	13.0 (3.8 to 34.7)
Waitemata DHB	8	8,737	1:1,092	9.2 (4.3 to 18.4)
Tairawhiti DHB	0	862		
West Coast DHB	0	467		
Whanganui DHB	0	1,171		
Total	**302**	**127,765**	**1:423**	**23.6 (21.1 to 26.5)**

FIGURE 5.2 TRANSFUSION-RELATED ADVERSE EVENTS (IMPUTABILITY ≥3) 2017 BY REPORTING DISTRICT HEALTH BOARD



6 Transfusion-Related Adverse Events: Imputability

During 2017, a total of 429 TRAE were reported to the National Haemovigilance programme. A total of 127 (29.6%) had a low (≤2) imputability score and were excluded from the analysis since they were unlikely to be attributable to transfusion. Excluded events were predominantly reported as either febrile non-haemolytic transfusion reactions (FNHTR) or unclassifiable complications of transfusion (UCT). Imputability score definitions (ISBT/IHN) are provided in Table 6.1.

TABLE 6.1 IMPUTABILITY SCORE DEFINITIONS

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

The number of reported events excluded due to low (≤2) imputability per year from 2009 to 2017 are shown in Table 6.2 and Table 6.3. As a proportion of all TRAE, the number with low (≤2) imputability has increased 92% since 2009 and in 2017, comprised nearly one third of all TRAE. These events are predominantly FNHTR (73%) and UCT (9%). This trend may be due to both increased reporting of mild rises in temperature that do meet criteria for FNHTR and an improvement in classifying adverse reactions; the latter being aided by an increasing awareness of clinicians in the value of providing complete clinical information and where necessary, a concerted effort by the Haemovigilance Steering Committee to obtain additional detail for accurate event classification.

TABLE 6.2 TRANSFUSION-RELATED ADVERSE EVENTS OF LOW ≤2 IMPUTABILITY 2009 – 2017

	2009	2010	2011	2012	2013	2014	2015	2016	2017
Total Events	554	635	514	532	507	463	460	404	429
Number Imputability ≤2	66	80	72	90	71	106	97	78	127
Percentage	11.9%	12.6%	14.0%	16.9%	14.0%	23.0%	21.1%	19.3%	29.6%

6

Transfusion-Related Adverse Events: Imputability continued

TABLE 6.3 TRANSFUSION-RELATED ADVERSE EVENTS OF LOW ≤2 IMPUTABILITY 2009 – 2017 BY EVENT TYPE

	Percentage of Annual Total Reports of Low Imputability ≤2								
	2009	**2010**	**2011**	**2012**	**2013**	**2014**	**2015**	**2016**	**2017**
FNHTR	34.3%	55.0%	72.6%	53.3%	70.4%	64.2%	69.1%	60.8%	**73.2%**
UCT	34.3%	23.8%	16.4%	16.7%	23.9%	26.4%	13.4%	16.5%	**9.4%**
Allergic	9.0%	6.3%	2.7%	14.4%	1.4%	1.9%	2.1%	2.5%	**1.6%**
DSTR	3.0%	1.3%	2.7%	4.4%	0%	0%	8.2%	7.6%	**5.5%**
Hypotension	3.0%	6.3%	2.7%	2.2%	0%	2.8%	3.1%	3.8%	**2.4%**
IBCT	10.4%	3.8%	2.7%	0%	0%	0.9%	0%	2.5%	**1.6%**
TAD	3.0%	3.8%	0%	4.4%	2.8%	0.9%	1.0%	0%	**0%**
TACO	0%	0%	0%	2.2%	1.4%	0%	2.1%	3.8%	**6.3%**
Acute Haemolytic	0%	0%	0%	1.1%	0%	0.9%	1.0%	1.3%	**0%**
TRALI	0%	0%	0%	0%	0%	1.9%	0%	1.3%	**0%**
DHTR	0%	0%	0%	1.1%	0%	0%	0%	0%	**0%**
Pain	1.5%	0%	0%	0%	0%	0%	0%	0%	**0%**
TTI	1.5%	0%	0%	0%	0%	0%	0%	0%	**0%**
Total Reports Imputablity ≤2	**66**	**80**	**72**	**90**	**71**	**106**	**97**	**78**	**127**

Table 6.4 shows all reported events in 2017 by event type and imputability score

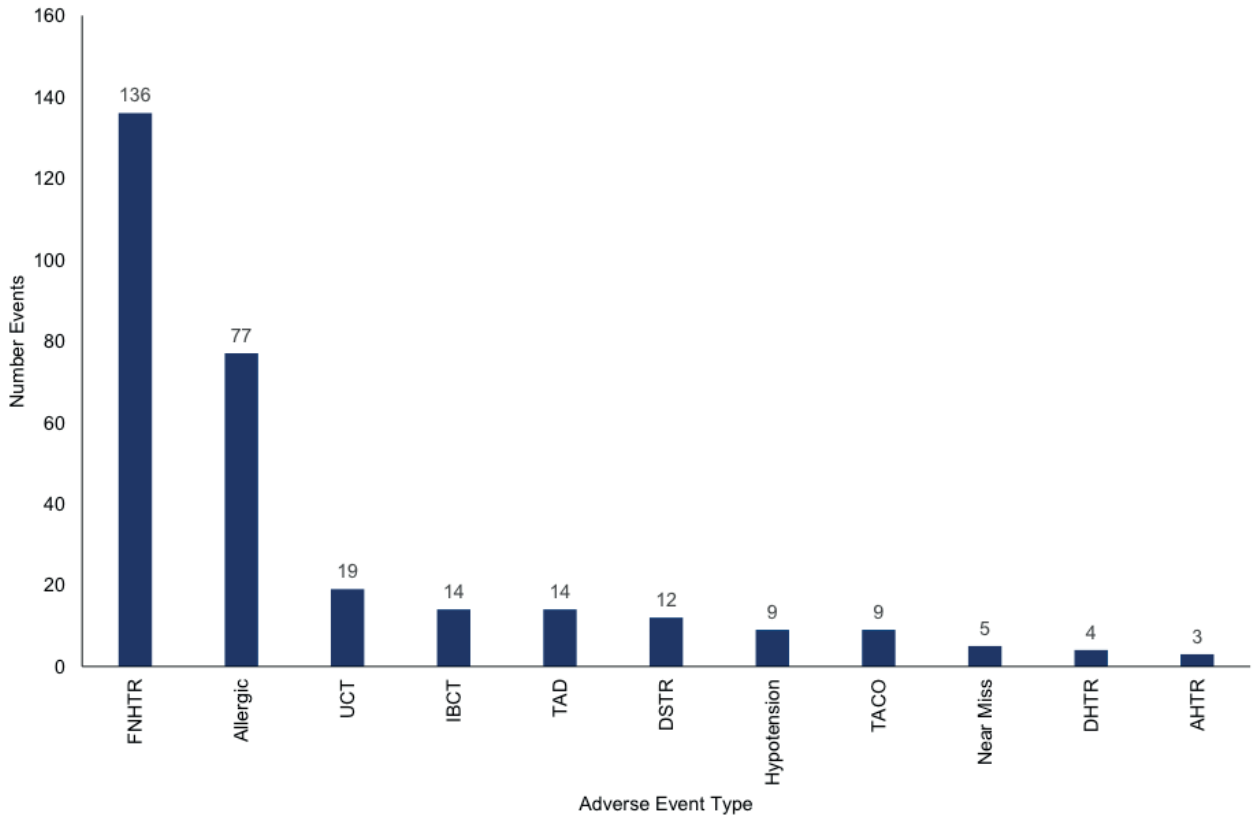
TABLE 6.4 TRANSFUSION-RELATED ADVERSE EVENTS 2017 BY EVENT TYPE AND IMPUTABILITY SCORE

Event Type	**Imputability Score**					**Total**	**Total ≥3**
	1	**2**	**3**	**4**	**5**		
FNHTR	60	33	105	31		229	136
Allergic	1	1	31	39	7	79	77
UCT	7	5	15	4		31	19
DSTR	7		2	3	7	19	12
TACO	3	5	6	2	1	17	9
IBCT	2				14	16	14
TAD			11	3		14	14
Hypotension	3		8	1		12	9
Near Miss					5	5	5
DHTR			2		2	4	4
AHTR			1	2		3	3
Total	**83**	**44**	**181**	**85**	**36**	**429**	**302**
Percentage Events	19.3%	10.3%	42.2%	19.8%	8.4%		

Data analysed and included in the remainder of the Annual Haemovigilance Report is restricted to the 302 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) 2017 BY EVENT TYPE



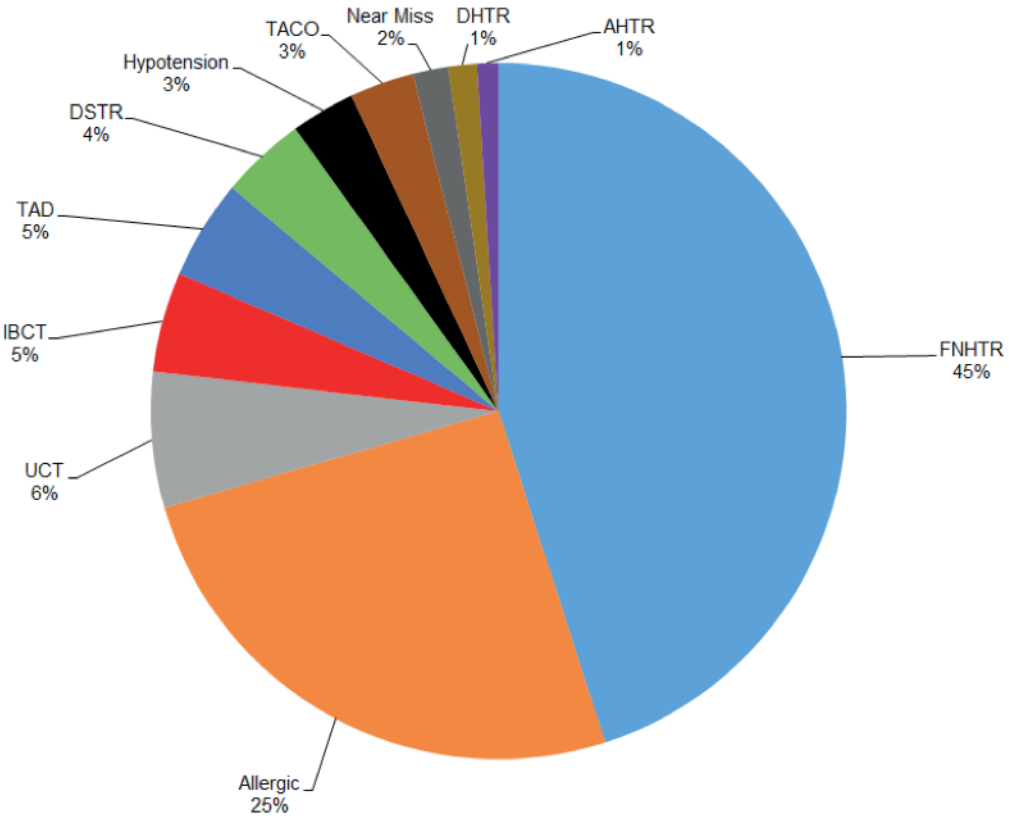
Key:

FNHTR	Febrile non-haemolytic transfusion reaction
Allergic	Allergic transfusion reaction
UCT	Unclassifiable complication of transfusion
IBCT	Incorrect blood component transfused
TAD	Transfusion-associated dyspnoea
DSTR	Delayed serologic transfusion reaction
TACO	Transfusion-associated circulatory overload
DHTR	Delayed haemolytic transfusion reaction
AHTR	Acute haemolytic transfusion reaction

6

Transfusion-Related Adverse Events: Imputability continued

FIGURE 6.2 TRANSFUSION-RELATED ADVERSE EVENTS (IMPUTABILITY ≥3) 2017 BY EVENT TYPE



There were 273 transfusion recipients associated with the 302 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) 2017 BY RECIPIENT GENDER

		Age (years)		
	Number	Mean	Minimum	Maximum
Female	140	65	7 days	98
Male	162	62	1 day	90
Total	**302**	**60**	**1 day**	**98**

Multiple TRAE were reported in 22 patients (Table 6.6).

TABLE 6.6 NUMBER OF RECIPIENTS HAVING MULTIPLE TRANSFUSION-RELATED ADVERSE EVENTS (IMPUTABILITY ≥3) 2017

		Events			
	Total	1 Event	2 Events	3 Events	4 Events
Recipient Numbers	273	251	16	5	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, 91% were assessed as non-severe (Grade 1). Severe (Grade ≥2) events were 8% of all events and 63% of these were either allergic or TACO in nature (Table 7.2).

