NZBLOOD
Te Ratonga Toto O Aotearoa

National Haemovigilance Programme

Annual Report
2016

Written by the New Zealand Blood Service Haemovigilance Steering Group:

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

Other contributors

- Dr Richard Charlewood, Transfusion Medicine 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.

Contents

1 Abbreviations and Glossary

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 transfiusions, 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

Introduction

2

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 twelfth Annual Haemovigilance Report for New Zealand.

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

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

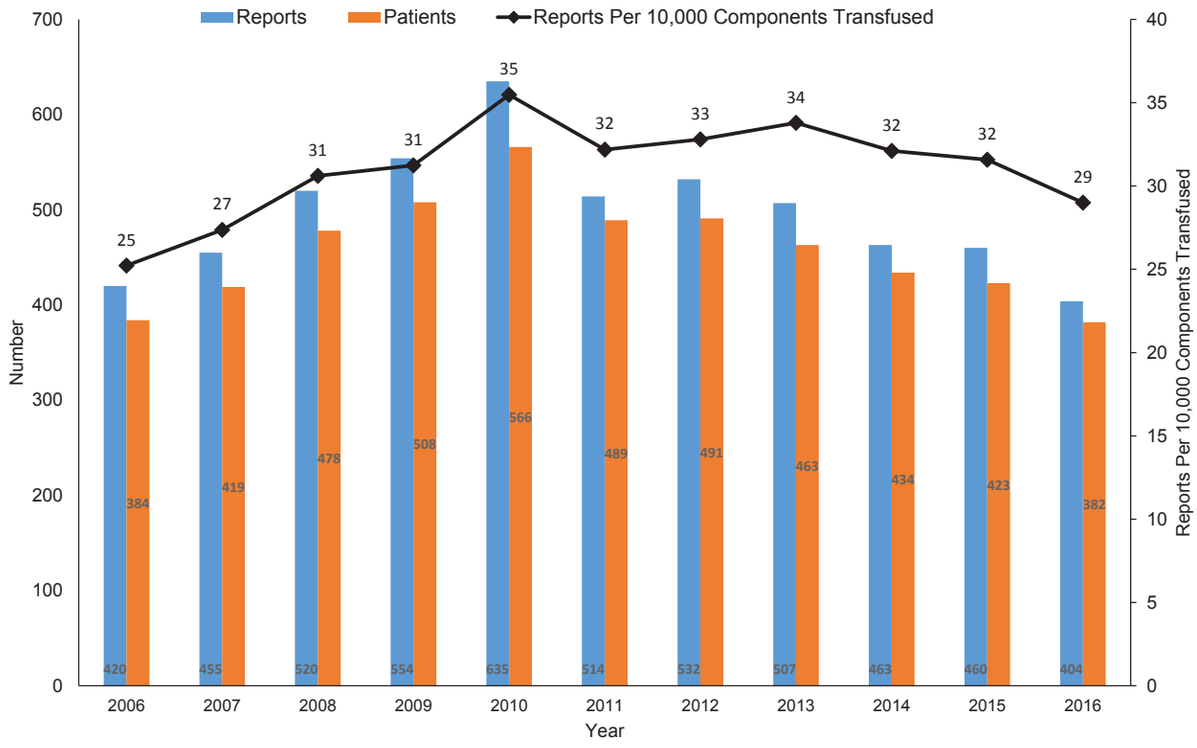
The reporting of TRAE to the National Haemovigilance Programme is voluntary. During 2016, there were 404 TRAE reported, involving 382 patients. Compared to 2015, both the total number of reported events and the ratio of reports to number of components transfused decreased (p=0.045) (Table 2.1). The year on year number of events and patients is shown in Figure 2.1.

TABLE 2.1 COMPARISON OF HAEMOVIGILANCE REPORTS : COMPONENTS TRANSFUSED 2008 – 2016

	2008	2009	2010	2011	2012	2013	2014	2015	2016
Total Components Transfused	158,181	162,587	159,568	151,919	149,668	136,995	135,135	132,060	130,185
Number Haemovigilance Reports Received	520	554	635	514	532	507	463	460	404
Percentage Change From Previous Year									
Components Transfused		2.8%	-1.9%	-4.8%	-1.5%	-8.5%	-1.4%	-2.3%	-1.4%
Haemovigilance Reports		6.5%	14.6%	-19.1%	3.5%	-4.7%	-8.7%	-0.6%	-12.2%
Reports : Components Transfused	**1:304**	**1:293**	**1:251**	**1:296**	**1:281**	**1:270**	**1:292**	**1:287**	**1:322**

2 Introduction continued

FIGURE 2.1 ANNUAL NUMBER OF TRANSFUSION-RELATED ADVERSE EVENTS 2006 – 2016



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 2016 to the number transfused in 2010, there has been a 19.9% reduction. For platelets and fresh frozen plasma, the corresponding figures are reductions of 1.5% and 33.0%, respectively. The majority of the fall in use of these blood components was seen from 2010 to 2013, with a subsequent slower decline.

There has however been a 51.2% increase in the number of units of cryoprecipitate transfused which likely reflects the introduction of massive transfusion protocols in a number of hospitals and the use in cardiovascular surgery.

TABLE 3.1 ANNUAL NUMBER OF BLOOD COMPONENTS TRANSFUSED 2010 – 2016

Blood Component	2010	2011	2012	2013	2014	2015	2016	% Change 2016 compared to 2010
Red Cells	122,745	116,071	113,014	103,565	102,718	99,915	98,535	
Red Cells Neo	1,898	1,749	1,732	1,664	1,553	1,260	1,327	
Total Red Cells	**124,643**	**117,820**	**114,746**	**105,229**	**104,271**	**101,175**	**99,862**	**-19.9%**
Platelets - APH	7,576	6,661	2,117	487	523	411	530	
Platelets - Pooled	5,403	2,349	614	0	0	0	0	
Platelets - APH PAS		774	5,354	5,627	4,033	3,818	3,813	
Platelets - Pooled PAS	48	2,988	5,037	6,457	7,429	7,683	8,447	
Platelets - Neo	589	485	661	817	616	621	624	
Total Platelets	**13,616**	**13,257**	**13,783**	**13,388**	**12,601**	**12,533**	**13,414**	**-1.5%**
Fresh Frozen Plasma	17,685	16,736	16,524	13,528	13,400	13,172	11,821	
Fresh Frozen Plasma Neo	187	127	200	175	151	162	161	
Total Fresh Frozen Plasma	**17,872**	**16,863**	**16,724**	**13,703**	**13,551**	**13,334**	**11,982**	**-33.0%**
Cryoprecipitate	2,951	3,228	3,745	4,167	4,198	4,482	4,463	51.2%
Cryodepleted Plasma	486	751	670	508	514	536	464	-4.5%
Total Components	**159,568**	**151,919**	**149,668**	**136,995**	**135,135**	**132,060**	**130,185**	**-18.4%**

3 Trends in Blood Component Transfusion in New Zealand continued

The annual blood component transfusion rates per 1,000 of the New Zealand population for the period 2010 to 2016 are shown in Table 3.2.

TABLE 3.2 ANNUAL RATE OF BLOOD COMPONENTS TRANSFUSED PER 1,000 NEW ZEALAND POPULATION 2010 – 2016

	Components Transfused per 1,000 Population						
	2010	**2011**	**2012**	**2013**	**2014**	**2015**	**2016**
Red Cells	28.6	26.9	26.0	23.7	23.1	22.0	21.2
Platelets	3.1	3.0	3.1	3.0	2.8	2.7	2.8
Fresh Frozen Plasma	4.1	3.8	3.8	3.1	3.0	2.9	2.5
Cryoprecipitate	0.7	0.7	0.8	0.9	0.9	1.0	0.9
All Components	**36.7**	**34.7**	**34.0**	**30.8**	**30.0**	**28.7**	**27.7**
Population Estimate*	4,350,700	4,384,000	4,408,100	4,442,100	4,509,700	4,595,700	4,696,500

* 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 2010, there has been a 19.6% reduction in the number of recipients of red cells.

TABLE 3.3 ANNUAL NUMBER OF RED CELL, PLATELET AND FRESH FROZEN PLASMA RECIPIENTS 2010 – 2016

Component	Number of Recipients (Percentage Change from Previous Year)							% Change 2016 from 2015
	2010	**2011**	**2012**	**2013**	**2014**	**2015**	**2016**	
Red Cells	28,130	27,101 (-3.7%)	26,673 (-1.6%)	24,978 (-6.4%)	24,349 (-2.5%)	23,437 (-3.7%)	22,620 (-3.5%)	-19.6%
Fresh Frozen Plasma	4,317	3,850 (-10.8%)	3,749 (-2.6%)	3,172 (-15.4%)	2,898 (-8.6%)	2,764 (-4.6%)	2,551 (-7.7%)	-40.9%
Platelets	3,703	3,623 (-2.2%)	3,531 (-2.5%)	3,272 (-7.3%)	3,190 (-2.5%)	3,198 (0.3%)	3,154 (-1.4%)	-14.8%

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 2016

TABLE 3.4 BLOOD COMPONENT TRANSFUSION RATES BY DISTRICT HEALTH BOARD 2016

District Health Board	Population*	Number Components Transfused		Transfusion Rate Per 10,000 Population	
		All Components	Red Cells	All Components	Red Cells
Waitemata DHB	591,241	9,422	8,282	159	140
Canterbury DHB	540,094	15,500	12,164	287	225
Counties Manukau DHB	534,690	12,096	10,322	226	193
Auckland DHB	507,665	29,278	18,742	577	369
Waikato DHB	399,866	12,540	9,277	314	232
Southern DHB	319,192	7,361	5,690	231	178
Capital and Coast DHB	306,881	12,945	8,768	422	286
Bay of Plenty DHB	226,908	4,850	4,257	214	188
MidCentral DHB	174,360	4,804	3,716	276	213
Northland DHB	171,557	3,801	3,041	222	177
Hawkes Bay DHB	161,548	3,566	3,009	221	186
Nelson Marlborough DHB	146,534	3,390	3,063	231	209
Hutt Valley DHB	146,034	1,929	1,766	132	121
Taranaki DHB	116,907	2,218	1,949	190	167
Lakes DHB	106,698	1,655	1,427	155	134
Whanganui DHB	63,058	1,067	995	169	158
South Canterbury DHB	59,254	1,519	1,378	256	233
Tairawhiti DHB	47,844	894	768	187	161
Wairarapa DHB	43,640	852	777	195	178
West Coast DHB	32,530	498	471	153	145
Total	**4,696,500**	**130,185**	**99,862**	**277**	**213**

http://nzdotstat.stats.govt.nz/wbos/Index.aspx?DataSetCode=TABLECODE7509 (Data extracted 9 February 2017)

4 Recipients of Blood Components

Table 4.1 below provides information on the number of individual recipients (multiple transfusion to the same recipient are counted as one) of red cell, platelet and FFP components transfused during 2016.

TABLE 4.1 RECIPIENTS OF BLOOD COMPONENTS 2016

		Blood Component		
		Red Cells	Platelets	FFP
Recipient Gender (number)	Female	12,681	1,244	1,038
	Male	9,918	1,906	1,510
	Unknown	21	4	3
	Total	**22,620**	**3,154**	**2,551**
Recipient Age (years)	Mean	62	53	58
	Median	68	61	64
	Maximum	106	116	116
	Minimum	0	0	0
Units Transfused per Recipient	Mean	4	4	5
	Median	2	2	2
	Maximum	149	126	188
	Minimum	1	1	1

Table 4.2 and Figure 4.1 show the yearly mean pretransfusion haemoglobin from 2006 to 2016 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 2016 (75.3g/L).

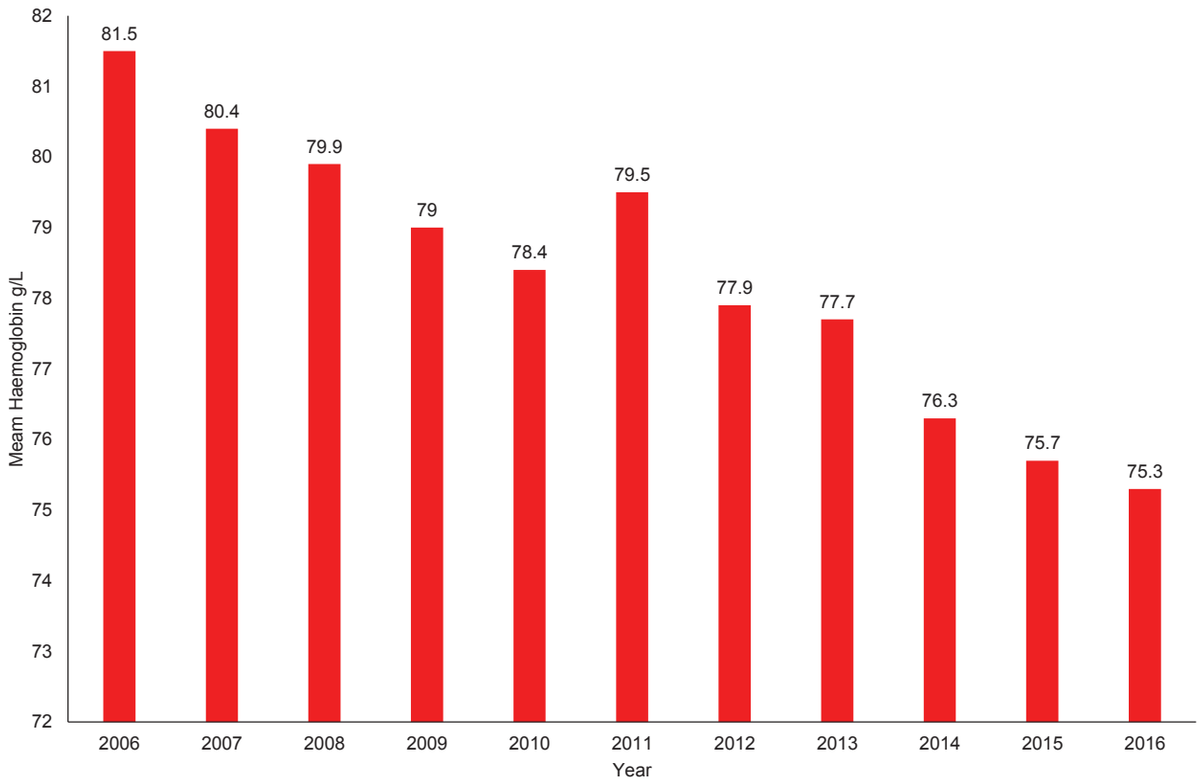
TABLE 4.2 ANNUAL MEAN PRETRANSFUSION HAEMOGLOBIN CONCENTRATION 2006 – 2016

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

Recipients of Blood Components
continued

4

FIGURE 4.1 ANNUAL MEAN PRETRANSFUSION HAEMOGLOBIN CONCENTRATION 2006 – 2016



5 Transfusion-Related Adverse Events: Reporting District Health Boards

During 2016, transfusion-related adverse events (TRAE) were reported from all New Zealand District Health Boards except Whanganui and the West Coast DHBs. The number of events of imputability ≥3 per District Health Board and the event rate per 10,000 component units transfused are shown in Table 5.1 and Figure 5.2. The 2016 national TRAE rate was 25.0 per 10,000 component units transfused compared to 27.5 per 10,000 components transfused in 2015.

