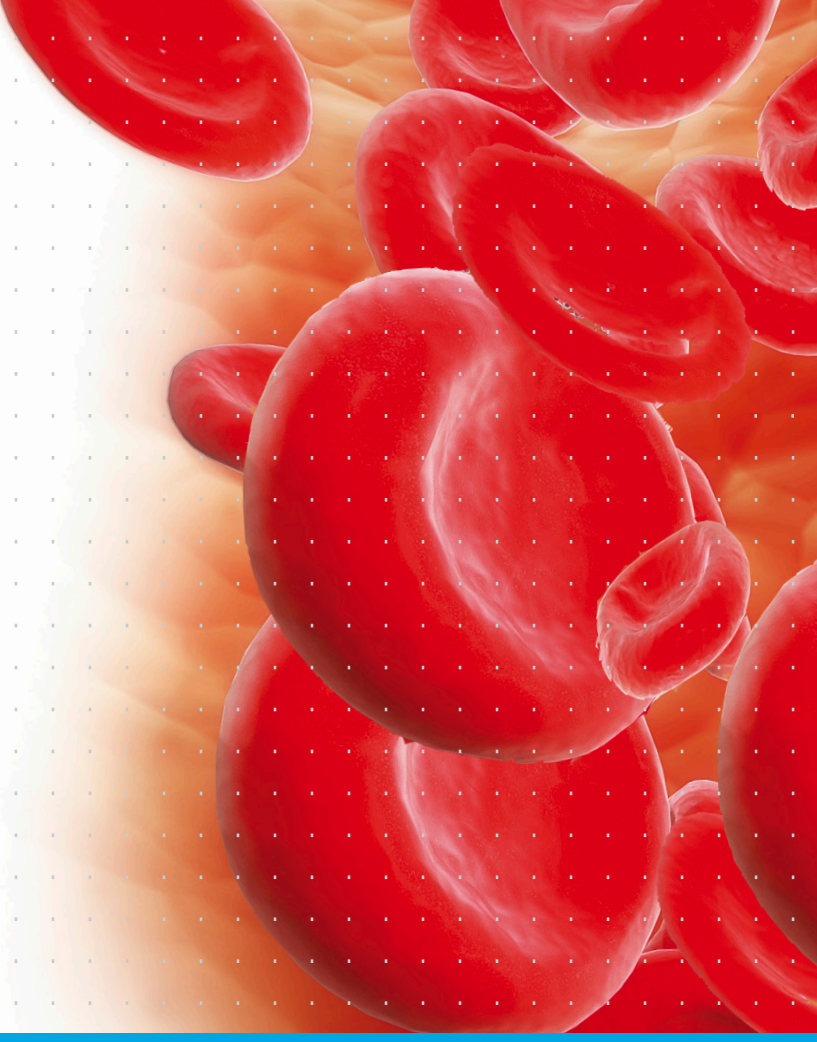
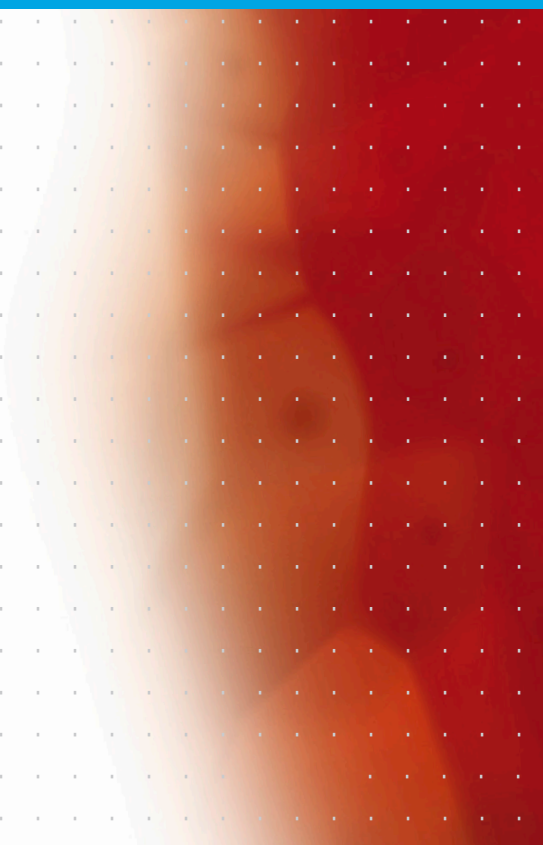
NATIONAL BLOOD AUTHORITY
AUSTRALIA



AUSTRALIAN HAEMOVIGILANCE REPORT

DATA FOR 2015–16



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Australian Haemovigilance Data

July 2015 - June 2016

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.

Not withstanding 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.

