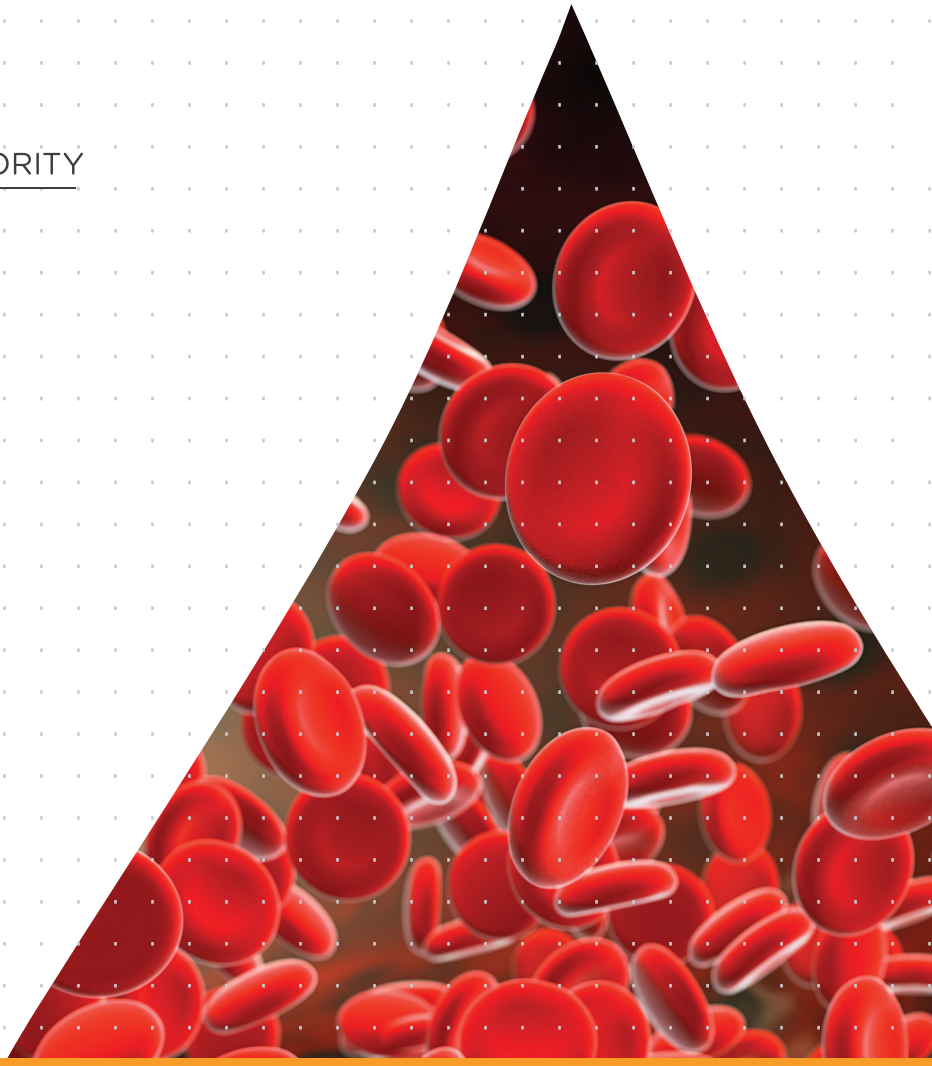
NATIONAL BLOOD AUTHORITY
AUSTRALIA



AUSTRALIAN HAEMOVIGILANCE REPORT

DATA FOR 2014–15

Australian Haemovigilance Report, Data for 2014-15 published by the National Blood Authority.

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CONTENTS

TABLES

TABLES

FIGURES

SECTION 1

Australian Haemovigilance Data

July 2014 - June 2015

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.

