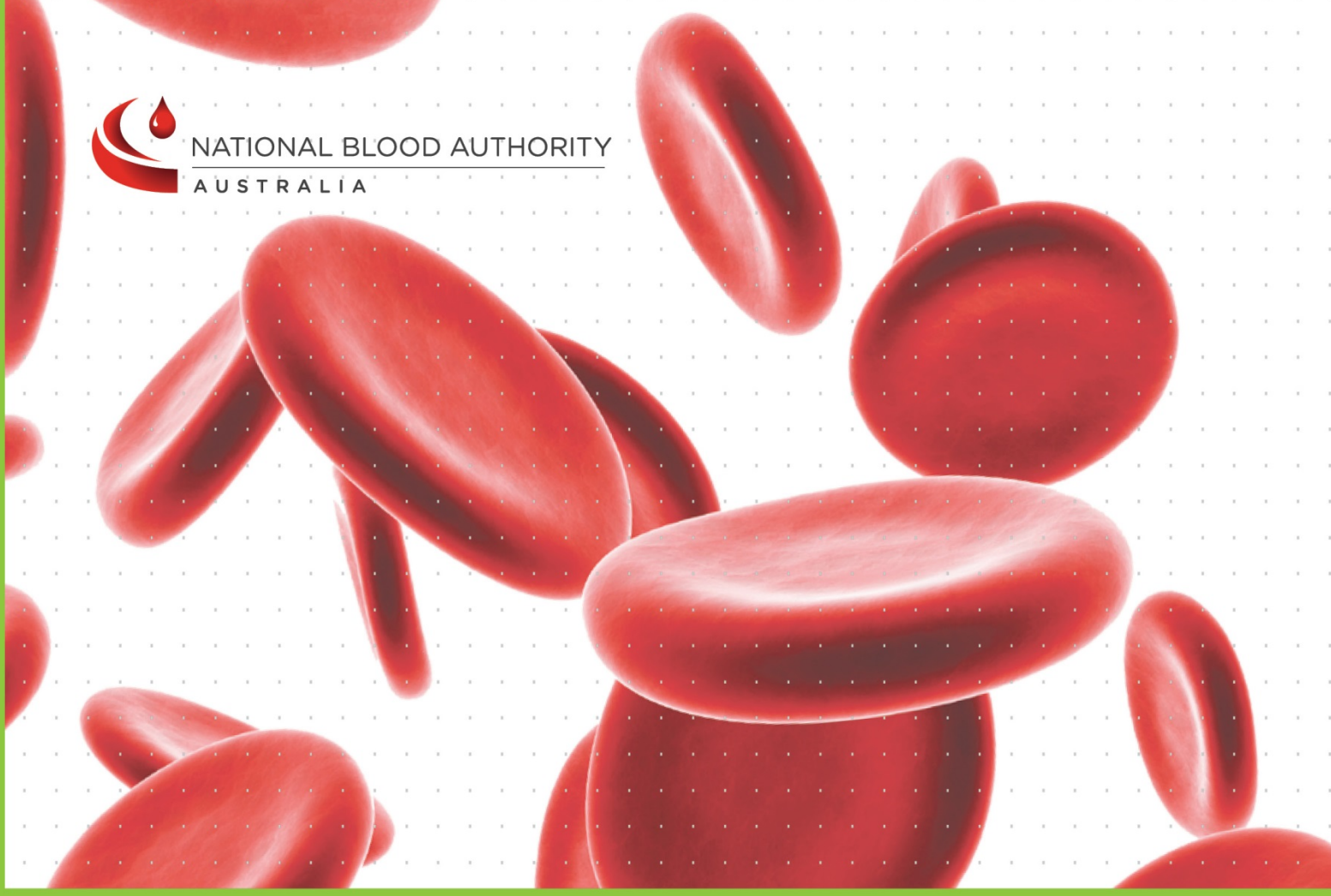
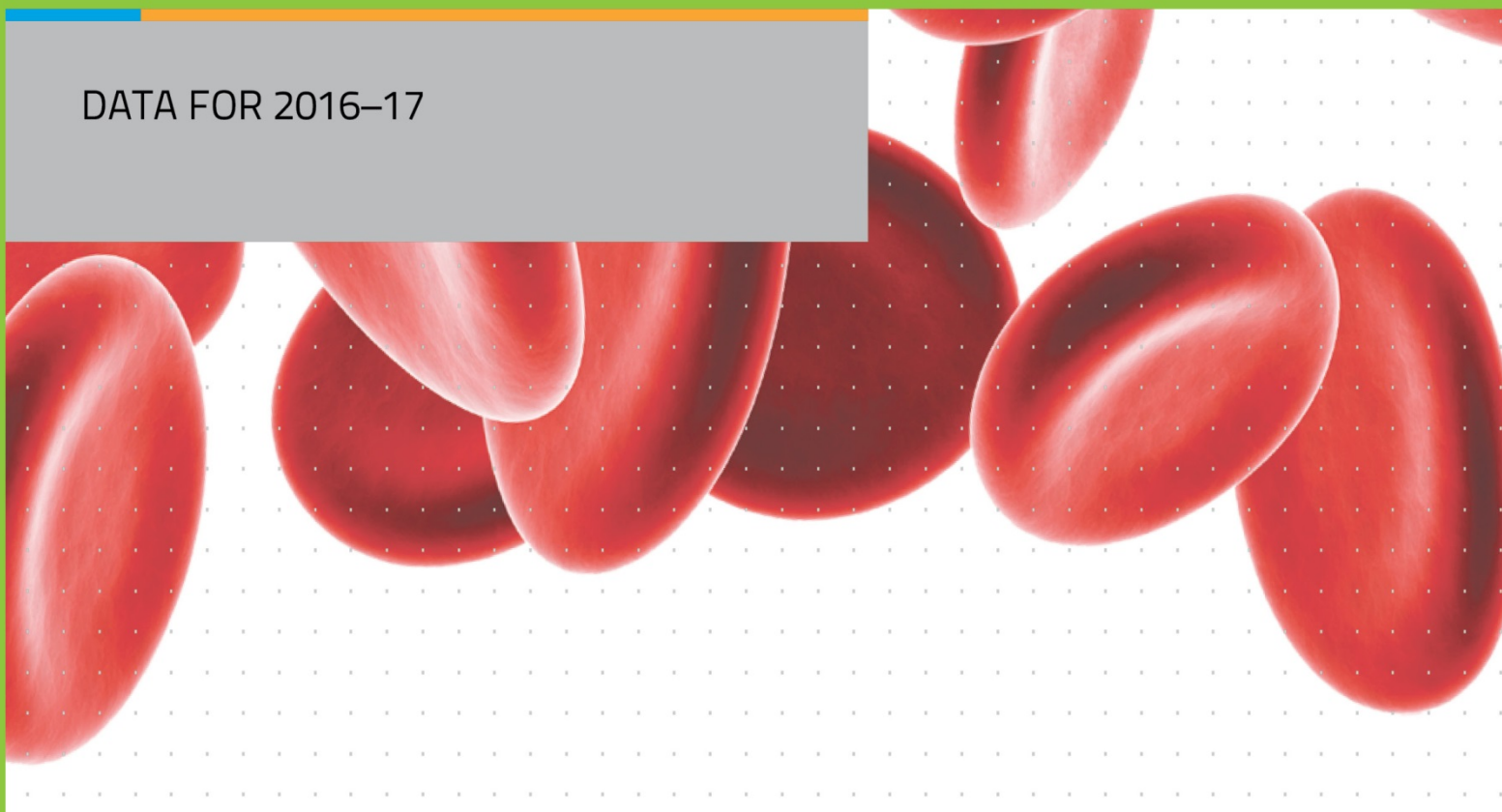


NATIONAL BLOOD AUTHORITY
AUSTRALIA

AUSTRALIAN HAEMOVIGILANCE REPORT

DATA FOR 2016–17



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July 2016 – June 2017

AUSTRALIAN HAEMOVIGILANCE DATA

Acknowledgements

This report is published on behalf of the states and territories who voluntarily provided data to the national system. The National Blood Authority (NBA) thank them for their contributions and ongoing commitment to haemovigilance.

Appreciation is also extended to the members of the Haemovigilance Advisory Committee (HAC) for their advice on improvements in adverse event reporting and analysis of the data for this report.

Caveat

Reporting of haemovigilance data to the national haemovigilance program is voluntary and data validation is not performed in all instances in Australia.