TABLE 7.1 SEVERITY SCORE DEFINITIONS FOR TRANSFUSION-RELATED ADVERSE EVENTS 2017

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

TABLE 7.2 TRANSFUSION-RELATED ADVERSE EVENTS (IMPUTABILITY ≥3) 2017 BY EVENT TYPE AND SEVERITY

Event Type	Severity				
	Grade 1	Grade 2	Grade 3	Grade 4	Total
FNHTR	133	3			136
Allergic	66	10	1		77
UCT	18		1		19
IBCT	14				14
TAD	13	1			14
DSTR	12				12
Hypotension	7	2			9
TACO	3	5	1		9
Near Miss	5				5
DHTR	3	1			4
AHTR	1	2			3
Total	**275**	**24**	**3**		**302**
Percentage Events	91.1%	7.9%	1.0%		

8 Transfusion-Related Adverse Events: Implicated Blood Components

A total of 127,765 blood component units were transfused in 2017. Of these, 299 units were implicated in the 302 reported adverse events. The overall adverse event rate in 2017 was 1 in 427 units transfused (23.4 per 10,000 units transfused, 95% CI 20.9 to 26.2). Table 8.1 shows the adverse event rates for the individual blood component types in 2017.

TABLE 8.1 TRANSFUSION-RELATED ADVERSE EVENTS (IMPUTABILITY ≥3) 2017 BY BLOOD COMPONENT TYPE

Component	Units Implicated in TRAE[1]	Units Transfused	Frequency	Rate / 10,000 Units Transfused (95%CI)
Platelets Pooled PAS	31	8,945	1:289	34.7 (24.2 to 49.3)
Platelets Apheresis PAS	15	4,855	1:324	30.9 (18.3 to 51.4)
Red Cells	232	97,445	1:420	23.8 (20.9 to 27.1)
Fresh Frozen Plasma	19	12,272	1:646	15.5 (9.7 to 24.3)
Cryoprecipitate	2	4,147	1:2,074	4.8 (0.1 to 18.8)
Platelets (Apheresis)[2]	0	1,233		0.0 (0 to 37.5)
Cryodepleted Plasma	0	101		0.0 (0 to 439.9)
Total	**299**	**127,765**	**1:427**	**23.4 (20.9 to 26.2)**

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

[2] *Platelets suspended in plasma includes 685 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) 2017 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	**97,445**	**12,272**	**1,233**	**3,622**	**8,945**	**4,147**	**101**		
FNHTR	1:792			1:3,622	1:895	1:4,147		1	0
Allergic	1:2,634	1:818		1:453	1:639	1:4,147		1	1
UCT	1:6,960			1:1,207	1:4,473			0	0
IBCT	1:13,921	1:6,136		1:3,622				0	0
TAD	1:8,859			1:3,622	1:8,945			1	0
DSTR	1:8,120							0	0
Hypotension	1:12,181	1:12,272						0	0
TACO	1:13,921	1:12,272						1	0
Near Miss	1:32,482				1:8,945			0	0
DHTR	1:24,361							0	0
AHTR	1:32,482							0	0
Total	**1:426**	**1:646**		**1:259**	**1:319**	**1:2,074**		**4**	**1**

[1] *Event associated with transfusion of granulocytes (buffy coats)*

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 reactions were the most frequently reported type of TRAE (48%). A total of 229 reports of FNHTR were received; 136 were of imputability ≥3 and included in the analysis. Of the reported events, 33 were of low ≤2 imputability and probably due to the patient's underlying medical condition. An additional 60 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) 2017 BY RECIPIENT GENDER

	Number	Age (years)		
		Mean	Minimum	Maximum
Female	62	64	6	98
Male	74	59	1 day	90
All	**136**	**62**	**1 day**	**98**

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

TABLE 9.2 FNHTR EVENTS (IMPUTABILITY ≥3) 2017 BY ASSOCIATED SIGNS AND SYMPTOMS

Symptom	Number			% Events		
	Female (=62)	Male (n=74)	Total (n=136)	Female	Male	Total
Chills / Rigors	36	40	76	58%	54%	56%
Increase in blood pressure	7	10	17	11%	14%	13%
Restlessness / Anxiety	8	5	13	13%	7%	10%
Dyspnoea	3	9	12	5%	12%	9%
Cough	1	7	8	2%	9%	6%
Tachycardia	3	3	6	5%	4%	4%
Nausea	4	2	6	6%	3%	4%
Abdominal pain	4	1	5	6%	1%	4%
Stridor / Wheeze	0	3	3	0%	4%	2%
Loin pain	2	1	3	3%	1%	2%
Vomiting	3	0	3	5%	0%	2%
Fall in blood pressure	1	1	2	2%	1%	1%
Chest pain	2	0	2	3%	0%	1%
Mean temperature rise	1.6°C	1.8°C	1.7°C			

9 Febrile Non-Haemolytic Transfusion Reactions (FNHTR)
continued

Of the reported FNHTR events, 13 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) 2017 BY RECIPIENT GENDER

	Number	Temperature Rise (°C)			Age (Years)		
		Mean	Min	Max	Mean	Min	Max
Female	5	2.8	2.2	3.9	54	16	77
Male	8	3.2	2.3	5.4	56	8	85
Total	**13**	**3.0**	**2.2**	**5.4**	**55**	**8**	**85**

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 2017, there were 77 (25%) events classified as allergic in nature. Of these, 66 (85.7%) were non-severe and in the remaining 11 (14.3%), ten were classified as severe and one as life-threatening. Table 10.1 shows allergic events by recipient gender along with data on recipient age.

TABLE 10.1 ALLERGIC EVENTS (IMPUTABILITY ≥3) 2017 BY RECIPIENT GENDER

	Number	Age (years)		
		Mean	Minimum	Maximum
Female	26	47	5	74
Male	51	44	3	90
All	**77**	**45**	**3**	**90**

Table 10.2 provides information on signs and symptoms associated with non-severe (Grade 1) allergic events compared to severe and life threatening (Grade 2 and 3) events reported in 2017.

10 Allergic Transfusion Reactions
continued

TABLE 10.2 ALLERGIC EVENTS (IMPUTABILITY ≥3) 2017 BY ASSOCIATED SIGNS AND SYMPTOMS

Symptom	Allergic Events					
	Grade 1 (n=66)			Grade 2 & 3 (n=11)		
	Number	% Symptoms	% Grade 1 Events	Number	% Symptoms	% Grade 2 & 3 Events
Urticaria	50	50.5%	75.8%	10	22.7%	90.9%
Chills / Rigors	8	8.1%	12.1%	5	11.4%	45.5%
Dyspnoea	5	5.1%	7.6%	5	11.4%	45.5%
Restlessness / Anxiety	5	5.1%	7.6%	5	11.4%	45.5%
Non-urticarial	9	9.1%	13.6%	0	0.0%	0.0%
Stridor / Wheeze	4	4.0%	6.1%	4	9.1%	36.4%
Cough	4	4.0%	6.1%	2	4.5%	18.2%
Chest Pain	1	1.0%	1.5%	3	6.8%	27.3%
Generalised Itchiness	4	4.0%	6.1%	0	0.0%	0.0%
Increase in Blood Pressure	3	3.0%	4.5%	0	0.0%	0.0%
Tachycardia	0	0.0%	0.0%	3	6.8%	27.3%
Hypoxaemia	0	0.0%	0.0%	3	6.8%	27.3%
Fall in Blood Pressure	0	0.0%	0.0%	2	4.5%	18.2%
Loin Pain	1	1.0%	1.5%	1	2.3%	9.1%
Periorbital Oedema	2	2.0%	3.0%	0	0.0%	0.0%
Pain at Injection Site	1	1.0%	1.5%	0	0.0%	0.0%
Abdominal Pain	0	0.0%	0.0%	1	2.3%	9.1%
Joint Pain	1	1.0%	1.5%	0	0.0%	0.0%
Vomiting	1	1.0%	1.5%	0	0.0%	0.0%

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) 2017 BY BLOOD COMPONENT TYPE

Component	Number Events	Number Units Transfused	Frequency	Rate / 10,000 Units Transfused (95%CI)
Platelets Apheresis PAS	8	3,622	1:453	220.9 (103.6 to 443.6)
Platelets Pooled PAS	14	8,945	1:639	156.5 (90.6 to 265.2)
Fresh Frozen Plasma	15	12,272	1:818	122.2 (72.2 to 203.5)
Red Cells	37	97,445	1:2,634	38.0 (27.4 to 52.5)
Cryoprecipitate	1	4,147	1:4,147	24.1 (0 to 151.0)
Platelets Apheresis Plasma[1]	0	1,266		0 (0 to 365.0)
Cryodepleted Plasma	0	101		0 (0 to 4399.2)
Total	**75**	**127,798**	**1:1,704**	**58.7 (46.7 to 73.6)**

[1] *Includes Platelets - Neonatal.*

11

Transfusion-Related Acute Lung Injury (TRALI)

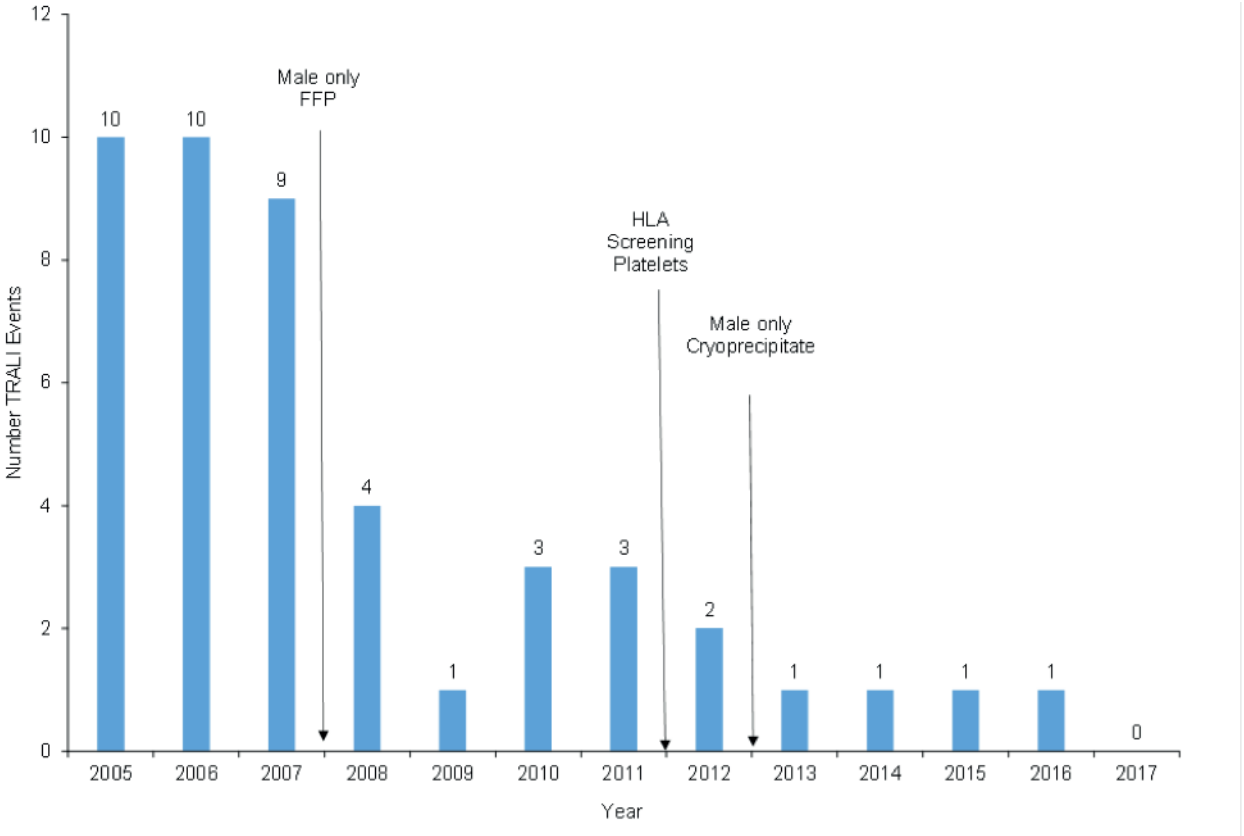
Definition:

New acute lung injury (ALI): acute onset during or within 6 hours of completion of transfusion, hypoxaemia (PaO2/FiO2 < 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 2017 there were no reported events 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.

FIGURE 11.1 ANNUAL NUMBER OF TRALI EVENTS 2005 – 2017



The components implicated yearly in TRALI events between 2005 and 2017 are detailed in Table 11.1.