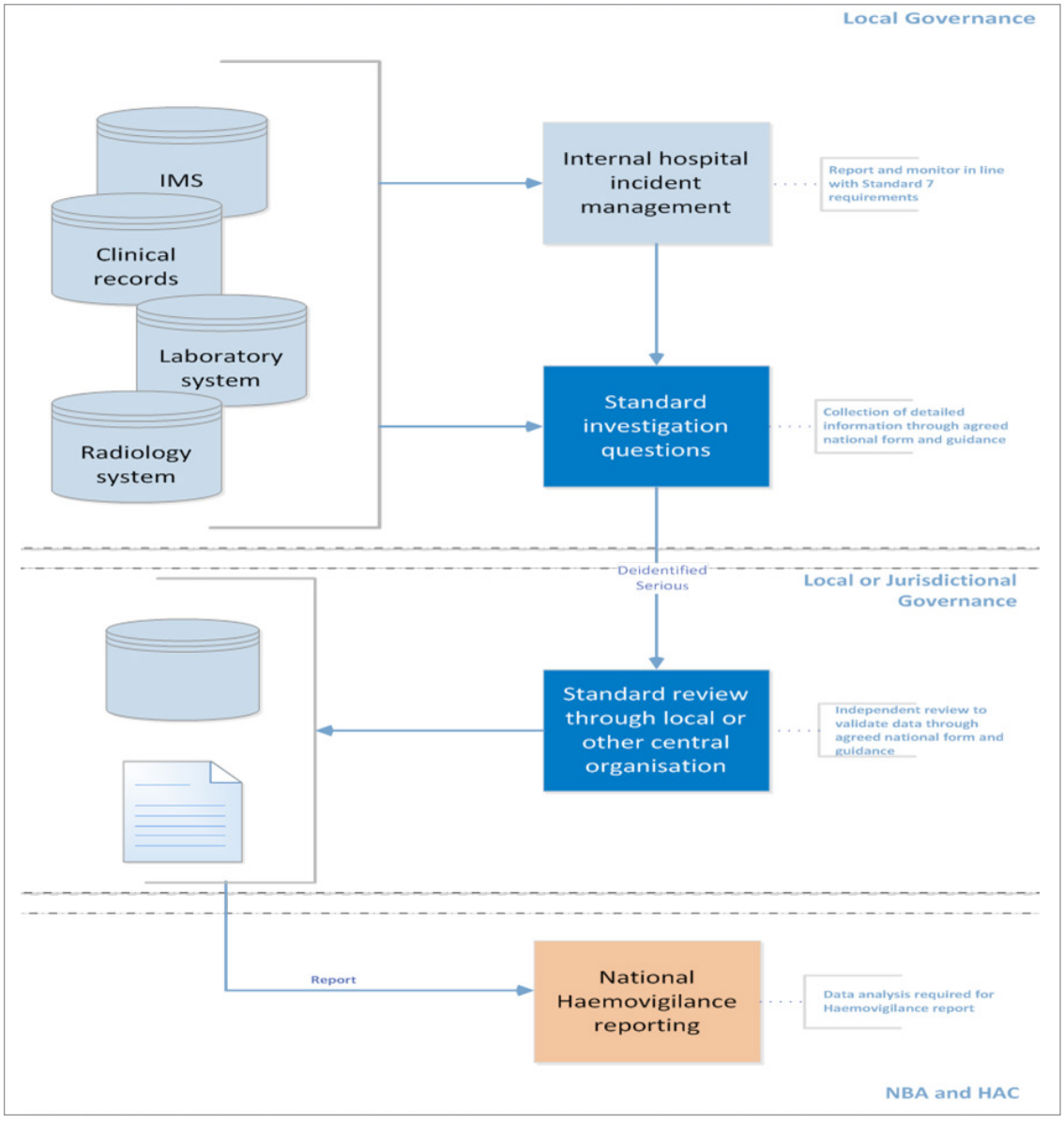

Figure 1: Haemovigilance Reporting Processes in Australia

Summary of findings for 2014-2015

Table 1: Adverse events by state, 2014–15

	FNHTR	Allergic	TACO	IBCT	Anaphylactic	DHTR	AHTR	TTI	TRALI	All reports		Population*	Red cell issue
										Total	Per cent	Per cent	Per Cent
NSW	158	62	10	19	10	1	0	3	1	264	38.8%	32.00%	30.30%
VIC	19	12	8	4	8	7	0	1	0	59	8.7%	24.90%	27.30%
QLD	107	53	11	5	1	4	11	7	3	202	29.7%	20.10%	21.20%
SA	96	36	10	0	1	1	4	1	0	149	21.9%	7.20%	9.20%
TAS	0	1	0	0	0	0	0	0	0	1	0.1%	2.20%	1.80%
NT	0	0	0	2	0	3	0	0	0	5	0.7%	1.00%	0.70%
ACT	0	0	0	0	0	0	0	0	0	0	0.0%	1.60%	1.60%
Total	**380**	**164**	**39**	**30**	**20**	**16**	**15**	**12**	**4**	**680**	**100.0%**	**100.00%**	**100.00%**

Notes

1. ACT reported zero adverse events
2. WA did not contribute data
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

* ABS-3101.0 Australian Demographics - www.abs.gov.au

Table 2: Adverse events by imputability score, 2014–15

Event Type	Excluded / Unlikely	Possible	Likely / Probable	Confirmed / Certain	N/A /Not assessable	Total	Per Cent
FNHTR	55	230	71	17	7	380	55.9%
Allergic	7	86	42	19	10	164	24.1%
TACO	0	19	13	7	0	39	5.7%
IBCT	0	5	6	19	0	30	4.4%
Anaphylactic	0	11	5	4	0	20	2.9%
DHTR	0	4	8	4	0	16	2.4%
AHTR	2	0	2	5	6	15	2.2%
TTI	1	4	0	2	5	12	1.8%
TRALI	1	2	1	0	0	4	0.6%
Total	**66**	**361**	**148**	**77**	**28**	**680**	
Per cent	**9.7%**	**53.1%**	**21.8%**	**11.3%**	**4.1%**	**100.0%**	

Notes

1. ACT reported zero adverse events
2. WA did not contribute data
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, 2014–15

Adverse event	Red Cells	Platelets	Fresh Frozen Plasma	Cryoprecipitate	Cryo-Depleted	Unknown	Total
FNHTR	345	29	6	0	0	0	380
Allergic	60	57	41	5	1	0	164
TACO	36	1	1	1	0	0	39
IBCT	24	2	4	0	0	0	30
Anaphylactic	4	9	6	0	1	0	20
DHTR	16	0	0	0	0	0	16
AHTR	11	2	0	0	0	2	15
TTI	4	8	0	0	0	0	12
TRALI	4		0	0	0	0	4
Total	**504**	**108**	**58**	**6**	**2**	**2**	**680**
Per cent	**74.1%**	**15.9%**	**8.5%**	**0.9%**	**0.3%**	**0.3%**	**100.0%**

Notes

1. ACT reported zero adverse events
2. WA did not contribute data
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, 2014–15

Adverse event	Death	Life-threatening	Severe morbidity	Minor morbidity	No morbidity	Outcome not available	Total
FNHTR	0	0	5	271	100	4	380
Allergic	0	4	4	128	26	2	164
TACO	0	3	10	23	2	1	39
IBCT	0	0	1	11	9	9	30
Anaphylactic	0	8	5	7	0	0	20
DHTR	0	1	0	13	2	0	16
AHTR	0	0	1	6	1	7	15
TTI	0	1	0	2	8	1	12
TRALI	0	1	1	2	0	0	4
Total	**0**	**18**	**27**	**463**	**148**	**24**	**680**
Per cent	**0.0%**	**2.6%**	**4.0%**	**68.1%**	**21.8%**	**3.5%**	**100.0%**

Notes

1. ACT reported zero adverse events
2. WA did not contribute data
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, 2014–15

Adverse event	Male	Female	Not reported	Total
FNHTR	106	115	159	380
Allergic	49	49	66	164
TACO	16	13	10	39
IBCT	7	4	19	30
Anaphylactic	4	6	10	20
DHTR	5	10	1	16
AHTR	7	8	0	15
TTI	6	3	3	12
TRALI	0	3	1	4
All reports	**200**	**211**	**269**	**680**
Per cent	**29.4%**	**31.0%**	**39.6%**	**100.0%**

Notes

1. Sex data not availahle for NSW
2. ACT reported zero adverse events for 2014–15
3. WA did not contribute data
4. All TTIs were suspected but not confirmed bacterial infections
5. Number of patients or transfusion episodes is unavailable

Table 6: Adverse events by age and sex, 2014–15

Adverse event	Male	Female	Not reported	Total
0–4 years	5	4	10	19
5–14 years	6	1	5	12
15–24 years	3	7	10	20
25–34 years	5	16	19	40
35–44 years	9	20	14	43
45–54 years	20	27	36	83
55–64 years	35	29	47	111
65–74 years	41	37	59	137
75 years or older	76	68	60	204
Not stated		2	9	11
Total	**200**	**211**	**269**	**680**
Per cent	**29.4%**	**31.0%**	**39.6%**	**100.0%**

Notes

1. Sex data not availahle for NSW
2. ACT reported zero adverse events for 2014–15
3. WA did not contribute data
4. Number of patients or transfusion episodes is unavailable

Table 7: Serious adverse events by outcome severity and imputability score, 2014–15

	Death	Life-threatening	Severe morbidity	All reports	
				Total	Per cent
Possible	0	5	13	18	40.0%
Likely/Probable	0	9	6	15	33.3%
Confirmed/Certain	0	4	8	12	26.7%
Total	**0**	**18**	**27**	**45**	**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. ACT reported zero adverse events
4. WA did not contribute data
5. Number of patients or transfusion episodes is unavailable

Cumulative results for 2010-2011 to 2014-2015

Table 8: Adverse events by state, 2010–11 to 2014–15

	2010–11	2011–12	2012–13	2013–14	2014–15	All reports	
						Number	Per cent
NSW	186	191	194	218	264	1,053	36.0%
VIC	97	81	59	86	59	382	13.1%
QLD	142	177	0	151	202	672	23.0%
SA	147	151	157	154	149	758	25.9%
TAS	5	2	4	1	1	13	0.4%
NT	5	9	11	7	5	37	1.3%
ACT	0	4	4	0	0	8	0.3%
All reports	**582**	**615**	**429**	**617**	**680**	**2,923**	**100.0%**

Notes

1. NSW did not report detailed data (such as blood products, outcome severity and imputability score) for 2010–11
2. ACT reported zero adverse events for 2010-11, 2013–14 and 2014–15
3. QLD did not contribute data for 2012–13
4. WA did not contribute data
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, 2010–11 to 2014–15

Hospital type	2010–11	2011–12	2012–13	2013–14	2014–15	Total hospitals	Per cent
Public hospital	546	561	426	540	646	2,719	93.0%
All private hospitals	**36**	**54**	**3**	**77**	**34**	**204**	7.0%
Private hospital (exclude private free standing day hospital)	36	54	3	77	29	199	6.8%
Private free-standing day hospital	0	0	0	0	5	5	0.2%
Total hospitals	**582**	**615**	**429**	**617**	**680**	**2,923**	100.0%