FIGURE 5.1 DISTRICT HEALTH BOARD BOUNDARIES

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

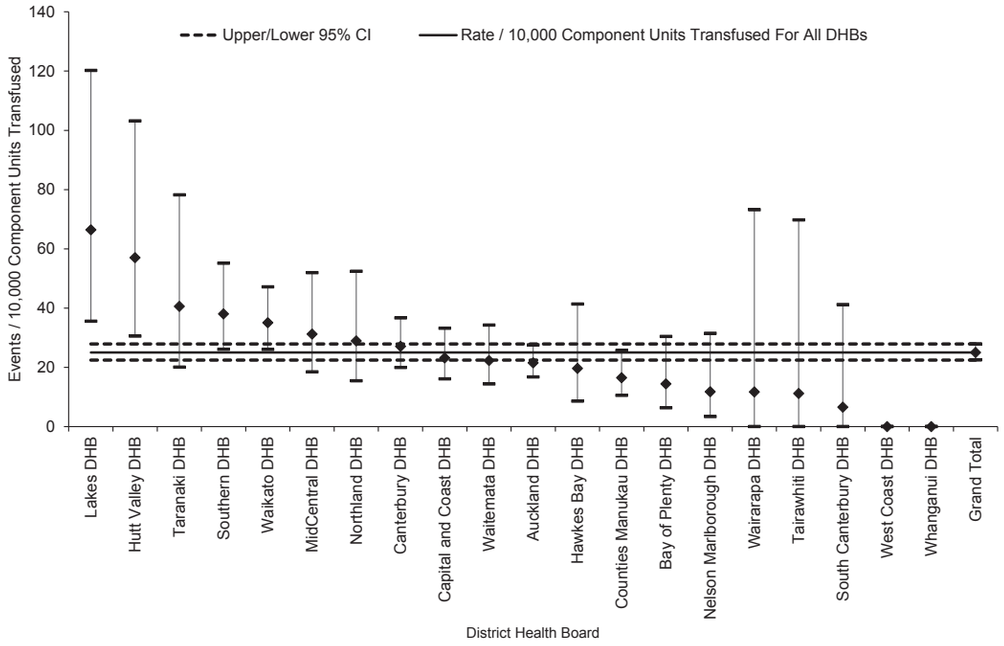
Transfusion-Related Adverse Events: Reporting District Health Boards continued

5

TABLE 5.1 TRANSFUSION-RELATED ADVERSE EVENTS (IMPUTABILITY ≥3) 2016 BY REPORTING DISTRICT HEALTH BOARD

District Health Board	Events	Units Transfused	Frequency	Rate / 10,000 Units Transfused (95%CI)
Lakes DHB	11	1,655	1:150	66.5 (35.6 to 120.2)
Hutt Valley DHB	11	1,929	1:175	57.0 (30.5 to 103.2)
Taranaki DHB	9	2,218	1:246	40.6 (20.1 to 78.2)
Southern DHB	28	7,361	1:263	38.0 (26.1 to 55.2)
Waikato DHB	44	12,540	1:285	35.1 (26.0 to 47.2)
MidCentral DHB	15	4,804	1:320	31.2 (18.5 to 51.9)
Northland DHB	11	3,801	1:346	28.9 (15.5 to 52.4)
Canterbury DHB	42	15,500	1:369	27.1 (20.0 to 36.7)
Capital and Coast DHB	30	12,945	1:432	23.2 (16.1 to 33.2)
Waitemata DHB	21	9,422	1:449	22.3 (14.4 to 34.3)
Auckland DHB	63	29,278	1:465	21.5 (16.8 to 27.6)
Hawkes Bay DHB	7	3,566	1:509	19.6 (8.6 to 41.4)
Counties Manukau DHB	20	12,096	1:605	16.5 (10.5 to 25.7)
Bay of Plenty DHB	7	4,850	1:693	14.4 (6.3 to 30.4)
Nelson Marlborough DHB	4	3,390	1:848	11.8 (3.4 to 31.5)
Wairarapa DHB	1	852	1:852	11.7(0 to 73.2)
Tairawhiti DHB	1	894	1:894	11.2 (0 to 69.8)
South Canterbury DHB	1	1,519	1:1519	6.6 (0 to 41.2)
West Coast DHB	0	498		
Whanganui DHB	0	1,067		
Total	**326**	**130,185**	**1:399**	**25.0 (22.5 to 27.9)**

FIGURE 5.2 TRANSFUSION-RELATED ADVERSE EVENTS (IMPUTABILITY ≥3) 2016 BY REPORTING DISTRICT HEALTH BOARD



6 Transfusion-Related Adverse Events: Imputability

During 2016, a total of 404 TRAE were reported to the National Haemovigilance programme. A total of 78 (19.3%) 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 2016 are shown in Table 6.2 and Table 6.3. As a proportion of all TRAE, the number with low ≤2 imputability has almost doubled since 2009 and in 2016, comprised nearly one fifth of all TRAE. These events are predominantly FNHTR (61%) and UCT (17%). 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 – 2016

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

6 Transfusion-Related Adverse Events: Imputability continued

TABLE 6.3 TRANSFUSION-RELATED ADVERSE EVENTS OF LOW ≤2 IMPUTABILITY 2009 – 2016 BY EVENT TYPE

	Percentage of Annual Total Reports of Low Imputability ≤2							
	2009	2010	2011	2012	2013	2014	2015	2016
FNHTR	34.3%	55.0%	72.6%	53.3%	70.4%	64.2%	69.1%	60.8%
UCT	34.3%	23.8%	16.4%	16.7%	23.9%	26.4%	13.4%	16.5%
Allergic	9.0%	6.3%	2.7%	14.4%	1.4%	1.9%	2.1%	2.5%
DSTR	3.0%	1.3%	2.7%	4.4%	0%	0%	8.2%	7.6%
Hypotension	3.0%	6.3%	2.7%	2.2%	0%	2.8%	3.1%	3.8%
IBCT	10.4%	3.8%	2.7%	0%	0%	0.9%	0%	2.5%
TAD	3.0%	3.8%	0%	4.4%	2.8%	0.9%	1.0%	0%
TACO	0%	0%	0%	2.2%	1.4%	0%	2.1%	3.8%
Acute Haemolytic	0%	0%	0%	1.1%	0%	0.9%	1.0%	1.3%
TRALI	0%	0%	0%	0%	0%	1.9%	0%	1.3%
DHTR	0%	0%	0%	1.1%	0%	0%	0%	0%
Pain	1.5%	0%	0%	0%	0%	0%	0%	0%
TTI	1.5%	0%	0%	0%	0%	0%	0%	0%
Total Reports Imputablity ≤2	**67**	**80**	**73**	**90**	**71**	**106**	**97**	**78**

All reported events in 2016 by event type and imputability score is shown in Table 6.4.

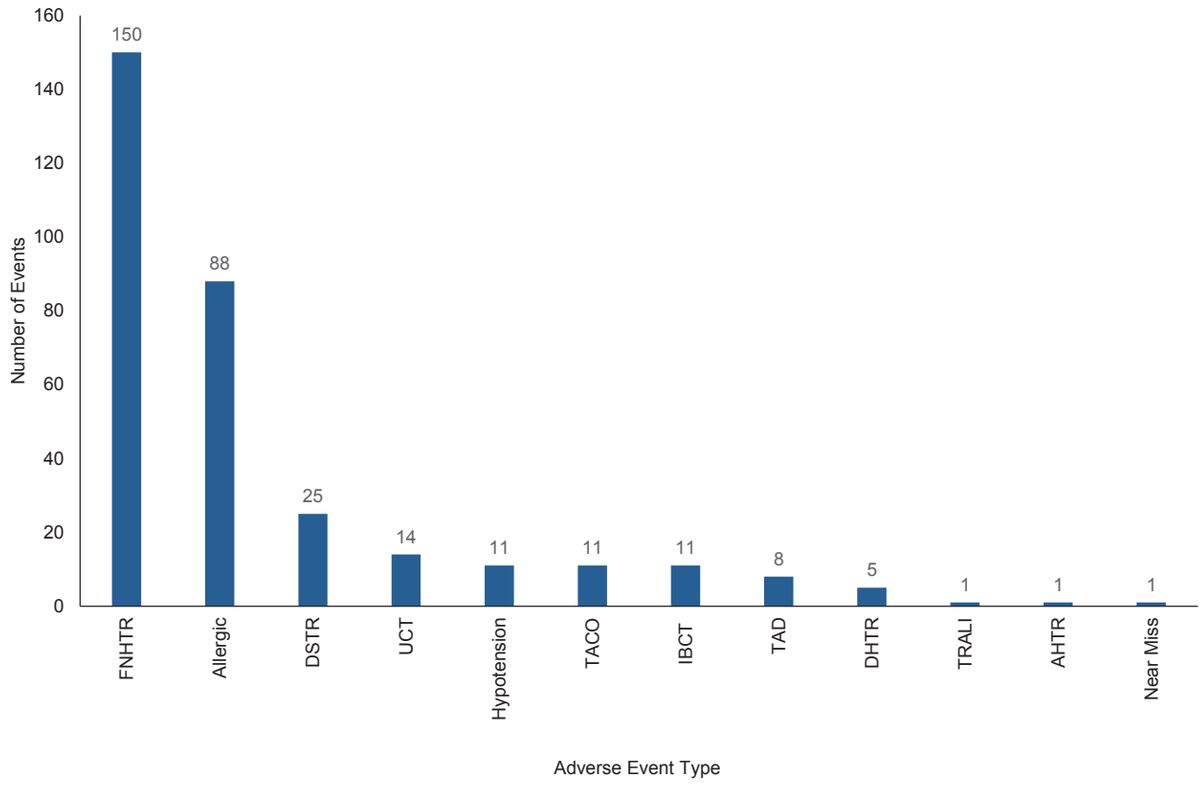
TABLE 6.4 TRANSFUSION-RELATED ADVERSE EVENTS 2016 BY EVENT TYPE AND IMPUTABILITY SCORE

Event Type	Imputability Score					Total	Total ≥3
	1	2	3	4	5		
FNHTR	25	23	106	43	1	198	150
Allergic	1		25	45	18	89	88
DSTR	6		2	7	16	31	25
UCT	6	7	12	2		27	14
Hypotension	1	2	8	3		14	11
TACO	2	1	6	4	1	14	11
IBCT	2				11	13	11
TAD			8			8	8
DHTR			1	2	2	5	5
TRALI	1		1			2	1
AHTR		1		1		2	1
Near Miss					1	1	1
Total	**44**	**34**	**169**	**107**	**50**	**404**	**326**
Percentage Events	10.9%	8.4%	41.8%	26.5%	12.4%		

Data analysed and included in the remainder of the Annual Haemovigilance Report is restricted to the 326 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) 2016 BY EVENT TYPE



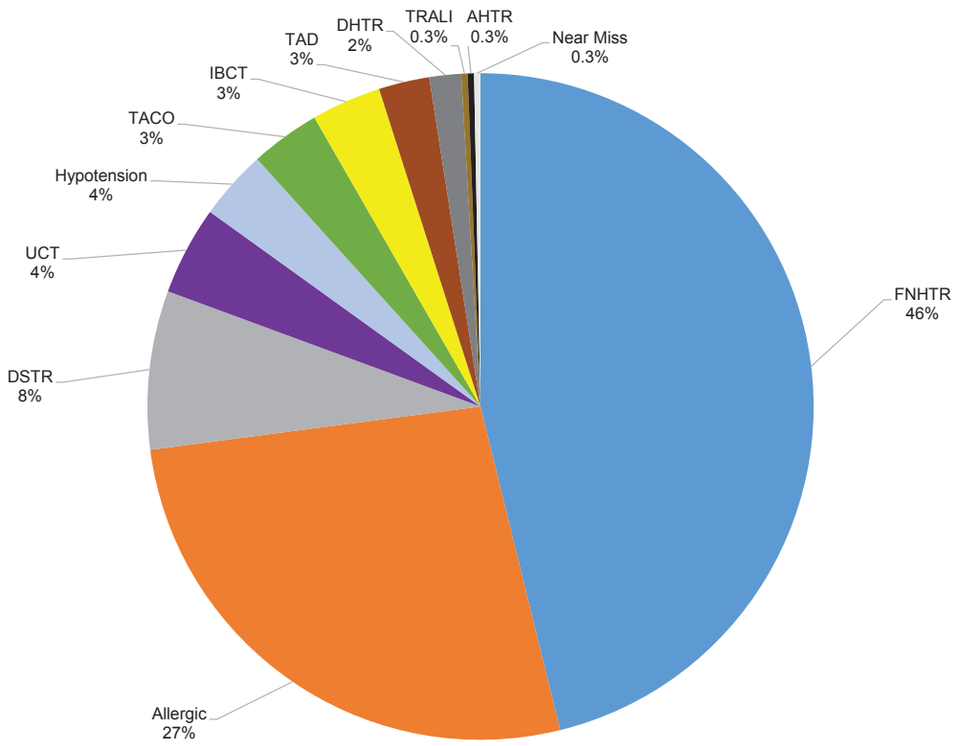
Key:

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

Transfusion-Related Adverse Events: Imputability continued

6

FIGURE 6.2 TRANSFUSION-RELATED ADVERSE EVENTS (IMPUTABILITY ≥3) 2016 BY EVENT TYPE



There were 311 transfusion recipients associated with the 326 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) 2016 BY RECIPIENT GENDER

		Age (years)		
	Number	Mean	Minimum	Maximum
Female	181	54	1 day	92
Male	145	54	1 day	89
Total	**326**	**54**	**1 day**	**92**

Multiple TRAE were reported in 15 patients (Table 6.6).

TABLE 6.6 NUMBER OF RECIPIENTS HAVING MULTIPLE TRANSFUSION-RELATED ADVERSE EVENTS (IMPUTABILITY ≥3) 2016

		Events	
	Total	1 Event	2 Events
Recipient Number	326	296	15

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, 93% were assessed as non-severe (grade 1). Severe (grade ≥2) events were 7% of all events and 73% of these were either allergic or TACO in nature (Table 7.2). There was one TACO event implicated in the death (grade 4) of one patient in 2016 (Table 7.2).

TABLE 7.1 SEVERITY SCORE DEFINITIONS FOR TRANSFUSION-RELATED ADVERSE EVENTS 2016

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) 2016 BY EVENT TYPE AND SEVERITY

Event Type	Severity				
	Grade 1	Grade 2	Grade 3	Grade 4	Total
FNHTR	149	1			150
Allergic	77	8	3		88
DSTR	25				25
UCT	13	1			14
Hypotension	10	1			11
IBCT	11				11
TACO	5	3	2	1	11
TAD	8				8
DHTR	4	1			5
AHTR		1			1
Near Miss	1				1
TRALI		1			1
Total	**303**	**17**	**5**	**1**	**326**
Percentage Events	92.9%	5.2%	1.5%	0.3%	

Transfusion-Related Adverse Events: Severity continued

7

Grade 4 Events 2009 – 2016

Between 2009 and 2016, seven transfusion recipients, who had TRAE, died and the death was probably or definitely related to the adverse event (i.e. severity Grade 4).

TABLE 7.3 GRADE 4 ADVERSE EVENTS 2009 - 2016

Adverse Event	Year	Imputability	Age (years)	Gender
TRALI	2009	Possible	75	Male
TRALI	2010	Possible	62	Male
TACO	2013	Likely/Probable	93	Female
TACO	2014	Certain	86	Male
ABO Incompatible Transfusion	2015	Certain	90	Female
TAD	2015	Certain	75	Male
TACO	2016	Possible	84	Male

The number and proportion of each adverse event type that was of grade 4 severity for the period 2009 – 2016 is shown in Table 7.4.