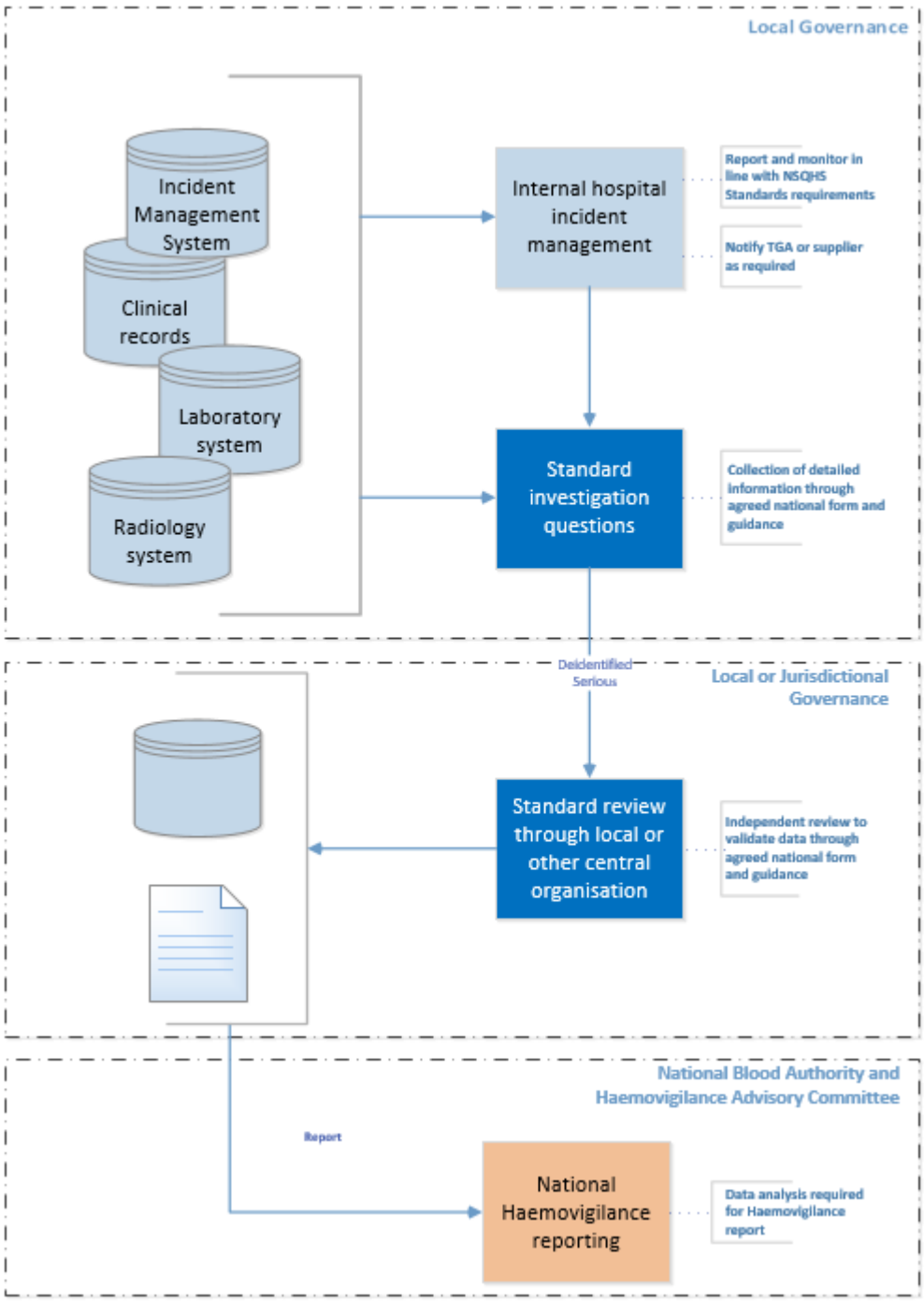
When using the data from this report it is important to note that it has quality issues in relation to data completeness, standardisation and relevance.

Notwithstanding these limitations, the NBA is publishing this data as an aid to relevant analysis and to maintain the time series of data published during the last ten years.

- Data in this report are in accordance with the National Blood Authority National Haemovigilance Data Dictionary (NHDD) 2010
- Data contributions vary across years and between states/territories.
- Near misses and denominator data (number of transfusions) are not collected and reported at national level.
- All the adverse events in this report are reported cases rather than confirmed cases.
- The definitions for the adverse events in the 2010 NHDD, Appendix I align with those used by the International Haemovigilance Network (IHN) and International Society Blood Transfusion (ISBT). However, it is not expected that they are applied rigorously.
- The national data set accepts the categorisation assigned by the contributing jurisdiction and the reviewing clinicians, regardless of minor differences to definitions.

Collection and reporting process

- Data is provided to the national haemovigilance program according to each jurisdiction's review and reporting requirements.
- Data is reconciled by the Blood Service.
- State and territory health departments aggregate and de-identify data and report to the NBA.



Summary of findings for 2016-17

Table 1: Adverse events by state, 2016-17

	FNHTR	Allergic	TACO	IBCT	Anaphylactic	DHTR	AHTR	TTI	TRALI	All reports		Population	Red cell issue
										Total	Per cent	Per cent	Per cent
NSW	81	34	16	23	0	14	3	0	4	175	27.9%	32.0%	29.9%
VIC	24	12	9	12	7	2	1	0	2	69	11.0%	25.6%	28.0%
QLD	158	48	18	4	4	3	7	0	4	246	39.2%	20.0%	21.2%
SA	13	33	4	1	0	0	0	1	2	54	8.6%	7.0%	9.0%
WA	23	26	6	5	9	0	2	0	0	71	11.3%	10.5%	8.2%
TAS	3	2	0	0	0	0	0	0	0	5	0.8%	2.1%	1.7%
NT	2	2	0	0	0	1	0	0	0	5	0.8%	1.0%	0.6%
ACT	0	0	2	0	1	0	0	0	0	3	0.5%	1.7%	1.5%
Total	**304**	**157**	**55**	**45**	**21**	**20**	**13**	**1**	**12**	**628**	**100.0%**	**100.0%**	**100.0%**

Notes
1. All TTIs were suspected but not confirmed bacterial infections
2. Number of patients or transfusion episodes is unavailable
3. STIR uses a higher level temperature threshold for the reporting of FNHTR

Table 2: Adverse events by imputability score, 2016-17

Event Type	Excluded / Unlikely	Possible	Likely / Probable	Confirmed / Certain	N/A /Not assessable	Total	Per Cent
FNHTR	60	162	75	2	5	304	48.4%
Allergic	7	29	93	22	6	157	25.0%
TACO	5	23	26	0	1	55	8.8%
IBCT	0	2	1	16	1	20	3.2%
Anaphylactic	1	21	18	5	0	45	7.2%
DHTR	1	3	5	11	1	21	3.3%
AHTR	0	5	5	3	0	13	2.1%
TTI	0	0	0	1	0	1	0.2%
TRALI	2	9	1	0	0	12	1.9%
Total	**76**	**254**	**224**	**60**	**14**	**628**	**100.0%**
Per cent	**12.1%**	**40.4%**	**35.7%**	**9.6%**	**2.2%**	**100.0%**	

Notes
1. All TTIs were suspected but not confirmed bacterial infections
2. Number of patients or transfusion episodes is unavailable
3. STIR uses a higher level temperature threshold for the reporting of FNHTR

Table 3: Adverse events by blood product, 2016-17

Adverse event	Red cells	Platelets	Fresh frozen plasma	Cryoprecipitate	Cryo-depleted Plasma	Unknown	Total
FNHTR	273	26	4	0	0	1	304
Allergic	41	66	43	1	2	4	157
TACO	51	1	1	0	0	2	55
IBCT	14	2	2	1	1	0	20
Anaphylactic	15	12	17	1	0	0	45
DHTR	20	0	0	0	0	1	21
AHTR	12	0	1	0	0	0	13
TTI	1	0	0	0	0	0	1
TRALI	8	0	4	0	0	0	12
Total	**435**	**107**	**72**	**3**	**3**	**8**	**628**
Per cent	**69.3%**	**17.0%**	**11.5%**	**0.5%**	**0.5%**	**1.3%**	**100.0%**

Notes
1. All TTIs were suspected but not confirmed bacterial infections
2. Number of patients or transfusion episodes is unavailable
3. STIR uses a higher level temperature threshold for the reporting of FNHTR

Table 4: Adverse events by clinical outcome severity, 2016-17

Adverse event	Death	Life-threatening	Severe morbidity	Minor morbidity	No morbidity	Outcome not available	Grand Total
FNHTR	0	0	30	191	56	27	304
Allergic	0	5	11	119	10	12	157
TACO	0	4	16	28	3	4	55
IBCT	0	1	0	3	7	9	20
Anaphylactic	1	12	6	18	3	5	45
DHTR	0	1	0	15	3	2	21
AHTR	0	1	3	7	1	1	13
TTI	0	0	0	1	0	0	1
TRALI	0	4	5	2	0	1	12
Total	**1**	**28**	**71**	**384**	**83**	**61**	**628**
Per cent	**0.2%**	**4.5%**	**11.3%**	**61.1%**	**13.2%**	**9.7%**	**100.0%**

Notes
1. All TTIs were suspected but not confirmed bacterial infections
2. Number of patients or transfusion episodes is unavailable
3. STIR uses a higher level temperature threshold for the reporting of FNHTR

Table 5: Reported adverse events by sex, 2016-17

Adverse event	Male	Female	Not reported	Total
FNHTR	127	103	74	304
Allergic	66	59	32	157
TACO	21	19	15	55
IBCT	4	6	10	20
Anaphylactic	10	17	18	45
DHTR	8	13	0	21
AHTR	2	8	3	13
TTI	1	0	0	1
TRALI	4	5	3	12
All reports	**243**	**230**	**155**	**628**
Per cent	**38.7%**	**36.6%**	**24.7%**	**100.0%**

Notes
1. Limited sex data available for NSW
2. Number of patients or transfusion episodes is unavailable

Table 6: Adverse events by age and sex, 2016-17

Adverse event	Male	Female	Not reported	Total
0–4 years	4	7	4	15
5–14 years	3	5	6	14
15–24 years	8	9	3	20
25–34 years	14	22	3	39
35–44 years	22	16	12	50
45–54 years	18	27	11	56
55–64 years	36	33	31	100
65–74 years	71	43	29	143
75 years or older	66	68	45	179
Not stated	1	0	11	12
Total	**243**	**230**	**155**	**628**
Per cent	**38.7%**	**36.6%**	**24.7%**	**100.0%**

