DATA FOR
2019–2020

AUSTRALIAN HAEMOVIGILANCE REPORT

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SECTION 1

Australian Haemovigilance Data

July 2019 – June 2020

Acknowledgements

This report is published on behalf of the states and territories who voluntarily provided data to the national program. 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 there are quality issues in relation to data completeness, standardisation, and relevance.

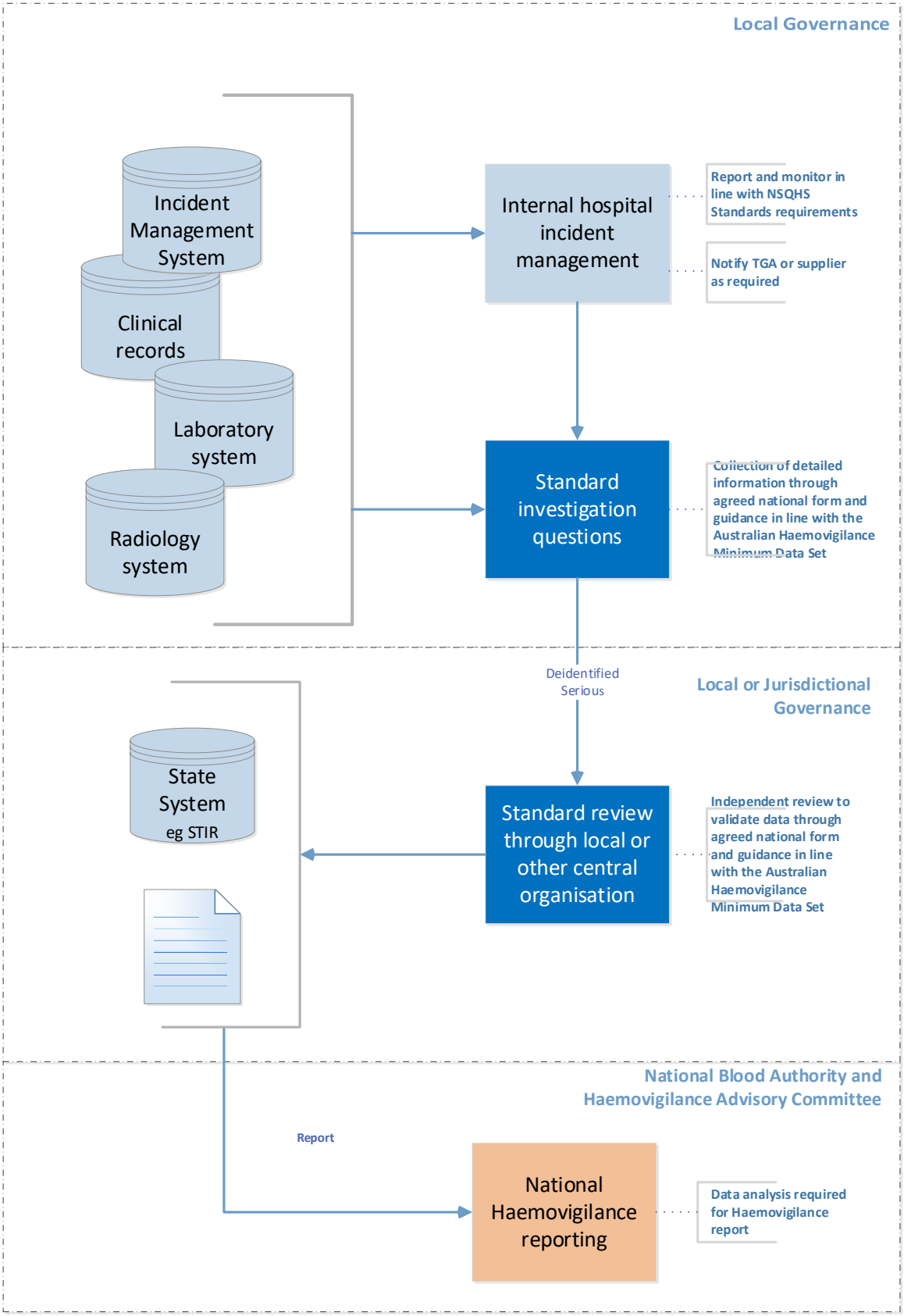
Notwithstanding these limitations, the NBA is publishing this data as an aid to relevant analysis and to maintain the time series of data published during the last ten years.

- 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. 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.
- All states and territories except QLD reported the data in line with the 2015 AHMDS for 2019-20. QLD uses the 2010 NHDD except for the imputability scores which are based on the 2015 AHMDS.
- All states and territories have contributed to the data since 2015-16. However, the level and data provided vary across years and between states and territories.
- The use of different haemovigilance reporting processes across the jurisdictions which may lead to data inconsistencies.
- Near misses and denominator data (number of transfusions) are not collected and reported at a national level.
- All the 2019-20 transfusion-transmitted infection (TTI) data have been verified with the states and territories and Australian Red Cross Lifeblood (Lifeblood).
- The Serious Transfusion Incident Reporting (STIR) used a higher-level temperature threshold for the reporting of febrile non-haemolytic transfusion reaction (FNHTR) before 2018-19.

Collection and reporting process

In Australia, haemovigilance is undertaken at local or state/territory, supported by a national data collection and reporting process. Data is collected at the local or state/territory level and the local area is responsible for the review of reported incidents to assess the validity and imputability of the incident with respect to whether it was reported correctly, the seriousness of the incident, and assessment of the cause of the incident being related to the transfusion. Some states and territories/local organisations provide their data to STIR to conduct this review, while others manage

this process themselves, or do not do a review outside of the local level. Following review, the data is validated in line with the AHMDS before reporting the data to the NBA.



Note: NSQHS – National Safety and Quality Health Service, TGA – Therapeutic Goods Administration

Introduction

States and territories use different haemovigilance reporting processes which may lead to different number of adverse events reported to the national haemovigilance program. For example, the Victorian Blood Matters Serious Transfusion Incident Reporting (STIR) for participating states (VIC, TAS, NT and ACT), reports serious adverse events and excludes non-transfusion related adverse events. QLD reports all adverse events according to the definitions of these and does not exclude non-transfusion related adverse events.

The report commences with data on all events reported to the NBA, and then for consistency and comparability, events have been categorised as non-transfusion related adverse events; transfusion-related non-serious adverse events, and transfusion-related serious adverse events.

Results for all adverse events, 2015-16 to 2019-20

This section presents the data and key results for all adverse events from 2015-16 to 2019-20.

Table 1 shows that:

- all states and territories except NT reported an increase in adverse events in 2019-20, with VIC increasing by 63.8% and NSW by 55.6%
- the adverse event rate per 100,000 population ranges from 1.12 for TAS to 5.83 for QLD in 2019-20
- the use of different haemovigilance reporting processes across the jurisdictions which may lead to data inconsistencies.

Table 1: All adverse events by state, 2015-16 to 2019-20

	2015-16	2016-17	2017-18	2018-19	2019-20	-		
						Percent	Rate per 100,000 population	% Change from 2018-19
NSW	281	175	61	72	112	16.6%	1.38	55.6%
VIC	54	69	57	58	95	14.1%	1.43	63.8%
QLD	250	246	202	233	299	44.3%	5.83	28.3%
SA	62	54	61	52	69	10.2%	3.92	32.7%
WA	73	71	85	68	83	12.3%	3.15	22.1%
TAS	0	5	11	0	6	0.9%	1.12	NA
NT	3	5	2	12	5	0.7%	2.04	-58.3%
ACT	1	3	9	5	6	0.9%	1.40	20.0%
Total	**724**	**628**	**488**	**500**	**675**	**100%**	**2.65**	**35.0%**

Note: The population data is from the ABS 31010DO001_201912 Australian Demographic Statistics, Dec 2019

Table 2 shows that:

- the most common adverse events reported are febrile non-haemolytic transfusion reaction (FNHTR) and allergic reaction (Allergic) by percentage, population, and incidence rate
- transfusion-associated circulatory overload (TACO) is likely to be under-reported when the number of reports is compared with the incidence rate
- reported transfusion-transmitted infections (TTI) and incorrect blood component transfused (IBCT) increased by 300% (n=9) and 182% (n=20) respectively in 2019-20 compared to small numbers in 2018-19
- adverse events such as delayed serologic transfusion reaction (DSTR), hypotensive reaction (Hypotensive) and transfusion associated dyspnoea (TAD) have been reported from 2017-18 in line with the 2015 AHMDS.

Table 2: All adverse events and incidence data, 2015-16 to 2019-20

	2015–16	2016–17	2017–18	2018–19	2019–20	2019–20			Incidence*
						Percent	Rate per 100,000 population	% of change from 2018-19	(unless specified)
FNHTR	365	304	210	169	222	32.9%	0.87	31.4%	0.1–1% of transfusions with universal leucocyte depletion
Allergic	193	157	107	179	241	35.7%	0.94	34.6%	1–3% of transfusion of plasma containing components
TACO	51	55	52	42	60	8.9%	0.24	42.9%	Approximately 1% of transfused patients
IBCT	41	20	23	11	31	4.6%	0.12	181.8%	Not available
Anaphylactic	30	45	20	29	24	3.6%	0.09	-17.2%	1:20,000–50,000 transfusions
DHTR	16	21	19	15	18	2.7%	0.07	20.0%	1:2,500–11,000 or 1:71,667
AHTR	9	13	8	15	24	3.6%	0.09	60.0%	1:76,000
TTI	17	1	15	3	12	1.8%	0.05	300.0%	1:100,000 platelet transfusions
									1:500,000 red cell transfusions
TRALI	2	12	3	1	2	0.3%	0.01	100.0%	1:1,200–1:190,000 transfusions
PTP	0	0	1	1	0	0.0%	-	-100.0%	Rare
DSTR	Not reported	Not reported	10	16	25	3.7%	0.10	56.3%	Not available
Hypotensive	Not reported	Not reported	6	4	3	0.4%	0.01	-25.0%	Not available
ABO	Not reported	Not reported	2	1	1	0.1%	0.00	0.0%	1:40,000
TAD	Not reported	Not reported	0	7	7	1.0%	0.03	0.0%	Not available
Other	Not reported	Not reported	12	7	5	0.7%	0.02	-28.6%	Not available
Total	**724**	**628**	**488**	**500**	**675**	**100%**	**2.65**	35.0%	

Notes

1. **The population data is from the ABS 31010DO001_201912 Australian Demographic Statistics, Dec 2019**
2. ***Australian Red Cross Lifeblood (2020), Blood Component Information: An extension of blood component labels**

Table 3 shows that most adverse events were reported by public hospitals. For more information, refer to the **Hospital participation in haemovigilance program** section.