Notes

1. VIC and QLD contributed private hospital data
2. ACT reported zero adverse events for 2010-11, 2013–14 and 2014–15
3. NSW did not specify hospital type information for 2010–11 but the data was classified as public hospital as NSW only reports public hospital data to the natioanl haemovigilance program
4. QLD did not contribute data for 2012–13
5. WA did not contribute data
6. Number of patients or transfusion episodes is unavailable

Table 10: Australian adverse event data, 2010–11 to 2014–15

Adverse event	2010–11	2011–12	2012–13	2013–14	2014–15	All reports		Transfusion risk per unit transfused*
						Number	Per cent	(unless specified)
FNHTR	321	320	231	337	380	1,589	54.4%	0.1–1% of transfusions with universal leucocyte depletion
Allergic	142	147	111	144	164	708	24.2%	1–3% of transfusion of plasma containing components
TACO	24	27	17	28	39	135	4.6%	<1% of transfused patients
IBCT	30	62	43	33	30	198	6.8%	Not available
Anaphylactic	33	16	13	19	20	101	3.5%	1:20,000–1:50,000
DHTR	10	17	6	12	16	61	2.1%	1:2,500–1:11,000
AHTR	2	10	2	8	15	37	1.3%	1:76,000
TTI	11	12	5	27	12	67	2.3%	1:75,000 platelet transfusions
					+			1:500,000 red cell transfusions
TRALI	8	4	1	3	4	20	0.7%	1:1,200–1:190,000 transfusions
PTP	1	0	0	6	0	7	0.2%	Rare
Grand Total	**582**	**615**	**429**	**617**	**680**	**2,923**	100.0%	

Notes

1. NSW did not report detailed data (such as blood products, outcome severity and imputability score) for 2010–11
2. ACT reported zero adverse events for 2010-11, 2013–14 and 2014–15
3. QLD did not contribute data for 2012–13
4. WA did not contribute data
5. All TTIs were suspected but not confirmed bacterial infections
6. STIR uses a higher level temperature threshold for the reporting of FNHTR
7. Number of patients or transfusion episodes is unavailable

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

Table 11: Serious adverse events, 2010–11 to 2014–15

	2010–11	2011–12	2012–13	2013–14	2014–15	All reports	
						Total	Per cent
FNHTR	12	9	12	7	5	45	17.6%
Allergic	9	15	9	15	8	56	22.0%
TACO	10	16	8	16	13	63	24.7%
IBCT	3	4	5	0	1	13	5.1%
Anaphylactic	7	8	8	13	13	49	19.2%
DHTR	1	7	1	1	1	11	4.3%
AHTR	1	4	0	1	1	7	2.7%
TTI	3	0	1	0	2	6	2.4%

Notes

1. NSW did not report detailed data (such as blood products, outcome severity and imputability score) for 2010–11
2. ACT reported zero adverse events for 2010-11, 2013–14 and 2014–15
3. QLD did not contribute data for 2012–13
4. WA did not contribute data
5. All TTIs were suspected but not confirmed bacterial infections
6. Number of patients or transfusion episodes is unavailable

Table 12: Serious adverse events by product, 2010–11 to 2014–15

	Red Cells	Platelets	Fresh frozen plasma	Cryoprecipitate	Total
FNHTR	35	9	1	0	45
Allergic	15	20	21	0	56
IBCT	12	0	1	0	13
TACO	59	0	3	1	63
Anaphylactic	14	18	17	0	49
DHTR	11	0	0	0	11
AHTR	7	0	0	0	7
TTI	5	0	0	0	5
TRALI	5	0	0	0	5
PTP	0	1	0	0	1
All reports	**163**	**48**	**43**	**1**	**255**
Per cent	**63.9%**	**18.8%**	**16.9%**	**0.4%**	**100.0%**

Notes

1. NSW did not report detailed data (such as blood products, outcome severity and imputability score) for 2010–11
2. ACT reported zero adverse events for 2010-11, 2013–14 and 2014–15

Table 13: Serious adverse events by transfusion time, 2010–11 to 2014–15

	2010–11	2011–12	2012–13	2013–14	2014–15	All reports	
						Total	Per cent
Between 7am and 7pm	35	34	16	20	31	136	53.3%
Between 7pm and 7am	10	22	11	21	12	76	29.8%
Not reported	3	8	17	13	2	43	16.9%
All reports	**48**	**64**	**44**	**54**	**45**	**255**	**100.0%**

Notes

1. SA did not report transfusion time data from 2010-11 to 2014-15
2. NSW did not report detailed data (such as blood products, outcome severity and imputability score) for 2010–11
3. ACT reported zero adverse events for 2010-11, 2013–14 and 2014–15
4. QLD did not contribute data for 2012–13
5. WA did not contribute data
6. Number of patients or transfusion episodes is unavailable

Table 14: Serious adverse events by week day/weekend, 2010–11 to 2014–15

	2010–11	2011–12	2012–13	2013–14	2014–15	All reports	
						Total	Per cent
Week day	37	43	36	40	33	189	74.1%
Weekend	11	21	8	14	12	66	25.9%
Not reported	0	0	0	0	0	0	0.0%
All reports	**48**	**64**	**44**	**54**	**45**	**255**	**100.0%**

Notes

1. NSW did not report detailed data (such as blood products, outcome severity and imputability score) for 2010–11
2. ACT reported zero adverse events for 2010–11, 2013–14 and 2014–15
3. QLD did not contribute data for 2012–13
4. WA did not contribute data
5. Number of patients or transfusion episodes is unavailable

Table 15: Serious adverse events by age group, 2010–11 to 2014–15

	2010–11	2011–12	2012–13	2013–14	2014–15	All reports	
						Total	Per cent
0–4 years	2	2	1	0	3	8	3.1%
5–14 years	0	3	2	3	4	12	4.7%
15–24 years	7	3	4	2	0	16	6.3%
25–34 years	0	3	3	2	3	11	4.3%
35–44 years	2	3	6	5	0	16	6.3%
45–54 years	5	4	3	4	5	21	8.2%
55–64 years	6	16	5	10	4	41	16.1%
65–74 years	9	16	8	8	14	55	21.6%
75 years or older	14	14	12	18	12	70	27.5%
Not stated	3	0	0	2	0	5	2.0%
All reports	**48**	**64**	**44**	**54**	**45**	**255**	**100.0%**

Notes

1. NSW did not report detailed data (such as blood products, outcome severity and imputability score) for 2010–11
2. ACT reported zero adverse events for 2010–11, 2013–14 and 2014–15
3. QLD did not contribute data for 2012–13
4. WA did not contribute data
5. Number of patients or transfusion episodes is unavailable

Febrile non haemolytic transfusion reaction (FNHTR)

Table 16: FNHTR summary data, 2014–15

2014–15 Data Summary (n=380)					
Age		**Sex**		**Day of Transfusion**	
0–4 years	3	Male	106	Week day	309
5–14 years	4	Female	115	Weekend	71
15–24 years	9	Uncategorised	159		
25–34 years	11	**Facility Location**		**Time of Transfusion**	
35–44 years	20	Major City	180	Between 7am and 7pm	168
45–54 years	56	Inner Regional	16	Between 7pm and 7am	103
55–64 years	64	Outer Regional	26	Not reported	109
65–74 years	83	Remote	0		
75+ years	125	Very Remote	0		
Not specified	5	Not reported	158		
Clinical Outcome Severity		**Imputability**		**Blood Component**	
Death	0	Excluded/Unlikely	55	Whole blood	0
Life threatening	0	Possible	230	Red cells	345
Severe morbidity	5	Likely/Probable	71	Platelets	29
Minor morbidity	271	Confirmed/Certain	17	Fresh Frozen Plasma	6
No morbidity	100	Not assessable	7	Cryoprecipitate	0
Outcome not available	4			Cryodepleted plasma	0
				Not reported	0