Notes
1. Limited sex data available for NSW
2. Number of patients or transfusion episodes is unavailable

Table 7: Serious adverse events by outcome severity and imputability score, 2016-17

	Death	Life-threatening	Severe morbidity	All reports	
				Total	Per cent
Possible	0	9	33	42	48.3%
Likely/Probable	1	13	22	36	41.4%
Confirmed/Certain	0	6	3	9	10.3%
Total	**1**	**28**	**58**	**87**	**100.0%**

Notes
1. Not assessable and excluded/unlikely imputability scores are not included in the analysis
2. Outcome severity with unknown outcomes, minor and no morbidities are not included in the analysis
3. Number of patients or transfusion episodes is unavailable

Cumulative results for 2012-13 to 2016-17

Table 8: Adverse events by state, 2012-13 to 2016-17

	2012–13	2013–14	2014–15	2015–16	2016–17	2016–17
						Per cent
NSW	194	218	264	281	175	27.9%
VIC	59	86	59	54	69	11.0%
QLD	0	151	202	250	246	39.2%
SA	157	154	149	62	54	8.6%
WA	0	0	0	73	71	11.3%
TAS	4	1	1	0	5	0.8%
NT	11	7	5	3	5	0.8%
ACT	4	0	0	1	3	0.5%
All reports	**429**	**617**	**680**	**724**	**628**	**100.0%**

Notes
1. ACT reported zero adverse events for 2013–14 and 2014–15
2. QLD did not contribute data for 2012–13
3. WA did not contribute data from 2012–13 to 2014–15
4. Number of patients or transfusion episodes is unavailable
5. STIR uses a higher level temperature threshold for the reporting of FNHTR and cases are validated by an expert group prior to finalisation of the report

Table 9: Adverse events by hospital type, 2012-13 to 2016-17

Hospital type	2012–13	2013–14	2014–15	2015–16	2016–17	Total hospitals	Per cent
Public hospital	426	540	646	653	588	2,853	92.7%
All private hospitals	**3**	**77**	**34**	**71**	**40**	**225**	**7.3%**
Private hospital (excludes private free standing day hospital)	3	77	29	69	40	218	7.1%
Private free-standing day hospital	0	0	5	0	0	5	0.2%
Medical and diagnostic laboratory	0	0	0	2	0	2	0.1%
Total hospitals	**429**	**617**	**680**	**724**	**628**	**3,078**	**100.0%**

Notes
1. ACT reported zero adverse events for 2013–14 and 2014–15
2. QLD did not contribute data for 2012–13
3. WA did not contribute data from 2012–13 to 2014–15
4. Only VIC, QLD and WA contributed private hospital data
5. Number of patients or transfusion episodes is unavailable
6. Private hospitals include private free-standing day hospital and other private hospitals (exclude private free standing day hospitals)

Table 10: Australian adverse event data, 2012-13 to 2016-17

Adverse event	2012–13	2013–14	2014–15	2015–16	2016–17	All reports		Transfusion risk per unit transfused*
						Number	Per cent	(unless specified)
FNHTR	231	337	380	365	304	1,617	52.5%	0.1–1% of transfusions with universal leucocyte depletion
Allergic	111	144	164	193	157	769	25.0%	1–3% of transfusion of plasma containing components
TACO	17	28	39	51	55	190	6.2%	<1% of transfused patients
IBCT	43	33	30	41	20	167	5.4%	Not available
Anaphylactic	13	19	20	30	45	127	4.1%	1:20,000–1:50,000
DHTR	6	12	16	16	21	71	2.3%	1:2,500–1:11,000
AHTR	2	8	15	9	13	47	1.5%	1:76,000
TTI	5	27	12	17	1	62	2.0%	1:75,000 platelet transfusions 1:500,000 red cell transfusions
TRALI	1	3	4	2	12	22	0.7%	1:1,200–1:190,000 transfusions
PTP	NA	6	NA	NA	NA	6	0.2%	Rare
Grand Total	**429**	**617**	**680**	**724**	**628**	**3078**	**100.0%**	

Notes
1. ACT reported zero adverse events for 2013–14 and 2014–15
2. QLD did not contribute data for 2012–13
3. WA did not contribute data from 2012–13 to 2014–15
4. Only VIC, QLD and WA contributed private hospital data
5. All TTIs were suspected but not confirmed bacterial infections
6. Number of patients or transfusion episodes is unavailable

*Australian Red Cross Blood Service (2015), Blood Component Information: An extension of blood component labels

Table 11: Serious adverse events by state, 2012-13 to 2016-17

	2012–13	2013–14	2014–15	2015–16	2016–17	2016–17
						Per cent
NSW	17	15	6	6	14	16.1%
VIC	17	22	23	12	32	36.8%
QLD	0	7	14	20	24	27.6%
SA	0	8	2	7	8	9.2%
WA	0	0	0	4	7	8.0%
TAS	3	1	0	0	1	1.1%
NT	4	1	0	0	0	0.0%
ACT	3	0	0	0	1	1.1%
All reports	**44**	**54**	**45**	**49**	**87**	**100.0%**

Notes
1. ACT reported zero adverse events for 2013–14 and 2014–15
2. QLD did not contribute data for 2012–13
3. WA did not contribute data from 2012–13 to 2014–15
4. Number of patients or transfusion episodes is unavailable
5. STIR uses a higher level temperature threshold for the reporting of FNHTR and cases are validated by an expert group prior to finalisation of the report

Table 12: Serious adverse events, 2012-13 to 2016-17

	2012–13	2013–14	2014–15	2015–16	2016–17	All reports	
						Total	Per cent
FNHTR	12	7	5	6	20	50	17.9%
Allergic	9	15	8	15	15	62	22.2%
TACO	8	16	13	12	19	68	24.4%
IBCT	5	0	1	1	1	8	2.9%
Anaphylactic	8	13	13	13	19	66	23.7%
DHTR	1	1	1	0	1	4	1.4%
AHTR	0	1	1	1	4	7	2.5%
TTI	1	0	1	0	0	2	0.7%
TRALI	0	0	2	1	8	11	3.9%
PTP	0	1	0	0	0	1	0.4%
All reports	**44**	**54**	**45**	**49**	**87**	**279**	**100.0%**

Notes
1. ACT reported zero adverse events for 2013–14 and 2014–15
2. QLD did not contribute data for 2012–13
3. WA did not contribute data from 2012–13 to 2014–15
4. All TTIs were suspected but not confirmed bacterial infections
5. Number of patients or transfusion episodes is unavailable

Table 13: Serious adverse events by product, 2012-13 to 2016-17

	Red cells	Platelets	Fresh frozen plasma	Cryo-depleted plasma	Cryoprecipitate	Unknown	Total
FNHTR	40	8	2	0	0	0	50
Allergic	18	21	19	2	0	2	62
TACO	66	1	0	0	1	0	68
IBCT	8	0	0	0	0	0	8
Anaphylactic	14	28	23	0	1	0	66
DHTR	4	0	0	0	0	0	4
AHTR	6	1	0	0	0	0	7
TTI	2	0	0	0	0	0	2
TRALI	8	0	3	0	0	0	11
PTP	0	1	0	0	0	0	1
All reports	**166**	**60**	**47**	**2**	**2**	**2**	**279**
Per cent	**59.5%**	**21.5%**	**16.8%**	**0.7%**	**0.7%**	**0.7%**	**100.0%**

Notes
1. ACT reported zero adverse events for 2013–14 and 2014–15
2. QLD did not contribute data for 2012–13
3. WA did not contribute data from 2012–13 to 2014–15
4. All TTIs were suspected but not confirmed bacterial infections
5. Number of patients or transfusion episodes is unavailable

Table 14: Serious adverse events by transfusion time, 2012-13 to 2016-17

	2012–13	2013–14	2014–15	2015–16	2016–17	All reports	
						Total	Per cent
Between 7am and 7pm	16	20	31	36	39	142	50.9%
Between 7pm and 7am	11	21	12	12	45	101	36.2%
Not reported	17	13	2	1	3	36	12.9%
All reports	**44**	**54**	**45**	**49**	**87**	**279**	**100.0%**

Notes
1. SA did not report transfusion time data from 2012–13 to 2014–15
2. ACT reported zero adverse events for 2013–14 and 2014–15
3. QLD did not contribute data for 2012–13
4. WA did not contribute data from 2012–13 to 2014–15
5. Number of patients or transfusion episodes is unavailable

Table 15: Serious adverse events by week day/weekend, 2012-13 to 2016-17

	2012–13	2013–14	2014–15	2015–16	2016–17	All reports	
						Total	Per cent
Week day	36	40	33	42	69	220	78.9%
Weekend	8	14	12	7	18	59	21.1%
All reports	**44**	**54**	**45**	**49**	**87**	**279**	**100.0%**

Notes
1. ACT reported zero adverse events for 2013–14 and 2014–15
2. QLD did not contribute data for 2012–13
3. WA did not contribute data from 2012–13 to 2014–15
4. Number of patients or transfusion episodes is unavailable