Table 3: All adverse events by hospital type, 2015-16 to 2019-20

	2015-16	2016-17	2017-18	2018-19	2019-20	2019-20		
						Percent	Rate per 100,000 population	% Change from 2018-19
Public hospital	653	588	454	429	617	91.4%	2.42	90.9%
Private hospitals	71	40	34	71	58	8.6%	0.23	9.1%
Total hospitals	**724**	**628**	**488**	**500**	**675**	**100%**	**2.65**	**100.0%**

Note: The population data is from the ABS 31010DO001_201912 Australian Demographic Statistics, Dec 2019

Results for all adverse events, 2019-20

This section presents the data and key results for all reported adverse events for 2019-20.

Table 4 shows that the percentages of red blood cell (RBC) issued from the Australian Red Cross Lifeblood (Lifeblood) are reasonably consistent with the population percentage for each state and territory. In contrast, QLD reported a much higher percentage of adverse events (44.3%) when compared with the population percentage and RBC issue percentage. This is mainly for FNHTRs (154) and allergic reactions (96). NSW reported less TACOs (6 out of 60) than VIC, QLD, and SA, and more IBCTs (16 out of 31) than other states and territories. The use of different haemovigilance reporting processes across the jurisdictions which may lead to data inconsistencies.

Table 4: All adverse events by state, 2019-20

	Allergic	FNHTR	TACO	IBCT	Anaphylactic	DHTR	AHTR	TTI	TRALI	DSTR	Hypotensive	ABO	TAD	Other	All reports		Population	Red blood cell issues
															Total	Percent	Percent	Percent
NSW	51	28	6	16	0	0	2	3	1	0	3	0	2	0	112	16.6%	31.9%	31.4%
VIC	17	16	15	5	9	7	2	0	1	19	0	0	2	2	95	14.1%	26.1%	27.1%
QLD	96	154	14	5	6	6	13	5	0	0	0	0	0	0	299	44.3%	20.1%	20.8%
SA	40	2	16	1	2	3	4	0	0	0	0	0	1	0	69	10.2%	6.9%	8.6%
WA	35	16	5	3	7	2	2	3	0	6	0	1	1	2	83	12.3%	10.3%	8.0%
TAS	1	2	1	0	0	0	0	1	0	0	0	0	0	1	6	0.9%	2.1%	2.0%
NT	1	2	1	0	0	0	1	0	0	0	0	0	0	0	5	0.7%	1.0%	0.6%
ACT	0	2	2	1	0	0	0	0	0	0	0	0	1	0	6	0.9%	1.7%	1.5%
Total	**241**	**222**	**60**	**31**	**24**	**18**	**24**	**12**	**2**	**25**	**3**	**1**	**7**	**5**	**675**	**100%**	**100%**	**100%**

Note: The population data is from the ABS 31010DO001_201 912 Australian Demographic Statistics, Dec 2019

Table 5: All adverse events by imputability score, 2019-20

Event type	Excluded	Unlikely	Possible	Probable (likely)	Definite (certain)	Not assessable	Total	Percent
FNHTR	5	40	122	40	2	13	222	32.9%
Allergic	2	1	55	131	50	2	241	35.7%
TACO	0	1	19	23	13	4	60	8.9%
IBCT	0	0	1	0	25	5	31	4.6%
Anaphylactic	0	0	12	9	3	0	24	3.6%
DHTR	0	0	4	4	10	0	18	2.7%
AHTR	0	1	8	6	6	3	24	3.6%
TTI	2	0	2	2	2	4	12	1.8%
TRALI	0	0	1	1	0	0	2	0.3%
DSTR	0	0	1	7	17	0	25	3.7%
Hypotensive	0	0	2	0	0	1	3	0.4%
ABO	0	0	0	0	1	0	1	0.1%
TAD	0	0	3	2	0	2	7	1.0%
Other	0	0	4	0	1	0	5	0.7%
Total	**9**	**43**	**234**	**225**	**130**	**34**	**675**	
Percent	**1.3%**	**6.4%**	**34.7%**	**33.3%**	**19.3%**	**5.0%**	**100%**	

Note: QLD reported most of the non-transfusion related FNHTRs

Table 5 shows that 87.3% (589) of reported adverse events (imputability=possible, likely, and definite) are related to blood transfusion. Non transfusion related adverse events (imputability=excluded, unlikely, and not assessable) accounted for 12.7% (86) and should be excluded from analysis.

A breakdown of adverse events by clinical outcome severity in **Table 6** shows:

- of the three deaths reported, only one (anaphylactic) death related to transfusion
- life-threatening and severe morbidity events accounted for 11.6% of total reports
- 63.1% of reported adverse events related to minor morbidities.

Table 6: All adverse events by clinical outcome severity, 2019-20

Adverse event	Death	Life-threatening	Severe morbidity	Minor morbidity	No morbidity	Outcome not available	Total
FNHTR	1	1	12	167	32	9	222
Allergic	0	9	5	186	40	1	241
TACO	0	8	12	31	8	1	60
IBCT	1	1	2	2	15	10	31
Anaphylactic	1	11	5	2	5	0	24
DHTR	0	0	1	12	4	1	18
AHTR	0	3	1	18	2	0	24
TTI	0	3	1	0	5	3	12
TRALI	0	2	0	0	0	0	2
DSTR	0	0	0	2	23	0	25
Hypotensive	0	0	0	1	1	1	3
ABO	0	0	0	1	0	0	1
TAD	0	1	0	3	2	1	7
Other	0	0	0	1	4	0	5
Total	**3**	**39**	**39**	**426**	**141**	**27**	**675**
Percent	**0.4%**	**5.8%**	**5.8%**	**63.1%**	**20.9%**	**4.0%**	**100%**

Table 7 highlights that 61.5% of adverse events were reported to be red cell transfusions, followed by platelets (24.7%) and fresh frozen plasma (10.2%).

Table 7: All adverse events by blood product, 2019-20

Adverse event	Red cells	Platelets	Fresh frozen plasma	Cryoprecipitate	Cryo-depleted Plasma	Multiple products	Other products	Total
FNHTR	192	28	2	0	0	0	0	222
Allergic	61	103	57	9	4	5	2	241
TACO	56	2	2	0	0	0	0	60
IBCT	27	2	1	1	0	0	0	31
Anaphylactic	6	10	6	2	0	0	0	24
DHTR	16	1	0	0	0	0	1	18
AHTR	16	8	0	0	0	0	0	24
TTI	1	11	0	0	0	0	0	12
TRALI	2	0	0	0	0	0	0	2
DSTR	24	1	0	0	0	0	0	25
Hypotensive	3	0	0	0	0	0	0	3
ABO	0	0	1	0	0	0	0	1
TAD	7	0	0	0	0	0	0	7
Other	4	1	0	0	0	0	0	5
Total	**415**	**167**	**69**	**12**	**4**	**5**	**3**	**675**
Percent	**61.5%**	**24.7%**	**10.2%**	**1.8%**	**0.6%**	**0.7%**	**0.4%**	**100%**

Table 8 shows that 8% (54) more adverse events were reported for males than females for most types of adverse events except DSTR.

Table 8: All adverse events by sex, 2019-20

Adverse event	Male	Female	Not reported	Total
FNHTR	113	93	16	222
Allergic	107	89	45	241
TACO	30	24	6	60
IBCT	12	7	12	31
Anaphylactic	14	10	0	24
DHTR	9	9	0	18
AHTR	15	7	2	24
TTI	5	5	2	12
TRALI	1	0	1	2
DSTR	8	17	0	25
Hypotensive	0	1	2	3
ABO	1	0	0	1
TAD	4	2	1	7
Other	2	3	0	5
Total	**321**	**267**	**87**	**675**
Percent	**47.6%**	**39.6%**	**12.9%**	**100%**

Table 9 shows more reported adverse events in males than females in the older age groups and the under 5 age group. Females had more reported adverse events than males in the age groups between 25 and 54.

Table 9: All adverse events by age and sex, 2019-20

Adverse event	Male	Female	Not reported	Total
0–4 years	12	6	4	22
5–14 years	12	13	3	28
15–24 years	14	9	2	25
25–34 years	16	19	12	47
35–44 years	12	18	7	37
45–54 years	32	36	7	75
55–64 years	49	32	12	93
65–74 years	61	59	14	134
75 years or older	105	72	22	199
Not stated	8	3	4	15
Total	**321**	**267**	**87**	**675**
Percent	**47.6%**	**39.6%**	**12.9%**	**100%**

Adverse events reported by day and time and remoteness area are shown in **Table 10** and **Table 11.**

Table 10: All adverse events by time and weekday and remoteness area, 2019-20

	Weekday												
	Between 7am and 7pm					Between 7pm and 7am				Unknown			
	Major City	Inner Regional	Outer Regional	Remote	Total 7am to 7pm	Major City	Inner Regional	Outer Regional	Total 7pm to 7am	Major City	Inner Regional	Total Unknown	Total Weekday
FNHTR	53	7	19	0	79	57	7	26	90	2	1	3	172
Allergic	99	9	7	0	115	57	4	14	75	4	0	4	194
TACO	21	5	0	1	27	21	0	3	24	1	0	1	52
IBCT	6	3	0	0	9	10	3	0	13	1	0	1	23
Anaphylactic	13	3	0	0	16	4	0	0	4	0	0	0	20
DHTR	3	1	2	0	6	6	0	2	8	1	0	1	15
AHTR	11	2	2	0	15	2	1	1	4	1	0	1	20
TTI	1	1	0	0	2	2	0	3	5	0	0	0	7
TRALI	0	0	0	0	0	1	0	0	1	0	0	0	1
DSTR	6	0	0	0	6	12	0	0	12	1	0	1	19
Hypotensive	1	0	0	0	1	2	0	0	2	0	0	0	3
ABO	1	0	0	0	1	0	0	0		0	0	0	1
TAD	0	1	0	0	1	3	0	0	3	0	0	0	4
Other	1	0	0	0	1	0	1	0	1	0	0	0	2
Total	**216**	**32**	**30**	**1**	**279**	**177**	**16**	**49**	**242**	**11**	**1**	**12**	**533**

Table 11: All adverse events by time and weekend and remoteness area, 2019-20

	Weekend											
	Between 7am and 7pm				Between 7pm and 7am				Unknown			
	Major City	Inner Regional	Outer Regional	Total 7am to 7pm	Major City	Inner Regional	Outer Regional	Total 7pm to 7am	Major City	Total Unknown	Total Weekend	Total All
FNHTR	14	2	8	24	15	2	8	25	1	1	50	222
Allergic	21	1	3	25	14	2	5	21	1	1	47	241
TACO	1	0	0	1	6	0	1	7	0	0	8	60
IBCT	3	1	0	4	3	1	0	4	0	0	8	31
Anaphylactic	2	0	1	3	0	0	1	1	0	0	4	24
DHTR	1	0	0	1	2	0	0	2	0	0	3	18
AHTR	3	0	0	3	0	0	1	1	0	0	4	24
TTI	1	0	0	1	0	0	2	2	2	2	5	12
TRALI	0	0	0	0	1	0	0	1	0	0	1	2
DSTR	0	0	0	0	6	0	0	6	0	0	6	25
Hypotensive	0	0	0	0	0	0	0	0	0	0	0	3
ABO	0	0	0	0	0	0	0	0	0	0	0	1
TAD	2	0	0	2	1	0	0	1	0	0	3	7
Other	1	1	0	2	0	1	0	1	0	0	3	5
Total	**49**	**5**	**12**	**66**	**48**	**6**	**18**	**72**	**4**	**4**	**142**	**675**

Contributory factors for all adverse events, 2015-16 to 2019-20

States and territories report data on factors contributing to each adverse event where applicable.

