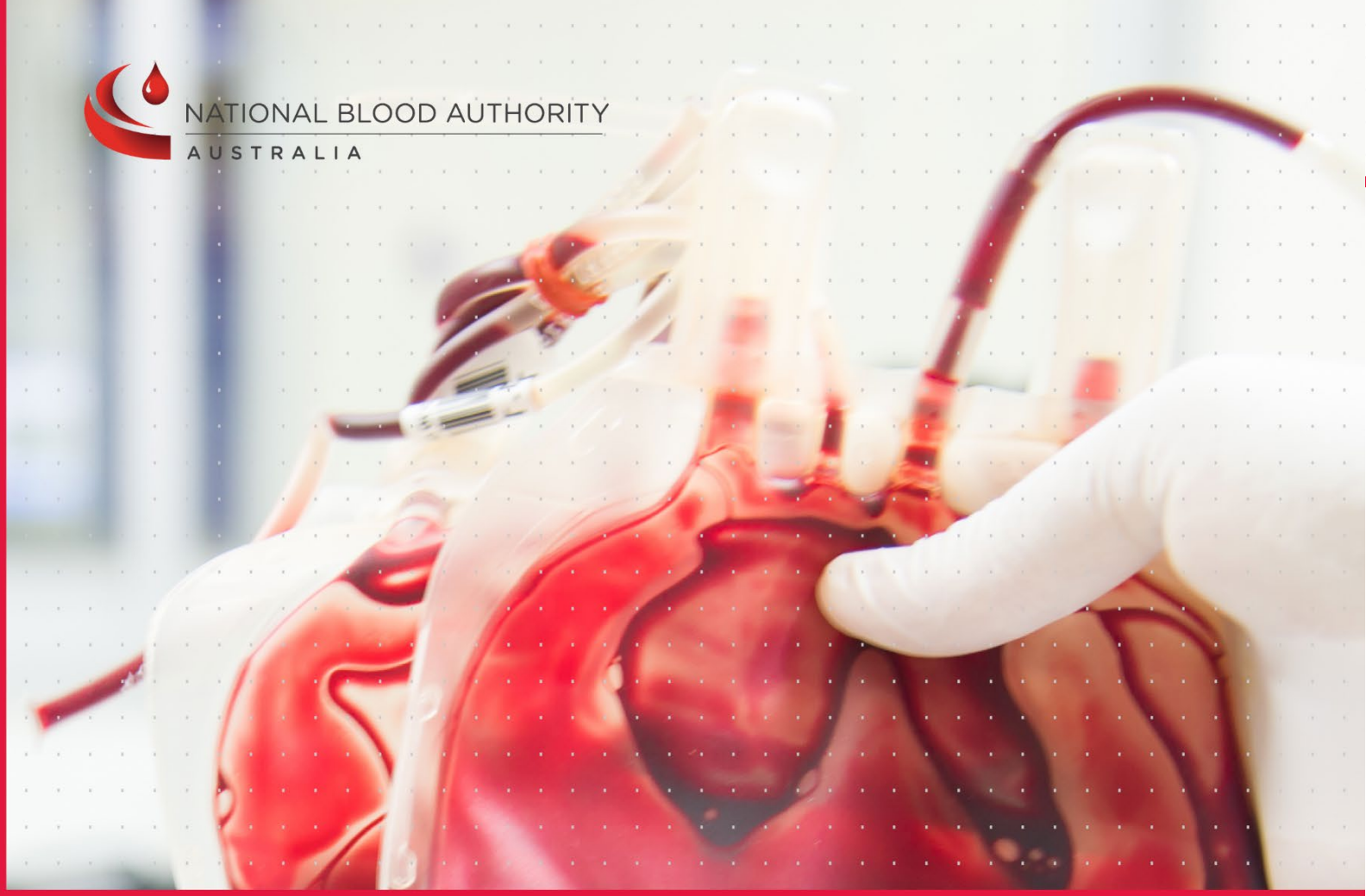
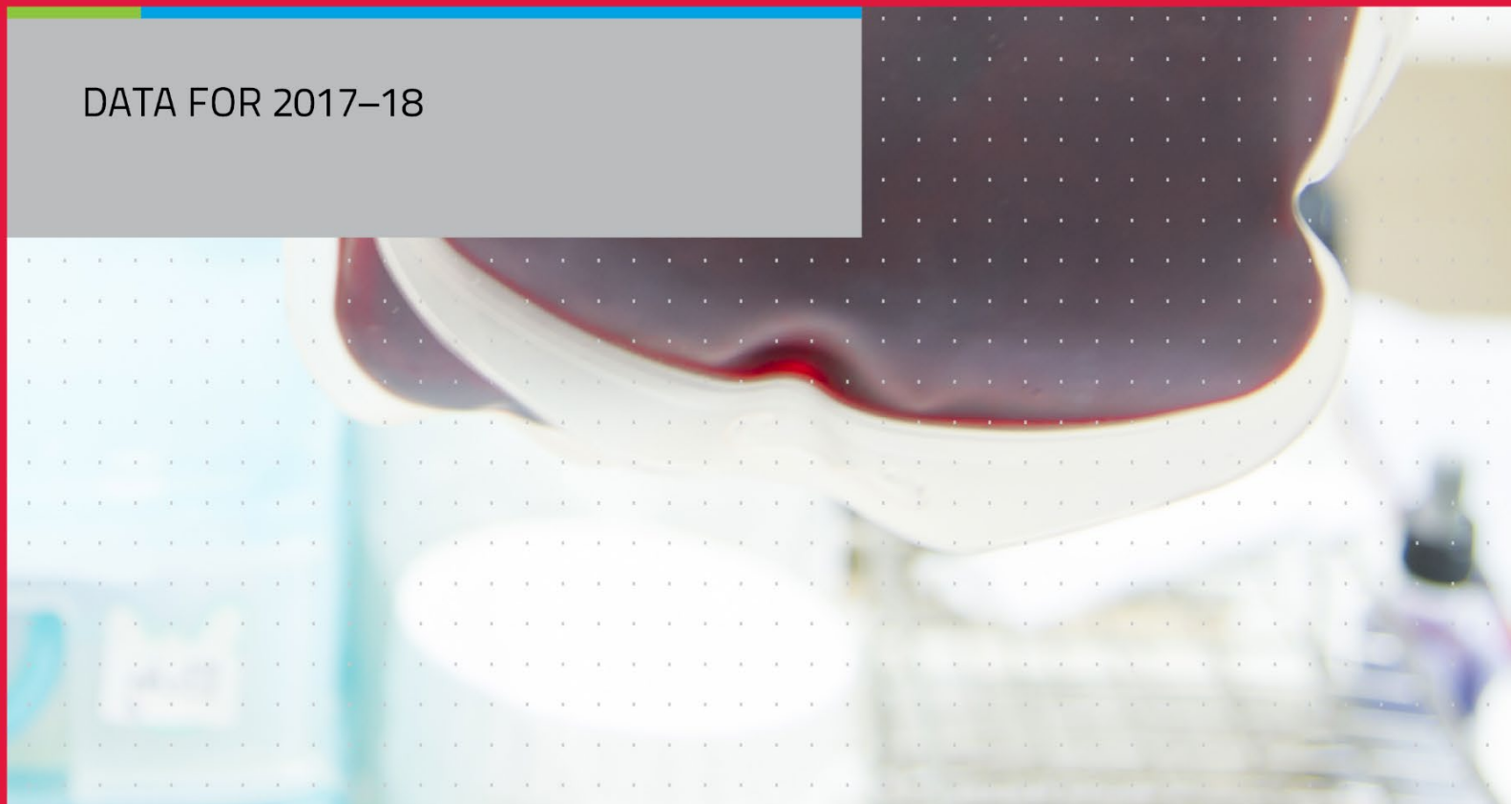
NATIONAL BLOOD AUTHORITY
AUSTRALIA



AUSTRALIAN HAEMOVIGILANCE REPORT

DATA FOR 2017–18



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CONTENTS

TABLES AND FIGURES

SECTION 1

July 2017 – June 2018

AUSTRALIAN HAEMOVIGILANCE DATA

Acknowledgements

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

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

Caveat

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

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

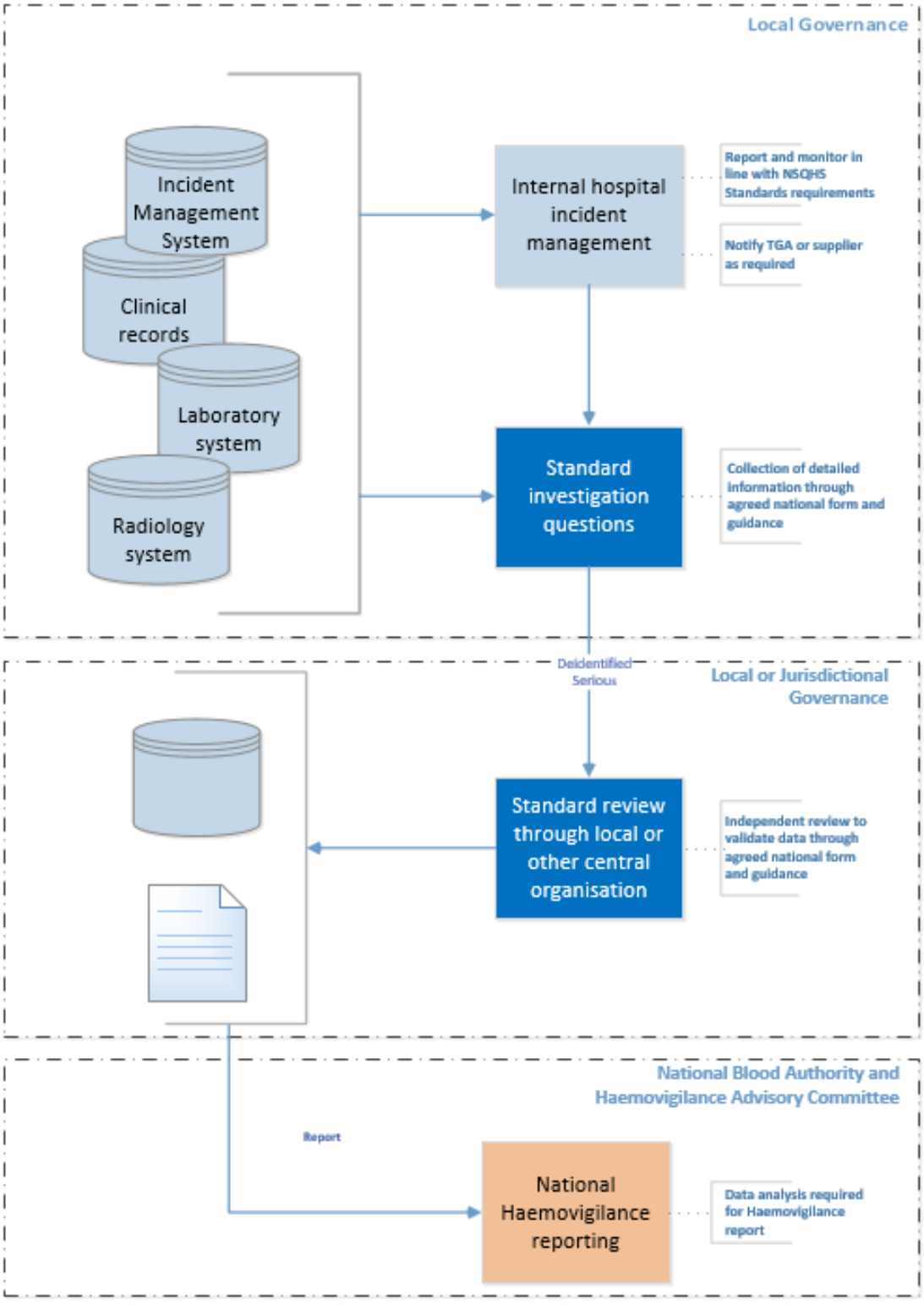
Notwithstanding these limitations, the NBA is publishing this data as an aid to relevant analysis and to maintain the time series of data published during the last ten years.