Notes

1. NSW did not report sex and facility location data
2. SA did not report time of transfusion data
3. ACT reported zero adverse events
4. WA did not contribute data
5. Number of patients or transfusion episodes is unavailable

Table 17: FNHTR clinical outcome severity by imputability, 2014–15

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	3	2	0	0	5
Minor morbidity	43	176	37	13	2	271
No morbidity	12	49	31	4	4	100
Outcome not available	0	2	1	0	1	4
Total	**55**	**230**	**71**	**17**	**7**	**380**

Notes

1. WA did not contribute data

Allergic reaction

Table 18: Allergic reaction data summary 2014–15

2014–15 Data Summary (n=164)					
Age		**Sex**		**Day of Transfusion**	
0–4 years	11	Male	49	Week day	142
5–14 years	4	Female	49	Weekend	22
15–24 years	9	Uncategorised	66		
25–34 years	19	**Facility Location**		**Time of Transfusion**	
35–44 years	17	Major City	73	Between 7am and 7pm	91
45–54 years	15	Inner Regional	8	Between 7pm and 7am	28
55–64 years	27	Outer Regional	21	Not reported	45
65–74 years	27	Remote	0		
75+ years	32	Very Remote	0		
Not specified	3	Not reported	62		
Clinical Outcome Severity		**Imputability**		**Blood Component**	
Death	0	Excluded/Unlikely	7	Whole blood	0
Life threatening	4	Possible	86	Red cells	60
Severe morbidity	4	Likely/Probable	42	Platelets	57
Minor morbidity	128	Confirmed/Certain	19	Fresh Frozen Plasma	41
No morbidity	26	Not assessable	10	Cryoprecipitate	5
Outcome not available	2			Cryodepleted plasma	1
				Not reported	0

Notes

1. NSW did not report sex and facility location data
2. NSW and SA did not report time of transfusion data
3. ACT reported zero adverse events
4. WA did not contribute data
5. Number of patients or transfusion episodes is unavailable

Table 19: Allergic reaction clinical outcome severity by imputability, 2014–15

Clinical Outcome Severity	Imputability					Total
	Excluded / Unlikely	Possible	Likely / Probable	Confirmed / Certain	N/A /Not assessable	
Life-threatening	0	0	2	2	0	4
Severe morbidity	0	2	1	1	0	4
Minor morbidity	4	76	32	15	1	128
No morbidity	3	8	7	1	7	26
Outcome not available	0	0	0	0	2	2
Total	**7**	**86**	**42**	**19**	**10**	**164**

Notes

1. WA did not contribute data

Transfusion-associated circulatory overload (TACO)

Table 20: TACO data summery, 2014–15

2014–15 Data Summary (n=39)					
Age		**Sex**		**Day of Transfusion**	
0–4 years	0	Male	16	Week day	32
5–14 years	0	Female	13	Weekend	7
15–24 years	0	Uncategorised	10		
25–34 years	0	**Facility Location**		**Time of Transfusion**	
35–44 years	0	Major City	20	Between 7am and 7pm	17
45–54 years	3	Inner Regional	6	Between 7pm and 7am	12
55–64 years	5	Outer Regional	3	Not reported	10
65–74 years	12	Remote	0		
75+ years	19	Very Remote	0		
Not specified	0	Not reported	10		
Clinical Outcome Severity		**Imputability**		**Blood Component**	
Death	0	Excluded/Unlikely	0	Whole blood	0
Life threatening	3	Possible	19	Red cells	36
Severe morbidity	10	Likely/Probable	13	Platelets	1
Minor morbidity	23	Confirmed/Certain	7	Fresh Frozen Plasma	1
No morbidity	2	Not assessable	0	Cryoprecipitate	1
Outcome not available	1			Cryodepleted plasma	0
				Not reported	0

Notes

1. NSW did not report sex and facility location data
2. SA did not report time of transfusion data
3. ACT reported zero adverse events
4. WA did not contribute data
5. Number of patients or transfusion episodes is unavailable

Table 21: TACO clinical outcome severity by imputability, 2014–15

Clinical Outcome Severity	Imputability					Total
	Excluded / Unlikely	Possible	Likely / Probable	Confirmed / Certain	N/A /Not assessable	
Life-threatening	0	1	2	0	0	3
Severe morbidity	0	4	2	4	0	10
Minor morbidity	0	12	9	2	0	23
No morbidity	0	2	0	0	0	2
Outcome not available		0	0	1	0	1
Total	**0**	**19**	**13**	**7**	**0**	**39**

Notes

1. WA did not contribute data

Incorrect blood component transfused (IBCT)

Table 22: IBCT data summary, 2014–15

2014–15 Data Summary (n=30)					
Age		**Sex**		**Day of Transfusion**	
0–4 years	3	Male	7	Week day	27
5–14 years	0	Female	4	Weekend	3
15–24 years	1	Uncategorised	19		
25–34 years	2	**Facility Location**		**Time of Transfusion**	
35–44 years	3	Major City	8	Between 7am and 7pm	19
45–54 years	3	Inner Regional	1	Between 7pm and 7am	10
55–64 years	9	Outer Regional	2	Not reported	1
65–74 years	2	Remote	0		
75+ years	6	Very Remote	0		
Not specified	1	Not reported	19		
Clinical Outcome Severity		**Imputability**		**Blood Component**	
Death	0	Excluded/Unlikely	0	Whole blood	0
Life threatening	0	Possible	5	Red cells	24
Severe morbidity	1	Likely/Probable	6	Platelets	2
Minor morbidity	11	Confirmed/Certain	19	Fresh Frozen Plasma	4
No morbidity	9	Not assessable	0	Cryoprecipitate	0
Outcome not available	9			Cryodepleted plasma	0
				Not reported	0

Notes

1. NSW did not report sex and facility location data
2. SA did not report time of transfusion data
3. ACT reported zero adverse events
4. WA did not contribute data
5. Number of patients or transfusion episodes is unavailable

Table 23: IBCT clinical outcome severity by imputability, 2014–15

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	1	0	1
Minor morbidity	0	1	2	8	0	11
No morbidity	0	1	1	7	0	9
Outcome not available	0	3	3	3	0	9
Total	**0**	**5**	**6**	**19**	**0**	**30**

Notes

1. WA did not contribute data

Table 24: Contributory factors cited in IBCT, 2010–11 to 2014–15

Contributory Factor	2010–11	2011–12	2012–13	2013-14	2014-15
None identified	0	9	0	1	0
Product characteristic	4	0	0	0	0
Transfusion in emergency setting	4	2	6	3	7
Deliberate clinical decision	0	1	0	0	1
Prescribing/ordering	5	7	0	14	6
Specimen collection/labelling	11	7	11	0	1
Laboratory (testing/dispensing)	5	24	22	12	15
Transport, storage, handling	0	1	1	1	1
Administration of product	8	5	9	10	13
Indications did not meet hospital transfusion guidelines	2	12	27	15	0
Procedure did not adhere to hospital transfusion guidelines	14	1	0	3	8
Other	8	4	12	12	0

Notes

1. Contributory factors are not identified for the adverse events reported by QLD and SA
2. WA did not contribute data
3. ACT reported zero adverse events