Table 12 shows that:

- the most frequent contributory factors reported are 'None identified' and 'Product characteristic'
- 'Administration of product' factor reported increased five-fold, from 10 in 2018-19 to 64 in 2019-20.

Table 12: Contributory factors for all adverse events, 2015-16 to 2019-20

Summary Data	2015-16	2016-17	2017-18	2018-19	2019-20	% Change from 2018-19
None identified	286	256	171	245	330	34.7%
Product characteristic	360	319	193	182	174	-4.4%
Transfusion in emergency setting	17	11	13	19	24	26.3%
Deliberate clinical decision	36	33	29	40	46	15.0%
Prescribing/ordering	15	18	12	5	5	0.0%
Specimen collection/labelling	0	0	1	3	2	-33.3%
Laboratory (testing/dispensing)	23	11	13	9	16	77.8%
Transport, storage, handling	1	1	1	1	1	0.0%
Administration of product	15	18	42	10	64	540.0%
Indications do not meet guidelines	2	9	8	5	6	20.0%
Procedure did not adhere to hospital transfusion guidelines	15	18	19	9	7	-22.2%
Other	20	58	53	48	81	68.8%

Contributory factors for all adverse events for 2019-20

Table 13 shows a breakdown of reported contributory factors by adverse event and outcome severity for 2019-20.

- 'Administration of product' was reported to be associated with FNHTRs and allergic reactions
- 'Transfusion in emergency setting' was reported to be associated with IBCTs
- 'Laboratory (testing/dispensing) was also reported to be associated with IBCTs (12), with two life-threatening cases in 2019-20.

Table 13: Contributory factors by adverse event and by clinical outcome severity, 2019-20

Contributory Factors	Adverse event														Clinical outcome severity					
	FNHTR	Allergic	TACO	IBCT	TTI Bacterial	Anaphylactic	DHTR	AHTR	TRALI	DSTR	Hypotensive	ABO	TAD	Other	Outcome not available	No morbidity	Minor morbidity	Severe morbidity	Life-threatening	Death
None identified	113	113	33	2	5	13	8	16	2	10	3	0	7	5	13	84	198	13	20	2
Product characteristic	49	80	11	1	4	8	4	2	0	15	0	0	0	0	4	34	108	16	12	0
Transfusion in emergency setting	2	6	1	10	0	1	1	2	0	0	0	1	0	0	4	8	9	1	1	1
Deliberate clinical decision	12	18	5	2	0	3	1	3	0	2	0	0	0	0	1	17	22	2	4	0
Prescribing/ordering	0	1	1	3	0	0	0	0	0	0	0	0	0	0	2	2	1	0	0	0
Specimen collection/labelling	0	0	0	2	0	0	0	0	0	0	0	0	0	0	0	1	0	1	0	0
Laboratory (testing/dispensing)	0	0	0	12	0	0	0	3	0	0	0	1	0	0	2	8	3	1	2	0
Transport, storage, handling	0	0	0	1	0	0	0	0	0	0	0	0	0	0	0	0	1	0	0	0
Administration of product	21	25	6	7	0	2	3	0	0	0	0	0	0	0	2	7	50	4	1	0
Indications do not meet guidelines	0	2	1	2	0	1	0	0	0	0	0	0	0	0	1	1	2	0	2	0
Procedure did not adhere to hospital transfusion guidelines	0	1	0	6	0	0	0	0	0	0	0	0	0	0	3	2	2	0	0	0
Other	32	21	14	6	3	1	3	1	0	0	0	0	0	0	2	10	58	8	3	0

Note: One adverse event can be associated with more than one contributory factor

Classification of adverse events

The NBA classified all adverse events into three categories based on outcome severity and imputability ratings shown in **Table 14** as follows.

Non-transfusion related adverse event (AE): A non-transfusion related adverse event is an event classified as 'excluded or unlikely', 'not assessable' to be related to blood transfusion regardless of outcome severity rating.

Transfusion-related non-serious adverse event (non-SAE): A transfusion-related non-serious adverse event is an event classified as 'possible', 'likely/probable 'or 'confirmed/certain' to be related to blood transfusion and results in 'outcome not available' or 'no morbidity' or 'minor morbidity' to a patient.

Transfusion-related serious adverse event (SAE): A transfusion related serious adverse event is an event classified as 'possible', 'likely/probable' or 'confirmed/certain' to be related to blood transfusion and results in 'severe morbidity' or a 'life-threatening' or 'death' to a patient.

Table 14: Adverse event groups based on imputability score and outcome severity

<table>
<tr><th>Outcome severity</th><th colspan="2">Imputability score</th></tr>
<tr><th></th><th>Excluded or Unlikely / Not Assessable</th><th>Definite (certain) / Probable (likely) / Possible</th></tr>
<tr><td>Death</td><td rowspan="6">Non-transfusion related AE</td><td rowspan="3">Transfusion-related SAE</td></tr>
<tr><td>Life-threatening</td></tr>
<tr><td>Severe morbidity</td></tr>
<tr><td>Minor morbidity</td><td rowspan="3">Transfusion-related non-SAE</td></tr>
<tr><td>No morbidity</td></tr>
<tr><td>Outcome not available</td></tr>
</table>

Table 15 shows reported adverse events reclassified as per the rules defined above and the highlights are:

- most reports (75.7% or 2,282) are transfusion-related non-SAEs
- transfusion-related SAEs reported represented 10.8% (326)
- 13.5% (407) of all reports are non-transfusion related AEs.

Table 15: Adverse events by event group, 2015-16 to 2019-20

Adverse event group	2015-16	2016-17	2017-18	2018-19	2019-20	Total	% of 2019-20
Non-transfusion related AE	77	90	93	61	86	407	**12.7%**
Transfusion-related non-SAE	598	451	330	385	518	2,282	**76.7%**
Transfusion-related SAE	49	87	65	54	71	326	**10.5%**
Total	**724**	**628**	**488**	**500**	**675**	**3,015**	**100%**

Table 16 shows non-transfusion related AEs by state from 2015-16 to 2019-20. The Victorian Blood Matters Serious Transfusion Incident Reporting (STIR) for participating states (VIC, TAS, NT and ACT), reports serious adverse events and excludes non-transfusion related adverse events, while QLD has included the non-transfusion related adverse events.

Table 16: Non-transfusion related AEs by state, 2015-16 to 2019-20

	2015-16	2016-17	2017-18	2018-19	2019-20	Total	% of 2019-20
NSW	12	12	2	3	17	46	**19.8%**
VIC	1	0	1	3	2	7	**2.3%**
QLD	41	65	45	39	55	245	**64.0%**
SA	18	9	35	7	5	74	**5.8%**
WA	5	3	9	9	6	32	**7.0%**
TAS	0	0	0	0	0	0	**0.0%**
NT	0	0	0	0	0	0	**0.0%**
ACT	0	1	1	0	1	3	**1.2%**
Total	**77**	**90**	**93**	**61**	**86**	**407**	**100%**

Table 17 shows that QLD reported the largest percentage of transfusion-related non-SAEs (39.3% or 897) over the past five years, followed by NSW (26.4% or 602) and WA (13.7% or 312).

Table 17: Transfusion-related non-SAEs by state, 2015-16 to 2019-20

	2015-16	2016-17	2017-18	2018-19	2019-20	Total	% of 2019-20
NSW	263	149	45	61	84	602	**16.2%**
VIC	41	37	34	31	68	211	**13.1%**
QLD	189	157	143	183	225	897	**43.4%**
SA	37	37	25	43	62	204	**12.0%**
WA	64	61	67	53	67	312	**12.9%**
TAS	0	4	10	0	4	18	**0.8%**
NT	3	5	0	12	5	25	**1.0%**
ACT	1	1	6	2	3	13	**0.6%**
Total	**598**	**451**	**330**	**385**	**518**	**2,282**	**100%**

Table 18 shows that VIC reported the largest percentage of transfusion-related SAEs (35.3% or 115) over the past five years due to only collecting serious adverse events for national reporting, followed by QLD (27.0% or 88) and NSW (16.3% or 53).

Table 18: Transfusion-related SAEs by state, 2015-16 to 2019-20

	2015-16	2016-17	2017-18	2018-19	2019-20	Total	% of 2019-20
NSW	6	14	14	8	11	53	**15.5%**
VIC	12	32	22	24	25	115	**35.2%**
QLD	20	24	14	11	19	88	**26.8%**
SA	7	8	1	2	2	20	**2.8%**
WA	4	7	9	6	10	36	**14.1%**
TAS	0	1	1	0	2	4	**2.8%**
NT	0	0	2	0	0	2	**0.0%**
ACT	0	1	2	3	2	8	**2.8%**
Total	**49**	**87**	**65**	**54**	**71**	**326**	**100%**

Hospital participation in haemovigilance reporting

States and territories reported the hospital participation data in **Figure 1** for 2019-20:

- 495 hospitals participated in the national haemovigilance reporting, including 420 public hospitals and 75 private hospitals
- 26.3% (130) participating hospitals reported adverse events, including 106 public hospitals and 24 private hospitals
- QLD had the highest number of reporting hospitals for both public and private and the highest number of participating hospitals for private
- private hospitals from NSW, SA and NT didn't participate in the national haemovigilance reporting
- only three states (VIC, QLD and WA) reported adverse events for private hospitals