Table 16: Serious adverse events by age group, 2012-13 to 2016-17

	2012–13	2013–14	2014–15	2015–16	2016–17	All reports	
						Total	Per cent
0–4 years	1	0	3	3	4	11	3.9%
5–14 years	2	3	4	4	4	17	6.1%
15–24 years	4	2	0	2	6	14	5.0%
25–34 years	3	2	3	3	6	17	6.1%
35–44 years	6	5	0	4	7	22	7.9%
45–54 years	3	4	5	5	7	24	8.6%
55–64 years	5	10	4	4	12	35	12.5%
65–74 years	8	8	14	8	20	58	20.8%
75 years or older	12	18	12	16	19	77	27.6%
Not stated	0	2	0	0	2	4	1.4%
All reports	**44**	**54**	**45**	**49**	**87**	**279**	**100.0%**

Notes
1. ACT reported zero adverse events for 2013–14 and 2014–15
2. QLD did not contribute data for 2012–13
3. WA did not contribute data from 2012–13 to 2014–15
4. Number of patients or transfusion episodes is unavailable

Febrile non haemolytic transfusion reaction (FNHTR)

Table 17: FNHTR data summary, 2016-17

2016–17 Data Summary (n=304)					
Age		**Sex**		**Day of Transfusion**	
0–4 years	2	Male	127	Week day	238
5–14 years	6	Female	103	Weekend	66
15–24 years	2	Uncategorised	74		
25–34 years	12	**Facility Location**		**Time of Transfusion**	
35–44 years	22	Major City	124	Between 7am and 7pm	135
45–54 years	23	Inner Regional	34	Between 7pm and 7am	165
55–64 years	56	Outer Regional	65	Not reported	4
65–74 years	85	Remote	0		
75+ years	92	Very Remote	0		
Not specified	4	Not reported	81		
Clinical Outcome Severity		**Imputability**		**Blood Component**	
Death	0	Excluded/Unlikely	60	Red cells	273
Life threatening	0	Possible	162	Platelets	26
Severe morbidity	30	Likely/Probable	75	Fresh Frozen Plasma	4
Minor morbidity	191	Confirmed/Certain	2	Cryoprecipitate	0
No morbidity	56	Not assessable	5	Cryodepleted plasma	0
Outcome not available	27			Not reported	1

Notes
1. NSW did not report the facility location data and limited reporting of sex data
2. Number of patients or transfusion episodes is unavailable

Table 18: FNHTR clinical outcome severity by imputability, 2016-17

Clinical Outcome Severity	Imputability					Total
	Excluded / Unlikely	Possible	Likely / Probable	Confirmed / Certain	N/A /Not assessable	
Life-threatening	0	0	0	0	0	0
Severe morbidity	9	13	7	0	1	30
Minor morbidity	34	101	53	2	1	191
No morbidity	14	29	10	0	3	56
Outcome not available	3	19	5	0	0	27
Total	**60**	**162**	**75**	**2**	**5**	**304**

Allergic reaction

Table 19: Allergic reaction data summary, 2016-17

2016–17 Data Summary (n=157)					
Age		**Sex**		**Day of Transfusion**	
0–4 years	5	Male	66	Week day	120
5–14 years	4	Female	59	Weekend	37
15–24 years	12	Uncategorised	32		
25–34 years	16	**Facility Location**		**Time of Transfusion**	
35–44 years	14	Major City	101	Between 7am and 7pm	90
45–54 years	18	Inner Regional	11	Between 7pm and 7am	62
55–64 years	22	Outer Regional	11	Not reported	5
65–74 years	27	Remote	0		
75+ years	33	Very Remote	0		
Not specified	6	Not reported	34		
Clinical Outcome Severity		**Imputability**		**Blood Component**	
Death	0	Excluded/Unlikely	7	Red cells	41
Life threatening	5	Possible	29	Platelets	66
Severe morbidity	11	Likely/Probable	93	Fresh Frozen Plasma	43
Minor morbidity	119	Confirmed/Certain	22	Cryoprecipitate	1
No morbidity	10	Not assessable	6	Cryodepleted plasma	2
Outcome not available	12			Not reported	4

Notes

1. NSW did not report the facility location data and limited reporting of sex data
2. Number of patients or transfusion episodes is unavailable

Table 20: Allergic reaction clinical outcome severity by imputability, 2016-17

Clinical Outcome Severity	Imputability					Total
	Excluded / Unlikely	Possible	Likely / Probable	Confirmed / Certain	N/A /Not assessable	
Life-threatening	0	0	5	0	0	5
Severe morbidity	1	4	5	1	0	11
Minor morbidity	4	20	73	18	4	119
No morbidity	0	3	3	2	2	10
Outcome not available	2	2	7	1	0	12
Total	**7**	**29**	**93**	**22**	**6**	**157**

Transfusion-associated circulatory overload (TACO)

Table 21: TACO data summary, 2016-17

2016–17 Data Summary (n=55)					
Age		**Sex**		**Day of Transfusion**	
0–4 years	2	Male	21	Week day	45
5–14 years	1	Female	19	Weekend	10
15–24 years	0	Uncategorised	15		
25–34 years	2	**Facility Location**		**Time of Transfusion**	
35–44 years	2	Major City	33	Between 7am and 7pm	20
45–54 years	4	Inner Regional	6	Between 7pm and 7am	34
55–64 years	7	Outer Regional	0	Not reported	1
65–74 years	9	Remote	0		
75+ years	27	Very Remote	0		
Not specified	1	Not reported	16		
Clinical Outcome Severity		**Imputability**		**Blood Component**	
Death	0	Excluded/Unlikely	5	Red cells	51
Life threatening	4	Possible	23	Platelets	1
Severe morbidity	16	Likely/Probable	26	Fresh Frozen Plasma	1
Minor morbidity	28	Confirmed/Certain	0	Cryoprecipitate	0
No morbidity	3	Not assessable	1	Cryodepleted plasma	0
Outcome not available	4			Not reported	2

Notes
1. NSW did not report the facility location data and limited reporting of sex data
2. Number of patients or transfusion episodes is unavailable

Table 22: TACO clinical outcome severity by imputability, 2016-17

Clinical Outcome Severity	Imputability					Total
	Excluded / Unlikely	Possible	Likely / Probable	Confirmed / Certain	N/A /Not assessable	
Life-threatening	0	2	2	0	0	4
Severe morbidity	1	6	9	0	0	16
Minor morbidity	3	10	14	0	1	28
No morbidity	0	2	1	0	0	3
Outcome not available	1	3	0	0	0	4
Total	**5**	**23**	**26**	**0**	**1**	**55**

Incorrect blood component transfused (IBCT)

Table 23: IBCT data summary, 2016-17

2016–17 Data Summary (n=20)					
Age		**Sex**		**Day of Transfusion**	
0–4 years	2	Male	4	Week day	18
5–14 years	0	Female	6	Weekend	2
15–24 years	0	Uncategorised	10		
25–34 years	2	**Facility Location**		**Time of Transfusion**	
35–44 years	2	Major City	5	Between 7am and 7pm	3
45–54 years	2	Inner Regional	0	Between 7pm and 7am	16
55–64 years	2	Outer Regional	1	Not reported	1
65–74 years	3	Remote	0		
75+ years	7	Very Remote	0		
Not specified	0	Not reported	14		
Clinical Outcome Severity		**Imputability**		**Blood Component**	
Death	0	Excluded/Unlikely	0	Red cells	14
Life threatening	1	Possible	2	Platelets	2
Severe morbidity	0	Likely/Probable	1	Fresh Frozen Plasma	2
Minor morbidity	3	Confirmed/Certain	16	Cryoprecipitate	1
No morbidity	7	Not assessable	1	Cryodepleted plasma	1
Outcome not available	9			Not reported	0

Notes
1. NSW did not report the facility location data and limited reporting of sex data
2. Number of patients or transfusion episodes is unavailable

Table 24: IBCT clinical outcome severity by imputability, 2016-17

Clinical Outcome Severity	Imputability					Total
	Excluded / Unlikely	Possible	Likely / Probable	Confirmed / Certain	N/A /Not assessable	
Life-threatening	0	0	0	1	0	1
Severe morbidity	0	0	0	0	0	0
Minor morbidity	0	1	0	2	0	3
No morbidity	0	0	0	6	1	7
Outcome not available	0	1	1	7	0	9
Total	**0**	**2**	**1**	**16**	**1**	**20**

Table 25: Contributory factors cited in IBCT, 2012-13 to 2016-17

Contributory Factor	2012–13	2013-14	2014-15	2015-16	2016-17
None identified	1	1	0	7	0
Product characteristic	0	0	0	1	13
*Transfusion in emergency setting	6	3	7	10	5
*Deliberate clinical decision	0	0	1	4	2
*Prescribing/ordering	0	14	6	12	13
*Specimen collection/labelling	11	0	1	0	0
*Laboratory (testing/dispensing)	22	12	15	22	10
*Transport, storage, handling	1	1	1	0	1
*Administration of product	9	10	13	8	14
*Indications do not meet guidelines	0	3	0	1	3
*Procedure did not adhere to hospital transfusion guidelines	27	15	8	14	15
Other	12	12	0	2	10

Notes
1. Contributory factors are not reported for SA
2. * refers to potentially avoidable human errors

