



DATA FOR
2020–2021

AUSTRALIAN HAEMOVIGILANCE REPORT



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AT A GLANCE

The National Blood Authority (NBA) has been collecting haemovigilance data from states and territories and publishing reports under the National Blood Agreement since 2008. All states and territories have participated in the national haemovigilance reporting since 2015-16. The following data was derived from the 12th Australian Haemovigilance Report (2020-21). One hundred and thirty three hospitals (107 public hospitals and 26 private hospitals) reported adverse events for 2020-21. All adverse events are reported events and it should be noted that there are some quality issues in relation to data completeness, standardisation and relevance. The use of different haemovigilance reporting processes across the jurisdictions, may lead to data inconsistencies.

State and territories reported 706 adverse events and 76 (or 11%) transfusion-related serious adverse events (SAE) to the national haemovigilance program in 2020-21.

A transfusion-related serious adverse event (SAE) in this report 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.

Victoria (VIC) reported 97 adverse events and 27 transfusion-related SAEs that represented 28% of their total reported adverse events, whereas New South Wales (NSW) reported 152 adverse events and 24 transfusion-related SAEs, representing 16% of the total adverse events reported.

Figure 1 shows all reported adverse events and transfusion-related SAES by state and territory.

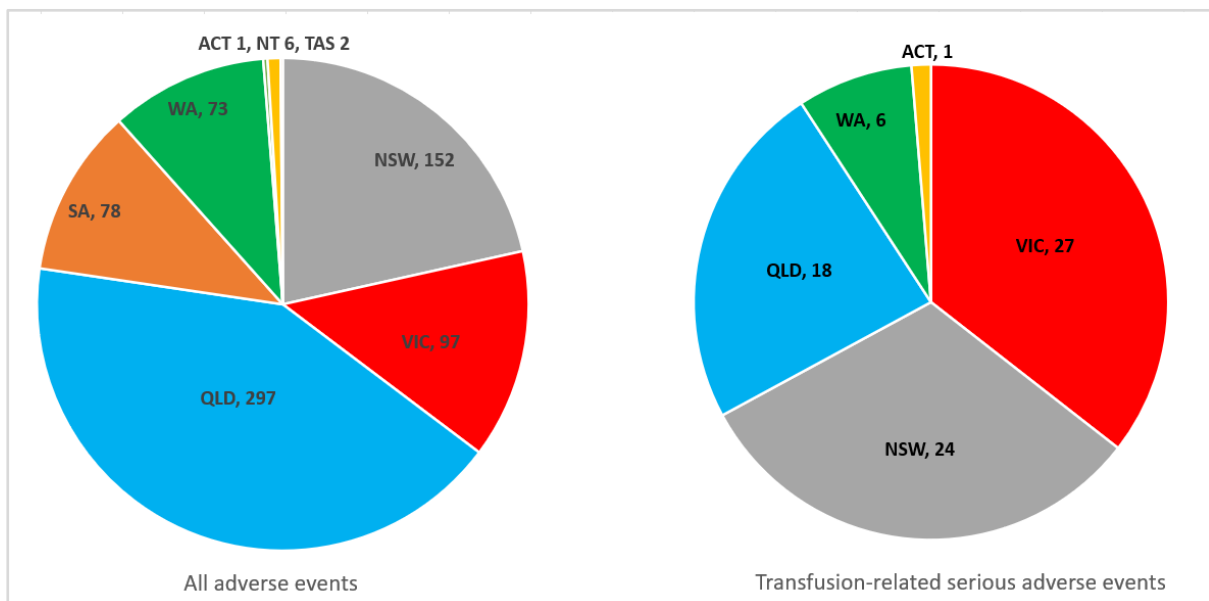


Figure 1: Number of transfusion-related serious adverse events and all adverse events by state and territory

The number of febrile non-haemolytic transfusion reaction (FNHTR) events was 43% of the total reported adverse events (303 of 706), but they were 21% of the total transfusion-related SAEs (16 of 76). Anaphylactic reactions represented 4% of the total reported adverse events (25 of 706), but were 25% of the total transfusion-related SAEs (19 of 76).



Figure 2 shows transfusion-related SAEs by event.

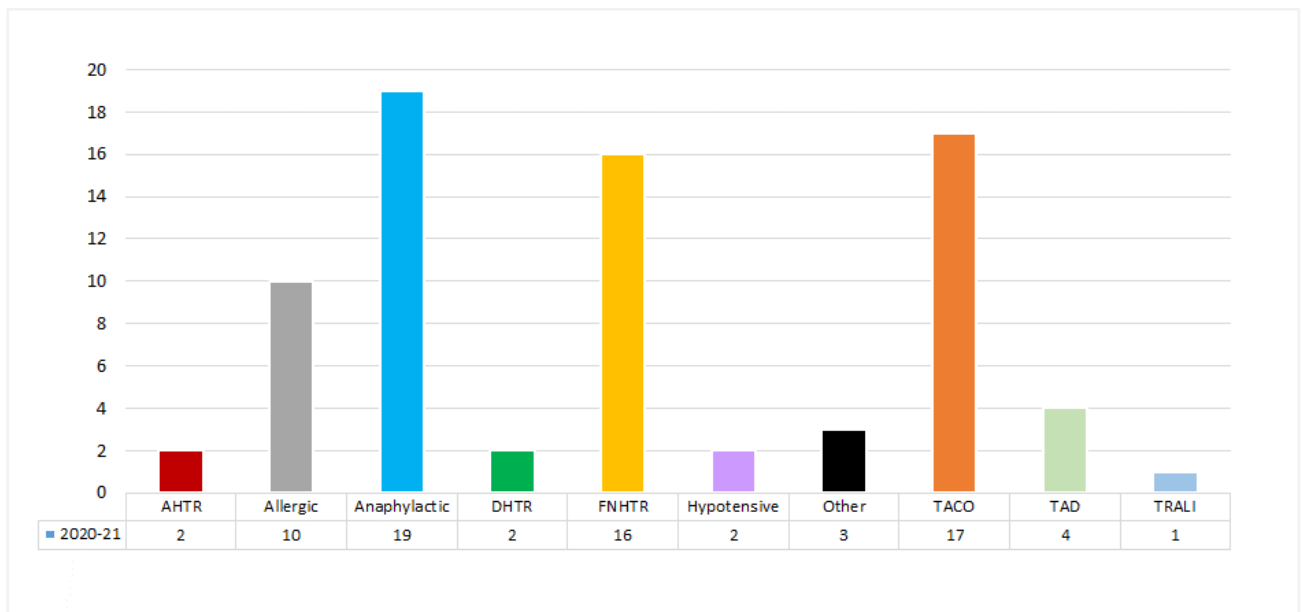


Figure 2: Number of transfusion-related serious adverse events

Figure 3 shows the rate per 100,000 population for transfusion-related SAEs and all adverse events by state and territory.

The rate per 100,000 population for all adverse events nationally is 2.8, with Australian Capital Territory (ACT) and Tasmania (TAS) under 0.5 and Queensland (QLD) at 5.7.