11 Transfusion-Related Acute Lung Injury (TRALI) continued

TABLE 11.1 COMPONENTS IMPLICATED IN TRALI EVENTS 2005 – 2017

Year	Implicated Components (multiple components implicated in a number of events)								
	Number TRALI Reports	Red Cells	Fresh Frozen Plasma	Apheresis Platelets Plasma	Pooled Platelets Plasma	Apheresis Platelets PAS	Pooled Platelets PAS	Cryoprecipitate	Cryodepleted Plasma
2005	10	7	5	3	1			1	1
2006	10	4	5	5	2			1	
2007	9	4	6						
2008	4	2		1	1				
2009	1	1							
2010	3	2		1					
2011	3		2		1				
2012	2		1			1	2		
2013	1	1							
2014	1	1							
2015	1	1	1				1	1	
2016	1						1		
2017	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 2017, there were 9 reported TACO events (2.9% of total events). Three were non-severe, five were Grade 2 (severe) and one was Grade 3 (life-threatening). Table 12.1 shows the TACO events by recipient gender, along with data on recipient age.

TABLE 12.1 TACO EVENTS (IMPUTABILITY ≥3) 2017 BY RECIPIENT GENDER

		Age (Years)		
	Number	Mean	Minimum	Maximum
Female	3	57	33	86
Male	6	73	64	80
All	**9**	**68**	**33**	**86**

Table 12.2 shows the recorded clinical features of the TACO events reported during 2017.

TABLE 12.2 TACO EVENTS (IMPUTABILITY ≥3) 2017 BY ASSOCIATED SIGNS AND SYMPTOMS

Symptom	Number			% TACO Events
	Female	Male	Total	
Dyspnoea	2	6	8	88.9%
Increase in Blood Pressure	0	5	5	55.6%
Stridor / Wheeze	2	2	4	44.4%
Fall in O2 Saturation	1	3	4	44.4%
Pulmonary Oedema	3	1	4	44.4%
Chills / Rigors	0	3	3	33.3%
Tachycardia	1	2	3	33.3%
Hypoxaemia	2	1	3	33.3%
Restlessness / Anxiety	0	2	2	22.2%
Raised JVP	1	1	2	22.2%

12 Transfusion-Associated Circulatory Overload (TACO) continued

Table 12.3 shows the blood components implicated in TACO events reported each year from 2007 to 2017.

TABLE 12.3 COMPONENTS IMPLICATED IN TACO EVENTS (IMPUTABILITY ≥3) 2007 – 2017

Year	Implicated Components (multiple components implicated in a number of events)										
	Number TACO Reports	Red Cells	Fresh Frozen Plasma	Pooled Platelets Plasma	Cryoprecipitate	Apheresis Platelets PAS	Pooled Platelets PAS	Apheresis Platelets Plasma	Fractionated Products	Cryodepleted Plasma	Granulocytes
2007	14	10	2	2					1		
2008	20	17	5	3					1		
2009	24	21	4					2			
2010	13	10	2	2	2			2		1	
2011	19	18	4	1	1		2				
2012	27	24	2			1	2	1	1		
2013	16	13	4		3	4	2				1
2014	12	12									
2015	16	14	2		1	1				1	
2016	11	11	1			1					
2017	9	8	1				1				
Total	**181**	**158**	**27**	**8**	**7**	**7**	**7**	**5**	**3**	**2**	**1**
Percentage		87.2%	14.9%	4.4%	3.9%	3.9%	3.9%	2.8%	1.7%	1.1%	0.6%

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 – 2017

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)
Total	**123**	**1,123,295**	**1:9,132**	**1.1 (0.9 to 1.3)**

Transfusion-Associated Circulatory Overload (TACO) continued

12

From 2010 to 2017, 4% of all reported events were classified as TACO, however they were responsible for 20% of events graded with a severity score ≥2 (Table 12.5).

TABLE 12.5 SEVERE TACO EVENTS (IMPUTABILITY ≥3) 2010 – 2017

		Severity Grade			
		Grade 2 (Severe)	Grade 3 (Life Threatening)	Grade 4 (Death)	Total
All Adverse Events	Number	295	43	6	343
TACO Events	Number	57	11	3	71
	Percentage of Grade	19.3%	25.6%	50%	20.7%

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

CASE A

A 54-year-old female four months post-transplant for AML with a haemoglobin of 76g/L. The patient was transfused a unit of platelets at 1030hrs, a unit of red cells at 1330hrs and the transfusion of the implicated red cell unit (269mL) was started at 1630hrs. Shortly after midnight, she was found to be wheezy with a cough, dyspnoea, hypoxaemia and pulmonary oedema and had developed a tachycardia (pulse 74 / min at baseline; 115 / minute during the event), tachypnoea (baseline and at event respiratory rates, 18 and 40 / min respectively), hypertension (baseline and at event 112/70 and 220/100 respectively and hypoxia (O_2 saturations 98% and 90% on room air at baseline and during event respectively). She also had bilateral pedal oedema. Chest x-ray showed pulmonary oedema. Post-transfusion NT-proBNP was 1607 pmol/L (normal at any age < 35 pmol/L; indicative of heart failure, for age, > 212 pmol/L) but there were no pre-transfusion levels to compare against. She was given frusemide intravenously and gradually improved over the next 24 hours. The event was classified as TACO; severity Grade 2; imputability, certain.

13 Transfusion-Associated Dyspnoea (TAD)

Definition:

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

During 2017, there were 14 events classified as TAD. There were ten reports involving female patients and four reports involving male recipients. All the events were classified as non-severe (Grade 1) except for one report from a male which was graded severe (Grade 2).

Table 13.1 shows the number of TAD events reported each year from 2008 to 2017.

TABLE 13.1 ANNUAL NUMBER OF TAD EVENTS (IMPUTABILITY ≥3) 2008 – 2017

Year	TAD Events	Total Component Units Transfused	Frequency	Rate / 100,000 Units Transfused (95%CI)
2008	8	158,101	1:19,763	0.5 (0.2 to 1.0)
2009	13	162,587	1:12,507	0.8 (0.5 to 1.4)
2010	9	159,568	1:17,730	0.6 (0.3 to 1.1)
2011	6	151,919	1:25,320	0.4 (0.2 to 0.9)
2012	15	149,668	1:9,978	1.0 (0.6 to 1.7)
2013	26	136,995	1:5,269	1.9 (1.3 to 2.8)
2014	4	135,135	1:33,784	0.3 (0.1 to 0.8)
2015	2	132,060	1:66,030	0.2 (0.0 to 0.6)
2016	8	130,185	1:16,273	0.6 (0.3 to 1.2)
2017	14	127,765	1:9,126	1.1 (0.6 to 1.9)
Total	**105**	**1,443,983**	**1:13,752**	**0.7 (0.6 to 0.9)**

Hypotensive Transfusion Reactions 14

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 2017, there were nine events classified as hypotensive transfusion reactions. Red cell units transfused were implicated in all the TRAEs. Of the nine reports, seven were classified as non-severe (Grade 1) and two reports as severe (Grade 2).

Table 14.1 shows the components implicated in hypotensive events reported each year from 2009 to 2017.

TABLE 14.1 COMPONENTS IMPLICATED IN HYPOTENSIVE EVENTS (IMPUTABILITY ≥3) 2009 – 2017

Year	Total Hypotensive Events	Implicated Components						
		Red Cells	Apheresis Platelets Plasma	Apheresis Platelets PAS	Fresh Frozen Plasma	Pooled Platelets Plasma	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	9	9			1			
Total	**83**	**68**	**5**	**3**	**3**	**1**	**2**	**1**
Percentage		81.9%	6.0%	3.6%	3.6%	1.3%	2.4%	1.2%

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 2017, there were three reported events classified as an acute haemolytic transfusion reaction. The details of two of the events are provided below.

CASE B

A 36-year-old female with heavy menstrual bleeding secondary to uterine fibroids and a haemoglobin of 54 g/L received a unit of red cells. An hour and 20 minutes later, she had a 2°C temperature rise with chills, rigors and pain in her thighs. Serum bilirubin rose from 4 µmol/L 90 minutes pre-transfusion, to 40 µmol/L at 10 minutes after the event. Eight hours later LDH was 327 u/L.

Pre-transfusion red cell antibody screen (RCAS), and DAT were negative. The red cell units that had been selected for transfusion were crossmatch-compatible by an abbreviated compatibility test (to ensure ABO compatibility). On the post-reaction sample, though the RCAS was negative, the DAT was positive (IgG), but the eluate was not tested, and it was crossmatch-incompatible with the red cell unit transfused.

The event was recorded as an acute haemolytic transfusion reaction due to an antibody to a low frequency antigen.

Acute Haemolytic Transfusion Reactions (AHTR) continued

15

CASE C

An 84-year-old female admitted with PR bleeding and anaemia. Six days prior to the transfusion which caused the adverse event the red cell antibody screen had been negative and two days prior, a new sample was received and anti-S was identified. In the days preceding the transfusion that caused the adverse event, she had been transfused four units of red cells which were all S-negative though two were found, subsequently, to be Jk^b positive. On the day the adverse event occurred, during the transfusion of a red cell unit, about two hours into the transfusion, the patient became anxious, restless, breathless, and developed chills, rigors, and vomiting. The respiratory rate increased from 18 to 22 per minute and the SaO_2 fell from 99% to 92%. The patient's baseline blood pressure was 93/48, and, at the time of the adverse event it was 176/78.

The patient's pre-transfusion haemoglobin was 87g/L, bilirubin unknown. Eight hours after the event the haemoglobin was 75g/L, bilirubin 115µmol/L and haptoglobin 0.06g/L. Both pre- and post-transfusion samples appeared normal. Anti-S and anti-Jk^b were identified in the post-transfusion sample, DAT was positive (IgG weak, C3b, C3d weak) in the post-transfusion sample, and anti-Jk^b was eluted. The red cell unit being transfused at the time of the event proved to be S-negative, Jk^b positive.

Antibodies to the antigens of the Kidd blood group system, Jk^a and Jk^b, are commonly implicated in delayed haemolytic transfusion reactions. This is probably due to the known tendency for the level of these antibodies to fall to undetectable levels after the initial immunisation event and then be rapidly re-stimulated following further exposure to the antigen.

These antibodies if re-stimulated by a red cell transfusion can then react with the newly transfused red cells that if they have the appropriate blood group antigen are now incompatible and can result in a 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 2017, there were four reports of DHTR and 12 reports of DSTR of imputability ≥3. Table 16.1 shows these events by recipient gender along with data on recipient age. Table 16.2 details the specificities of the blood group antibodies implicated in the DHTR and DSTR events.

TABLE 16.1 DELAYED TRANSFUSION REACTIONS (IMPUTABILITY ≥3) 2017 BY EVENT TYPE AND RECIPIENT GENDER

		Number	Age (years)		
			Mean	Minimum	Maximum
DHTR	Female	2	54	48	59
	Male	2	62	55	69
DSTR	Female	5	64	34	83
	Male	7	58	24	76

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

16

TABLE 16.2 DELAYED TRANSFUSION REACTIONS (IMPUTABILITY ≥3) 2017 BY SPECIFICITY OF RED CELL ANTIBODY

Antibody Specificity	Number (Percentage)		
	Delayed Haemolytic	Delayed Serological	Total
Anti-C	1 (25%)	1 (8%)	2 (13%)
Anti-D	1 (25%)		1 (6%)
Anti-Jk^3	1 (25%)		1 (6%)
Anti-Jk^a	1 (25%)	2 (17%)	3 (19%)
Anti-E		3 (25%)	3 (19%)
Anti-K		3 (25%)	3 (19%)
Anti-Fy^a		1 (8%)	1 (6%)
Anti-Fy^b		1 (8%)	1 (6%)
Anti-S		1 (8%)	1 (6%)
Total	**4**	**12**	**16**
Blood Group System			
Rh	2 (50%)	4 (33%)	6 (38%)
Kidd	2 (50%)	2 (17%)	4 (25%)
Kell		3 (25%)	3 (19%)
Duffy		2 (17%)	2 (13%)
MNSs		1 (8%)	1 (6%)

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

CASE D

A 54-year-old male with relapsed IgG lambda multiple myeloma received an HLA-matched sibling allogeneic haematopoietic stem cell transplant from his sister.

The patient was group A RhD positive and had a negative red cell antibody screen. The female donor was group A RhD negative. An antibody screen on the donor was not part of routine transplant work-up, however donor accreditation testing at the time of haematopoietic stem cell collection revealed a positive antibody screen. Anti-D was detected with a titre >50 and quantitation by flow cytometry was 4.8IU/mL, consistent with a moderate titre.