TABLE 7.4 PROPORTION OF ALL EVENTS THAT WERE GRADE 4 2009 - 2016

Adverse Event Type	All Reports		Grade 4 (Death)	
	Number	Percentage	Number	Percentage by Event
FNHTR	1,509	44.2%		
Allergic	1,033	30.2%		
UCT	194	5.7%		
IBCT	157	4.6%		
TACO	138	4.0%	3	2.2%
DSTR	116	3.4%		
TAD	84	2.5%	1	1.2%
Hypotension	74	2.2%		
DHTR	30	0.9%		
Near Miss	26	0.8%		
Acute Haemolytic	21	0.6%	1	4.8%
TRALI	13	0.4%	2	15.4%
Pain	10	0.3%		
TTI	7	0.2%		
Component Related	5	0.1%		
Total	**3,417**		**7**	**0.2%**

7 Transfusion-Related Adverse Events: Severity continued

The breakdown year-wise of adverse events that were of grade 4 severity, related to the total number of blood components transfused during the year, is shown in Table 7.5

TABLE 7.5 GRADE 4 EVENTS RELATED TO THE NUMBER OF COMPONENTS TRANSFUSED 2009 – 2016

Year	Number Grade 4 Events	Total Components Transfused	Frequency	Rate /100,000 Components Transfused (95%CI)
2009	1	162,587	1:162,587	0.6 (-0.3 to 3.9)
2010	1	159,568	1:159,568	0.6 (-0.3 to 3.9)
2011		151,919		0
2012		149,668		0
2013	1	136,995	1:136,995	0.7 (-0.3 to 4.6)
2014	1	135,135	1:135,135	0.7 (-0.3 to 4.6)
2015	2	132,060	1:66,030	1.5 (0.0 to 5.9)
2016	1	130,185	1:130,185	0.8 (-0.3 to 4.8)
Total	**7**	**1,158,117**	**1:165,445**	**0.6 (0.3 to 1.3)**

During the period 2009 – 2016, there were slightly fewer male recipients than females. However the difference is statistically insignificant. The data is shown in Table 7.6

TABLE 7.6 GENDER OF RECIPIENTS GRADE 4 ADVERSE EVENTS 2009 - 2016

Year	Recipients			Grade 4 Events		
	Female	Male	Total	Female	Male	Total
2009	19,490	17,035	36,525		1	1
2010	19,340	16,760	36,100		1	1
2011	18,468	16,065	34,533			
2012	17,979	15,915	33,894			
2013	16,733	15,644	32,377	1		1
2014	16,366	14,047	30,413		1	1
2015	15,600	13,768	29,368	1	1	2
2016	13,863	13,334	27,197		1	1
Total	**137,839**	**122,568**	**260,407**	**2**	**5**	**7**

Grade 4 events appear to occur mainly in the elderly. Table 7.7 compares such events for the period 2009 – 2016 in those aged 64 or less with those aged 65 and over. There were no grade 4 events reported in any patient less than 60 years old.

TABLE 7.7 COMPARISON OF AGE OF RECIPIENTS GRADE 4 ADVERSE EVENTS 2009 - 2016

Recipient age (Years)	Number of Recipients	Grade 4 events	Rate per 100,000 Recipients
≥ 65	144,005	6	4.2
≤ 64	116,402	1	0.9

8 Transfusion-Related Adverse Events: Implicated Blood Components

A total of 130,185 blood component units were transfused in 2016. Of these, 329 units were implicated in the 326 reported adverse events. The overall adverse event rate in 2016 was 1 in 397 units transfused (25.3 per 10,000 units transfused, 95% CI 22.7 to 28.2). Table 8.1 shows the adverse event rates for the individual blood component types in 2016.

TABLE 8.1 TRANSFUSION-RELATED ADVERSE EVENTS (IMPUTABILITY ≥3) 2016 BY BLOOD COMPONENT TYPE

Component	Units Implicated in TRAE[1]	Units Transfused	Frequency	Rate / 10,000 Units Transfused (95%CI)
Platelets Pooled PAS	31	8,447	1:272	36.7 (25.7 to 52.2)
Fresh Frozen Plasma	32	11,982	1:374	26.7 (18.8 to 37.8)
Platelets Apheresis PAS	10	3,813	1:381	26.2 (13.5 to 48.9)
Red Cells	250	99,862	1:399	25.0 (22.1 to 28.3)
Cryoprecipitate	5	4,463	1:893	11.2 (4.0 to 27.0)
Platelets (Apheresis)[2]	1	1,154	1:1154	8.7 (0 to 54.1)
Cryodepleted Plasma	0	464	0/464	(0 to 99)
Total	**329**	**130,185**	**1:396**	**25.3 (22.7 to 28.2)**

1 Includes TRAE where multiple component types transfused.

2 Includes 624 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) 2016 BY EVENT TYPE AND BLOOD COMPONENT TYPE

	Red Cells	Fresh Frozen Plasma	Platelets Apheresis	Platelets Apheresis PAS	Platelets Pooled PAS	Cryoprecipitate	Cryodepleted Plasma	Fractionated Plasma Products[1]	Multiple Components	Other[2]
Number Units Transfused	**99,862**	**11,982**	**1,154**	**3,813**	**8,447**	**4,463**	**464**			
FNHTR	134	3		1	9	1			2	
Allergic	36	21		6	15	3			7	
DSTR	25									
Hypotension	11							8		
UCT	10				2				1	1
TACO	9	1		1						
TAD	7								1	
DHTR	5									
IBCT	2	1								
Acute	1									
Near Miss	1									
TRALI					1					
Total	**242**	**26**	**0**	**8**	**27**	**4**	**0**	**8**	**11**	

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

2 Events associated with transfusion of Autologous Stem Cells

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 (49%). A total of 198 reports of FNHTR were received; 150 were of imputability ≥3 and included in the analysis. Of the reported events, 23 were of low ≤2 imputability and probably due to the patient's underlying medical condition. An additional 25 submitted reports of febrile reactions did not meet criteria for FNHTR and thus were excluded by 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) 2016 BY RECIPIENT GENDER

	Number	Age (years)		
		Mean	Minimum	Maximum
Female	78	62	1 day	92
Male	72	57	1 day	89
All	**150**	**60**	**1 day**	**92**

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) 2016 BY ASSOCIATED SIGNS AND SYMPTOMS

Symptom	Number			% Events		
	Female (n=78)	Male (n=72)	Total (n=150)	Female	Male	Total
Chills / Rigors	37	36	73	40.7%	53.7%	46.2%
Increase in blood pressure	17	8	25	18.7%	11.9%	15.8%
Tachycardia	8	5	13	8.8%	7.5%	8.2%
Restlessness / Anxiety	8	5	13	8.8%	7.5%	8.2%
Dyspnoea	9	3	12	9.9%	4.5%	7.6%
Cough	3	2	5	3.3%	3.0%	3.2%
Nausea	1	3	4	1.1%	4.5%	2.5%
Non-urticarial rash	2	1	3	2.2%	1.5%	1.9%
Stridor / Wheeze	1	2	3	1.1%	3.0%	1.9%
Hypoxaemia	2	0	2	2.2%	0.0%	1.3%
Chest pain	2	0	2	2.2%	0.0%	1.3%
Urticaria	0	1	1	0.0%	1.5%	0.6%
Fall in blood pressure	1	0	1	1.1%	0.0%	0.6%
Loin pain	0	1	1	0.0%	1.5%	0.6%
Mean temperature rise	2.8°C	1.5°C	2.1°C			

9 Febrile Non-Haemolytic Transfusion Reactions (FNHTR)
continued

Of the reported FNHTR events, 10 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) 2016 BY RECIPIENT GENDER

	Number	Temperature Rise (°C)			Age (Years)		
		Mean	Min	Max	Mean	Min	Max
Female	5	2.6	2.1	3.0	54	27	69
Male	5	2.2	2.0	2.5	54	35	69
Total	**10**	**2.4**	**2.0**	**3.0**	**54**	**27**	**69**

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 2016, there were 88 (27%) events classified as allergic in nature. Of these, 77 (87.5%) were non-severe and the remaining 11 (12.5%) were severe or life-threatening. Table 10.1 shows allergic events by recipient gender along with data on recipient age.

TABLE 10.1 ALLERGIC EVENTS (IMPUTABILITY ≥3) 2016 BY RECIPIENT GENDER

	Number	Age (years)		
		Mean	Minimum	Maximum
Female	51	37	1	82
Male	37	37	1 day	86
All	**88**	**37**	**1 day**	**86**

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 2016.

TABLE 10.2 ALLERGIC EVENTS (IMPUTABILITY ≥3) 2016 BY ASSOCIATED SIGNS AND SYMPTOMS

Symptom	Allergic Events					
	Grade 1 (n=77)			Grade 2 & 3 (n=11)		
	Number	% Symptoms	% Grade 1 Events	Number	% Symptoms	% Grade 2 & 3 Events
Urticaria	61	52.1%	79.2%	7	21.9%	63.6%
Restlessness / Anxiety	12	10.3%	15.5%	3	9.4%	27.3%
Periorbital oedema	7	6.0%	9.1%	2	6.3%	18.2%
Chills / Rigors	6	5.1%	7.8%	2	6.3%	18.2%
Hypoxaemia	6	5.1%	7.8%	2	6.3%	18.2%
Non-urticarial	5	4.3%	6.5%	0	0.0%	0.0%
Stridor / Wheeze	4	3.4%	5.2%	3	9.4%	27.3%
Dyspnoea	4	3.4%	5.2%	2	6.3%	18.2%
Increase in blood pressure	4	3.4%	5.2%	1	3.1%	9.1%
Tachycardia	3	2.6%	3.9%	2	6.3%	18.2%
Swollen tongue	2	1.7%	2.6%	1	3.1%	9.1%
Cough	2	1.7%	2.6%	1	3.1%	9.1%
Fall in blood pressure	1	0.9%	1.3%	4	12.5%	36.4%
Conjunctive oedema		0.0%	0.0%	1	3.1%	9.1%
Loin pain		0.0%	0.0%	1	3.1%	9.1%
Chest pain		0.0%	0.0%	0	0.0%	0.0%

10 Allergic Transfusion Reactions
continued

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

TABLE 10.3 ALLERGIC EVENTS (IMPUTABILITY ≥3) 2016 BY BLOOD COMPONENT TYPE

Component	Number Events	Number Units Transfused	Frequency	Rate / 10,000 Units Transfused (95%CI)
Platelets Pooled PAS	15	8,447	1:563	17.8 (10.5 to 29.6)
Fresh Frozen Plasma	21	11,982	1:571	17.5 (11.3 to 26.9)
Platelets Apheresis PAS	5	3,813	1:763	13.1 (4.6 to 31.6)
Platelets Apheresis Plasma[1]	1	1,154	1:1154	8.7 (0 to 54.1)
Cryoprecipitate	3	4,463	1:1488	6.7 (1.3 to 20.7)
Red Cells	36	99,862	1:2774	3.6 (2.6 to 5.0)
Cryodepleted Plasma	0	464	0/464	(0 to 99)
Total	**81**	**130,185**	**1:1607**	**6.2 (5.0 to 7.7)**

1 Includes Platelets - Neonatal.

Acute Haemolytic Transfusion Reactions (AHTR)

11

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 2016, there was one reported event classified as an acute haemolytic transfusion reaction. The details of the event are provided below.

CASE A

A 59 year old female with myelodysplasia and a haemoglobin of 92 g/L received 8 mL of red cells before becoming breathless and very anxious, accompanied by chills, rigors and vomiting. She developed hypertension (185/90 mmHg) and pulse oximetry revealed an oxygen saturation of 88%. Pretransfusion the temperature was 37.3°C and was 38.8°C at the time of the adverse event. The serum bilirubin rose from 12 µmol/L the day prior to the transfusion and up to 28 µmol/L 30 minutes after the adverse event and returned to the baseline within 24 hours. The haptoglobin fell to 0.02 g/L 30 minutes after the adverse event.

Pretransfusion, the red cell antibody screen (RCAS) was positive and anti-c identified plus an auto AHG reactive antibody, the DAT was positive, anti-IgG 3^+ positive. The red cell unit that was selected to be transfused was prophylactically antigen matched, a serological crossmatch was not performed.

The serological investigation of the adverse event showed that the red cell unit transfused was strongly incompatible but a second unit not transfused was compatible. The red cell phenotypes of the two red cell units matched that of the patient.

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

12 Transfusion-Related Acute Lung Injury (TRALI)

Definition:

New acute lung injury (ALI): acute onset during or within 6 hours of completion of transfusion, hypoxaemia (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 2016, there was one reported event of TRALI in New Zealand. The case is summarised below:

Case B

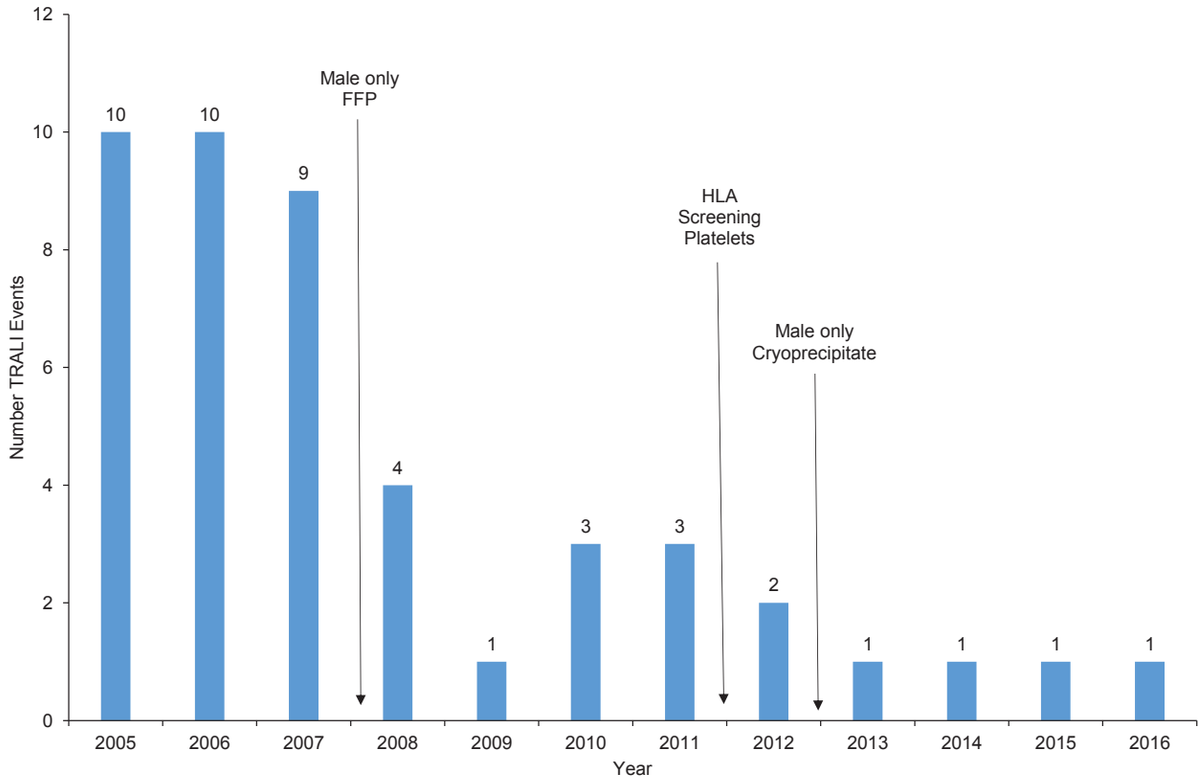
A 70 year old female with a background history of MDS presented with chest pains – initially left sub-scapular and pleuritic in nature, and later, central. For this she underwent a percutaneous coronary intervention procedure prior to which she received a unit of pooled platelets. Half an hour after the transfusion, she became acutely breathless and developed a wheeze, tachycardia (pulse rate baseline and during event, 98 / min and 127 / min respectively) and hypotension (BP, baseline and during event, 93 / 66 mmHg and 60 / 47 mmHg respectively). Though baseline oxygen saturations are not available, during the reaction she became hypoxic with O_2 saturation of 91%. An immediate post-event chest x-ray showed some left basal consolidation, no abnormalities in other parts of the lungs, and no cardiomegaly. Retrospectively, it was noted that the white cell and neutrophil counts had fallen from baseline values of 2.2 and 1.2 x 10^9/L respectively to 0.5 and 0.1 x 10^9/L respectively with recovery, two days later, to 1.9 and 0.9 x 10^9/L respectively. Transient leucopenia, neutropenia, and monocytopenia have been described in TRALI. Empirically, she was treated with frusemide and hydrocortisone and she made a good recovery. Though not quite typical, this case was classified as a TRALI; severity grade two; imputability, possible. Female donors contributing to the platelet pool were contacted for testing for antibodies to HLA / HNA but none has actually been tested.