Anaphylactic or anaphylactoid reaction

Table 25: Anaphylactic or anaphylactoid reaction data summary, 2014–15

2014–15 Data Summary (n=20)					
Age		**Sex**		**Day of Transfusion**	
0–4 years	0	Male	4	Week day	16
5–14 years	4	Female	6	Weekend	4
15–24 years	0	Uncategorised	10		
25–34 years	4	**Facility Location**		**Time of Transfusion**	
35–44 years	2	Major City	10	Between 7am and 7pm	15
45–54 years	2	Inner Regional	0	Between 7pm and 7am	3
55–64 years	2	Outer Regional	0	Not reported	2
65–74 years	5	Remote	0		
75+ years	1	Very Remote	0		
Not specified	0	Not reported	10		
Clinical Outcome Severity		**Imputability**		**Blood Component**	
Death	0	Excluded/Unlikely	0	Whole blood	0
Life threatening	8	Possible	11	Red cells	4
Severe morbidity	5	Likely/Probable	5	Platelets	9
Minor morbidity	7	Confirmed/Certain	4	Fresh Frozen Plasma	6
No morbidity	0	Not assessable	0	Cryoprecipitate	0
Outcome not available	0			Cryodepleted plasma	1
				Not reported	0

Notes

1. NSW did not report sex and facility location data
2. SA did not report time of transfusion data
3. ACT reported zero adverse events
4. WA did not contribute data
5. Number of patients or transfusion episodes is unavailable

Table 26: Anaphylactic or anaphylactoid reactions clinical outcome severity by imputability, 2014–15

Clinical Outcome Severity	Imputability				Total
	Excluded / Unlikely	Possible	Likely / Probable	Confirmed / Certain	N/A /Not assessable	
Life-threatening	0	4	3	1	0	8
Severe morbidity	0	3	1	1	0	5
Minor morbidity	0	4	1	2	0	7
No morbidity	0	0	0	0	0	0
Outcome not available	0	0	0	0	0	0
Total	**0**	**11**	**5**	**4**	**0**	**20**

Notes

1. WA did not contribute data

Delayed haemolytic transfusion reaction (DHTR)

Table 27: DHTR data summary, 2014–15

2014–15 Data Summary (n=16)					
Age		**Sex**		**Day of Transfusion**	
0–4 years	0	Male	5	Week day	13
5–14 years	0	Female	10	Weekend	3
15–24 years	0	Uncategorised	1		
25–34 years	1	**Facility Location**		**Time of Transfusion**	
35–44 years	1	Major City	10	Between 7am and 7pm	11
45–54 years	3	Inner Regional	2	Between 7pm and 7am	4
55–64 years	1	Outer Regional	3	Not reported	1
65–74 years	3	Remote	0		
75+ years	7	Very Remote	0		
Not specified	0	Not reported	1		
Clinical Outcome Severity		**Imputability**		**Blood Component**	
Death	0	Excluded/Unlikely	0	Whole blood	0
Life threatening	1	Possible	4	Red cells	16
Severe morbidity	0	Likely/Probable	8	Platelets	0
Minor morbidity	13	Confirmed/Certain	4	Fresh Frozen Plasma	0
No morbidity	2	Not assessable	0	Cryoprecipitate	0
Outcome not available	0			Cryodepleted plasma	0
				Not reported	0

Notes

1. NSW did not report sex and facility location data
2. SA did not report time of transfusion data
3. ACT reported zero adverse events
4. WA did not contribute data
5. Number of patients or transfusion episodes is unavailable

Table 28: DHTR clinical outcome severity by imputability, 2014–15

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	4	6	3	0	13
No morbidity	0	0	1	1	0	2
Outcome not available	0	0	0	0	0	0
Total	**0**	**4**	**8**	**4**	**0**	**16**

Notes

1. WA did not contribute data

Acute haemolytic transfusion reaction (AHTR)

Table 29: AHTR data summary, 2014–15

2014–15 Data Summary (n=15)					
Age		**Sex**		**Day of Transfusion**	
0–4 years	1	Male	7	Week day	15
5–14 years	0	Female	8	Weekend	0
15–24 years	0	Uncategorised			
25–34 years	1	**Facility Location**		**Time of Transfusion**	
35–44 years	0	Major City	12	Between 7am and 7pm	8
45–54 years	0	Inner Regional	3	Between 7pm and 7am	3
55–64 years	0	Outer Regional	0	Not reported	4
65–74 years	3	Remote	0		
75+ years	9	Very Remote	0		
Not specified	1	Not reported	0		
Clinical Outcome Severity		**Imputability**		**Blood Component**	
Death	0	Excluded/Unlikely	2	Whole blood	0
Life threatening	0	Possible	0	Red cells	11
Severe morbidity	1	Likely/Probable	2	Platelets	2
Minor morbidity	6	Confirmed/Certain	5	Fresh Frozen Plasma	0
No morbidity	1	Not assessable	6	Cryoprecipitate	0
Outcome not available	7			Cryodepleted plasma	0
				Not reported	2

Notes

1. NSW did not report sex and facility location data
2. SA did not report time of transfusion data
3. ACT reported zero adverse events
4. WA did not contribute data
5. Number of patients or transfusion episodes is unavailable

Table 30: AHTR clinical outcome severity by imputability, 2014–15

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	1	0	1
Minor morbidity	1	0	2	3	0	6
No morbidity	0	0	0	1	0	1
Outcome not available	1	0	0	0	6	7
Total	**2**	**0**	**2**	**5**	**6**	**15**

Notes

1. WA did not contribute data

Transfusion-transmitted infection (TTI)

Table 31: TTI data summary, 2014–15

2014–15 Data Summary (n=12)					
Age		**Sex**		**Day of Transfusion**	
0–4 years	0	Male	6	Week day	10
5–14 years	0	Female	3	Weekend	2
15–24 years	1	Uncategorised	3		
25–34 years	2	**Facility Location**		**Time of Transfusion**	
35–44 years	0	Major City	2	Between 7am and 7pm	4
45–54 years	0	Inner Regional	3	Between 7pm and 7am	6
55–64 years	1	Outer Regional	4	Not reported	2
65–74 years	2	Remote	0		
75+ years	5	Very Remote	0		
Not specified	1	Not reported	3		
Clinical Outcome Severity		**Imputability**		**Blood Component**	
Death	0	Excluded/Unlikely	1	Whole blood	0
Life threatening	1	Possible	4	Red cells	4
Severe morbidity	0	Likely/Probable	0	Platelets	8
Minor morbidity	2	Confirmed/Certain	2	Fresh Frozen Plasma	0
No morbidity	8	Not assessable	5	Cryoprecipitate	0
Outcome not available	1			Cryodepleted plasma	0
				Not reported	0

Notes

1. NSW did not report sex and facility location data
2. SA did not report time of transfusion data
3. ACT reported zero adverse events
4. WA did not contribute data
5. Number of patients or transfusion episodes is unavailable

Table 32: TTI clinical outcome severity by imputability, 2014–15

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	1	0	0	1	0	**2**
No morbidity	0	4	0	0	4	**8**
Outcome not available	0	0	0	0	1	**1**
Total	**1**	**4**	**0**	**2**	**5**	**12**

Notes

1. WA did not contribute data

Transfusion related acute lung injury (TRALI)

Table 33: TRALI data summary, 2014–15

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

Notes

1. NSW did not report sex and facility location data
2. SA did not report time of transfusion data
3. ACT reported zero adverse events
4. WA did not contribute data
5. Number of patients or transfusion episodes is unavailable

Table 34: TRALI clinical outcome severity by imputability, 2014–15

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	1	0	0	0	1
Minor morbidity	1	1	0	0	0	2
No morbidity	0	0	0	0	0	0
Outcome not available	0	0	0	0	0	0
Total	**1**	**2**	**1**	**0**	**0**	**4**