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

The national data set accepts the categorisation assigned by the contributing jurisdiction and the reviewing clinicians, regardless of minor differences to definitions

Collection and reporting process

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



Summary of findings for 2017-18

Table 1: Adverse events by state, 2017-18

	FNHTR	Allergic	TACO	IBCT	Anaphylactic	DHTR	AHTR	TTI	TRALI	PTP	DSTR	Hypotensive	ABO	Other	All reports		Population	Red cell issue
															Total	Per cent	Per cent	Per cent
NSW	23	13	3	13	5	2	0	2	0	0	0	0	0	0	61	12.5%	32.0%	30.5%
VIC	8	6	16	7	9	3	0	1	1	0	4	1	1	0	57	11.7%	25.8%	27.9%
QLD	131	38	13	1	1	5	7	3	1	1	0	0	1	0	202	41.4%	20.0%	21.1%
SA	12	25	10	0	1	3	0	0	0	0	0	4	0	6	61	12.5%	7.0%	8.8%
WA	19	24	7	2	4	6	1	9	1	0	6	1	0	5	85	17.4%	10.4%	7.7%
TAS	9	1	0	0	0	0	0	0	0	0	0	0	0	1	11	2.3%	2.1%	1.8%
NT	2	0	0	0	0	0	0	0	0	0	0	0	0	0	2	0.4%	1.0%	0.6%
ACT	6	0	3	0	0	0	0	0	0	0	0	0	0	0	9	1.8%	1.7%	1.5%
Total	**210**	**107**	**52**	**23**	**20**	**19**	**8**	**15**	**3**	**1**	**10**	**6**	**2**	**12**	**488**	**100.0%**	**100.0%**	**100.0%**

Notes

1. All states/territories contributed the data
2. All TTIs were suspected but not confirmed bacterial infections
3. Number of patients or transfusion episodes is unavailable
4. STIR uses a higher level temperature threshold for the reporting of FNHTR
5. In 2017-18, some states reported new adverse events in accordance with the new AHMDS. Refer to each adverse event reporting for details

Table 2: Adverse events by imputability score, 2017-18

Event Type	Excluded / Unlikely	Possible	Likely / Probable	Confirmed / Certain	N/A /Not assessable	Total	Per Cent
FNHTR	42	110	52	1	5	210	43.0%
Allergic	13	23	57	12	2	107	21.9%
TACO	4	18	22	6	2	52	10.7%
IBCT	1	0	1	20	1	23	4.7%
Anaphylactic	0	6	11	3	0	20	4.1%
DHTR	2	0	3	14	0	19	3.9%
AHTR	0	3	2	0	3	8	1.6%
TTI	2	2	3	6	2	15	3.1%
TRALI	1	1	1	0	0	3	0.6%
PTP	0	1	0	0	0	1	0.2%
DSTR	0	0	2	7	1	10	2.0%
Hypotensive	1	1	0	0	4	6	1.2%
ABO	0	1	1	0	0	2	0.4%
Other	0	4	1	0	7	12	2.5%
Total	**66**	**170**	**156**	**69**	**27**	**488**	
Per cent	**13.5%**	**34.8%**	**32.0%**	**14.1%**	**5.5%**	**100.0%**	

Notes

1. All states/territories contributed the data
2. All TTIs were suspected but not confirmed bacterial infections
3. Number of patients or transfusion episodes is unavailable
4. STIR uses a higher level temperature threshold for the reporting of FNHTR
5. In 2017-18, some states reported new adverse events in accordance with the new AHMDS. Refer to each adverse event reporting for details

Table 3: Adverse events by blood product, 2017-18

Adverse event	Red cells	Platelets	Fresh frozen plasma	Cryoprecipitate	Cryo-depleted Plasma	Multiple products	Autologous blood	Other products	Unknown	Total
FNHTR	173	31	3	0	0	1	2	0	0	210
Allergic	30	43	28	4	1	0	0	1	0	107
TACO	47	3	1	0	0	1	0	0	0	52
IBCT	17	1	0	1	0	4	0	0	0	23
Anaphylactic	3	8	6	1	0	1	0	0	1	20
DHTR	18	1	0	0	0	0	0	0	0	19
AHTR	5	3	0	0	0	0	0	0	0	8
TTI	6	9	0	0	0	0	0	0	0	15
TRALI	2	1	0	0	0	0	0	0	0	3
PTP	0	0	1	0	0	0	0	0	0	1
DSTR	10	0	0	0	0	0	0	0	0	10
Hypotensive	3	1	2	0	0	0	0	0	0	6
ABO	2	0	0	0	0	0	0	0	0	2
Other	7	2	1	0	0	0	2	0	0	12
Total	**323**	**103**	**42**	**6**	**1**	**7**	**4**	**1**	**1**	**488**
Per cent	**66.2%**	**21.1%**	**8.6%**	**1.2%**	**0.2%**	**1.4%**	**0.8%**	**0.2%**	**0.2%**	**100.0%**

Notes

1. All states/territories contributed the data
2. All TTIs were suspected but not confirmed bacterial infections
3. Number of patients or transfusion episodes is unavailable
4. STIR uses a higher level temperature threshold for the reporting of FNHTR
5. In 2017-18, some states reported new adverse events in accordance with the new AHMDS. Refer to each adverse event reporting for details

Table 4: Adverse event by clinical severity, 2017-18

Adverse event	Death	Life-threatening	Severe morbidity	Minor morbidity	No morbidity	Outcome not available	Grand Total
FNHTR	0	1	14	158	34	3	210
Allergic	0	2	7	81	15	2	107
TACO	0	11	9	30	2	0	52
IBCT	0	0	0	2	17	4	23
Anaphylactic	0	12	6	2	0	0	20
DHTR	0	0	6	9	3	1	19
AHTR	0	0	1	3	4	0	8
TTI	0	1	2	3	9	0	15
TRALI	0	1	1	1	0	0	3
PTP	0	0	0	1	0	0	1
DSTR	0	0	0	3	6	1	10
Hypotensive	0	0	3	3	0	0	6
ABO	1	0	0	1	0	0	2
Other	0	0	0	8	4	0	12
Total	**1**	**28**	**49**	**305**	**94**	**11**	**488**
Per cent	**0.2%**	**5.7%**	**10.0%**	**62.5%**	**19.3%**	**2.3%**	**100.0%**

Notes

1. All states/territories contributed the data
2. All TTIs were suspected but not confirmed bacterial infections
3. Number of patients or transfusion episodes is unavailable
4. STIR uses a higher level temperature threshold for the reporting of FNHTR
5. In 2017-18, some states reported new adverse events in accordance with the new AHMDS. Refer to each adverse event reporting for details

Table 5: Reported adverse events by sex, 2017-18

Adverse event	Male	Female	Not reported	Total
FNHTR	109	79	22	210
Allergic	46	49	12	107
TACO	28	21	3	52
IBCT	6	5	12	23
Anaphylactic	9	6	5	20
DHTR	10	7	2	19
AHTR	4	4	0	8
TTI	9	4	2	15
TRALI	1	2	0	3
PTP	0	1	0	1
DSTR	4	6	0	10
Hypotensive	4	2	0	6
ABO	1	1	0	2
Other	5	7	0	12
All reports	**236**	**194**	**58**	**488**
Per cent	**48.4%**	**39.8%**	**11.9%**	**100.0%**

Notes

1. Limited sex data available for NSW
2. Number of patients or transfusion episodes is unavailable
3. In 2017-18, some states reported new adverse events in accordance with the new AHMDS. Refer to each adverse event reporting for details

Table 6: Adverse events by age and sex, 2017-18

Adverse event	Male	Female	Not reported	Total
0–4 years	14	2	1	17
5–14 years	8	12	1	21
15–24 years	12	9	2	23
25–34 years	6	11	4	21
35–44 years	5	19	5	29
45–54 years	18	21	6	45
55–64 years	35	21	12	68
65–74 years	54	37	17	108
75 years or older	84	62	10	156
Not stated	0	0	0	0
Total	**236**	**194**	**58**	**488**
Per cent	**48.4%**	**39.8%**	**11.9%**	**100.0%**

Notes
1. Sex data not available for NSW
2. Number of patients or transfusion episodes is unavailable

Table 7: Serious adverse events by outcome and imputability score, 2017-18

	Death	Life-threatening	Severe morbidity	All reports	
				Total	Per cent
Possible	1	5	8	14	21.5%
Likely/Probable	0	15	20	35	53.8%
Confirmed/Certain	0	6	10	16	24.6%
Total	**1**	**26**	**38**	**65**	**100.0%**

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

Cumulative results for 2013-14 to 2017-18

Table 8: Adverse events by state, 2013-14 to 2017-18

	2013–14	2014–15	2015–16	2016–17	2017–18	2017–18
						Per cent
NSW	218	264	281	175	61	12.5%
VIC	86	59	54	69	57	11.7%
QLD	151	202	250	246	202	41.4%
SA	154	149	62	54	61	12.5%
WA	0	0	73	71	85	17.4%
TAS	1	1	0	5	11	2.3%
NT	7	5	3	5	2	0.4%
ACT	0	0	1	3	9	1.8%
All reports	**617**	**680**	**724**	**628**	**488**	**100.0%**

Notes

1. ACT reported zero adverse events for 2013–14 and 2014–15
2. WA did not contribute data from 2013–14 to 2014–15
3. TAS reported zero events for 2015–16
4. Number of patients or transfusion episodes is unavailable
5. STIR uses a higher level temperature threshold for the reporting of FNHTR and cases are validated by an expert group prior to finalisation of the report

Table 9: Adverse events by hospital type, 2013-14 to 2017-18

Hospital type	2013–14	2014–15	2015–16	2016–17	2017–18	Total hospitals	Per cent
Public hospital	540	646	653	588	454	2,881	91.8%
All private hospitals	**77**	**34**	**71**	**40**	**34**	**256**	**8.2%**
Private hospital (excludes private free standing day hospital)	77	29	69	40	34	249	7.9%
Private free-standing day hospital	0	5	0	0	0	5	0.2%
Medical and diagnostic laboratory	0	0	2	0	0	2	0.1%
Total hospitals	**617**	**680**	**724**	**628**	**488**	**3,137**	**100.0%**

Notes

1. TAS reported zero adverse events for 2015–16
2. ACT reported zero adverse events for 2013–14 and 2014–15
3. WA did not contribute data from 2013–14 to 2014–15
4. Only VIC, QLD and WA contributed private hospital data
5. Number of patients or transfusion episodes is unavailable
6. Private hospitals include private free-standing day hospital and other private hospitals (exclude private free standing day hospitals)

Table 10: Australian adverse event data, 2013-14 to 2017-18

Adverse event	2013–14	2014–15	2015–16	2016–17	2017–18	All reports		Transfusion risk per unit transfused*
						Number	Per cent	(unless specified)
FNHTR	337	380	365	304	210	1,596	50.9%	0.1–1% of transfusions with universal leucocyte depletion
Allergic	144	164	193	157	107	765	24.4%	1–3% of transfusion of plasma containing components
TACO	28	39	51	55	52	225	7.2%	<1% of transfused patients
IBCT	33	30	41	20	23	147	4.7%	Not available
Anaphylactic	19	20	30	45	20	134	4.3%	1:20,000–1:50,000
DHTR	12	16	16	21	19	84	2.7%	1:2,500–1:11,000
AHTR	8	15	9	13	8	53	1.7%	1:76,000
TTI	27	12	17	1	15	72	2.3%	1:75,000 platelet transfusions 1:500,000 red cell transfusions
TRALI	3	4	2	12	3	24	0.8%	1:1,200–1:190,000 transfusions
PTP	6	0	0	0	1	7	0.2%	Rare
DSTR	NA	NA	NA	NA	10	10	0.3%	NA
Hypotensive	NA	NA	NA	NA	6	6	0.2%	NA
ABO	NA	NA	NA	NA	2	2	0.1%	NA
Other	NA	NA	NA	NA	12	12	0.4%	NA
Grand Total	**617**	**680**	**724**	**628**	**488**	**3137**	**100.0%**	