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

Transfusion-Related Acute Lung Injury (TRALI) continued

12

FIGURE 12.1 ANNUAL NUMBER OF TRALI EVENTS 2005 – 2016



12 Transfusion-Related Acute Lung Injury (TRALI) continued

The components implicated yearly in TRALI events between 2005 and 2016 are detailed in Table 12.1.

TABLE 12.1 COMPONENTS IMPLICATED IN TRALI EVENTS 2005 – 2016

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		
Total	**46**	**23**	**20**	**10**	**5**	**1**	**4**	**3**	**1**
Percentage	50%	43%	22%	11%	2%	9%	7%	2%	

Transfusion-Associated Circulatory Overload (TACO)

13

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 2016, there were 11 reported TACO events (3.4% of total events). Five were non-severe, three were grade 2 (severe), two were grade 3 (life-threatening) and one grade 4 (death). Table 13.1 shows the TACO events by recipient gender, along with data on recipient age.

TABLE 13.1 TACO EVENTS (IMPUTABILITY ≥3) 2016 BY RECIPIENT GENDER

		Age (Years)		
	Number	Mean	Minimum	Maximum
Female	4	65	19	91
Male	7	76	55	88
All	**11**	**72**	**19**	**91**

Table 13.2 shows the recorded clinical features of the TACO events reported during 2016.

TABLE 13.2 TACO EVENTS (IMPUTABILITY ≥3) 2016 BY ASSOCIATED SIGNS AND SYMPTOMS

Symptom	Number			% TACO Events
	Female	Male	Total	
Hypoxaemia	3	4	7	13.7%
Dyspnoea	1	5	6	11.8%
Stridor / Wheeze	1	5	6	11.8%
Pulmonary oedema	2	4	6	11.8%
Fall in O_2 saturation	2	3	5	9.8%
Increase in blood pressure	1	2	3	5.9%
Restlessness / Anxiety	1	2	3	5.9%
Raised JVP	1	2	3	5.9%
Shortness of breath	2	1	3	5.9%
Chills / Rigors	1	1	2	3.9%
Tachycardia	1	1	2	3.9%
Chest pain	1	1	2	3.9%
Cough		2	2	3.9%
Decrease in blood pressure		1	1	2.0%

13 Transfusion-Associated Circulatory Overload (TACO) continued

Table 13.3 shows the blood components implicated in TACO events reported each year from 2007 to 2016.

TABLE 13.3 COMPONENTS IMPLICATED IN TACO EVENTS (IMPUTABILITY ≥3) 2007 – 2016

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					
Total	**172**	**150**	**26**	**8**	**7**	**7**	**6**	**5**	**3**	**2**	**1**
Percentage		87.2%	15.2%	4.6%	4.0%	4.0%	3.4%	2.9%	1.7%	1.2%	0.6%

Table 13.4 shows the number of TACO events reported each year from 2010 to 2016.

TABLE 13.4 ANNUAL NUMBER OF TACO EVENTS (IMPUTABILITY ≥3) 2010 – 2016

Year	Reported TACO Events	Total Component Units Transfused	Frequency	Rate / 100,000 Units Transfused (95% CI)
2010	13	159,568	1:12,274	8.1 (4.6 to 14.1)
2011	19	151,919	1:7,996	12.5 (7.9 to 19.7)
2012	27	149,668	1:5,543	18.0 (12.3 to 26.4)
2013	16	136,995	1:8,562	11.7 (7.0 to 19.1)
2014	12	135,135	1:11,261	8.9 (4.9 to 15.7)
2015	16	132,060	1:8,254	12.1 (7.3 to 19.9)
2016	11	130,185	1:11,835	8.4 (4.5 to 15.3)
Total	**114**	**995,530**	**1:8,773**	**11.5 (9.5 to 13.8)**

Transfusion-Associated Circulatory Overload (TACO) continued

13

From 2010 to 2016, 4% of all reported events were classified as TACO, however they were responsible for 20% of events graded with a severity score ≥2 (Table 13.5).

TABLE 13.5 SEVERE TACO EVENTS (IMPUTABILITY ≥3) 2010 – 2016

		Severity Grade			
		Grade 2 (Severe)	Grade 3 (Life Threatening)	Grade 4 (Death)	Total
All Adverse Events	Number	271	42	6	293
TACO Events	Number	52	10	3	65
	Percentage of Grade	19%	24%	50%	20%

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

CASE C

An 88 year old male with a history of hypertension, aortic stenosis, and mitral regurgitation was undergoing treatment for a lower respiratory tract infection, bilateral upper limb cellulitis, and symptomatic anaemia (Hb 72 g/L). For his anaemia, he was prescribed a unit of red cells. About 40 minutes into the transfusion, at which point about 250 mL had been transfused, he became more breathless than previously. At this point the transfusion was stopped. On examination he was found to be wheezy and had developed a tachycardia (pulse 113 / min at baseline; 136 / minute during event), tachypnoea (baseline and at event respiratory rates, 18 and 32 / min respectively), and more profound hypoxia (O_2 saturations 93% and 88% on room air at baseline and during event respectively). He was febrile both at baseline and during the event (temp 38.1°C and 38.6°C respectively). Crackles were heard at both lung bases but more on the left side. JVP was elevated (5 cm). A chest x-ray performed within 20 minutes of the event showed increased interstitial markings suggestive of fluid overload, but no cardiomegaly, and airspace shadowing in the right lower lobe suggestive of infection. Post-transfusion NT-proBNP was 515 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. He was given frusemide intravenously and gradually improved over the next 24 hours. The event was classified as TACO; severity grade 3; imputability, probable.

14 Transfusion-Associated Dyspnoea (TAD)

Definition:

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

During 2016, there were eight events classified as TAD. There were six reports involving female patients and two reports involved male recipients. All the events were classified as non-severe (grade 1).

Table 14.1 shows the number of TAD events reported each year from 2008 to 2016

TABLE 14.1 ANNUAL NUMBER OF TAD EVENTS (IMPUTABILITY ≥3) 2008 – 2016

Year	TAD Events	Total Component Units Transfused	Frequency	Rate / 100,000 Units Transfused (95%CI)
2008	8	158,181	1:19,773	5.1 (2.4 to 10.2)
2009	13	162,587	1:12,507	8.0 (4.5 to 13.8)
2010	9	159,568	1:17,730	5.6 (2.8 to 10.9)
2011	6	151,919	1:25,320	3.9 (1.6 to 8.8)
2012	15	149,668	1:9,978	10.0 (5.9 to 16.7)
2013	26	136,995	1:5,269	19.0 (12.8 to 27.9)
2014	4	135,135	1:33,784	3.0 (0.9 to 7.9)
2015	2	132,060	1:66,030	1.5 (0 to 5.9)
2016	8	130,185	1:16,273	6.1 (2.9 to 12.4)
Total	**91**	**1,316,298**	**1:14,465**	**6.9 (5.6 to 8.5)**

Hypotensive Transfusion Reactions 15

Definition:

Decrease in systolic and/or diastolic blood pressure of >30 mmHg occurring during or within one hour of completing transfusion. All other categories of adverse reactions presenting with hypotension must have been excluded together with underlying conditions that could explain hypotension.

During 2016, there were 11 events classified as hypotensive transfusion reactions. Red cell units transfused were implicated in all the TRAEs. Ten reports were classified as non-severe (grade 1) and one report as severe (grade 2).

Table 15.1 shows the components implicated in hypotensive events reported each year from 2009 to 2016

TABLE 15.1 COMPONENTS IMPLICATED IN HYPOTENSIVE EVENTS (IMPUTABILITY ≥3) 2009 – 2016

Year	Total Hypotensive Events	Implicated Components					
		Red Cells	Apheresis Platelets Plasma	Apheresis Platelets PAS	Fresh Frozen Plasma	Pooled Platelets Plasma	Autologous Salvaged Red Cells
2009	13	9	3		1	2	
2010	14	14					
2011	12	10	2				
2012	14	10	1	3	1		
2013	2	1		1			
2014	3	2					1
2015	5	4			1		
2016	11	11					
Total	**74**	**61**	**6**	**4**	**3**	**2**	**1**
Percentage	82.4%	8.1%	5.4%	4.0%	2.7%	1.3%	

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

Definition:

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

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

During 2016, there were five reports of DHTR and 25 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) 2016 BY EVENT TYPE AND RECIPIENT GENDER

		Number	Age (years)		
			Mean	Minimum	Maximum
DHTR	Female	5	63	42	77
	Male				
DSTR	Female	9	61	30	78
	Male	16	65	36	85

16

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

TABLE 16.2 DELAYED TRANSFUSION REACTIONS (IMPUTABILITY ≥3) 2016 BY SPECIFICITY OF RED CELL ANTIBODY

Antibody Specificity	Number (Percentage)		
	Delayed Haemolytic	Delayed Serological	Total
Ant-Fy^{a} + E	1 (20%)	0 (0%)	1 (3.3%)
Anti-Fy^{a}	1 (20%)	1 (4%)	2 (6.7%)
Anti-Jk^{3}	1 (20%)	0 (0%)	1 (3.3%)
Anti-Jk^{a}	1 (20%)	4 (16%)	5 (16.7%)
Anti-Jk^{a} + E	1 (20%)	0 (0%)	1 (3.3%)
Anti-C	0 (0%)	2 (8%)	2 (6.7%)
Anti-C + E	0 (0%)	2 (8%)	2 (6.7%)
Anti-E	0 (0%)	2 (8%)	2 (6.7%)
Anti-E + Jk^{a}	0 (0%)	1 (4%)	1 (3.3%)
Anti-K	0 (0%)	6 (24%)	6 (20.0%)
Anti-K + E	0 (0%)	1 (4%)	1 (3.3%)
Anti-Kp^{a}	0 (0%)	1 (4%)	1 (3.3%)
Anti-Lu^{a}	0 (0%)	1 (4%)	1 (3.3%)
Anti-M	0 (0%)	1 (4%)	1 (3.3%)
Anti-S	0 (0%)	1 (4%)	1 (3.3%)
Anti-E + C	0 (0%)	1 (4%)	1 (3.3%)
Anti-Cw	0 (0%)	1 (4%)	1 (3.3%)
Total	**5**	**25**	**30**
Blood Group System			
Rh	0 (0%)	8 (32%)	8 (26.7%)
Kell	0 (0%)	7 (28%)	7 (23.3%)
Kidd	2 (40%)	4 (16%)	6 (20.0%)
Multiple	2 (40%)	2 (8%)	4 (13.3%)
Duffy	1 (20%)	1 (4%)	2 (6.7%)
MNSs	0 (0%)	2 (8%)	2 (6.7%)
Lutheran	0 (0%)	1 (4%)	1 (3.3%)

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

CASE D

A 63 year old female, day eight post-transfusion, Anti-Jk^a was identified, the direct antiglobulin test was IgG1+ve, C3d weak and Anti-Jk^a + E was eluted.

Post-transfusion laboratory results are detailed below.

	Days Post-Transfusion							
	Day 1	**Day 2**	**Day 3**	**Day 4**	**Day 5**	**Day 6**	**Day 7**	**Day 8**
RBC Antibody Screen	Neg				Neg			Positive
RBC units transfused	7				1	2		
DAT								IgG 1+ve C3d weak
Antibody Identification								Anti-Jk^a
Eluate								Anti-Jk^a+E
Haemoglobin (g/L)	56	85	79	77	74	73	74	64
Reticulocytes (x10^9/L)								259
Bilirubin (µmol/L)	4	4	5	7	7	13	16	25
Haptoglobin (g/L)								0.28

The event was recorded as DHTR, of grade 1 severity and likely/probable imputability.

Unclassifiable Complications of Transfusion (UCT)

17

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 2016, there were 27 reports received of adverse events which could not be classified into a definitive category. Of these, 13 were excluded from the analysis on the basis that the event could be attributable to a cause other than the transfusion. The remaining 14 events, included in the analysis, involved 11 female and three male recipients. Ten events involved only red cell components, two involved PAS pooled platelets and one, thawed autologous haemopoietic stem cells. One event involved multiple red cell and PAS pooled platelet components. The predominant clinical features of these UCT events are summarised in Table 17.1.

TABLE 17.1 UCT EVENTS (IMPUTABILITY ≥3) 2016 BY ASSOCIATED SIGNS AND SYMPTOMS

Symptom	Number of Events
Chest pain	5
Nausea	3
Infusion pain	1
Tachycardia	1
Arrhythmia	1
Arm numbness	1
Bradycardia	1
Back pain	1
Total	**14**

18 Reports Involving Paediatric Patients

During 2016, there were 34 events (10.4% of all events) involving recipients aged 15 years or younger. Allergic reactions were the most frequent adverse event reported in this age group (65%). Table 18.1 details the event type and severity of adverse events occurring in paediatric patients.

TABLE 18.1 ADVERSE EVENTS (IMPUTABILITY ≥3) 2016 IN RECIPIENTS ≤15 YEARS AGE BY EVENT TYPE

Event Type	Number	Percentage of Events	Gender		Severity Score		
			Female	Male	1	2	3
Allergic	22	65%	9	13	21	1	
FNHTR	8	24%	2	6	8		
IBCT	2	6%	1	1	2		
UCT	2	6%	1	1	2		
Total	**34**		**13**	**21**	**33**	**1**	

19 Transfusion Transmitted Infections (TTIs) and Lookbacks

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 shall be carried out by an external reference laboratory. Implicated donors are traced and asked to provide samples for retesting if they have not donated or have not been retested since their implicated donation.
- 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 2016, ten lookbacks were undertaken. Nine of these involved donors with repeatedly reactive results in routine infectious marker testing and one involved a recipient who was found to have HTLV antibodies as part of a routine pre-transplant work-up. The lookbacks are summarised on the next page.

Transfusion Transmitted Infections (TTIs) and Lookbacks continued

19

Donors Previously Tested Negative, Current Donation Repeat Reactive

Six investigations involved possible occult HBV infection (Ultrio Plus reactive but non-discriminating; anti-HBc positive). Two lookbacks involved donors who were Hepatitis B serology positive and NAT negative; and one lookback for syphilis.