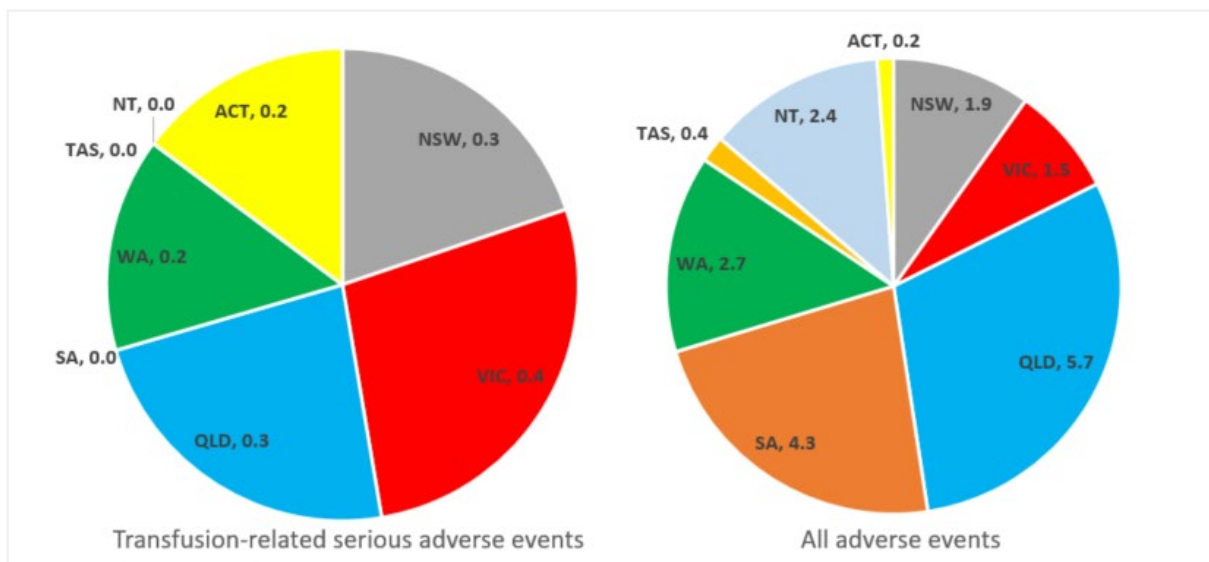


Figure 3: Rate per 100,000 populations for transfusion-related serious adverse events and all adverse events by state and territory



SECTION 1

Australian Haemovigilance Data

June 2021

Acknowledgements

This report is published on behalf of the states and territories who voluntarily provided data to the national program. The 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.

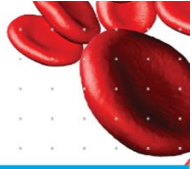
Caveats

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 thirteen years.

- All states and territories except QLD reported the data in line with the Australian Haemovigilance Minimum Data Set (AHMDS) 2015. QLD uses the NBA National Haemovigilance Data Dictionary (NHDD) 2010 except for the imputability scores which are based on the 2015 AHMDS.
- 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.
- Adverse events are presented in alphabetical order in the report tables and graphs.
- All states and territories have contributed data to the NBA 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 may lead to data inconsistencies.
- Near misses and denominator data (number of transfusions) are not collected and reported at a national level.
- All the 2020-21 transfusion-transmitted infection (TTI) data have been verified with the states and territories.
- The Serious Transfusion Incident Reporting (STIR) system used a higher-level temperature threshold for the reporting of FNHTR prior to 2018-19.
- STIR 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.



Collection and reporting process

In Australia, haemovigilance is undertaken at hospital, local health network or state/territory level, supported by a national data collection and reporting process. Data is collected at the hospital, local health network or state/territory level, and they are 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.

NT, ACT, VIC and TAS provide their data to the 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 providing the data to the NBA.

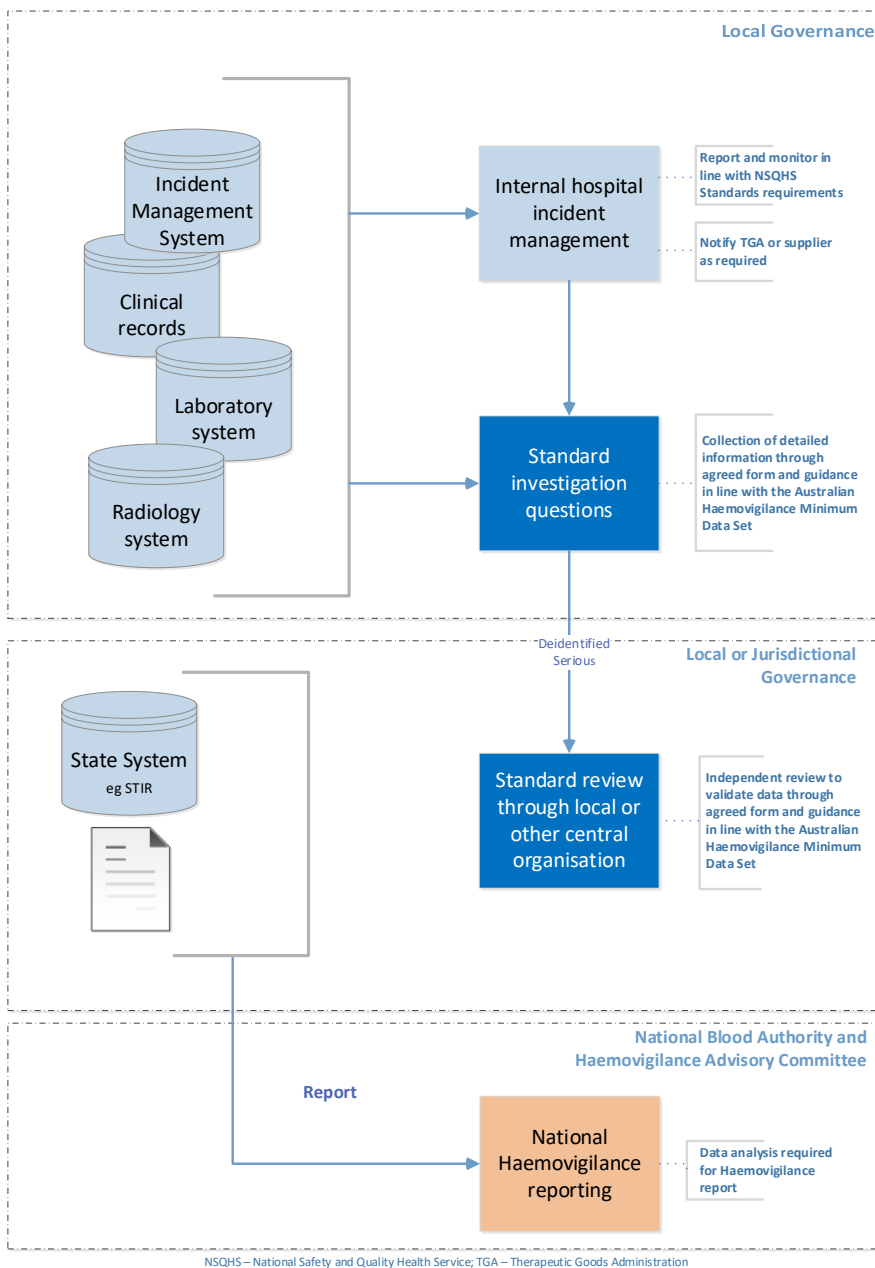


Figure 4: Reporting adverse events and haemovigilance in Australia

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 a different number of adverse events reported to the national haemovigilance program. All reported adverse events are shown in **Figure 5**.

- NSW, VIC, QLD, SA and TAS collectively reported 294 adverse events in 2008-09, which included limited data from NSW and QLD.
- NT and ACT started to participate in national reporting in 2009-10, and NSW and QLD increased their reporting in 2010-11.
- In 2012-13 QLD did not report as the QLD haemovigilance system ceased. QLD participated in the national reporting in 2013-14, using haemovigilance data collection forms developed by the NBA and QLD.
- In 2015-16 Western Australia (WA) commenced participation in national reporting.