Notes

1. TAS reported zero adverse events for 2015–16
2. ACT reported zero adverse events for 2013–14 and 2014–15
3. WA did not contribute data from 2013–14 to 2014–15
4. Only VIC, QLD and WA contributed private hospital data
5. All TTIs were suspected but not confirmed bacterial infections
6. Number of patients or transfusion episodes is unavailable
7. In 2017-18, some states reported new adverse events in accordance with the new AHMDS. Refer to each adverse event reporting for details

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

Table 11: Serious adverse events by state, 2013-14 to 2017-18

	2013–14	2014–15	2015–16	2016–17	2017–18	2017–18
						Per cent
NSW	15	6	6	14	14	21.5%
VIC	22	23	12	32	22	33.8%
QLD	7	14	20	24	14	21.5%
SA	8	2	7	8	1	1.5%
WA	0	0	4	7	9	13.8%
TAS	1	0	0	1	1	1.5%
NT	1	0	0	0	2	3.1%
ACT	0	0	0	1	2	3.1%
All reports	**54**	**45**	**49**	**87**	**65**	**100.0%**

Notes

1. ACT reported zero adverse events for 2013–14 and 2014–15
2. WA did not contribute data from 2013–14 to 2014–15
3. TAS reported zero events for 2015–16
4. Number of patients or transfusion episodes is unavailable
5. STIR uses a higher level temperature threshold for the reporting of FNHTR and cases are validated by an expert group prior to finalisation of the report

Table 12: Serious adverse events, 2013-14 to 2017-18

	2013–14	2014–15	2015–16	2016–17	2017–18	All reports	
						Total	Per cent
FNHTR	7	5	6	20	11	49	16.3%
Allergic	15	8	15	15	7	60	20.0%
TACO	16	13	12	19	16	76	25.3%
IBCT	0	1	1	1	0	3	1.0%
Anaphylactic	13	13	13	19	18	76	25.3%
DHTR	1	1	0	1	6	9	3.0%
AHTR	1	1	1	4	1	8	2.7%
TTI	0	1	0	0	3	4	1.3%
TRALI	0	2	1	8	2	13	4.3%
PTP	1	0	0	0	0	1	0.3%
ABO	NA	NA	NA	NA	1	1	0.3%
All reports	**54**	**45**	**49**	**87**	**65**	**300**	**100.0%**

Notes
1. TAS reported zero adverse events for 2015–16
2. ACT reported zero adverse events for 2013–14 and 2014–15
3. WA did not contribute data from 2013–14 to 2014–15
4. All TTIs were suspected but not confirmed bacterial infections
5. Number of patients or transfusion episodes is unavailable
6. In 2017-18, some states reported new adverse events in accordance with the new AHMDS. Refer to each adverse event reporting for details

Table 13: Serious adverse events by product, 2013-14 to 2017-18

	Red cells	Platelets	Fresh frozen plasma	Cryo-depleted plasma	Cryoprecipitate	Multiple products	Unknown	Total
FNHTR	41	6	1	0	0	1	0	49
Allergic	17	22	17	2	0	0	2	60
TACO	71	3	0	0	1	1	0	76
IBCT	3	0	0	0	0	0	0	3
Anaphylact	14	34	25	0	2	0	1	76
DHTR	8	1	0	0	0	0	0	9
AHTR	7	1	0	0	0	0	0	8
TTI	4	0	0	0	0	0	0	4
TRALI	10	0	3	0	0	0	0	13
PTP	0	1	0	0	0	0	0	1
ABO	1	0	0	0	0	0	**0**	1
All reports	**176**	**68**	**46**	**2**	**3**	**2**	**3**	**300**
Per cent	**58.7%**	**22.7%**	**15.3%**	**0.7%**	**1.0%**	**0.7%**	**1.0%**	**100.0%**

Notes
1. TAS reported zero adverse events for 2015–16
2. ACT reported zero adverse events for 2013–14 and 2014–15
3. WA did not contribute data from 2013–14 to 2014–15
4 All TTIs were suspected but not confirmed bacterial infections
5. Number of patients or transfusion episodes is unavailable
6. In 2017-18, some states reported new adverse events in accordance with the new AHMDS. Refer to each adverse event reporting for details

Table 14: Serious adverse events by transfusion time, 2013-14 to 2017-18

	2013–14	2014–15	2015–16	2016–17	2017–18	All reports	
						Total	Per cent
Between 7am and 7pm	20	31	36	39	34	160	53.3%
Between 7pm and 7am	21	12	12	45	31	121	40.3%
Not reported	13	2	1	3	0	19	6.3%
All reports	**54**	**45**	**49**	**87**	**65**	**300**	**100.0%**

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

Table 15: Serious adverse events by week day/weekend, 2013-14 to 2017-18

	2013–14	2014–15	2015–16	2016–17	2017–18	All reports	
						Total	Per cent
Week day	40	33	42	69	54	238	79.3%
Weekend	14	12	7	18	11	62	20.7%
All reports	**54**	**45**	**49**	**87**	**65**	**300**	**100.0%**

Notes
1. TAS reported zero adverse events for 2015–16
2. ACT reported zero adverse events for 2013–14 and 2014–15
3. WA did not contribute data from 2013–14 to 2014–15
4. Number of patients or transfusion episodes is unavailable

Table 16: Serious adverse events by age group, 2013-14 to 2017-18

	2013–14	2014–15	2015–16	2016–17	2017–18	All reports	
						Total	Per cent
0–4 years	0	3	3	4	3	13	4.3%
5–14 years	3	4	4	4	5	20	6.7%
15–24 years	2	0	2	6	6	16	5.3%
25–34 years	2	3	3	6	4	18	6.0%
35–44 years	5	0	4	7	3	19	6.3%
45–54 years	4	5	5	7	5	26	8.7%
55–64 years	10	4	4	12	9	39	13.0%
65–74 years	8	14	8	20	16	66	22.0%
75 years or older	18	12	16	19	14	79	26.3%
Not stated	2	0	0	2	0	4	1.3%
All reports	**54**	**45**	**49**	**87**	**65**	**300**	**100.0%**

Notes
1. TAS reported zero adverse events for 2015–16
2. ACT reported zero adverse events for 2013–14 and 2014–15
3. WA did not contribute data from 2013–14 to 2014–15
4. Number of patients or transfusion episodes is unavailable

Febrile non haemolytic transfusion reaction (FNHTR)

Table 17: FNHTR data summary, 2017-18

2017–18 Data Summary (n=210)					
Age		**Sex**		**Day of Transfusion**	
0–4 years	4	Male	109	Week day	167
5–14 years	2	Female	79	Weekend	43
15–24 years	5	Uncategorised	22		
25–34 years	7	**Facility Location**		**Time of Transfusion**	
35–44 years	9	Major City	121	Between 7am and 7pm	125
45–54 years	20	Inner Regional	35	Between 7pm and 7am	83
55–64 years	34	Outer Regional	53	Not reported	2
65–74 years	49	Remote	0		
75+ years	80	Very Remote	0		
Not specified	0	Not reported	1		
Clinical Outcome Severity		**Imputability**		**Blood Component**	
Death	0	Excluded/Unlikely	42	Red cells	173
Life-threatening	1	Possible	110	Platelets	31
Severe morbidity	14	Likely/Probable	52	Fresh Frozen Plasma	3
Minor morbidity	158	Confirmed/Certain	1	Cryoprecipitate	0
No morbidity	34	Not assessable	5	Cryodepleted plasma	0
Outcome not available	3			Autologous Blood	2
				Multiple	1
				Other	0
				Not reported	0

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

Table 18: FNHTR clinical outcome severity by imputability, 2017-18

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	4	4	6	0	0	14
Minor morbidity	23	90	41	1	3	158
No morbidity	15	13	5	0	1	34
Outcome not available	0	2	0	0	1	3
Total	**42**	**110**	**52**	**1**	**5**	**210**

Allergic reaction

Table 19: Allergic reaction data summary, 2017-18

2017–18 Data Summary (n=107)					
Age		**Sex**		**Day of Transfusion**	
0–4 years	8	Male	46	Week day	96
5–14 years	10	Female	49	Weekend	11
15–24 years	11	Uncategorised	12		
25–34 years	5	**Facility Location**		**Time of Transfusion**	
35–44 years	9	Major City	90	Between 7am and 7pm	58
45–54 years	12	Inner Regional	10	Between 7pm and 7am	48
55–64 years	15	Outer Regional	7	Not reported	1
65–74 years	15	Remote	0		
75+ years	22	Very Remote	0		
Not specified		Not reported			
Clinical Outcome Severity		**Imputability**		**Blood Component**	
Death	0	Excluded/Unlikely	13	Red cells	30
Life threatening	2	Possible	23	Platelets	43
Severe morbidity	7	Likely/Probable	57	Fresh Frozen Plasma	28
Minor morbidity	81	Confirmed/Certain	12	Cryoprecipitate	4
No morbidity	15	Not assessable	2	Cryodepleted plasma	1
Outcome not available	2			Autologous Blood	0
				Multiple	0
				Other	1
				Not reported	0

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

Table 20: Allergic reaction clinical outcome severity by imputability, 2017-18

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	2	0	3	2	0	7
Minor morbidity	7	18	48	8	0	81
No morbidity	4	5	2	2	2	15
Outcome not available	0	0	2	0	0	2
Total	**13**	**23**	**57**	**12**	**2**	**107**

Transfusion-associated circulatory overload (TACO)

Table 21: TACO data summary, 2017-18

2017–18 Data Summary (n=52)					
Age		**Sex**		**Day of Transfusion**	
0–4 years	0	Male	28	Week day	31
5–14 years	0	Female	21	Weekend	21
15–24 years	2	Uncategorised	3		
25–34 years	1	**Facility Location**		**Time of Transfusion**	
35–44 years	4	Major City	41	Between 7am and 7pm	21
45–54 years	2	Inner Regional	6	Between 7pm and 7am	30
55–64 years	4	Outer Regional	5	Not reported	1
65–74 years	12	Remote	0		
75+ years	27	Very Remote	0		
Not specified	0	Not reported	0		
Clinical Outcome Severity		**Imputability**		**Blood Component**	
Death	0	Excluded/Unlikely	4	Red cells	47
Life threatening	11	Possible	18	Platelets	3
Severe morbidity	9	Likely/Probable	22	Fresh Frozen Plasma	1
Minor morbidity	30	Confirmed/Certain	6	Cryoprecipitate	0
No morbidity	2	Not assessable	2	Cryodepleted plasma	0
Outcome not available	0			Autologous Blood	0
				Multiple	1
				Other	0
				Not reported	0

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

Table 22: TACO clinical outcome severity by imputability, 2017-18

Clinical Outcome Severity	Imputability					Total
	Excluded / Unlikely	Possible	Likely / Probable	Confirmed / Certain	N/A /Not assessable	
Life-threatening	0	0	6	3	2	11
Severe morbidity	2	1	5	1	0	9
Minor morbidity	2	15	11	2	0	30
No morbidity	0	2	0	0	0	2
Outcome not available	0	0	0	0	0	0
Total	**4**	**18**	**22**	**6**	**2**	**52**

Incorrect blood component transfused (IBCT)