The nine lookbacks involved 47 recipients of blood. Of the 47 recipients, 19 (40%) were deceased and for the remaining 28 recipients a request for testing was sent to the patient's General Practitioner or Hospital Consultant. Test results were received on 4 patients (14%) and in all these cases were negative for evidence of transfusion-transmitted infection (Table 19.1).

TABLE 19.1 REPEAT REACTIVE DONOR LOOKBACK INVESTIGATIONS 2016 BY INFECTION TYPE

Infectious Disease	Number Lookbacks	Recipients Identified	Deceased Recipients	Requests for Recipient Testing	Lookback Outcome
Occult HBV	6	34	12	22	HBV negative (3)
HBV	2	11	5	6	HBV negative (1)
Syphilis	1	2	2	0	
Total	**9**	**47**	**19**	**28**	**Negative (4)**

There was one case of recipient seroconversion for anti-HTLV. This most likely represented passive transfer of antibody by immunoglobulin treatment.

CASE E

The patient, a 16 month old male, had a negative anti-HTLV screen prior to a cord blood stem cell transplant. The graft failed and the patient was rescreened for anti-HTLV two months after the initial screen, prior to a second cord blood stem cell transplant. The screen was repeat reactive for anti-HTLV(EIA) at a reference laboratory, negative by PPA and indeterminate (two weak bands) by Western Blot. The cord blood had been screened and found to be anti-HTLV negative.

The patient had received 19 blood components from 36 blood donors and six doses of Intravenous Immunoglobulin (Privigen®, 5g)

Retention samples from the 36 blood donors were tested for anti-HTLV and all found to be non-reactive.

HTLV transmission has not been documented following transfusion of leucodepleted blood components. The manufacturer of Privigen®, CSL Behring, informed NZBS that donors for Privigen® are not screened for anti-HTLV antibodies.

20 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 these are forwarded to the manufacturer, CSL Behring (Australia) Pty Ltd. Periodic reports are provided to the Centre for Adverse Reaction Monitoring (CARM).

In 2016, 42 adverse reactions occurred 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® (35 reactions) and three reactions to Albumex®. In addition, three 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 21: Incorrect Blood Components Transfused (IBCT).

Table 20.1 shows the 42 adverse events by fractionated plasma product type. Additional information on events associated specifically with administration of Intragam®P is provided in Table 20.2 and with Privigen® in Table 20.3.

TABLE 20.1 TRANSFUSION-RELATED ADVERSE EVENTS (ANY CAUSALITY) 2016 ASSOCIATED WITH FRACTIONATED PLASMA PRODUCTS

Product Type	Event Type	Number of Reports
Intragam®P	Various (See Table 20.2)	21
Privigen®	Various (See Table 20.3)	13
RhD Immunoglobulin-VF	Inapproprate use	3
Albumex® 4	Febrile, hypotensive	2
Evogam®	Allergic	1
Albumex® 20	Pain and itch	1
RiaSTAP®	Exposure Event	1
Total		**42**

TABLE 20.2 TRANSFUSION-RELATED ADVERSE EVENTS (ANY CAUSALITY) 2016 ASSOCIATED WITH INTRAGAM®P

		Causality					Severity	
Type of Reaction	Total	Excluded	Unlikely	Possible	Probable	Highly probable	Non-severe	Severe
Allergic	9			1	4	4	9	
Febrile	3			1	2		3	
Pain	3			1	1	1	2	1
Aseptic meningitis	1					1	1	
Haemolytic	1					1	1	
Haemolytic and aseptic meningitis	1					1	1	
Headache / Pain	1			1			1	
Tightness in left chest and left arm	1					1	1	
Headache and possible fever	1				1		1	
Total	**21**			**4**	**8**	**9**	**20**	**1**

Adverse Events Associated with Fractionated Plasma Products continued

20

TABLE 20.3 TRANSFUSION-RELATED ADVERSE EVENTS (ANY CAUSALITY) 2016 ASSOCIATED WITH PRIVIGEN®

Type of Reaction	Total	Causality						Severity	
		Excluded	Unlikely	Possible	Probable	Highly probable	Certain	Non-severe	Severe
Febrile	3			1	1		1	3	
TTI	1			1				1	
Allergic	1				1			1	
Allergic, atypical	1					1		1	
Aseptic meningitis	1				1			1	
Febrile & Allergic (two reactions)	1				1			1	
Haemolytic	1					1		1	
Haemolytic, tachycardia & tachypnoea	1					1		1	
Acute respiratory decompensation possibly due to cardiac overload	1			1					1
Oxygen desaturation	1					1		1	
Pain	1				1			1	
Total	**13**			**3**	**5**	**4**	**1**	**12**	**1**

All but two of the adverse events to fractionated products were classified as non-severe. The two severe events were associated with the infusion of Intragam®P and Privigen® and were classified with a causality of possible or probable.

CASE F - Severe Event Involving Intragam®P

Male 68 years. Intervention to avoid possible injury, prolonged hospitalisation

This patient who was treated with Intragam®P for necrotising myopathy (myositis) developed chest tightness and pain on the first infusion day. Causality is possible.

This patient with necrotising myopathy was admitted to hospital for his first dose of IVIg at a dose of 1g/kg/day for 2 days. Late on the first day of treatment he complained of belching, indigestion-like pain and chest tightness. Symptoms lasted for approximately 30 minutes and occurred 30 minutes after the end of the infusion on that day. After medical review he was admitted to the coronary care unit. An ECG did not show ST elevations. The CK was 435 (60-220) on the day of treatment prior to IVIg and the Troponin T 47 later on the same day at 16:50hrs, 56 at 18:45hrs and 77 on day 2 at 09:00hrs. Clinical impression was that there was no evidence of obstructive angina. The Exercise Tolerance Test was negative and the chest pain was considered to be due to other causes than myocardial ischaemia. A myocardial perfusion scan has been requested. Mycophenolate had been stopped and will be restarted based on CBC blood test results. On review, the patient has had similar chest tightness following exertion but angina is not considered to be confirmed. The remainder of the IVIg dose was given (starting at 16:00hrs on the following day) and was completed without further pain or other symptoms. The patient was also started on cilazapril.

20 Adverse Events Associated with Fractionated Plasma Products
continued

CASE G - Severe event involving Privigen®

Male 77 years. Life threatening. Intervention to avoid hospitalisation. Possible.

Respiratory decompensation occurred in a patient being treated with Privigen® (IVIg) who had chronic lymphocytic leukaemia (CLL) and known hypogammaglobulinemia and was being treated for streptococcal pneumonia. TACO cannot be excluded. Causality is possible.

This 77 year old man with CLL and a history of splenectomy presented with streptococcal pneumonia. He was managed in the Intensive Care Unit with meropenem and vasoactive treatment to support his blood pressure (BP). Subsequently, he was improving slowly and due to low IgG levels was given Privigen®: dose charted 40g. Five hours into the infusion which was given at a slow rate of 28 mL/h, he suddenly became acutely short of breath, desaturated and required more support for BP. He was commenced on CPAP, the IVIg stopped and he improved clinically. The clinical impression was a likely septic shower or worsening of sepsis, or an adverse reaction to the IVIg. The event was notified because of the concurrent IVIg administration. The patient has received Intragam®P on two previous occasions: 11-Apr-2014: 2x 200mL and 5-Jun-2015 3x 200mL without adverse effect. The possibility of cardiac overload cannot be excluded.

Review of the frequency of events during the previous decade, 2007 – 2016, identified 336 events involving either an adverse reaction or exposure to a blood product when not indicated (see Table 20.4). 66% of events occurred to high-volume immunoglobulin products with 13% to Albumex® products, 8% to coagulation factor concentrates and 2% to various normal and hyperimmune immunoglobulins. 11% of events involved RhD Immunoglobulin-VF and most of these involved exposure to the product when not indicated, or supply of an incorrect dose.

Data for the frequencies of different types of adverse event are provided in Table 20.4. Review of data for the past decade shows that the most frequent types of adverse events were allergic reactions (35%), febrile reactions (15%) and pain (11%). Mixed or other adverse reactions occurred in 15% of cases and 12% involved supply of a wrong product or dose. Adverse events associated with thrombosis, hypotension, aseptic meningitis and volume overload were less frequent occurring at approximately 2 – 3% of events. The data for 2016 are consistent with the overall frequencies.

Adverse Events Associated with Fractionated Plasma Products
continued

20

TABLE 20.4 FREQUENCY OF ADVERSE EVENTS TO MANUFACTURED COMPONENTS 2007 - 2016

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	40
2016	8	12	6	0	1	4	2	0	2	4	4	42
Total for decade	**50**	**117**	**36**	**5**	**10**	**23**	**6**	**5**	**40**	**40**	**8**	**336**
	15%	35%	11%	1.5%	3.0%	7%	1.8%	1.5%	12%	12%	2.4%	

21 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 2016, there were 11 IBCT events reported. This compares to 12 IBCT events reported in 2015. The IBCT events for 2016 are detailed in Table 21.1.

TABLE 21.1 IBCT EVENTS 2016

IBCT Event Type of Product	Description	Site of Error
Incorrect product/ dose Red Cells (2) Fresh Frozen Plasma (1) Blood Products (3)	Patient with historic anti-M + anti-E. Transfused with seven units red cells where RhE antigen status was unknown. One unit subsequently identified as RhE positive. Good haemoglobin increments, no adverse event reported.	Laboratory
	Paediatric patient (3 years old) undergoing bypass surgery transfused with a unit labelled "Not For Paediatric Use". No evidence of reaction or adverse consequences.	Laboratory
	Protocol for surgery required patient to receive recombinant Factor VIII pre and post surgery. Factor VIII inhibitor bypassing fraction (FEIBA) issued and administered. When FVIII level did not increase error noticed.	Laboratory
	Patient for stem cell transplant, patient group A, donor group B. Two plasma exchanges to reduce anti-A titre. Blood bank issued group A plasma for exchange instead of group AB. Transplant re-scheduled and two further exchanges required prior to transplant.	Laboratory
	Factor VIII was prescribed for patient in the Emergency Department. Blood bank supplied recombinant Factor VIII which was administered to the patient. Patient should have been prescribed von Willebrand factor i.e. Biostate® (human coagulation Factor VIII and human von Willebrand factor). 1500IU Biostate® administered next day.	Clinical and Laboratory
	Albumex® 4 requested, Albumex® 20 issued and transfused.	Laboratory
Inappropriate transfusion RhD Immunoglobulin-VF (5)	Patient with immune anti-D. Transfused with RhD postive platelets, only platelets available. Patient given 250IU RhD Immunoglobulin-VF.	Clinical
	RhD Immunoglobulin-VF issued and administered to RhD negative patient previously sensitised to RhD.	Clinical
	RhD Immunoglobulin-VF administered to a RhD negative patient. Baby RhD negative. Midwife admitted to having not checked the hard copy of baby's blood group results prior to administering the anti-D and took the verbal instructions given at handover as true.	Clinical
	250IU vials of RhD Immunoglobulin-VF issued to a remote refrigerator instead of 625IU RhD Immunoglobulin-VF vials. A vial administered to patient. Further 625IU RhD Immunoglobulin-VF vial issued next day.	Laboratory and Clinical
	625IU vial of RhD Immunoglobulin-VF administered to RhD positive patient.	Clinical

Near Miss Events

22

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 2016, there were 14 events identified from the NZBS incident management system and one report from a DHB Blood Bank detailing a WBIT event. These events are summarised in Table 22.1.

TABLE 22.1 NEAR MISS EVENTS 2016 BY ERROR TYPE AND SITE

Error	Site of Error			
	Blood Bank	Processing	Clinical	Total
Wrong product/component issued (including wrong dose or wrong patient) (RBC = 3, Other Blood Products = 5)	5		3	8
Irradiation errors		2		2
WBIT			1	1
Expiry of blood components	1			1
Labelling error	2			2
Other	1			1
Total	**9**	**2**	**4**	**15**

CASE H

A request for Tetanus Immunoglobulin was sent to the blood bank for a patient. Zoster Immunoglobulin was issued and labelled as Tetanus Immunoglobulin. The error was detected in the clinical area and the product returned. Tetanus Immunoglobulin was issued and administered to the patient.

CASE I

Theatre staff uplifted an emergency group O RhD negative unit from a remote refrigerator. If they had contacted the blood bank they would have been informed that a valid pre-transfusion sample was available and the patient had anti-K and suitable compatible red cell units could be made available. The red cell units were not transfused.

The group O RhD negative emergency units were K negative.

22 Near Miss Events
continued

CASE J

Four bottles of 500mL Albumex® 4 were requested, the blood bank issed four units of red cells. The error was detected in the clinical area and the red cells returned and the correct product issued.

CASE K

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

CASE L

Prothrombinex® and Fresh Frozen Plasma were incorrectly ordered for a patient. There were two patients within the clinical area with the same family name, one male and one female. The error was detected in the clinical area and the components and products returned to the blood bank.

CASE M

A unit of red cells , group A RhD positive, was sent to a remote theatre refrigerator labelled with a similar name as another patient who was group O RhD positive. The group A RhD positive unit ended up in theatre with the group O RhD positive patient. The mistake was identified and the correct units for the patient obtained.

CASE N (Two events)

Red cell components irradiated but had not been relabelled to indicate that they had been irradiated and the expiry date had not been changed.

CASE O

Red cells issued for two patients by an electronic crossmatch, the red cell units had not been ABO RhD group confirmed when received by the blood bank.

NZBS Wrong Blood in Tube (WBIT) Events

23

Definition:

A "wrong blood in tube" error, sometimes referred to as "wrong name on tube", is when the pretransfusion sample was collected from the wrong patient or the sample was labelled with the details of another patient.

WBIT Events are normally identified when ABO and RhD testing shows a different blood group from the historic results for the patient in eProgesa. A current WBIT is where the sample received is proven to be incorrectly labelled. An 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 2016, historic ABO RhD blood groups were available in eProgesa for 66.2% (range 62.4% to 68%) of all pretransfusion samples submitted to NZBS Blood Banks. There were 17 WBIT errors identified. In three cases, the historic result was assumed to be incorrect. Table 23.1 shows the corrected WBIT rate for the 14 current WBIT events reported by the NZBS Blood Banks in 2016. The overall corrected WBIT rate was 2.4 per 10,000 samples (1:4,199).

TABLE 23.1 NZBS WBIT EVENTS 2016 BY BLOOD BANK SITE

	WBIT Events	Historic Groups	WBIT Frequency[1]	Rate / 10,000 Specimens (95% CI)[1]
Auckland	7	34,012	1:3037	3.3 (1.8 to 5.9)
Wellington	3	15,849	1:3302	3.0 (1.0 to 7.4)
Palmerston North	1	6,320	1:3950	2.5 (0 to 11.4)
Christchurch	2	14,382	1:4494	2.2 (0.5 to 6.6)
Waikato	1	17,307	1:10817	0.9(0 to 4.2)
Dunedin	0	6,182	0	0 (0 to 7.5)
NZBS Total	**14**	**94,052**	**1:4199**	**2.4 (1.6 to 3.6)**

1 Corrected to account for silent errors.

Table 23.2 shows the cumulative number of WBIT errors for the six NZBS Blood Banks over a ten year period from 2007 to 2016. The overall corrected WBIT rate was 2.6 per 10,000 samples (1:3,887). 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).