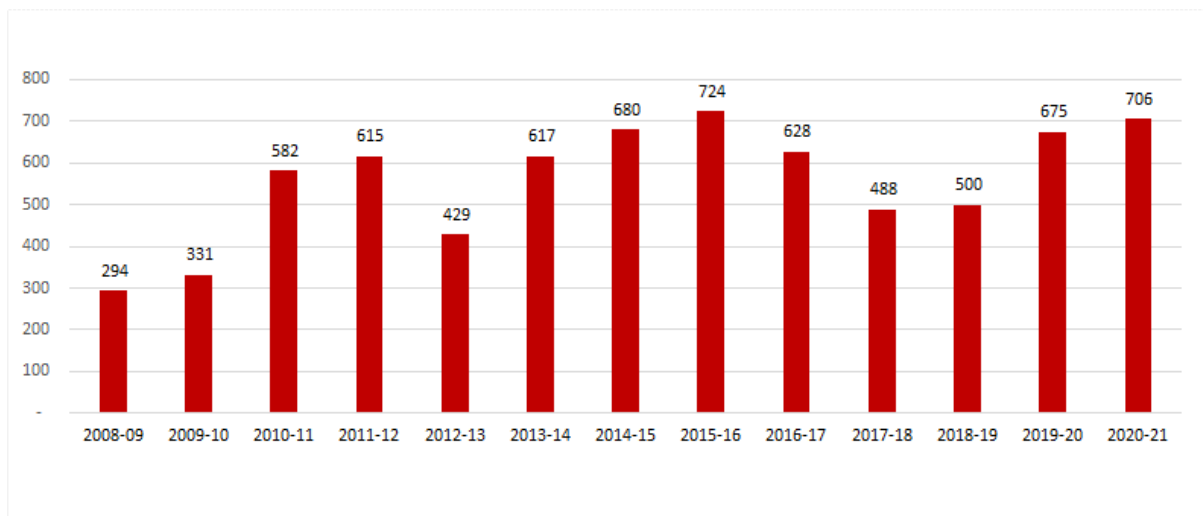


Figure 5: All reported adverse events, 2008-09 to 2020-21

The report presents the data and analysis for all adverse events for five years from 2016-17 to 2020-21, and for 2020-21 only.



Results for all adverse events, 2016-17 to 2020-21

This section presents the data and key results for all adverse events from 2016-17 to 2020-21.

Table 1 shows that:

- four states and territories, NSW, VIC, SA and NT reported an increase in adverse events in 2020-21
- the adverse event rate per 100,000 population ranges from 0.22 for ACT to 5.72 for QLD in 2020-21

Table 1: All adverse events by state, 2016-17 to 2020-21

	2016-17	2017-18	2018-19	2019-20	2020-21	2020-21		
						Percent	Rate per 100,000 population	% change from 2019-20
NSW	175	61	72	112	152	21.5%	1.88	35.7%
VIC	69	57	58	95	97	13.7%	1.48	2.1%
QLD	246	202	233	299	297	42.1%	5.72	-0.7%
SA	54	61	52	69	78	11.0%	4.34	13.0%
WA	71	85	68	83	73	10.3%	2.67	-12.0%
TAS	5	11	0	6	2	0.3%	0.35	-66.7%
NT	5	2	12	5	6	0.8%	2.41	20.0%
ACT	3	9	5	6	1	0.1%	0.22	-83.3%
Total	628	488	500	675	706	100%	2.75	4.6%

Notes

1. The population data is from the ABS 3101.0 - Australian Demographic Statistics, Dec 2020

Table 2 shows that:

- the most common adverse events reported are FNHTR and Allergic and total 67.8% of the total reported adverse events in 2020-21
- adverse events such as delayed serologic transfusion reaction (DSTR), Hypotensive and TAD have been reported from 2017-18 in line with the 2015 AHMDS.



Table 2: All adverse events and incidence data, 2016-17 to 2020-21

	2016-17	2017-18	2018-19	2019-20	2020-21	2020-21			Incidence* (unless specified)
						Percent	Rate per 100,000 population	% of change from 2019-20	
ABO	Not reported	2	1	1	0	0.0%	-	-100.0%	1:40,000
AHTR	13	8	15	24	16	2.3%	0.06	-33.3%	1:76,000
Allergic	157	107	179	241	176	24.9%	0.69	-27.0%	1-3% of transfusion of plasma containing components
Anaphylactic	45	20	29	24	25	3.5%	0.10	4.2%	Not available
DHTR	21	19	15	18	20	2.8%	0.08	11.1%	1:2,500-11,000 or 1:71,667
DSTR	Not reported	10	16	25	32	4.5%	0.12	28.0%	Not available
FNHTR	304	210	169	222	303	42.9%	1.18	36.5%	0.1-1% of transfusions with universal leucocyte depletion
Hypotensive	Not reported	6	4	3	7	1.0%	0.03	133.3%	Not available
IBCT	20	23	11	31	34	4.8%	0.13	9.7%	1:20,000-50,000 transfusions
Other	Not reported	12	7	5	5	0.7%	0.02	0.0%	Not available
PTP	0	1	1	0	1	0.1%	0.00	-	Rare
TACO	55	52	42	60	69	9.8%	0.27	15.0%	Approximately 1% of transfused patients
TAD	Not reported	0	7	7	11	1.6%	0.04	57.1%	Not available
TRALI	12	3	1	2	1	0.1%	0.00	-50.0%	1:1,200-1:190,000 transfusions
TTI	1	15	3	12	6	0.8%	0.02	-50.0%	1:100,000 platelet transfusions 1:500,000 red cell transfusions
Total	628	488	500	675	706	100%	2.75	4.6%	

Notes

1. The population data is from the ABS 3101.0 - Australian Demographic Statistics, Dec 2020
2. *Australian Red Cross Lifeblood (2020), Blood Component Information: An extension of blood component labels

Table 3 shows that 87.1% of events were reported by public hospitals. There was an increase of reporting from private hospitals by 56.9% in 2020-21. For more information, refer to the **Hospital participation in haemovigilance reporting** section.

Table 3: All adverse events by hospital type, 2016-17 to 2020-21

	2016-17	2017-18	2018-19	2019-20	2020-21	2020-21		
						Percent	Rate per 100,000 population	% change from 2019-20
Public hospital	588	454	429	617	615	87.1%	2.40	-0.3%
Private hospitals	40	34	71	58	91	12.9%	0.35	56.9%
Total hospitals	628	488	500	675	706	100%	2.75	4.6%

Note: The population data is from the ABS 3101.0 - Australian Demographic Statistics, Dec 2020

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

Table 4 shows that:

- the most frequent contributory factors reported are 'None identified' and 'Product characteristic'
- contributory factors reported for 'Procedure did not adhere to hospital transfusion guidelines' and 'Prescribing/ordering' increased more than three-fold, from 2019-20 to 2020-21.



Table 4: Contributory factors for all adverse events, 2016-17 to 2020-21

Summary Data	2016-17	2017-18	2018-19	2019-20	2020-21	% change from 2019-20
None identified	256	171	245	330	346	4.8%
Product characteristic	319	193	182	174	161	-7.5%
Transfusion in emergency setting	11	13	19	24	16	-33.3%
Deliberate clinical decision	33	29	40	46	57	23.9%
Prescribing/ordering	18	12	5	5	18	260.0%
Specimen collection/labelling	0	1	3	2	4	100.0%
Laboratory (testing/dispensing)	11	13	9	16	18	12.5%
Transport, storage, handling	1	1	1	1	2	100.0%
Administration of product	18	42	10	64	60	-6.3%
Indications do not meet guidelines	9	8	5	6	13	116.7%
Procedure did not adhere to hospital transfusion guidelines	18	19	9	7	22	214.3%
Other	58	53	48	81	99	22.2%



Results for all adverse events, 2020-21

This section presents the data and key results for all reported adverse events for 2020-21.