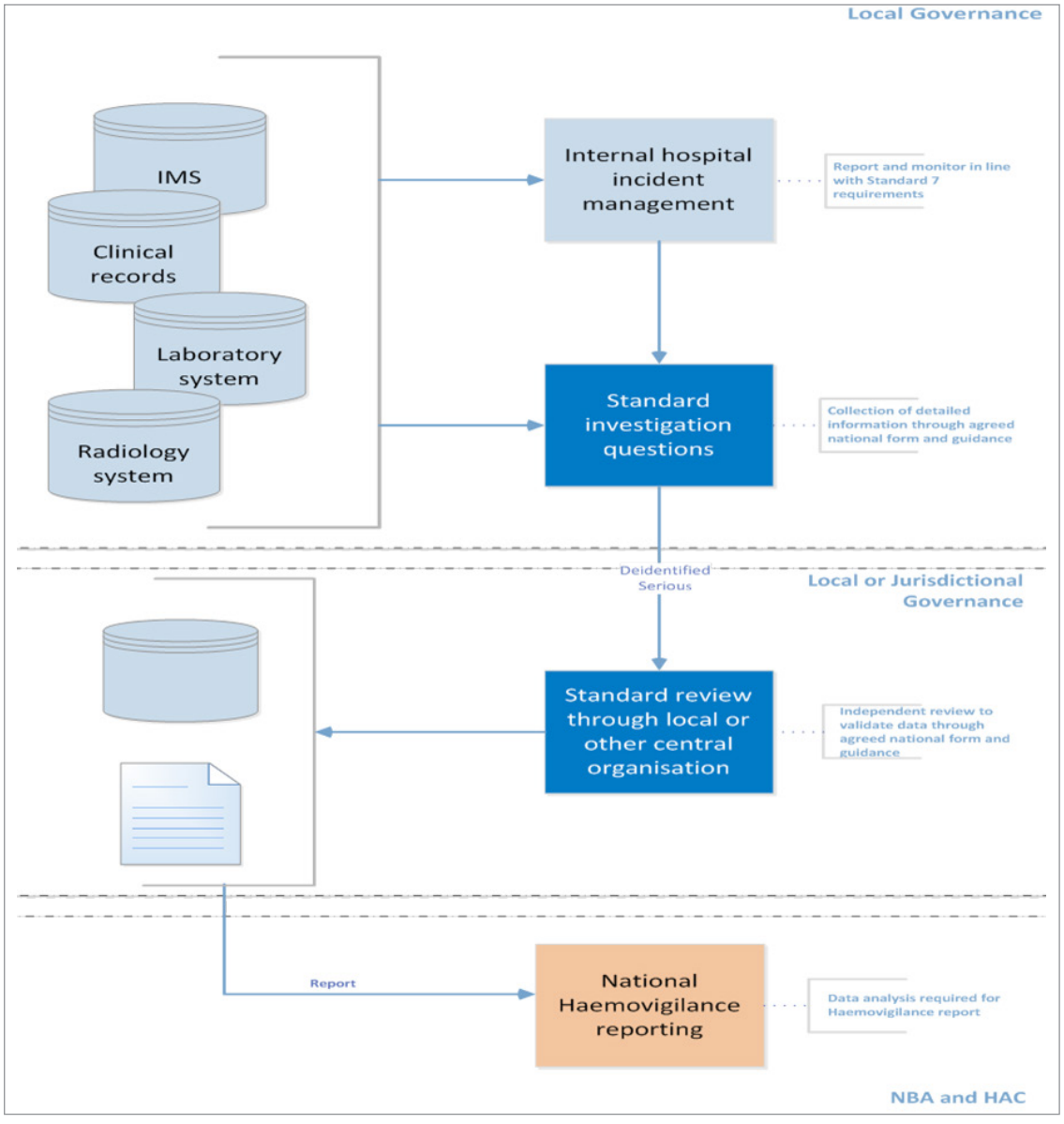

Figure 1: Haemovigilance Reporting Processes in Australia

Summary of findings for 2015-16

Table 1: Adverse events by state, 2015–16

	FNHTR	Allergic	TACO	IBCT	Anaphylactic	DHTR	AHTR	TTI	TRALI	All reports		Population	Red cell issue
										Total	Per cent	Per cent	Per cent
NSW	169	60	14	20	5	2	1	8	2	281	38.8%	31.7%	30.4%
VIC	12	11	9	9	8	4	1	0	0	54	7.5%	24.9%	27.4%
QLD	138	74	16	7	5	4	5	1	0	250	34.5%	20.2%	21.4%
SA	17	29	6	3	3	0	0	4	0	62	8.6%	7.1%	8.9%
WA	28	19	5	1	9	6	1	4	0	73	10.1%	11.2%	7.8%
TAS	0	0	0	0	0	0	0	0	0	0	0.0%	2.2%	1.8%
NT	1	0	0	1	0	0	1	0	0	3	0.4%	1.0%	0.7%
ACT	0	0	1	0	0	0	0	0	0	1	0.1%	1.7%	1.6%
Total	**365**	**193**	**51**	**41**	**30**	**16**	**9**	**17**	**2**	**724**	**100.0%**	**100.0%**	**100.0%**

Notes

1. All states/territories contributed the data including WA for 2015–16
2. TAS reported zero adverse events for 2015–16
3. All TTIs were suspected but not confirmed bacterial infections
4. Number of patients or transfusion episodes is unavailable
5. STIR uses a higher level temperature threshold for the reporting of FNHTR

Table 2: Adverse events by imputability score, 2015–16

Event Type	Excluded / Unlikely	Possible	Likely / Probable	Confirmed / Certain	N/A /Not assessable	Total	Per Cent
FNHTR	33	236	77	2	17	365	50.4%
Allergic	3	38	122	22	8	193	26.7%
TACO	2	22	22	5	0	51	7.0%
IBCT	2	1	1	33	4	41	5.7%
Anaphylactic	2	12	11	5	0	30	4.1%
DHTR	0	2	3	11	0	16	2.2%
AHTR	1	3	3	2	0	9	1.2%
TTI	1	4	9	0	3	17	2.3%
TRALI	0	1	0	0	1	2	0.3%
Total	**44**	**319**	**248**	**80**	**33**	**724**	
Per cent	**6.1%**	**44.1%**	**34.3%**	**11.0%**	**4.6%**	**100.0%**	

Notes

1. All states/territories contributed the data including WA for 2015–16
2. TAS reported zero adverse events for 2015–16
3. All TTIs were suspected but not confirmed bacterial infections
4. Number of patients or transfusion episodes is unavailable
5. STIR uses a higher level temperature threshold for the reporting of FNHTR

Table 3: Adverse events by blood product, 2015–16

Adverse event	Red cells	Platelets	Fresh frozen plasma	Cryoprecipitate	Cryo-depleted Plasma	Unknown	Total
FNHTR	313	46	5	1	0	0	365
Allergic	51	83	52	3	3	1	193
TACO	49	0	2	0	0	0	51
IBCT	28	8	4	1	0	0	41
Anaphylactic	7	18	4	1	0	0	30
DHTR	16	0	0	0	0	0	16
AHTR	7	1	0	0	0	1	9
TTI	4	11	1	1	0	0	17
TRALI	1	1	0	0	0	0	2
Total	**476**	**168**	**68**	**7**	**3**	**2**	**724**
Per cent	**65.7%**	**23.2%**	**9.4%**	**1.0%**	**0.4%**	**0.3%**	**100.0%**

Notes

1. All states/territories contributed the data including WA for 2015–16
2. TAS reported zero adverse events for 2015–16
3. All TTIs were suspected but not confirmed bacterial infections
4. Number of patients or transfusion episodes is unavailable
5. STIR uses a higher level temperature threshold for the reporting of FNHTR

Table 4: Adverse events by clinical outcome severity, 2015–16

Adverse event	Death	Life-threatening	Severe morbidity	Minor morbidity	No morbidity	Outcome not available	Grand Total
FNHTR	0	1	7	202	147	8	365
Allergic	0	2	14	159	18	0	193
TACO	0	1	11	33	6	0	51
IBCT	0	1	0	4	24	12	41
Anaphylactic	0	8	5	14	3	0	30
DHTR	0	0	0	14	1	1	16
AHTR	0	0	1	6	2	0	9
TTI	0	0	0	9	8	0	17
TRALI	1	0	0	1	0	0	2
Total	**1**	**13**	**38**	**442**	**209**	**21**	**724**
Per cent	**0.1%**	**1.8%**	**5.2%**	**61.0%**	**28.9%**	**2.9%**	**100.0%**

Notes

1. All states/territories contributed the data including WA for 2015–16
2. TAS reported zero adverse events for 2015–16
3. All TTIs were suspected but not confirmed bacterial infections
4. Number of patients or transfusion episodes is unavailable
5. STIR uses a higher level temperature threshold for the reporting of FNHTR

Table 5: Adverse events by sex, 2015–16

Adverse event	Male	Female	Not reported	Total
FNHTR	105	88	172	365
Allergic	72	61	60	193
TACO	18	18	15	51
IBCT	10	8	23	41
Anaphylactic	12	13	5	30
DHTR	4	10	2	16
AHTR	6	2	1	9
TTI	4	5	8	17
TRALI	0	0	2	2
All reports	**231**	**205**	**288**	**724**
Per cent	**31.9%**	**28.3%**	**39.8%**	**100.0%**

Notes
1. Sex data not available for NSW
2. TAS reported zero adverse events for 2015–16
3. Number of patients or transfusion episodes is unavailable

Table 6: Adverse events by age and sex, 2015–16

Adverse event	Male	Female	Not reported	Total
0–4 years	9	3	9	21
5–14 years	6	6	3	15
15–24 years	7	4	12	23
25–34 years	14	8	20	42
35–44 years	8	25	22	55
45–54 years	20	18	29	67
55–64 years	29	40	48	117
65–74 years	64	44	52	160
75 years or older	74	57	67	198
Not stated	0	0	26	26
Total	**231**	**205**	**288**	**724**
Per cent	**31.9%**	**28.3%**	**39.8%**	**100.0%**

Notes
1. Sex data not available for NSW
2. TAS reported zero adverse events for 2015–16
3. Number of patients or transfusion episodes is unavailable

Table 7: Serious adverse events by outcome severity and imputability score, 2015–16

	Death	Life-threatening	Severe morbidity	All reports	
				Total	Per cent
Possible	1	4	8	13	26.5%
Likely/Probable	0	6	22	28	57.1%
Confirmed/Certain	0	2	6	8	16.3%
Total	**1**	**12**	**36**	**49**	**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. TAS reported zero adverse events
4. Number of patients or transfusion episodes is unavailable

Cumulative results for 2011–12 to 2015–16

Table 8: Adverse events by state, 2011–12 to 2015–16

	2011–12	2012–13	2013–14	2014–15	2015–16	All reports	
						Number	Per cent
NSW	191	194	218	264	281	1,148	37.5%
VIC	81	59	86	59	54	339	11.1%
QLD	177	0	151	202	250	780	25.4%
SA	151	157	154	149	62	673	22.0%
WA	0	0	0	0	73	73	2.4%
TAS	2	4	1	1	0	8	0.3%
NT	9	11	7	5	3	35	1.1%
ACT	4	4	0	0	1	9	0.3%
All reports	**615**	**429**	**617**	**680**	**724**	**3,065**	**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 2011–12 to 2014–15
4. TAS reported zero events for 2015–16
5. Number of patients or transfusion episodes is unavailable
6. 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, 2011–12 to 2015–16