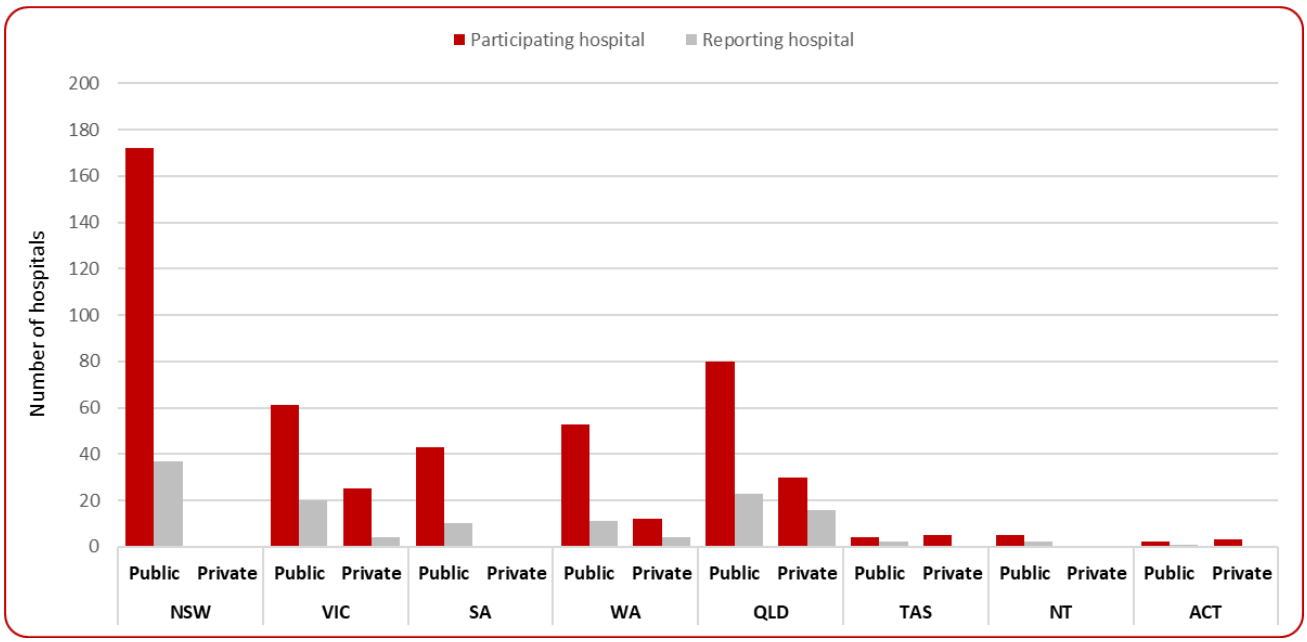


Figure 1: Number of participating and reporting hospitals by public/private and state, 2019-20

Table 19 shows the number of participating hospitals reported adverse events by state and public/private.

Table 19: Number of participating and reporting hospitals by public/private and state, 2019-20

		NSW	VIC	QLD	SA	WA	TAS	NT	ACT
Participating hospitals	Public	172	61	80	43	53	4	5	2
	Private	0	25	30	0	12	5	0	3
Reporting hospitals	Public	37	20	23	10	11	2	2	1
	Private	0	4	16	0	4	0	0	0

Nationally, 5.2 adverse events per hospital were reported for 2019-20. This varied between states and territories, ranging from 2.5 in NT to 7.7 in QLD. A breakdown of adverse events by three classifications shows the following key results as shown in **Table 20.**

- QLD reported the highest rate of non-transfusion related AEs per hospital at 1.4, followed by ACT at 1.0
- SA reported the highest rate of transfusion-related non-SAE per hospital at 6.2, followed by QLD at 5.8
- noting that only serious AEs are collected and reported by the STIR, those participating states and territories except NT reported a higher rate of transfusion-related SAEs per hospital than other states and territories, with ACT at 2.0, VIC at 1.0 and TAS at 1.0

Table 20: Number of adverse events per hospital by state, 2019-20

	NSW	VIC	QLD	SA	WA	TAS	NT	ACT	Total
Number of reporting hospitals	**37**	**24**	**39**	**10**	**15**	**2**	**2**	**1**	**130**
Number of adverse events	**112**	**95**	**299**	**69**	**83**	**6**	**5**	**6**	**675**
Non-transfusion related AE	17	2	55	5	6	0	0	1	86
Transfusion-related non-SAE	84	68	225	62	67	4	5	3	518
Transfusion-related SAE	11	25	19	2	10	2	0	2	71
Adverse events per hospital	**3.0**	**4.0**	**7.7**	**6.9**	**5.5**	**3.0**	**2.5**	**6.0**	**5.2**
Non-transfusion related AE	0.5	0.1	1.4	0.5	0.4	0.0	0.0	1.0	0.7
Transfusion-related non-SAE	2.3	2.8	5.8	6.2	4.5	2.0	2.5	3.0	4.0
Transfusion-related SAE	0.3	1.0	0.5	0.2	0.7	1.0	0.0	2.0	0.5

2015-16 to 2019-20 reclassified

This section presents the reclassified adverse event data and key results for 2015-16 to 2019-20.

Table 21 and **Table 22** show that FNHTR contributed to the highest number of non-transfusion related AEs (62.9%) and transfusion-related non-SAEs (42.4%), followed by allergic reactions with 14.0% for non-transfusion related AEs and 33.4% for transfusion related non-SAEs.

Table 21: Non-transfusion related AEs, 2015-16 to 2019-20

Adverse event	2015-16	2016-17	2017-18	2018-19	2019-20	All reports	
						Total	Percent
FNHTR	50	65	47	36	58	256	62.9%
Allergic	11	13	15	13	5	57	14.0%
TACO	2	6	6	2	5	21	5.2%
IBCT	6	1	2	5	5	19	4.7%
Anaphylactic	2	1	0	0	0	3	0.7%
DHTR	0	2	2	0	0	4	1.0%
AHTR	1	0	3	2	4	10	2.5%
TTI	4	0	4	0	6	14	3.4%
TRALI	1	2	1	1	0	5	1.2%
DSTR	0	0	1	1	0	2	0.5%
Hypotensive	0	0	5	0	1	6	1.5%
TAD	0	0	0	0	2	2	0.5%
Other	0	0	7	1	0	8	2.0%
Total	**77**	**90**	**93**	**61**	**86**	**407**	**100%**

Table 22: Transfusion-related non-SAEs, 2015-16 to 2019-20

	2015-16	2016-17	2017-18	2018-19	2019-20	All reports	
						Total	Percent
FNHTR	309	219	152	131	156	967	42.4%
Allergic	167	129	85	159	222	762	33.4%
TACO	37	30	30	19	37	153	6.7%
IBCT	34	18	21	6	23	102	4.5%
Anaphylactic	15	25	2	11	7	60	2.6%
DHTR	16	18	11	14	17	76	3.3%
AHTR	7	9	4	13	16	49	2.1%
TTI	13	1	8	2	3	27	1.2%
TRALI	0	2	0	0	0	2	0.1%
PTP	0	0	1	1	0	2	0.1%
DSTR	NA	NA	9	15	25	49	2.1%
Hypotensive	NA	NA	1	4	2	7	0.3%
ABO	NA	NA	1	0	1	2	0.1%
TAD	NA	NA	0	7	4	11	0.5%
Other	NA	NA	5	3	5	13	0.6%
Total	**598**	**451**	**330**	**385**	**518**	**2,282**	**100%**

Table 23 shows that 326 transfusion-related SAEs of 12 different types were reported to the national haemovigilance program. TACO and anaphylactic reactions related to 82.5% of reported SAEs. Allergic reactions and FNHTRs accounted for 17.8% and 14.4% SAEs respectively.

Table 23: Transfusion-related SAEs, 2015-16 to 2019-20

	2015-16	2016-17	2017-18	2018-19	2019-20	All reports	
						Total	Percent
FNHTR	6	20	11	2	8	47	14.4%
Allergic	15	15	7	7	14	58	17.8%
TACO	12	19	16	21	18	86	26.4%
IBCT	1	1	0	0	3	5	1.5%
Anaphylactic	13	19	18	18	17	85	26.1%
DHTR	0	1	6	1	1	9	2.8%
AHTR	1	4	1	0	4	10	3.1%
TTI	0	0	3	1	3	7	2.1%
TRALI	1	8	2	0	2	13	4.0%
ABO	NA	NA	1	1	0	2	0.6%
TAD	NA	NA	0	0	1	1	0.3%
Other	NA	NA	0	3	0	3	0.9%
Total	**49**	**87**	**65**	**54**	**71**	**326**	**100%**

Table 24 shows a breakdown of non-transfusion related AEs by imputability score and outcome.

- 6 in 10 non-transfusion related AEs are FNHTRs
- most non-transfusion related AEs were reported to cause either no morbidity (126 out of 407) or only minor morbidity outcomes (207 out of 407)
- two deaths, 4 life-threatening cases and 36 severity morbidity cases are not reported to be related to transfusion. These events should be excluded from analysis.

Table 24: Non-transfusion related AEs by imputablity score and outcome severity, 2015-16 to 2019-20

	Dearth		life-threatening		Severe morbidity		Minor morbidity		No morbidity		Outcome not available		Total
	Excluded or Unlikely	Not Assessable	Excluded or Unlikely	Not Assessable	Excluded or Unlikely	Not Assessable	Excluded or Unlikely	Not Assessable	Excluded or Unlikely	Not Assessable	Excluded or Unlikely	Not Assessable	
FNHTR	1	0	1	0	21	1	120	24	58	12	11	7	256
Allergic	0	0	0	0	4	1	18	13	10	8	3	0	57
TACO	0	0	0	2	3	2	9	1		1	1	2	21
IBCT	0	1	0	0	0	0	0	3	4	11	0	0	19
Anaphylactic	0	0	0	0	0	0	3	0	0	0	0	0	3
DHTR	0	0	0	0	0	0	2	0	0	0	1	1	4
AHTR	0	0	0	0	0	0	2	1	2	5	0	0	10
TTI	0	0	1	0	0	0	1	1	2	6	1	2	14
TRALI	0	0	0	0	1	0	1	1	0	0	2	0	5
DSTR	0	0	0	0	0	0	0	0	0	1	0	1	2
Hypotensive	0	0	0	0	1	2	0	2	0	1	0	0	6
TAD	0	0	0	0	0	0	0	1	0	1	0	0	2
Other	0	0	0	0	0	0	0	4	0	4	0	0	8
Total	**1**	**1**	**2**	**2**	**30**	**6**	**156**	**51**	**76**	**50**	**19**	**13**	**407**

Table 25 shows a breakdown of non-SAEs by imputability score and outcome severity.

- 30% (522) of non-SAEs caused no harm to patients
- 73% (1,670) of non-SAEs were reported to be related to minor morbidities to patients
- 33% (758) of non-SAEs were reported to be possibility related to blood transfusion32% (736) of non-SAEs were reported to be likely related to blood transfusion.

Table 25: Transfusion-related non-SAEs by imputablity score and outcome severity, 2015-16 to 2019-20

	Minor morbidity			No morbidity			Outcome not available			Total
	Possible	Probable (likely)	Definite (certain)	Possible	Probable (likely)	Definite (certain)	Possible	Probable (likely)	Definite (certain)	
FNHTR	487	205	9	184	53	0	23	6	0	967
Allergic	144	408	91	54	40	13	2	9	1	762
TACO	56	61	14	15	3	1	3	0	0	153
IBCT	2	0	7	0	3	55	2	1	32	102
Anaphylactic	15	19	6	10	4	1	3	2	0	60
DHTR	14	13	32	0	2	12	1	0	2	76
AHTR	19	16	8	3	2	0	1	0	0	49
TTI	3	9	1	6	3	5	0	0	0	27
TRALI	2	0	0	0	0	0	0	0	0	2
PTP	2	0	0	0	0	0	0	0	0	2
DSTR	1	1	7	3	10	27	0	0	0	49
Hypotensive	3	0	0	2	1	0	1	0	0	7
ABO	0	1	1	0	0	0	0	0	0	2
TAD	4	2	0	2	2	0	1	0	0	11
Other	6	1	0	4	1	1	0	0	0	13
Total	**758**	**736**	**176**	**283**	**124**	**115**	**37**	**18**	**35**	**2,282**

Table 26 shows a breakdown of SAEs by imputability score and outcome severity.