Table 5 shows that the percentages of red blood cell (RBC) issued from Lifeblood are reasonably consistent with the population percentage for each state and territory. In contrast, QLD reported a much higher percentage of adverse events (42%) when compared with the population percentage and RBC issue percentage. This is due to reported FNHTRs events at 196. The use of different haemovigilance reporting processes across the jurisdictions may lead to these data inconsistencies.

Table 5: All adverse events by state, 2020-21

	AHTR	Allergic	Anaphylactic	DHTR	DSTR	FNHTR	Hypotensive	IBCT	Other	PTP	TACO	TAD	TRALI	TTI	All reports		Population		Red blood cell issues	
															Total	Percent	Percent	Percent		
NSW	0	54	1	1	2	53	6	15	0	0	15	5	0	0	152	21.5%	31.5%	31.9%		
VIC	1	18	11	7	22	19	1	3	4	0	10	1	0	0	97	13.7%	25.6%	26.8%		
QLD	15	41	5	10	0	196	0	2	0	0	22	0	0	6	297	42.1%	20.3%	20.6%		
SA	0	40	2	1	0	3	0	10	0	1	17	4	0	0	78	11.0%	7.0%	8.3%		
WA	0	22	6	1	8	26	0	3	1	0	5	1	0	0	73	10.3%	10.7%	8.4%		
TAS	0	0	0	0	0	1	0	1	0	0	0	0	0	0	2	0.3%	2.2%	1.9%		
NT	0	1	0	0	0	5	0	0	0	0	0	0	0	0	6	0.8%	1.0%	0.7%		
ACT	0	0	0	0	0	0	0	0	0	0	0	0	1	0	1	0.1%	1.8%	1.5%		
Total	16	176	25	20	32	303	7	34	5	1	69	11	1	6	706	100%	100%	100%		

Note: The population data is from the ABS 3101.0 - Australian Demographic Statistics, Dec 2020

Table 6 shows that 84% (593) of reported adverse events (imputability=possible, likely, and definite) are related to blood transfusion.

Table 6: All adverse events by imputability score, 2020-21

Adverse event	Excluded	Unlikely	Possible	Probable (likely)	Definite (certain)	Not assessable	Total	Percent
AHTR	0	0	2	11	2	1	16	2.3%
Allergic	0	5	34	97	34	6	176	24.9%
Anaphylactic	0	0	5	14	6	0	25	3.5%
DHTR	0	0	3	4	12	1	20	2.8%
DSTR	0	0	1	11	20	0	32	4.5%
FNHTR	3	57	148	81	11	3	303	42.9%
Hypotensive	0	0	4	2	0	1	7	1.0%
IBCT	2	0	0	2	7	23	34	4.8%
Other	1	0	4	0	0	0	5	0.7%
PTP	0	0	0	0	0	1	1	0.1%
TACO	1	4	26	31	6	1	69	9.8%
TAD	0	2	5	3	1	0	11	1.6%
TRALI	0	0	0	1	0	0	1	0.1%
TTI	0	1	5	0	0	0	6	0.8%
Total	7	69	237	257	99	37	706	
Percent	1.0%	9.8%	33.6%	36.4%	14.0%	5.2%	100%	

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



A breakdown of adverse events by clinical outcome severity in **Table 7** shows:

- one (TACO) reported death was related to transfusion
- life-threatening and severe morbidity events accounted for 12% of total reports
- 64% of reported adverse events related to minor morbidities.

Table 7: All adverse events by clinical outcome severity, 2020-21

Adverse event	Death	Life-threatening	Severe morbidity	Minor morbidity	No morbidity	Outcome not available	Total
AHTR	0	1	1	13	1	0	16
Allergic	0	4	7	132	25	8	176
Anaphylactic	0	14	5	5	1	0	25
DHTR	0	0	2	10	8	0	20
DSTR	0	0	0	4	28	0	32
FNHTR	0	1	19	233	35	15	303
Hypotensive	0	0	2	3	0	2	7
IBCT	0	1	0	3	19	11	34
Other	0	2	1	1	1	0	5
PTP	0	0	1	0	0	0	1
TACO	1	4	13	42	7	2	69
TAD	0	1	4	3	3	0	11
TRALI	0	0	1	0	0	0	1
TTI	0	0	0	2	4	0	6
Total	1	28	56	451	132	38	706
Percent	0.1%	4.0%	7.9%	63.9%	18.7%	5.4%	100%

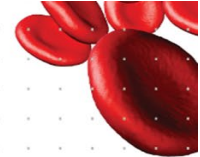


Table 8 shows a breakdown of all adverse events by imputability score and outcome for 2020-21. The imputability scores of 'Excluded' and 'Unlikely' are combined for adverse events in this table.

Table 8: All adverse events by imputability score and outcome severity, 2020-21

Adverse Event	Death	Life-threatening	Severe morbidity	Minor morbidity	No morbidity	Outcome not available	Total
Excluded or Unlikely	0	0	5	59	12	0	76
Allergic	0	0	0	4	1	0	5
FNHTR	0	0	4	50	6	0	60
IBCT	0	0	0	0	2	0	2
Other	0	0	0	0	1	0	1
TACO	0	0	0	4	1	0	5
TAD	0	0	1	1	0	0	2
TTI	0	0	0	0	1	0	1
Possible	0	7	22	162	41	5	237
AHTR	0	0	0	2	0	0	2
Allergic	0	1	1	22	9	1	34
Anaphylactic	0	2	1	2	0	0	5
DHTR	0	0	0	2	1	0	3
DSTR	0	0	0	0	1	0	1
FNHTR	0	1	9	114	20	4	148
Hypotensive	0	0	1	3	0	0	4
Other	0	2	1	1	0	0	4
TACO	0	1	7	13	5	0	26
TAD	0	0	2	1	2	0	5
TTI	0	0	0	2	3	0	5
Probable (likely)	1	10	19	174	36	17	257
AHTR	0	0	0	11	0	0	11
Allergic	0	0	3	73	15	6	97
Anaphylactic	0	8	3	2	1	0	14
DHTR	0	0	2	2	0	0	4
DSTR	0	0	0	2	9	0	11
FNHTR	0	0	6	59	8	8	81
Hypotensive	0	0	1	0	0	1	2
IBCT	0	0	0	1	1	0	2
TACO	1	2	2	23	1	2	31
TAD	0	0	1	1	1	0	3
TRALI	0	0	1	0	0	0	1
Definite (certain)	0	9	8	50	32	0	99
AHTR	0	1	1	0	0	0	2
Allergic	0	2	3	29	0	0	34
Anaphylactic	0	4	1	1	0	0	6
DHTR	0	0	0	5	7	0	12
DSTR	0	0	0	2	18	0	20
FNHTR	0	0	0	10	1	0	11
IBCT	0	0	0	1	6	0	7
TACO	0	1	3	2	0	0	6
TAD	0	1	0	0	0	0	1
Not Assessable	0	2	2	6	11	16	37
AHTR	0	0	0	0	1	0	1
Allergic	0	1	0	4	0	1	6
DHTR	0	0	0	1	0	0	1
FNHTR	0	0	0	0	0	3	3
Hypotensive	0	0	0	0	0	1	1
IBCT	0	1	0	1	10	11	23
PTP	0	0	1	0	0	0	1
TACO	0	0	1	0	0	0	1
Total	1	28	56	451	132	38	706

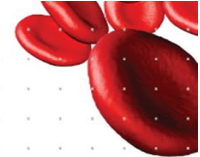


Table 9 highlights that 68% of adverse events were reported to be related to red cell transfusions, compared to red cells units issued being 62% of total fresh blood products issued in 2020-21, followed by platelets (14%) and fresh frozen plasma (8%).