Hospital type	2011–12	2012–13	2013–14	2014–15	2015–16	Total hospitals	Per cent
Public hospital	561	426	540	646	653	2,826	92.2%
All private hospitals	**54**	**3**	**77**	**34**	**69**	**237**	**7.7%**
Private hospital (excludes private free standing day hospital)	54	3	77	29	69	232	7.6%
Private free-standing day hospital	0	0	0	5	0	5	0.2%
Medical and diagnostic laboratory	0	0	0	0	2	2	0.1%
Total hospitals	**615**	**429**	**617**	**680**	**724**	**3,065**	**100.0%**

Notes

1. TAS reported zero adverse events for 2015–16
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 2011–12 to 2014–15
5. Only VIC, QLD and WA contributed private hospital data
6. Number of patients or transfusion episodes is unavailable
7. Private hospitals include private free-standing day hospital and other private hospitals (exclude private free standing day hospitals).

Table 10: Australian adverse event data, 2011–12 to 2015–16

Adverse event	2011–12	2012–13	2013–14	2014–15	2015–16	All reports		Transfusion risk per unit transfused*
						Number	Per cent	(unless specified)
FNHTR	320	231	337	380	365	1,633	53.3%	0.1–1% of transfusions with universal leucocyte depletion
Allergic	147	111	144	164	193	759	24.8%	1–3% of transfusion of plasma containing components
TACO	27	17	28	39	51	162	5.3%	<1% of transfused patients
IBCT	62	43	33	30	41	209	6.8%	Not available
Anaphylactic	16	13	19	20	30	98	3.2%	1:20,000–1:50,000
DHTR	17	6	12	16	16	67	2.2%	1:2,500–1:11,000
AHTR	10	2	8	15	9	44	1.4%	1:76,000
TTI	12	5	27	12	17	73	2.4%	1:75,000 platelet transfusions 1:500,000 red cell transfusions
TRALI	4	1	3	4	2	14	0.5%	1:1,200–1:190,000 transfusions
PTP	0	0	6	0	0	6	0.2%	Rare
Grand Total	**615**	**429**	**617**	**680**	**724**	**3,065**	**100.0%**	

Notes

1. TAS reported zero adverse events for 2015–16
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 2011–12 to 2014–15
5. Only VIC, QLD and WA contributed private hospital data
6. All TTIs were suspected but not confirmed bacterial infections
7. 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 states, 2011–12 to 2015–16

	2011–12	2012–13	2013–14	2014–15	2015–16	All reports	
						Number	Per cent
NSW	6	17	15	6	6	50	19.5%
VIC	41	17	22	23	12	115	44.9%
QLD	9	0	7	14	20	50	19.5%
SA	2	0	8	2	7	19	7.4%
WA	0	0	0	0	4	4	1.6%
TAS	0	3	1	0	0	4	1.6%
NT	3	4	1	0	0	8	3.1%
ACT	3	3	0	0	0	6	2.3%
All reports	**64**	**44**	**54**	**45**	**49**	**256**	**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 2011–12 to 2014–15
4. TAS reported zero events for 2015–16
5. Number of patients or transfusion episodes is unavailable
6. 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, 2011–12 to 2015–16

	2011–12	2012–13	2013–14	2014–15	2015–16	All reports	
						Total	Per cent
FNHTR	9	12	7	5	6	39	15.2%
Allergic	15	9	15	8	15	62	24.2%
TACO	16	8	16	13	12	65	25.4%
IBCT	4	5	0	1	1	11	4.3%
Anaphylactic	8	8	13	13	13	55	21.5%
DHTR	7	1	1	1	0	10	3.9%
AHTR	4	0	1	1	1	7	2.7%
TTI	0	1	0	1	0	2	0.8%
TRALI	1	0	0	2	1	4	1.6%
PTP	0	0	1	0	0	1	0.4%
All reports	**64**	**44**	**54**	**45**	**49**	**256**	**100.0%**

Notes

1. TAS reported zero adverse events for 2015–16
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 2011–12 to 2014–15
5. All TTIs were suspected but not confirmed bacterial infections
6. Number of patients or transfusion episodes is unavailable

Table 13: Serious adverse events by product, 2011–12 to 2015–16

	Red cells	Platelets	Fresh frozen plasma	#REF!	Cryoprecipitate	Total
FNHTR	32	6	1		0	39
Allergic	19	24	17	2	0	62
TACO	64	0	0		1	65
IBCT	11	0	0		0	11
Anaphylactic	14	25	16		0	55
DHTR	10	0	0		0	10
AHTR	6	1	0		0	7
TTI	2	0	0		0	2
TRALI	4	0	0		0	4
PTP	0	1	0		0	1
All reports	**162**	**57**	**34**	**2**	**1**	**256**
Per cent	**63.3%**	**22.3%**	**13.3%**	**0.8%**	**0.4%**	**100.0%**

Notes

1. TAS reported zero adverse events for 2015–16
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 2011–12 to 2014–15
5. All TTIs were suspected but not confirmed bacterial infections
6. Number of patients or transfusion episodes is unavailable

Table 14: Serious adverse events by time of transfusion, 2011–12 to 2015–16

	2011–12	2012–13	2013–14	2014–15	2015–16	All reports	
						Total	Per cent
Between 7am and 7pm	34	16	20	31	36	137	53.5%
Between 7pm and 7am	22	11	21	12	12	78	30.5%
Not reported	8	17	13	2	1	41	16.0%
All reports	**64**	**44**	**54**	**45**	**49**	**256**	**100.0%**

Notes

1. SA did not report transfusion time data from 2012–13 to 2014–15
2. TAS reported zero adverse events for 2015–16
3. ACT reported zero adverse events for 2013–14 and 2014–15
4. QLD did not contribute data for 2012–13
5. WA did not contribute data from 2011–12 to 2014–15
6. Number of patients or transfusion episodes is unavailable

Table 15: Serious adverse events by week day/weekend, 2011–12 to 2015–16

	2011–12	2012–13	2013–14	2014–15	2015–16	All reports	
						Total	Per cent
Week day	43	36	40	33	42	194	75.8%
Weekend	21	8	14	12	7	62	24.2%
Not reported	0	0	0	0	0	0	0.0%
All reports	**64**	**44**	**54**	**45**	**49**	**256**	**100.0%**

Notes

1. TAS reported zero adverse events for 2015–16
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 2011–12 to 2014–15
5. Number of patients or transfusion episodes is unavailable

Table 16: Serious adverse events by age group, 2011–12 to 2015–16

	2011–12	2012–13	2013–14	2014–15	2015–16	All reports	
						Total	Per cent
0–4 years	2	1	0	3	3	9	3.5%
5–14 years	3	2	3	4	4	16	6.3%
15–24 years	3	4	2	0	2	11	4.3%
25–34 years	3	3	2	3	3	14	5.5%
35–44 years	3	6	5	0	4	18	7.0%
45–54 years	4	3	4	5	5	21	8.2%
55–64 years	16	5	10	4	4	39	15.2%
65–74 years	16	8	8	14	8	54	21.1%
75 years or older	14	12	18	12	16	72	28.1%
Not stated	0	0	2	0	0	2	0.8%
All reports	**64**	**44**	**54**	**45**	**49**	**256**	**100.0%**

Notes

1. TAS reported zero adverse events for 2015–16
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 2011–12 to 2014–15
5. Number of patients or transfusion episodes is unavailable

Febrile non haemolytic transfusion reaction (FNHTR)