- Four reported deaths were possibly or likely to be related to transfusion, with two anaphylactic reactions, one Transfusion-related acute lung injury (TRALI) and one ABO incompatibility
- 40% of reported SAEs (131 out of 326) were life-threatening
- 59% of SAEs (191 out of 326) were reported to be related to severe morbidity, including 53 TACOs, 44 FNHTRs and 38 allergic reactions.

Table 26: Transfusion-related SAEs by imputablity score and outcome severity, 2015-16 to 2019-20

	Death			Life-threatening			Severe morbidity		Total
	Possible	Probable (likely)	Definite (certain)	Possible	Probable (likely)	Definite (certain)	Possible	Probable (likely)	
FNHTR	0	0	0	2	1	0	26	18	47
Allergic	0	0	2	2	16	5	9	24	58
TACO	0	0	5	8	20	7	15	31	86
IBCT	0	0	2	0	1	2	0	0	5
Anaphylactic	1	1	15	16	24	5	13	10	85
DHTR	0	0	1	0	0	7	0	1	9
AHTR	0	0	3	1	0	2	2	2	10
TTI	0	0	2	0	1	1	1	2	7
TRALI	1	0	0	5	2	0	4	1	13
ABO	1	0	0	0	0	1	0	0	2
TAD	0	0	0	1	0	0	0	0	1
Other	0	0	0	1	0	0	2	0	3
Total	**3**	**1**	**30**	**36**	**65**	**30**	**72**	**89**	**326**

Recommendations

This report makes six recommendations in four areas based on the NBA's 2018-21 Haemovigilance Work Plan. The NBA and the HAC have set up working groups to implement the first five recommendations

Guideline development

1. Publish the revised AHMDS.
2. Publish the Guidance on Investigation and Management of Acute Transfusion Reactions.

National tools and resources

3. Develop case studies for identified clinical priorities.
4. Update the haemovigilance reporting forms in line with the new version of AHMDS when released.

Education and training

5. Identify training needs for haemovigilance.

Research and development

6. Include haemovigilance as a future topic in the National Blood Sector Research and Development Program.

SECTION 2

Lifeblood

Donor Vigilance Report 2019-2020

30 November 2020

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, experience and retention and is integral to Lifeblood's Clinical and Quality Governance Framework. This report provides a national overview of the donor adverse event rates by donation category for the 2019-20 financial year (FY) along with comparative data from the three previous years.

2. Reporting parameters

2.1. Donation categories

Lifeblood collects both whole blood and specific blood components (plasma and platelets). The donor's suitability for a donation type is assessed prior to each donation.

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 an automated machine that separates whole blood into cellular components and plasma. 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. Lifeblood commenced the roll-out of a new plasmapheresis platform in May 2019; almost all centres had transitioned to the new platform by June 2020. Plasmapheresis donors using the new plasmapheresis platform only receive saline at the end of the donation. A plasmapheresis donation takes an average of approximately 41 minutes[2] and a plateletpheresis donation, 72 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).

By virtue of the collection process, the adverse event profile is quite different for the different donation types. Comparisons across donation types can be valuable but must also be considered in the context of the different processes for each collection type and differing donor demographics and donor experience. For instance, the higher rate of phlebotomy-related events in apheresis compared with whole blood relates to the longer collection time, the nature of the draw and return cycles including the return of red cells and delivery of saline solution and the use of anticoagulant. The higher rate of citrate reactions and haematomas in plateletpheresis compared with plasmapheresis is related to the higher rate of citrate delivery and longer procedure.

2.2. Denominator cohort and rates

The denominator cohort used to calculate donor adverse event rates were those attendances that progressed to a donation attempt and have a needle inserted, regardless of whether the target collection volume was achieved. Definitions for new and returning donors are provided in the Glossary (Appendix 1). Adverse event rates have been calculated per 10,000 donation attempts. Rates for total donor adverse events will only count a donation once even if the donation was associated with more than one type of adverse event or multiple events of the same type. As such the total donor adverse rate will be lower than the sum of individual reaction rates.

2.3. Donor adverse events

Donor adverse events (DAE) are recorded in Lifeblood's Incident and Quality DAE module. The 2019-20 FY data includes events registered by 31 July 2020. Donor adverse events are categorised into the following four

[1] Based on minimum collection of 450mL for males and females 2016-17 to 2019-20
[2] Based on minimum collection of 422mL for females and 488 for males excluding anticoagulant 2016-17 to 2019-20
[3] Based on collection of double-dose platelet 2016-17 to 2019-20

categories:

a) 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 maybe 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.

b) Phlebotomy related injury:

These refer to complications arising 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).

c) 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. A machine or process issue can result in damage to the donor's red cells (haemolysis), insufficient administration of anticoagulant or air entering the line. If undetected and cells are returned to the donor, this may lead to a donor adverse event.

d) Other category:

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

3. Results

3.1. Donations in the reporting period

The number of donations meeting inclusion criteria for the reporting period for FY 2016-17 to 2019-20 are provided in **Table 1a**. In 2019-20 there was a 10% increase in plasmapheresis donations and a negligible reduction in whole blood and plateletpheresis.

Table 1b. provides an overview of donor demographics for 2019-20 and the change from 2018-19. In 2019-20, both whole blood and plasmapheresis had a significantly higher proportion of donations from females compared with 2018-19. The whole blood cohort also had a significantly higher proportion of donations from new female and male donors and males aged less than 30. In contrast, the plasma cohort had significantly lower proportion of donations from both new male and female donors and donors aged less than 30.

Table 1a: Number of donations in the denominator cohort for FY 2016-17 to 2019-20

Donation Type	2016-17	2017-18	2018-19	2019-20
Whole Blood	712,808	700,546	703,986	701,475
Plasmapheresis	579,178	646,488	745,666	822,903
Plateletpheresis	32,337	27,782	29,127	27, 501
Total	**1,324,323**	**1,374,816**	**1,478,779**	**1,551,879**

Table 1b: Donor demographics by donation category for FY 2019-20 and change from 2018-19

Donation Type	Number of Donations (% change)	% of Total Donations for the year	Females				Males			
			% of Donations	Mean age in years	% <30 years	% new donors	% of donations	Mean age in years	% <30 years	% of new donors

			(change)				(change)			
Whole Blood	701,475 (-0.36%)	45.20	49.99 (+0.59)^	42.02 (-0.15)	27.89 (-0.2) #	20.84 (+1.15)^	50.01 (-0.59)	45.68 (-0.87)	18.49 (+0.22)^	15.18 (+1.08)^
Plasma	822,903 (+10.36%)	53.03	42.90 (+0.83)^	42.98 (+0.01)	26.78 (-0.24)^	11.03 (-1.07)^	57.10 (-0.83)	46.22 (+0.10)	18.51 (-0.75)^	6.46 (-0.47)^
Platelets	27, 501 (-5.58%)	1.77	0.27 (-0.23)	53.28 (+1.69)			99.73 (+0.23)	45.16 (+0.08)	17.68 (-1.02)^	
Total	1,551,879 (+4.94%)	100.00	45.35 (+0.61)	42.50 (-0.05)			54.65 (-0.61)	45.96 (-0.08)		

^*p<0.05* #*p>0.05* (Chi-squared p values)

3.2. Donor adverse events by donation category

Total donor adverse event rates per 10,000 donations by donation type from 2016-17 to 2019-20 are provided in Table 2a. Tables 2b and 2c provide rates for individual events for 2019-20. The total rate for the year will only include a donation once even if more than one event was reported in association with that donation. The total rates in Table 2a for 2019-20 are therefore less than the sum of individual rates provided in Tables 2b and 2c.

Table 2a: Total donor adverse event rates per 10,000 donations for FY 2016-17 to 2019-20

Donation Type	Total adverse event rate per 10,000 donations (rate change from previous year)				Comparison of FY 19-20 with 18-19 Relative Risk (95% Confidence Interval; p value) Number of donations for one additional event
	2016-17	2017-18	2018-19	2019-20	
Whole Blood	310.57 (-6.51)	299.05 (-11.52)	297.09 (-1.96)	321.76 (+24.67)	1.08 (1.06-1.10; p<0.001) 406
Plasmapheresis	188.89 (-10.20)	261.60 (+72.71)	324.13 (+62.53)	455.08 (+130.95)	1.40 (1.38-1.43; <0.001) 77
Plateletpheresis	753.63 (-49.02)	976.17 (+222.54)	1,047.14 (+70.97)	990.15 (-56.99)	0.95 (0.90-0.99; p=0.03) -176
Total	268.17 (-10.89)	295.12 (+26.95)	325.50 (+30.38)	404.30 (+78.80)	1.24 (1.23-1.26; p<0.001) 127

Table 2b: Donor adverse event rates per 10,000 donations by donation type for 2019-20 and rate change from 2018-19

Event type	Whole Blood n=701,475		Plasmapheresis n=822,903		Plateletpheresis n=27,501		Total n=1,551,879	
	Event (n)	Rate (change)	Event (n)	Rate (change)	Event (n)	Rate (change)	Event (n)	Rate (change)
Vasovagal events	15,785	225.03 (+14.44)	9,661	117.40 (-6.02)	352	128.00 (-5.55)	25,798	166.24 (+1.12)
Phlebotomy Related								
Arterial Puncture	31	0.44 (+0.10)	21	0.26 (+0.02)	0	0.00 (0.00)	52	0.34 (+0.06)
Cellulitis	4	0.06 (-0.04)	4	0.05 (+0.01)	1	0.36 (+0.36)	9	0.06 (-0.01)
Delayed Bleeding	143	2.04 (+0.16)	645	7.84 (+0.87)	7	2.55 (+0.83)	795	5.12 (+0.68)
Haematoma	4,533	64.62 (+7.43)	13,380	162.60 (+62.33)	1,080	392.71 (+1.32)	18,993	122.39 (+36.89)
Nerve Injury/Irritation	668	9.52 (+1.88)	961	11.68 (+4.46)	18	6.55 (+0.71)	1,647	10.61 (+3.22)
Other injury	36	0.51 (-0.04)	72	0.87 (-0.19)	4	1.45 (-0.95)	112	0.72 (-0.13)
Painful arm^	1,785	25.45 (+5.07)	5,235	63.62 (+28.86)	190	69.09 (+20.68)	7,210	46.46 (+18.27)
Thrombophlebitis	19	0.27 (-0.04)	32	0.39 (+0.01)	2	0.73 (+0.39)	53	0.34 (0.00)
Other Event Type								
Anaphylaxis	0	0.00 (-0.03)	2	0.02 (+0.01)	0	0.00 (0.00)	2	0.01 (-0.01)
Chest Pain	36	0.51 (-0.12)	68	0.83 (0.00)	0	0.00 (-0.69)	104	0.67 (-0.06)
Local Allergic Reaction	129	1.84 (-3.13)	223	2.71 (-4.09)	3	1.09 (-2.0)	355	2.29 (-3.57)
Other event/injury	128	1.82 (-0.06)	205	2.49 (-0.31)	9	3.27 (-1.88)	342	2.20 (-0.21)

^ *Rate reflects painful arm when not reported in association with another phlebotomy injury including haematoma*

Table 2c: Specific apheresis-related donor adverse event rates per 10,000 donations for FY 2019-20 and rate change from 2018-19.