Table 9: All adverse events by blood product, 2020-21

Adverse event	Red cells	Platelets	Fresh frozen plasma	Cryoprecipitate	Cryo-depleted Plasma	Multiple products	Other products	Total
AHTR	8	5	2	1	0	0	0	16
Allergic	55	83	27	8	2	1	0	176
Anaphylactic	5	12	6	1	0	1	0	25
DHTR	19	1	0	0	0	0	0	20
DSTR	31	1	0	0	0	0	0	32
FNHTR	264	32	5	0	1	1	0	303
Hypotensive	6	1	0	0	0	0	0	7
IBCT	23	8	2	0	0	1	0	34
Other	4	0	1	0	0	0	0	5
PTP	1	0	0	0	0	0	0	1
TACO	59	7	0	1	0	1	1	69
TAD	6	4	1	0	0	0	0	11
TRALI	0	1	0	0	0	0	0	1
TTI	1	5	0	0	0	0	0	6
Total	482	160	44	11	3	5	1	706
Percent	68.3%	22.7%	6.2%	1.6%	0.4%	0.7%	0.1%	100%
Percent Issues by product	61.6%	13.6%	8.0%	15.6%	0.6%		0.7%	100.0%

Table 10 shows that 7% (48) more adverse events were reported for males than females, and 60 more reports for FNHTR were male.

Table 10: All adverse events by sex, 2020-21

Adverse event	Male	Female	Not reported	Total
AHTR	8	8	0	16
Allergic	84	76	16	176
Anaphylactic	16	9	0	25
DHTR	7	13	0	20
DSTR	13	19	0	32
FNHTR	178	118	7	303
Hypotensive	3	4	0	7
IBCT	16	12	6	34
Other	2	3	0	5
PTP	0	1	0	1
TACO	29	39	1	69
TAD	4	7	0	11
TRALI	0	1	0	1
TTI	2	4	0	6
Total	362	314	30	706
Percent	51.3%	44.5%	4.2%	100%



Table 11 shows more adverse events reported for males than females in the older age groups (55-64 and 75 years or older). Females had more reported adverse events than males in the 25 to 54 age groups.

Table 11: All adverse events by age and sex, 2020-21

Adverse event	Male	Female	Not reported	Total
0-4 years	11	19	1	31
5-14 years	18	11	1	30
15-24 years	21	14	1	36
25-34 years	18	24	4	46
35-44 years	18	30	2	50
45-54 years	18	29	5	52
55-64 years	52	28	6	86
65-74 years	79	81	6	166
75 years or older	127	78	2	207
Not stated	0	0	2	2
Total	362	314	30	706
Percent	51.3%	44.5%	4.2%	100%

Adverse events reported by day and time and remoteness area are shown in **Table 12** and **Table 13**.

Table 12: All adverse events by time and weekday and remoteness area, 2020-21

	Weekday															
	Between 7am and 7pm						Between 7pm and 7am					Unknown				
	Major city	Inner regional	Outer regional	Remote	Very remote	Total 7am to 7pm	Major city	Inner regional	Outer regional	Remote	Total 7pm to 7am	Major city	Inner regional	Total unknown	Total weekday	Total all
AHTR	10	1	2	1	0	14	1	0	1	0	2	0	0	0	16	16
Allergic	95	4	10	0	0	109	21	2	3	1	27	1	1	2	138	176
Anaphylactic	10	2	2	0	0	14	4	0	0	0	4	0	0	0	18	25
DHTR	5	0	1	2	0	8	7	0	1	0	8	0	0	0	16	20
DSTR	12	0	0	0	0	12	15	0	0	0	15	2	0	2	29	32
FNHTR	101	13	37	1	0	152	49	5	13	0	67	4	0	4	223	303
Hypotensive	4	0	0	0	0	4	1	1	0	0	2	0	0	0	6	7
IBCT	14	2	0	1	0	17	5	2	0	0	7	2	0	2	26	34
Other	5	0	0	0	0	5	0	0	0	0	0	0	0	0	5	5
PTP	0	0	0	0	0	0	0	0	0	0	0	1	0	1	1	1
TACO	22	2	5	0	1	30	18	1	1	0	20	2	1	3	53	69
TAD	7	1	0	0	0	8	2	1	0	0	3	0	0	0	11	11
TRALI	1	0	0	0	0	1	0	0	0	0	0	0	0	0	1	1
TTI	4	0	1	0	0	5	1	0	0	0	1	0	0	0	6	6
Total	290	25	58	5	1	379	124	12	19	1	156	12	2	14	549	706



Table 13: All adverse events by time and weekend and remoteness area, 2020-21

	Weekend													
	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	Total unknown	Total weekend	Total all	
AHTR	0	0	0	0	0	0	0	0	0	0	0	0	16	
Allergic	17	2	4	0	23	11	1	0	12	3	3	38	176	
Anaphylactic	6	0	0	0	6	1	0	0	1	0	0	7	25	
DHTR	0	0	3	0	3	1	0	0	1	0	0	4	20	
DSTR	1	0	0	0	1	2	0	0	2	0	0	3	32	
FNHTR	42	2	8	1	53	19	5	2	26	1	1	80	303	
Hypotensive	0	0	0	0	0	1	0	0	1	0	0	1	7	
IBCT	6	0	0	0	6	0	1	0	1	1	1	8	34	
Other	0	0	0	0	0	0	0	0	0	0	0	0	5	
PTP	0	0	0	0	0	0	0	0	0	0	0	0	1	
TACO	8	1	2	0	11	5	0	0	5	0	0	16	69	
TAD	0	0	0	0	0	0	0	0	0	0	0	0	11	
TRALI	0	0	0	0	0	0	0	0	0	0	0	0	1	
TTI	0	0	0	0	0	0	0	0	0	0	0	0	6	
Total	80	5	17	1	103	40	7	2	49	5	5	157	706	

Table 14 shows a breakdown of reported contributory factors by adverse event and outcome severity for 2020-21.

- ‘Product characteristic’ was reported to be associated with nearly half (13 out of 28) life-threatening cases
- ‘Administration of product’ was reported to be mostly likely associated with FNHTR
- ‘Procedure did not adhere to hospital transfusion guidelines’ and ‘Laboratory (testing/dispensing)’ were reported to be associated with IBCT
- 53% (32 out of 60) of severity morbidity cases had no identified contributory factors
- 42% (346 out of 816) of contributory factors were not identified.