Table 17: FNHTR data summary, 2015–16

2015–16 Data Summary (n=365)					
Age		**Sex**		**Day of Transfusion**	
0–4 years	8	Male	105	Week day	267
5–14 years	2	Female	88	Weekend	98
15–24 years	10	Uncategorised	172		
25–34 years	12	**Facility Location**		**Time of Transfusion**	
35–44 years	20	Major City	126	Between 7am and 7pm	211
45–54 years	29	Inner Regional	19	Between 7pm and 7am	126
55–64 years	48	Outer Regional	51	Not reported	28
65–74 years	98	Remote	0		
75+ years	116	Very Remote	0		
Not specified	22	Not reported	169		
Clinical Outcome Severity		**Imputability**		**Blood Component**	
Death	0	Excluded/Unlikely	33	Red cells	313
Life threatening	1	Possible	236	Platelets	46
Severe morbidity	7	Likely/Probable	77	Fresh Frozen Plasma	5
Minor morbidity	202	Confirmed/Certain	2	Cryoprecipitate	1
No morbidity	147	Not assessable	17	Cryodepleted plasma	0
Outcome not available	8			Not reported	0

Notes

1. NSW did not report sex and facility location data
2. TAS reported zero adverse events
3. Number of patients or transfusion episodes is unavailable

Table 18: FNHTR clinical outcome severity by imputability, 2015–16

Clinical Outcome Severity	Imputability					Total
	Excluded / Unlikely	Possible	Likely / Probable	Confirmed / Certain	N/A /Not assessable	
Life-threatening	1	0	0	0	0	1
Severe morbidity	1	3	3	0	0	7
Minor morbidity	16	122	54	2	8	202
No morbidity	11	111	20		5	147
Outcome not available	4	0	0	0	4	8
Total	**33**	**236**	**77**	**2**	**17**	**365**

Allergic reaction

Table 19: Allergic reaction data summary, 2015–16

2015–16 Data Summary (n=193)					
Age		**Sex**		**Day of Transfusion**	
0–4 years	4	Male	72	Week day	163
5–14 years	8	Female	61	Weekend	30
15–24 years	13	Uncategorised	60		
25–34 years	17	**Facility Location**		**Time of Transfusion**	
35–44 years	22	Major City	120	Between 7am and 7pm	142
45–54 years	30	Inner Regional	3	Between 7pm and 7am	47
55–64 years	34	Outer Regional	10	Not reported	4
65–74 years	32	Remote	0		
75+ years	30	Very Remote	0		
Not specified	3	Not reported	60		
Clinical Outcome Severity		**Imputability**		**Blood Component**	
Death	0	Excluded/Unlikely	3	Red cells	51
Life threatening	2	Possible	38	Platelets	83
Severe morbidity	14	Likely/Probable	122	Fresh Frozen Plasma	52
Minor morbidity	159	Confirmed/Certain	22	Cryoprecipitate	3
No morbidity	18	Not assessable	8	Cryodepleted plasma	3
Outcome not available	0			Not reported	1

Notes

1. NSW did not report sex and facility location data
2. TAS reported zero adverse events
3. Number of patients or transfusion episodes is unavailable

Table 20: Allergic reaction clinical outcome severity by imputability, 2015–16

Clinical Outcome Severity	Imputability					Total
	Excluded / Unlikely	Possible	Likely / Probable	Confirmed / Certain	N/A /Not assessable	
Life-threatening	0	1	1	0	0	2
Severe morbidity	0	1	10	2	1	14
Minor morbidity	0	30	106	17	6	159
No morbidity	3	6	5	3	1	18
Outcome not available	0	0	0	0	0	0
Total	**3**	**38**	**122**	**22**	**8**	**193**

Transfusion-associated circulatory overload (TACO)

Table 21: TACO data summary, 2015–16

2015–16 Data Summary (n=51)					
Age		**Sex**		**Day of Transfusion**	
0–4 years	1	Male	18	Week day	42
5–14 years	0	Female	18	Weekend	9
15–24 years	0	Uncategorised	15		
25–34 years	1	**Facility Location**		**Time of Transfusion**	
35–44 years	3	Major City	35	Between 7am and 7pm	28
45–54 years	0	Inner Regional	2	Between 7pm and 7am	21
55–64 years	10	Outer Regional	0	Not reported	2
65–74 years	10	Remote	0		
75+ years	26	Very Remote	0		
Not specified	0	Not reported	14		
Clinical Outcome Severity		**Imputability**		**Blood Component**	
Death	0	Excluded/Unlikely	2	Red cells	49
Life threatening	1	Possible	22	Platelets	0
Severe morbidity	11	Likely/Probable	22	Fresh Frozen Plasma	2
Minor morbidity	33	Confirmed/Certain	5	Cryoprecipitate	0
No morbidity	6	Not assessable	0	Cryodepleted plasma	0
Outcome not available	0			Not reported	0

Notes

1. NSW did not report sex and facility location data
2. TAS reported zero adverse events
3. Number of patients or transfusion episodes is unavailable

Table 22: TACO clinical outcome severity by imputability, 2015–16

Clinical Outcome Severity	Imputability					Total
	Excluded / Unlikely	Possible	Likely / Probable	Confirmed / Certain	N/A /Not assessable	
Life-threatening	0	1	0	0	0	1
Severe morbidity	0	1	7	3	0	11
Minor morbidity	2	14	15	2	0	33
No morbidity	0	6	0	0	0	6
Outcome not available	0	0	0	0	0	0
Total	**2**	**22**	**22**	**5**	**0**	**51**

Incorrect blood component transfused (IBCT)

Table 23: IBCT data summary, 2015–16

2014–15 Data Summary (n=41)					
Age		**Sex**		**Day of Transfusion**	
0–4 years	4	Male	10	Week day	32
5–14 years	1	Female	8	Weekend	9
15–24 years	0	Uncategorised	23		
25–34 years	7	**Facility Location**		**Time of Transfusion**	
35–44 years	2	Major City	16	Between 7am and 7pm	29
45–54 years	4	Inner Regional	2	Between 7pm and 7am	9
55–64 years	10	Outer Regional	2	Not reported	3
65–74 years	5	Remote	0		
75+ years	8	Very Remote	1		
Not specified	0	Not reported	20		
Clinical Outcome Severity		**Imputability**		**Blood Component**	
Death	0	Excluded/Unlikely	2	Red cells	28
Life threatening	1	Possible	1	Platelets	8
Severe morbidity	0	Likely/Probable	1	Fresh Frozen Plasma	4
Minor morbidity	4	Confirmed/Certain	33	Cryoprecipitate	1
No morbidity	24	Not assessable	4	Cryodepleted plasma	0
Outcome not available	12			Not reported	0

Notes

1. NSW did not report sex and facility location data
2. TAS reported zero adverse events
3. Number of patients or transfusion episodes is unavailable

Table 24: IBCT clinical outcome severity by imputability, 2015–16

Clinical Outcome Severity	Imputability					Total
	Excluded / Unlikely	Possible	Likely / Probable	Confirmed / Certain	N/A /Not assessable	
Life-threatening	0	0	1	0	0	1
Severe morbidity	0	0	0	0	0	0
Minor morbidity	0	1	0	2	1	4
No morbidity	2	0	0	19	3	24
Outcome not available	0	0	0	12	0	12
Total	**2**	**1**	**1**	**33**	**4**	**41**

Table 25: Contributory factors cited in IBCT, 2011–12 to 2015–16

Contributory Factor	2011–12	2012–13	2013-14	2014-15	2015-16
None identified	9	0	1	0	7
Product characteristic	0	0	0	0	1
Transfusion in emergency setting	2	6	3	7	10
Deliberate clinical decision	1	0	0	1	4
Prescribing/ordering	7	0	14	6	12
Specimen collection/labelling	7	11	0	1	0
Laboratory (testing/dispensing)	24	22	12	15	22
Transport, storage, handling	1	1	1	1	0
Administration of product	5	9	10	13	8
Indications did not meet hospital transfusion guidelines	12	27	15	0	1
Procedure did not adhere to hospital transfusion guidelines	1	0	3	8	14
Other	4	12	12	0	2