Table 23: IBCT data summary, 2017-18

2017–18 Data Summary (n=23)					
Age		**Sex**		**Day of Transfusion**	
0–4 years	2	Male	6	Week day	19
5–14 years	0	Female	5	Weekend	4
15–24 years	1	Uncategorised	12		
25–34 years	2	**Facility Location**		**Time of Transfusion**	
35–44 years	4	Major City	15	Between 7am and 7pm	7
45–54 years	3	Inner Regional	7	Between 7pm and 7am	15
55–64 years	2	Outer Regional	1	Not reported	1
65–74 years	6	Remote	0		
75+ years	3	Very Remote	0		
Not specified	0	Not reported	0		
Clinical Outcome Severity		**Imputability**		**Blood Component**	
Death	0	Excluded/Unlikely	1	Red cells	17
Life threatening	0	Possible	0	Platelets	1
Severe morbidity	0	Likely/Probable	1	Fresh Frozen Plasma	0
Minor morbidity	2	Confirmed/Certain	20	Cryoprecipitate	1
No morbidity	17	Not assessable	1	Cryodepleted plasma	0
Outcome not available	4			Autologous Blood	0
				Multiple	4
				Other	0
				Not reported	0

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

Table 24: IBCT clinical outcome severity by imputability, 2017-18

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	2	0	2
No morbidity	1	0	1	14	1	17
Outcome not available	0	0	0	4	0	4
Total	**1**	**0**	**1**	**20**	**1**	**23**

Table 25: Contributory factors cited in IBCT, 2013-14 to 2017-18

Contributory Factor	2013-14	2014-15	2015-16	2016-17	2017-18
None identified	1	0	7	0	2
Product characteristic	0	0	1	13	10
*Transfusion in emergency setting	3	7	10	5	4
*Deliberate clinical decision	0	1	4	2	1
*Prescribing/ordering	14	6	12	13	10
*Specimen collection/labelling	0	1	0	0	1
*Laboratory (testing/dispensing)	12	15	22	10	7
*Transport, storage, handling	1	1	0	1	1
*Administration of product	10	13	8	14	16
*Indications do not meet guidelines	3	0	1	3	1
*Procedure did not adhere to hospital transfusion guidelines	15	8	14	15	16
Other	12	0	2	10	12

Notes

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

Anaphylactic or anaphylactoid reaction

Table 26: Anaphylactic or anaphylactoid reaction data summary, 2017-18

2017–18 Data Summary (n=20)					
Age		**Sex**		**Day of Transfusion**	
0–4 years	2	Male	9	Week day	16
5–14 years	4	Female	6	Weekend	4
15–24 years	1	Uncategorised	5		
25–34 years	4	**Facility Location**		**Time of Transfusion**	
35–44 years	0	Major City	20	Between 7am and 7pm	11
45–54 years	0	Inner Regional	0	Between 7pm and 7am	8
55–64 years	3	Outer Regional	0	Not reported	1
65–74 years	3	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	3
Life threatening	12	Possible	6	Platelets	8
Severe morbidity	6	Likely/Probable	11	Fresh Frozen Plasma	6
Minor morbidity	2	Confirmed/Certain	3	Cryoprecipitate	1
No morbidity	0	Not assessable	0	Cryodepleted plasma	0
Outcome not available	0			Autologous Blood	0
				Multiple	1
				Other	0
				Not reported	1

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

Table 27: Anaphylactic or anaphylactoid reaction clinical outcome by imputability, 2017-18

Clinical Outcome Severity	Imputability					Total
	Excluded / Unlikely	Possible	Likely / Probable	Confirmed / Certain	N/A /Not assessable	
Death	0	0	0	0	0	0
Life-threatening	0	3	7	2	0	12
Severe morbidity	0	3	2	1	0	6
Minor morbidity	0	0	2	0	0	2
No morbidity	0	0	0	0	0	0
Outcome not available	0	0	0	0	0	0
Total	**0**	**6**	**11**	**3**	**0**	**20**

Delayed haemolytic transfusion reaction (DHTR)

Table 28: DHTR data summary, 2017-18

2017–18 Data Summary (n=19)					
Age		**Sex**		**Day of Transfusion**	
0–4 years	0	Male	10	Week day	17
5–14 years	1	Female	7	Weekend	2
15–24 years	0	Uncategorised	2		
25–34 years	0	**Facility Location**		**Time of Transfusion**	
35–44 years	0	Major City	18	Between 7am and 7pm	11
45–54 years	2	Inner Regional	0	Between 7pm and 7am	7
55–64 years	2	Outer Regional	1	Not reported	1
65–74 years	8	Remote	0		
75+ years	6	Very Remote	0		
Not specified	0	Not reported	0		
Clinical Outcome Severity		**Imputability**		**Blood Component**	
Death	0	Excluded/Unlikely	2	Red cells	18
Life threatening	0	Possible	0	Platelets	1
Severe morbidity	6	Likely/Probable	3	Fresh Frozen Plasma	0
Minor morbidity	9	Confirmed/Certain	14	Cryoprecipitate	0
No morbidity	3	Not assessable	0	Cryodepleted plasma	0
Outcome not available	1			Autologous Blood	0
				Multiple	0
				Other	0
				Not reported	0

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

Table 29: DHTR clinical outcome severity by imputability, 2017-18

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	1	5	0	6
Minor morbidity	2	0	2	5	0	9
No morbidity	0	0	0	3	0	3
Outcome not available	0	0	0	1	0	1
Total	**2**	**0**	**3**	**14**	**0**	**19**

Acute haemolytic transfusion reaction (AHTR)

Table 30: AHTR data summary, 2017-18

2017–18 Data Summary (n=8)					
Age		**Sex**		**Day of Transfusion**	
0–4 years	0	Male	4	Week day	7
5–14 years	0	Female	4	Weekend	1
15–24 years	0	Uncategorised	0		
25–34 years	0	**Facility Location**		**Time of Transfusion**	
35–44 years	1	Major City	4	Between 7am and 7pm	5
45–54 years	0	Inner Regional	4	Between 7pm and 7am	3
55–64 years	0	Outer Regional	0	Not reported	0
65–74 years	1	Remote	0		
75+ years	6	Very Remote	0		
Not specified	0	Not reported	0		
Clinical Outcome Severity		**Imputability**		**Blood Component**	
Death	0	Excluded/Unlikely	0	Red cells	5
Life threatening	0	Possible	3	Platelets	3
Severe morbidity	1	Likely/Probable	2	Fresh Frozen Plasma	0
Minor morbidity	3	Confirmed/Certain	0	Cryoprecipitate	0
No morbidity	4	Not assessable	3	Cryodepleted plasma	0
Outcome not available	0			Autologous Blood	0
				Multiple	0
				Other	0
				Not reported	0

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

Table 31: AHTR clinical outcome severity by imputability, 2017-18

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	1	0	0	1
Minor morbidity	0	2	1	0	0	3
No morbidity	0	1	0	0	3	4
Outcome not available	0	0	0	0	0	0
Total	**0**	**3**	**2**	**0**	**3**	**8**

Transfusion-transmitted infection (TTI)

Table 32: TTI data summary, 2017-18

2017–18 Data Summary (n=15)					
Age		**Sex**		**Day of Transfusion**	
0–4 years	1	Male	9	Week day	13
5–14 years	0	Female	4	Weekend	2
15–24 years	1	Uncategorised	2		
25–34 years	0	**Facility Location**		**Time of Transfusion**	
35–44 years	1	Major City	14	Between 7am and 7pm	9
45–54 years	1	Inner Regional	1	Between 7pm and 7am	6
55–64 years	2	Outer Regional	0	Not reported	0
65–74 years	5	Remote	0		
75+ years	4	Very Remote	0		
Not specified	0	Not reported	0		
Clinical Outcome Severity		**Imputability**		**Blood Component**	
Death	0	Excluded/Unlikely	2	Red cells	6
Life threatening	1	Possible	2	Platelets	9
Severe morbidity	2	Likely/Probable	3	Fresh Frozen Plasma	0
Minor morbidity	3	Confirmed/Certain	6	Cryoprecipitate	0
No morbidity	9	Not assessable	2	Cryodepleted plasma	0
Outcome not available	0			Autologous Blood	0
				Multiple	0
				Other	0
				Not reported	0

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

Table 33: TTI clinical outcome severity by imputability, 2017-18

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	1	1	0	2
Minor morbidity	0	2	1	0	0	3
No morbidity	2	0	1	4	2	9
Outcome not available	0	0	0	0	0	0
Total	**2**	**2**	**3**	**6**	**2**	**15**

Transfusion related acute lung injury (TRALI)

Table 34: TRALI data summary, 2017-18

2017–18 Data Summary (n=3)					
Age		**Sex**		**Day of Transfusion**	
0–4 years	0	Male	1	Week day	2
5–14 years	0	Female	2	Weekend	1
15–24 years	0	Uncategorised	0		
25–34 years	0	**Facility Location**		**Time of Transfusion**	
35–44 years	0	Major City	3	Between 7am and 7pm	1
45–54 years	0	Inner Regional	0	Between 7pm and 7am	2
55–64 years	1	Outer Regional	0	Not reported	0
65–74 years	2	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	2
Life threatening	1	Possible	1	Platelets	1
Severe morbidity	1	Likely/Probable	1	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

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

Table 35: TRALI clinical outcome severity by imputability, 2017-18

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

Post-transfusion purpura (PTP)

Table 36: PTP data summary, 2017-18

2017–18 Data Summary (n=1)					
Age		**Sex**		**Day of Transfusion**	
0–4 years	0	Male	0	Week day	0
5–14 years	0	Female	1	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	0	Red cells	0
Life threatening	0	Possible	1	Platelets	0
Severe morbidity	0	Likely/Probable	0	Fresh Frozen Plasma	1
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

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

Table 37: PTP clinical outcome severity by imputability, 2017-18

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 transfusion reaction (DSTR)

Table 38: DSTR data summary, 2017-18

2017–18 Data Summary (n=10)					
Age		**Sex**		**Day of Transfusion**	
0–4 years	0	Male	4	Week day	6
5–14 years	0	Female	6	Weekend	4
15–24 years	0	Uncategorised	0		
25–34 years	1	**Facility Location**		**Time of Transfusion**	
35–44 years	1	Major City	10	Between 7am and 7pm	7
45–54 years	2	Inner Regional	0	Between 7pm and 7am	3
55–64 years	0	Outer Regional	0	Not reported	0
65–74 years	3	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	10
Life threatening	0	Possible	0	Platelets	0
Severe morbidity	0	Likely/Probable	2	Fresh Frozen Plasma	0
Minor morbidity	3	Confirmed/Certain	7	Cryoprecipitate	0
No morbidity	6	Not assessable	1	Cryodepleted plasma	0
Outcome not available	1			Autologous Blood	0
				Multiple	0
				Other	0
				Not reported	0

Notes
1. NSW did not report all the facility location data and report some sex data
2. Number of patients or transfusion episodes is unavailable
3. WA and VIC reported DSTR in accordance with the new AHMDS in 2017-18

Table 39: DSTR clinical outcome severity by imputability, 2017-18

Clinical Outcome Severity	Imputability					Total
	Excluded / Unlikely	Possible	Likely / Probable	Confirmed / Certain	N/A /Not assessable	
Life-threatening	0	0	0	0	0	0
Severe morbidity	0	0	0	0	0	0
Minor morbidity	0	0	1	2	0	3
No morbidity	0	0	1	5	0	6
Outcome not available	0	0	0	0	1	1
Total	**0**	**0**	**2**	**7**	**1**	**10**

Hypotensive transfusion reaction (hypotensive)