Transfusion support was with A RhD negative products, compatible with both donor and recipient. The patient had a relatively uncomplicated early transplant course and required only two units of group A RhD negative red cells on day +8. Neutrophil and platelet engraftment occurred on day +14. He was discharged from the inpatient unit on day +18. The haemoglobin remained stable until discharge, between 90 g/L and 100 g/L and then spontaneously increased to 107 g/L on day +19.

On the evening of day +20 he presented acutely with fever, back pain and malaise. Urine was initially dark, but progressed to frank haemoglobinuria within 12 hours. Haemoglobin had dropped to 75 g/L and there was biochemical evidence of severe haemolysis with a positive direct antiglobulin test (DAT), IgG+ and C3b/C3d+. Anti-D was detected in the eluate and the plasma Anti-D titre was 512. The blood film showed widespread spherocytosis with polychromasia and occasional nucleated red cells; no significant fragments were seen. Haemolysis peaked the next morning with Bilirubin 132 µmol/L and haemoglobin down further to 58 g/L, despite transfusion of two units of red cells. Retrospective serology showed that the DAT was negative on day +15, weakly positive on day +18, and by day +19 the DAT was positive (3+).

Red cell exchange with RhD negative red cells was considered but as the haemolytic process was expected to be self-limiting and the patient remained stable, the patient was supported with intravenous fluids and blood component transfusions. Renal function remained normal and the haemolysis showed improvement on day +22 and with resolution by day +23. The patient was transfused a total of 7 units of A RhD negative red cells from day +21 to day +23. Repeat serological investigations on day +23 showed a change in blood group to the donor type of A RhD negative, a negative DAT and persistence of Anti-D in the plasma. There was no further evidence of haemolysis and clinical symptoms had resolved.

Retrospective serology showed that the DAT was weakly positive on day +18 and strongly positive the next day, with Anti-D in the eluate and plasma from day +19, with these having been negative on day +15.

Anti-D persisted in the plasma with the repeat titre on Day +57 being 256 and on day +94, 64.

This case represents massive immune haemolysis due to RhD incompatibility that is typical of passenger lymphocyte syndrome.

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 2017, there were 31 reports of adverse events which could not be classified into a definitive category. Twelve were excluded from analysis on the basis that the event could be attributable to a cause other than the transfusion. The remaining 19, included in the analysis, involved 14 female and five male recipients. Fourteen events involved only red cell components, two involved PAS pooled platelets and three PAS apheresis platelets.

TABLE 17.1 UCT EVENTS (IMPUTABILITY ≥3) 2017 BY ASSOCIATED SIGNS AND SYMPTOMS

Symptom	Number of Events
Chest pain	2
Other	2
Infusion pain	2
Tachycardia	1
Arrhythmia	1
Increased blood pressure	2
Other pain	2
Abdominal pain	3
Excessive sweating	1
Ventricular fibrillation	1
Arthus reaction	1
Swollen hands	1
Total	**19**

18 Reports Involving Paediatric Patients

During 2017, there were 24 events (8% of all events) involving recipients aged 15 years or younger. Allergic reactions were the most frequent adverse event reported in this age group (54%). Table 18.1 details the event type and severity of adverse events occurring in paediatric patients.

TABLE 18.1 ADVERSE EVENTS (IMPUTABILITY ≥3) 2017 IN RECIPIENTS ≤15 YEARS AGE BY EVENT TYPE

Event Type	Number	Percentage of Events	Gender		Severity Score		
			Female	Male	1	2	3
Allergic	13	54%	2	11	11	2	
FNHTR	5	21%	1	4	5		
IBCT	3	13%	1	2	3		
UCT	2	8%	1	1	2		
Decrease in blood pressure	1	4%	1		1		
Total	**24**		**6**	**18**	**22**	**2**	

Transfusion Transmitted Infections (TTIs) and Lookbacks

19

During 2017, no TTI events were reported

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, HCV or HTLV infection. All previous donations in the preceding 24 months are documented, and the fate of previous donations shall be undertaken and where appropriate the clinicians responsible for the recipient's care are notified and arrangements made to inform and counsel the recipient and arrange for testing of the recipient.
- NZBS is informed that a recipient of blood components or products has developed laboratory test results and/or disease symptoms indicating that a blood component or product may have been infectious for hepatitis B, hepatitis C, HIV, HTLV, CJD, a bacterial infection or any other infection that may be transmitted through blood transfusion. Archived samples of these donations are retested and confirmatory testing 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 2017, four lookbacks were undertaken. All the lookbacks involved repeat reactive donors who had previously tested negative.

Donors Previously Tested Negative, Current Donation Repeat Reactive

Three investigations involved possible Occult HBV and one for Syphilis.

The four lookbacks involved 16 recipients of blood. Of the 16 recipients, three (19%) were deceased and for the remaining 13 recipients a request for testing was sent to the patient's General Practitioner or Hospital Consultant. Test results were received on three patients (23%) and in all these cases were negative for evidence of transfusion-transmitted infection (Table 19.1).

TABLE 19.1 REPEAT REACTIVE DONOR LOOKBACK INVESTIGATIONS 2017 BY INFECTION TYPE

Infectious Disease	Number Lookbacks	Recipients Identified	Deceased Recipients	Requests for Recipient Testing	Lookback Outcome
Occult HBV	3	14	2	12	HBV negative (3)
Syphilis	1	2	1	1	
Total	**4**	**16**	**3**	**13**	**Negative (3)**

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 2017, there were 14 IBCT events reported. This compares to 11 IBCT events reported in 2016. The IBCT events for 2017 are detailed in Table 20.1.

TABLE 20.1 IBCT EVENTS 2017

IBCT Event Type of Product	Description	Site of Error
Incorrect product/ dose Red Cells (5) Fresh Frozen Plasma (1) Platelets (1) Blood Products (1)	Patient with historic Anti-E + Anti-K. Anti-K only antibody detected on pre-transfusion sample. Transfused with a unit of RhE positive red cells. No adverse event reported.	Laboratory
	Units of irradiated neonatal red cells transfused greater than 24 hours post irradiation.	Laboratory
	Incorrect IV Immunoglobulin product transfused to a patient on two consecutive days	Laboratory
	Unit of fresh frozen plasma transfused after being returned and placed back into storage after being out of controlled storage for 1 hour 45 minutes. Removed after hours and transfused.	Laboratory
	Unit of irradiated neonatal red cell transfused greater three days post irradiation.	Laboratory
	Unit of (CMV seropositive) neonatal red cells transfused	Laboratory
	RhD negative patient received unit RhD positive platelets in error. RhD Immunoglobulin administered to patient	Laboratory
	Patient with Anti-E transfused with a red cell unit RhE positive, the unit had been RhE mistyped	Laboratory
Inappropriate transfusion	Patient transfused with 3500IU Prothrombinex®-VF, patient not on warfarin.	Clinical
	Consultant advised that a patient received one unit of fresh frozen plasma on the basis that the patient had received 14 red cell units over 15 days. Patient coagulation studies over the same time period showed stable normal range of INR, APPT and fibrinogen levels	Clinical
	Clinical area requests the first of two units of red cells that were charted on a prescription in the patient's notes. 50mL of red cells transfused and doctor walked into the patient's room and stopped the transfusion as the patient's haemoglobin was 139g/L.	Clinical
	Unit charted for an incorrect patient. 25mL red cells transfused to the patient not requiring a blood transfusion and the transfusion was stopped.	Clinical
	625IU vial of RhD Immunoglobulin-VF requested, 250IU vial dispensed by the laboratory and administered. Further 625IU vial of RhD Immunoglobulin-VF administered.	Laboratory

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 2017, there were 17 events identified within the NZBS incident management system and five reported from a DHB Blood Bank detailing near miss events. These events are summarised in Table 21.1.

TABLE 21.1 NEAR MISS EVENTS 2017 BY ERROR TYPE AND SITE

Error	Site of Error			
	Blood Bank	Processing	Clinical	Total
Wrong product/component issued (including wrong dose or wrong patient), two events involving red cells, one platelets and eight blood products	10		1	11
Irradiation errors		4		4
Expiry of blood components	3			3
Labelling error	4			4
Total	**17**	**4**	**1**	**22**

CASE E (Three Events)

Incorrect IV Immunoglobulin product issued.

On two occasions Privigen® was approved to be issued for a specific patient. The clinical area requested the issue of Intragam® P from the blood bank and Intragam® P was issued. 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. There was a follow-up to determine why the clinical staff were requesting Intragam® P and not Privigen® which had been approved.

The clinical area requested Privigen® and the blood bank staff member issued Intragam® P.

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 issued.

CASE F (Two Events)

Incorrect dose of IV Immunoglobulin issued.

In two cases the incorrect dose of two IV Immunoglobulin products were issued by the blood bank, in both instances the dose was less than that requested.

21 Near Miss Events continued

CASE G (Two Events)

A clinical area requested recombinant Factor VIII, however recombinant Factor IX was issued. The error was detected in the clinical area, and the incorrect product returned to the blood bank and the correct product issued.

CASE H

Theatre requested platelets for Patient A, however platelets for Patient B were sent. Platelets were returned and correct Platelets issued for Patient A.

CASE I

Clinical area requested platelets, however blood bank issued red cells. Red cells were returned to the blood bank and platelets issued.

CASE J

Clinical unit requested red cells for patient A, and was sent to the clinical area ward and spiked prior to transfusion. Unit should have been requested for a transfusion to Patient B. The error was identified prior to the transfusion of Patient B and the unit returned to the blood bank and discarded.

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 2017, there were 168,080 donations collected from 78,838 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 2017. There were 18 donors confirmed positive for HBV and 15 confirmed positive for syphilis.

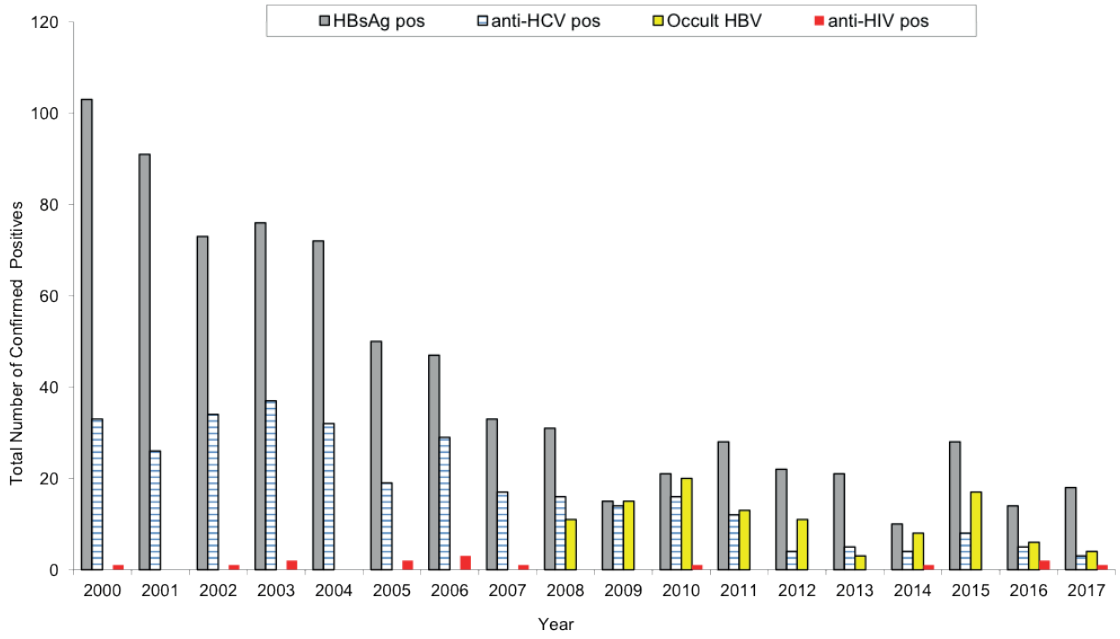
TABLE 22.1 DONORS WITH CONFIRMED POSITIVE INFECTIOUS DISEASE SEROLOGY 2017

		HBV	HCV	HIV	Syphilis	HBV Occult	HTLV I/II
Number	New Donors (n = 15,563)	18	3	1	12	0	0
	Repeat Donor (n = 63,275)	0	0	0	3	4	0
	Total Donors (n = 78,838)	18	3	1	15	4	0
Rate per 10,000 Donations	New Donors	115.7	19.3	6.4	77.1	0	0
	Repeat Donors	0	0	0	4.7	6.3	0
	All Donations	22.8	3.8	1.3	19.0	5.1	0
Frequency of Positive Donor	New Donor	1:865	1:5,188	1:15,563	1:1,297		
	Repeat Donor				1:21,092	1:15,819	
	Overall Donor Frequency	1:4,380	1:26,279	1:78,838	1:5,256	1:19,710	

Figure 22.1 shows the number of confirmed positive results each year from 2000 to 2017. 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.