Notes

1. Contributory factors are not reported for SA
2. TAS reported zero adverse events

Anaphylactic or anaphylactoid reaction

Table 26: Anaphylactic or anaphylactoid reaction data summary, 2015–16

2015–16 Data Summary (n=30)					
Age		**Sex**		**Day of Transfusion**	
0–4 years	2	Male	12	Week day	22
5–14 years	3	Female	13	Weekend	8
15–24 years	0	Uncategorised	5		
25–34 years	3	**Facility Location**		**Time of Transfusion**	
35–44 years	4	Major City	21	Between 7am and 7pm	19
45–54 years	2	Inner Regional	3	Between 7pm and 7am	9
55–64 years	5	Outer Regional	1	Not reported	2
65–74 years	6	Remote	0		
75+ years	5	Very Remote	0		
Not specified	0	Not reported	5		
Clinical Outcome Severity		**Imputability**		**Blood Component**	
Death	0	Excluded/Unlikely	2	Red cells	7
Life threatening	8	Possible	12	Platelets	18
Severe morbidity	5	Likely/Probable	11	Fresh Frozen Plasma	4
Minor morbidity	14	Confirmed/Certain	0	Cryoprecipitate	1
No morbidity	3	Not assessable	0	Cryodepleted plasma	0
Outcome not available	0		5	Not reported	0

Notes

1. NSW did not report sex and facility location data
2. TAS reported zero adverse events
3. Number of patients or transfusion episodes is unavailable

Table 27: Anaphylactic or anaphylactoid reaction clinical outcome severity by imputability, 2015–16

Clinical Outcome Severity	Imputability					Total
	Excluded / Unlikely	Possible	Likely / Probable	Confirmed / Certain	N/A /Not assessable	
Life-threatening	0	2	4	2	0	8
Severe morbidity	0	3	1	1	0	5
Minor morbidity	2	5	6	1	0	14
No morbidity	0	2	0	1	0	3
Outcome not available	0	0	0		0	0
Total	**2**	**12**	**11**	5	**0**	**30**

Delayed haemolytic transfusion reaction (DHTR)

Table 28: DHTR data summary, 2015–16

2015–16 Data Summary (n=9)					
Age		**Sex**		**Day of Transfusion**	
0–4 years	1	Male	6	Week day	8
5–14 years	1	Female	2	Weekend	1
15–24 years	0	Uncategorised	1		
25–34 years	0	**Facility Location**		**Time of Transfusion**	
35–44 years	0	Major City	7	Between 7am and 7pm	7
45–54 years	1	Inner Regional	0	Between 7pm and 7am	2
55–64 years	1	Outer Regional	0	Not reported	0
65–74 years	2	Remote	1		
75+ years	3	Very Remote	0		
Not specified	0	Not reported	1		
Clinical Outcome Severity		**Imputability**		**Blood Component**	
Death	0	Excluded/Unlikely	1	Red cells	7
Life threatening	0	Possible	3	Platelets	1
Severe morbidity	0	Likely/Probable	3	Fresh Frozen Plasma	0
Minor morbidity	1	Confirmed/Certain	2	Cryoprecipitate	0
No morbidity	6	Not assessable	0	Cryodepleted plasma	0
Outcome not available	2			Not reported	1

Notes

1. NSW did not report sex and facility location data
2. TAS reported zero adverse events
3. Number of patients or transfusion episodes is unavailable

Table 29: DHTR clinical outcome severity by imputability, 2015–16

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	2	3	9	0	14
No morbidity	0	0	0	1	0	1
Outcome not available	0	0	0	1	0	1
Total	0	**2**	**3**	**11**	**0**	**16**

Acute haemolytic transfusion reaction (AHTR)

Table 30: AHTR data summary, 2015–16

2015–16 Data Summary (n=9)					
Age		**Sex**		**Day of Transfusion**	
0–4 years	1	Male	6	Week day	8
5–14 years	1	Female	2	Weekend	1
15–24 years	0	Uncategorised	1		
25–34 years	0	**Facility Location**		**Time of Transfusion**	
35–44 years	0	Major City	7	Between 7am and 7pm	7
45–54 years	1	Inner Regional	0	Between 7pm and 7am	2
55–64 years	1	Outer Regional	0	Not reported	0
65–74 years	2	Remote	1		
75+ years	3	Very Remote	0		
Not specified	0	Not reported	1		
Clinical Outcome Severity		**Imputability**		**Blood Component**	
Death	0	Excluded/Unlikely	1	Red cells	7
Life threatening	0	Possible	3	Platelets	1
Severe morbidity	0	Likely/Probable	3	Fresh Frozen Plasma	0
Minor morbidity	1	Confirmed/Certain	2	Cryoprecipitate	0
No morbidity	6	Not assessable	0	Cryodepleted plasma	0
Outcome not available	2			Not reported	1

Notes

1. NSW did not report sex and facility location data
2. TAS reported zero adverse events
3. Number of patients or transfusion episodes is unavailable

Table 31: AHTR clinical outcome severity by imputability, 2015–16

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	1	0	0	1
No morbidity	1	1	2	2	0	6
Outcome not available	0	2	0	0	0	2
Total	**1**	**3**	**3**	**2**	**0**	**9**

Transfusion-transmitted infection (TTI)

Table 32: TTI data summary, 2015–16

2015–16 Data Summary (n=17)					
Age		**Sex**		**Day of Transfusion**	
0–4 years	0	Male	4	Week day	15
5–14 years	0	Female	5	Weekend	2
15–24 years	0	Uncategorised	8		
25–34 years	1	**Facility Location**		**Time of Transfusion**	
35–44 years	2	Major City	7	Between 7am and 7pm	12
45–54 years	1	Inner Regional	2	Between 7pm and 7am	3
55–64 years	5	Outer Regional	0	Not reported	2
65–74 years	3	Remote	0		
75+ years	4	Very Remote	0		
Not specified	1	Not reported	8		
Clinical Outcome Severity		**Imputability**		**Blood Component**	
Death	0	Excluded/Unlikely	1	Red cells	4
Life threatening	0	Possible	4	Platelets	11
Severe morbidity	0	Likely/Probable	9	Fresh Frozen Plasma	1
Minor morbidity	9	Confirmed/Certain	0	Cryoprecipitate	1
No morbidity	8	Not assessable	3	Cryodepleted plasma	0
Outcome not available	0			Not reported	0

Notes

1. NSW did not report sex and facility location data
2. TAS reported zero adverse events
3. Number of patients or transfusion episodes is unavailable

Table 33: TTI clinical outcome severity by imputability, 2015–16

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	1	0	7	0	1	**9**
No morbidity	0	4	2	0	2	**8**
Outcome not available	0	0	0	0	0	**0**
Total	**1**	**4**	**9**	**0**	**3**	**17**

Transfusion related acute lung injury (TRALI)

Table 34: TRALI data summary, 2015–16

2015–16 Data Summary (n=2)					
Age		**Sex**		**Day of Transfusion**	
0–4 years	1	Male	0	Week day	1
5–14 years	0	Female	0	Weekend	1
15–24 years	0	Uncategorised	2		
25–34 years	0	**Facility Location**		**Time of Transfusion**	
35–44 years	0	Major City	0	Between 7am and 7pm	1
45–54 years	0	Inner Regional	0	Between 7pm and 7am	1
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	2		
Clinical Outcome Severity		**Imputability**		**Blood Component**	
Death	0	Excluded/Unlikely	0	Red cells	1
Life threatening	1	Possible	1	Platelets	1
Severe morbidity	0	Likely/Probable	0	Fresh Frozen Plasma	0
Minor morbidity	1	Confirmed/Certain	0	Cryoprecipitate	0
No morbidity	0	Not assessable	1	Cryodepleted plasma	0
Outcome not available	0			Not reported	0

Notes

1. NSW did not report sex and facility location data
2. TAS reported zero adverse events
3. Number of patients or transfusion episodes is unavailable