Notes

1. WA did not contribute data

Contributory factors

Table 35 : Contributory factors data summary, 2014-15

Summary Data	
Contributory Factors	Number of reports
None identified	141
Not reported	147
Product characteristic	328
*Transfusion in emergency setting	12
*Deliberate clinical decision	11
*Prescribing/ordering	7
*Specimen collection/labelling	3
*Laboratory (testing/dispensing)	17
*Transport, storage, handling	1
*Administration of product	17
*Indications do not meet guidelines	3
*Procedure did not adhere to hospital transfusion guidelines	8
Other	17

Notes

1. Contributory factors are not reported for SA
2. WA did not contribute data
3. ACT reported zero adverse events

* refers to potentially avoidable human errors

Table 36: Contributory factors cited by adverse event and by clinical outcome severity, 2014–15

Contributory Factors	Adverse event									Clinical outcome severity					
	FNHTR	Allergic	TACO	IBCT	TTI Bacterial	Anaphylactic / Anaphylactoid	DHTR	AHTR (not ABO)	TRALI	Outcome not available	No morbidity	Minor morbidity	Severe morbidity	Life-threatening	Death
None identified	171	62	21	0	4	1	15	12	2	11	115	154	4	4	0
Product characteristic	194	96	12	0	4	19	1	1	1	4	16	279	17	12	0
Transfusion in emergency setting	0	4	0	7	0	1	0	0	0	2	3	7	0	0	0
Deliberate clinical decision	6	3	0	1	0	0	0	0	1	1	0	9	1	0	0
Prescribing/ordering	0	1	0	6	0	0	0	0	0	2	3	2	0	0	0
Specimen collection/labelling	1	0	0	1	1	0	0	0	0	1	0	1	0	1	0
Laboratory (testing/dispensing)	1	1	0	15	0	0	0	0	0	4	3	10	0	0	0
Transport, storage, handling	0	0	0	1	0	0	0	0	0	0	0	0	1	0	0
Administration of product	4	0	0	13	0	0	0	0	0	3	7	7	0	0	0
Indications do not meet guidelines	1	0	2	0	0	0	0	0	0	0	0	1	2	0	0
Procedure did not adhere to hospital transfusion guidelines	0	0	0	8	0	0	0	0	0	0	3	5	0	0	0
Other	4	2	6	0	3	0	0	2	0	0	6	7	3	1	0

Notes

1. SA did not provide contributory data
2. ACT reported zero adverse events
3. WA did not contribute data
4. Number of patients or transfusion episodes is unavailable
5. STIR useds a higher level temperature threshold for the reporting of FNHTR

SECTION 2

Australian Donor Vigilance Data

July 2014 - June 2015

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 American Association of Blood Banks (AABB) to standardise donor haemovigilance definitions internationally. In 2014, agreement was reached on standard definitions and this report uses these new definitions. This will enable benchmarking of Australian blood donor safety with blood services internationally.

Because of the decision to adopt the ISBT definitions, this report will include data which was gathered and classified following the introduction of electronic reporting. The first full year of electronic records is for the period 2011–12. Not uncommonly, donors report the occurrence of a donation adverse event to the Blood Service many months or even years after the event occurred, often at their next donation and usually prompted by the donor wellness question. Historical data in this report has been updated to incorporate this delayed reporting. There still may be under-reporting of adverse events.

Between 1 July 2014 and 30 June 2015 there were a total of 1.3 million donations, including 0.75 million whole blood donations, 0.51 million plasmapheresis donations and 0.04 million plateletpheresis donations. There were 38,069 donor adverse events reported. The overall reported rate of donation- related adverse events has increased slightly from 284 per 10,000 donations for the previous 12 months to 293 per 10,000 donations. The event numbers reported are as at 30 March 2016.

The increase in the incidence of total adverse events for 2014-15 has been influenced mainly by an expansion of the functionality of the Donor Adverse Event database to include the capacity to report more than one donation complication at a single donation, such as a vasovagal reaction associated with a phlebotomy injury. This has resulted in an increase in the number of reported phlebotomy injuries since November 2013, when dual reporting was enabled.

ISBT classification of donor adverse events

For over 15 years, the Blood Service has been using qualitative adverse event definitions based on the symptoms reported by the donor, the duration and physical signs observed by Blood Service staff using a severity scale (mild, moderate, severe or serious). The ISBT defines events according to clinical features and functional impact on the donor; this approach is in keeping with current risk assessment and management processes used in health care settings in Australia and internationally.

The major differences in reporting are around donors who are referred for, or who seek, external medical or hospital care. Historically any donor who has required external medical care has been classified as experiencing a serious donation reaction or complication. ISBT only reports donors who have required hospital admission overnight or longer, and donors who have required ongoing non-hospital treatment for a period of more than 12 months.

Definitions of immediate (occurring at the donation site) and delayed (occurring after the donor has left the donation site) donation complications are unchanged, although ISBT has also defined a 24 hour post-donation period during which significant systemic events such as acute myocardial infarct or transient ischaemic attack (TIA) can be considered attributable to blood donation. For serious events such as these, the ISBT requires an assessment of imputability, rating the likelihood that the event is donation-related as possible, probable or definite. The Blood Service had previously considered any such events occurring for up to 72 hours following donation as potentially attributable.

Table 37: Correlation between the classification of events using ISBT definitions and the Blood Service's historic 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><th>ISBT</th><th>BLOOD SERVICE</th><th>ISBT</th><th>BLOOD SERVICE</th><th>ISBT</th><th>BLOOD SERVICE</th><th>ISBT</th><th>BLOOD SERVICE</th></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="5">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 (induding 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="5">** 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 accident</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></tr>
<tr><td>Compartment syndrome</td><td>Not listed separately from extravasation</td></tr>
</table>

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 which has improved understanding of the impacts of blood donation, changes in collection procedures and in donor selection criteria on the safety of donors.

Since 2010, the accuracy and completeness of the information reported has improved steadily since the introduction of electronic reporting. Staff education and compliance monitoring has resulted in improved reporting in 2014-15.

In early 2011 the "donor wellness check" was introduced. Donors are asked at each donation whether they experienced any problems related to their previous donation. The donor wellness check effectively identifies delayed donor reactions and phlebotomy injuries which become apparent after the donor leaves the donor centre. Reports of adverse reactions can be received up to several years after the event as a result of the donor wellness check.

There was a significant increase in plateletpheresis reactions and modest increase in plasmapheresis donor reactions in 2012-13 following the introduction of mandatory reporting of all citrate reactions regardless of the intensity of symptoms reported from October 2012.

Refinements to the reporting system in November 2013 made it possible to report more than one type of donation reaction for each donation. Previously collection centre staff reported the most significant event (mostly faints and pre-faints) experienced by a donor; now faints and pre-faints which are associated with phlebotomy related problems such as pain and bruising have both fainting and the phlebotomy injury reported, rather than just the faint. This change has resulted in an increase in the number of phlebotomy injuries reported.

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.

There was a progressive reduction in the total number of collections from 2011–12 to 2014–15 with a 21% reduction in the number of whole blood collections; however, the number of apheresis collections increased by 38.5% between 2011–12 and 2014–15 (refer to Table 38).

Table 38: Total number of collections by donation type, 2011–12 to 2014–15

Collections	2011–12	2012–13	2013–14	2014-15
Whole Blood	945,900	858,594	783,346	747,684
All apheresis procedures	396,983	464,289	518,579	549,671
Plasmapheresis	357,701	427,945	482,857	509,269
Plateletpheresis	39,282	36,344	35,722	40,402
Total collections	**1,342,883**	**1,322,883**	**1,301,925**	**1,297,355**

There were 38,069 adverse events reported in 2014–15. Immediate vasovagal reactions are the most commonly reported adverse donation reactions, with an incidence of 1.8%, with the majority of such donors experiencing dizziness, weakness, sweating and nausea; 11% 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). 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.