22 Donor Infectious Disease Screening continued

FIGURE 22.1 ANNUAL NUMBER OF DONORS WITH CONFIRMED POSITIVE INFECTIOUS DISEASE SEROLOGY 2000 – 2017



23 Bacterial Testing Of Platelet Concentrates

NZBS undertakes pre-release sampling for bacterial culture on all platelet components. This was introduced in late 2015 for the period covered by this report. 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 National Health Service Blood & Transplant (NHSBT) in England.

Sampling of the component takes place a minimum of 36 hours following collection after which the components are 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. The components 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 and both remainder of the unit is negative and the 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 2017 a total of 14,120 platelet components were tested. 108 (0.77%) of these gave an initial positive result. A breakdown of the results is provided in Table 23.2. 2.

TABLE 23.2 RESULTS OF PLATELET BACTERIAL CULTURE PERFORMED IN 2017

Classification	Number (Percentage)		
	Apheresis Platelets	Platelet Pools	Total
Non reactive	2,645 (99.32%)	11,365 (99.2%)	14,010 (99.22%)
Initial positive	16 (0.68%)	92 (0.78%)	108 (0.77%)
False positive	16 (0.60%)	59 (0.51%)	75 (0.53%)
Indeterminate	2 (0.08%)	21 (0.18%)	23 (0.16%)
True positive	0 (0.0%)	12 (0.10%)	12 (0.08%)

23 Bacterial Testing Of Platelet Concentrates continued

The NZBS true positive rate is similar to the 0.12% confirmed positive rate reported by the Australian Red Cross Blood Service in 2016 *(https://kirby.unsw.edu.au/sites/default/files/kirby/report/SERP_Transfusion-transmissible-infections-in-Australia-Surveillance-Report-2017.pdf).*

The bacterial species identified in the 12 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	7	4	3
Enterobacter cloacae complex	1	0	1
Staphylococcus warneri	1	0	1
Staphylococcus saccharolyticus	1	0	1
Staphylococcus capitis	2	0	2
Total	**12**	**4**	**8**

One of the four transfused patients developed a temperature of 38.5°C following the transfusion. The patient was already on antibiotics at the time of the transfusion. Blood cultures were negative. The other three patients had no signs or symptoms attributable to the transfusion. One of the three was already on broad spectrum antibiotics. The relatively high proportion of Propionibacterium. Acnes cases identified and subsequently transfused is similar to that seen in 2016. This organism grows very slowly and is therefore often detected after the component has been transfused.

No cases of bacterial sepsis were reported to the NZBS haemovigilance office during the year.

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 and 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 2017, 47 adverse reactions and product administration errors were reported to fractionated blood products and these broadly showed the same pattern and frequencies seen in recent years. The largest number of reactions occurred to high-volume immunoglobulin products, Intragam®P, Privigen® and Evogam® (38 reactions); four reactions occurred to Albumex®.

In addition, two cases occurred of exposure to RhD Immunoglobulin-VF where the wrong dose was administered or use was inappropriate. The events associated with an incorrect product or dose are described in Chapter 20: Incorrect Blood Components Transfused (IBCT).

Table 24.1 shows the 47 adverse events by fractionated plasma product type. Additional information on events associated specifically with administration of Intragam®P is provided in Table 24.2 and with Privigen® in Table 24.3.

TABLE 24.1 TRANSFUSION-RELATED ADVERSE EVENTS (ANY CAUSALITY) 2017 ASSOCIATED WITH FRACTIONATED PLASMA PRODUCTS

Product Type	Event Type	Number of Reports
Intragam®P	Various (See Table 24.2)	24
Privigen®	Various (See Table 24.3)	13
Albumex® 4	Incorrect product transfused, hypotensive, allergic, breathlessness	4
Prothrombinex®-VF	Mixed symptoms and signs	2
Rh(D) Immunoglobulin-VF	Inappropriate use	2
Evogam®	Incorrect dose	1
Biostate®	Allergic	1
Total		**47**

TABLE 24.2 TRANSFUSION-RELATED ADVERSE EVENTS (ANY CAUSALITY) 2017 ASSOCIATED WITH INTRAGAM®P

Type of Reaction	Total	Causality						Severity	
		Excluded	Unlikely	Possible	Probable	Highly probable	Certain	Non-severe	Severe
Allergic	9			1	4	4		9	
Febrile	2			1	1			2	
Pain	5			1	1	2	1	5	
Haemolytic	3	1		1		1		1	2
Hypotensive	2			1	1			2	
Thrombotic	1			1					1
Other	1				1				1
Visible particle in bottle	1	1						1	
Total	**24**	**2**		**6**	**8**	**7**	**1**	**20**	**4**

24 Adverse Events Associated with Fractionated Plasma Products

continued

TABLE 24.3 TRANSFUSION-RELATED ADVERSE EVENTS (ANY CAUSALITY) 2017 ASSOCIATED WITH PRIVIGEN®

Type of Reaction	Total	Causality						Severity	
		Excluded	Unlikely	Possible	Probable	Highly probable	Certain	Non-severe	Severe
Febrile	4			3	1		1	4	
Allergic	2			1	1			2	
Haemolytic	2			1	1			2	
Hypotensive	1			1				1	
Other	1			1				1	
Pain	3	1				2		3	
Total	**13**	**1**		**7**	**3**	**2**	**1**	**13**	

Eight events were classified as severe, four involving the infusion of Intragam® P. The severity of the adverse events associated with different fractionated products is detailed in Table 24.4.

TABLE 24.4 SEVERITY OF ADVERSE EVENTS IN 2017 ASSOCIATED WITH FRACTIONATED PRODUCTS

Product Type	Severity	
	Non-severe	Severe
Intragam®P	20	4
Privigen®	13	
Albumex® 4	3	1
Prothrombinex®-VF		2
Rh(D) Immunoglobulin-VF	2	
Evogam®	1	
Biostate®		1
Total	**39**	**8**

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

Adverse Events Associated with Fractionated Plasma Products

24

continued

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

Case K - Severe Event Involving Biostate®

The patient received Biostate® for the second time, having been treated previously in 2010 without adverse effect. The treatment was provided as prophylaxis for operative dental treatment in a patient who had acquired (autoimmune) von Willebrand disease.

The patient developed an acute severe allergic reaction and was transferred to the emergency department of the regional hospital. All symptoms settled promptly, and he was discharged from hospital later on the same day. Laboratory testing identified an acute anaphylactic-type reaction had occurred. The patient has no history of other allergic disorders. Subsequently, the patient received prophylaxis with high dose intravenous Immunoglobulin (IVIg) and showed partial suppression of acquired von Willebrand disease.

Causality for an anaphylactic reaction is highly probable; Severity Grade 3

Case L - Severe event involving Prothrombinex®-VF

The patient has systemic lupus erythematosus and had developed antibodies to Prothrombinex®-VF that resulted in a bleeding syndrome. He had also developed a lupus anticoagulant that created a prothrombotic syndrome that required warfarin anticoagulation. The patient has had multiple serious bleeding episodes and thrombotic events including myocardial infarction and has received Rituximab treatment. He had required treatment with Prothrombinex®-VF for acute bleeding on at least five occasions.

The incident involved treatment with 3000IU Prothrombinex®-VF following an ankle injury. The patient suddenly developed lumbar back pain, the infusion was stopped and he lay down. The patient then vomited and had rigors. He was taken to the hospital emergency department and presented with chest tightness, chest pain and headache. He had mildly reduced oxygen saturation on room air, a moderately increased respiratory rate and temperature increase to 38.8°C, and moderately increased pulse but normal blood pressure. His chest was clear and he had no abdominal pain, rash or skin itching were observed. Serum tryptase levels were elevated indicating an anaphylactic type reaction had occurred.

When required in future, further Prothrombinex®-VF will be infused in hospital after small test doses and under methylprednisolone prophylaxis.

Causality for an anaphylactic reaction is probable; Severity Grade 3

24 Adverse Events Associated with Fractionated Plasma Products
continued

Case M - Intragam® P

The patient has secondary hypogammaglobulinaemia and recurrent chest infections due to chronic lymphocytic leukaemia. Intragam® P was re-started on 26/7/2017 as prophylaxis for chest infections after previous courses in 2014 and 2015.

On the occasion of the incident, after starting the second 200 mL bottle of Intragam® P, the patient developed chills, flushing, dyspnoea, wheeze, cough, raised JVP, hypertension, tachycardia, restlessness and anxiety. A moderately severe increase in pulse and blood pressure were also recorded, before all signs and symptoms returned to normal eight hours later. The infusion was stopped and the patient treated with hydrocortisone and felodipine 2.5 mg IV. Temperature showed a mild increase but was well within the normal range and O_2 saturation was stable. A chest X-ray when the reaction settled showed no evidence of heart failure or infection and no significant change from earlier X-rays. Serum tryptase was not increased and subsequent infusions of a different batch of Intragam® P were uneventful.

A subsequent review by the Haematologist considered that the patient was predisposed to the acute allergic event by a rhinovirus infection identified subsequently in molecular studies.

Causality for an allergic reaction is probable; Severity Grade 3

Case N - Intragam® P

An 80-year-old patient developed Guillain-Barré Syndrome and was treated with a course of Intragam® P at a dose of 33 g/day for five days. On the day after completing the infusion she was noted to have a sudden drop in haemoglobin from the previous day. Hb 123 g/L pre-treatment, falling to 73 g/L and later to 70 g/L. As the patient was also found to have a left iliopsoas haematoma, the fall in haemoglobin is now considered to be multifactorial; both secondary to haemorrhage and an unquantified degree of haemolysis. A reticulocyte count was not performed during the acute event or subsequently. Clexane thromboprophylaxis was stopped and she was transfused two units of red cells. On 5-Sep-2017 (4 wks after completing Intragam® P) her blood screen still showed a mild anaemia.

Causality for a haemolytic reaction is possible; Severity Grade 3

Case O - Albumex® 4

This 62-year-old man had undergone cardiac surgery and required volume replacement. Albumex® 4 was given at a rate of 1000 mL/h. Pre-treatment observations were: BP 92/55 and pulse 98/m. After 15 minutes the patient had a sudden, marked fall in BP with mean arterial pressure (MAP) less than 48 mm Hg. The infusion was stopped and the patient was managed by increasing a noradrenaline infusion and giving 500 mL crystalloid solution. The patient had recovered fully 10 minutes later.

Causality for the hypotensive reaction is probable; Severity Grade 3

Adverse Events Associated with Fractionated Plasma Products
continued

24

Case P - Intragam® P

A 26-year-old man had a complex medical history that involved a bone marrow transplant (BMT) for B cell ALL six years earlier followed by severe rhinovirus infection, HSV & CMV (reactivation) infections, bronchiolitis obliterans with organising pneumonia (BOOP), nephrotic syndrome, thought to be induced by graft versus host disease (GvHD) and acute kidney injury with interstitial nephritis, which was later attributed to pneumococcal pneumonia. The incident event was an acute respiratory illness that was diagnosed on broncho-alveolar lavage as Respiratory Syncytial Virus (RSV) infection. He was treated for this with Ribavirin and very high dose IV Immunoglobulin given in regular small doses as an outpatient. He became febrile after the third infusion, but this settled promptly after paracetamol.

He was readmitted after an acute presentation to the emergency department several days later with acute fatigue, headaches, weakness and shortness of breath. He was severely anaemic Hb 48g/L, and had a positive DAT with Anti-A eluted from his red cells, reduced haptoglobins <0.3 g/L and raised reticulocytes 218 $x10^9$ /L. He was transfused with three units of red cells over the next two weeks. The patient had recovered from haemolysis three months after the haemolysis was recognised.

Causality for haemolysis after a large dose of Immunoglobulin is certain; Severity Grade 3.

Case Q - Prothrombinex®-VF

This 74-year-old man who had been receiving warfarin as thromboprophylaxis for a St Jude's heart valve, developed a large gastrointestinal haemorrhage. He had a haemoglobin of 46 g/L and an INR of 5.0 on admission, and was treated with vitamin K 10mg IV and Prothrombinex®-VF 3500 IU to reverse warfarin anticoagulation. The INR decreased to 1.7 and he was transfused with four units of red cells. The haemoglobin increased to 95 g/L, but fell slowly to 77 g/L, five days later.

Following the Prothrombinex®-VF infusion the patient's platelet count decreased from 116 to 64 $x10^9$ /L on the evening of the day of admission and fell progressively on the successive four days to 20, before increasing to 43, eight days later. Fragmented red cells were reported in the blood film. Evidence of consumption coagulopathy was present with raised APTT 42 – 77s, reduced fibrinogen of 1.2 – 1.5 g/L and FDPs >15,000. Plasma exchange with FFP replacement phase was carried out as the thrombocytopenia was considered to possibly be due to ADAMTS 13 deficiency, but was stopped after the diagnosis was not sustained by further testing. All coagulation parameters subsequently normalised but a specific cause has not been reported.