Table 14: Contributory factors by adverse event and by clinical outcome severity, 2020-21

Contributory Factors	Adverse event														Clinical outcome severity					
	AHTR	Allergic	Anaphylactic	DHTR	DSTR	FNHTR	Hypotensive	IBCT	Other	PTP	TACO	TAD	TRALI	TTI	Outcome not available	No morbidity	Minor morbidity	Severe morbidity	Life-threatening	Death
None identified	13	97	5	9	6	170	5	1	0	0	30	9	0	1	27	49	231	32	7	0
Product characteristic	0	58	15	6	21	38	1	3	2	0	14	2	1	0	2	38	98	10	13	0
Transfusion in emergency setting	0	1	2	2	0	6	0	3	0	0	2	0	0	0	0	6	7	2	1	0
Deliberate clinical decision	0	10	4	1	7	20	0	5	2	0	7	1	0	0	2	13	37	2	2	1
Prescribing/ordering	1	0	0	0	0	1	0	7	0	0	3	1	0	5	0	10	5	1	1	1
Specimen collection/labelling	0	0	0	0	1	0	0	3	0	0	0	0	0	0	0	4	0	0	0	0
Laboratory (testing/dispensing)	0	1	0	0	0	0	0	17	0	0	0	0	0	0	7	9	2	0	0	0
Transport, storage, handling	0	0	0	0	0	0	0	2	0	0	0	0	0	0	0	1	1	0	0	0
Administration of product	1	0	0	2	0	43	0	10	0	0	4	0	0	0	4	7	43	4	1	1
Indications do not meet guidelines	0	1	1	0	0	1	0	8	0	0	2	0	0	0	4	4	3	0	1	1
Procedure did not adhere to hospital transfusion guidelines	0	0	0	0	0	2	1	17	0	0	2	0	0	0	4	11	4	2	0	1
Other	1	10	1	1	0	65	1	6	1	0	12	1	0	0	2	11	77	7	2	0

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



Hospital participation in haemovigilance reporting

States and territories reported the following hospital participation and reporting data shown in **Figure 6** for 2020-21. A Participating Hospital is a hospital that participates in a State or Territory Haemovigilance Reporting System and reports zero or more adverse events. A Reporting Hospital is a participating hospital that reports one or more adverse events.

- 534 hospitals participated in the national haemovigilance reporting, including 433 public hospitals and 101 private hospitals
- 25% (133) of participating hospitals reported adverse events, including 107 public hospitals and 26 private hospitals
- only three states (VIC, QLD and WA) reported adverse events for private hospitals and QLD had the highest number of reporting and participating hospitals for private hospitals
- private hospitals in NSW, SA and NT did not participate in national haemovigilance reporting.

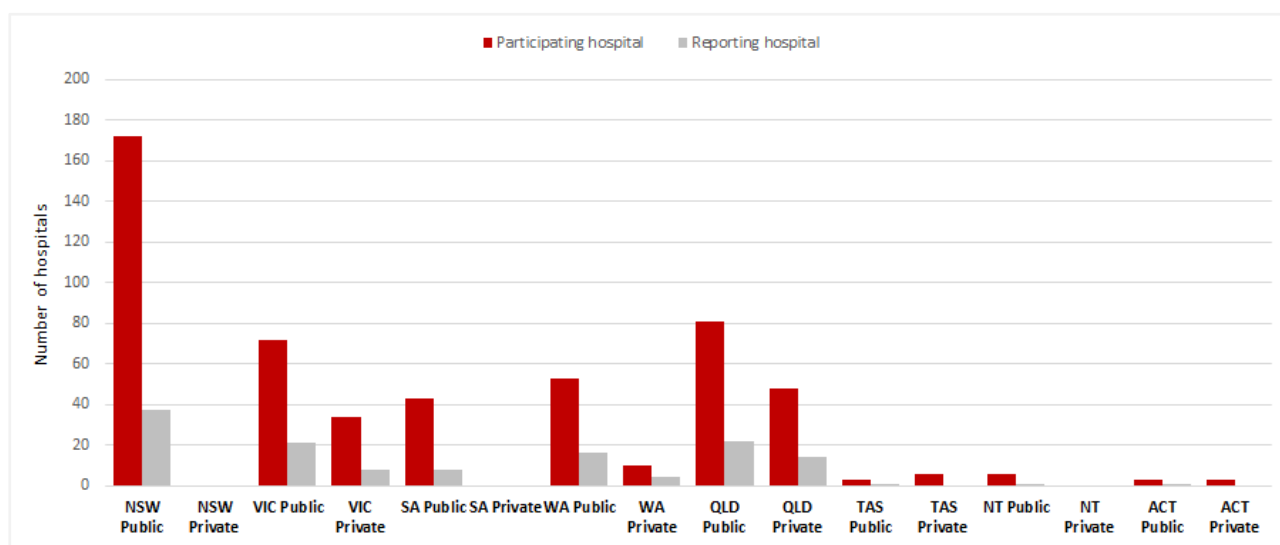


Figure 6: Number of participating and reporting hospitals by public/private and state/territory, 2020-21

Table 15 shows the number of participating hospitals reporting adverse events by state/territory and public/private.

Table 15: Number of participating and reporting hospitals by public/private and state/territory, 2020-21

	NSW	VIC	QLD	SA	WA	TAS	NT	ACT	Total	
Participating hospitals	Public	172	72	81	43	53	3	6	3	433
	Private	0	34	48	0	10	6	0	3	101
Reporting hospitals	Public	37	21	22	8	16	1	1	1	107
	Private	0	8	14	0	4	0	0	0	26

Nationally, 5.3 adverse events per hospital were reported for 2020-21. This varied between states and territories, ranging from 1.0 in ACT to 9.8 in SA in **Table 16**.

Table 16: Number of adverse events per hospital by state and territory, 2020-21

	NSW	VIC	QLD	SA	WA	TAS	NT	ACT	Total
Number of reporting hospitals	37	29	36	8	20	1	1	1	133
Number of adverse events	152	97	297	78	73	2	6	1	706
Adverse events per hospital	4.1	3.3	8.3	9.8	3.7	2.0	6.0	1.0	5.3



Recommendations

This report restates the five recommendations made in the 2019-20 report. Further work is being undertaken to understand the barriers and incentives to national haemovigilance in Australia that will inform future recommendations.

Guideline development

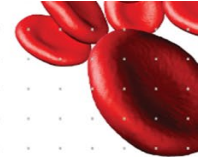
1. Publish the revised AHMDS.
2. Publish the Guidance on Investigation and Management of Acute Transfusion Reactions.

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.