Delayed vasovagal reactions are less common than immediate reactions occurring in only 0.31% of donors. Ten per cent of delayed reactions are associated with loss of consciousness, which represents a significant risk to the donor who is not under observation at the time of the event. Donors who are slow to recover from vasovagal reactions (with symptoms lasting more than one hour) and donors who have fainted and sustained an injury may require hospital treatment. The overall reported rate of donation- related adverse events was 1:35 in 2014–15, compared to 1:37 in 2013–14.

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 2 below.

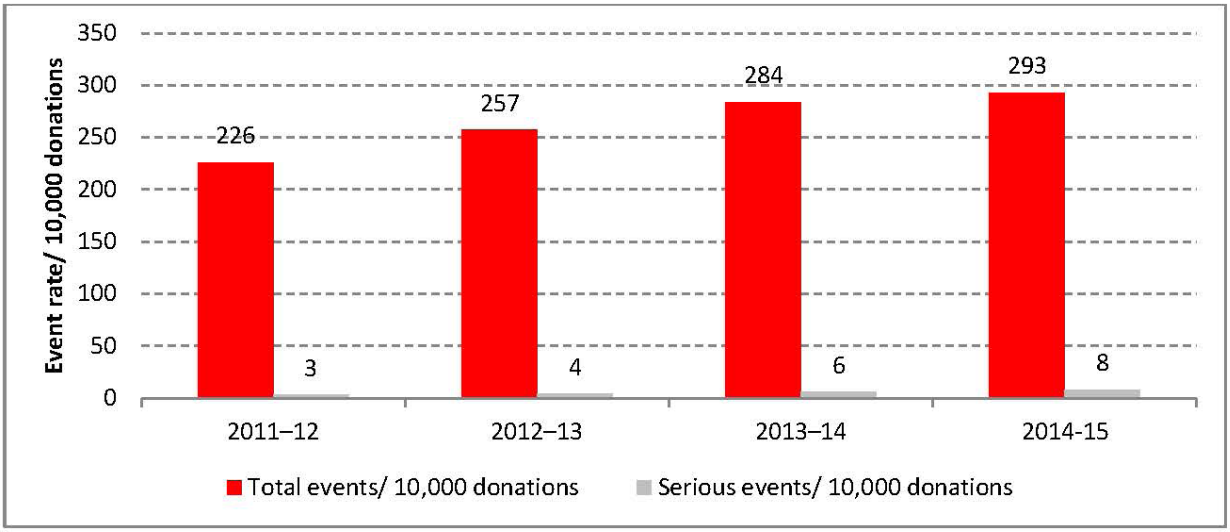

Figure 2: Total donation-associated events, 2011–12 to 2014–15

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, 2011–12 to 2014–15 (per 10,000 donations)

Donor Event	2011–12	2012–13	2013–14	2014-15
Immediate vasovagal reaction	184	195	182	183
Delayed vasovagal reaction	23	29	34	34
Acute cardiac symptoms	0.02	0.02	0.02	0.03
Acute myocardial infarction*	<0.01 (1 event)	0.03	0.02	<0.01 (1 event)
Cardiac arrest	0	0	0	0
Transient ischaemic attack (TIA)	0	0	0	0
Cerebrovascular accident	0	0	0	0
Generalised (anaphylactic) reaction	0	0	0.1	0.1
Haematoma	9	12	14	15
Nerve injury	2	3	4	5
Other arm pain	3	5	12	25
Delayed bleeding	0	0	1	1
Superficial Thrombophlebitis	0.2	0.3	0.3	0.3
DVT	0	0.1	0	0.1
Compartment syndrome	0	0	0	0
Citrate reaction**	2	10	32	33
Haemolysis**	0	0	0.1	0.1
Infiltration**	0	0.1	0.6	0.7
Other***	3	2	4	3
Total	**226**	**257**	**284**	**293**

Notes

1. * each case is evaluated individually to determine underlying risk factors, it was very likely that this event was not relate to blood donation.
2. ** apheresis collections only.
3. *** includes non-cardiac chest pain, palpitations or awareness of heart beat, injuries sustained in falls during fainting, headaches during and after donation, cramps, nausea or abdominal pain during or immediately following procedure, onset of wheeze or asthma during donation, prolonged fatigue following donation.

The significant increase in citrate reactions in 2013–14 is the result of increased reporting of these events. Before this citrate reactions were only reported when donors had experienced intense citrate-related symptoms.

Adverse events by donation type

1. *Whole Blood* – the rate of adverse reactions is stable overall. There has been a small decrease in the number of vasovagal reactions as a result of the policy change limiting donation by young donors to a single donation per year. However there has been an increase in the number of phlebotomy injuries reported since the ability to capture more than one adverse event at each donation has been possible. There has been no change in donation protocols.
2. *Plasmapheresis* – roll out of new apheresis software commenced in April 2014 and was completed by the end of July 2014. This resulted in a change in the collection protocol such that 250ml of normal saline is administered after the second return as opposed to after the first return. This change has been associated with an increase in mild and moderate donor reactions; however the incidence of delayed reactions has decreased. This is pleasing as delayed reactions are more likely to be associated with donor injury.
3. There has also been an increase in the number of reported mild citrate reactions (as a result of changes to reporting requirement) and phlebotomy injuries (as a result of changes in the ability to report more than one event at each donation, as previously discussed).
4. *Plateletpheresis* – it is extremely common for platelet donors to experience reactions to citrate anticoagulant. The increase in reactions between 2012–13 and 2013–14 was related to increased reporting of reactions. The decrease in reaction over 2014–15 is the result of a decision to offer all plateletpheresis donors oral calcium supplements immediately prior to donation; in addition, the donor website now contains advice to donors on appropriate dietary preparation for 24 hours prior to donation. 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 shows annual rates of all adverse events by donation type from 2011–12 to 2014–15. Table 41 details donor complication rates by reaction type and injury per 10,000 donations for 2014–15

Table 40: Adverse donor reaction rate by procedure, 2011–12 to 2014–15 (per 10,000 donations)

Procedure	2011–12	2012–13	2013–14	2014-15
Whole Blood	271	317	330	350
Plasmapheresis	118	147	215	216
Plateletpheresis	98	121	161	182
All apheresis	300	453	942	654
Total procedures	**226**	**257**	**284**	**293**

The increase in plasma reactions is mainly in citrate reactions and vasovagal reactions of less than 60 minutes duration, not associated with loss of consciousness or injury.