Anaphylactic or anaphylactoid reaction

Table 26: Anaphylactic or anaphylactoid reaction data summary, 2016-17

2016–17 Data Summary (n=45)					
Age		**Sex**		**Day of Transfusion**	
0–4 years	4	Male	10	Week day	35
5–14 years	2	Female	17	Weekend	10
15–24 years	6	Uncategorised	18		
25–34 years	6	**Facility Location**		**Time of Transfusion**	
35–44 years	3	Major City	20	Between 7am and 7pm	15
45–54 years	2	Inner Regional	2	Between 7pm and 7am	30
55–64 years	6	Outer Regional	0	Not reported	0
65–74 years	8	Remote	0		
75+ years	7	Very Remote	0		
Not specified	1	Not reported	23		
Clinical Outcome Severity		**Imputability**		**Blood Component**	
Death	1	Excluded/Unlikely	1	Red cells	15
Life threatening	12	Possible	21	Platelets	12
Severe morbidity	6	Likely/Probable	18	Fresh Frozen Plasma	17
Minor morbidity	18	Confirmed/Certain	5	Cryoprecipitate	1
No morbidity	3	Not assessable	0	Cryodepleted plasma	0
Outcome not available	5			Not reported	0

Notes

1. NSW did not report the facility location data and limited reporting of sex data
2. Number of patients or transfusion episodes is unavailable

Table 27: Anaphylactic or anaphylactoid reaction clinical outcome severity by imputability, 2016-17

Clinical Outcome Severity	Imputability					Total
	Excluded / Unlikely	Possible	Likely / Probable	Confirmed / Certain	N/A /Not assessable	
Death	0	0	1	0	0	1
Life-threatening	0	4	5	3	0	12
Severe morbidity	0	4	1	1	0	6
Minor morbidity	1	8	8	1	0	18
No morbidity	0	2	1	0	0	3
Outcome not available	0	3	2	0	0	5
Total	**1**	**21**	**18**	5	**0**	**45**

Delayed haemolytic transfusion reaction (DHTR)

Table 28: DHTR data summary, 2016-17

2016–17 Data Summary (n=21)					
Age		**Sex**		**Day of Transfusion**	
0–4 years	0	Male	8	Week day	15
5–14 years	1	Female	13	Weekend	6
15–24 years	0	Uncategorised			
25–34 years	1	**Facility Location**		**Time of Transfusion**	
35–44 years	2	Major City	17	Between 7am and 7pm	9
45–54 years	3	Inner Regional	1	Between 7pm and 7am	12
55–64 years	3	Outer Regional	3	Not reported	0
65–74 years	5	Remote	0		
75+ years	6	Very Remote	0		
Not specified	0	Not reported	0		
Clinical Outcome Severity		**Imputability**		**Blood Component**	
Death	0	Excluded/Unlikely	1	Red cells	20
Life threatening	1	Possible	3	Platelets	0
Severe morbidity	0	Likely/Probable	5	Fresh Frozen Plasma	0
Minor morbidity	15	Confirmed/Certain	11	Cryoprecipitate	0
No morbidity	3	Not assessable	1	Cryodepleted plasma	0
Outcome not available	2			Not reported	1

Notes
1. NSW did not report the facility location data and limited reporting of sex data
2. Number of patients or transfusion episodes is unavailable

Table 29: DHTR clinical outcome severity by imputability, 2016-17

Clinical Outcome Severity	Imputability					Total
	Excluded / Unlikely	Possible	Likely / Probable	Confirmed / Certain	N/A /Not assessable	
Life-threatening	0	0	0	1	0	1
Severe morbidity	0	0	0	0	0	0
Minor morbidity	0	3	3	9	0	15
No morbidity	0	0	2	1	0	3
Outcome not available	1	0	0	0	1	2
Total	**1**	**3**	**5**	**11**	**1**	**21**

Acute haemolytic transfusion reaction (AHTR)

Table 30: AHTR data summary, 2016-17

2016–17 Data Summary (n=13)					
Age		**Sex**		**Day of Transfusion**	
0–4 years	0	Male	2	Week day	12
5–14 years	0	Female	8	Weekend	1
15–24 years	0	Uncategorised	3		
25–34 years	0	**Facility Location**		**Time of Transfusion**	
35–44 years	1	Major City	7	Between 7am and 7pm	6
45–54 years	4	Inner Regional	1	Between 7pm and 7am	7
55–64 years	2	Outer Regional	2	Not reported	0
65–74 years	4	Remote	0		
75+ years	2	Very Remote	0		
Not specified	0	Not reported	3		
Clinical Outcome Severity		**Imputability**		**Blood Component**	
Death	0	Excluded/Unlikely	0	Red cells	12
Life threatening	1	Possible	5	Platelets	0
Severe morbidity	3	Likely/Probable	5	Fresh Frozen Plasma	1
Minor morbidity	7	Confirmed/Certain	3	Cryoprecipitate	0
No morbidity	1	Not assessable	0	Cryodepleted plasma	0
Outcome not available	1			Not reported	0

Notes
1. NSW did not report the facility location data and limited reporting of sex data
2. Number of patients or transfusion episodes is unavailable

Table 31: AHTR clinical outcome severity by imputability, 2016-17

Clinical Outcome Severity	Imputability					Total
	Excluded / Unlikely	Possible	Likely / Probable	Confirmed / Certain	N/A /Not assessable	
Life-threatening	0	0	0	1	0	1
Severe morbidity	0	2	0	1	0	3
Minor morbidity	0	2	4	1	0	7
No morbidity	0	0	1	0	0	1
Outcome not available	0	1	0	0	0	1
Total	**0**	**5**	**5**	**3**	**0**	**13**

Transfusion-transmitted infection (TTI)

Table 32: TTI data summary, 2016-17

2016–17 Data Summary (n=1)					
Age		**Sex**		**Day of Transfusion**	
0–4 years	0	Male	1	Week day	1
5–14 years	0	Female	0	Weekend	0
15–24 years	0	Uncategorised	0		
25–34 years	0	**Facility Location**		**Time of Transfusion**	
35–44 years	0	Major City	1	Between 7am and 7pm	1
45–54 years	0	Inner Regional	0	Between 7pm and 7am	0
55–64 years	0	Outer Regional	0	Not reported	0
65–74 years	0	Remote	0		
75+ years	1	Very Remote	0		
Not specified	0	Not reported	0		
Clinical Outcome Severity		**Imputability**		**Blood Component**	
Death	0	Excluded/Unlikely	0	Red cells	1
Life threatening	0	Possible	0	Platelets	0
Severe morbidity	0	Likely/Probable	0	Fresh Frozen Plasma	0
Minor morbidity	1	Confirmed/Certain	1	Cryoprecipitate	0
No morbidity	0	Not assessable	0	Cryodepleted plasma	0
Outcome not available	0			Not reported	0

Notes

1. NSW did not report the facility location data and limited reporting of sex data
2. Number of patients or transfusion episodes is unavailable

Table 33: TTI clinical outcome severity by imputability, 2016-17

Clinical Outcome Severity	Imputability					Total
	Excluded / Unlikely	Possible	Likely / Probable	Confirmed / Certain	N/A /Not assessable	
Life-threatening	0	0	0	0	0	0
Severe morbidity	0	0	0	0	0	0
Minor morbidity	0	0	0	1	0	1
No morbidity	0	0	0	0	0	0
Outcome not available	0	0	0	0	0	0
Total	**0**	**0**	**0**	**1**	**0**	**1**

Transfusion related acute lung injury (TRALI)

Table 34: TRALI data summary, 2016-17

2016–17 Data Summary (n=12)					
Age		**Sex**		**Day of Transfusion**	
0–4 years	0	Male	4	Week day	8
5–14 years	0	Female	5	Weekend	4
15–24 years	0	Uncategorised	3		
25–34 years	0	**Facility Location**		**Time of Transfusion**	
35–44 years	4	Major City	8	Between 7am and 7pm	4
45–54 years	0	Inner Regional	0	Between 7pm and 7am	6
55–64 years	2	Outer Regional	0	Not reported	2
65–74 years	2	Remote	0		
75+ years	4	Very Remote	0		
Not specified	0	Not reported	4		
Clinical Outcome Severity		**Imputability**		**Blood Component**	
Death	0	Excluded/Unlikely	2	Red cells	8
Life threatening	4	Possible	9	Platelets	0
Severe morbidity	5	Likely/Probable	1	Fresh Frozen Plasma	4
Minor morbidity	2	Confirmed/Certain	0	Cryoprecipitate	0
No morbidity	0	Not assessable	0	Cryodepleted plasma	0
Outcome not available	1			Not reported	0

Notes
1. NSW did not report the facility location data and limited reporting of sex data
2. Number of patients or transfusion episodes is unavailable

Table 35: TRALI clinical outcome severity by imputability, 2016-17

Clinical Outcome Severity	Imputability				Total
	Excluded / Unlikely	Possible	Likely / Probable	Confirmed / Certain	N/A /Not assessable	
Life-threatening	0	3	1	0	0	4
Severe morbidity	1	4	0	0	0	5
Minor morbidity	0	2	0	0	0	2
No morbidity	0	0	0	0	0	0
Outcome not available	1	0	0	0	0	1
Total	**2**	**9**	**1**	**0**	**0**	**12**

Contributory Factors

Table 36: Contributory factors data summary, 2016-17

Summary Data	
Contributory Factors	Number of reports
None identified	202
Not reported	54
Product characteristic	319
*Transfusion in emergency setting	11
*Deliberate clinical decision	33
*Prescribing/ordering	18
*Specimen collection/labelling	0
*Laboratory (testing/dispensing)	11
*Transport, storage, handling	1
*Administration of product	18
*Indications do not meet guidelines	9
*Procedure did not adhere to hospital transfusion guidelines	18
Other	58