Table 40: Hypotensive data summary, 2017-18

2017–18 Data Summary (n=6)					
Age		**Sex**		**Day of Transfusion**	
0–4 years	0	Male	4	Week day	6
5–14 years	1	Female	2	Weekend	0
15–24 years	0	Uncategorised	0		
25–34 years	0	**Facility Location**		**Time of Transfusion**	
35–44 years	0	Major City	6	Between 7am and 7pm	0
45–54 years	0	Inner Regional	0	Between 7pm and 7am	6
55–64 years	0	Outer Regional	0	Not reported	0
65–74 years	5	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	3
Life threatening	0	Possible	1	Platelets	1
Severe morbidity	3	Likely/Probable	0	Fresh Frozen Plasma	2
Minor morbidity	3	Confirmed/Certain	0	Cryoprecipitate	0
No morbidity	0	Not assessable	4	Cryodepleted plasma	0
Outcome not available	0			Autologous Blood	0
				Multiple	0
				Other	0
				Not reported	0

Notes
1. NSW did not report all the facility location data and report some sex data
2. Number of patients or transfusion episodes is unavailable
3. WA, VIC and SA reported hypotensive reaction in accordance with the new AHMDS in 2017-18

Table 41: Hypotensive clinical outcome severity by imputability, 2017-18

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	1	0	0	0	2	3
Minor morbidity	0	1	0	0	2	3
No morbidity	0	0	0	0	0	0
Outcome not available	0	0	0	0	0	0
Total	**1**	**1**	**0**	**0**	**4**	**6**

ABO incompatibility (ABO)

Table 42: ABO data summary, 2017-18

2017–18 Data Summary (n=2)					
Age		**Sex**		**Day of Transfusion**	
0–4 years	0	Male	1	Week day	2
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	2
45–54 years	1	Inner Regional	1	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	1	Excluded/Unlikely	0	Red cells	2
Life threatening	0	Possible	1	Platelets	0
Severe morbidity	0	Likely/Probable	1	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

Notes
1. NSW did not report all the facility location data and report some sex data
2. Number of patients or transfusion episodes is unavailable
3. QLD and VIC reported ABO incompatibility in accordance with the new AHMDS in 2017-18

Table 43: ABO clinical outcome severity by imputability, 2017-18

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

Other adverse events

Table 44: Other data summary, 2017-18

2017–18 Data Summary (n=12)					
Age		**Sex**		**Day of Transfusion**	
0–4 years	0	Male	5	Week day	12
5–14 years	3	Female	7	Weekend	0
15–24 years	2	Uncategorised	0		
25–34 years	0	**Facility Location**		**Time of Transfusion**	
35–44 years	0	Major City	9	Between 7am and 7pm	10
45–54 years	1	Inner Regional	3	Between 7pm and 7am	2
55–64 years	4	Outer Regional	0	Not reported	0
65–74 years	1	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	7
Life threatening	0	Possible	4	Platelets	2
Severe morbidity	0	Likely/Probable	1	Fresh Frozen Plasma	1
Minor morbidity	8	Confirmed/Certain	0	Cryoprecipitate	0
No morbidity	4	Not assessable	7	Cryodepleted plasma	0
Outcome not available	0			Autologous Blood	2
				Multiple	0
				Other	0
				Not reported	0

Notes
1. NSW did not report all the facility location data and report some sex data
2. Number of patients or transfusion episodes is unavailable
3. WA, SA and TAS reported "other" adverse events in accordance with the new AHMDS in 2017-18

Table 45: Other clinical outcome severity by imputability, 2017-18

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	4	0	0	4	8
No morbidity	0	0	1	0	3	4
Outcome not available	0	0	0	0	0	0
Total	**0**	**4**	**1**	**0**	**7**	**12**

Contributory factors

Table 46: Contributory factors data summary, 2017-18

Summary Data	
Contributory Factors	Number of reports
None identified	129
Not reported	42
Product characteristic	193
*Transfusion in emergency setting	13
*Deliberate clinical decision	29
*Prescribing/ordering	12
*Specimen collection/labelling	1
*Laboratory (testing/dispensing)	13
*Transport, storage, handling	1
*Administration of product	42
*Indications do not meet guidelines	8
*Procedure did not adhere to hospital transfusion guidelines	19
Other	53

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

Table 47: Contributory factors cited by adverse event and by clinical outcome severity, 2017-18

Contributory Factors	Adverse event														Clinical outcome severity					
	FNHTR	Allergic	TACO	IBCT	TTI Bacterial	Anaphylactic	DHTR	AHTR	TRALI	PTP	DSTR	Hypertensive	ABO	Other	Outcome not available	No morbidity	Minor morbidity	Severe morbidity	Life-threatening	Death
None identified/reported	62	35	26	2	6	5	9	6	0	1	4	5	0	10	2	40	109	9	11	0
Product characteristic	95	49	7	10	5	13	5	0	1	0	2	0	0	6	7	30	115	27	14	0
*Transfusion in emergency setting	1	1	3	4	0	1	2	0	0	0	0	0	1	0	1	5	2	2	2	1
*Deliberate clinical decision	8	6	7	1	0	4	0	0	0	0	0	0	0	3	0	2	20	5	2	0
*Prescribing/ordering	0	0	2	10	0	0	0	0	0	0	0	0	0	0	3	7	1	1	0	0
*Specimen collection/labelling	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0	1	0	0	0	0
*Laboratory (testing/dispensing)	0	0	0	7	3	0	1	1	0	0	0	0	0	1	2	8	2	1	0	0
*Transport, storage, handling	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0	1	0	0	0	0
*Administration of product	6	6	9	16	2	0	0	1	0	0	0	0	1	1	3	16	19	3	0	1
*Indications do not meet guidelines	1	3	1	1	1	0	0	0	1	0	0	0	0	0	0	2	4	1	1	0
*Procedure did not adhere to hospital transfusion guidelines	1	0	1	16	0	0	0	0	0	0	0	0	1	0	1	14	2	1	0	1
Other	23	8	4	12	1	1	2	1	0	0	0	0	1	0	4	8	35	2	4	0

Notes
1. Contributory factors are not reported for SA
2. In 2017-18, some states reported new adverse events in accordance with the new AHMDS. Refer to each adverse event reporting for details
3. * refers to potentially avoidable human errors

SECTION 2

July 2017 – June 2018

DONOR HAEMOVIGILANCE DATA

Executive Summary

Donor vigilance is the systematic monitoring of adverse reactions and incidents in blood donor care with a view to improving quality and safety for blood donors. Australia uses the revised classification and definitions of adverse donation events in the Standard for Surveillance of Complications Related to Blood Donation, December 2014 (refer to Appendix 1 for a summary of the definitions). This was developed by the Working Group on Donor Vigilance of the International Society of Blood Transfusion Working Party on Haemovigilance (of which Australia is an active member) in collaboration with the International Haemovigilance Network and the AABB Donor Haemovigilance Working Group.

Historical data in this report has been updated to incorporate delayed reporting of adverse reactions by blood donors returning to donate, which may occur months or even years after the event. For this reason, the number of donor adverse events reported for each year may differ from the number reported in previous years. The number of delayed reports received is generally low and has minimal impact on the overall incidence of adverse donation events.

A new methodology for data extraction has been used for this report to improve reporting accuracy, in particular excluding duplicate reports and providing data for attendances in which the donor had blood samples taken for tests without progressing to a donation (*Venepuncture Only*). The new approach has been applied retrospectively to update data in this report from previous years to enable a valid comparison. It should be noted that the data in this report cannot be compared to data in previous reports due to the change in methodology.

Between 1 July 2017 and 30 June 2018 there were 1.36 million collections, including 0.69 million whole blood collections, 0.64 million plasmapheresis collections and 0.03 million plateletpheresis collections.

In 2017-18, 2.93% of collections (293/10,000) were associated with at least one donor adverse event, compared to 2.67% (267/10,000) in 2016-17. More than one donor adverse event may be associated with a single donation. In 2017-18, 308 unique donor adverse events were reported per 10,000 collections compared with 280 per 10,000 in 2016-17. The increase in donor adverse events rates for the 2017-18 reporting year is primarily attributable to the new changes in reporting haematomas which now includes haematomas with diameters of less than 5cm. If the increase in hematomas are accounted

for, the rate of other donor adverse events generally compares favourably with other years with a documented reduction in vasovagal reactions. The data in this report are accurate as at 15 May 2019.

Whilst blood donation is generally a safe process, there are recognised donor complications which occur. Donor haemovigilance systems permit evaluation of the impact of changes in donation procedures and also of the success of interventions designed to further improve donor safety. The implementation of these systems has permitted real time reporting, and enabled detailed analysis, which has improved understanding of impacts of blood donation, changes in collection procedures and in donor selection criteria on the safety of donors. Appendix 2 summarises the significant changes in processes and procedures which have occurred since 2010; the donor haemovigilance system is a means of monitoring these changes, which must be considered when interpreting changes observed during each reporting period.

In the current reporting period there have been 3 major donor policy changes which would be expected to impact the incidence of donor adverse reactions. From December 2017 the following changes have been in place:

1. The requirement for all first time donors to donate whole blood prior to donating plasma was removed in December 2017. Male and female first time whole blood and apheresis donors have a higher reaction rate compared with all other donor groups, and this will impact the overall incidence of reactions in plasmapheresis donors. It is important to note, however, that the incidence of all types of reactions is subject to close monitoring to ensure the policy change does not significantly increase donor risk.

2. The minimum age for plasma donation by female donors was reduced from 20 to 18 years in December 2017. In 2011 the minimum age for plasma donation for female donors was increased from 18 to 20 based on the higher rates of donor adverse events observed in this group. The recent policy change to reduce the minimum age to 18 was supported by a review in 2017 that took into consideration both domestic and international experience and found no evidence to suggest that younger donors are more sensitive to plasmapheresis donation than older donors. In addition, because plasmapheresis has a lower impact on iron stores and a smaller net fluid loss compared with whole blood donation, there may be a safety advantage for young females to give plasma rather than whole blood. This cohort is also subject to close monitoring.

3. In January 2018 the minimum donation age for whole blood donation for both males and females was increased from 16 years to 18 years. Whilst this group of donors is at higher risk of adverse donation reactions, they accounted for only 2.5% of collections annually in 2016 and hence the increase in minimum age in January 2018 is unlikely to have a significant impact on the overall donor adverse event rates observed in 2017-2018.

There have been two procedural changes implemented which have impacted the reported incidence of donor adverse reactions.

1. Until September 2017, only haematomas with a diameter of >5cm were reported via the Donor Adverse Events database. Smaller haematomas were recorded on the donation record, but not reported via the Donor Adverse Events database. Since September 2017, all haematomas, regardless of size, have been reported through the Donor Adverse Event database. This has resulted in a significant increase in the number of reported events.

2. In February and March of 2018, in-centre water loading and use of applied muscle tension at selected points during donation in all whole blood donors was rolled out nationally. This project has been associated with a decrease in vasovagal reactions in whole blood donors.

Over the past 5 years there has been a steady decrease in the number of whole blood collections as a result of patient blood management initiatives; the number of plateletpheresis collections has also fallen as a result of increased double plateletpheresis collections coupled with reduced single plateletpheresis collections. The number of plasmapheresis collections has increased year on year as the demand for plasma-derived products increases (refer to Table 48). As each collection type has a different donor adverse event profile the changing donation mix impacts both the incidence and types of overall donor adverse events.

Calculating donor adverse event rates

Between 1 July 2017 and 30 June 2018 there were 1.36 million collections, including 0.69 million whole blood, 0.64 million plasmapheresis and 0.03 million plateletpheresis (Table 48).

Table 48: Total number of collections by type, 2013-14 to 2017-18

Collection type	2013-14	2014-15	2015-16	2016-17	2017-18
Whole blood	783,342	745,580	716,437	703,552	690,756
Plasmapheresis	482,861	490,476	548,274	573,621	639,076
Plateletpheresis	35,723	31,170	31,650	32,181	27,630
Total collections	**1,301,926**	**1,267,226**	**1,296,361**	**1,309,354**	**1,357,462**

The Blood Service definition of collection (above) requires a minimum volume to be collected for the specific donation type. To provide a more accurate representation of the donor adverse event rates, the cohort used to calculate donor adverse event rates is expanded to include attendances where the donation needle is inserted regardless of any volume collected; i.e. intended collections. All donor adverse event data in this report is based on intended collections (Table 49).