23 NZBS Wrong Blood in Tube (WBIT) Events continued

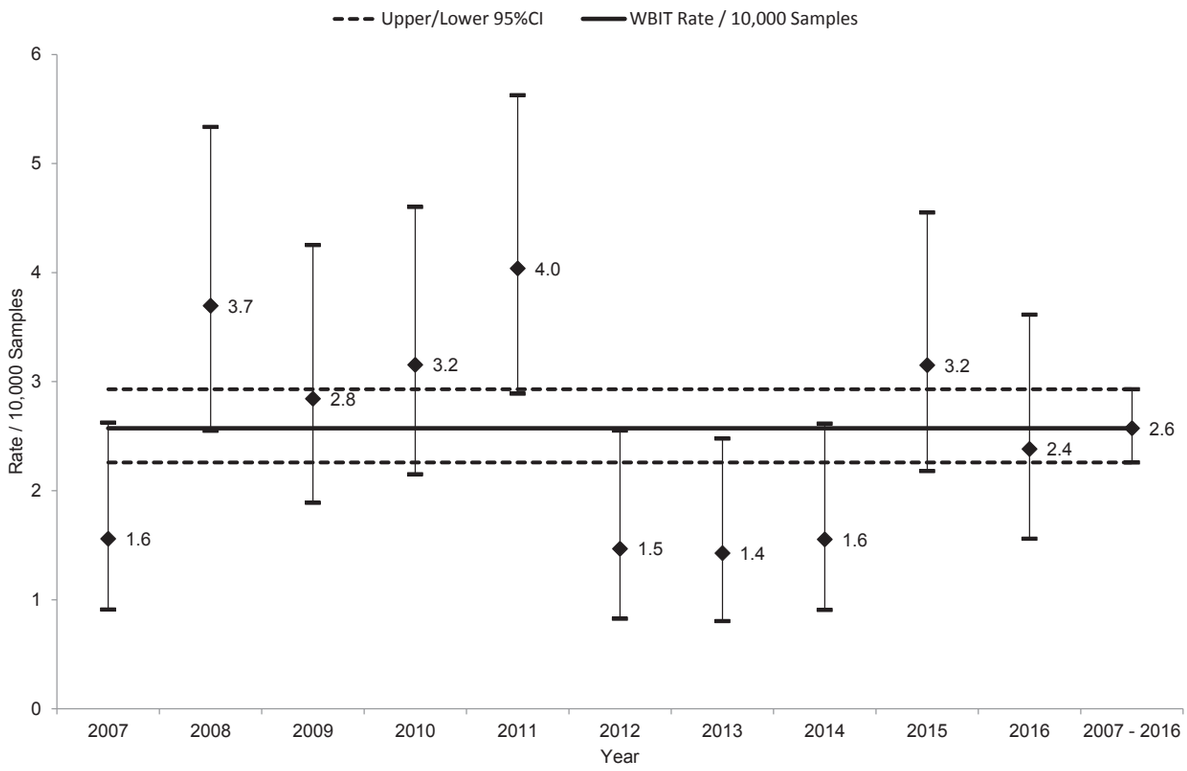
TABLE 23.2 NZBS WBIT EVENTS 2007 – 2016 BY BLOOD BANK SITE

	WBIT Events	Historic Groups	WBIT Frequency[1]	Rate/10,000 Samples (95% CI)[1]
Wellington	42	133,548	1:1987	5.0 (4.0 to 6.4)
Palmerston North	10	57,187	1:3574	2.8 (1.7 to 4.6)
Auckland	47	306,650	1:4078	2.5 (2.0 to 3.1)
Christchurch	19	148,548	1:4886	2.0 (1.4 to 2.9)
Dunedin	7	61,669	1:5506	1.8 (1.0 to 3.3)
Waikato	17	175,580	1:6455	1.5 (1.1 to 2.3)
NZBS Total	**142**	**883,182**	**1:3887**	**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 2016 is shown in Figure 23.1.

FIGURE 23.1 ANNUAL NZBS WBIT EVENT RATE 2007 – 2016



Bacterial Monitoring of Platelet Concentrates

24

In late 2015 NZBS implemented a system of testing all platelet components for evidence of bacterial contamination prior to their release. Sampling of the component takes place a minimum of 36 hours post production. The components are then released to inventory for clinical issue. Implementation of the system was associated with an extension of the platelet shelf life from five to seven days. The approach used by NZBS mirrors that in place in England for some years.

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. It is therefore difficult to compare the results of testing of the new system with the results of the monitoring system reported in previous haemovigilance reports. NZBS has adopted the classification produced by the AABB for interpretation of results. This is summarised in Table 24.1.

TABLE 24.1 DEFINITIONS USED TO CLASSIFY POSITIVE CULTURE RESULTS

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

During 2016 a total of 13,659 platelet components were tested. 128 (0.94%) of these gave an initial positive result. A breakdown of the results is provided in Table 24.2.

24 Bacterial Monitoring of Platelet Concentrates continued

TABLE 24.2 RESULTS OF PLATELET BACTERIAL CULTURE PERFORMED IN 2016

Classification	Number (percentage)
Initial positive	125 (0.92%)
False positive	86 (0.63%)
Indeterminate	26 (0.2%)
True positive	13 (0.1%)

The NZBS true positive rate compares well to that seen in comparable blood services utilising a similar sampling model to that used here. The NZBS initial reactive rate is however significantly higher than that seen in comparable blood services. The rate varies across NZBS sites and is being investigated.

The bacterial species identified in the 16 true positive samples is shown in Table 24.3. This also identifies the number of culture positive platelet components that were transfused.

TABLE 24.3 BACTERIAL SPECIES IDENTIFIED IN CONFIRMED POSITIVE CASES

Species	Number		
	Total	Transfused	Not Transfused
Propionibacterium acnes	7	5	2
Staphylococcus epidermidis	1	0	1
Staphylococcus marcescens	1	0	1
Staphylococcus epi (CN staphylococcus)	1	0	1
Staphylococcus saccharolyticus	1	1	0
Staphylococcus species	1	0	1
Streptococcus pyogenes	1	0	1

None of the transfused components were associated with clinical symptoms suggestive of infection. Two of the six recipients were already on broad spectrum antibiotics at the time of transfusion. The relatively high number of P. acnes cases identified and subsequently transfused is consistent with the international experience. 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 scheme during the year.

25 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 2016, there were 171,716 donations collected from 81,630 donors. Of these donors, 79% were repeat donors and 21% were previously untested new donors.

Table 25.1 shows the number of donors with confirmed positive serology in 2016. There were 14 donors confirmed positive for HBV and 13 confirmed positive for syphilis

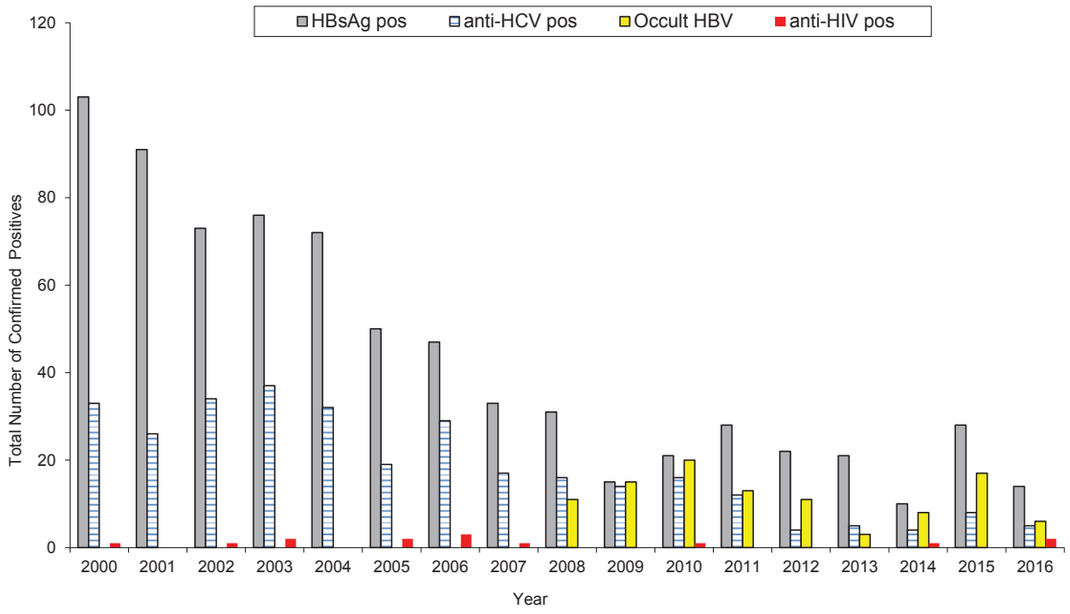
TABLE 25.1 DONORS WITH CONFIRMED POSITIVE INFECTIOUS DISEASE SEROLOGY 2016

		HBV	HCV	HIV	Syphilis	HBV Occult	HTLV I/II
Number	New Donors (n = 16,789)	14	3	1	6	0	0
	Repeat Donor (n = 64,841)	0	2	1	7	6	0
	Total Donors (n = 81,630)	14	5	2	13	6	0
Rate Per 100,000 Donations	New Donors	83.4	17.9	6.0	35.7	0	0
	Repeat Donors	0	3.1	1.5	10.8	9.3	0
	All Donations	17.2	6.1	2.5	15.9	7.4	0
Frequency of Positive Donors	New Donor	1:1,199	1:5,596	1:16,789	1:2,798		
	Repeat Donor		1:32,421	1:64,841	1:9,263	1:10,807	
	Overall Donor Frequency	1:5,831	1:16,326	1:40,815	1:6,279	1:13,605	

Figure 25.1 shows the number of confirmed positive results each year from 2000 to 2016. 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.

25 Donor Infectious Disease Screening continued

FIGURE 25.1 ANNUAL NUMBER OF DONORS WITH CONFIRMED POSITIVE INFECTIOUS DISEASE SEROLOGY 2000 – 2016



26 Residual Risk of Viral Infection from Fresh Component Transfusion

Although other risks of transfusion are significantly more likely, the one complication of transfusion that recipients tend to focus on most is viral infection. Blood services' approach to this has been to refine donor selection and to test each donation for evidence of past or current infection. New Zealand Blood Service and its predecessor regional blood services, have not had a single confirmed transmission of HIV or HCV in New Zealand since testing was introduced in 1986 and 1992 respectively. Since nucleic acid testing was introduced in late 2006, there have similarly been no confirmed transmissions of HBV.

In the absence of any observed transmissions, the risk to recipients is now modelled using donors' donation frequency and the incidence of infections in donors. The residual risk to donors is derived from the calculated frequency of window period donations. This assumes that window period donations represent the dominant source of risk. While this is highly likely for HIV and HCV, it is much less likely for hepatitis B where infection from occult carriers is, in our clinical experience, the more likely cause.

The best described, and most robust model, uses the incidence of new infections between donations in repeat donors, together with the window period of the virus, to derive a risk that a donation is in the window period[1]. This works well for repeat donors, but does not work for first time donors, as there is no inter-donation interval for first time donors.

Modelling the risk from first time donors is more difficult. We have used a model developed in Australia that derives the risk based on the window period of the infection and the time taken for the infection to be diagnosed[2]. Although this model is not as robust in its assumptions as the repeat donor model, its impact is offset by first time donors only accounting for approximately 6% of donations during the period studied.

Residual Risk of Viral Infection from Fresh Component Transfusion continued

26

The data from first time and repeat donors was then analysed using the two models in a Monte Carlo simulation[3] to take account of the degree of imprecision around the window periods, proportions of donors with identified infections and, for first-time donors, the duration of undiagnosed infections. This simulation generated the results shown below (Table 26.1).

TABLE 26.1 RESIDUAL RISK ESTIMATES FOR HUMAN IMMUNODEFICIENCY VIRUS, HEPATITIS B AND HEPATITIS C TRANSFUSION-TRANSMITTED INFECTION IN NEW ZEALAND

Infection	Mean Risk	95% Prediction Interval
HIV	1 in 9.55 million	1 in 3.09 to 26.24 million
Hepatitis C	1 in 7.82 million	1 in 4.06 to 14.04 million
Hepatitis B	1 in 0.85 million	1 in 0.47 to 1.57 million

However, although the modelled risk for hepatitis B is greater than for hepatitis C and HIV, the true risk to patients is harder to establish. This is because the model for calculating hepatitis B risk does not take occult hepatitis B or recipient immunity into account. Occult hepatitis B is a state where the liver is infected by hepatitis B but the virus is only multiplying intermittently and at low levels. As a result, the screening tests for hepatitis B are negative, but very low levels of viral DNA, enough to cause infection, may still be present. As the New Zealand population has a relatively high proportion of hepatitis B core antibody positive donors (approx. 6.8%[4]), reflecting past infection, the subset of donors with occult hepatitis B is correspondingly higher than many western countries. This would increase the risk. The model also does not take into account the proportion of recipients who are immune to hepatitis B, either from vaccination or past infection. Neither occult infection nor vaccinations affect HIV or HCV estimations.

It is difficult to compare residual risks accurately between countries due to subtle differences in methodology, testing techniques and the wide statistical ranges around the point estimates. Nevertheless, a comparison of New Zealand's point estimates with those of four other industrialised countries shows that New Zealand data is consistent with other blood services' experience (Table 26.2).

TABLE 26.2 RESIDUAL RISK PER MILLION DONATIONS IN FIVE COUNTRIES

	HIV	Hepatitis C	Hepatitis B
NZ	0.10	0.13	1.18
UK[5]	0.16	0.04	0.63
Canada[6]	0.12	0.15	0.60
Australia[7]	0.14	0.28	0.75
USA[8]	0.54	0.60	2.73

In summary, the risks of transfusion-transmitted HIV, hepatitis B or hepatitis C remain very small and probably negligible in the context of the other risks that a patient requiring transfusion is facing.

References

1. Schreiber GB, Busch MP, Kleinman SH, Korelitz JJ. The Risk of Transfusion-Transmitted Viral Infections. N Engl J Med. 1996; 334(26):1685–90.
2. Seed CR, Kiely P, Keller AJ. Residual risk of transfusion transmitted human immunodeficiency virus, hepatitis B virus, hepatitis C virus and human T lymphotrophic virus. Intern Med J. 2005 Oct; 35(10):592–8.
3. Metropolis N. The beginning of the Monte Carlo method. Los Alamos Sci. 1987; Special Is:125–30. Available from: http://jackman.stanford.edu/mcmc/metropolis1.pdf
4. Flanagan P, Charlewood R, Horder R, Dravitsky M, Hollis H. Reducing the risk of transfusion transmitted Hepatitis B in New Zealand. Vox Sang. 2005; 89(S2):23–4.
5. Bolton-Maggs PHB, Poles D, on behalf of the Serious Hazards of Transfusion (SHOT) Steering Group. The 2015 Annual SHOT Report. Serious Hazards of Transfusion. Manchester, United Kingdom; 2016.
6. O'Brien SF, Yi Q-L, Fan W, Scalia V, Fearon M a, Allain J-P. Current incidence and residual risk of HIV, HBV and HCV at Canadian Blood Services. Vox Sang. 2012; 103(1):83–6.
7. Seed CR, Kiely P, Keller AJ. Residual risk of transfusion transmitted human immunodeficiency virus, hepatitis B virus, hepatitis C virus and human T lymphotrophic virus. Intern Med J. 2005; 35(10):592-8.
8. Zou S, Stramer SL, Dodd RY. Donor testing and risk: current prevalence, incidence, and residual risk of transfusion-transmissible agents in US allogeneic donations. Transfus Med Rev. 2012; 26(2):119–28.