Event type	Plasmapheresis n=822,903		Plateletpheresis n=27,501		Total n= 850,404	
	Event (n)	Rate (change)	Event (n)	Rate (change)	Event (n)	Rate (change)
Citrate Reaction+	7,841	95.28 (+37.91)	1,154	419.62 (-102.58)	8,995	105.77 (+30.92)
Haemolysis*	30	0.36 (+0.36)	0	0.00 (0.00)	30	0.35 (+0.35)
Infiltration/extravasation	2,304	28.00 (+20.50)	107	38.91 (+15.22)	2,411	28.35 (+20.24)
Omitted Anticoagulant^	0	0.00 (0.00)	0	0.00 (0.00)	0	0.00 (0.00)

+ Plasma includes 333 moderate and 13 severe cases, Platelets includes 50 moderate and 0 severe cases

** Events with a high index of suspicion that haemolysis occurred and red cells were returned to the donor.*

^DAE is not reported if the donor remains asymptomatic

3.2.1. Whole blood

Total DAE rates for whole blood increased significantly by 8.3% from 297.09 per 10,000 donations in 2018-19 to 321.76 per 10,000 donations in 2019-20 (RR[4]:1.08; 95%CI[5]: 1.06-1.10; p<0.001). The increase is attributed primarily to the significant increases observed in rates for vasovagal reactions (210.59 to 225.03 per 10,000 donations; RR: 1.07; 95%CI: 1.05-1.09; p<0.001) and haematoma (57.19 to 64.62 to per 10,000 donations; RR: 1.13; 95%CI: 1.08-1.18; p<0.001). In 2019-20 there was an additional vasovagal every 693 whole blood donations and an additional haematoma for every 1,346 donations.

The standardised 2019-20 vasovagal rate adjusting for gender, new donors and donors aged less than 30 years using the 2018-2019 population is 219.21 per 10,000 donations. The differences in demographic and donation experience therefore account for approximately 40% of the difference observed between 2018-19 and 2019-20. The remaining difference is an increase observed in new donors (Refer Table 3a). The increase in reported vasovagal rates in new donors is likely to be multifactorial and may relate in part to reduced compliance with in-centre water loading and applied muscle tensing exercises.

The increase in haematoma events may still relate to the haematoma definition change in September 2017 which introduced the reporting of all haematomas, not just those greater than 5cm. The higher proportion of females and new donors compared with 2018-19 may also be contributory. There has not been an increase in the rates for haematomas requiring external care in 2019-20 compared with 2018-19 (1.14 per 10,000 donations in 2018-19 vs 0.96 per 10,000 donations in 2019-20; RR 0.84; 95%CI: 0.61-1.16; p=0.29), suggesting the increase in reporting relates to more minor events.

3.2.2. Plasmapheresis

In May 2019 Lifeblood commenced the introduction a new machine for plasmapheresis collection. The new platform collects a smaller extracorporeal volume per cycle than the previous platform, offering potential benefits for both donor experience, including reducing risk of vasovagal reactions, and product quality. At 30 June 2020, almost all centres had transitioned to the new platform. Approximately 58% of plasmapheresis collections in 2019-20 were using the new machines.

The transition to the new machine has been associated with a reduction in vasovagal reactions, from 123.42 in 2018-19 to 117.40 per 10,000 donations (RR: 0.95; 95%CI: 0.92-0.98; p<0.001). There has however been an increase in rates for phlebotomy injuries and infiltration/extravasation events. This includes; an additional haematoma every 161 donations, an additional painful arm (where no other cause identified) every 347 donations, and an additional infiltration/extravasation event every 488 donations. Factors contributing to this may include that the new platform needs more cycles to collect the same plasma volume and in association with this is more sensitive to phlebotomy technique. These rates were monitored closely during 2019-20. A tool-kit of phlebotomy improvement measures were implemented, including a standardised way to secure the venepuncture needle. These initiatives have been associated with a progressive reduction in haematoma and painful arm rates over the course of the reporting year.

An increase in citrate reactions were also observed, noting that 96% of citrate reactions were mild. The increase in citrate reactions may be explained by the citrate being delivered in a smaller volume over a shorter period.

Although there has been an increase in some events, these rates were either similar to or significantly lower than rates observed with plateletpheresis collections. Further, the overall rate of plasmapheresis adverse events requiring external care in 2019-20 (6.44 per 10,000 donations) was not significantly different to the overall 2018-19 rate (6.84 per 10,000 donations), during which time 95% of collections were on the original platform.

[4] Relative Risk
[5] Confidence Interval

3.2.3. Plateletpheresis

In general, the donor adverse rate for plateletpheresis has significantly decreased primarily as a result of the decrease in the rate of citrate reactions by 19.64% from 522.20 to 419.62 per 10,000 donations (RR; 0.80; 95% CI: 0.75-0.87; p<0.001), and to a lesser extent the smaller decrease in vasovagal reactions by 4.2% from 133.55 to 128.00 per 10,000 donations (RR: 0.96; 95% CI: 0.83-1.11; p=0.56). These reductions have in part been offset by an increase in the rate for painful arm equating to an extra event every 484 donations. Whilst the underlying causes of these changes are not clear the analysis does not include a subgroup analysis such as age and experience which may account for the changes.

3.2.4. All **donation** types

Local skin reaction rates have reduced across all categories and is attributed to a change from antiseptic swabs to antiseptic wipes from early December 2018, after reaction rates of up to 12 per 10,000 were observed in the months of September to November 2018, which were attributed to the particular swab. The overall 2019-20 rate was 2.29 per 10,000, down from 5.86 per 10,000 in the previous year (RR 0.39; 95% CI; 0.35-0.44; p<0.001).

3.3. 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 2019-20 was 166.24 per 10,000 donations; steady from the previous year rate of 165.12 per 10,000, noting that there has been a reduction in vasovagal rates in apheresis but increases in whole blood.

3.3.1. Age, gender and donor experience

In keeping with historical trends, in 2019-20 significantly higher rates of vasovagal were observed in new donors compared with returning donors, younger donors compared with older cohorts and females compared with males.

Donation experience:
Donors new to a donation type have significantly higher risks of a vasovagal than their returning counterparts. This is in part due to deferral or self-deferral for those who have previously experienced symptoms. Also, returning donors become more familiar with the donation process and mitigation strategies.

Whole blood
The relative risk of a new whole blood donor having a vasovagal reaction compared with a returning whole blood donor was 3.81 and 7.42 for females and males respectively (Table 3a). An additional event was reported in a new donor every 19 donations for females and 22 for males. The rates for new male and female whole blood donors were significantly higher in 2019-20 compared with 2018-19. In contrast, there was no difference in rates for returning donors.

Plasmapheresis
In 2019-20, the relative risk of a vasovagal in a donor new to plasma compared with a returning plasma donor was 6.00 for females and 12.25 for males (Table 3b). An additional vasovagal was reported in new plasma donors every 17 donations for females and 24 for males, compared with returning donors. The excess risk for a donor new to whole blood having a vasovagal reaction compared to a donor new to plasma was 0.22% for females and 0.63% for males.

Rates for both male and female new plasma donors were significantly lower in 2019-20 compared with 2018-19. In contrast, the rate for returning males was significantly higher in 2019-20 compared with 2018-19, whereas there was no difference in rates for returning females.

Table 3a: Vasovagal rates in new and returned female and male whole blood donors for FY 2019-2020

New or Returned Donor	Females			Males		
	Events (n)	Donations (n)	Rate per 10,000	Events (n)	Donation (n)	Rate per 10,000
Returned **2019-20**	5,438	277,567	195.92	2,103	297,549	70.68
Returned **2018-19**	5,454	279,278	195.29	2,123	306,001	69.38
New **2019-20**	5,452	73,098	745.85	2,792	53,261	524.21
New **2018-19**	4,817	68,486	703.36	2,431	50,221	484.06
Comparison groups	**Relative Risk (95% CI); p value** [number of donations for an extra event]			**Relative Risk (95% CI); p value** [number of donations for an extra event]		
New vs returned in 2019-20	3.81 (3.67-3.95; p<0.001) [19]			7.42 (7.01-7.84; p<0.001) [22]		
New 2019 vs 2018	1.06 (1.02-1.10; p=0.002) [236]			1.08 (1.03-1.14; p=0.003) [249]		
Returning 2019 vs 2018	1.00 (0.97-1.04; p=0.87)			1.01 (0.96-1.08; p=0.55)		

Table 3b: Vasovagal rates in new and returned female and male plasma donors for FY 2018-19 and 2019-20

New or Returned Donor	Females			Males		
	Events (n)	Donations (n)	Rate per 10,000	Events (n)	Donations (n)	Rate per 10,000
Returned 2019-20	3,788	314,054	120.62	1,655	439,562	37.65
Returned 2018-19	3,228	275,723	117.07	1,316	402,056	32.73
New 2019-20	2,818	38,944	723.60	1,400	30,343	461.39
New 2018-19	3,145	37,966	828.37	1,514	29,921	506.00
Comparison groups	**Relative Risk (95% CI); p value** [number of donations for an extra event]			**Relative Risk (95% CI); p value** [number of donations for an extra event]		
New vs Returned in 2019-20	6.00 (5.72-6.29; p<0.001) [17]			12.25 (11.42-13.14; p<0.001) [24]		
New Plasma vs New Whole blood in 2019-20	0.97 (0.93-1.01; p=0.18) [450]			0.88 (0.83-0.94; p<0.001) [160]		
Returned 2019-20 vs 2018-19	1.03 (0.98-1.08; p=0.21)			1.15 (1.07-1.24; p<0.001)		
New 2019-20 vs 2018-19	0.87 (0.83-0.92; p<0.001) [96]			0.91 (0.85-0.98; p=0.01) [225]		

Donor age and gender

The risk of a vasovagal is higher in females than males across all age groups and reduces with age in both groups (Figure 1). Whilst the lower rates observed in older donors are largely attributed to donation experience, an analysis of new donors less than 30 years compared with those 30 or older, demonstrates that the younger cohort continued to have a significantly higher rate of vasovagal for both whole blood (for females 1069.94 vs 526.24; for males 813.82 vs 365.25; p<0.001) and plasma (for females 897.65 vs 595.37; for males 638.16 vs 360.64; p<0.001), suggesting age as an independent risk (Table 3c).