Table 49: Number of intended collections by type, 2013-14 to 2017-18

Intended collection[1]	2013-14	2014-15	2015-16	2016-17	2017-18
Whole blood[#]	783,342	748,501	724,970	711,842	699,689
Plasmapheresis	482,862	493,422	553,037	579,183	646,093
Plateletpheresis	35,723	31,232	31,835	32,368	27,783
Total	1,301,927	1,273,155	1,309,842	1,323,393	1,373,565

[#] Includes whole blood, therapeutic and autologous collections

There were 40,274 collections associated with at least one donor adverse event in 2017-18, giving an overall incidence of 2.93% (Figure 1). Events that occur in the donor centre are termed immediate events. Events that occur after the donor has left the donor centre are classified as delayed events.

Vasovagal reactions (VVR) occurring at the donor centre, either during or immediately following donation, are the most commonly reported adverse donation reactions, with an incidence of 1.57 % (Table 50). Most vasovagal reactions are characterised by dizziness, weakness, sweating and nausea; only 6.9% of immediate reactions are associated with loss of consciousness (Table 53). Only 0.2% of donors experiencing a vasovagal reaction at the donor centre sustain an injury (Table 53), which usually occurs when a donor feels unsteady or loses consciousness and falls.

Vasovagal reactions can occur up to 6-8 hours after the donor has left the donor centre following the donation. These delayed vasovagal reactions are less common than immediate reactions occurring in only 0.23% of collections (Table 50). Approximately 14% of delayed reactions are associated with loss of consciousness (Table 53). Just over 2% of donors experiencing a delayed vasovagal reaction sustain an injury (Table 53), usually as a result of falling.

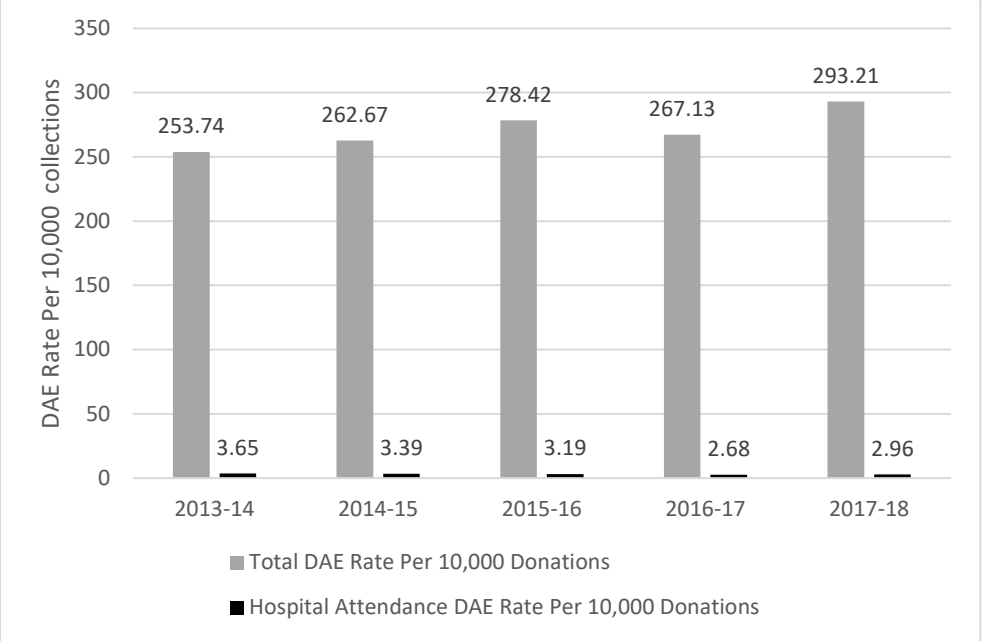
Whilst most donors recover rapidly from a vasovagal reaction, a small number of individuals experience protracted symptoms despite appropriate immediate management and a very small number of donors sustain injuries when they have a vasovagal reaction. These donors may require hospital treatment. In 2017-18, hospital referral was required in 0.0296% or 2.96/10,000 collections (Table 54 and 55).

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

[1] Where a donation needle was inserted but the attempt unsuccessful (nil or low volume), the National Blood Management System (NBMS) codes the collection type based on the original appointment type. For example, a donor attending with a whole blood appointment who is converted to plasma in interview and has an unsuccessful plasma donation, is allocated to a whole blood collection.

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

Figure 1: Collections associated with one or more donor adverse event (DAE) 2013-14 to 2017-18



Note: Data in Figure 1 reports on collections associated with one or more donor adverse event. If more than one type of donor adverse event is reported in association with a single collection, the collection is only counted once.
Attendances were omitted from analysis if the National Blood Management System phlebotomy coding system could not distinguish whether the attendance was a Venepuncture Only (blood test only) or an unsuccessful (nil or low volume) donation attempt. In 2018-19, approximately 8000 attendances were omitted from analysis for this reason. The total donor adverse event rate in the omitted group was 570/10,000 collections (5.7%).

The rate of donor adverse events has increased since 2016-2017 primarily due to the new reporting requirements for phlebotomy injuries which required haematomas less than 5cm to be recorded in the Donor Adverse Event database. A reconciliation of historical records for the 12 months prior to the reporting change has confirmed that the increase in the number of haematomas is the result of this change, and not the result of an increase in actual injuries. The incidence of donors reporting arm pain (which does not have the characteristics of a nerve injury) increased significantly following education delivered to all collection centre teams in September 2017 at the time of the changed reporting requirements.

In early 2017, because of the withdrawal of the previously used skin disinfection product (1% chlorhexidine in isopropyl alcohol) from the Australian market, a new skin disinfection product (chlorhexidine 2% in isopropyl alcohol) was introduced. Although local allergic reactions occur infrequently, there was a significant increase in the number of reactions following the change; 0.88 to 1.54 per 10,000 collections from 2016-17 to 2017-18. Alternative skin disinfection is available for donors who experience a localised allergic reaction.

There has been a small decrease in the overall frequency of vasovagal reactions compared to the previous year. This is partially attributed to the decline in the frequency of vasovagal reactions in whole blood donors following the rollout of applied muscle tension and in-centre water loading.

Table 50: Donor adverse event rate by category per 10,000 collections; 2013-14 to 2017-18

Type of reaction / event	2013-14	2014-15	2015-16	2016-17	2017-18
Systemic events					
Immediate Vasovagal Reaction	175.09	178.04	182.50	175.70	157.15
Delayed Vasovagal Reaction	29.86	29.77	28.09	24.51	22.85
Chest Pain/Chest Tightness	0.68	0.85	0.79	0.73	0.81
Allergic Reaction - Localised	0.48	0.44	0.38	0.88	1.54
Allergic/Anaphylactic Reaction	0.14	0.05	0.04	0.04	0.03
Cardiac Arrest/Respiratory Arrest	0.00	0.01	0.00	0.00	0.00
Local arm injuries					
Haematoma	13.65	14.93	14.59	14.48	55.32
Painful Arm	8.47	9.43	9.50	10.13	15.65
Nerve Injury/Irritation	3.84	5.33	5.85	5.74	6.55
Other injury / event	2.74	2.55	1.81	1.76	1.65
Delayed Bleeding	0.59	1.00	1.30	1.28	2.50
Extravasation/Compartment Syndrome	0.65	0.70	1.14	1.16	2.18
Thrombophlebitis	0.25	0.31	0.38	0.36	0.36
Arterial Puncture	0.17	0.31	0.19	0.20	0.18
Tendon Injury	0.05	0.07	0.02	0.14	0.05
Post Donation Thrombosis	0.03	0.07	0.02	0.01	0.01
Other phlebotomy or vessel injury	0.00	0.00	0.00	0.02	0.09
Cellulitis	0.00	0.00	0.00	0.00	0.01
Apheresis specific events					
Citrate Reaction	23.27	31.79	46.10	43.03	40.73
Haemolysis	0.09	0.05	0.05	0.00	0.00
Omitted Anticoagulant	0.04	0.02	0.02	0.00	0.02
Infiltration/extravasation	0.00	0.00	0.00	0.00	0.04
Air Embolism	0.00	0.00	0.00	0.00	0.00
Unknown					
Other	0.63	0.03	0.05	0.05	0.05
Totals	**260.72**	**275.75**	**292.82**	**280.22**	**307.77**

Data in Table 50 reflects the **rate of unique donor adverse events** per 10,000 collections. When more than one donor adverse event is associated with a single collection, each event is counted, hence the rate tabled above is greater than the rates tabled in Figure 1 and Table 51.

Donor adverse events by donation type

Table 51 (below) summarises the donor adverse reaction rate for different donation types.

Whole Blood – Whole blood donation is associated with the highest frequency of vasovagal reactions (Table 53). Until December 2017, all first-time donors made a whole blood donation. The incidence of vasovagal reactions in both male and female first time donors of all ages is almost twice that of donors of the same age and gender who have made only one previous donation. The increased incidence of vasovagal reactions in whole blood donors can be at least partially explained by donor inexperience, which includes a higher proportion of first time donors. Between 60-70% of donors return to donate after their first donation, however, in the subset of donors who experience an adverse reaction, only 30% subsequently return to donate; the lower rate of donor adverse reactions in returning donors is the result of self-deferral by individuals who are at higher risk of vasovagal reactions.

Plasmapheresis – Plasma donation continues to have the lowest rate of donation complications of all donation types (Table 53). All plasma donors receive 500ml normal saline as part of the donation protocol, which reduces the impact of volume taken during the donation. The introduction of new donors direct to plasma (NDDP) and the increased recruitment of inexperienced donors is associated with an increase in the overall rate of reactions in plasma donors, mainly in the rate of pre-faints, faints, citrate reactions and phlebotomy injuries. Compared to other plasma donors with donation experience, donors making their first plasma donation have a higher risk of vasovagal reactions and citrate reactions despite saline administration during donation and provision of calcium supplements before donation respectively. The incidence of phlebotomy injuries is higher in apheresis donors because of the longer procedure, the active withdrawal of blood and return of cell and citrate to the donor, and the use of anticoagulant which, although rapidly metabolised contributes to a higher incidence of haematoma.

Plateletpheresis – Platelet collections take longer than plasma collections. Platelet donors do not receive saline compensation and are exposed to significantly higher doses of citrate anticoagulant than plasma donors. As a consequence, platelet donors experience significantly higher rates of both citrate reactions and immediate vasovagal reactions without loss of consciousness, than plasma donors (Table 53). In addition, platelet donors are more likely to develop significant bruising and, to a lesser extent, other phlebotomy injuries as a result of the longer duration of platelet donation.

