NATIONAL BLOOD AUTHORITY
AUSTRALIA

DATA FOR
2018–2019

AUSTRALIAN HAEMOVIGILANCE REPORT

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SECTION 1

Australian Haemovigilance Data

July 2018 – June 2019

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) thanks 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.

Caveats

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

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

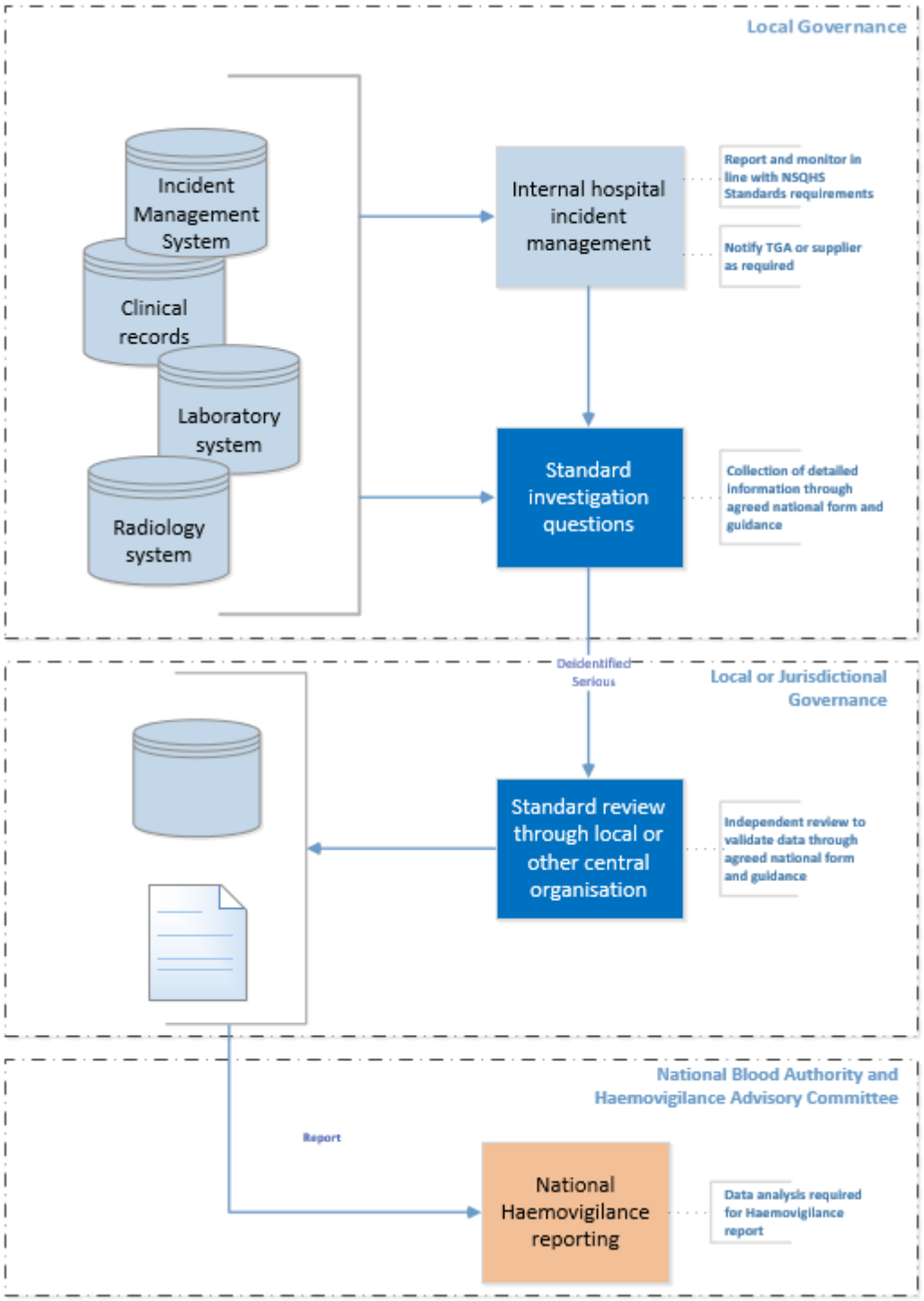
Notwithstanding these limitations, the NBA is publishing this data as an aid to relevant analysis and to maintain the time series of data published during the last ten years.

- Data in this report are in accordance with either the National Blood Authority National Haemovigilance Data Dictionary (NHDD) 2010 or the Australian Haemovigilance Minimum Data Set (AHMDS) 2015.
- 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 Appendix I of the 2010 NHDD and 2015 AHMDS align with those used by the International Haemovigilance Network (IHN) and International Society Blood Transfusion (ISBT) unless otherwise stated. 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 for bacterial contamination and TRALI is reconciled with data from Lifeblood.
- State and territory health departments aggregate and de-identify data and report to the NBA.



Summary of findings for 2018-19

Table 1: Adverse events by state, 2018–19

	FNHTR	Allergic	TACO	IBCT	Anaphylactic	DHTR	AHTR	TTI	TRALI	PTP	DSTR	Hypotensive	ABO	TAD	Other	All reports		Population	Red cell issue
																Total	Percent	Percent	Percent
NSW	9	45	3	1	7	0	2	1	0	0	0	2	0	2	0	72	14.4%	32.0%	30.8%
VIC	8	5	14	6	8	5	0	0	0	0	8	0	0	0	4	58	11.6%	25.9%	27.5%
QLD	118	78	8	2	6	6	11	1	1	1	0	0	1	0	0	233	46.6%	20.1%	20.9%
SA	12	21	9	1	3	2	0	1	0	0	0	1	0	1	1	52	10.4%	6.9%	8.9%
WA	14	25	6	1	4	2	1	0	0	0	8	1	0	4	2	68	13.6%	10.4%	7.9%
TAS	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0.0%	2.1%	1.8%
NT	6	4	0	0	1	0	1	0	0	0	0	0	0	0	0	12	2.4%	1.0%	1.5%
ACT	2	1	2	0	0	0	0	0	0	0	0	0	0	0	0	5	1.0%	1.7%	0.6%
Total	**169**	**179**	**42**	**11**	**29**	**15**	**15**	**3**	**1**	**1**	**16**	**4**	**1**	**7**	**7**	**500**	**100.0%**	**100.0%**	**100.0%**

Notes

1. All states/territories contributed the data
2. All TTIs were suspected but not confirmed bacterial infection
3. STIR uses a higher level temperature threshold for the reporting of FNHTR
4. QLD uses the 2010 AHMDS for all reporting
5. In 2018-19, some states reported new adverse events in accordance with the 2015 AHMDS. Refer to each adverse event reporting for details

Table 2: Adverse events by imputability score, 2018–19

Event Type	Excluded / Unlikely	Possible	Likely / Probable	Confirmed / Certain	N/A /Not assessable	Total	Percent
FNHTR	32	92	39	2	4	169	33.8%
Allergic	9	66	94	6	4	179	35.8%
TACO	1	15	22	3	1	42	8.4%
IBCT	1	0	2	4	4	11	2.2%
Anaphylactic	0	7	11	11	0	29	5.8%
DHTR	0	6	1	8	0	15	3.0%
AHTR	2	7	4	2	0	15	3.0%
TTI	0	2	1	0	0	3	0.6%
TRALI	1	0	0	0	0	1	0.2%
PTP	0	1	0	0	0	1	0.2%
DSTR	0	3	2	10	1	16	3.2%
Hypotensive	0	3	1	0	0	4	0.8%
ABO	0	0	0	1	0	1	0.2%
TAD	0	5	2	0	0	7	1.4%
Other	0	5	1	0	1	7	1.4%
Total	**46**	**212**	**180**	**47**	**15**	**500**	
Percent	**9.2%**	**42.4%**	**36.0%**	**9.4%**	**3.0%**	**100.0%**	

Notes

1. All states/territories contributed the data
2. All TTIs were suspected but not confirmed bacterial infection
3. STIR uses a higher level temperature threshold for the reporting of FNHTR
4. QLD uses the 2010 AHMDS for all reporting
5. In 2018-19, some states reported new adverse events in accordance with the 2015 AHMDS. Refer to individual adverse event reporting further in Section 1

Table 3: Adverse events by blood product, 2018–19

Adverse event	Red cells	Platelets	Fresh frozen plasma	Cryoprecipitate	Cryo-depleted Plasma	Multiple products	Total
FNHTR	148	17	3	1	0	0	169
Allergic	46	89	37	2	2	3	179
TACO	36	4	1	0	0	1	42
IBCT	9	1	0	1	0	0	11
Anaphylactic	10	11	7	0	0	1	29
DHTR	15	0	0	0	0	0	15
AHTR	7	4	3	1	0	0	15
TTI	3	0	0	0	0	0	3
TRALI	1	0	0	0	0	0	1
PTP	1	0	0	0	0	0	1
DSTR	16	0	0	0	0	0	16
Hypotensive	4	0	0	0	0	0	4
ABO	1	0	0	0	0	0	1
TAD	7	0	0	0	0	0	7
Other	7	0	0	0	0	0	7
Total	**311**	**126**	**51**	**5**	**2**	**5**	**500**
Percent	**62.2%**	**25.2%**	**10.2%**	**1.0%**	**0.4%**	**1.0%**	**100.0%**

Notes

1. All states/territories contributed the data
2. All TTIs were suspected but not confirmed bacterial infection
3. STIR uses a higher level temperature threshold for the reporting of FNHTR
4. QLD uses the 2010 AHMDS for all reporting
5. In 2018-19, some states reported new adverse events in accordance with the 2015 AHMDS. Refer to each adverse event reporting for details