27 Adverse Events Associated with Blood Donation

The year on year number of annual blood donations by donation type is shown in Table 27.1. 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 27.1 ANNUAL NUMBER OF BLOOD DONATIONS 2005 – 2016 BY DONATION TYPE

Year	Number							
	Whole Blood		Plasmapheresis		Plateletpheresis		Total	
	Donors	Donations	Donors	Donations	Donors	Donations	Donors	Donations
2005	95,382	156,684	1,227	6,479	979	5,098	97,588	168,261
2006	91,929	151,934	2,647	12,880	957	5,148	95,533	169,962
2007	88,584	150,308	4,064	23,514	957	5,493	93,605	179,315
2008	90,364	152,760	4,190	26,985	1,009	5,998	95,563	185,743
2009	89,159	151,689	3,012	18,106	1,143	6,578	93,314	176,373
2010	89,623	153,044	3,407	18,243	1,136	6,499	94,166	177,786
2011	86,986	147,093	4,723	28,886	1,119	6,491	92,828	182,470
2012	83,040	139,845	5,037	30,179	1,138	6,527	89,215	176,551
2013	75,069	125,684	5,078	29,585	830	4,942	80,977	160,211
2014	72,754	120,668	5,910	38,099	595	3,570	79,259	162,337
2015	71,511	119,554	7,586	46,983	555	3,377	79,652	169,914
2016	69,857	114,779	8,789	54,059	425	2,878	79,071	171,716

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.

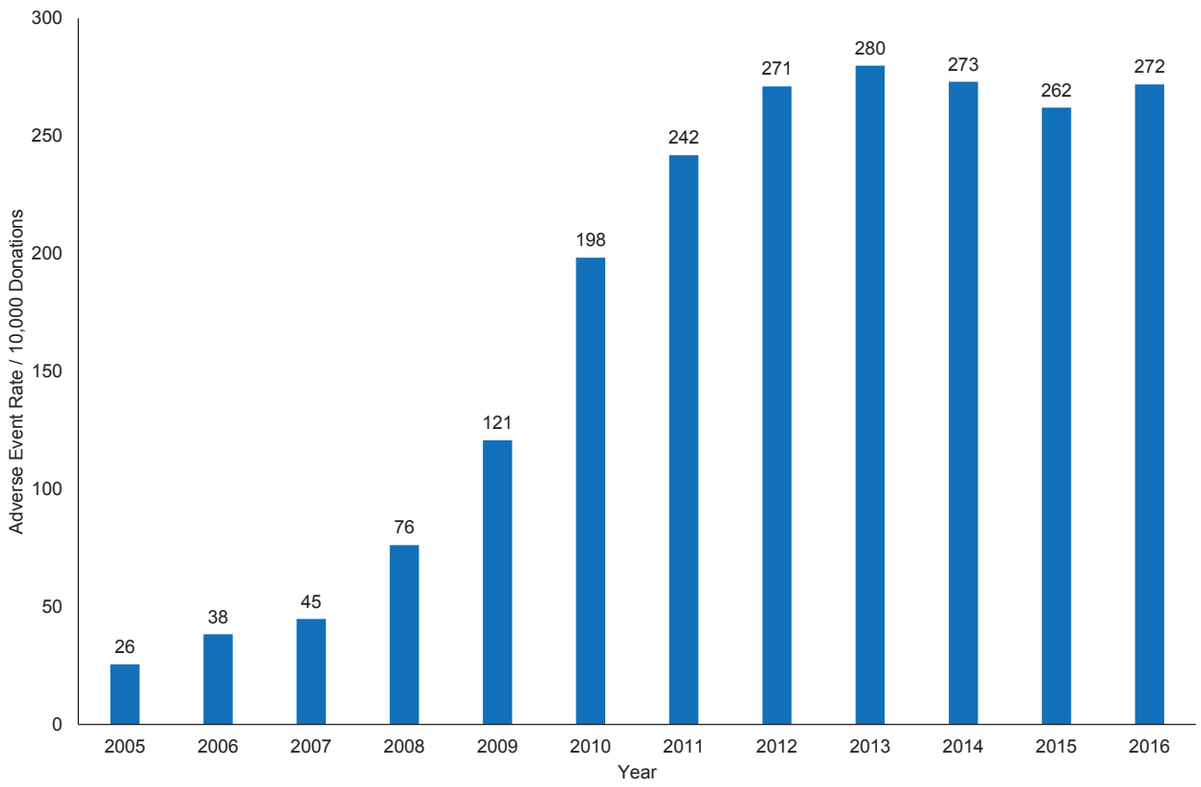
NZBS utilises definitions for these adverse events contained in the Standards for Surveillance of Complications Related to Blood Donation (2014) developed by the Working Group on Donor Vigilance, International Society of Blood Transfusion Working Party on Haemovigilance (Appendix III). A standardised 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 27.1). Prior to this, the increase seen, likely reflected efforts within NZBS to improve consistency of reporting across the sites.

Adverse Events Associated with Blood Donation continued

27

FIGURE 27.1 ANNUAL DONATION-RELATED ADVERSE EVENT RATE PER 10,000 DONATIONS 2005 – 2016



During 2016, there were 171,716 donations (114,779 whole blood, 54,059 plasmapheresis and 2,878 plateletpheresis donations) collected. Adverse events were reported in relation to 4,668 of the donations and involving 4,373 donors. The overall frequency of reported donation-related adverse events was 1:37. Adverse events are more frequently reported with apheresis procedures, particularly plateletpheresis, than whole blood donations (Table 27.2).

TABLE 27.2 DONATION-RELATED ADVERSE EVENTS 2016 BY COLLECTION METHOD

Procedure	Donors	Donations with Events	Total Donations	Frequency	Rate / 10,000Donations (95%CI)
Whole Blood Donation	3,004	3,090	114,779	1:37	269 (253 to 271)
Plasmapheresis	1,164	1,292	54,059	1:42	239 (203 to 228)
Plateletpheresis	205	286	2,878	1:10	994 (624 to 812)
All Apheresis Procedures	1,369	1,578	56,937	1:36	277 (228 to 253)
Total Procedures	**4,373**	**4,668**	**171,716**	**1:37**	**272 (247 to 262)**

27 Adverse Events Associated with Blood Donation continued

A number of donors experienced more than one adverse event with a single donation, so in total, there were 4,668 reported events with 3,090 involving whole blood donations and 1,578 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 (65.5%) was an immediate vasovagal reaction. For apheresis procedures, the most common event (60.7%) was bruising/haematoma. Donation-related adverse events by reaction type and collection method are shown in Table 27.3 and Table 27.4.

TABLE 27.3 DONATION-RELATED ADVERSE EVENTS 2016 BY REACTION TYPE

Adverse Event	All Blood Donations (Total Collections 171,716)			
	Number Events[1]	Percentage	Frequency	Rate / 10,000 Donations (95% CI)
Immediate Vasovagal	2,329	53.06%	1:74	135.6 (130.2 to 141.1)
Haematoma	1,511	34.43%	1:114	88.0 (83.6 to 92.4)
Painful Arm	201	4.58%	1:854	11.7 (10.1 to 13.3)
Nerve Irritation / Injury	113	2.57%	1:1,520	6.6 (5.4 to 7.8)
Delayed Vasovagal	105	2.39%	1:1,635	6.1 (4.9 to 7.3)
Other Complications	58	1.32%	1:2,961	3.4 (2.5 to 4.2)
Re-bleeding	56	1.28%	1:3,066	3.3 (2.4 to 4.1)
Local Allergic Reaction	5	0.11%	1:34,343	<1 (0 to 0.5)
Other Serious Complications	4	0.09%	1:42,929	<1 (0 to 0.5)
Arterial Puncture	3	0.07%	1:57,239	<1 (0 to 0.4)
Other Major Vessel Injury	3	0.07%	1:57,239	<1 (0 to 0.4)
Thrombophlebitis	1	0.02%	1:171,716	<1 (0 to 0.2)
Total	**4,389**		**1:39**	**255.6 (248.1 to 263.1)**

1 Apheresis-specific complications excluded, i.e., citrate reactions and red cell return failures (total 279 reported events).

Adverse Events Associated with Blood Donation continued

27

TABLE 27.4 DONATION-RELATED ADVERSE EVENTS 2016 BY REACTION TYPE AND COLLECTION METHOD

Adverse Event	Type of Blood Donation					
	Whole Blood (Total Collections = 114,779)			Apheresis (Total Collections = 56,937)		
	% All Events	Freq.	Rate / 10,000 Donations (95% CI)	% All Events	Freq.	Rate / 10,000 Donations (95% CI)
Immediate Vasovagal	65.5%	1:55	180 (173 to 188)	21.1%	1:220	45 (40 to 51)
Haematoma	24.2%	1:150	67 (62 to 71)	60.7%	1:76	131 (122 to 141)
Painful Arm	3.4%	1:1,063	9 (8 to 11)	7.6%	1:612	16 (13 to 20)
Delayed Vasovagal	2.6%	1:1,400	7 (6 to 9)	1.9%	1:2,476	4 (3 to 6)
Nerve Irritation / Injury	2.5%	1:1,453	7 (6 to 9)	2.8%	1:1,675	6 (4 to 8)
Re-bleeding	0.9%	1:3,826	3 (2 to 4)	2.1%	1:2,190	5 (3 to 7)
Other Complications	0.5%	1:7,652	1 (1 to 2)	3.5%	1:1,324	8 (6 to 10)
Local Allergic Reaction	0.2%	1:22,956	0 (0 to 1)			
Arterial Puncture	0.1%	1:38,260	0 (0 to 1)			
Other Serious Complications	0.1%	1:57,390	0 (0 to 1)	0.2%	1:2,847	0 (0 to 1)
Other Major Vessel Injury	0.03%	1:114,779	0 (0 to 1)	0.2%	1:2,847	0 (0 to 1)
Thrombophlebitis				0.1%	1:5,693	0 (0 to 1)
Total		**1:36**	**275 (267 to 282)**		**1:46**	**216 (204 to 228)**

		Apheresis-specific Complications		
	Number Adverse Events	% Reaction	Freq.	Rate / 10,000 Donations (95% CI)
RBC not returned	499	66.5%	1:114	88 (80 to 96)
Citrate Toxicity	248	33.1%	1:230	44 (38 to 49)
Haemolysis	3	0.4%	1:18,979	1 (0 to 2)
Total Apheresis-Specific Events	**750**		**1:76**	**132 (123 to 141)**

27 Adverse Events Associated with Blood Donation continued

During 2016, there were 114,779 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 27.5).

TABLE 27.5 WHOLE BLOOD DONATION-RELATED ADVERSE EVENTS 2016 BY REACTION TYPE FOR NEW AND REPEAT DONORS

Adverse Event	New Donors (n=12,933)			Repeat Donors (n=101,846)		
	% Reactions	Freq.	Rate Per 1,000 Donations	% Reactions	Freq.	Rate Per 1,000 Donations
Immediate Vasovagal	79.6%	1:14	734.6	57.2%	1:90	110.6
Haematoma	14.2%	1:76	131.4	30.2%	1:171	58.3
Delayed Vasovagal	2.3%	1:462	21.7	2.7%	1:1,886	5.3
Painful Arm	1.9%	1:562	17.8	4.3%	1:1,198	8.3
Nerve Irritation / Injury	1.1%	1:995	10.1	3.4%	1:1,543	6.5
Other Complications	0.4%	1:2,587	3.9	0.5%	1:11,316	0.9
Re-bleeding	0.3%	1:4,311	2.3	1.4%	1:3,772	2.7
Local Allergic Reaction	0.1%	1:12,933	0.8	0.2%	1:25,462	0.4
Other Major Vessel Injury	0.1%	1:12,933	0.8			
Arterial Puncture				0.2%	1:33,949	0.3
Other Serious Complications				0.1%	1:50,923	0.2
Total		**1:11**	**923.2**		**1:52**	**193.4**

The frequency of donation-related adverse events in whole blood donors is inversely related to age, and is highest in donors under the age of 20 years. In this youngest group of donors, aged 16 to 19 years, the adverse event rate is 1:13 donations and the odds ratio is 2.93 (Table 27.6).

TABLE 27.6 WHOLE BLOOD DONATION-RELATED ADVERSE EVENTS 2016 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	841	11,141	1:13	75.5 (70.7 to 80.5)	2.93 (2.71 to 3.17)
20 - 24 Years	613	13,133	1:21	46.7 (43.2 to 50.4)	1.76 (1.61 to 1.92)
25 - 29 Years	412	11,617	1:28	35.5 (32.2 to 39.0)	1.32 (1.19 to 1.47)
30 - 34 Years	245	8,773	1:36	27.9 (24.7 to 31.6)	1.03 (0.90 to 1.18)
35 - 39 Years	179	8,482	1:47	21.1 (18.2 to 24.4)	0.77 (0.66 to 0.90)
40 - 44 Years	146	9,844	1:67	14.8 (12.6 to 17.4)	0.54 (0.46 to 0.64)
45 - 49 Years	143	10,355	1:72	13.8 (11.7 to 16.3)	0.50 (0.42 to 0.60)
50 - 54 Years	139	11,103	1:80	12.5 (10.6 to 14.8)	0.46 (0.38 to 0.54)
55 - 59 Years	143	11,403	1:80	12.5 (10.6 to 14.8)	0.46 (0.39 to 0.54)
≥60 Years	229	18,171	1:79	12.6 (11.1 to 14.3)	0.46 (0.40 to 0.52)
All	3,090	114,022	1:37	27.1 (26.2 to 28.1)	

27

Adverse Events Associated with Blood Donation continued

Vasovagal reactions are the most common whole blood donation-related adverse event. Table 27.7 shows that the higher rate of vasovagal reactions in new donors versus repeat donors is seen across all age groups. There is a steady reduction in the likelihood of a vasovagal reaction with increasing age.

TABLE 27.7 WHOLE BLOOD VASOVAGAL EVENTS 2016 BY DONOR AGE GROUP FOR NEW DONORS AND REPEAT DONORS

Age Group	Gender	New Donors (n = 13,429)		Repeat Donors (n = 100,593)	
		Frequency	Rate / 1,000 Donations (95%CI)	Frequency	Rate / 1,000 Donations (95%CI)
16 – 19	Female	1:9	109.5 (98.7 to 121.4)	1:21	46.8 (40.3 to 54.4)
	Male	1:17	59.7 (51.3 to 69.4)	1:35	28.8 (22.4 to 36.9)
20 – 24	Female	1:10	96.5 (80.2 to 115.6)	1:33	30.3 (26.6 to 34.6)
	Male	1:15	69.0 (55.4 to 85.5)	1:53	18.9 (15.1 to 23.7)
25 – 29	Female	1:12	84.3 (67.3 to 105.1)	1:56	17.9 (14.8 to 21.7)
	Male	1:17	59.3 (45.4 to 77.0)	1:79	12.7 (9.7 to 16.6)
30 – 34	Female	1:18	55.7 (38.2 to 80.1)	1:62	16.0 (12.6 to 20.4)
	Male	1:17	60.0 (43.0 to 82.8)	1:92	10.9 (8.0 to 14.9)
35 – 39	Female	1:18	55.9 (37.5 to 82.2)	1:93	10.7 (7.9 to 14.4)
	Male	1:22	45.6 (27.7 to 73.3)	1:119	8.4 (5.9 to 12.0)
40 – 44	Female	1:54	18.6 (8.2 to 38.6)	1:150	6.7 (4.7 to 9.3)
	Male	1:35	28.7 (14.3 to 54.4)	1:184	5.4 (3.5 to 8.3)
45 – 49	Female	1:29	34.9 (18.9 to 62.2)	1:195	5.1 (3.5 to 7.5)
	Male	1:30	33.2 (14.8 to 68.2)	1:217	4.6 (3.0 to 7.1)
50 – 54	Female	1:23	42.9 (22.5 to 78.2)	1:147	6.8 (5.0 to 9.3)
	Male	1:42	23.7 (7.1 to 61.4)	1:415	2.4 (1.3 to 4.3)
55 – 59	Female	1:24	41.0 (19.6 to 80.2)	1:133	7.5 (5.6 to 10.2)
	Male	1:32	31.5 (9.6 to 80.9)	1:786	1.3 (0.6 to 2.7)
≥60	Female	1:16	64.2 (29.3 to 128.8)	1:134	7.5 (5.9 to 9.6)
	Male	1:31	32.6 (7.2 to 95.5)	1:785	1.3 (0.7 to 2.3)
Total	Female	1:12	84.2 (77.9 to 91.0)	1:69	14.5 (13.6 to 15.6)
	Male	1:18	56.2 (50.9 to 62.1)	1:139	7.2 (6.5 to 8.0)
	Total	**1:14**	**70.7 (66.5 to 75.2)**	**1:89**	**11.2 (10.6 to 11.9)**

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.