Notes
1. Contributory factors are not reported for SA
2. * refers to potentially avoidable human errors

Table 37: Contributory factors cited by adverse event and by clinical outcome severity, 2016-17

Contributory Factors	Adverse event									Clinical outcome severity					
	FNHTR	Allergic	TACO	IBCT	TTI Bacterial	Anaphylactic	DHTR	AHTR	TRALI	Outcome not available	No morbidity	Minor morbidity	Severe morbidity	Life-threatening	Death
None identified/reported	121	82	27	0	1	5	10	5	5	5	42	176	25	8	0
Product characteristic	156	75	20	13	0	39	7	4	5	53	37	173	38	18	0
*Transfusion in emergency setting	2	1	1	5	0	1	1	0	0	7	0	2	2	0	0
*Deliberate clinical decision	20	4	5	2	0	1	0	1	0	2	4	23	3	0	1
*Prescribing/ordering	0	1	2	13	0	1	0	1	0	7	7	3	1	0	0
*Specimen collection/labelling	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
*Laboratory (testing/dispensing)	0	0	0	10	0	0	0	1	0	6	2	3	0	0	0
*Transport, storage, handling	0	0	0	1	0	0	0	0	0	0	1	0	0	0	0
*Administration of product	0	0	2	14	0	1	0	1	0	7	5	3	1	1	1
*Indications do not meet guidelines	1	1	2	3	0	0	1	1	0	3	2	1	2	1	0
*Procedure did not adhere to hospital transfusion guidelines	1	0	1	15	0	0	0	1	0	8	7	2	0	1	0
Other	27	5	3	10	0	5	2	2	4	10	6	32	2	7	1

Notes
1. Contributory factors are not reported for SA
2. * refers to potentially avoidable human errors

SECTION 2

July 2016 – June 2017

DONOR HAEMOVIGILANCE DATA

Executive Summary

Donor vigilance is the systematic monitoring of adverse reactions and incidents in blood donor care with a view to improving quality and safety for blood donors. Australia contributed to a joint initiative by the International Society for Blood Transfusion (ISBT), the International Haemovigilance Network (IHN) and the AABB to standardise donor haemovigilance definitions internationally. In 2014, agreement was reached on standard definitions and this report is the second to be published using these definitions. Appendix 1 shows the correlation between the classification of events using ISBT definitions and the Blood Service's historic definitions.

Historical data in this report has been updated to incorporate this delayed reporting of adverse reactions by blood donors returning to donate; this is usually prompted by the donor wellness question which prompts donors to report previous reactions. The donor may report reactions months or even years after it occurred.

Between 1 July 2016 and 30 June 2017 there were just over 1.33 million donations, including 0.71 million whole blood donations, 0.59 million plasmapheresis donations and 0.04 million plateletpheresis donations. There were 40,995 donor adverse events reported. The overall reported rate of donation related adverse events has seen a slight decrease from 311/10,000 donations for the previous 12 months to 308/10,000 donations. The event numbers in this in this report are accurate as at 6 October 2017.

Donation adverse event trends

Whilst blood donation is generally a safe process, there are recognised donor complications which can occur. Donor haemovigilance systems permit evaluation of the impact of changes in donation procedures and also of the success of interventions designed to further improve donor safety. The implementation of these systems has permitted real time reporting, and enabled detailed analysis, which has improved understanding of impacts of blood donation, changes in collection procedures and in donor selection criteria on the safety of donors.

Since the introduction of electronic reporting in 2010, the accuracy and completeness of the information reported has improved steadily. Several changes have been implemented resulting in a progressive increase in the number of donation reactions reported. These changes include the introduction of the "donor wellness check" in 2011 which has resulted in improved reporting of delayed donor reactions and phlebotomy injuries which become apparent after the donor leaves the donor centre. In late 2012 mandatory reporting of all citrate reactions in plasmapheresis and plateletpheresis donors was introduced, resulting in a significant increase in the number of reports of plateletpheresis reactions and modest increase in plasmapheresis donor reactions. In November 2013 refinements to the reporting system made it possible to report more than one type of donation reaction for each donation; this has resulted in an increase in the number of phlebotomy injuries which occurred in association with a faint or pre-faint. Since 2015, a program of staff education and compliance monitoring has resulted in improved reporting compliance.

These changes have enabled detailed analysis, which has improved understanding of the true impacts of blood donation on donor health, and the effects of changes in collection procedures and in donor selection criteria on the safety of donors. It has enabled identification donor groups at highest risk of donation reactions, which permits targeted intervention programs to reduce the risk and severity of reactions in these high risk groups.

There have been significant changes in the number and types of collections undertaken over the past 5 years. Whilst the total number of collections each year has remained relatively stable, there has been an 18% reduction in the number of whole blood collections and a 37% increase in plasmapheresis collections. The number of plateletpheresis collections each year has remained relatively stable, although the number of platelet doses collected has increased as a result as an increase in the number of double dose platelet collections, and a decline in the number of single dose platelet collections. In 2012-13, 32% of platelet collections were single dose collections; in 2016 -17, the proportion of single platelet collections fell to 21% of all platelet collections.

Table 38: Total number of collections by donation type, 2012-13 to 2016-17

Collections	2012-13	2013-14	2014-15	2015-16	2016-17
Whole Blood	858,594	783,346	747,684	718,341	705,587
All apheresis procedures	464,289	518,579	549,671	602,713	624,870
Plasmapheresis	427,945	482,857	509,269	564,640	587,444
Plateletpheresis	36,344	35,722	40,402	38,073	37,426
Total collections	**1,322,883**	**1,301,925**	**1,297,355**	**1,321,054**	**1,330,457**

There were 40,995 adverse events reported in 2016-17, giving an incidence of 3.08%. The overall reported rate of donation related adverse reactions has been stable for the past 2 years at 1:32. Events that occur in the donor centre are termed immediate events. Events which occur after the donor has left the donor centre are classified as delayed events.

Immediate vasovagal reactions are the most commonly reported adverse donation reactions, with an incidence of 1.9%. The majority of donors experience dizziness, weakness, sweating and nausea; only 7% of immediate reactions are associated with loss of consciousness. Vasovagal reactions can occur during or after the donation (sometimes as long as 6-8 hours following the donation).

Delayed vasovagal reactions are less common than immediate reactions occurring in only 0.27% of donors. Twelve percent of delayed reactions are associated with loss of consciousness. This represents a significant risk to the donor who is not under observation at the time of the event. Whilst most donors recover rapidly from a vasovagal reaction, a small number of individuals experience protracted symptoms despite appropriate immediate management and a very small number of donors sustain injuries when they faint. These donors may require hospital treatment. In 2016-17, hospital referral was required in 0.06% (6 in every 10,000) of donations.

Local phlebotomy site injuries caused by needle insertion are the next most common category of donation complication. The most frequently reported phlebotomy injuries include bruising, local pain and nerve irritation; less frequent but potentially more serious local complications include direct nerve injury, local thrombosis, tendon injury and arterial puncture.

Total donation-associated events and serious donation-related events are shown in Figure 1 below.

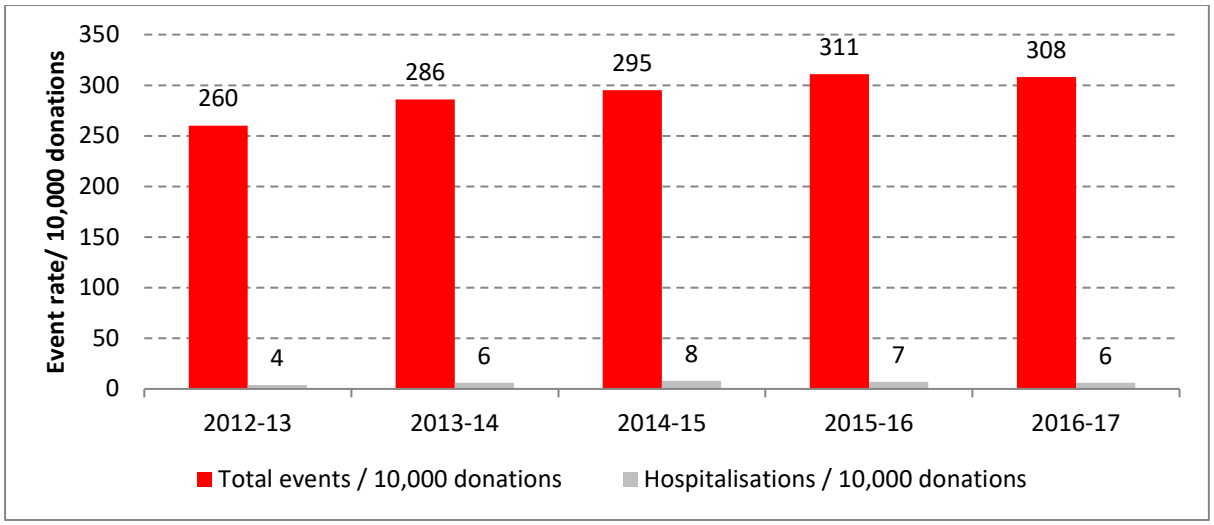


Figure 1: Total donation-associated events, 2012–13 to 2016–17

The incidence of the different types of adverse events for all donations is shown in Table 39**.** The rate of adverse reactions is stable overall. There has been a minor decrease in the overall frequency of vasovagal reactions compared to the previous year. This increase has been in non-syncopal reactions occurring on-site. There has been a significant decrease (P<0.0001) in the number of delayed reactions reported in 2016-17.