Table 4: Adverse events by clinical outcome severity, 2018–19

Adverse event	Death	Life-threatening	Severe morbidity	Minor morbidity	No morbidity	Outcome not available	Grand Total
FNHTR	0	1	3	127	38	0	169
Allergic	0	2	6	129	42	0	179
TACO	0	11	10	19	1	1	42
IBCT	0	0	0	1	10	0	11
Anaphylactic	0	12	6	7	4	0	29
DHTR	0	0	1	11	3	0	15
AHTR	0	0	0	12	3	0	15
TTI	0	0	1	2	0	0	3
TRALI	0	0	0	0	0	1	1
PTP	0	0	0	1	0	0	1
DSTR	0	0	0	4	12	0	16
Hypotensive	0	0	0	1	3	0	4
ABO	0	0	1	0	0	0	1
TAD	0	0	0	4	3	0	7
Other	0	1	2	2	2	0	7
Total	**0**	**27**	**30**	**320**	**121**	**2**	**500**
Percent	**0.0%**	**5.4%**	**6.0%**	**64.0%**	**24.2%**	**0.4%**	**100.0%**

Notes

1. All states/territories contributed the data
2. All TTIs were suspected but not confirmed bacterial infection
3. STIR uses a higher level temperature threshold for the reporting of FNHTR
4. QLD uses the 2010 AHMDS for all reporting
5. In 2018-19, some states reported new adverse events in accordance with the 2015 AHMDS. Refer to each adverse event reporting for details

Table 5: Reported adverse events by sex, 2018–19

Adverse event	Male	Female	Not reported	Total
FNHTR	78	83	8	169
Allergic	70	69	40	179
TACO	21	19	2	42
IBCT	7	3	1	11
Anaphylactic	13	10	6	29
DHTR	7	8	0	15
AHTR	7	6	2	15
TTI	3	0	0	3
TRALI	1	0	0	1
PTP	1	0	0	1
DSTR	7	9	0	16
Hypotensive	0	3	1	4
ABO	0	1	0	1
TAD	2	3	2	7
Other	6	1	0	7
Total	**223**	**215**	**62**	**500**
Percent	**44.6%**	**43.0%**	**12.4%**	**100.0%**

Notes

1. Sex data incomplete for NSW
2. In 2018-19, some states reported new adverse events in accordance with the 2015 AHMDS. Refer to each adverse event reporting for details

Table 6: Adverse events by age and sex, 2018–19

Adverse event	Male	Female	Not reported	Total
0–4 years	2	8	3	13
5–14 years	9	9	1	19
15–24 years	15	9	2	26
25–34 years	13	15	6	34
35–44 years	10	20	5	35
45–54 years	17	31	9	57
55–64 years	29	27	9	65
65–74 years	40	35	13	88
75 years or older	88	61	8	157
Not stated	0	0	6	6
Total	**223**	**215**	**62**	**500**
Percent	**44.6%**	**43.0%**	**12.4%**	**100.0%**

Note: Sex data incomplete for NSW

Table 7: Serious adverse events by outcome severity and imputability score, 2018–19

	Death	Life-threatening	Severe morbidity	All reports	
				Total	Percent
Possible	0	6	12	18	33.3%
Likely/Probable	0	14	11	25	46.3%
Confirmed/Certain	0	7	4	11	20.4%
Total	**0**	**27**	**27**	**54**	**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

Cumulative results for 2013-14 to 2018-19

Table 8: Adverse events by state, 2014–15 to 2018–19

	2014–15	2015–16	2016–17	2017–18	2018–19	2018-19
						Percent
NSW	264	281	175	61	72	14.4%
VIC	59	54	69	57	58	11.6%
QLD	202	250	246	202	233	46.6%
SA	149	62	54	61	52	10.4%
WA	0	73	71	85	68	13.6%
TAS	1	0	5	11	0	0.0%
NT	5	3	5	2	12	2.4%
ACT	0	1	3	9	5	1.0%
Total	**680**	**724**	**628**	**488**	**500**	**100.0%**

Notes

1. ACT reported zero adverse events for 2014–15
2. TAS reported zero events for 2015–16 and 2018–19
3. WA did not contribute data for 2014–15
4. 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
5. QLD uses the 2010 AHMDS for all reporting

Table 9: Adverse events by hospital type, 2014–15 to 2018–19

Hospital type	2014–15	2015–16	2016–17	2017–18	2018–19	Total hospitals	Percent
Public hospital	646	653	588	454	429	2,770	91.7%
All private hospitals	**34**	**71**	**40**	**34**	**71**	**250**	**8.3%**
Private hospital (excludes private free standing day hospital)	29	69	40	34	48	220	7.3%
Private free-standing day hospital	5	0	0	0	23	28	0.9%
Medical and diagnostic laboratory	0	2	0	0	0	2	0.1%
Total hospitals	**680**	**724**	**628**	**488**	**500**	**3,020**	**100.0%**

Notes

1. ACT reported zero adverse events for 2014–15
2. TAS reported zero events for 2015–16 and 2018–19
3. WA did not contribute data for 2014–15
4. Only VIC, QLD and WA contributed private hospital data
5. Private hospitals include private free-standing day hospital and other private hospitals

Table 10: Australian adverse event data, 2014–15 to 2018–19

Adverse event	2014–15	2015–16	2016–17	2017–18	2018–19	All reports		Transfusion risk per unit transfused*
						Number	Percent	(unless specified)
FNHTR	380	365	304	210	169	1,428	47.3%	0.1–1% of transfusions with universal leucocyte depletion
Allergic	164	193	157	107	179	800	26.5%	1–3% of transfusion of plasma containing components
TACO	39	51	55	52	42	239	7.9%	Approximately 1% of transfused patients
IBCT	30	41	20	23	11	125	4.1%	Not available
Anaphylactic	20	30	45	20	29	144	4.8%	1:20,000–1:50,000 transfusions
DHTR	16	16	21	19	15	87	2.9%	1:2,500–1:11,000
AHTR	15	9	13	8	15	60	2.0%	1:76,000
TTI	12	17	1	15	3	48	1.6%	1:100,000 platelet transfusions
								1:500,000 red cell transfusions
TRALI	4	2	12	3	1	22	0.7%	1:1,200–1:190,000 transfusions
PTP	NA	NA	NA	1	1	2	0.1%	Rare
DSTR	NA	NA	NA	10	16	26	0.9%	NA
Hypotensive	NA	NA	NA	6	4	10	0.3%	NA
ABO	NA	NA	NA	2	1	3	0.1%	1:40,000
TAD	NA	NA	NA	NA	7	7	0.2%	NA
Other	NA	NA	NA	12	7	19	0.6%	NA
Total	**680**	**724**	**628**	**488**	**500**	**3,020**	**100.0%**	

*Australian Lifeblood (2020), Blood Component Information: An extension of blood component labels

Notes

1. ACT reported zero adverse events for 2014–15
2. TAS reported zero events for 2015–16 and 2018–19
3. WA did not contribute data for 2014–15
4. All TTIs were suspected but not confirmed bacterial infections
5. In 2018-19, some states reported new adverse events in accordance with the 2015 AHMDS. Refer to each adverse event reporting for details

Table 11: Serious Adverse events by state, 2014–15 to 2018–19

	2014–15	2015–16	2016–17	2017–18	2018–19	2018-19
						Percent
NSW	6	6	14	14	8	14.8%
VIC	23	12	32	22	24	44.4%
QLD	14	20	24	14	11	20.4%
SA	2	7	8	1	2	3.7%
WA	0	4	7	9	6	11.1%
TAS	0	0	1	1	0	0.0%
NT	0	0	0	2	0	0.0%
ACT	0	0	1	2	3	5.6%
Total	**45**	**49**	**87**	**65**	**54**	**100.0%**

Notes

1. TAS reported zero events for 2015–16 and 2018–19
2. ACT reported zero adverse events for 2014–15
3. WA did not contribute data for 2014–15
4. All TTIs were suspected but not confirmed bacterial infections
5. In 2018-19, some states reported new adverse events in accordance with the 2015 AHMDS. Refer to each adverse event reporting for details

Table 12: Serious adverse events, 2014–15 to 2018–19

	2014–15	2015–16	2016–17	2017–18	2018–19	All reports	
						Total	Percent
FNHTR	5	6	20	11	2	44	14.7%
Allergic	8	15	15	7	7	52	17.3%
TACO	13	12	19	16	21	81	27.0%
IBCT	1	1	1	0	0	3	1.0%
Anaphylactic	13	13	19	18	18	81	27.0%
DHTR	1	0	1	6	1	9	3.0%
AHTR	1	1	4	1	0	7	2.3%
TTI	1	0	0	3	1	5	1.7%
TRALI	2	1	8	2	0	13	4.3%
ABO	NA	NA	NA	1	1	2	0.7%
Other	NA	NA	NA	0	3	3	1.0%
Total	**45**	**49**	**87**	**65**	**54**	**300**	**100.0%**

Notes

1. TAS reported zero events for 2015–16 and 2018–19
2. ACT reported zero adverse events for 2014–15
3. WA did not contribute data for 2014–15
4. All TTIs were suspected but not confirmed bacterial infections
5. In 2018-19, some states reported new adverse events in accordance with the 2015 AHMDS. Refer to each adverse event reporting for details

Table 13: Serious adverse events by product, 2014–15 to 2018–19

	Red cells	Platelets	Fresh frozen plasma	Cryo-depleted plasma	Cryoprecipitate	Multiple products	Unknown	Total
FNHTR	35	7	1	0	0	1	0	44
Allergic	14	23	9	2	0	2	2	52
TACO	73	5	0	0	1	2	0	81
IBCT	3	0	0	0	0	0	0	3
Anaphylactic	15	37	26	0	2	0	1	81
DHTR	8	1	0	0	0	0	0	9
AHTR	6	1	0	0	0	0	0	7
TTI	5	0	0	0	0	0	0	5
TRALI	10	0	3	0	0	0	0	13
ABO	2	0	0	0	0	0	0	2
Other	3	0	0	0	0	0	0	3
Total	**174**	**74**	**39**	**2**	**3**	**5**	**3**	**300**
Percent	**58.0%**	**24.7%**	**13.0%**	**0.7%**	**1.0%**	**1.7%**	**1.0%**	**100.0%**