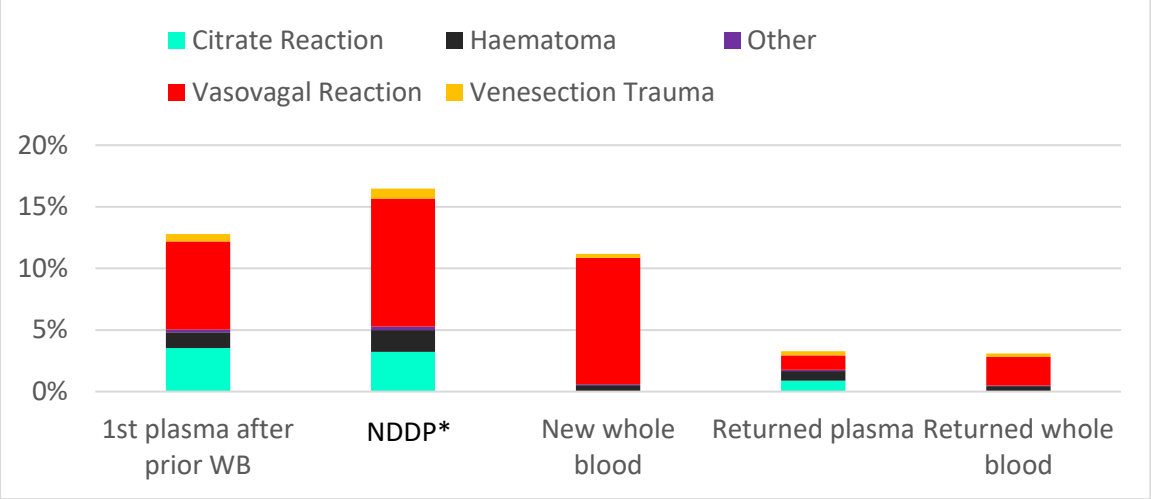
Venepuncture only – Some attendances require the collection of a blood sample (for example to confirm a low haemoglobin result on finger prick testing) and do not proceed to a collection. Based on a sample of 9,697 venepuncture only attendances in 2017-18, 0.47% (47.43/10,000) were associated with a donor adverse event. Within this sample group of 9,697, there were 48 unique donor adverse events reported; nerve injury/irritation (5), painful arm (13), haematoma (16) and vasovagal reactions (14).

Table 51: Collections associated with one or more donor adverse event (per 10,000 collections), 2013-14 to 2017-18

Collection type	2013-14	2014-15	2015-16	2016-17	2017-18
Whole blood	303.99	310.98	316.23	309.11	296.77
Plasmapheresis	138.38	162.78	198.76	188.33	259.99
Plateletpheresis	711.03	682.95	801.01	753.83	975.78
All apheresis	177.83	193.75	231.54	218.26	289.50
Total	**253.74**	**262.67**	**278.42**	**267.13**	**293.21**

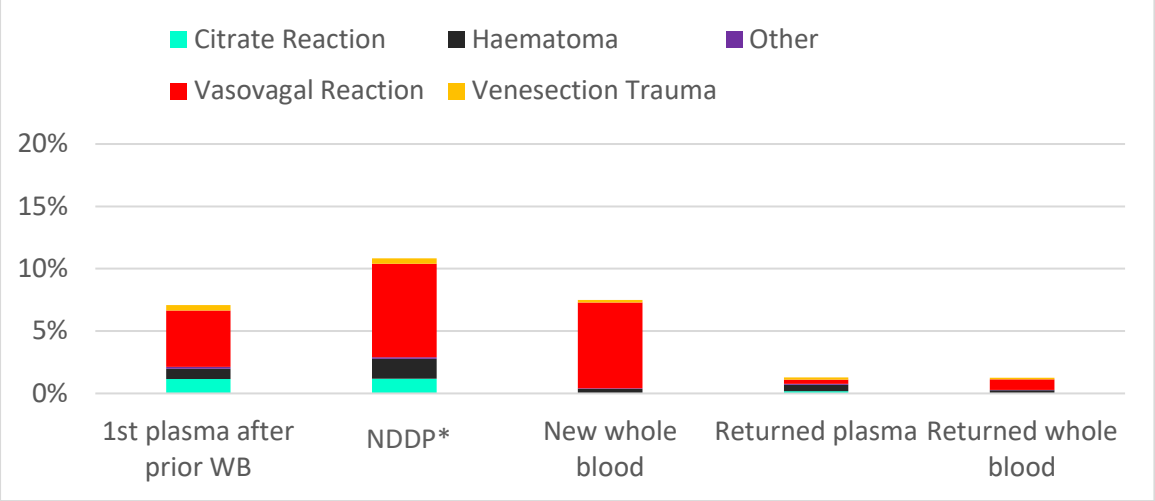
Figures 2 and 3 show the annualised incidence of vasovagal reactions, phlebotomy injuries and citrate reactions in new donors compared to returning donors. Data represents distinct donor adverse events. If a donor reports more than one adverse event with a single donation, all events are captured.

Figure 2: Incidence of adverse events in female donors by donation type and new or returning status for 2017–18



*New donor direct to plasma

Figure 3: Incidence of donor adverse events in male donors by donation type and new or returning status for 2017-18



*New donor direct to plasma

The higher overall incidence of reactions in new donors direct to plasma compared to first time whole blood donors or first time plasma donors is the result of the well documented high rate of vasovagal reactions in first time donors[1,2] (even first time plasma donors who have completed several previous whole blood donations), the higher incidence of citrate reactions which is observed in all first time plasma donors, and the higher frequency of phlebotomy injuries in all apheresis donors.

The rate of external medical referral for new donors direct to plasma is lower than the rate of external referrals for new whole blood donors for the same period of time (Table 52).

Table 52: Collections associated with a donor adverse event requiring hospital or GP attendance for first time whole blood donors and new donors direct to plasma (NDDP) (December 2017 to June 2018)

Reaction type	Donation type	Hospital attendance* (number)	Incidence of hospital attendance (%)	GP attendance or referral^ (number)	Incidence of GP attendance/referral (%)
Vasovagal Reactions	New whole blood	32	0.07	21	0.05
	NDDP	4	0.06	1	0.02
Phlebotomy Injuries	New whole blood	1	0.00	18	0.04
	NDDP	0	0.00	1	0.02
Chest pain / tightness	New whole blood	1	0.00	2	0.00
	NDDP	0	0.00	0	0.00
Other	New whole blood	0	0.00	2	0.00
	NDDP	0	0.00	0	0.00
Total	**New whole blood**	**34**	**0.08**	**43**	**0.10**
	NDDP	**4**	**0.06**	**2**	**0.03**

* Referral by or transfer from the Blood Service or donor self–referrals.

^ Referral by Blood Service or self–referral.

Table 53: Donor adverse event rate by category (per 10,000 collections), 2017-18

			Rate per 10,000 collections			
			Whole Blood n = 699,689	**Plasmapheresis** n = 646,093	**Plateletpheresis** n = 27,783	**TOTAL** n = 1,373,565
Immediate vasovagal reaction	Without LOC	Without injury	197.72	91.23	139.29	146.44
		With injury	0.04	0.02	0.36	0.04
	With LOC	Without injury	14.12	6.92	3.96	10.53
		With injury	0.43	0.12	1.08	0.30
Delayed vasovagal reaction	Without LOC	Without injury	26.13	12.99	5.40	19.53
		With injury	0.27	0.06	0.00	0.17
	With LOC	Without injury	4.43	1.24	1.80	2.88
		With injury	0.47	0.11	0.00	0.29
Blood and fluid outside vessel	Haematoma		35.67	65.87	304.50	55.32
	Arterial puncture		0.24	0.12	0.00	0.18
	Delayed bleeding		1.56	3.58	1.08	2.50
	Extravasation/Compartment Syndrome		0.13	4.15	7.92	2.18
Arm pain	Nerve injury/irritation		7.10	5.94	6.48	6.55
	Tendon Injury		0.01	0.09	0.00	0.05
	Other phlebotomy or vessel injury		0.11	0.06	0.00	0.09
	Painful arm		12.73	18.57	21.24	15.65
Related to apheresis	Citrate reaction		0.00	63.53	559.69	40.73
	Infiltration/extravasation		0.00	0.08	0.36	0.04
	Omitted Anticoagulant		0.00	0.00	1.08	0.02
	Haemolysis		0.00	0.00	0.00	0.00
	Air embolism		0.00	0.00	0.00	0.00
Infection/ inflammation /allergy	Allergic Reaction - Localised		1.63	1.45	1.08	1.54
	Allergic/Anaphylactic Reaction		0.03	0.03	0.00	0.03
	Thrombophlebitis		0.33	0.39	0.72	0.36
	Cellulitis		0.00	0.02	0.00	0.01
	Cardiac	Chest Pain/Chest Tightness	0.81	0.80	0.72	0.81
		Cardiac arrest	0.00	0.00	0.00	0.00
	Post Donation Thrombosis		0.01	0.00	0.00	0.01
	Other injury / event		1.29	2.01	2.16	1.65
Unknown	Other		0.03	0.08	0.00	0.05
Total			**305.29**	**279.46**	**1058.92**	**307.95**

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 2017-18, the rate of hospital attendances and GP attendances for donation-related complications per 10,000 collections was 2.96 and 4.56 respectively (Table 54). 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.

Of the total donor adverse events reported in 2017-18, there were 35 donors with chest pain/tightness who attended a hospital between July 2017 and June 2018, of whom 9 were admitted for cardiac investigations; all had been previously well but had risk factors for coronary disease. Five donors were found to have coronary artery disease: one donor suffered a myocardial infarct approximately 7 hours following a whole blood donation and required a single stent inserted. There were three whole blood donors and one plasmapheresis donor who 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 to hospital for chest pain; in 13 cases the diagnosis was anxiety; in 11 cases no definitive diagnosis was made; and in six cases there were no outcomes available. Most hospital attendances are brief presentations to the Emergency Department, and admission to hospital is rare.

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 were venous thrombosis (one donor) and superficial thrombophlebitis (37 donors).

Table 54: Donor adverse events requiring GP or hospital attendance in 2017-18[#]

	GP Attendance/ Referrals* (n)	Rate per 10,000 collections	Hospital Attendances^ (n)	Rate per 10,000 collections	Total Referrals / Attendances (n)	Rate per 10,000 collections
Whole Blood	364	5.20	248	3.54	612	8.74
Plasmapheresis	251	3.88	152	2.35	403	6.23
Plateletpheresis	12	4.32	6	2.16	18	6.48
Total	627	4.56	406	2.96	1,033	7.52

[#] Confirmation of attendance and outcomes are not always available.

* Referrals to GP by Blood Service and donor self–referrals.

^ Referrals by or transfer from the Blood Service and donor self–referrals. Attendance by ambulance at the donor centre is only included if the donor is transferred to hospital.

Hospital referral rates have fallen steadily in whole blood donors since 2014 -15 and has remained stable in apheresis donors. (Refer to Table 55 below).

Table 55: Donor adverse events requiring hospital attendance 2013-14 to 2017-18

	2013-14	2014-15	2015-16	2016-17	2017-18
	Rate per 10,000 collections (number)				
Whole blood	4.51 (353)	4.33 (324)	4.08 (296)	3.34 (238)	3.54 (248)
Plasmapheresis	2.2 (106)	1.82 (90)	1.95 (108)	1.93 (112)	2.35 (152)
Plateletpheresis	4.48 (16)	5.44 (17)	4.4 (14)	1.54 (5)	2.16 (6)
All apheresis	2.35 (122)	2.04 (107)	2.09 (122)	1.91 (117)	2.34 (158)
Total collections	**3.65 (475)**	**3.39 (431)**	**3.19 (418)**	**2.68 (355)**	**2.96 (406)**

The majority of donors attending hospital are referred from donor centres because their recovery from a vasovagal reactions 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 adverse donation reactions - impact of donor gender, age and donation status

The frequency of donation associated events is higher in younger blood donors and in female blood donors. There is a steady reduction in the risk of a donation reaction with increasing age (Table 56 and 57). 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 donor adverse events in this age group, combined with their increased requirements for iron and hence risk of iron deficiency, prompted a decision to increase the minimum age for blood donation from 16 to 18 years. The high incidence of reactions in young donors and female donors is consistent with international experience.