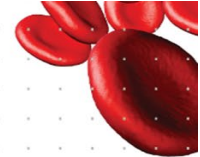
Education and training

5. Identify training needs for haemovigilance.

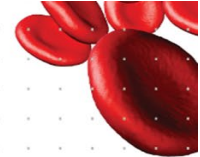


Description of adverse events from 2015 AHMDS

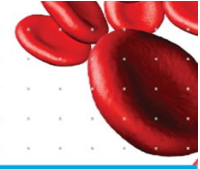
Adverse Event	Definition – Where possible this is the ISBT Definition
<p>ABO incompatibility (ABO)</p>	<p>All cases where a blood component was transfused which was (unintentionally) ABO incompatible. Include all such events</p> <ul style="list-style-type: none"> • even if only a small quantity of blood was transfused, and/or • if no adverse reaction occurred <p>All cases are to be included, whether the first error occurred in the blood establishment, in the blood transfusion laboratory or in clinical areas.</p> <p>Note that these are a subgroup of the IBCT category.</p> <p>Transfusion of ABO incompatible products to a patient is considered a ‘sentinel event’ and is also subject to other reporting channels outside of the National Haemovigilance Program.</p>
<p>Acute haemolytic transfusion reaction (other than ABO incompatibility) (AHTR)</p>	<p>An AHTR has its onset within 24 hours of a transfusion. Clinical or laboratory features of haemolysis are present.</p> <p>Common signs of AHTR are fever, chills/rigors, facial flushing, chest pain, abdominal pain, back/flank pain, nausea/vomiting, diarrhoea, hypertension, pallor, jaundice, oligoanuria, diffuse bleeding and dark urine.</p> <p>Common laboratory features are hemoglobinaemia, haemoglobinuria, decreased serum haptoglobin, unconjugated hyperbilirubinaemia, increased LDH and AST levels and decreased haemoglobin levels.</p> <p>Not all clinical or laboratory features are present in case of AHTR.</p>
<p>Allergic reaction (Allergic)</p>	<p>An allergic reaction may present only with mucocutaneous signs and symptoms during or within 4 hours of transfusion:</p> <ul style="list-style-type: none"> • morbilliform rash with itching • urticaria • localised angioedema • oedema of lips, tongue and uvula • periorbital pruritus, erythema and oedema • conjunctival oedema <p>This type of allergic reaction is called ‘minor allergic reaction’ in some haemovigilance systems.</p>
<p>Anaphylactoid or anaphylactic reaction (Anaphylactic)</p>	<p>An allergic reaction can also involve respiratory and/or cardiovascular systems and present like an anaphylactic reaction. There is anaphylactic reaction when, in addition to mucocutaneous symptoms, there is airway compromise or severe hypotension requiring vasopressor treatment (or associated symptoms like hypotonia, syncope). The respiratory signs and symptoms may be laryngeal (tightness in the throat, dysphagia, dysphonia, hoarseness, stridor) or</p>



Adverse Event	Definition – Where possible this is the ISBT Definition
	pulmonary (dyspnea, cough, wheezing/bronchospasm, hypoxemia). Such a reaction usually occurs during or very shortly after transfusion.
Delayed haemolytic transfusion reaction (DHTR)	A DHTR usually manifests between 24 hours and 28 days after a transfusion and clinical or laboratory features of haemolysis are present. Signs and symptoms are similar to AHTR but are usually less severe. DHTR may sometimes manifests as an inadequate rise of post-transfusion haemoglobin level or unexplained fall in haemoglobin after a transfusion. Blood group serology usually shows abnormal results.
Delayed serologic reaction (DSTR)	There is a DSTR when, after a transfusion, there is demonstration of clinically significant antibodies against red blood cells which were previously absent (as far as is known) and when there are no clinical or laboratory features of haemolysis. This term is synonymous with alloimmunisation.
Febrile non-haemolytic transfusion reaction (FNHTR)	<p>Presents with one or more of the following during or within 4 hours of transfusion without any other cause such as haemolytic transfusion reaction, bacterial contamination or underlying condition:</p> <ul style="list-style-type: none"> • fever ($\geq 38^{\circ}\text{C}$ oral or equivalent and a change of $\geq 1^{\circ}\text{C}$ from pre-transfusion value) • chills • rigors <p>This may be accompanied by headache and nausea.</p> <p>FNHTR could be present in absence of fever (if chills or rigors without fever).</p> <p>For the purpose of national and international comparison, only the most serious cases of FNHTR defined below should be reported to the National Haemovigilance Program:</p> <ul style="list-style-type: none"> • fever ($\geq 39^{\circ}\text{C}$ oral or equivalent and a change of $\geq 2^{\circ}\text{C}$ from pre-transfusion value and chills/rigors)
Hypotensive transfusion reaction (Hypotensive)	This reaction is characterized by hypotension defined as a drop in systolic blood pressure of ≥ 30 mm Hg occurring during or within one hour of completing transfusion and a systolic blood pressure ≤ 80 mm Hg.
Incorrect blood component transfused (IBCT)	<p>All reported episodes, where a patient was transfused with a blood component that did not meet the appropriate requirements or that was intended for another patient. Include even if</p> <ul style="list-style-type: none"> • the component was ABO compatible and/or • only a small quantity of blood was transfused and/or • there was no adverse reaction



Adverse Event	Definition – Where possible this is the ISBT Definition
Other types of adverse events (other)	Other types of adverse events not defined in this AHMDS but defined and published by the ISBT at http://www.isbtweb.org/working-parties/haemovigilance/
Post-transfusion purpura (PTP)	PTP is characterized by thrombocytopenia arising 5-12 days following transfusion of cellular blood components with findings of antibodies in the patient directed against the Human Platelet Antigen (HPA) system.
Transfusion-associated circulatory overload (TACO)	TACO is characterised by any 4 of the following: <ul style="list-style-type: none"> • acute respiratory distress • tachycardia • increased blood pressure • acute or worsening pulmonary oedema on frontal chest radiograph • evidence of positive fluid balance Occurring within 6 hours of completion of transfusion. An elevated BNP is supportive of TACO.
Transfusion Associated Dyspnoea (TAD)	TAD is characterized by respiratory distress within 24 hours of transfusion that does not meet the criteria of TRALI, TACO, or allergic reaction. Respiratory distress should be the most prominent clinical feature and should not be explained by the patient's underlying condition or any other known cause.
Transfusion associated graft-versus-host disease (TA-GVHD)	TA-GVHD clinically features the following 1–6 weeks post transfusion, with no other apparent cause: <ul style="list-style-type: none"> • fever • rash • liver dysfunction • diarrhoea • pancytopenia TA-GVHD is confirmed by GVHD-typical biopsy and genetic analysis to show chimerism of donor and recipient lymphocytes.
Transfusion-related acute lung injury (TRALI)	In patients with no evidence of acute lung injury (ALI) prior to transfusion, TRALI is diagnosed if a new ALI is present (all five criteria should be met) during or within 6 hours of completion of transfusion: <ul style="list-style-type: none"> • Acute onset • Hypoxemia <ul style="list-style-type: none"> ○ PaO₂ / FiO₂ < 300 mm Hg or ○ Oxygen saturation is < 90% on room air or ○ Other clinical evidence • Bilateral infiltrates on frontal chest radiograph • No evidence of left atrial hypertension (i.e. circulatory overload)



Adverse Event	Definition – Where possible this is the ISBT Definition
	<ul style="list-style-type: none"> No temporal relationship to an alternative risk factor for ALI, during or within 6 hours of completion of transfusion. <p>Alternate risk factors for ALI are:</p> <ul style="list-style-type: none"> Direct Lung Injury <ul style="list-style-type: none"> Aspiration Pneumonia Toxic inhalation Lung contusion Near drowning Indirect lung injury <ul style="list-style-type: none"> Severe sepsis Shock Multiple trauma Burn injury Acute pancreatitis Cardiopulmonary bypass Drug overdose <p>TRALI should be indicated with a possible imputability to transfusion if it presents a temporal relationship to an alternative risk factor for ALI as described above.</p> <p>TRALI is therefore a clinical syndrome and neither presence of anti-HLA or anti-HNA antibodies in donor(s) nor confirmation of cognate antigens in recipient is required for diagnosis</p>
Transfusion transmitted infection (TTI)	<p>The recipient had evidence of infection following transfusion of blood components and there was no evidence of infection prior to transfusion and no evidence of an alternative source of infection.</p> <p><i>Transfusion transmitted bacterial infection</i></p> <p>Transfusion transmitted bacterial infection should be clinically suspected if:</p> <ul style="list-style-type: none"> fever $>39^{\circ}\text{C}$ or a change of $>2^{\circ}\text{C}$ from pre transfusion value and rigors and tachycardia >120 beats/min or a change of >40 beats/min from pre transfusion value or a rise or drop of 30mmHg in systolic blood pressure within 4 hours of transfusion are present <p>Possible transfusion transmitted bacterial infection:</p> <ul style="list-style-type: none"> detection of bacteria by approved techniques in the transfused blood component but not in the recipient's blood or