Notes

1. TAS reported zero events for 2015–16 and 2018–19
2. ACT reported zero adverse events for 2014–15
3. WA did not contribute data for 2014–15
4. All TTIs were suspected but not confirmed bacterial infections
5. In 2018-19, some states reported new adverse events in accordance with the 2015 AHMDS. Refer to each adverse event reporting for details

Table 14: Serious adverse events by transfusion time, 2014–15 to 2018–19

	2014–15	2015–16	2016–17	2017–18	2018–19	All reports	
						Total	Percent
Between 7am and 7pm	31	36	39	34	33	173	57.7%
Between 7pm and 7am	12	12	45	31	21	121	40.3%
Not reported	2	1	3	0	0	6	2.0%
Total	**45**	**49**	**87**	**65**	**54**	**300**	**100.0%**

Notes

1. ACT reported zero adverse events for 2014–15
2. TAS reported zero events for 2015–16 and 2018–19
3. WA did not contribute data for 2014–15
4. SA did not report transfusion time data for 2014–15

Table 15: Serious adverse events by week day/weekend, 2014–15 to 2018–19

	2014–15	2015–16	2016–17	2017–18	2018–19	All reports	
						Total	Percent
Week day	33	42	69	54	44	242	80.7%
Weekend	12	7	18	11	10	58	19.3%
Total	**45**	**49**	**87**	**65**	**54**	**300**	**100.0%**

Notes

1. ACT reported zero adverse events for 2014–15
2. TAS reported zero events for 2015–16 and 2018–19
3. WA did not contribute data for 2014–15

Table 16: Serious adverse events by age group, 2014–15 to 2018–19

	2014–15	2015–16	2016–17	2017–18	2018–19	All reports	
						Total	Percent
0–4 years	3	3	4	3	2	15	5.0%
5–14 years	4	4	4	5	3	20	6.7%
15–24 years	0	2	6	6	3	17	5.7%
25–34 years	3	3	6	4	1	17	5.7%
35–44 years	0	4	7	3	2	16	5.3%
45–54 years	5	5	7	5	3	25	8.3%
55–64 years	4	4	12	9	9	38	12.7%
65–74 years	14	8	20	16	10	68	22.7%
75 years or older	12	16	19	14	21	82	27.3%
Not stated	0	0	2	0	0	2	0.7%
Total	**45**	**49**	**87**	**65**	**54**	**300**	**100.0%**

Notes

1. ACT reported zero adverse events for 2014–15
2. TAS reported zero events for 2015–16 and 2018–19
3. WA did not contribute data for 2014–15

Febrile non haemolytic transfusion reaction (FNHTR)

Table 17: FNHTR data summary, 2018–19

2018–19 Data Summary (n=169)					
Age		**Sex**		**Day of Transfusion**	
0–4 years	4	Male	78	Week day	132
5–14 years	4	Female	83	Weekend	37
15–24 years	6	Uncategorised	8		
25–34 years	10	**Facility Location**		**Time of Transfusion**	
35–44 years	4	Major City	130	Between 7am and 7pm	83
45–54 years	21	Inner Regional	13	Between 7pm and 7am	84
55–64 years	23	Outer Regional	14	Not reported	2
65–74 years	33	Remote	3		
75+ years	63	Very Remote	0		
Not specified	1	Not reported	9		
Clinical Outcome Severity		**Imputability**		**Blood Component**	
Death	0	Excluded/Unlikely	32	Red cells	148
Life-threatening	1	Possible	92	Platelets	17
Severe morbidity	3	Likely/Probable	39	Fresh Frozen Plasma	3
Minor morbidity	127	Confirmed/Certain	2	Cryoprecipitate	1
No morbidity	38	Not assessable	4	Cryodepleted plasma	0
Outcome not available	0			Autologous Blood	0
				Multiple	0
				Other	0
				Not reported	0

Table 18: FNHTR clinical outcome severity by imputability, 2018–19

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	2	0	1	0	0	3
Minor morbidity	19	77	27	2	2	127
No morbidity	11	15	10	0	2	38
Outcome not available	0	0	0	0	0	0
Total	**32**	**92**	**39**	**2**	**4**	**169**

Allergic reaction

Table 19: Allergic reaction data summary, 2018–19

2018–19 Data Summary (n=179					
Age		**Sex**		**Day of Transfusion**	
0–4 years	6	Male	70	Week day	155
5–14 years	11	Female	69	Weekend	24
15–24 years	15	Uncategorised	40		
25–34 years	18	**Facility Location**		**Time of Transfusion**	
35–44 years	20	Major City	123	Between 7am and 7pm	112
45–54 years	21	Inner Regional	5	Between 7pm and 7am	63
55–64 years	21	Outer Regional	6	Not reported	4
65–74 years	30	Remote	0		
75+ years	34	Very Remote	0		
Not specified	3	Not reported	45		
Clinical Outcome Severity		**Imputability**		**Blood Component**	
Death	0	Excluded/Unlikely	9	Red cells	46
Life threatening	2	Possible	66	Platelets	89
Severe morbidity	6	Likely/Probable	94	Fresh Frozen Plasma	37
Minor morbidity	129	Confirmed/Certain	6	Cryoprecipitate	2
No morbidity	42	Not assessable	4	Cryodepleted plasma	2
Outcome not available	0			Autologous Blood	0
				Multiple	3
				Other	0
				Not reported	0

Table 20: Allergic reaction clinical outcome severity by imputability, 2018–19

Clinical Outcome Severity	Imputability					Total
	Excluded / Unlikely	Possible	Likely / Probable	Confirmed / Certain	N/A /Not assessable	
Life-threatening	0	0	2	0	0	2
Severe morbidity	1	4	1	0	0	6
Minor morbidity	5	38	78	5	3	129
No morbidity	3	24	13	1	1	42
Outcome not available	0	0	0	0	0	0
Total	**9**	**66**	**94**	**6**	**4**	**179**

Transfusion-associated circulatory overload (TACO)

Table 21: TACO data summary, 2018–19

2018–19 Data Summary (n=42)					
Age		**Sex**		**Day of Transfusion**	
0–4 years	0	Male	21	Week day	34
5–14 years	0	Female	19	Weekend	8
15–24 years	2	Uncategorised	2		
25–34 years	0	**Facility Location**		**Time of Transfusion**	
35–44 years	2	Major City	32	Between 7am and 7pm	20
45–54 years	2	Inner Regional	5	Between 7pm and 7am	22
55–64 years	4	Outer Regional	2	Not reported	0
65–74 years	10	Remote	0		
75+ years	22	Very Remote	0		
Not specified	0	Not reported	3		
Clinical Outcome Severity		**Imputability**		**Blood Component**	
Death	0	Excluded/Unlikely	1	Red cells	36
Life threatening	11	Possible	15	Platelets	4
Severe morbidity	10	Likely/Probable	22	Fresh Frozen Plasma	1
Minor morbidity	19	Confirmed/Certain	3	Cryoprecipitate	0
No morbidity	1	Not assessable	1	Cryodepleted plasma	0
Outcome not available	1			Autologous Blood	0
				Multiple	1
				Other	0
				Not reported	0

Table 22: TACO clinical outcome severity by imputability, 2018–19

Clinical Outcome Severity	Imputability					Total
	Excluded / Unlikely	Possible	Likely / Probable	Confirmed / Certain	N/A /Not assessable	
Life-threatening	0	3	7	1	0	11
Severe morbidity	0	4	6	0	0	10
Minor morbidity	1	7	9	2	0	19
No morbidity	0	1	0	0	0	1
Outcome not available	0	0	0	0	1	1
Total	**1**	**15**	**22**	**3**	**1**	**42**

Incorrect blood component transfused (IBCT)

Table 23: IBCT data summary, 2018–19

2018–19 Data Summary (n=11)					
Age		**Sex**		**Day of Transfusion**	
0–4 years	0	Male	7	Week day	10
5–14 years	0	Female	3	Weekend	1
15–24 years	0	Uncategorised	1		
25–34 years	0	**Facility Location**		**Time of Transfusion**	
35–44 years	2	Major City	6	Between 7am and 7pm	6
45–54 years	2	Inner Regional	3	Between 7pm and 7am	4
55–64 years	2	Outer Regional	1	Not reported	1
65–74 years	2	Remote	0		
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	9
Life threatening	0	Possible	0	Platelets	1
Severe morbidity	0	Likely/Probable	2	Fresh Frozen Plasma	0
Minor morbidity	1	Confirmed/Certain	4	Cryoprecipitate	1
No morbidity	10	Not assessable	4	Cryodepleted plasma	0
Outcome not available	0			Autologous Blood	0
				Multiple	0
				Other	0
				Not reported	0

Table 24: IBCT clinical outcome severity by imputability, 2018–19

Clinical Outcome Severity	Imputability					Total
	Excluded / Unlikely	Possible	Likely / Probable	Confirmed / Certain	N/A /Not assessable	
Life-threatening	0	0	0	0	0	0
Severe morbidity	0	0	0	0	0	0
Minor morbidity	0	0	0	1	0	1
No morbidity	1	0	2	3	4	10
Outcome not available	0	0	0	0	0	0
Total	**1**	**0**	**2**	**4**	**4**	**11**