27 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 3 chewable Nestlé Quick-Eze antacid tablets each containing 800mg calcium carbonate followed by a further 3 tablets with the onset of symptoms of citrate toxicity, and repeated if necessary every 20-30 minutes to a maximum dose of 9 tablets. Comparing the national rate of citrate reactions reported in 2016 to that in 2013, a decrease of 42% has occurred (p=<0.001) (Table 27.8).

TABLE 27.8 DONATION-RELATED ADVERSE EVENTS ASSOCIATED WITH CITRATE TOXICITY DURING PLATELETPHERESIS 2013 – 2016

	Year				% Change	p Value
	2013	2014	2015	2016		
Number Citrate Adverse Events	493	238	202	166		
Number Plateletpheresis Procedures	4,942	3,570	3,377	2,878		
Rate / 1,000 Procedures	100	67	60	58	-42%	<0.001

28 Request Form and Specimen Labelling Errors

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

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

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

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

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

The minimum requirements for pretransfusion request forms and specimen labelling (for NZBS Blood Banks) are outlined in Table 28.1.

TABLE 28.1 NZBS PRETRANSFUSION REQUEST FORM AND SPECIMEN LABELLING REQUIREMENTS

Request Form Handwritten or Preprinted 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 2016, a total of 141,792 pretransfusion specimens were received by the six NZBS Blood Banks. Errors were identified in 3,457 specimens/forms. The overall error rate for the six NZBS Blood Banks was 24.4 per 1,000 specimens received, which is equivalent to an error rate of 1:41 specimens. The error rate in 2016 was a 10.4% increase from that reported in 2015 (22.1 per 1,000 specimens or 1:45). Table 28.2 details the error rate per 1,000 specimens for the six NZBS Blood Banks in 2016.

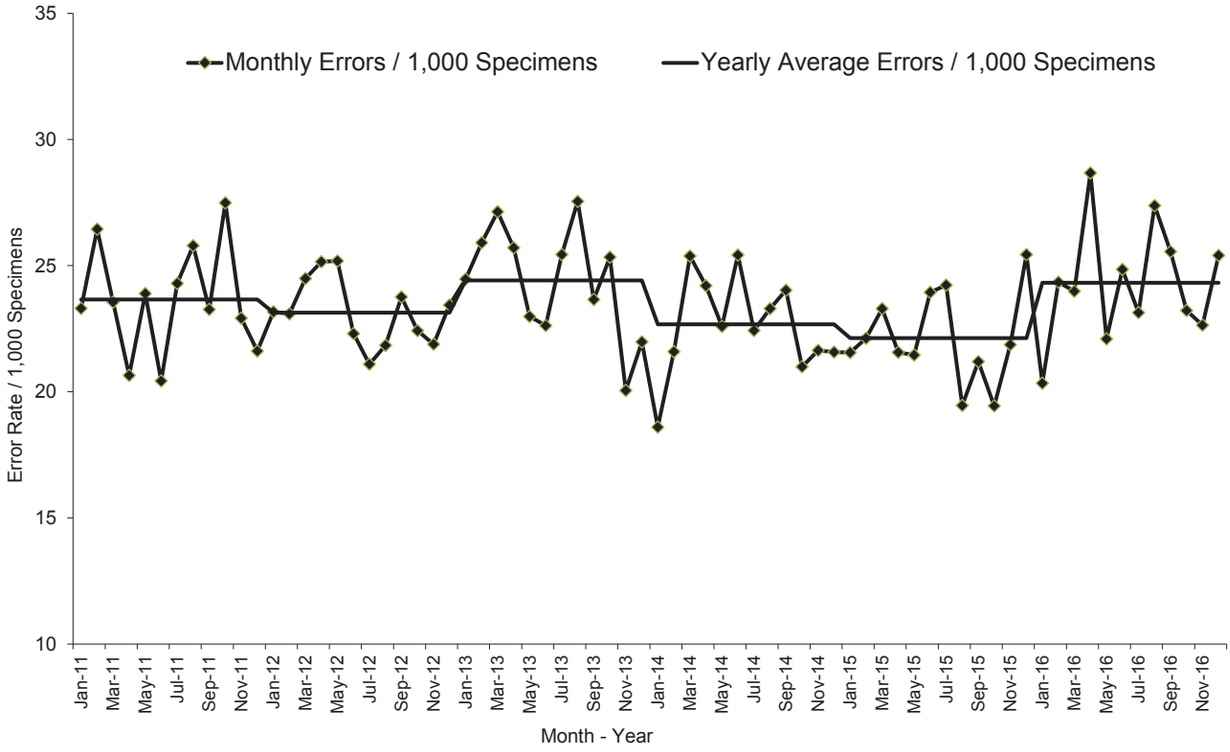
28 Request Form and Specimen Labelling Errors continued

TABLE 28.2 PRETRANSFUSION REQUEST FORM AND SPECIMEN LABELLING ERRORS 2016 BY NZBS BLOOD BANK SITE

Blood Bank	Errors	Total Specimens	Error Rate	Rate / 1,000 Specimens (95% CI)
Christchurch	735	23,442	1:32	31.4 (29.2 to 33.7)
Dunedin	294	9,808	1:33	30.0 (26.8 to 33.5)
Palmerston North	278	9,144	1:33	30.4 (27.1 to 34.1)
Wellington	679	23,173	1:34	29.3 (27.2 to 31.6)
Waikato	582	25,397	1:44	22.9 (21.1 to 24.8)
Auckland	889	50,828	1:57	17.5 (16.4 to 18.7)
NZBS	3,457	141,792	1:41	24.4 (23.6 to 25.2)

The monthly and yearly mean error rate per 1,000 pretransfusion specimens received by the NZBS Blood Banks from 2011 to 2016 is detailed in Figure 28.1.

FIGURE 28.1 PRETRANSFUSION REQUEST FORM AND SPECIMEN LABELLING ERROR RATE PER 1,000 SPECIMENS 2011 – 2016



The types of errors and the corrective actions taken are summarised in Table 28.3. Some request forms and specimens received had more than one type of error present. The total number of errors was 3,466. The most frequent type of error (19%) was “Declaration not signed (specimen signed)” followed by “Specimen not signed (declaration signed)”. The most common error resulting in a request for recollection (14.0%) was “Missing / incomplete / incorrect patient details (major error)”.

Request Form and Specimen Labelling Errors continued

28

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

TABLE 28.3 PRETRANSFUSION REQUEST FORM AND SPECIMEN LABELLING ERRORS 2016 BY ERROR TYPE

Error	Number	% Total	Frequency	Rate / 1,000 Specimens	Action Required
Declaration not signed (sample is signed)	659	19.0%	1:215	4.6	Correction by collector or Recollect
Sample not signed (declaration is signed)	601	17.3%	1:236	4.2	Correction by collector or Recollect
Missing Patient Details (Major Error)	485	14.0%	1:292	3.4	Recollect
Pre-printed patient ID label on sample	336	9.7%	1:422	2.4	Recollect
Adhesive remaining, indicating label removed	263	7.6%	1:539	1.9	Recollect
Moderate error on sample	222	6.4%	1:639	1.6	Correction by collector or Recollect
Signature On Sample And Declaration Differ	215	6.2%	1:659	1.5	Recollect
Technical [1]	175	5.0%	1:810	1.2	Recollect
Moderate error on form	114	3.3%	1:1,244	0.8	Correction by collector or Recollect
Unlabelled Sample	106	3.1%	1:1,338	0.7	Recollect
Declaration and sample not signed	80	2.3%	1:1,772	0.6	Recollect
Presence of partial pre-printed label	78	2.3%	1:1,818	0.6	Recollect
Incorrect pretransfusion request form	59	1.7%	1:2,403	0.4	Correction by collector or Recollect
Original Details Overwritten	49	1.4%	1:2,894	0.3	Recollect
Wrong Blood In Tube (WBIT) - current sample	16	0.5%	1:8,862	0.1	Recollect
Other Clerical Error	5	0.1%	1:28,358	0.03	Correction by collector or Recollect
Wrong Blood In Tube (WBIT) - historic sample	3	0.1%	1:47,264	0.02	Recollect
Total	**3,466**				

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

28 Request Form and Specimen Labelling Errors continued

The overall rate of request for recollection of pretransfusion specimens by NZBS Blood Banks for 2016 was 15.4 per 1,000 specimens received. Table 28.4 summarises the recollection rates for each NZBS Blood Bank in 2016. Overall, 68% of errors resulted in a request for recollection of the pretransfusion specimen.

TABLE 28.4 PRETRANSFUSION SAMPLE RECOLLECTION REQUESTS 2016 BY NZBS BLOOD BANK SITE

	Recollection Requests	Total Number of Specimens	Frequency	% Errors Requiring Re-collection	Rate / 1,000 Specimens (95% CI)
Christchurch	500	23,442	1:47	68%	21.3 (19.6 to 23.3)
Wellington	482	23,173	1:48	71%	20.8 (19.0 to 22.7)
Palmerston North	184	9,144	1:50	66%	20.1 (17.4 to 23.2)
Dunedin	169	9,808	1:58	64%	17.2 (14.8 to 20.0)
Waikato	348	25,397	1:73	60%	13.7 (12.3 to 15.2)
Auckland	497	50,828	1:102	56%	9.8 (9.0 to 10.7)
NZBS	**2,180**	**141,792**	**1:65**	**68%**	**15.4 (14.7 to 16.0)**

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

HV
For Haemovigilance Office Use Only

Appendix I. Transfusion-Related Adverse Event Notification Form
continued

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

Appendix II. Notification of Adverse Reactions to Fractionated Blood Products

NZBS Use Only:

NZBLOOD Te Ratonga Toto O Aotearoa

FRACTIONATED BLOOD PRODUCT - ADVERSE EVENT NOTIFICATION

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

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

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

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

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

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

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

Date adverse event detected: / / 20

Details:

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

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

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

111F00310 08/2017

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

NZBS Use Only:

NZBLOOD Te Ratonga Toto O Aotearoa **FRACTIONATED BLOOD PRODUCT - ADVERSE EVENT NOTIFICATION**

Assessment and Imputability of Adverse Event

Previous therapy with suspected blood product? *(summary only)* ☐ Yes ☐ No ☐ Not applicable
- *Product Name:*
- *Date Started:*
- *Frequency:*

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.

111F00310 08/2017

Appendix III. Reporting Adverse Events Associated with Blood Donation

NATIONAL
107M00509

REPORTING OF ADVERSE EVENTS RELATED TO BLOOD DONATION

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

1. PURPOSE

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

2. SCOPE

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

3. KEY RESPONSIBILITIES

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

4. ITEMS REQUIRED

4.1. Related documents

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

5. DEFINITIONS

5.1. Definitions and description of categories of adverse event.

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

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

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

Author: Anup Chand	Effective Date: 10/08/2015	Page 1 of 8
Authoriser: Maree Clarkin	Copy No:	Previous ID: 107M00508
QA Approver: Jacqueline Hoole	Copyholder ID:	Manual(s): DS Mobile, DS WB Collect, DS Apheresis, DAPS

Appendix III. Reporting Adverse Events Associated with Blood Donation continued

NATIONAL
107M00509

REPORTING OF ADVERSE EVENTS RELATED TO BLOOD DONATION

A. Complications mainly with local symptoms.

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

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

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

Bleeding may arise from:

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

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

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

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

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

Appendix III. Reporting Adverse Events Associated with Blood Donation continued

NATIONAL
107M00509

REPORTING OF ADVERSE EVENTS RELATED TO BLOOD DONATION

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

A2. Complications mainly characterised by pain.

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

Other Painful arm

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

A3. Localised Infection/inflammation

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

- Thrombophlebitis: The redness, swelling and tenderness extend along the course of the vein. Thrombophlebitis in a superficial vein gives rise to a subcutaneous red, hard and tender cord. Thrombophlebitis in a deep vein gives more severe symptoms and may be associated with fever.
- Cellulitis: The redness, swelling and tenderness affect the soft tissues and are not localised to the course of the vein.

Appendix III. Reporting Adverse Events Associated with Blood Donation continued

NATIONAL
107M00509

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
107M00509

REPORTING OF ADVERSE EVENTS RELATED TO BLOOD DONATION

Vasovagal reactions are divided into two main groups:

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

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

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

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

Thus;

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

And lastly subdivision is based on the location of reaction;

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

C. Complications related to apheresis.

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

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

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

Appendix III. Reporting Adverse Events Associated with Blood Donation continued

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

D. Allergic Reactions.

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

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

E. Other serious complications related to blood donation

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

F. Other complications

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

Grading of severity.

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

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

Appendix III. Reporting Adverse Events Associated with Blood Donation continued

NATIONAL
107M00509

REPORTING OF ADVERSE EVENTS RELATED TO BLOOD DONATION

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

6. PROCEDURE

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

6.2. Provide appropriate nursing care to donor immediately.

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

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

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

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

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

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

Appendix III. Reporting Adverse Events Associated with Blood Donation continued

NATIONAL
107M00509

REPORTING OF ADVERSE EVENTS RELATED TO BLOOD DONATION

7. TRAINING REQUIREMENTS

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

Appendix IV. Donor Adverse Event Report Form

NZBLOOD
Te Ratonga Toto O Aotearoa

NATIONAL
107F00511

DONOR ADVERSE EVENT REPORT

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

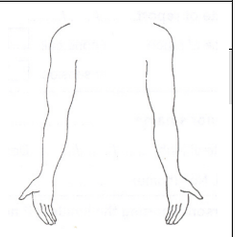
OFFICE USE ONLY: Database Record No:	

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

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

ADVERSE EVENT DETAILS

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



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

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

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

E. OTHER SERIOUS COMPLICATIONS RELATED TO BLOOD DONATION
F. OTHER COMPLICATIONS

Author: Lyndel Voice
Authoriser: Maree Clarkin
QA Approver: Jacqui Hoole

Effective Date: 16/11/2015

Page 1 of 2
Previous ID: 107F00510
Refer to document(s): 107M005

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:*

Page 2 of 2

SAVE LIVES
GIVE BLOOD

New Zealand Government