Causality for thrombocytopenia and consumption coagulopathy after IV Immunoglobulin is not certain; Severity Grade 3 .

24 Adverse Events Associated with Fractionated Plasma Products
continued

Review of the frequency of events during 2007 – 2017, identified 445 events involving either an adverse reaction or exposure to a blood product, see Table 24.5. 69% of events occurred to high-volume immunoglobulin products with 11% to Albumex® products, 6% to coagulation factor concentrates and 1% to various normal and hyperimmune immunoglobulins. 9% of events involved RhD immunoglobulin and most involved exposure to the product when not indicated, or supply of an incorrect dose.

TABLE 24.5 TRANSFUSION-RELATED ADVERSE EVENTS ASSOCIATED WITH FRACTIONATED PLASMA PRODUCTS 2007 – 2017

Year	Total Events	Percent
Intragam® P, Privigen®, NextGen® 16% Ig	309	69.4%
RhD Immunoglobulin-VF / WinRho® / RhoPhylac®	42	9.4%
Albumex® 4	33	7.4%
Albumex® 20	18	4.0%
Prothrombinex™-HT / Prothrombinex®-VF	17	3.8%
Biostate® / AHF-HP	10	2.2%
Evogam®	7	1.6%
MonoFIX®-VF	3	0.7%
Tetanus Immunoglobulin-VF	3	0.7%
Normal Immunoglobulin-VF	1	0.2%
Hepatitis B Immunoglobulin-VF	1	0.2%
Zoster Immunoglobulin-VF	1	0.2%
Total	**445**	

Data for the frequencies of different types of adverse event are provided in Table 24.6. The data for 2017 is consistent with the overall frequencies in the 11 year period, 2007– 2017. Review of data for the 11 years shows that the most frequent types of adverse events were:

- Allergic reactions 35%
- Febrile reactions 14%
- Pain 11%
- Mixed or other adverse reactions 15%
- Supply of a wrong product or dose 12%
- Adverse events associated with thrombosis, hypotension, aseptic meningitis and volume overload were less frequent occurring at approximately 2 – 3% of events.

Adverse Events Associated with Fractionated Plasma Products

24

continued

TABLE 24.6 FREQUENCY OF ADVERSE EVENTS TO MANUFACTURED COMPONENTS 2007 – 2017

Year	Febrile	Allergic	Pain	Thrombotic	Hypotensive	Haemolytic	Aseptic meningitis	Volume overload	Wrong product or dose	Other adverse events	Other exposure events	Total Reported Events
2007	5	15	1	0	1	0	1	1	0	5	0	29
2008	2	8	3	1	3	1	0	1	0	2	0	21
2009	1	14	2	1	0	1	0	0	0	0	0	19
2010	7	16	1	0	1	1	1	2	14	3	0	46
2011	7	7	0	1	0	1	0	0	4	7	0	27
2012	5	8	1	0	0	6	1	1	7	4	0	33
2013	7	9	14	1	0	4	0	0	3	5	0	43
2014	7	10	5	1	2	2	0	0	4	5	0	36
2015	1	18	3	0	2	3	1	0	6	5	4	43
2016	8	12	6	0	1	4	2	0	2	4	4	43
2017	6	13	7	1	3	5	0	0	4	8	0	47
Total	**56**	**130**	**43**	**6**	**13**	**28**	**6**	**5**	**44**	**48**	**8**	**387**
	14%	34%	11%	2%	3%	7%	2%	1%	11%	12%	2%	

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 – 2017 BY DONATION TYPEE

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

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

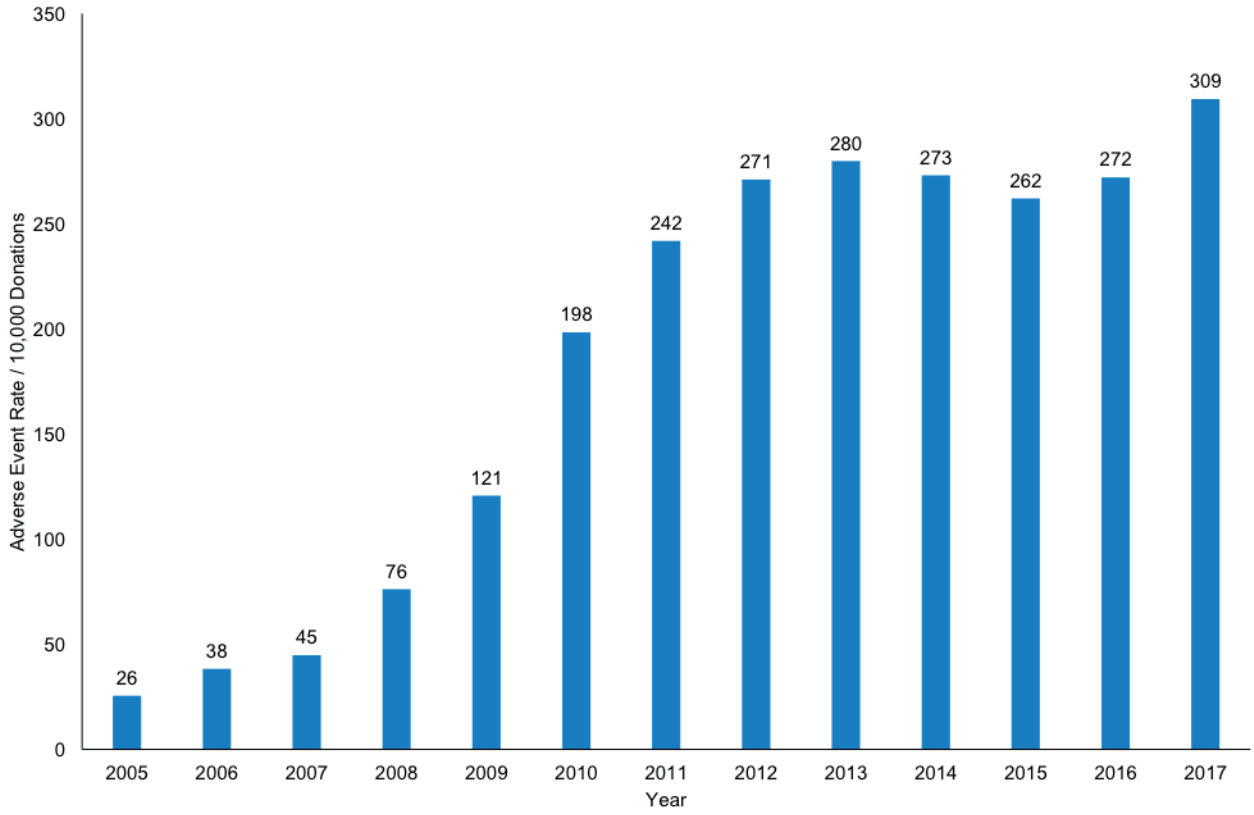
NZBS utilises definitions for these adverse events contained in the Standards for Surveillance of Complications Related to Blood Donation (2014) developed by the Working Group on Donor Vigilance, International Society of Blood Transfusion Working Party on Haemovigilance (Appendix III). A standardised 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 – 2017



Two donors experienced an adverse event that was classified as severe. Both were female donors, one donating whole blood, and the second donating platelets by apheresis. Both experienced an immediate vasovagal event that resulted in injury to the donor. Both donors were permanently deferred from further blood donations.

The criteria for classification of a reaction as 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.

In 2017, a total of 143 donors following an adverse event were permanently deferred from further donations, 16 donors donating either plasma or platelets by apheresis and 127 were whole blood donors. 87% of the donors permanently deferred had a vasovagal adverse event.

25 Adverse Events Associated with Blood Donation continued

During 2017, there were 168,079 donations (111,188 whole blood, 54,125 plasmapheresis and 2,766 plateletpheresis, donations) collected. Adverse events were reported in relation to 5,198 of the donations and involving 4,901 donors. The overall frequency of reported donation-related adverse events was 1:32. 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 2017 BY COLLECTION METHOD

Procedure	Donors	Donations with Events	Total Donations	Frequency	Rate / 10,000 Donations (95%CI)
Whole Blood Donation	3,450	3,528	111,188	1:32	31.7 (30.0 to 32.1)
Plasmapheresis	1,236	1,389	54,125	1:39	25.7 (21.6 to 24.1)
Plateletpheresis	215	281	2,766	1:10	101.6 (68.3 to 88.3)
All Apheresis Procedures	1,451	1,670	56,891	1:34	29.4 (24.2 to 26.8)
Total Procedures	**4,901**	**5,198**	**168,079**	**1:32**	**30.9 (28.4 to 30.0)**

A number of donors experienced more than one adverse event with a single donation, so in total, there were 5,198 reported events with 3,528 involving whole blood donations and 1,670 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 (58.4%) was an immediate vasovagal reaction. For apheresis procedures, the most common event (61.2% was bruising/haematoma). Donation-related adverse events by reaction type and collection method are shown in Table 25.3 and Table 25.4.

Adverse Events Associated with Blood Donation continued

25

TABLE 25.3 DONATION-RELATED ADVERSE EVENTS 2017 BY REACTION TYPE

Adverse Event	All Blood Donations (Total Collection 168,079)			
	Number Events[1]	Percentage	Frequency	Rate / 10,000 Donations (95% CI)
Immediate Vasovagal	2,358	47.7%	1:71	140 (135 to 146)
Haematoma	1,817	36.8%	1:93	108 (103 to 113)
Painful Arm	283	5.7%	1:594	17 (15 to 19)
Re-bleeding	173	3.5%	1:972	10 (9 to 12)
Nerve Irritation / Injury	121	2.4%	1:1,389	7 (6 to 9)
Delayed Vasovagal	104	2.1%	1:1,616	6 (5 to 8)
Other Complications	65	1.3%	1:2,586	4 (3 to 5)
Arterial Puncture	8	0.2%	1:21,010	0 (0 to 1)
Local Allergic Reaction	6	0.12%	1:28,013	0 (0 to 1)
Other Serious Complications	5	0.10%	1:33,616	0 (0 to 1)
Cellulitis	2	0.04%	1:84,040	0 (0 to 0)
Thrombophlebitis	1	0.02%	1:168,079	0 (0 to 0)
Other Major Vessel Injury	1	0.02%	1:168,079	0 (0 to 0)
Total	**4,944**		**1:34**	**294 (286 to 302)**

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

25 Adverse Events Associated with Blood Donation continued

TABLE 25.4 DONATION-RELATED ADVERSE EVENTS 2017 BY REACTION TYPE AND COLLECTION METHOD

Adverse Event	Type of Blood Donation					
	Whole Blood (Total Collections 111,188)			Apheresis (Total Collections 56,891)		
	% All Events	Freq.	Rate / 10,000 Donations (95% CI)	% All Events	Freq.	Rate / 10,000 Donations (95% CI)
Immediate Vasovagal	58.4%	1:53	190 (183 to 199)	18.3%	1:236	42 (37 to 48)
Haematoma	27.9%	1:110	91 (86 to 97)	61.2%	1:71	141 (132 to 152)
Painful Arm	4.3%	1:717	14 (12 to 16)	9.7%	1:444	22 (19 to 27)
Re-bleeding	3.3%	1:942	11 (9 to 13)	4.2%	1:1,034	10 (7 to 13)
Delayed Vasovagal	2.3%	1:1,356	7 (6 to 9)	1.7%	1:2,586	4 (3 to 6)
Nerve Irritation / Injury	2.2%	1:1,373	7 (6 to 9)	3.0%	1:1,422	7 (5 to 10)
Other Complications	1.2%	1:2,586	4 (3 to 5)	1.7%	1:2,586	4 (3 to 6)
Arterial Puncture	0.2%	1:15,884	1 (0 to 1)	0.08%	1:56,891	0 (0 to 1)
Local Allergic Reaction	0.2%	1:18,531	1 (0 to 1)			
Other Serious Complications	0.1%	1:22,238	0 (0 to 1)			
Cellulitis	0.03%	1:111,188	0 (0 to 1)	0.08%	1:56,891	0 (0 to 1)
Other Major Vessel Injury	0.03%	1:111,188	0 (0 to 1)			
Generalised Allergic Reaction						
Thrombophlebitis				0.08%	1:56,891	0 (0 to 1)
Total		**1:31**	**326 (316 to 337)**		**1:227**	**44 (39 to 50)**

	Number Adverse Events	Apheresis-only Complications		
		% Reaction	Freq.	Rate / 10,000 Donations (95% CI)
RBC not returned	445	63.7%	1:128	78 (71 to 86)
Citrate Toxicity	251	35.9%	1:227	44 (39 to 50)
Haemolysis	3	0.4%	1:18,964	1 (0 to 2)
Total Apheresis-Specific Events	**699**		**1:81**	**123 (114 to 132)**

Adverse Events Associated with Blood Donation continued

25

During 2017, there were 111,188 whole blood donations with 89% of these collected from repeat donors. Except for re-bleeding, the frequency of all donation-related adverse events was higher in first-time donors compared to repeat donors. The distribution of event types within the two groups was similar with vasovagal reactions and haematoma events predominating (Table 25.5).