Table 25: Contributory factors cited in IBCT, 2014–15 to 2018–19

Contributory Factor	2014–15	2015–16	2016–17	2017–18	2018–19
None identified	0	7	0	2	0
Product characteristic	0	1	13	10	0
*Transfusion in emergency setting	7	10	5	4	4
*Deliberate clinical decision	1	4	2	1	1
*Prescribing/ordering	6	12	13	10	4
*Specimen collection/labelling	1	0	0	1	2
*Laboratory (testing/dispensing)	15	22	10	7	6
*Transport, storage, handling	1	0	1	1	1
*Administration of product	13	8	14	16	4
*Indications do not meet guidelines	0	1	3	1	0
*Procedure did not adhere to hospital transfusion guidelines	8	14	15	16	6
Other	0	2	10	12	5

* refers to potentially avoidable human errors

Anaphylactic or anaphylactoid reaction

Table 26: Anaphylactic or anaphylactoid reaction data summary, 2018–19

2018–19 Data Summary (n=29)					
Age		**Sex**		**Day of Transfusion**	
0–4 years	1	Male	13	Week day	23
5–14 years	4	Female	10	Weekend	6
15–24 years	2	Uncategorised	6		
25–34 years	1	**Facility Location**		**Time of Transfusion**	
35–44 years	3	Major City	20	Between 7am and 7pm	14
45–54 years	4	Inner Regional	2	Between 7pm and 7am	14
55–64 years	5	Outer Regional	0	Not reported	1
65–74 years	2	Remote	0		
75+ years	5	Very Remote	0		
Not specified	2	Not reported	7		
Clinical Outcome Severity		**Imputability**		**Blood Component**	
Death	0	Excluded/Unlikely	0	Red cells	10
Life threatening	12	Possible	7	Platelets	11
Severe morbidity	6	Likely/Probable	11	Fresh Frozen Plasma	7
Minor morbidity	7	Confirmed/Certain	11	Cryoprecipitate	0
No morbidity	4	Not assessable	0	Cryodepleted plasma	0
Outcome not available	0			Autologous Blood	0
				Multiple	1
				Other	0
				Not reported	0

Table 27: Anaphylactic or anaphylactoid reaction clinical outcome severity by imputability, 2018–19

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

Delayed haemolytic transfusion reaction (DHTR)

Table 28: DHTR data summary, 2018–19

2018–19 Data Summary (n=15)					
Age		**Sex**		**Day of Transfusion**	
0–4 years	0	Male	7	Week day	13
5–14 years	0	Female	8	Weekend	2
15–24 years	0	Uncategorised	0		
25–34 years	1	**Facility Location**		**Time of Transfusion**	
35–44 years	0	Major City	11	Between 7am and 7pm	2
45–54 years	1	Inner Regional	2	Between 7pm and 7am	10
55–64 years	2	Outer Regional	0	Not reported	3
65–74 years	0	Remote	1		
75+ years	11	Very Remote	1		
Not specified	0	Not reported	0		
Clinical Outcome Severity		**Imputability**		**Blood Component**	
Death	0	Excluded/Unlikely	0	Red cells	15
Life threatening	0	Possible	6	Platelets	0
Severe morbidity	1	Likely/Probable	1	Fresh Frozen Plasma	0
Minor morbidity	11	Confirmed/Certain	8	Cryoprecipitate	0
No morbidity	3	Not assessable	0	Cryodepleted plasma	0
Outcome not available	0			Autologous Blood	0
				Multiple	0
				Other	0
				Not reported	0

Table 29: DHTR clinical outcome severity by imputability, 2018–19

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	6	1	4	0	11
No morbidity	0	0	0	3	0	3
Outcome not available	0	0	0	0	0	0
Total	**0**	**6**	**1**	**8**	**0**	**15**

Acute haemolytic transfusion reaction (AHTR)

Table 30: AHTR data summary, 2018–19

2018–19 Data Summary (n=15)					
Age		**Sex**		**Day of Transfusion**	
0–4 years	0	Male	7	Week day	13
5–14 years	0	Female	6	Weekend	2
15–24 years	0	Uncategorised	2		
25–34 years	2	**Facility Location**		**Time of Transfusion**	
35–44 years	2	Major City	10	Between 7am and 7pm	13
45–54 years	2	Inner Regional	2	Between 7pm and 7am	2
55–64 years	3	Outer Regional	0	Not reported	0
65–74 years	1	Remote	1		
75+ years	5	Very Remote	0		
Not specified	0	Not reported	2		
Clinical Outcome Severity		**Imputability**		**Blood Component**	
Death	0	Excluded/Unlikely	2	Red cells	7
Life threatening	0	Possible	7	Platelets	4
Severe morbidity	0	Likely/Probable	4	Fresh Frozen Plasma	3
Minor morbidity	12	Confirmed/Certain	2	Cryoprecipitate	1
No morbidity	3	Not assessable	0	Cryodepleted plasma	0
Outcome not available	0			Autologous Blood	0
				Multiple	0
				Other	0
				Not reported	0

Table 31: AHTR clinical outcome severity by imputability, 2018–19

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	7	3	2	0	12
No morbidity	2	0	1	0	0	3
Outcome not available	0	0	0	0	0	0
Total	**2**	**7**	**4**	**2**	**0**	**15**

Transfusion-transmitted infection (TTI)

Table 32: TTI data summary, 2018–19

2018–19 Data Summary (n=3)					
Age		**Sex**		**Day of Transfusion**	
0–4 years	0	Male	3	Week day	2
5–14 years	0	Female	0	Weekend	1
15–24 years	0	Uncategorised	0		
25–34 years	0	**Facility Location**		**Time of Transfusion**	
35–44 years	0	Major City	2	Between 7am and 7pm	0
45–54 years	0	Inner Regional	0	Between 7pm and 7am	3
55–64 years	1	Outer Regional	0	Not reported	0
65–74 years	1	Remote	0		
75+ years	1	Very Remote	0		
Not specified	0	Not reported	1		
Clinical Outcome Severity		**Imputability**		**Blood Component**	
Death	0	Excluded/Unlikely	0	Red cells	3
Life threatening	0	Possible	2	Platelets	0
Severe morbidity	1	Likely/Probable	1	Fresh Frozen Plasma	0
Minor morbidity	2	Confirmed/Certain	0	Cryoprecipitate	0
No morbidity	0	Not assessable	0	Cryodepleted plasma	0
Outcome not available	0			Autologous Blood	0
				Multiple	0
				Other	0
				Not reported	0

Table 33: TTI clinical outcome severity by imputability, 2018–19

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	1	0	0	0	**1**
Minor morbidity	0	1	1	0	0	**2**
No morbidity	0	0	0	0	0	**0**
Outcome not available	0	0	0	0	0	**0**
Total	**0**	**2**	**1**	**0**	**0**	**3**

Transfusion related acute lung injury (TRALI)

Table 34: TRALI data summary, 2018–19

2018–19 Data Summary (n=1)					
Age		**Sex**		**Day of Transfusion**	
0–4 years	0	Male	1	Week day	0
5–14 years	0	Female	0	Weekend	1
15–24 years	0	Uncategorised	0		
25–34 years	1	**Facility Location**		**Time of Transfusion**	
35–44 years	0	Major City	1	Between 7am and 7pm	1
45–54 years	0	Inner Regional	0	Between 7pm and 7am	0
55–64 years	0	Outer Regional	0	Not reported	0
65–74 years	0	Remote	0		
75+ years	0	Very Remote	0		
Not specified	0	Not reported	0		
Clinical Outcome Severity		**Imputability**		**Blood Component**	
Death	0	Excluded/Unlikely	1	Red cells	1
Life threatening	0	Possible	0	Platelets	0
Severe morbidity	0	Likely/Probable	0	Fresh Frozen Plasma	0
Minor morbidity	0	Confirmed/Certain	0	Cryoprecipitate	0
No morbidity	0	Not assessable	0	Cryodepleted plasma	0
Outcome not available	1			Autologous Blood	0
				Multiple	0
				Other	0
				Not reported	0

Table 35: TRALI clinical outcome severity by imputability, 2018–19

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

Post-transfusion purpura (PTP)

Table 36: PTP data summary, 2018–19

2018–19 Data Summary (n=1)					
Age		**Sex**		**Day of Transfusion**	
0–4 years	0	Male	1	Week day	1
5–14 years	0	Female	0	Weekend	0
15–24 years	0	Uncategorised	0		
25–34 years	0	**Facility Location**		**Time of Transfusion**	
35–44 years	0	Major City	1	Between 7am and 7pm	0
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	0		
Clinical Outcome Severity		**Imputability**		**Blood Component**	
Death	0	Excluded/Unlikely	0	Red cells	1
Life threatening	0	Possible	1	Platelets	0
Severe morbidity	0	Likely/Probable	0	Fresh Frozen Plasma	0
Minor morbidity	1	Confirmed/Certain	0	Cryoprecipitate	0
No morbidity	0	Not assessable	0	Cryodepleted plasma	0
Outcome not available	0			Autologous Blood	0
				Multiple	0
				Other	0
				Not reported	0

Table 37: PTP clinical outcome severity by imputability, 2018–19

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	1	0	0	0	1
No morbidity	0	0	0	0	0	0
Outcome not available	0	0	0	0	0	0
Total	**0**	**1**	**0**	**0**	**0**	**1**

Delayed serologic reaction (DSTR)

Table 38: DSTR data summary, 2018–19

2018–19 Data Summary (n=16)					
Age		**Sex**		**Day of Transfusion**	
0–4 years	0	Male	7	Week day	13
5–14 years	0	Female	9	Weekend	3
15–24 years	0	Uncategorised	0		
25–34 years	0	**Facility Location**		**Time of Transfusion**	
35–44 years	0	Major City	15	Between 7am and 7pm	6
45–54 years	1	Inner Regional	1	Between 7pm and 7am	5
55–64 years	3	Outer Regional	0	Not reported	5
65–74 years	5	Remote	0		
75+ years	7	Very Remote	0		
Not specified	0	Not reported	0		
Clinical Outcome Severity		**Imputability**		**Blood Component**	
Death	0	Excluded/Unlikely	0	Red cells	16
Life threatening	0	Possible	3	Platelets	0
Severe morbidity	0	Likely/Probable	2	Fresh Frozen Plasma	0
Minor morbidity	4	Confirmed/Certain	10	Cryoprecipitate	0
No morbidity	12	Not assessable	1	Cryodepleted plasma	0
Outcome not available	0			Autologous Blood	0
				Multiple	0
				Other	0
				Not reported	0