The incidence of phlebotomy injuries is stable, as is the rate of apheresis specific complications.

In early 2017, following the introduction of a new skin disinfection product (chlorhexidine 2% in isopropyl alcohol) because of the withdrawal of the previously used skin disinfection product (1% chlorhexidine) from the Australian market, reports of localised allergic skin reactions have increased significantly. The reactions remain very infrequent, and alternative skin disinfection is available for donors who experience a localised allergic reaction.

Table 39: Donation-associated events by category and frequency, 2012-13 to 2016-17 (per 10,000 donations)

Donor Event	2012–13	2013–14	2014-15	2015-16	2016-17
			Systemic events		
Immediate vasovagal reaction	195	183	183	191	190
Delayed vasovagal reaction	29	34	34	31	27
Localised allergic reaction	0.4	0.5	0.5	0.4	0.9
Generalised (anaphylactic) reaction	0	0.1	0.1	0	0
Acute cardiac symptoms*	0.4	0.7	0.8	0.8	0.7
Cardiac arrest	0	0	0	0	0
Transient ischaemic attack (TIA)	0	0	0	0	0
Cerebrovascular accident	0	0	0	0	0
			Local arm injuries		
Haematoma	12	14	15	15	15
Other arm pain	5	12	17	17	18
Nerve injury	3	4	5	6	6
Delayed bleeding	0.3	0.6	1	1	1
Superficial Thrombophlebitis	0.3	0.3	0.3	0.4	0.4
DVT	0.1	0	0.1	0	0
Compartment syndrome	0	0	0	0	0
			Apheresis specific events		
Citrate reaction	10	32	34	46	45
Infiltration	0.1	0.7	0.7	1.2	1.2
Haemolysis	0	0.1	0.1	0	0
Air embolism	0	0	0	0	0
			Other events		
Other events**	2	3	3	2	2
Total events	**257**	**286**	**295**	**311**	**308**

Notes

1. * donors who experience palpitations /angina/acute myocardial infarction within 24 hours of donation. Each case is evaluated to determine underlying risk factors
2. ** includes non-cardiac chest pain, injuries sustained in falls during fainting, headaches occurring during or after donation, cramps, nausea or abdominal pain occurring during or immediately following a procedure, onset of wheeze or asthma during or after a donation, marked or prolonged fatigue following a donation.

Adverse events by donation type

1. *Whole Blood* – Whole blood donation is associated with the highest frequency of pre-syncopal and syncopal reactions ("vasovagal reactions"). All but a very small number of first-time donors make a whole blood donation; the risk of vasovagal reactions in both male and female first time donors of all ages is almost twice that of donors of the same age and gender who have made only one previous donation. Between 60 and 70% of donors return to donate after their first donation, however, in the subset of donors who experience an adverse reaction, only 30% subsequently return to donate; thus, the lower rate of adverse reactions in returning donors is due, at least in part to selection bias.
2. *Plasmapheresis* – Plasma donation is associated with the lowest rate of donation complications of all donation types. All plasma donors receive 500mL normal saline as part of the donation protocol, which significantly reduces the impact of volume taken during the donation. Despite the continued growth of the plasma donor panel, the rate of pre-faints, faints and phlebotomy injuries is stable, and the incidence of citrate reactions has fallen as a result of the introduction of routinely offering all plasma and platelet donors oral calcium supplements before each donation.
3. *Plateletpheresis* – Platelet collections take significantly longer than plasma collections, platelet donors do not receive saline compensation and they are exposed to significantly higher doses of citrate anticoagulant than plasma donors. As a consequence, platelet donors experience significantly higher rates of both citrate reactions and pre-syncopal vasovagal reactions than plasma donors. In addition, platelet donors are more likely to develop significant bruising and other phlebotomy injuries as a result of the longer duration of platelet donation.

Table 40 shows annual rates of all adverse events by donation type from 2012-13 to 2016-17.

Table 40: Adverse event reaction rate by procedure, 2012-13 to 2016-17 (per 10,000 donations)

Procedure	2012–13	2013–14	2014-15	2015-16	2016-17
Whole Blood	319	333	352	361	368
All apheresis procedures	152	217	217	252	241
Plasmapheresis	124	163	182	216	209
Plateletpheresis	480	947	655	778	737
Total procedures	**257**	**286**	**295**	**311**	**308**

Table 41: Donation associated events by reaction type and injury, 2016-17

			Rate/10,000 donations		
			Whole Blood (n=705,587)	Plasmapheresis (n=587,444)	Plateletpheresis (n=37,426)
Immediate vasovagal reaction	Without LOC	Without injury	257.93	80.71	130.93
		With injury	0.51	0.1	0
	With LOC	Without injury	18.93	5.57	3.21
		With injury	1.39	0.22	0.27
Delayed vasovagal reactions	Without LOC	Without injury	32.03	13.28	7.75
		With injury	1.2	0.27	0
	With LOC	Without injury	4.21	1.04	0
		With injury	0.69	0.19	0
Blood outside vessel	Haematoma		15.67	12.48	51.84
	Arterial puncture		0.57	0	0
	Delayed bleeding		1.39	1.21	0.8
Arm pain	Nerve injury/irritation		8.28	3.78	5.34
	Other arm pain		21.7	14.35	20.57
Related to apheresis	Citrate reaction			69.13	507.13
	Haemolysis			0	0
	Air Embolism			0	0
	Infiltration			2.42	5.34
Infection/ inflammation/ allergic reaction	Local allergic reaction		0.82	1.04	0.27
	Generalised (anaphylactic) reaction		0.03	0.07	0
	Thrombophlebitis		0.3	0.43	0.8
Other	Cardiac	Cardiac arrest	0	0	0
		Acute myocardial infarction	0.04	0	0
		Acute cardiac symptoms	0.72	0.71	0.53
	Cerebrovascular accident		0.01	0	0
	Transient ischaemic attack		0	0	0
	DVT		0	0.02	0
	Other		1.36	2.09	2.67
Total			**368**	**209**	**737**

Serious complications of blood donation

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

- hospitalisation if it is attributable to the reaction, based on the evaluation of hospital medical staff
- attendance at a healthcare facility to manage a complication and to prevent ongoing impairment
- involvement in an accident (with or without significant injury) if the accident was probably or definitely related to the donation
- death following a donation complication if the death was probably, possibly or definitely related to the donation.

During 2016-2017, 826 donors attended hospital and 1,001 attended their general practitioner (GP) for donation related complications (Table 42). There were no donation associated deaths. The majority of hospital attendances are by donors directly referred from the donor centre, either because of an injury sustained in a fall during a vasovagal reaction or because a donor is very slow to recover from a vasovagal reaction. Donors experiencing chest pain are generally referred for assessment in the Emergency Department. 30 donors with chest pain were referred to hospital between July 2016 and June 2017 of whom 9 were admitted for cardiac investigations; all had been previously well but had risk factors for coronary disease. One donor suffered a myocardial infarct approximately 7 hours following a whole blood donation and required a single stent inserted and 2 whole blood donors were found to have coronary artery disease following hospital referral for chest pain. During follow up, feedback from the donors' treating cardiologists indicated that blood donation was unlikely to be the cause of the cardiac events in these donors. Of the remaining donors referred for chest pain the diagnosis was anxiety (in 17 donors) or no definitive diagnosis was made (for 22 donors). Most hospital attendances are brief presentations to the Emergency Department, and admission to hospital is rare. A number of donors self-refer to hospital following a delayed vasovagal reaction.

Attendance at GPs may be initiated by donors who have experienced a delayed faint, or more frequently, because of arm pain due to a large haematoma or nerve irritation. Rare causes of arm pain requiring medical treatment are venous thrombosis (11 donors) and superficial thrombophlebitis (38 donors).

Table 42: Summary of external medical referrals, 2016-17

	Number of hospital referrals	Hospital referral rate/ 10,000 donations	Number of GP referrals	GP referral rate/ 10,000 donations
Whole Blood	579	8	652	9
Plasmapheresis	238	4	324	6
Plateletpheresis	9	2	25	7
Total	**826**	**6**	**1,001**	**8**

Hospital referral rates have fallen steadily in whole blood donors since 2014 -15 and has remained stable in apheresis donors. (Refer to **Table 43** *below).*

Table 43: The rate per 10,000 donations and total numbers of adverse donor reactions (in bracket) requiring hospital attendance, 2012-13 to 2016-17

Procedure	2012–13	2013–14	2014-15	2015-16	2016-17
Whole Blood	4 (348)	5 (356)	10 (761)	9 (653)	8 (579)
All apheresis procedures	8 (124)	3 (136)	4 (226)	4 (247)	4 (247)
Plasmapheresis	2 (105)	2 (120)	4 (191)	4 (224)	4 (238)
Plateletpheresis	5 (19)	4 (16)	9 (35)	6 (23)	2 (9)
Total procedures	**4 (472)**	**4 (492)**	**7 (955)**	**7 (900)**	**6 (826)**

The majority of donors attending hospital are whole blood donors. There have not been any significant changes in whole blood collection procedures or in the demographics of the whole blood donor pool which would account for the significant increase in hospital referrals. The increase is attributable mainly to transfer donors to hospital if their recovery from a vasovagal reaction is slow (more than 60-70 minutes), recognising that early administration of intravenous fluids is the most effective means of treating this group of donors. In keeping with good clinical practice, the majority of donors who complain of chest pain are referred to hospital.