Figure 1: Vasovagal rate per 10,000 donations (across all donation types) for males and females by age group for 2019-20

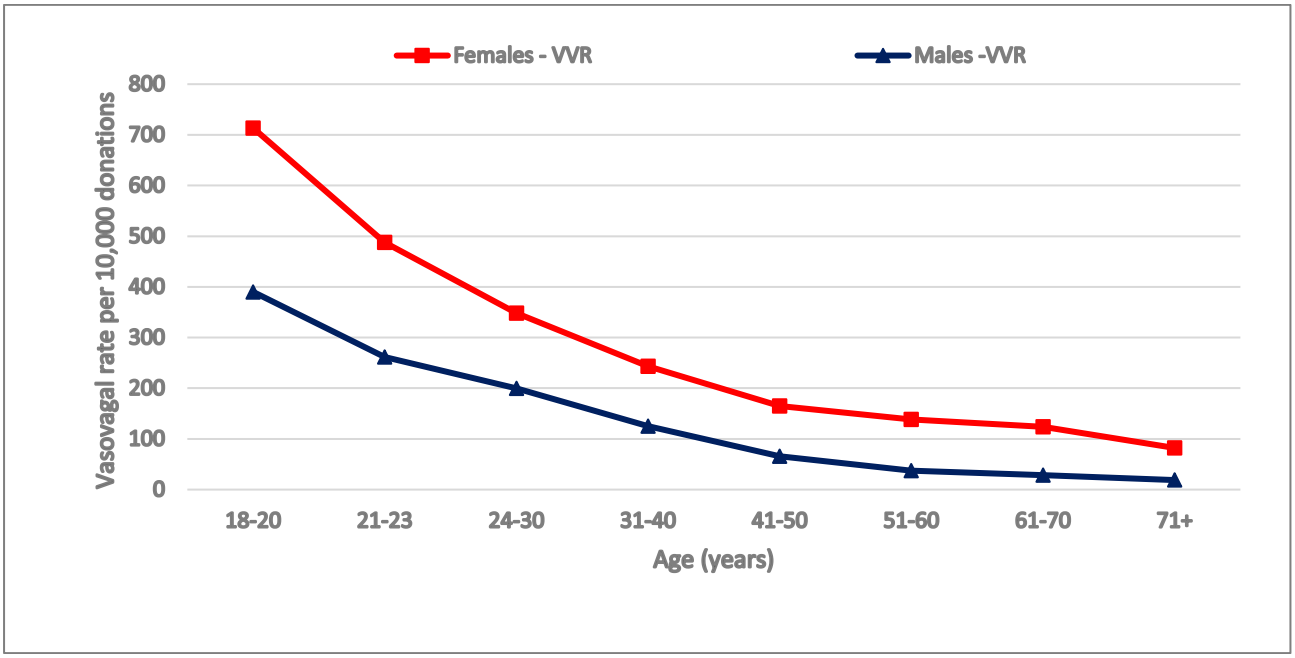


Table 3c: Vasovagal rates for new donors aged less than 30 and 30 years and over

	Females			Males		
	Vasovagal events (n)	Donations (n)	Rate per 10,000 donations	Vasovagal events (n)	Donations (n)	Rate per 10,000 donations
Whole blood <30	3,159	29,525	1069.94	1,536	18,874	813.82
Whole blood ≥ 30	2,293	43,573	526.24	1,256	34,387	365.25
Plasmapheresis <30	1,483	16,521	897.65	703	11,016	638.16
Plasmapheresis ≥30	1,335	22,423	595.37	697	19,327	360.64
Comparison cohorts	**Relative Risk (95% CI); p value** [number of donations for an extra event]			**Relative Risk (95% CI); p value** [number of donations for an extra event]		
Whole blood <30 vs ≥30	2.03 (1.93-2.14; p<0.001) [19]			2.23 (2.07-2.40; p<0.001) [23]		
Plasma, <30 vs ≥30	1.51 (1.40-1.62; p<0.001) [33]			1.77 (1.60-1.96; p<0.001) [36]		
Females vs Males whole blood <30	1.31 (1.24-1.39; p<0.001) [39]					
Females vs Males plasma <30	1.41 (1.29-1.53; p<0.001) [39]					

3.3.2. Vasovagal events associated with loss of consciousness and or injury

Table 4a provides rates of vasovagal events by location and if associated with loss of consciousness and/or injury. Approximately 90% of all vasovagal reactions occurred on-site. In general rates of vasovagal events with loss of consciousness in 2019-20 overall, were similar to those in 2018-19 (13.61 vs 13.26 per 10,000 donations: RR: 1.03; 95% CI: 0.97-1.09; p=0.41). Events occurring on-site were less likely to be associated with loss of consciousness (6.9% vs 16.0%; RR: 0.43; 95% CI 0.39- 0.47; p<0.001) and those sustaining loss of consciousness, had a lower rate of injury if the event occurred on-site (2.3% vs 11.24%; RR: 0.21; 95% CI 0.14-0.31; p<0.001).

In 2019-20 there were 55 reports (0.35 per 10,000 donations) of vasovagal reactions occurring whilst driving, approximately half were in association with apheresis. The total rate was down from 0.52 per 10,000 donations in the 2018-19 FY. In 2019-20, five motor vehicle accidents without long lasting injury 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. Data 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. In general rates of vasovagal events with loss of consciousness in 2019-20 overall, were similar to those in 2018-19 (13.61 vs 13.26 per 10,000 donations: RR: 1.03; 95% CI: 0.97-1.09; p=0.41) (Table 4b).

Table 4a: Vasovagal events per 10,000 donations* by donation category for FY 2019-20

Event			Whole Blood n=701,475		Plasmapheresis n=822,903		Plateletpheresis n=27,501		Total n=1,551,879	
			n	Rate per 10,000	n	Rate per 10,000	n	Rate per 10,000	n	Rate per 10,000
On-site vasovagal reaction	Without LOC	No injury	13,338	190.14	8,135	98.86	314	114.18	21,787	140.39
		Injury	2	0.03	4	0.05	0	0.00	6	0.04
	With LOC	No injury	1,009	14.38	537	6.53	20	7.27	1,566	10.09
		Injury	30	0.43	7	0.09	0	0.00	37	0.24
	Total		14,370	204.85	8,679	105.47	334	121.45	23,383	150.68
Off-site vasovagal reaction	Without LOC	No injury	1,196	17.05	935	11.36	20	7.27	2,151	13.86
		Injury	3	0.04	0	0.00	0	0.00	3	0.02
	With LOC	No injury	271	3.86	92	1.12	0	0.00	363	2.34
		Injury	30	0.43	16	0.19	0	0.00	46	0.30
	Total		1,498	21.36	1,043	12.67	20	7.27	2,561	16.50
Total	onsite and offsite		15,785	225.03	9,661	117.40	352	128.00	25,798	166.24

**A single donation can be associated with more than one vasovagal event. The totals values may be less than the sum of the column values as the totals adjusts for those donations which have more than one vasovagal event, and will only count that donation once.*

Table 4b: Rates of vasovagal events with loss of consciousness per 10,000 donations 2016-17 to 2019-20

Donation Category	FY 2016-17		FY 2017-18		FY 2018-19		FY 2019-20		Comparison 19/20 with 18/19	
	n	Rate per 10,000	n	Rate per 10,000	n	Rate per 10,000	n	Rate per 10,000	Relative Risk (95% CI)	P value
Whole Blood	1,633	22.91	1,384	19.76	1,224	17.39	1,340	19.10	1.10 (1.02-1.19)	p=0.02
Plasmapheresis	415	7.17	543	8.40	718	9.63	752	9.14	0.95 (0.86-1.05)	p=0.32
Plateletpheresis	13	4.02	19	6.84	19	6.52	20	7.27	1.11 (0.60-2.09)	p=0.73
Total	2,061	15.56	1,946	14.15	1,961	13.26	2,112	13.61	1.03 (0.97-1.09)	p=0.41

3.3.3. Donor adverse events requiring external referral

The overall rate of events requiring external care has significantly reduced from 8.14 per 10,000 in 2018-19 FY to 6.97 per 10,000 in 2019-20 (RR: 0.86; 95%CI: 0.79-0.93; p<0.001) (Table 5). Vasovagal reactions continue to remain the single most common event associated with a hospital attendance; approximately 87% and 71% of whole blood and plasmapheresis events respectively.

Table 5: Rates for donor adverse events requiring external care (per 10,000 donations) for 2019-20 and rate change from 2018-19

Donation type	GP attendance*		Ambulance attendance^		Hospital attendance*		Total	
	Event (n)	Rate per 10,000 (change)	Event (n)	Rate per 10,000 (change)	Event (n)	Rate per 10,000 (change)	Event (n)	Rate per 10,000 (change)
Whole Blood	264	3.76 (-1.51)	68	0.97 (+0.08)	208	2.97 (-0.47)	540	7.70 (-1.9)
Plasmapheresis	279	3.39 (-0.61)	35	0.43 (-0.07)	216	2.62 (+0.27)	530	6.44 (-0.41)
Plateletpheresis	6	2.18 (-1.25)	1	0.36 (+0.36)	4	1.45 (-0.95)	11	4.00 (-1.84)
Total	549	3.54 (-1.05)	104	0.67 (-0.01)	428	2.76 (-0.11)	1,081	6.97 (-1.17)

**Initiated by Lifeblood or donor.*
^Attendance by ambulance not requiring transfer to hospital.

4. Conclusion

In what has been a challenging year for our donor centres, staff and donors, Lifeblood has continued to remain vigilant and responsive to managing donor safety. This includes the close clinical oversight of the transition to the new plasmapheresis platform and ensuring the safety of our donors during the COVID-19 pandemic.

An increase in the total adverse event rate was observed in 2019-20 compared with 2018-19 (404.30 vs 325.50 per 10,000 donations). This was primarily a result of the increase in plasmapheresis phlebotomy-related events and citrate reactions and whole blood vasovagal reactions. The increases are in predominantly mild events, given that there has been a concurrent significant decrease in rates for events requiring external care overall. With the implementation of a tool-kit of phlebotomy improvement measures including a standardised way to secure the venepuncture needle, since July 2019 there has been a progressive reduction in the haematoma and painful arm rates. It is anticipated that rates will improve further in 2020-21 as both staff and donors become more experienced with the new plasmapheresis platform and recently implemented initiatives take effect. As the new apheresis machine platform provides a larger dose of citrate at the beginning of the procedure, we are planning further work on understanding the efficacy of calcium supplementation in our apheresis donors including optimal dose timing, given blood levels take time to peak post dosage.