Note: WA and VIC reported DSTR in accordance with the 2015 AHMDS in 2018-19

Table 39: DSTR clinical outcome severity by imputability, 2018–19

Clinical Outcome Severity	Imputability					Total
	Excluded / Unlikely	Possible	Likely / Probable	Confirmed / Certain	N/A /Not assessable	
Life-threatening	0	0	0	0	0	0
Severe morbidity	0	0	0	0	0	0
Minor morbidity	0	0	0	4	0	4
No morbidity	0	3	2	6	1	12
Outcome not available	0	0	0	0	0	0
Total	**0**	**3**	**2**	**10**	**1**	**16**

Hypotensive transfusion reaction (Hypotensive)

Table 40: Hypotensive data summary, 2018–19

2018–19 Data Summary (n=4)					
Age		**Sex**		**Day of Transfusion**	
0–4 years	0	Male	3	Week day	2
5–14 years	0	Female	1	Weekend	2
15–24 years	0	Uncategorised	0		
25–34 years	1	**Facility Location**		**Time of Transfusion**	
35–44 years	1	Major City	2	Between 7am and 7pm	2
45–54 years	1	Inner Regional	0	Between 7pm and 7am	2
55–64 years	0	Outer Regional	0	Not reported	0
65–74 years	1	Remote	0		
75+ years	0	Very Remote	0		
Not specified	0	Not reported	2		
Clinical Outcome Severity		**Imputability**		**Blood Component**	
Death	0	Excluded/Unlikely	0	Red cells	4
Life threatening	0	Possible	3	Platelets	0
Severe morbidity	0	Likely/Probable	1	Fresh Frozen Plasma	0
Minor morbidity	1	Confirmed/Certain	0	Cryoprecipitate	0
No morbidity	3	Not assessable	0	Cryodepleted plasma	0
Outcome not available	0			Autologous Blood	0
				Multiple	0
				Other	0
				Not reported	0

Note: WA, SA and NSW reported hypotensive reaction in accordance with the 2015 AHMDS in 2018-19

Table 41: Hypotensive clinical outcome severity by imputability, 2018–19

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	1	0	0	0	1
No morbidity	0	2	1	0	0	3
Outcome not available	0	0	0	0	0	0
Total	**0**	**3**	**1**	**0**	**0**	**4**

ABO incompatibility (ABO)

Table 42: ABO data summary, 2018–19

2018–19 Data Summary (n=1)					
Age		**Sex**		**Day of Transfusion**	
0–4 years	0	Male	0	Week day	1
5–14 years	0	Female	1	Weekend	0
15–24 years	0	Uncategorised	0		
25–34 years	0	**Facility Location**		**Time of Transfusion**	
35–44 years	0	Major City	1	Between 7am and 7pm	1
45–54 years	0	Inner Regional	0	Between 7pm and 7am	0
55–64 years	0	Outer Regional	0	Not reported	0
65–74 years	0	Remote	0		
75+ years	1	Very Remote	0		
Not specified	0	Not reported	0		
Clinical Outcome Severity		**Imputability**		**Blood Component**	
Death	0	Excluded/Unlikely	0	Red cells	1
Life threatening	0	Possible	0	Platelets	0
Severe morbidity	1	Likely/Probable	0	Fresh Frozen Plasma	0
Minor morbidity	0	Confirmed/Certain	1	Cryoprecipitate	0
No morbidity	0	Not assessable	0	Cryodepleted plasma	0
Outcome not available	0			Autologous Blood	0
				Multiple	0
				Other	0
				Not reported	0

Note: SA reported ABO incompatibility in accordance with the 2015 AHMDS in 2018-19

Table 43: ABO clinical outcome severity by imputability, 2018–19

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	0	0	0	0	0
No morbidity	0	0	0	0	0	0
Outcome not available	0	0	0	0	0	0
Total	**0**	**0**	**0**	**1**	**0**	**1**

Transfusion associated dyspnoea (TAD)

Table 44: ABO data summary, 2018–19

2018–19 Data Summary (n=7)					
Age		**Sex**		**Day of Transfusion**	
0–4 years	0	Male	2	Week day	5
5–14 years	0	Female	3	Weekend	2
15–24 years	0	Uncategorised	2		
25–34 years	0	**Facility Location**		**Time of Transfusion**	
35–44 years	1	Major City	5	Between 7am and 7pm	5
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	3	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	7
Life threatening	0	Possible	5	Platelets	0
Severe morbidity	4	Likely/Probable	2	Fresh Frozen Plasma	0
Minor morbidity	3	Confirmed/Certain	0	Cryoprecipitate	0
No morbidity	0	Not assessable	0	Cryodepleted plasma	0
Outcome not available	0			Autologous Blood	0
				Multiple	0
				Other	0
				Not reported	0

Note: NSW, WA, and SA reported TAD in accordance with the 2015AHMDS in 2018-19

Table 45: TAD clinical outcome severity by imputability, 2018–19

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	1	0	0	4
Minor morbidity	0	2	1	0	0	3
No morbidity	0	0	0	0	0	0
Outcome not available	0	0	0	0	0	0
Total	**0**	**5**	**2**	**0**	**0**	**7**

Other adverse events

Table 46: Other data summary, 2018–19

2018–19 Data Summary (n=7)					
Age		**Sex**		**Day of Transfusion**	
0–4 years	2	Male	6	Week day	6
5–14 years	0	Female	1	Weekend	1
15–24 years	1	Uncategorised	0		
25–34 years	0	**Facility Location**		**Time of Transfusion**	
35–44 years	0	Major City	6	Between 7am and 7pm	4
45–54 years	1	Inner Regional	1	Between 7pm and 7am	3
55–64 years	0	Outer Regional	0	Not reported	0
65–74 years	0	Remote	0		
75+ years	3	Very Remote	0		
Not specified	0	Not reported	0		
Clinical Outcome Severity		**Imputability**		**Blood Component**	
Death	0	Excluded/Unlikely	0	Red cells	7
Life threatening	1	Possible	5	Platelets	0
Severe morbidity	2	Likely/Probable	1	Fresh Frozen Plasma	0
Minor morbidity	2	Confirmed/Certain	0	Cryoprecipitate	0
No morbidity	2	Not assessable	1	Cryodepleted plasma	0
Outcome not available	0			Autologous Blood	0
				Multiple	0
				Other	0
				Not reported	0

Note: WA, SA and VIC reported "other" adverse events in accordance with the 2015 AHMDS in 2018-19

Table 47: Other clinical outcome severity by imputability, 2018–19

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

Contributory factors

Table 48: Contributory factors data summary, 2018–19

Summary Data	
Contributory Factors	Number of reports
None identified	245
Product characteristic	182
*Transfusion in emergency setting	19
*Deliberate clinical decision	40
*Prescribing/ordering	5
*Specimen collection/labelling	3
*Laboratory (testing/dispensing)	9
*Transport, storage, handling	1
*Administration of product	10
*Indications do not meet guidelines	5
*Procedure did not adhere to hospital transfusion guidelines	9
Other	48

* refers to potentially avoidable human errors

Table 49: Contributory factors cited by adverse event and by clinical outcome severity, 2018–19

Contributory Factors	Adverse event															Clinical outcome severity					
	FNHTR	Allergic	TACO	IBCT	TTI Bacterial	Anaphylactic	DHTR	AHTR	TRALI	PTP	DSTR	Hypotensive	ABO	TAD	Other	Outcome not available	No morbidity	Minor morbidity	Severe morbidity	Life-threatening	Death
None identified	114	67	25	0	0	6	3	10	1	0	10	2	0	5	2	1	50	179	9	6	0
Product characteristic	31	102	6	0	1	21	4	3	0	0	6	2	0	2	4	1	54	100	12	15	0
*Transfusion in emergency setting	1	5	2	4	0	0	3	0	0	1	2	0	0	0	1	0	5	10	2	2	0
*Deliberate clinical decision	10	14	4	1	0	4	1	0	0	0	2	1	0	1	2	0	3	30	3	4	0
*Prescribing/ordering	0	0	1	4	0	0	0	0	0	0	0	0	0	0	0	0	4	0	0	1	0
*Specimen collection/labelling	0	0	0	2	0	0	1	0	0	0	0	0	0	0	0	0	2	1	0	0	0
*Laboratory (testing/dispensing)	0	0	0	6	0	0	1	0	0	0	0	0	1	0	1	0	7	1	1	0	0
*Transport, storage, handling	0	0		1	0	0	0	0	0	0	0	0	0	0	0	0	1	0	0	0	0
*Administration of product	3	0	2	4	0	0	1	0	0	0	0	0	0	0	0	0	4	4	1	1	0
*Indications do not meet guidelines	0	2	0	0	0	2	0	0	0	0	1	0	0	0	0	0	1	2	0	2	0
*Procedure did not adhere to hospital transfusion guidelines	0	1	1	6	1	0	0	0	0	0	0	0	0	0	0	0	6	2	1	0	0
Other	21	11	3	5	1	3	2	1	0	0	0	0	0	0	1	0	8	32	4	4	0

* refers to potentially avoidable human errors

Notes

1. In 2018-19, some states reported new adverse events in accordance with the 2015 AHMDS. Refer to each adverse event reporting for details

SECTION 2

Donor vigilance data

July 2018 - June 2019

Whilst blood donation is generally a safe process, there are recognised complications which can occur. Lifeblood's donor vigilance system monitors adverse events in blood donors that have a temporal relationship to blood donation. The system underpins Lifeblood's comprehensive and continuous improvement approach to the mitigation and management of donor adverse events to improve donor safety and experience and is integral to Lifeblood's Clinical and Quality Governance Framework (See Appendix 1 - Current policies and interventions to minimise the risk of donor adverse events).