Donor gender and age and adverse reactions to donation

The frequency of donation associated events is higher in younger blood donors and in female blood donors. There is a steady reduction in the likelihood of a donation reaction with increasing age (See Table 44 and Table 45 below). The majority of the donation reactions in younger donors are characterised by brief dizziness, associated with sweating and nausea, usually lasting for less than 15 minutes. The higher rate of adverse events in this age group was one of the reasons that prompted a decision to increase the minimum age for blood donation from 16 to 18 years.

Table 44: Adverse donation reactions in female donors by age, including odds ratio, 2016-17

Age group	Number of events	Total donors in age group	Frequency	Rate/1,000 donations	Odds ratio (95% CI)
16-17	1,371	7,875	1:7	174.10	4.5829 (4.3176-4.8646)
18-20	1,958	29,237	1:15	66.97	1.5346 (1.4632-1.6095)
21-23	4,047	39,485	1:10	102.49	2.6223 (2.5316-2.7164)
24-30	5,619	90,465	1:16	62.11	1.4719 (1.4278-1.5175)
31-40	4,077	94,385	1:23	43.20	0.9239 (0.8929-0.9561)
41-50	3,202	99,203	1:31	32.28	0.649 (0.6250-0.6739)
51-60	3,291	111,462	1:34	29.53	0.5778 (0.5567-0.5997)
61-70	2,053	82,047	1:40	25.02	0.4937 (0.4717-0.5169)
71+	153	9,976	1:65	15.34	0.3213 (0.2737-0.3771)
Total	**25,771**	**564,137**	**1:22**	**45.68**	

Table 45: Adverse donation reactions in male donors by age, including odds ratio, 2016-17

Age group	Number of events	Total donors in age group	Frequency	Rate/1,000 donations	Odds ratio (95% CI)
16-17	514	4,762	1:9	107.94	5.9653 (5.4357-6.545)
18-20	1,043	26,066	1:25	40.01	2.069 (1.9405-2.2060)
21-23	1,903	33,423	1:18	56.94	3.157 (3.0050-3.3166)
24-30	3,337	94,800	1:28	35.20	1.9495 (1.8749-2.0271)
31-40	3,153	120,620	1:38	26.14	1.355 (1.3023-1.4099)
41-50	2,191	137,872	1:63	15.96	0.7375 (0.7046-0.7720)
51-60	1,910	173,872	1:91	10.99	0.4639 (0.4421-0.4869)
61-70	1,095	133,002	1:121	8.23	0.3507 (0.3297-0.3731)
71+	78	21,371	1:274	3.65	0.1713 (0.1371-0.2142)
Total	**15,224**	**745,201**	**1:49**	**20.43**	

The higher incidence of reactions in young donors and female donors is consistent with international experience.

Current strategies to reduce the risk of adverse events

1. Donor selection criteria:
   a. An increase in the minimum weight to 50kg, and a minimum total blood volume of 3,333ml, was implemented in 2015.
   b. Permanent deferral of donors who are at significant risk of experiencing a recurrence of serious adverse reactions.
2. Interventions which reduce the risk of an adverse donation reaction
   a. Provide advice to donors on strategies to minimise the risk of a reaction during and after donation on donateblood.com.au (rest and fluid intake, avoidance of strenuous physical activity and alcohol post donation).
   b. Provision of specific information cards to donors at the time of an adverse event detailing immediate management and preventative actions relevant to subsequent donations.
   c. Use of a mid-donation saline protocol for plasma donors which includes the administration of 500ml of saline to reduce the risk of vasovagal reactions.
   d. Using a stepwise approach to increasing collection volume for plasmapheresis donors donating plasma for fractionation based on nomograms* for percent Total Blood Volume.
   e. Using a stepwise approach for plasmapheresis donors donating Clinical Fresh Frozen Plasma with end saline also based on a nomogram for Total Blood Volume.
   f. Since December 2016, all plasma- and plateletpheresis donors have been routinely provided with 900mg of elemental calcium in a palatable peppermint lozenge. This has resulted in a significant, sustained reduction in the incidence of citrate reactions in platelet donors and female plasma donors.
3. Haemovigilance and Clinical Governance activities
   a. Communication with comparable international blood services to ensure 'best practice' protocols.
   b. Regular adverse events data review and trend analysis is conducted by the Donor Haemovigilance Team, with reporting provided at donor centre, state and national level.
   c. Formal clinical governance processes including review of staff scope of practice and training, the conduct of clinical audits, robust data capture and analysis of adverse events, regular management and external review of donor adverse event trends with corrective action taken as required.

*A nomogram is a chart or graph used to show relationships between several variables (such as height and weight) to enable a third value (the collection volume, which is based on the total blood volume) to be read directly at the intersection point of the first 2 values.

APPENDIX 1

Appendix 1: International Society of Blood Transfusion (ISBT) definitions

COMPARISON OF ISBT AND AUSTRALIAN RED CROSS BLOOD SERVICE DONOR ADVERSE EVENTS CLASSIFICATIONS							
SYSTEMIC COMPLICATIONS				**LOCAL COMPLICATIONS**		**APHERESIS COMPLICATIONS**	
ISBT	BLOOD SERVICE	ISBT	BLOOD SERVICE	ISBT	BLOOD SERVICE	ISBT	BLOOD SERVICE
Occurring onsite		**Occurring offsite**		**Blood outside vessels**	**No specific sub-category**		Mild citrate reaction
Immediate	**Immediate**	**Delayed***	**Delayed**	Haematoma	Haematoma	Citrate reaction	Moderate citrate reaction
Vasovagal reaction without LOC	Mild VVR(<15 minutes duration)	Vasovagal reaction without LOC	Mild VVR(<15 minutes duration)	Arterial puncture	Arterial puncture		Severe citrate reaction
	Moderate VVR (15-60 minutes duration)		Moderate VVR (15-60 minutes duration)	Delayed bleeding	Delayed bleeding	Haemolysis	Suspected haemolysis
	Severe VVR (>60 minutes duration)		Severe VVR (>60 minutes duration)	**Arm pain**	***No specific sub-category***	Anaphylaxis	Anaphylaxis
Vasovagal reaction with LOC	Severe VVR	Vasovagal reaction with LOC	Severe VVR	Nerve injury/irritation	Nerve injury/irritation	Other apheresis complications**	Air embolus
Vasovagal reaction with LOC + seizure +/- incontinence		Vasovagal reaction with LOC + seizure +/- incontinence		Other arm pain	Painful arm		Omitted anticoagulant -mild
Vasovagal reaction with injury	Severe complicated VVR	Vasovagal reaction with injury	Severe complicated VVR	**Infection, inflammation, local allergy**	***No specific sub-category***		Omitted anticoagulant - moderate
Acute cardiac symptoms	Chest pain (including non-cardiac chest pain)	Acute cardiac symptoms	Chest pain (including non-cardiac chest pain)	Cellulitis	*No specific category*		Omitted antcoagulant - severe
Acute myocardial infarction		Acute myocardial infarction		Thrombophlebitis	Superficial thrombophlebitis		Wrong solution administered
Transient ischaemic attack (TIA)	*No specific category*	Transient ischaemic attack (TIA)	*No specific category*	**Other**	***No specific sub-category***	** The complications listed are extremely rare; from a reporting perspective, the occurrence of any of the any of the apheresis adverse events in this category would result in a full incident investigation, including root cause analysis	
Cerebrovascular accident	*No specific category*	Cerebrovascular acident	*No specific category*	DVT	Thrombosis not involving axillary vein		
Cardiac arrest	Cardiac arrest	Cardiac arrest	Cardiac arrest		Thrombosis involving axillary vein		
Death	Death	Death	Death	Arteriovenous fistula	*No specific category*		
* Occurring within 24 hours of blood donation and definitely, possibly or likely due to blood donation				Infiltration	Extravasation/compartment syndrome		
				Compartment syndrome	*Not listed separately from extravasation*		

ABBREVIATIONS

AABB	American Association of Blood Banks
ABO	The human red cell ABO blood group system
ACT	Australian Capital Territory
AHTR	Acute haemolytic transfusion reaction (other than ABO incompatibility)
ATR	Acute transfusion reactions
DHTR	Delayed haemolytic transfusion reaction
DVT	Deep vein thrombosis
FNHTR	Febrile non haemolytic transfusion reaction
GP	General Practitioner
HAC	Haemovigilance Advisory Committee
HBsAg	Hepatitis B surface antigen
HBV	Hepatitis B virus
HCV	Hepatitis C virus
HIV	Human Immunodeficiency virus
HTC	Haemophilia Treatment Centre
HTLV	Human T-cell lymphoma virus
IBCT	Incorrect blood component transfused
IHN	International Haemovigilance Network
ISBT	International Society for Blood Transfusion
LOC	Loss of consciousness
NAT	Nucleic acid testing
NBA	National Blood Authority
NHDD	National Haemovigilance Data Dictionary
NSW	New South Wales
NT	Northern Territory
PTP	Post transfusion purpura
QLD	Queensland
SA	South Australia
STIR	Serious Transfusion Incident Reporting
TACO	Transfusion-associated circulatory overload
TAS	Tasmania
TIA	Transient ischaemic attack
TRALI	Transfusion-related acute lung injury
TTI	Transfusion-transmitted infection
vCJD	Variant Creutzfeldt-Jakob disease
VIC	Victoria
VVR	Vasovagal reaction
WA	Western Australia

ACKNOWLEDGEMENTS LIST

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AUSTRALIA