Table 41: Donation-associated events by reaction type and injury, 2014–15

			Rate per 10,000 donations		
			Whole Blood (n=747,684)	Plasmapheresis (n=509,269)	Plateletpheresis (n=40,402)
Systemic Reactions					
Immediate vasovagal reaction	Without LOC	Without injury	238.64	70.94	141.33
		With injury	0.49	0.08	0.99
	With LOC	Without injury	17.43	4.28	6.19
		With injury	1.04	0.12	0.74
Delayed vasovagal reaction	Without LOC	Without injury	38.93	15.57	11.39
		With injury	1.86	0.27	1.24
	With LOC	Without injury	4.49	0.77	0.50
		With injury	0.83	0.24	0.50
Other systemic reactions	Cardiac	Acute cardiac symptoms	0.04	0.02	0.00
		Acute myocardial infarction	0.01	0.00	0.00
	Generalised (anaphylactic) reaction		0.03	0.12	0.00
Local Arm Injuries					
Blood outside vessel	Haematoma		15.11	11.96	40.84
	Arterial puncture		0.62	0.02	0.00
	Delayed bleeding		1.11	0.94	0.25
Arm Pain	Nerve injury/irritation		6.81	3.44	4.21
	Other arm pain		18.64	13.96	20.54
	Local allergic reaction		0.48	0.41	0.50
	Thrombophlebitis		0.32	0.27	0.00
	Deep vein thrombosis (DVT)		0.05	0.06	0.25
Other local arm injuries	Other		1.93	4.05	7.43
Apheresis collections only					
Apheresis related complications (for Apheresis collections only)	Citrate reaction		N/A	52.23	411.86
	Haemolysis		N/A	0.12	0.00
	Air Embolism		N/A	0.00	0.00
	Infiltration		N/A	1.35	3.96
Total			**350**	**182**	**654**

Note: loss of consciousness (LOC)

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 2014–15, 987 donors attended hospital and 1,260 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. 104 donors with chest pain were referred to hospital between July 2014 and June 2015 of whom 13 were admitted for cardiac investigations; all had been previously well but had risk factors for coronary disease. One donor suffered a myocardial infarct approximately 6 hours following a whole blood donation and required coronary artery bypass grafts. Three whole blood donors and one plasmapheresis donor 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 31 donors) and no definitive diagnosis was made (for 62 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 (8 donors) and superficial thrombophlebitis (37 donors).

Table 42: Summary of external medical referrals, 2014–15

	Number of hospital referrals	Hospital referral rate/ 10,000 donations	Number of GP referrals	GP referral rate/ 10,000 donations
Whole Blood	761	10	938	13
Plasmapheresis	191	4	286	6
Plateletpheresis	35	9	36	9
Total	**987**	**8**	**1,260**	**10**

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 requiring hospital attendance, 2011–12 to 2014–15

	2011–12	2012–13	2013–14	2014-15
Whole Blood	4 (351)	4 (348)	5 (356)	10 (761)
Plasmapheresis	2 (65)	2 (105)	2 (120)	4 (191)
Plateletpheresis	3 (12)	5 (19)	4 (16)	9 (35)

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 the transfer of 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 younger donors prompted a policy change in 2014 to limit donations from this age group to one donation per annum. Safety and wellbeing of 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

Age group	Number of events	Total donors in age group	Frequency	Rate/1000 donations	Odds ratio (95% CI)
16–17yrs	1,563	10,036	1:6	157.23	4.3112 (4.0780 - 4.5577)
18–20yrs	2,044	31,535	1:15	64.12	1.5870 (1.5144 - 1.6631)
21–23yrs	3,962	38,855	1:10	100.68	3.9293 (3.7912 - 4.0724)
24–30yrs	4,751	80,420	1:17	58.39	2.8104 (2.7115 - 2.9128)
31–40yrs	3,253	78,723	1:24	40.80	0.9459 (0.9108 - 0.9823)
41–50yrs	2,911	99,327	1:34	28.76	0.6217 (0.5977 - 0.6467)
51–60yrs	3,256	122,570	1:38	25.93	0.5404 (0.5205 - 0.5611)
61–70yrs	1,825	81,044	1:44	21.88	0.4701 (0.4479 - 0.4934)
71+	146	8,855	1:61	15.70	0.3691 (0.3132 - 0.4349)
Total	**23,711**	**551,365**	**1:23**	**42.38**	

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

Age group	Number of events	Total donors in age group	Frequency	Rate/1000 donations	Odds ratio (95% CI)
16–17yrs	705	6,746	1:10	106.43	6.2343 (5.7559 - 6.7524)
18–20yrs	1,056	30,894	1:29	33.83	1.8761 (1.7603 - 1.9996)
21–23yrs	1,959	35,499	1:18	54.90	3.3015 (3.1439 - 3.4670)
24–30yrs	3,146	92,011	1:29	33.82	2.0347 (1.9546 - 2.1182)
31–40yrs	2,667	109,439	1:41	24.23	1.3389 (1.2831 - 1.3972)
41–50yrs	1,962	141,616	1:72	13.68	0.6732 (0.6417 - 0.7063)
51–60yrs	1,810	187,464	1:104	9.50	0.4256 (0.4051 - 0.4473)
61–70yrs	901	125,530	1:139	7.03	0.3277 (0.3062 - 0.3506)
71+	70	16,787	1:240	4.17	0.2107 (0.1681 - 0.2691)
Total	**14,148**	**745,986**	**1:53**	**18.97**	

The high incidence of reactions in young donors and female donors is consistent with international experience: in a recent review of donor adverse events by the Alliance of Blood Operators Medical Group (ABO Medical Group) the Blood Donor Safety Issues White Paper March 21, 2014[1], the reported odds ratios for young and female donors are shown in Table 46.

Table 46: Risk factors for vasovagal reactions (ABO Medical Group data)

Risk factor	Risk of reaction, odds ratio
16-18 years (all sexes)	3.89
17-20 years (all sexes)	2.75-4.01
19-24 years (all sexes)	2.37
Female (all ages)	1.20-2.52

REFERENCE:

1 Alliance of Blood Operators Medical Group (ABO Medical Group) the Blood Donor Safety Issues White Paper March 21, 2014. Available at https://allianceofbloodoperators.org/media/115526/abo-blood-donor-safety-issues-white-paper_march-21-2014_final.pdf

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

1. Donor centres have access to a donor adverse events dashboard, updated daily. This provides real time feedback on their performance, and enables benchmarking between donor centres with similar donor and collection characteristics, and provides immediate feedback on those events which are notified after the donor leaves the donor centre. This improves staff awareness and focuses attention on preventative strategies.
2. Plain English information provided to donors at donateblood.com.au, in donor centres and on the Donor Questionnaire provides simple advice on preparation for blood donation using evidence based strategies such as pre-donation salty snacks and in-centre pre-donation fluid loading.
3. Provide plain English advice to donors on strategies to minimise the risk of a reaction during and after donation (use of applied muscle tension, rest and fluid intake, avoidance of strenuous physical activity and alcohol post donation).
4. Provision of specific information cards to donors at the time of an adverse event detailing immediate management and preventative actions relevant to subsequent donations.
5. Permanent deferral of donors with significant risk of recurrence of serious adverse reactions.
6. 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.
7. Using a stepwise approach to increasing collection volume for plasmapheresis donors donating plasma for fractionation based on nomograms* for percent Total Blood Volume.
8. Using a stepwise approach for plasmapheresis donors donating Clinical Fresh Frozen Plasma with end saline also based on a nomogram for Total Blood Volume.
9. Implementations of specific guidelines for managing young donors – females less than 20 years of age are not recruited to plasma donation.
10. 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.
11. Offering pre-donation oral calcium supplements for plateletpheresis donors to minimise the severity of citrate reactions. More palatable combined calcium and magnesium replacement was introduced in 2015 to improve the acceptability to apheresis donors.
12. Communication with comparable international blood services to ensure 'best practice' protocols.
13. 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.

14. One pilot of iron supplementation to reduce the risk of iron deficiency associated with blood donation has been completed; the final analysis of the results is currently underway; a second study was completed in July 2016.
15. Research initiatives aimed at maintaining donor health and wellbeing and reducing the number and severity of donation adverse events: an interventional study is planned for 2016 looking at the impact of donor education in the use of applied muscle tension and water loading to reduce vasovagal reactions.

*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 two values.

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