Table 56: Collections associated with one or more donor adverse event (DAE) in female donors by age, 2017-18

Age Group	Collections associated with DAE (n)	Total collections (n)	Ratio	DAE Rate per 10,000	Relative risk*	Confidence intervals (95%)
16-17	295	2,170	1:7	1,359.45	3.35	3.01-3.72
18-20	3,269	33,123	1:10	986.93	2.62	2.53-2.71
21-23	2,942	43,099	1:15	682.61	1.76	1.69-1.82
24-30	5,489	103,079	1:19	532.50	1.39	1.35-1.43
31-40	4,138	105,085	1:25	393.78	0.95	0.92-0.99
41-50	3,310	106,257	1:32	311.51	0.72	0.70-0.75
51-60	3,211	117,801	1:37	272.58	0.62	0.59-0.64
61-70	2,129	86,359	1:41	246.53	0.57	0.54-0.59
71+	192	13,152	1:69	145.99	0.35	0.31-0.40
All	24,975	610,125	1:24	409.34		

*Relative risk is calculated based on risk event in all other age groups.

Table 57: Collections associated with one or more donor adverse event (DAE) in male donors by age, 2017-18

Age Group	Collections associated with DAE (n)	Total collections (n)	Ratio	DAE Rate per 10,000	Relative Risk*	Confidence intervals (95%)
16-17	113	1,247	1:11	906.17	4.55	3.81-5.43
18-20	1,323	24,951	1:19	530.24	2.8	2.65-2.96
21-23	1,346	34,427	1:26	390.97	2.04	1.93-2.16
24-30	3,275	99,439	1:30	329.35	1.82	1.75-1.89
31-40	3,234	131,164	1:41	246.56	1.29	1.24-1.34
41-50	2,228	136,643	1:61	163.05	0.78	0.75-0.82
51-60	2,159	172,480	1:80	125.17	0.56	0.54-0.59
61-70	1,469	137,938	1:94	106.50	0.48	0.46-0.51
71+	151	25,146	1:167	60.05	0.29	0.25-0.34
All	15,298	763,435	1:50	200.38		

*Relative risk is calculated based on risk event in all other age groups.
Age data for 5 donors is unavailable for these tables, one of whom reported a donor adverse event.

Current strategies to reduce the risk of donor adverse events

1. Donor selection criteria:
    a. An increase in the minimum weight to 50kg, and a minimum total blood volume of 3,333ml, was implemented in 2015.
    b. An increase in the minimum age for donation from 16 to 18 years, effective from 14 January 2018.
    c. Permanent deferral of donors who are at significant risk of experiencing a recurrence of serious donor adverse reactions.
2. Interventions that reduce the risk of an adverse donation reaction

    Whole blood donation
    a. Use of in centre water-loading for whole blood donors has been used since 2017.
    b. Applied muscle tension combined with water loading for all whole blood donors was rolled out in all Donor Centres between February and March 2018.
    c. Provide advice to donors on strategies to minimise the risk of a reaction during and after donation on donateblood.com.au (use of applied muscle tension, rest and fluid intake, avoidance of strenuous physical activity and alcohol post donation).
    d. Provision of specific information cards to donors at the time of an adverse event detailing immediate management and preventative actions relevant to subsequent donations.

    Plasmapheresis and plateletpheresis donation
    e. Fluid replacement using 500ml normal saline for plasma donors to reduce the risk of vasovagal reaction.
    f. Using a stepwise approach to increasing collection volume for plasmapheresis donors donating plasma for fractionation based on nomograms* for percent Total Blood Volume.
    g. Routine provision of oral calcium supplementation to all plasma- and plateletpheresis donors using 900mg of elemental calcium in a palatable peppermint lozenge to minimise the risk of citrate reactions.

3. Haemovigilance and Clinical Governance activities
    a. Communication with comparable international blood services to ensure 'best practice' protocols.
    b. Regular donor adverse events data review and trend analysis is conducted by the Donor Vigilance Team, with reporting provided at donor centre, state and national level.
    c. Formal clinical governance processes including review of staff scope of practice and training, the conduct of clinical audits, robust data capture and analysis of donor adverse events, regular management and external review of donor adverse event trends with corrective action taken as required.

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

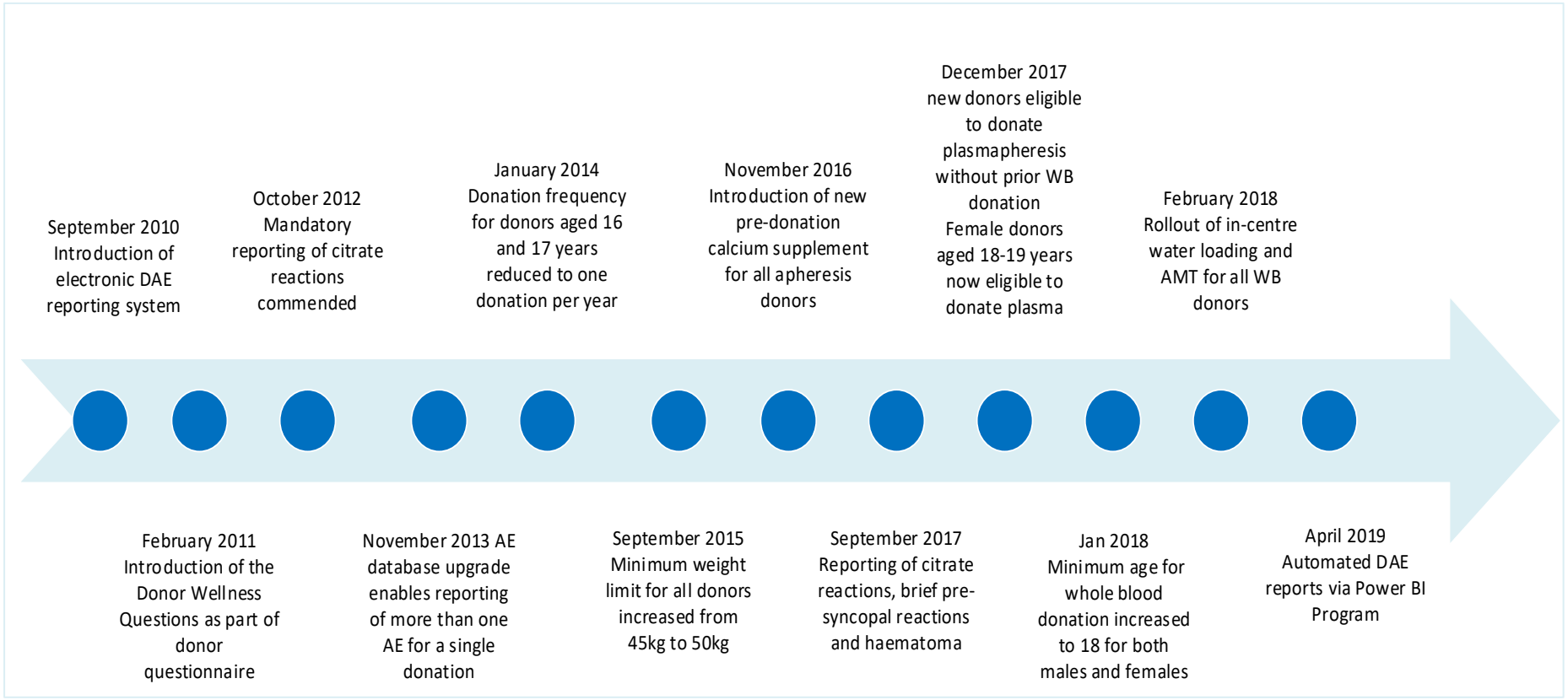
APPENDIX 1

Appendix 1. International Society of Blood Transfusion (ISBT) Definitions

<table>
<tr><th colspan="8">COMPARISON OF ISBT AND AUSTRALIAN RED CROSS BLOOD SERVICE DONOR ADVERSE EVENTS CLASSIFICATIONS</th></tr>
<tr><th colspan="4">SYSTEMIC COMPLICATIONS</th><th colspan="2">LOCAL COMPLICATIONS</th><th colspan="2">APHERESIS COMPLICATIONS</th></tr>
<tr><td>ISBT</td><td>BLOOD SERVICE</td><td>ISBT</td><td>BLOOD SERVICE</td><td>ISBT</td><td>BLOOD SERVICE</td><td>ISBT</td><td>BLOOD SERVICE</td></tr>
<tr><td colspan="2">Occurring onsite</td><td colspan="2">Occurring offsite</td><td>Blood outside vessels</td><td>No specific sub-category</td><td rowspan="3">Citrate reaction</td><td>Mild citrate reaction</td></tr>
<tr><td>Immediate</td><td>Immediate</td><td>Delayed*</td><td>Delayed</td><td>Haematoma</td><td>Haematoma</td><td>Moderate citrate reaction</td></tr>
<tr><td rowspan="3">Vasovagal reaction without LOC</td><td>Mild VVR(<15 minutes duration)</td><td rowspan="3">Vasovagal reaction without LOC</td><td>Mild VVR(<15 minutes duration)</td><td>Arterial puncture</td><td>Arterial puncture</td><td>Severe citrate reaction</td></tr>
<tr><td>Moderate VVR (15-60 minutes duration)</td><td>Moderate VVR (15-60 minutes duration)</td><td>Delayed bleeding</td><td>Delayed bleeding</td><td>Haemolysis</td><td>Suspected haemolysis</td></tr>
<tr><td>Severe VVR (>60 minutes duration)</td><td>Severe VVR (>60 minutes duration)</td><td>Arm pain</td><td>No specific sub-category</td><td>Anaphylaxis</td><td>Anaphylaxis</td></tr>
<tr><td>Vasovagal reaction with LOC</td><td rowspan="2">Severe VVR</td><td>Vasovagal reaction with LOC</td><td rowspan="2">Severe VVR</td><td>Nerve injury/irritation</td><td>Nerve injury/irritation</td><td rowspan="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 (including non-cardiac chest pain)</td><td>Acute cardiac symptoms</td><td rowspan="2">Chest pain (including non-cardiac chest pain)</td><td>Cellulitis</td><td>No specific category</td><td>Omitted antcoagulant - severe</td></tr>
<tr><td>Acute myocardial infarction</td><td>Acute myocardial infarction</td><td>Thrombophlebitis</td><td>Superficial thrombophlebitis</td><td>Wrong solution administered</td></tr>
<tr><td>Transient ischaemic attack (TIA)</td><td>No specific category</td><td>Transient ischaemic attack (TIA)</td><td>No specific category</td><td>Other</td><td>No specific sub-category</td><td colspan="2" rowspan="4">** The complications listed are extremely rare; from a reporting perspective, the occurrence of any of the any of the apheresis adverse events in this category would result in a full incident investigation, including root cause analysis</td></tr>
<tr><td>Cerebrovascular accident</td><td>No specific category</td><td>Cerebrovascular acident</td><td>No specific category</td><td rowspan="2">DVT</td><td>Thrombosis not involving axillary vein</td></tr>
<tr><td>Cardiac arrest</td><td>Cardiac arrest</td><td>Cardiac arrest</td><td>Cardiac arrest</td><td>Thrombosis involving axillary vein</td></tr>
<tr><td>Death</td><td>Death</td><td>Death</td><td>Death</td><td>Arteriovenous fistula</td><td>No specific category</td></tr>
<tr><td colspan="4" rowspan="2">* Occurring within 24 hours of blood donation and definitely, possibly or likely due to blood donation</td><td>Infiltration</td><td>Extravasation/compartment syndrome</td><td colspan="2" rowspan="2"></td></tr>
<tr><td>Compartment syndrome</td><td>Not listed separately from extravasation</td></tr>
</table>

APPENDIX 2

Appendix 2. Timeline of significant changes in policies and procedures which have contributed to improvements in donor safety



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 Geoffrey Bartle	Consumer Representative
Ms Linley Bielby	VIC Health
Dr Heather Buchan	Australian Commission on Safety and Quality in Health Care
Ms Maria Burgess	ACT Health
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Australian Government and State and Territory Contributors

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ACT Health
NT Department of Health

Australian Red Cross Blood Service

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