Table 35: TRALI clinical outcome severity by imputability, 2015–16

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

Contributory factors

Table 36: Contributory factors data summary, 2015–16

Summary Data	
Contributory Factors	Number of reports
None identified	224
Not reported	62
Product characteristic	360
*Transfusion in emergency setting	17
*Deliberate clinical decision	36
*Prescribing/ordering	15
*Specimen collection/labelling	0
*Laboratory (testing/dispensing)	23
*Transport, storage, handling	1
*Administration of product	15
*Indications do not meet guidelines	2
*Procedure did not adhere to hospital transfusion guidelines	15
Other	20

Notes

1. Contributory factors are not reported for SA
2. TAS reported zero adverse events
3. * refers to potentially avoidable human errors

Table 37: Contributory factors cited by adverse event and by clinical outcome severity, 2015–16

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	133	88	26	7	5	10	9	8	0	4	62	193	26	1	0
Product characteristic	214	94	16	1	11	18	3	1	2	4	122	210	11	12	1
Transfusion in emergency setting	1	1	1	10	0	1	3	0	0	3	7	5	1	1	0
Deliberate clinical decision	12	15	1	4	1	3	0	0	0	2	9	23	1	1	0
Prescribing/ordering	1	0	1	12	0	1	0	0	0	5	7	2	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	22	0	0	1	0	0	10	9	4	0	0	0
Transport, storage, handling	1	0	0	0	0		0	0	0	0	1	0	0	0	0
Administration of product	2	1	2	8	0	2	0	0	0	3	4	8	0	0	0
Indications do not meet guidelines	1	0	0	1	0	0	0	0	0	0	2	0	0	0	0
Procedure did not adhere to hospital transfusion guidelines	0	0	0	14	0	0	1	0	0	3	7	5	0	0	0
Other	2	0	5	2	8	0	1	0	2	2	2	15	0	0	1

Notes

1. Contributory factors are not reported for SA
2. TAS reported zero adverse events

SECTION 2

Donor Haemovigilance Report

July 2015 - June 2016

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 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 they occurred.

Between 1 July 2015 and 30 June 2016 there were 1.32 million donations, including 0.72 million whole blood donations, 0.56 million plasmapheresis donations and 0.04 million plateletpheresis donations. There were 41,128 donor adverse events reported. The overall reported rate of donation related adverse events has increased from 295/10,000 donations for the previous 12 months to 311/10,000 donations. The event numbers in this in this report are accurate as at 13 October 2016.

The increase in the incidence of adverse events for 2015-16 has been influenced by changes in the make up of the donor panel. This includes many donors transitioning to plasmapheresis from whole blood donation. New donors, including those who were previously whole blood donors, are known to have higher rates of adverse reactions compared to repeat plasmapheresis donors. There has also been an increase in the proportion of female plasmapheresis donors. Females of all ages have higher rates of adverse reactions than males.

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 of the success of interventions designed to further improve donor safety. This has permitted real time reporting, and enabled detailed analysis that has improved understanding of the 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, resulting in a progressive increase in the rate of donation reactions recorded. 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 that become apparent after the donor leaves the donor centre. In late 2012 mandatory reporting of all citrate reactions in apheresis donors was introduced, resulting in a significant increase in the rate of plateletpheresis reactions recorded and a modest increase in plasmapheresis donor reactions recorded. 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 rate of phlebotomy injuries recorded which occurred in association with a faint or pre-faint. In 2015-16, a program of staff education and compliance monitoring has resulted in improved reporting compliance.

These changes have enabled more complete and accurate data collection. Detailed analysis has improved our 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 of 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 has been a progressive reduction in the total number of collections each year: since 2011-12 there has been a 24% reduction in the number whole blood collections. The reduction in whole blood collections between 2014-15 and 2015-16 was 4%. On the other hand, there was a 11% increase in the number of plasma collections between 2014-15 and 2015-16 (refer to Table 38).

Table 38: Total number of collections by donation type, 2011-12 to 2015-16

Collections	2011-12	2012–13	2013–14	2014-15	2015-16
Whole Blood	945,899	858,594	783,346	747,684	718,341
All apheresis procedures	390,782	464,289	518,579	549,671	602,713
Plasmapheresis	351, 699	427,945	482,857	509,269	564,640
Plateletpheresis	39,083	36,344	35,722	40,402	38,073
Total collections	**1,336,681**	**1,322,883**	**1,301,925**	**1,297,355**	**1,321,054**

There were 41,128 adverse events reported in 2015-16, giving an incidence of 3.11%. The overall reported rate of donation related adverse events was 1:32 in 2015-16, compared to 1:35 in 2014-15. Most events are mild and resolve spontaneously over a relatively short time. Events which 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%, representing approximately 60-70% of the total number of reactions. The majority of these 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 0.31% of donors, approximately 10% of all reported donor adverse reactions. 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 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 2015-16, hospital referral was required in 0.07% (7 in every 10,000) of donations.

The other major category of adverse event is related to local complications at the donation site caused by the needle. The most frequent phlebotomy injuries include bruising and local pain; less frequent but potentially more serious local complications include local thrombosis and arterial puncture.

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

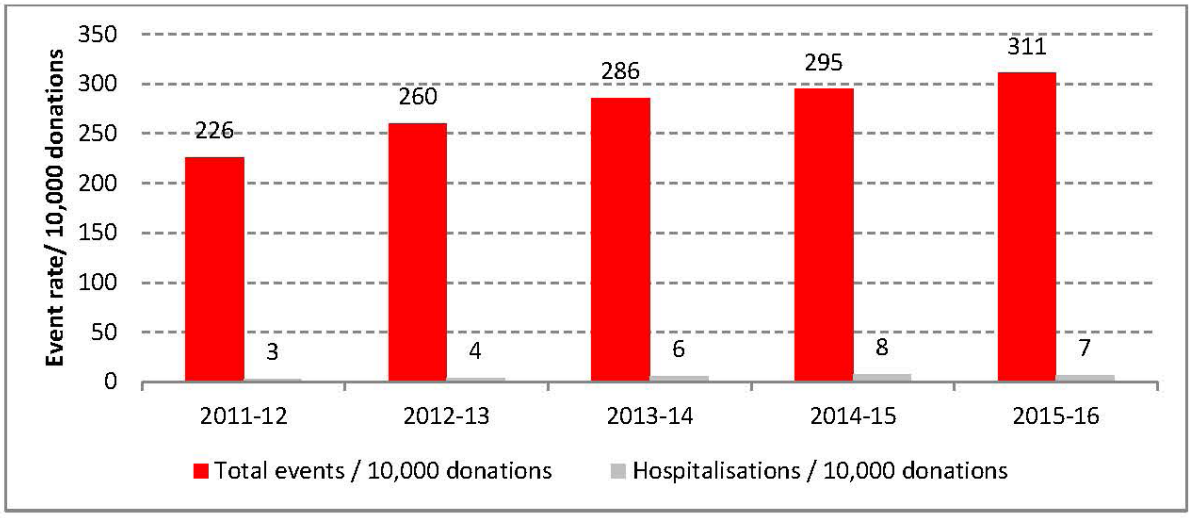

Figure 2: Total donation associated events, 2011-12 to 2015-16

The incidence of the different types of adverse events for all donations is shown in Table 39.