Key findings of the 2019-20 donor vigilance report:

1. Vasovagal rates:

Vasovagal rates associated with plasmapheresis were significantly reduced compared with 2018-19. This is primarily attributed to the transition to the new plasmapheresis machine, with some of the effect relating to the higher proportion of experienced plasma donors in 2019-20.

Vasovagal rates associated with whole blood donation significantly increased, however rates of events associated with injury did not increase. The increase in vasovagal rates is attributed in part to the higher proportion of new donors in 2019-20. The remaining increase is that observed in the new donor cohort and may relate to reduced compliance with in-centre water loading and applied muscle tensing exercises.

Lifeblood will enhance communication around these strategies which have previously been shown to be effective at reducing vasovagal reactions.

2. Phlebotomy injuries and infiltration/extravasation events:

Plasmapheresis rates for haematoma, painful arm and infiltration/extravasation events were higher in the 2019-20 period compared with the previous year. This is again attributed primarily to the implementation of the new platform. A smaller contribution of the change relates to donor demographics and possibly to a lesser extent, ongoing staff hypervigilance following the change to the haematoma reporting definitions in September 2017. With the implementation of a tool-kit of phlebotomy improvement measures including a standardised way to secure the venepuncture needle, since July 2019 there has been a progressive reduction in the haematoma and painful arm rates. It is anticipated that rates will improve further in 2020-21 as both staff and donors become more experienced with the new platform and recently implemented initiatives take effect.

Lifeblood's donor vigilance system will continue to evolve to improve the collection and reporting of data which can inform targeted interventions, research and support process evaluation, to ensure that blood donation remains as safe as possible.

APPENDIXES

Appendix 1: Glossary

Term	Description
Australian Haemovigilance Minimum Data Set	The Australian Haemovigilance Minimum Data Set (AHMDS) provides data definitions and elements in line with international and national standards for haemovigilance data collection and reporting. The first edition of the AHMDS (known as the 2010 National Haemovigilance Data Dictionary) is superseded by the 2015 AHMDS.
Haemovigilance	A set of surveillance procedures covering the entire blood transfusion chain, from the donation and processing of blood and its components, to their provision and transfusion to patients, to their follow-up. It includes monitoring, reporting, investigating and analysing adverse events related to the donation, processing and transfusion of blood, as well as development and implementation of recommendations to prevent the occurrence or recurrence of adverse events. National Safety and Quality Health Service Standards, Second Edition
Attempted donation	An attendance that includes a donation needle-in regardless of whether the target volume was collected. If the donor has a finger-prick test and/or venous sample but does not have a donation needle inserted, this is not considered an attempted donation.
New or first-time whole blood donor	No prior whole blood attempts. Donors may have previously attempted a plasmapheresis donation.
Returned whole blood donor	Previously attempted at least one whole blood donation. These donors may or may not have made an apheresis donation in the past.
New or first-time plasmapheresis donor	No prior plasma attempts. Donors may have attempted whole blood in the past.
Returned plasmapheresis donor	Previously attempted at least one plasmapheresis donation. These donors may or may not have attempted whole blood in the past.

Appendix 2: State/territory haemovigilance process improvement

In 2019-20, state/territory departments of health continue to improve their progress for haemovigilance data collection and reporting.

NSW

During the reporting period, NSW Health implemented a staged transition to a new incident management platform ims+, resulting in two different datasets. Additional data fields in ims+ has led to more incident notifications containing more information, and capacity to match incidents with the AHMDS.

In direct response to the challenges experienced with the completeness of information within the notifications, Blood Watch published Haemovigilance IIMS reporting resources in July 2019, to improve the quality of notifications. Review of the 2019-2020 data demonstrates a significant uptake of the use of the resources and subsequent improvement in complete notifications.

VIC

Review of STIR reporting forms has included the introduction of questions, in appropriate forms (IBCT, near miss, WBIT), relating to errors associated with the use of electronic medical records.

From 1 July 2020, STIR commenced accepting reports of RhD isoimmunisations and hypotensive reactions. Along with these changes we updated our STIR reporting guideline.

In September 2020, STIR had the first launch of the Annual report for 2018-19, by virtual meeting.

Dissemination of information from STIR includes the continued use of Bulletins to health services describing events that may impact patient care and presentations at conferences: an oral presentation on incorrect blood component transfused events as reported to STIR was given at ISBT Regional Congress in December (Virtual).

QLD

The strategies implemented across hospitals over the reporting period include education activities such as:

- clinician workshops and education sessions on the administration and monitoring of blood and blood products, to minimise the risks associated with the administration of blood and blood products and to alert clinical staff to early signs and symptoms of adverse reactions to transfusions
- inclusion of the Australian Red Cross Lifeblood information packs at orientation programs for new clinical staff
- regular conduct of Blood Management Committee meetings, reviewing best practice and adverse event cases
- completion of the BloodSafe Clinical Transfusion Practice Module/Refresher (5 modules)
- investigation of transfusion reactions by Haematology, Pathology Blood Bank and Transfusion Clinical Nurse Consultant
- improved management and reporting of Lifeblood notifications regarding initial machine positive results for patients.

SA

There are currently a number of haemovigilance-related activities underway that are focused on system, education and quality improvement:

- The Department has been monitoring the utilisation of red blood cells by inpatients since 2006 through the SA Blood Utilisation Study. The information from this study has been incorporated into a Reporting Tool which allows major metropolitan hospitals to better understand their red cell usage patterns.
- The implementation of the Enterprise Patient Administration System (EPAS) across SA Health required the development of clinician friendly blood and blood product transfusion order sets that meet current national transfusion guidelines and legislative requirements.

- The BloodSafe Transfusion Nurse Consultants conduct regular audits to monitor variability in ordering practices and compliance with Standard 7 haemovigilance activities.
- The review of SLS to ensure it remains in line with the National Haemovigilance Minimum Dataset involved the development of a detailed topic guide to educate transfusion nurses on the changes. The guide included detailed definitions, tips for accurate reporting, information for managers and a section on the reporting requirements for transfusion reactions that are Sentinel events, or require internal and/or external reporting.
- The SA Blood Management Council has recommended that all medical, nursing, and support staff complete training provided by BloodSafe eLearning Australian with the aim of improving the recognition and reporting of adverse events.

WA

The need for progress and improvement in the reporting area had been flagged following the 2018-19 report. This year's report is presented in two sections. The first part providing insight into and analysis of transfusion-related adverse events reported in the last year. The second part looks at reporting trends over the last five years. For the first time the 2019-20 report contains recommendations on observed trends. A strong focus was placed on moving away from simply presenting numbers and towards a more informative report.

WA gathered further information from the hospitals regarding Allergic reactions as these are WA's most commonly reported adverse event. Based on the information provided WA were able to make recommendations involving the identification and follow up treatment of these events. WA took a closer look at antibodies which are commonly implicated in DSTR and DHTR adverse events. Case studies were more thoroughly researched and dispersed within the report to link to the relevant data.

TAS

The Tasmanian Health Service Safety Learning and Reporting System (SLRS) system records and ensures safety events throughout the system, including blood safety events, are followed up and appropriately actioned.

New IT systems introduced at the Launceston General Hospital to streamline ordering and receipt of blood products which reduces risk of transcription errors.

NT

The occurrence rate of reported transfusion rates during the period of 2019 – 2020 has remained steady in comparison to the 2018 – 2019 data.

All of the reported transfusion reactions are investigated and discussed at the Transfusion Incident Review Group (TIRG) meetings, and when deemed appropriate, at the NT Transfusion Committee (NTTC) meetings.

Staff and facility education and support remains paramount in accordance with NSQHS Standard 7, which assists in keeping the number of adverse events to a minimum within this jurisdiction.

ACT

The ACT has been actively involved in haemovigilance since 2003. An ACT wide transfusion practitioners' network was implemented in 2019 to support safe and appropriate transfusion practice across the Territory. This group includes representation from both public and private hospitals and laboratories.

Through the successful implementation of Patient Blood Management strategies across the ACT, packed red blood cell usage has reduced by 34% since 2012. This reduction in usage will have had a corresponding impact on reducing transfusion-related incidents. The most common incidents in the ACT are febrile non haemolytic reactions which are not reported to either STIR or the national haemovigilance program.

88% of fresh blood products are distributed via the major public hospitals.

ABBREVIATIONS

ABO	The human red cell ABO blood group system
ACT	Australian Capital Territory
AE	Adverse event
AHMDS	Australian Haemovigilance Minimum Data Set
AHTR	Acute haemolytic transfusion reaction (other than ABO incompatibility)
Allergic	Allergic reaction
ATR	Acute transfusion reactions
CI	Confidence interval
DAE	Donor adverse event
DHTR	Delayed haemolytic transfusion reaction
DSTR	Delayed serologic reaction
FNHTR	Febrile non-haemolytic transfusion reaction
FY	Financial year
GP	General Practitioner
HAC	Haemovigilance Advisory Committee
IBCT	Incorrect blood component transfused
IHN	International Haemovigilance Network
Lifeblood	Australian Red Cross Lifeblood
ISBT	International Society for Blood Transfusion
LOC	Loss of consciousness
NBA	National Blood Authority
Non-SAE	Non-serious adverse event
NHDD	National Haemovigilance Data Dictionary
NSQHS	National Safety and Quality Health Service
NSW	New South Wales
NT	Northern Territory
PTP	Post transfusion purpura
QLD	Queensland
RBC	Red blood cell
RR	Relative risk
SA	South Australia
SAE	Serious adverse event
SLRS	Tasmanian Health Service Safety Learning and Reporting System
STIR	Serious Transfusion Incident Reporting
TACO	Transfusion-associated circulatory overload
TAD	Transfusion associated dyspnoea
TAS	Tasmania
TRALI	Transfusion-related acute lung injury
TTI	Transfusion-transmitted infection
VIC	Victoria
VVR	Vasovagal rate
WA	Western Australia

ACKNOWLEDGEMENTS LIST

National Blood Authority Haemovigilance Advisory Committee (HAC)

Members

Associate Professor Alison Street	NBA Board member and NBA appointed HAC Chair
Mr Brett Aitken	Australian Private Hospitals Association
Mr Geoffrey Bartle	Consumer Representative
Ms Linley Bielby	VIC Health
Ms Maria Burgess	ACT Health
Dr James Daly	Australian Red Cross Lifeblood
Dr Chris Hogan	Non-affiliated Haematologist
Ms Penny O'Beid	NSW Health
Dr Sharon Nowrojee	WA Health
Associate Professor David Roxby	Australian and New Zealand Society of Blood Transfusion
Dr Neil Everest	Commonwealth Department of Health
Professor Erica Wood	Non-affiliated Haematologist
Associate Professor Lilon Bandler	NBA Patient Blood Management Advisory Committee Chair

Expert Advisors

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Dr Angela Gowland	Therapeutic Goods Administration
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NSW Health Clinical Excellence Commission Blood Watch Program
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

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