TABLE 25.5 WHOLE BLOOD DONATION-RELATED ADVERSE EVENTS 2017 BY REACTION TYPE FOR NEW AND REPEAT DONORS

Adverse Event	New Donors (n=11,840)			Repeat Donors (n=99,348)		
	% Reactions	Freq.	Rate / 1,000 Donations	% Reactions	Freq.	Rate / 1,000 Donations
Immediate Vasovagal	38.2%	1:12	82.7	24.3%	1:87	11.5
Haematoma	8.6%	1:54	18.7	16.8%	1:126	8.0
Painful Arm	1.1%	1:423	2.4	2.7%	1:782	1.3
Nerve Irritation / Injury	0.7%	1:623	1.6	1.3%	1:1,602	0.6
Delayed Vasovagal	0.7%	1:696	1.4	1.4%	1:1,528	0.7
Other Complications	0.4%	1:1,316	0.8	0.7%	1:2,922	0.3
Re-bleeding	0.2%	1:1,973	0.5	2.4%	1:887	1.13
Arterial Puncture	0.1%	1:3,947	0.3	0.09%	1:24,837	0.04
Local Allergic Reaction	0.1%			0.13%	1:16,558	0.06
Other Major Vessel Injury				0.02%	1:99,348	0.01
Cellulitis				0.02%	1:99,348	0.01
Other Serious Complications				0.11%	1:19,870	0.05
Total		**1:9**	**108.3**		**1:42**	**23.6**

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 1:12 donations and the odds ratio is 2.87 (Table 25.6).

25 Adverse Events Associated with Blood Donation continued

TABLE 25.6 WHOLE BLOOD DONATION-RELATED ADVERSE EVENTS 2017 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	910	10,518	1:12	86.5 (81.3 to 92.0)	2.87 (2.66 to 3.09)
20 – 24 Years	642	12,054	1:19	53.3 (49.4 to 57.4)	1.70 (1.56 to 1.86)
25 – 29 Years	472	11,785	1:25	40.1 (36.7 to 43.7)	1.26 (1.14 to 1.39)
30 – 34 Years	308	9,182	1:30	33.5 (30.0 to 37.4)	1.05 (0.93 to 1.18)
35 – 39 Years	195	8,476	1:43	23.0 (20.0 to 26.4)	0.71 (0.62 to 0.82)
40 – 44 Years	161	9,507	1:59	16.9 (14.5 to 19.7)	0.52 (0.44 to 0.61)
45 – 49 Years	189	10,104	1:53	18.7 (16.2 to 21.5)	0.58 (0.50 to 0.67)
50 – 54 Years	165	10,084	1:61	16.4 (14.1 to 19.0)	0.50 (0.43 to 0.59)
55 – 59 Years	177	10,827	1:61	16.3 (14.1 to 18.9)	0.50 (0.43 to 0.59)
≥60 Years	309	17,718	1:57	17.4 (15.6 to 19.5)	0.54 (0.48 to 0.60)
Total	**3,528**	**110,255**	**1:31**	**32.0 (31.0 to 33.1)**	

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.

Adverse Events Associated with Blood Donation continued

25

TABLE 25.7 WHOLE BLOOD VASOVAGAL EVENTS 2017 BY DONOR AGE GROUP FOR NEW DONORS AND REPEAT DONORS

Age Group	Gender	New Donors (n = 11,840)		Repeat Donors (n = 99,348)	
		Frequency	Rate / 1,000 Donations (95%CI)	Frequency	Rate / 1,000 Donations (95%CI)
16 – 19	Female	1:8	123.1 (111.4 to 136.0)	1:23	44.3 (37.8 to 51.9)
	Male	1:13	77.8 (67.7 to 89.2)	1:33	30.5 (23.9 to 38.9)
20 – 24	Female	1:10	103.0 (85.9 to 122.9)	1:29	34.2 (30.1 to 38.8)
	Male	1:14	70.7 (55.1 to 90.3)	1:57	17.6 (13.7 to 22.5)
25 – 29	Female	1:12	86.6 (69.0 to 108.1)	1:45	22.1 (18.7 to 26.1)
	Male	1:16	64.1 (48.5 to 84.1)	1:69	14.6 (11.3 to 18.7)
30 – 34	Female	1:14	70.6 (50.9 to 96.8)	1:47	21.1 (17.1 to 25.9)
	Male	1:16	63.4 (45.5 to 87.6)	1:101	9.9 (7.2 to 13.6)
35 – 39	Female	1:18	57.0 (37.5 to 85.2)	1:87	11.5 (8.6 to 15.3)
	Male	1:27	37.0 (21.6 to 61.7)	1:145	6.9 (4.6 to 10.2)
40 – 44	Female	1:27	36.6 (20.9 to 62.2)	1:126	7.9 (5.8 to 10.8)
	Male	1:34	29.3 (13.9 to 57.7)	1:233	4.3 (2.6 to 6.9)
45 – 49	Female	1:27	36.7 (20.4 to 63.7)	1:115	8.7 (6.5 to 11.6)
	Male	1:25	39.3 (19.7 to 74.1)	1:256	3.9 (2.4 to 6.3)
50 – 54	Female	1:19	53.9 (31.0 to 90.9)	1:143	7.0 (5.0 to 9.6)
	Male	1:75	13.4 (0.6 to 50.7)	1:399	2.5 (1.3 to 4.5)
55 – 59	Female	1:14	74.1 (41.7 to 126.1)	1:108	9.3 (7.0 to 12.2)
	Male	1:149	6.7 (-2.6 to 40.8)	1:319	3.1 (1.9 to 5.1)
≥60	Female	1:13	76.9 (39.3 to 141.5)	1:127	7.9 (6.2 to 10.1)
	Male	1:94	10.6 (-3.9 to 63.6)	1:704	1.4 (0.8 to 2.5)
Total	Female	1:11	94.6 (87.8 to 101.8)	1:61	16.5 (15.4 to 17.6)
	Male	1:16	62.6 (56.7 to 69.2)	1:137	7.3 (6.5 to 8.1)
	Total	**1:13**	**79.7 (75.1 to 84.6)**	**1:81**	**12.3 (11.6 to 13.0)**

In line with international practice, NZBS has introduced measures to reduce the frequency of adverse reactions in younger donors. Current guidance contained in the Council of Europe Guide to the Preparation, Use and Quality Assurance of Blood Components identifies that a standard whole blood donation can be undertaken from a donor weighing at least 50kg. In addition, in younger donors, an estimate of total blood volume is made based on donor weight and height. Donors with an estimated blood volume of less than 3,500 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 2017 to that in 2013, a decrease of 41% has occurred (p=<0.001) (Table 25.8).

TABLE 25.8 DONATION-RELATED ADVERSE EVENTS ASSOCIATED WITH CITRATE TOXICITY DURING PLATELETPHERESIS 2013 – 2017

	Year					% Change	p Value
	2013	2014	2015	2016	2017		
Number Citrate Adverse Events	493	238	202	166	164		
Number Plateletpheresis Procedures	4,942	3,570	3,377	2,878	2,766		
Rate / 1,000 Procedures	100	67	60	58	59	-41%	<0.001

Request Form and Specimen Labelling Errors

26

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

International guidelines require that labels on pre-transfusion 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 pre-transfusion testing purposes and are discarded.

Over the past ten years, the six NZBS Blood Banks (Auckland, Waikato, Palmerston North, Wellington, Christchurch and Dunedin) have been recording errors and corrective actions associated with pre-transfusion specimens. Data is entered into a Microsoft Access™ database at each site and then analysed. Reports are reviewed by Hospital Transfusion Committees and by the NZBS Clinical Advisory Group.

The minimum requirements for pre-transfusion request forms and specimen labelling (for NZBS Blood Banks) are outlined in Table 26.1.

TABLE 26.1 NZBS PRE-TRANSFUSION 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 2017, a total of 142,456 pre-transfusion specimens were received by the six NZBS Blood Banks. Errors were identified in 3,519 specimens/forms. The overall error rate for the six NZBS Blood Banks was 24.7 per 1,000 specimens received, which is equivalent to an error rate of 1:40 specimens. The error rate in 2017 was a 1.2% increase from that reported in 2016 (24.4 per 1,000 specimens or 1:41). Table 26.2 details the error rate per 1,000 specimens for the six NZBS Blood Banks in 2017.

26 Request Form and Specimen Labelling Errors continued

TABLE 26.2 PRE-TRANSFUSION REQUEST FORM AND SPECIMEN LABELLING ERRORS 2017 BY NZBS BLOOD BANK SITE

Blood Bank	Errors	Total Specimens	Error Rate	Rate / 1,000 Specimens (95% CI)
Dunedin	316	9,690	1:31	32.6 (29.3 to 36.3)
Palmerston North	291	8,997	1:31	32.3 (28.9 to 36.2)
Wellington	766	23,758	1:31	32.2 (30.1 to 34.6)
Christchurch	643	23,468	1:36	27.4 (25.4 to 29.6)
Waikato	673	26,020	1:39	25.9 (24.0 to 27.9)
Auckland	830	50,523	1:61	16.4 (15.4 to 17.6)
NZBS	**3,519**	**142,456**	**1:40**	**24.7 (23.9 to 25.5)**

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 3,612. The most frequent type of error (19%) was 'Missing Patient Details' followed by the 'Declaration not Signed' and 'Specimen not 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 pre-transfusion 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".

Request Form and Specimen Labelling Errors continued

26

TABLE 26.3 PRE-TRANSFUSION REQUEST FORM AND SPECIMEN LABELLING ERRORS 2017 BY ERROR TYPE

Error	Number	% Total	Frequency	Rate / 1,000 Specimens	Action Required
Missing Patient Details (Major Error)	698	19.3%	204	49.0	Recollect
Declaration not signed (sample is signed)	495	13.7%	288	34.7	Correction by collector or recollect
Sample not signed (declaration is signed)	492	13.6%	290	34.5	Correction by collector or recollect
Technical[1]	372	10.3%	383	26.1	Recollect
Adhesive remaining, indicating label removed	316	8.7%	451	22.2	Recollect
Pre-printed patient ID label on sample	311	8.6%	458	21.8	Recollect
Moderate error on sample	266	7.4%	536	18.7	Correction by collector or recollect
Signature On Sample And Declaration Differ	221	6.1%	645	15.5	Recollect
Unlabelled Sample	127	3.5%	1,122	8.9	Recollect
Moderate error on form	98	2.7%	1,454	6.9	Correction by collector or recollect
Presence of partial pre-printed label	76	2.1%	1,874	5.3	Recollect
Declaration and sample not signed	64	1.8%	2,226	4.5	Recollect
Original Details Overwritten	49	1.4%	2,907	3.4	Recollect
Wrong Blood in Tube	15	0.4%	9,497	1.1	Recollect
Other Clerical Error	12	0.3%	11,871	0.8	Recollect
Total	**3,612**		**39**	**253.6**	

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

26 Request Form and Specimen Labelling Errors continued

The overall rate of request for recollection of pre-transfusion specimens by NZBS Blood Banks for 2017 was 14.6 per 1,000 specimens received. Table 26.4 summarises the recollection rates for each NZBS Blood Bank in 2017. Overall, 59% of errors resulted in a request for recollection of the pre-transfusion specimen.