Method for Reporting Donor Adverse Events

Reporting Period

This report provides donor adverse event rates for the 2018-19 financial year (FY) along with comparative data from the three previous years. The method of collecting donor adverse event data continues to evolve to improve reporting robustness and access to real-time data. As such, data presented in this report may not be consistent with data presented in previous reports. The data in this report is accurate as at 14 September 2019.

A whole blood donation involves the collection of approximately 500mL of blood which takes an average of 8-9 minutes[1] from when the needle is inserted. This donation process does not involve the return of any blood components back to the donor.

The donation of plasma and/or platelet components is by apheresis and involves the use of a cell-separating machine. The machine draws blood from the donor and mixes it with anticoagulant (citrate) solution to prevent clotting. It then separates out the plasma and/or platelets and returns the remainder of the blood (which includes the donor's red cells), along with a small amount of anticoagulant solution, to the donor. This cycle is repeated until the target collection volume is reached. Plasmapheresis is associated with larger collection volumes than plateletpheresis and as an additional safety measure, plasmapheresis donors receive 500mL of saline solution through the donation needle at the middle and/or end of the donation. A plasmapheresis donation takes an average of approximately 41 minutes[2] and a plateletpheresis donation, 73 minutes[3]. Since 2015-16, plateletpheresis donations have been predominantly collected from male donors as a risk mitigation strategy for transfusion-related acute lung injury (TRALI).

[1] Based on minimum collection of 450mL for males and females
[2] Based on minimum collection volume of 422mL for females and 488mL for males excluding anticoagulant
[3] Based on collection of double-dose platelet
[1,2,3] Collection times are based on data from FY 2015/16 to 2018/19

Donor Adverse Event Categories

Donor adverse events are categorised into the following four categories:

Vasovagal reactions

Donors may feel faint and experience symptoms such as dizziness, light-headedness and nausea. In some cases the donor may faint (lose consciousness). These symptoms may be triggered by anxiety or pain and/or occur as a result of the reduction in blood volume. In many cases when donors feel faint or faint, there are multiple contributing factors.

Phlebotomy related injury

These refer to the complications that can arise from having a needle inserted. These include bleeding or bruising (haematoma) which may result from incorrect placement or dislodgment of the needle from the vein, piercing of an artery (arterial puncture), irritation or damage to a nerve (nerve injury), infection (cellulitis) or inflammation (phlebitis) which may be associated with clot formation (thrombophlebitis).

Apheresis specific events

These events relate to exposure to citrate, the return of red cells, the administration of saline solution and apheresis machine/process issues. Citrate binds calcium temporarily reducing calcium levels in the blood which can cause symptoms such as tingling around the mouth, a metallic taste in the mouth or altered sensation of hands and feet. Leakage of blood and/or saline solution into the tissues may occur during a return cycle (infiltration/extravasation) and lead to swelling and bruising in the arm and in very rare circumstances compartment syndrome.

Donation procedures and machine safety features minimise the risk of machine issues and operator error. Machine or process issues can result in damage to the donor's red cells (haemolysis), air entering the line or insufficient administration of anticoagulant, which may lead to a donor adverse event. Should this occur, processes are in place to manage and refer donors accordingly and investigate the root cause.

Other category

This captures all other events that occur within 24 hours of the donation including allergic reactions, chest pain and major thrombotic events. In these cases, an assessment is made as to the imputability of the donation as the cause.

Denominator Cohort

The denominator cohort used to calculate donor adverse event rates are those attendances that progress to a donation attempt and have a needle inserted, regardless of whether the target collection volume was achieved. The number of donations that make up the denominator cohort for FY 2015-16 to 2018-19 are provided in Table 50. Of note, FY 2018-19 is the first year that plasmapheresis donations have exceeded whole blood. Table 51 provides an overview of the donor demographic for FY 2018-19.

Table 50: Number of donations in the denominator cohort for FY 2015-16 to 2018-19

Donation Type	2015-16	2016-17	2017-18	2018-19
Whole Blood	724,988	712,808	700,546	703,986
Plasmapheresis	553,007	579,178	646,488	745,666
Plateletpheresis	31,807	32,337	27,782	29,127
Total	1,309,802	1,324,323	1,374,816	1,478,779

Table 51: Donor demographics by donation category for FY 2018-19

Donation Type	Number of Donations	% of Total Donations	Females		Males	
			% of donations	Mean age (years)	% of donations	Mean age (years)
Whole Blood	703,986	47.61	49.40	42.17	50.60	46.03
Plasmapheresis	745,666	50.42	42.07	42.97	57.93	46.12
Plateletpheresis	29,127	1.97	0.50	51.59	99.50	45.08
Total	1,478,779	100.00	44.74	42.55	55.26	46.04

Donor Adverse Events

Donor Adverse Events by Donation Category

An overview of the donor adverse event rates applicable across all donation categories are provided in Table 52. The rates for apheresis-specific donor adverse events are provided in Table 53.

Whole blood

Whole blood donations have lower rates of phlebotomy-related events but have a significantly higher rate of vasovagal reactions (210.59 per 10,000 donations) compared with plasma (123.42 per 10,000 donations; RR: 1.71, 95% CI 1.66-1.75; p<0.0001) and platelets (133.55 per 10,000 donations; RR: 1.58, 95% CI 1.43-1.74; p <0.0001). This is attributed to the higher proportion of first time (new) blood donors in this group. Approximately 20% and 14% of whole blood donations are made by new female and male donors respectively, compared with plasmapheresis where 12.1% and 6.9% of donations are made by female and male donors respectively who have not previously donated plasma, noting that one third of these were new donors and therefore had not made a prior whole blood donation.

Apheresis

The higher rate of phlebotomy-related events in apheresis donations compared with whole blood relates to the longer collection time, the use of citrate anticoagulant, the return of red cells and the delivery of saline solution. A higher rate of haematomas and painful arm are observed in plateletpheresis compared with plasmapheresis and is postulated to be the result of the longer collection time and a higher dose of citrate anti-coagulant. The higher rate of citrate reactions in plateletpheresis is related to the higher dose of citrate delivered during plateletpheresis compared with plasmapheresis. All plateletpheresis and plasmapheresis donors are offered calcium supplements prior to their donation with the aim of reducing the likelihood of a citrate reaction. Of note, approximately 94% of all citrate reactions are mild and most cases are managed using simple measures such as reducing return flow rates and calcium supplements.

Table 52: Donor adverse event rates per 10,000 donations by donation type for FY 2018-19

Event type	Whole Blood n=703,986		Plasmapheresis n=745,666		Plateletpheresis n=29,127		Total n=1,478,779	
	n	Rate	n	Rate	n	Rate	n	Rate
Vasovagal events	14,825	210.59	9,203	123.42	389	133.55	24,417	165.12
Phlebotomy Related								
Arterial Puncture	24	0.34	18	0.24	0	0.00	42	0.28
Cellulitis	7	0.1	3	0.04	0	0.00	10	0.07
Delayed Bleeding	132	1.88	520	6.97	5	1.72	657	4.44
Haematoma	4,026	57.19	7,477	100.27	1,140	391.39	12,643	85.50
Nerve Injury/Irritation	538	7.64	538	7.22	17	5.84	1093	7.39
Other injury	39	0.55	79	1.06	7	2.4	125	0.85
Painful arm^	1,435	20.38	2,592	34.76	141	48.41	4,168	28.19
Thrombophlebitis	22	0.31	28	0.38	1	0.34	51	0.34
Other Event Type								
Anaphylaxis	2	0.03	1	0.01	0	0.00	3	0.02
Chest Pain	44	0.63	62	0.83	2	0.69	108	0.73
Local Allergic Reaction	350	4.97	507	6.80	9	3.09	866	5.86
Other event/injury	132	1.88	209	2.80	15	5.15	356	2.41

Table 53: Specific apheresis-related donor adverse event rates per 10,000 donations for FY 2018-19

Event type	Plasmapheresis n=745,666		Plateletpheresis n=29,127		Total n=774,793	
	n	Rate	n	Rate	n	Rate
Citrate Reaction	4,278	57.37	1,521	522.20	5,799	74.85
Haemolysis*	0	0.00	0	0.00	0	0.00
Infiltration/extravasation	559	7.50	69	23.69	628	8.11
Omitted Anticoagulant*	0	0.00	0	0.00	0	0.00

*An event is not recorded if the issue is detected and the donation stopped before cells are returned to the donor.

Trends over the 2015-16 to 2018-19 period

Donor adverse event rates have been influenced by several factors over the last four years. These include the impact of new mitigation strategies, changing donor demographics including the extent of previous donation experience, expanding donor adverse event categories to include the reporting of additional minor events and an increasing internal focus on donor adverse event reporting. Table 54 provides total donor adverse event rates by donation type. A donation may be associated with more than one type of adverse event. The total rate for the year will only include a donation once even if more than one event was reported for that donation.

Table 54: Total donor adverse event rates per 10,000 donations for FY 2015-16 to 2018-19

Donation Type	2015-16	2016-17	2017-18	2018-19
Whole Blood	317.08	310.57	299.05	297.09
Plasmapheresis	199.09	188.89	261.60	324.13
Plateletpheresis	802.65	753.63	976.17	1,047.14
Total	279.06	268.17	295.12	325.50

Whole blood

With respect to whole blood donations, total donor adverse event rates are significantly reduced in the 2018-19 FY compared with 2015-16 FY (297.09 vs 317.08 pre-10,000 donations; Relative Risk (RR): 0.94; 95% CI 0.92-0.95; p<0.0001). This is primarily a result of the decrease in vasovagal reactions (210.59 vs 292.45 per 10,000 donations: RR: 0.72; 95% CI:0.71-0.74; p<0.0001) which is the result of the introduction of in-centre pre-donation water loading (500mL) and use of applied muscle tension exercises during key points in the collection process.