Table 39: Donation-associated events by category and frequency, 2012-13 to 2015-16 (per 10,000 donations)

Donor Event	2011–12	2012–13	2013–14	2014-15	2015-16
			Systemic events		
Immediate vasovagal reaction	184	195	183	183	191
Delayed vasovagal reaction	23	29	34	34	31
Localised allergic reaction	0.3	0.4	0.5	0.5	0.4
Generalised (anaphylactic) reaction	0	0	0.1	0.1	0
Acute cardiac symptoms*	0.4	0.4	0.7	0.8	0.8
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	8.8	12	14	15	15
Other arm pain	3.4	5	12	17	17
Nerve injury	2.5	3	4	5	6
Delayed bleeding	0.3	0.3	0.6	1	1
Superficial Thrombophlebitis	0.2	0.3	0.3	0.3	0.4
DVT	0	0.1	0	0.1	0
Compartment syndrome	0	0	0	0	0
			Apheresis specific events		
Citrate reaction	2	10	32	34	46
Infiltration	0	0.1	0.7	0.7	1.2
Haemolysis	0	0	0.1	0.1	0
Air embolism	0	0	0	0	0
			Other events		
Other events**	1.4	2	3	3	2
Total events	**226**	257	286	295	311

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* – the rate of adverse reactions is stable overall. There has been a small increase in the frequency of vasovagal reactions compared to the previous year. This increase has been in non-syncopal reactions occurring on-site, which are the least likely to result in significant donor harm. There has been a small decrease in the number of delayed reactions. This decrease may reflect the decision to increase the minimum weight for donation from 45kg to 50kg in September 2015. Donors who weigh less than 50kg have a 6 times the risk of delayed reactions and twice the risk of immediate reactions.
2. *Plasmapheresis* – The rate of vasovagal reactions in plasma donors is significantly lower than in whole blood or platelet donors. The increase in donation reactions in plasmapheresis donors is attributable to an increase in the number of brief vasovagal reactions not associated with loss of consciousness or injury, and to an increase in the number of citrate reactions reported. This increase reflects changes in the make up of the plasmapheresis donor panel with an increase in the proportion of new and female donors.
3. *Plateletpheresis* – Citrate reactions in platelet donors are very common due to the higher dose of citrate needed for platelet collections. Citrate reactions are also associated with an increased risk of an associated vasovagal reaction. Furthermore, the rate of bruising and haematoma is significantly higher in platelet donors as a result of the longer duration of plateletpheresis procedures compared to whole blood or plasmapheresis.

Table 40 (below) shows annual rates of all adverse events by donation type from 2011-12 to 2015-16.

Table 40 Adverse event reaction rate by procedure, 2011-12 to 2015-16 (per 10,000 donations)

Procedure	2011–12	2012–13	2013–14	2014-15	2015-16
Whole Blood	271	319	333	352	361
All apheresis procedures	118	152	217	217	252
Plasmapheresis	98	124	163	182	216
Plateletpheresis	302	480	947	655	778
Total procedures	226	257	286	295	311

Table 41: Donation associated events by reaction type and injury, 2015-16

			Rate/10,000 donations		
			Whole Blood (n=718,341)	Plasmapheresis (n=564,640)	Plateletpheresis (n=38,073)
Immediate vasovagal reaction	Without LOC	Without injury	254.48	78.03	178.34
		With injury	0.57	0.04	0.26
	With LOC	Without injury	18.14	5.79	5.52
		With injury	1.36	0.18	1.58
Delayed vasovagal reactions	Without LOC	Without injury	34.62	15.69	8.93
		With injury	1.78	0.35	0
	With LOC	Without injury	4.79	1.06	0.53
		With injury	1.09	0.21	0
Blood outside vessel	Haematoma		14.21	13.73	45.7
	Arterial puncture		0.42	0.05	0.26
	Delayed bleeding		1.31	1.35	0.26
Arm pain	Nerve injury/irritation		7.91	3.98	3.68
	Other arm pain		17.87	15.09	24.43
Related to apheresis	Citrate reaction			74.28	493.79
	Haemolysis			0.11	0
	Air Embolism			0	0
	Infiltration			2.23	7.09
Infection/ inflammation/ allergic reaction	Local allergic reaction		0.32	0.43	0.53
	Generalised (anaphylactic) reaction		0	0.11	0
	Thrombophlebitis		0.26	0.46	0.53
Other	Cardiac	Cardiac arrest	0	0	0
		Acute myocardial infarction	0	0	0
		Acute cardiac symptoms	0	0	0
	Cerebrovascular accident		0.01	0.02	0
	Transient ischaemic attack		0	0	0
	DVT		0.01	0.02	0
	Other		2	3.26	6.57
Total			361	**216**	**778**

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 2015-16, 900 donors attended hospital and 1,196 attended their general practitioner (GP) for donation related complications (Table 42). There were no donation associated deaths. Slow recovery from a vasovagal reaction or injury resulting from a fall during a vasovagal reaction is the reason for the majority of hospital referrals by donor centres.

Donors experiencing chest pain are generally referred for assessment by an emergency department. 29 donors with chest pain were referred to hospital between July 2015 and June 2016 of whom 13 underwent cardiac investigations; all had been previously well but had risk factors for coronary disease. One donor suffered a myocardial infarct approximately 18 hours following a whole blood donation and required stents to 2 coronary arteries; and 1 whole blood donor and 1 plasmapheresis donor were found to have coronary artery disease following hospital referral for chest pain. Of the remaining donors who underwent cardiac investigations the final diagnosis in 5 donors was anxiety, 2 donors received a diagnosis of gastro-oesophageal reflux disease after coronary artery disease was excluded, 3 were diagnosed with musculoskeletal pain; in 8 donors no definitive diagnosis was made. 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 (2 donors) and superficial thrombophlebitis (47 donors).

Table 42: Summary of external medical referrals, 2015-16

	Number of hospital referrals	Hospital referral rate/ 10,000 donations	Number of GP referrals	GP referral rate/ 10,000 donations
Whole Blood	653	9	821	11
Plasmapheresis	224	4	329	6
Plateletpheresis	23	6	46	12
Total	**900**	**7**	**1,196**	**9**

Hospital referral rates have increased substantially in 2014-15 (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, 2011-12 to 2015-16.

Procedure	2011–12	2012–13	2013–14	2014-15	2015-16
Whole Blood	4 (351)	4 (348)	5 (356)	10 (761)	9 (653)
All apheresis procedures	2 (77)	8 (124)	3 (136)	4 (226)	4 (247)
Plasmapheresis	2 (65)	2 (105)	2 (120)	4 (191)	4 (224)
Plateletpheresis	3 (12)	5 (19)	4 (16)	9 (35)	6 (23)
Total procedures	3(428)	4 (472)	4 (492)	7 (955)	7 (900)

The majority of donors attending hospital are whole blood donors. There have not been any significant changes in whole blood collection procedures or in composition of the whole blood donor pool which would account for the significant increase in hospital referrals. The increase is attributable mainly to changes in the management of vasovagal reactions that are slow to resolve (greater than 60-70 minutes). These donors are now referred to hospital early for intravenous fluids as this is felt to be the optimal therapy. In keeping with good clinical practice, the majority of donors who complain of chest pain are also 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 prompted a policy change to limit donations from this age group to one donation per annum. Safety and wellbeing of our youth donors is a key area of focus for the Blood Service.

Table 44: Adverse donation reactions in female donors by age, including odds ratio, 2015-16

Age group	Number of events	Total donors in age group	Frequency	Rate/1,000 donations	Odds ratio (95% CI)
16-17	1,477	9,958	1:07	148.32	3.8438 (3.6317 - 4.0682)
18-20	2,057	29,551	1:14	69.61	1.6314 (1.5569 - 1.7093
21-23	4,002	37,875	1:09	105.66	2.7747 (2.6779 - 2.8750)
24-30	5,141	89,494	1:17	57.45	1.3602 (1.3180 - 1.4037)
31-40	3,671	80,532	1:22	45.58	0.9055 (0.8737 - 0.9385)
41-50	3,302	109,603	1:33	30.13	0.6047 (0.5826 - 0.6276)
51-60	3,490	112,679	1:32	30.97	0.6233 (0.6011 - 0.6464)
61–70	2,073	82,551	1:40	25.11	0.5035 (0.4811 - 0.5270)
71+	179	9,458	1:53	18.93	0.4032 (0.3476 - 0.4678)
Total	**25,392**	**561,701**	**1:22**	**45.21**	

Table 45: Adverse donation reactions in male donors by age, including odds ratio, 2015-16