TABLE 26.4 PRE-TRANSFUSION SAMPLE RECOLLECTION REQUESTS 2017 BY NZBS BLOOD BANK SITE

	Recollection Requests	Total Number of Specimens	Frequency	% Errors Requiring Re-collection	Rate / 1,000 Specimens (95% CI)
Wellington	501	23,758	1:47	65%	21.1 (19.3 to 23.0)
Dunedin	199	9,690	1:49	63%	20.5 (17.9 to 23.6)
Christchurch	364	23,468	1:64	57%	15.5 (14.0 to 17.2)
Palmerston North	132	8,997	1:68	45%	14.7 (12.4 to 17.4)
Waikato	340	26,020	1:77	51%	13.1 (11.8 to 14.5)
Auckland	545	50,523	1:93	66%	10.8 (9.9 to 11.7)
NZBS	**2,081**	**142,456**	**1:68**	**59%**	**14.6 (14.0 to 15.2)**

NZBS Wrong Blood in Tube (WBIT) Events

27

A 'Wrong Blood in Tube' error, sometimes referred to as 'Wrong Name on Tube', is when the pre-transfusion sample was collected from the wrong patient or the sample was labelled with the details of another patient. These types of errors are 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 sample received is proven to be incorrectly labelled. A historic WBIT is where the historic grouping result was likely based on a sampling or labelling error. Silent errors can occur when the wrong patient is bled but where the two patients have the same ABO and RhD groups. The corrected WBIT rate is calculated using the following equation:

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

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

Rather than relying on voluntary Haemovigilance reporting of near miss events, the NZBS incident management system collects accurate WBIT data from the six NZBS Blood Banks. In 2017, historic ABO RhD blood groups were available in eTraceline for 68% (range for the six NZBS Blood Banks 62% to 70%) of all pre-transfusion samples submitted to NZBS Blood Banks. There were 16 WBIT errors identified. In one case, the historic result was assumed to be incorrect. Table 27.1 shows the corrected WBIT rate for the 15 current WBIT events reported by the NZBS Blood Banks in 2017. The overall corrected WBIT rate was 2.5 per 10,000 samples (1:4,043).

TABLE 27.1 NZBS WBIT EVENTS 2017 BY BLOOD BANK SITE

	WBIT Events	Historic Groups	WBIT Frequency[1]	Rate / 10,000 Specimens (95% CI)[1]
Waikato	1	18,288	1:11,430	0.9 (0 to 3.9)
Wellington	1	16,744	1:10,465	1.0 0 to 4.3)
Auckland	3	34,893	1:7,269	1.4 (0.5 to 3.4)
Dunedin	1	6,291	1:3,932	2.5 (0 to 11.4)
Christchurch	5	14,684	1:1,836	5.4 (2.6 to 11.0)
Palmerston North	4	6,138	1:959	10.4 (4.3 to 22.7)
NZBS Total	**15**	**97,038**	**1:4,043**	**2.5 (1.6 to 3.7)**

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

Table 27.2 shows the cumulative number of WBIT errors for the six NZBS Blood Banks over an eleven-year-period from 2007 to 2017. The overall corrected WBIT rate was 2.6 per 10,000 samples (1:3,902). An international study (Dzik et al. Vox Sanguinis 2003: 85; 40-47) involving 10 countries reported an approximate median WBIT rate of 5 per 10,000 samples (1:2,000).

27 NZBS Wrong Blood in Tube (WBIT) Events continued

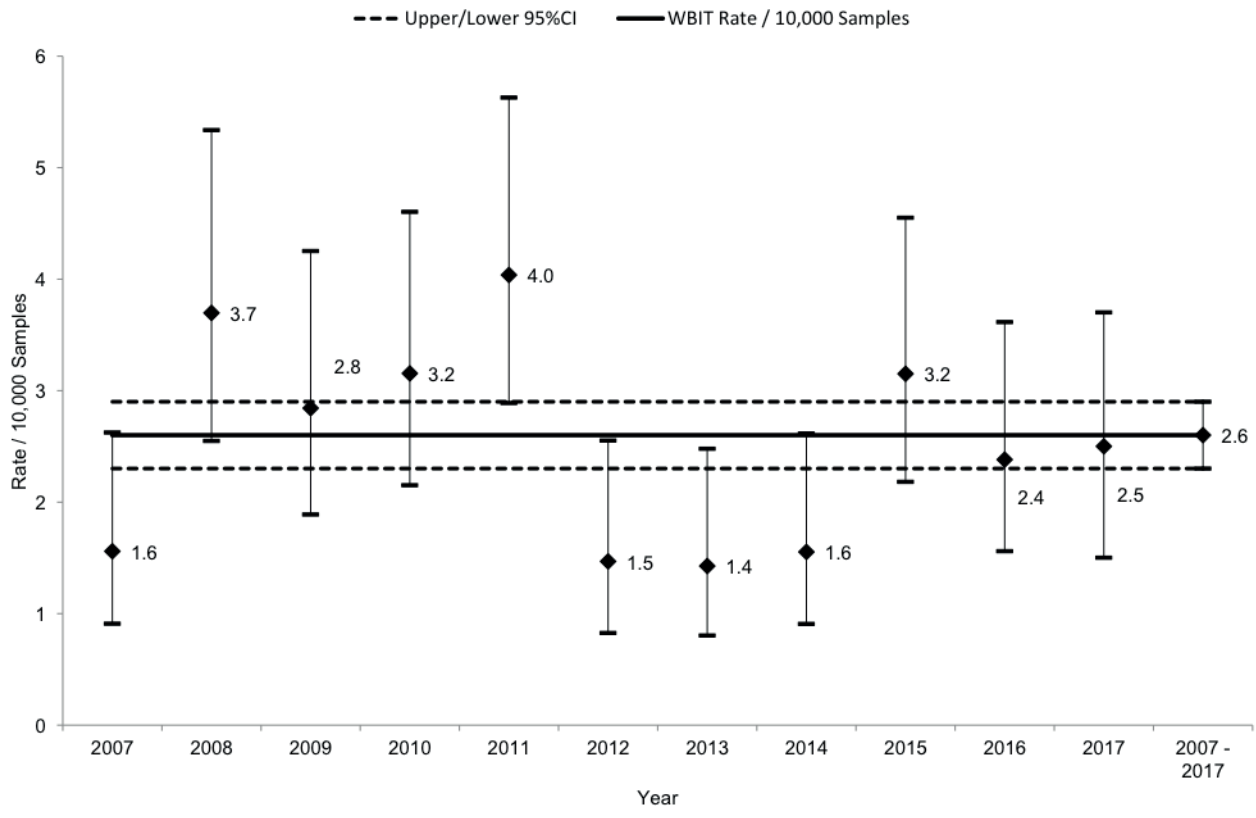
TABLE 27.2 NZBS WBIT EVENTS 2007 – 2017 BY BLOOD BANK SITE

	WBIT Events	Historic Groups	WBIT Frequency[1]	Rate/10,000 Samples (95% CI)[1]
Wellington	44	150,292	1:2,135	4.7 (3.7 to 5.9)
Palmerston North	13	63,325	1:3,044	3.3 (2.1 to 5.1)
Christchurch	24	163,232	1:4,251	2.4 (1.7 to 3.2)
Auckland	50	341,543	1:4,269	2.3 (1.9 to 2.9)
Dunedin	8	67,960	1:5,309	1.9 (1.1 to 3.3)
Waikato	18	193,868	1:6,732	1.5 (1.0 to 2.1)
NZBS Total	**157**	**980,220**	**1:3,902**	**2.6 (2.3 to 2.9)**

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

The annual NZBS WBIT event rate per 10,000 (95% CI) samples from 2007 to 2017 is shown in Figure 27.1.

FIGURE 27.1 ANNUAL NZBS WBIT EVENT RATE 2007 – 2017



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

National Haemovigilance Programme 111F04208

Page 1 of 4

Appendix I. Transfusion-Related Adverse Event Notification Form
continued

D. Severity score

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

E. Pretransfusion haematology

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

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

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

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

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

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

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

TMS informed: Yes / No

TMS name: .....

Date: .....

Time: .....

Blood Bank or Transfusion Nurse Specialist can notify TMS if necessary

G. Imputability Score

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

Reported by:

Contact Number:

Date:

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

HV | | | | | | | |
For Haemovigilance Office Use Only

Appendix I. Transfusion-Related Adverse Event Notification Form
continued

H. For Blood Bank/Transfusion Nurse Specialist Use Only

Transfusion History

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

Pages 1 & 2 completed Yes / No

Transfusion reaction investigation

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

Microbiology: Yes / No / Not tested

Unit / Patient / Both

Result:

Other:

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

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

Name:.....

Telephone: .....

Date:.....

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

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

I. For National Haemovigilance Office Only

Form received on.....

Acknowledgement sent.....

Further information requested Yes / No

Appendix I. Transfusion-Related Adverse Event Notification Form
continued

Reporting categories for transfusion-related adverse events	
Allergic reaction	Mucocutaneous signs and symptoms during or within 4 hours of transfusion: morbilliform rash with pruritus, urticaria, localised angioedema, oedema of lips, tongue and uvula, periorbital pruritus, erythema and oedema, conjunctival oedema. **Anaphylactic reaction** is when, in addition to mucocutaneous symptoms, there is airway compromise or cardiovascular involvement. Laryngeal symptoms include tightness in throat, dysphagia, dysphonia, hoarseness, stridor. Pulmonary symptoms include dyspnoea, cough, wheeze/bronchospasm, hypoxaemia. Cardiovascular symptoms include hypotension, hypotonia, syncope.
Febrile non-haemolytic transfusion reaction (FNHTR)	Fever ($\geq$38˚C and a change of $\geq$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 $\geq$ 1000mcg/L, with or without organ dysfunction, in the setting of repeated RBC transfusions.
Hyperkalaemia	Any abnormally high potassium level ($\geq$5mmol/L or $\geq$1.5 mmol/L net increase) within an hour of transfusion.
Incorrect blood component transfused (IBCT)	Patient was transfused with a blood product that did not meet the appropriate requirements or which was intended for another patient.
Near miss event	An error or deviation from standard procedures or policies that is discovered before the start of the transfusion and that could have led to a wrongful transfusion or a reaction in the recipient.
Post-transfusion Purpura (PTP)	Thrombocytopenia arising 5-12 days following transfusion of cellular blood components with findings of antibodies in the patient directed against the Human Platelet Antigen (HPA) system.
Transfusion associated circulatory overload (TACO)	Any 4 of the following: acute respiratory distress, tachycardia, increased blood pressure, acute or worsening pulmonary oedema on frontal chest radiograph, evidence of positive fluid balance. Occurring within 6 hours of completion of transfusion. An elevated BNP is supportive of TACO.
Transfusion associated dyspnoea (TAD)	Respiratory distress within 24 hours of transfusion that do not meet the criteria of TRALI, TACO, or allergic reaction. Not explained by the patient's underlying condition.
Transfusion associated graft versus host disease (TA-GVHD)	Clinical syndrome characterized by fever, rash, liver dysfunction, diarrhoea, pancytopenia and findings of characteristic histological appearances on biopsy occurring 1-6 weeks following transfusion with no other apparent cause. The diagnosis of TA-GVHD is further supported by the presence of chimerism.
Transfusion related acute lung injury (TRALI)	New acute lung injury (ALI): acute onset, hypoxaemia (PaO_2/FiO_2 < 300 mmHg, or oxygen saturation < 90% on room air, or other clinical evidence), bilateral infiltrates on frontal chest radiograph, no evidence of left atrial hypertension i.e. circulatory overload, no temporal relationship to an alternative risk factor for ALI. During or within 6 hours of completion of transfusion.
Transfusion transmitted infection (TTI)	Following investigation the recipient has evidence of infection post-transfusion, and there was no evidence of infection prior to transfusion and no evidence of an alternative source of infection.
Unclassifiable complication of transfusion (UCT)	Occurrence of an adverse effect or reaction temporally related to transfusion, which cannot be classified according to an already defined event with no risk factor other than transfusion.

Appendix II. Notification of Adverse Reactions to Fractionated Blood Products

NZBS Use Only:

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

111F00311 07/2018

Appendix II. Notification of Adverse Reactions 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?)*
☐ **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

Causality Assessment:
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.

111F00311 07/2018

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

NATIONAL
107M00510

REPORTING OF ADVERSE EVENTS RELATED TO BLOOD DONATION

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

NATIONAL
107M00510

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

NATIONAL
107M00510

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

NATIONAL
107M00510

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

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

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 Ratonga Toto O Aotearoa

NATIONAL
107F00511

DONOR ADVERSE EVENT REPORT

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

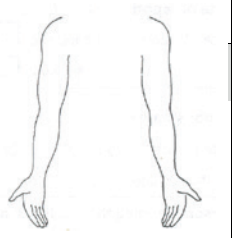
OFFICE USE ONLY: Database Record No:	

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

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

ADVERSE EVENT DETAILS

Complication		**Grade**	
		Non-severe	**Severe**
A. COMPLICATIONS MAINLY WITH LOCAL SYMPTOMS			
A1. Complications mainly characterised by the occurrence of blood outside blood vessels	Haematoma	☐	☐
	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			



Right Left

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

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

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

E. OTHER SERIOUS COMPLICATIONS RELATED TO BLOOD DONATION

F. OTHER COMPLICATIONS

Appendix IV. Donor Adverse Event Report Form continued

NZBLOOD Te Ratonga Toto O Aotearoa

NATIONAL
107F00511

DONOR ADVERSE EVENT REPORT

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

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

SAVE LIVES
GIVE BLOOD

New Zealand Government