Apheresis

There has been an increase in the overall reported rate of donor adverse events observed in both plasmapheresis and plateletpheresis collections over the four-year period. This is a result of the increase in vasovagal and phlebotomy injury rates. Vasovagal reactions have increased from 99.93 per 10,000 in 2016-17 FY to 123.42 per 10,000 in 2018-19 FY (RR: 1.24; 95% CI: 1.20-1.28; p<0.0001). This is suspected to be due to an increase in less experienced donors entering the plasma pool. Prior to December 2017, all donors were required to make a whole blood donation prior to a plasmapheresis donation. Whilst the proportion of donations made by first-time plasma donors has been similar over the last three FY periods (8.8, 8.9 and 9.1% for FY 2016-17 , 2017-18 and 2018-19 respectively), since December 2017 this first-time plasma cohort has constituted an increasing proportion of new donors who have not previously made a whole blood donation. In 2017-18, 19% of plasmapheresis donations made by first time plasma donors, were made by donors making their first donation compared with 33.8% in 2018-19 FY.

Rates of phlebotomy-related injuries have increased across all donation categories over the last two financial years (Table 55). One major contributing factor is the change to haematoma reporting introduced in 2017 that required all haematomas regardless of size to be reported, where previously only haematomas greater than 5cm were reported. As the change was implemented in September 2017, the full effect was not fully realised in the 2017-18 period, and accounts for some of the increase in the 2018-19 FY, which is the first full year of reporting. The limitations of the database do not permit a detailed analysis to determine if the increase is fully accounted for by haematomas less than 5cm.

The haematoma reporting change has coincided with significant increases in rates of painful arm (without haematoma or nerve injury) in all donation categories and in infiltration/extravasation and delayed bleeding in apheresis donations. This is considered to largely be due to improved reporting compliance as a result of heightened awareness by staff to report phlebotomy related trauma, associated with the reporting change to haematomas. It is relevant to note that there has been no change in the whole blood collection procedure, nor have there been change to the apheresis procedures in this period which would account for these increases. Of note, Lifeblood commenced the roll-out of a new plasmapheresis collection platform (Fresenius Aurora) on 20 May 2019. In the 2018-19 FY, 4,982 plasma donations were collected on the Aurora, accounting for approximately 0.7% of the total plasmapheresis collections for the year. Whilst the reported rates of some phlebotomy-related events have increased, the rate of sustaining one or more phlebotomy-related event (including a haematoma less than 5cm) in the 2018-19 FY is less than 1%, 2% and 5% for whole blood, plasmapheresis and plateletpheresis collections respectively.

Table 55: Phlebotomy-related injury rate per 10,000 donations for FY 2015-16 to 2018-19

	FY 2015-16		FY 2016-17		FY 2017-18		FY 2018-19		Comparison 18/19 with 15/16	
Whole Blood	**n**	**Rate**	**n**	**Rate**	**n**	**Rate**	**n**	**Rate**	**Relative Risk (95% CI)**	**P value**
Haematoma	903	12.46	925	12.98	2,530	36.11	4,026	57.19	1.58; (1.51-1.66)	<0.0001
Painful arm	620	8.55	727	10.20	919	13.12	1435	20.38	1.55; (1.43-1.69)	<0.0001
Plasmapheresis	**n**	**Rate**	**n**	**Rate**	**n**	**Rate**	**n**	**Rate**	**Relative Risk (95% CI)**	**P value**
Infiltration	119	2.15	129	2.23	277	4.28	559	7.5	1.75; (1.52-2.02)	<0.0001
Delayed Bleeding	77	1.39	76	1.31	232	3.59	520	6.97	1.94; (1.66-2.27)	<0.0001
Haematoma	829	14.99	809	13.97	4,277	66.16	7,477	100.27	1.52; (1.46-1.57)	<0.0001
Painful arm	594	10.74	594	10.26	1,228	18.99	2,592	34.76	1.83; (1.71-1.96)	<0.0001
Plateletpheresis	**n**	**Rate**	**n**	**Rate**	**n**	**Rate**	**n**	**Rate**	**Relative Risk (95% CI)**	**P value**
Infiltration	28	8.80	18	5.57	23	8.28	69	23.69	2.86; (1.79-4.56)	<0.0001
Haematoma	178	55.96	191	59.07	846	304.51	1,140	391.39	1.29; (1.18-1.40)	<0.0001
Painful arm	49	15.41	35	10.82	59	21.24	141	48.41	2.28; (1.68-3.09)	<0.0001

Vasovagal events

Vasovagal events are the most common donor adverse event if considered across all donation categories. The overall rate of vasovagal events across all donation categories for the FY 2018-19 was 165.12 per 10,000 donations (Table 52). Table 56 provides rates of vasovagal events by location and if associated with loss of consciousness and/or injury. Approximately 90% of vasovagal reactions occurred on-site. Events occurring on-site were less likely to be associated with loss of consciousness (6.9% vs 16.8%; RR: 0.41; 95% CI 0.37- 0.45; p<0.0001) and those sustaining loss of consciousness, had a lower rate of injury if the event occurred on-site (2.32% vs 11.26%; RR: 0.21; 95% CI 0.14-0.31; p<0.0001). In 2018-19 there were 79 reports (0.52 per 10,000 donations) of vasovagal reactions occurring whilst driving. Two motor vehicle accidents were reported in association with these events.

Whilst donors are encouraged to report adverse events that occur after leaving the donor centre, it is likely that minor off-site events are under-reported. Figures may therefore overstate both the proportion of events that occur on-site and the association between off-site events and loss of consciousness and/or injury

Table 56: Vasovagal events per 10,000 donations* by donation category for FY 2018-19

Event			Whole Blood n=703,986		Plasmapheresis n=745,666		Plateletpheresis n=29,127		Total n= 1,478,779	
			n	Rate	n	Rate	n	Rate	n	Rate
On-site vasovagal reaction	Without LOC	No injury	12,289	174.56	7,737	103.76	351	120.51	20,377	137.80
		Injury	1	0.01	1	0.01	0	0	2	0.01
	With LOC	No injury	846	12.02	609	8.17	18	6.18	1473	9.96
		Injury	27	0.38	8	0.11	0	0	35	0.24
	Total		**13,157**	**186.89**	**8,345**	**111.91**	**369**	**126.69**	**21,871**	**147.90**
Off-site vasovagal reaction	Without LOC	No injury	1392	19.77	831	11.14	20	6.87	2243	15.17
		Injury	3	0.04	2	0.03	0	0.00	5	0.03
	With LOC	No injury	311	4.42	91	1.22	0	0.00	402	2.72
		Injury	40	0.57	10	0.13	1	0.34	51	0.34
	Total		**1,745**	**24.79**	**933**	**12.51**	**21**	**7.21**	**2,699**	**18.25**

* A single donation can be associated with more than one vasovagal event. This table captures each vasovagal event separately. The total vasovagal events in this table therefore exceeds the total vasovagal events in Table 52, which in comparison reports the number of donations associated with at least one vasovagal event.

Table 57 demonstrates that in terms of severe vasovagal events, there has been a significant overall reduction over time in vasovagal events associated with loss of consciousness that is attributed to whole blood donors. Given that a vasovagal event associated with loss of consciousness is more likely to be associated with injury than a vasovagal without loss of consciousness, this is an important donor safety reduction to note over time.

Table 57: Vasovagal events associated with loss of consciousness per 10,000 donations by donation category for FY 2015-16 to 2018-19

Donation Category	FY 2015-16		FY 2016-17		FY 2017-18		FY 2018-19		Comparison 18/19 with 15/16	
	n	Rate	n	Rate	n	Rate	n	Rate	Relative Risk (95% CI)	P value
Whole Blood	1742	24.03	1633	22.91	1384	19.76	1224	17.39	0.72 (0.67-0.78)	<0.0001
Plasmapheresis	410	7.41	415	7.17	543	8.40	718	9.63	1.30 (1.15-1.47)	<0.0001
Plateletpheresis	28	8.80	13	4.02	19	6.84	19	6.52	0.74(0.41-1.33)	0.3136
Total	2180	16.64	2061	15.56	1946	14.15	1961	13.26	0.80 (0.75-0.85)	<0.0001

Vasovagal rates and donor experience

Significantly lower rates of vasovagal are observed in both male and female returning donors compared with new donors. The effect is observed in both whole blood and plasmapheresis and is greatest in males. The risk of a vasovagal event occurring in a returning donor is less because returning donors become increasingly familiar with the process and relevant mitigation strategies and new donors who experience a reaction on the first visit (and who are potentially more prone to future vasovagal events) are less likely to return, or if the reaction is severe, they are deferred from further donation.

The relative risk of a new whole blood donor having a vasovagal reaction compared with a returning whole blood donor is 3.61 and 6.98 for females and males respectively (Table 58).

The relative risk of a new plasma donor who has made a previous whole blood donation having a vasovagal reaction compared with a returning plasma donor is 6.37 for females and 12.96 for males (Table 59).

From December 2017, donors were no longer required to make a whole blood donor prior to donating plasma. In 2018-2019, the excess risk of a new donor who is donating plasma having a vasovagal reaction is 2.93% for females and 1.74% for males compared to first time whole blood donors. This is not unexpected given a first-time plasma donor who has previously donated whole blood has a higher rate of a vasovagal reaction than an experienced plasma donor.