Age group	Number of events	Total donors in age group	Frequency	Rate/1,000 donations	Odds ratio (95% CI)
16-17	647	6,680	1:10	96.86	5.2377 (4.8221-5.6891)
18-20	1,142	28,576	1:25	39.96	2.0395 (1.9180-2.1687)
21-23	2,078	34,729	1:17	59.83	3.3032 (3.1501-3.4638)
24-30	3,324	100,593	1:30	33.04	1.7704 (1.7029-1.8406)
31-40	3,120	112,957	1:36	27.62	1.4270 (1.3647-1.4775)
41-50	2,290	149,667	1:65	15.3	0.6864 (0.6564-0.7177)
51-60	2,047	179,202	1:88	11.42	0.4764 (0.4547-0.4992)
61–70	1,007	128,304	1:13	7.85	0.3305 (0.3099-0.3524)
71+	81	18,645	1:23	4.34	0.2021 (0.1623-0.2515)
Total	**15,736**	**759,353**	**1:48**	**20.72**	

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

Current interventions directed at improving the capture and reducing the risk of adverse events

1. In early 2016 a trial was conducted to assess the efficacy of educating donors in the use of applied muscle tension (AMT) and water loading to reduce vasovagal reactions. Based on this study, education activities directed at collections staff to support in-centre donor education will be undertaken in early 2017. This will provide the foundation for widespread implementation at all sites to reduce the risk of vasovagal reactions, especially in whole blood donors.
2. Based on the above mentioned study, pre-donation in-centre oral fluid loading is now actively promoted in donor centres.
3. Donors are now required to weigh at least 50kg to be eligible to donate whole blood or plasma. This was introduced in September 2015.
4. Advice is provided to donors on strategies to minimise the risk of a reaction during and after donation on www.donateblood.com.au (use of applied muscle tension, rest and fluid intake, avoidance of strenuous physical activity and alcohol post donation).
5. Specific information cards are provided to donors at the time of an adverse event detailing immediate management and preventative actions relevant to subsequent donations.
6. Permanent deferral of donors with a significant risk of recurrence of serious adverse reactions.
7. Use of a mid-donation saline replacement protocol for plasma donors which includes the administration of 500ml of saline (half mid-donation and half end-donation) to reduce the risk of vasovagal reactions.
8. Using a stepwise approach to increasing the planned collection volume of plasmapheresis donors donating plasma for fractionation based on nomograms* that estimate a donor's Total Blood Volume.
9. Using a stepwise approach for plasmapheresis donors donating Clinical Fresh Frozen Plasma with end-donation saline replacement based on a nomogram* that estimates a donor's Total Blood Volume.
10. Implementation of specific guidelines for managing young donors such that females less than 20 years of age are not recruited to plasma donation.
11. Youth donors (aged 16 and 17 years) have been restricted to one donation per annum from 1 January 2014 to reduce the risk of iron deficiency and the number of vasovagal reactions.
12. Pre-donation oral calcium supplements are routinely offered to plateletpheresis donors to minimise the severity of citrate reactions. A more palatable combined calcium and magnesium replacement preparation was introduced in 2015 to improve acceptability to apheresis donors.
13. Communication with comparable international blood services to ensure 'best practice' donation protocols.
14. Formal clinical governance processes are in place 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 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. ISBT definitions

<table>
<tr><th colspan="8">COMPARISON OF ISBT AND AUSTRALIAN RED CROSS BLOOD SERVICE DONOR ADVERSE EVENTS CLASSIFICATIONS</th></tr>
<tr><th colspan="4">SYSTEMIC COMPLICATIONS</th><th colspan="2">LOCAL COMPLICATIONS</th><th colspan="2">APHERESIS COMPLICATIONS</th></tr>
<tr><td>ISBT</td><td>BLOOD SERVICE</td><td>ISBT</td><td>BLOOD SERVICE</td><td>ISBT</td><td>BLOOD SERVICE</td><td>ISBT</td><td>BLOOD SERVICE</td></tr>
<tr><td colspan="2">Occurring onsite</td><td colspan="2">Occurring offsite</td><td>Blood outside vessels</td><td>No specific sub-category</td><td rowspan="3">Citrate reaction</td><td>Mild citrate reaction</td></tr>
<tr><td>Immediate</td><td>Immediate</td><td>Delayed*</td><td>Delayed</td><td>Haematoma</td><td>Haematoma</td><td>Moderate citrate reaction</td></tr>
<tr><td rowspan="3">Vasovagal reaction without LOC</td><td>Mild VVR(<15 minutes duration)</td><td rowspan="3">Vasovagal reaction without LOC</td><td>Mild VVR(<15 minutes duration)</td><td>Arterial puncture</td><td>Arterial puncture</td><td>Severe citrate reaction</td></tr>
<tr><td>Moderate VVR (15-60 minutes duration)</td><td>Moderate VVR (15-60 minutes duration)</td><td>Delayed bleeding</td><td>Delayed bleeding</td><td>Haemolysis</td><td>Suspected haemolysis</td></tr>
<tr><td>Severe VVR (>60 minutes duration)</td><td>Severe VVR (>60 minutes duration)</td><td>Arm pain</td><td>No specific sub-category</td><td>Anaphylaxis</td><td>Anaphylaxis</td></tr>
<tr><td>Vasovagal reaction with LOC</td><td rowspan="2">Severe VVR</td><td>Vasovagal reaction with LOC</td><td rowspan="2">Severe VVR</td><td>Nerve injury/irritation</td><td>Nerve injury/irritation</td><td rowspan="6">Other apheresis complications**</td><td>Air embolus</td></tr>
<tr><td>Vasovagal reaction with LOC + seizure +/- incontinence</td><td>Vasovagal reaction with LOC + seizure +/- incontinence</td><td>Other arm pain</td><td>Painful arm</td><td>Omitted anticoagulant -mild</td></tr>
<tr><td>Vasovagal reaction with injury</td><td>Severe complicated VVR</td><td>Vasovagal reaction with injury</td><td>Severe complicated VVR</td><td>Infection, inflammation, local allergy</td><td>No specific sub-category</td><td>Omitted anticoagulant - moderate</td></tr>
<tr><td>Acute cardiac symptoms</td><td rowspan="2">Chest pain (including non-cardiac chest pain)</td><td>Acute cardiac symptoms</td><td rowspan="2">Chest pain (including non-cardiac chest pain)</td><td>Cellulitis</td><td>No specific category</td><td>Omitted antcoagulant - severe</td></tr>
<tr><td>Acute myocardial infarction</td><td>Acute myocardial infarction</td><td>Thrombophlebitis</td><td>Superficial thrombophlebitis</td><td>Wrong solution administered</td></tr>
<tr><td>Transient ischaemic attack (TIA)</td><td>No specific category</td><td>Transient ischaemic attack (TIA)</td><td>No specific category</td><td>Other</td><td>No specific sub-category</td><td colspan="2" rowspan="4">** 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</td></tr>
<tr><td>Cerebrovascular accident</td><td>No specific category</td><td>Cerebrovascular acident</td><td>No specific category</td><td rowspan="2">DVT</td><td>Thrombosis not involving axillary vein</td></tr>
<tr><td>Cardiac arrest</td><td>Cardiac arrest</td><td>Cardiac arrest</td><td>Cardiac arrest</td><td>Thrombosis involving axillary vein</td></tr>
<tr><td>Death</td><td>Death</td><td>Death</td><td>Death</td><td>Arteriovenous fistula</td><td>No specific category</td></tr>
<tr><td colspan="4" rowspan="2">* Occurring within 24 hours of blood donation and definitely, possibly or likely due to blood donation</td><td>Infiltration</td><td>Extravasation/compartment syndrome</td><td colspan="2" rowspan="2"></td></tr>
<tr><td>Compartment syndrome</td><td>Not listed separately from extravasation</td></tr>
</table>

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

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QLD Health

SA Health BloodSafe Program

WA Department of Health

TAS Department of Health and Human Services

ACT Health

NT Department of Health

Australian Red Cross Blood Service

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NATIONAL BLOOD AUTHORITY
AUSTRALIA