Table 58: Vasovagal rates in new and returned female and male whole blood donors for FY 2018-2019

Returned or first donation	Females			Males		
	Vasovagal events (n)	Donations (n)	%	Vasovagal events (n)	Donations (n)	%
Whole blood returned	5,454	279,278	1.95	2,123	306,001	0.69
Whole blood first donation	4,817	68,486	7.03	2,431	50,221	4.84
Relative Risk (95% CI); p value First vs returned whole blood	3.61 (3.47-3.74); p <0.0001			6.98 (6.59-7.39); p <0.0001		

Table 59: Vasovagal rates in new and returned female and male plasma donors for FY 2018-2019

Returned, first plasma or first donation	Females			Males		
	Vasovagal events (n)	Donations (n)	%	Vasovagal events (n)	Donations (n)	%
Returned, previous plasma	3,228	275,723	1.17	1,316	402,056	0.33
First plasma, at least one previous whole blood	1,899	25,454	7.46	826	19,472	4.24
First plasma, no previous donations	1,246	12,512	9.96	688	10,449	6.58
Relative Risk (95% CI); p value						
First plasma no previous vs at least one whole blood	1.33 (1.25-1.43); p<0.0001			1.55 (1.41-1.71); p<0.0001		
First plasma, previous whole blood vs returned	6.37 (6.03-6.73); p <0.0001			12.96 (11.89-14.12); p <0.0001		
First plasma, no previous donations vs returned	8.51 (7.99-9.06); p <0.0001			20.12 (18.38-22.01); p<0.0001		

Vasovagal rates, gender and age

The relative risk of a vasovagal reduces with age in both males and females (Tables 60 and 61). Females and males aged 18-20 years have a relative risk of 3.36 and 4.61 respectively, compared with other donors in their gender cohort. A significant proportion of this increase is attributed to donor experience with younger donors being more likely to be first time or less experienced donors. The rates of vasovagal reactions are higher in females. Females aged 18-20 have a relative risk of 1.89 (95% CI 1.76-2.03) compared with males of the same age.

Table 60: Rates and relative risk for vasovagal events in females for all donation categories by age for 2018-19

Age	DAE (n)	Donations^ (n)	%	Relative Risk+	Confidence Intervals (95%)
18-20*	2,659	35,414	7.51	3.36	3.23-3.50
21-23	2,179	44,780	4.87	2.07	1.99-2.17
24-30	4,164	116,753	3.57	1.56	1.50-1.61
31-40	2,893	120,109	2.41	0.95	0.91-0.99
41-50	1,878	115,768	1.62	0.60	0.57-0.63
51-60	1,633	122,559	1.33	0.48	0.45-0.50
61-70	1,113	90,482	1.23	0.45	0.43—0.48
71+	126	15,732	0.80	0.31	0.26-0.37
Total^	**16,645**	**661,597**	**2.52**		

+ Risk compared to all other female donors
* The minimum age for blood donation is 18 years. Therapeutic donors are accepted from 16 years. In the 18-20 age group, eight donations were collected from donors aged 16-17.
^ One collection has been excluded as an age was not recorded.

Table 61: Rates and relative risk for vasovagal events in males for all donation categories by age for 2018-19

Age	DAE (n)	Donations^ (n)	%	Relative Risk+	Confidence Intervals (95%)
18-20*	967	24,392	3.96	4.61	4.32-4.93
21-23	882	35,046	2.52	2.86	2.67-3.06
24-30	2,081	110,659	1.88	2.33	2.22-2.45
31-40	1,886	149,302	1.26	1.43	1.36-1.51
41-50	913	147,516	0.62	0.60	0.56-0.65
51-60	581	176,945	0.33	0.29	0.27-0.32
61-70	410	143,022	0.29	0.26	0.24-0.29
71+	52	30,299	0.17	0.17	0.13-0.23
Total	**7,772**	**817,181**	**0.95**		

Events requiring external referral

Hospital attendance rates have remained relatively stable over the last two financial periods for all donation categories (Table 62). In 2018-19, there were 424 donor adverse events (2.87 per 10,000 donations) that were associated with a hospital attendance. Vasovagal reactions continue to remain the single most common event associated with a hospital attendance; approximately 91% and 75% of whole blood and plasmapheresis events respectively. In the 2018-19 FY, 100 events required an ambulance to attend the donor centre but did not require hospital transfer, and 679 events (4.59 per 10,000 donations) were associated with an attendance at the donor's general practitioner (GP) (Table 63).

Table 62: Donor adverse events requiring hospital attendance (per 10,000 donations), FY 2015-16 to 2018-19

Donation Type	2015-16		2016-17		2017-18		2018-19	
	n	Rate	*n*	Rate	*n*	Rate	*n*	Rate
Whole Blood	296	4.08	239	3.35	252	3.60	242	3.44
Plasmapheresis	109	1.97	112	1.93	152	2.35	175	2.35
Plateletpheresis	14	4.40	5	1.55	6	2.16	7	2.40
All Apheresis	123	2.10	117	1.91	158	2.34	182	2.35
Total	**419**	**3.2**	**356**	**2.69**	**410**	**2.98**	**424**	**2.87**

Table 63: Donor adverse events requiring external care (rates per 10,000 donations) for FY 2018-19

Donation type	GP attendance*		Ambulance attendance^		Hospital attendance*		Total	
	n	Rate	*n*	Rate	*n*	Rate	*n*	Rate
Whole Blood	371	5.27	63	0.89	242	3.44	676	9.60
Plasmapheresis	298	4.00	37	0.50	175	2.35	510	6.84
Plateletpheresis	10	3.43	0	0.00	7	2.40	17	5.84
Total	**679**	**4.59**	**100**	**0.68**	**424**	**2.87**	**1,203**	**8.14**

*Initiated by Lifeblood or donor.

^Attendance by ambulance not requiring transfer to hospital.

Conclusion

Over the course of the last four financial periods, donor adverse event rates have been influenced by new mitigation strategies, reporting requirements, the changing profile of donors and the increasing proportion of plasma to whole blood donations.

Vasovagal rates are the most common adverse event. These events are more likely to occur in females, younger donors and donors who are new to whole blood or new to plasmapheresis. The reduced rate of vasovagal reactions seen in whole blood over the last few years is related to the introduction of water loading and applied muscle tension exercises. The increased vasovagal rate seen in plasmapheresis is likely to be related to the increasing proportion of collections from relatively inexperienced donors.

Reported rates of phlebotomy-related injury have increased significantly over the last two financial years and is primarily the result of the reporting change in September 2017 which required that all haematomas, regardless of size, were reported, together with staff hypervigilance which has resulted in the reporting of more minor events.

There has been no change in the whole blood collection or apheresis procedures in this period, nor have there been significant changes to the staffing model or other environmental factors which would account for these increases.

In addition hospital attendance rates have remained relatively stable over the last two financial periods for all donation categories and vasovagal events associated with loss of consciousness, where injury is more likely to occur, have significantly decreased over time.

The Lifeblood donor vigilance system continues to evolve to improve the robustness and translation of adverse event data and serves to underpin our continuous improvement approach to mitigate donor adverse events and ensure the blood donation process is as safe as possible. The data will continue to inform research, guide targeted interventions and support process evaluation.

APPENDIXES

Appendix 1: Current policies and interventions to minimise the risk of donor adverse events

Donor assessment	The donor assessment process includes questionnaire, interview and physical checks to assess a donor's eligibility for donation. The process includes identifying previous donation-related events and medical history that may preclude donation and ensures that donors meet minimum criteria for age, weight and donation intervals: – Minimum age for whole blood and apheresis is 18 years (2018) – Weight limit 50kg for all donation categories (2015) – Physical checks ▪ Blood Pressure (all donors on each attendance) ▪ Pulse (apheresis donors) ▪ Haemoglobin screening test (all donors on each attendance)
Donor information and awareness	Several platforms are used to deliver information regarding: – Pre-donation strategies including pre-arrival hydration, in-centre water loading for whole blood donors and calcium supplementation for apheresis donors – Use of applied muscle tension exercises – Post-donation strategies including onsite recovery time, hydration and avoidance measures
Donation selection and process	All donors: – Assessment of veins prior to phlebotomy attempt Plasmapheresis: – Incremental increase in collection volume based on donor height and weight to maximum of 16% total blood volume capped at 800mL. – Saline replacement of 500mL Plateletpheresis: – Minimum platelet count required to proceed with collection
Management of donors with adverse events	Procedures and training support teams to identify and manage donor adverse events. Onsite care includes: – Administration of oral calcium for citrate reactions – Provision of advice cards to donors to support after-care – Observation period for donors who sustain vasovagal reactions. Those with prolonged recovery times are referred to hospital for ongoing care and evaluation. After-donation care includes: – 24-hour access to Lifeblood Medical Officer – Contacting donors who sustain a significant event to assess clinical outcome, contributory factors and suitability for future donations and if eligible, providing advice to minimise risk of future events. – Reducing collection volume for apheresis donors who are suitable to continue donating – Where the event is severe or recurrent, the donor is permanently deferred.
Clinical Governance	Lifeblood has a Clinical and Quality Governance Framework that supports the provision of a safe, high quality service that works to monitor, mitigate and manage donor adverse events, including: – Data monitoring and reporting to executive committees – Clinical audits – Continuous improvement and corrective action processes – International benchmarking

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
DAE	Donor adverse event
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
NBMS	National Blood Management System
NDDP	New donors direct to plasma
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
WB	Whole blood

ACKNOWLEDGEMENTS LIST

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Mr Brett Aitken	Australian Private Hospitals Association
Associate Professor Lilon Bandler	NBA Patient Blood Management Advisory Committee Chair
Mr Geoffrey Bartle	Consumer Representative
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VIC Department of Health and Human Services Blood Matters Program
QLD Health
SA Health BloodSafe Program
WA Department of Health
TAS Department of Health and Human Services
ACT Health
NT Department of Health

SECTION 2 – DONOR VIGILANCE was contributed by the Australian Red Cross Lifeblood.