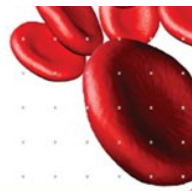
Adverse Event	Definition – Where possible this is the ISBT Definition
	<ul style="list-style-type: none">• detection of bacteria in the recipient’s blood following transfusion but not in the transfused blood component and no other reasons are ascertainable for the positive blood culture• <p>Confirmed transfusion transmitted bacterial infection:</p> <ul style="list-style-type: none">• detection of the same bacterial strain in the recipient’s blood and in the transfused blood product by approved techniques <p><i>Transfusion transmitted viral infection</i></p> <p>Following investigation, the recipient has evidence of infection post transfusion and no clinical or laboratory evidence of infection prior to transfusion and either, at least one component received by the infected recipient was donated by a donor who had evidence of the same infection, or, at least one component received by the infected recipient was shown to have been contaminated with the virus. Reports should at least consider HIV, Hepatitis B, Hepatitis C and CMV.</p> <p><i>Transfusion transmitted parasitic infection</i></p> <p>Detection of the same parasite in the recipient’s blood and parasite or specific antibodies in the donor blood.</p>



SECTION 2

Donor Safety Report

2020–21 Annual Report for National Blood Authority



1.Executive Summary

Lifeblood collects both whole blood and specific blood components (plasma and platelets). Whilst blood donation is generally a safe process, there are recognised side effects (adverse events) which can occur. Lifeblood is continually reviewing eligibility criteria, donation processes, technology, staff capabilities and donor education, in addition to relevant international guidelines and processes, to ensure donation remains as safe as possible. To support continuous improvement and evaluate new initiatives, Lifeblood has implemented a very sensitive surveillance system which records all side effects regardless of severity, that occur up to 24 hours after the donation. The rate of events requiring outside medical care is an indicator for more serious events that is considered the key indicator for changes in safety. This report provides an overview of the donor adverse event rates for the 2020-21 financial year. Events notified to Lifeblood by 31 July 2021 are included in the report.

More than 1.6 million donations were collected in 2020-21. Approximately 4.28% of donations were associated with at least one donor adverse event. This is a slight increase from 4.04% in the previous year and is primarily accounted for by the increase in minor phlebotomy-related events and mild citrate reactions associated with the rollout of the new plasma platform which was completed in July 2021. The rate of events requiring outside medical care in 2020-21 did not change from 2019-20, for plasma or overall, with less than 1 in 1,000 donations associated with an adverse event requiring outside medical care.

Vasovagal events (feeling faint or fainting) accounted for approximately one third of all adverse events. In 2020-21 there was a reduction in vasovagal rates across all donation types. Previous reports have addressed the increased rate of phlebotomy (needle)-related events that have been associated with the new plasma platform which rolled out from May 2019 and was completed in July 2021. Whilst the increase in needle-related events has been in minor events, in the last 18 months, Lifeblood has been actively implementing education and new processes, following which rate reductions for both haematoma (bruises) and painful arm rates have been observed. The ability to monitor adverse events in real-time using Lifeblood's sensitive surveillance system has ensured that we have been able to respond quickly and effectively to changes in safety.

2. Introduction

Lifeblood collects both whole blood and specific blood components (plasma and platelets). A whole blood donation involves the collection of approximately 500 mL of blood which takes an average of 8-9 minutes¹ 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 blood cell components and plasma. The machine draws blood from the donor and mixes it with anticoagulant (citrate) solution to prevent blood clots. 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 500 mL of saline solution through the donation needle at the end of the donation. A plasmapheresis donation takes an average of approximately 42 minutes² and a plateletpheresis donation 71 minutes³. Since 2015-16, plateletpheresis donations have been predominantly collected from male donors as a risk mitigation strategy for transfusion-related acute lung injury.

Whilst blood donation is generally a safe process, there are recognised complications which can occur. Lifeblood records all events, regardless of severity, that occur up to 24 hours after the donation. This sensitive adverse event reporting system allows small changes in rates to be detected and provides the opportunity to monitor the safety of new initiatives and support the continuous improvement approach to ensuring donation is as safe as possible. This report provides a summary of adverse event rates for 2020-21 with an overview of changes from the previous three years. Events reported within 30 days following the end of each financial year are included in the report. A description of the events referred to in this document is provided in Appendix 1.

Adverse event rates may change from year to year for a number of reasons including a change in technology, process or a change in donor characteristics. In general, new, younger and female donors are more likely to have an adverse reaction. The type and rates of adverse event differ between the donation types. For instance, the higher rate of phlebotomy (needle)-related events in apheresis compared with whole blood relates to factors such as the longer collection time and the return of blood and saline which increases the chance the needle may move. Plateletpheresis has a higher rate of haematomas and citrate (anticoagulant) reactions compared with plasmapheresis because of the longer collection time and the higher citrate dose.

3. Results

3.1 Donations in the reporting period

Adverse event rates are calculated as the number of events per 10,000 attempted donations, where attempted refers to being eligible to donate and having a donation needle in, regardless of whether the collection was successful. The number of attempted donations for each donation type for the last four financial years are provided in Table 1a.

Table 1a: Number of donations in the denominator cohort from 2017-18 to 2020-21

Donation type	2017-18	2018-19	2019-20	2020-21
Whole Blood	700,546	703,986	701,475	724,121
Plasmapheresis	646,488	745,666	822,903	873,448
Plateletpheresis	27,782	29,127	27,501	26,657
Total	1,374,816	1,478,779	1,551,879	1,624,226

¹ Based on minimum collection of 450mL for males and females 2018/19 to 2020/21

² Based on minimum collection of 422mL for females and 488 for males excluding anticoagulant 2018/19 to 2020/21

³ Based on collection of double-dose platelet 2018/19 to 2020/21

3.2 Donor adverse events by donation category

Approximately 4.28% of donations were associated with at least one donor adverse event. This is a slight increase on the previous year's rate and is primarily accounted for by the increase in minor phlebotomy-related events and mild citrate reactions associated with the rollout of the new plasma platform which was completed in July 2021. Further context is provided in the following sections.

Total donor adverse event rates from 2017-18 to 2020-21 are provided in Table 2a, Tables 2b, and 2c provide rates for individual events for 2020-21.

Table 2a: Total donor adverse event rates per 10,000 donations 2017-18 to 2020-21

Donation	Total adverse event rate per 10,000 donations			
	2017-18	2018-19	2019-20	2020-21
Whole Blood	299.05	297.09	321.76	296.35
Plasmapheresis	261.60	324.13	455.08	524.36
Plateletpheresis	976.17	1,047.14	990.15	869.94
Total	295.12	325.50	404.30	428.38

Table 2b: 2020-21 unique donor adverse event rates per 10,000 donations

	Whole Blood	Plasmapheresis	Plateletpheresis	All donations
All vasovagal events	200.51	108.57	108.41	149.55
Phlebotomy related				
Arterial puncture	0.37	0.07	0.38	0.21
Cellulitis	0.07	0.08	0.00	0.07
Delayed bleeding	2.15	6.39	2.25	4.43
Haematoma	64.22	183.02	328.62	132.44
Nerve injury/irritation	10.91	14.56	9.00	12.84
Other injury	0.46	0.96	0.38	0.73
Painful arm [^]	24.91	68.50	56.27	48.87
Thrombophlebitis	0.35	0.42	0.00	0.38
Other event type				
Anaphylaxis	0	0.02	0.00	0.01
Chest pain	0.59	0.63	0.75	0.62
Local allergic reaction	1.44	2.48	2.63	2.02
Other event/injury	1.60	2.84	4.50	2.31

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

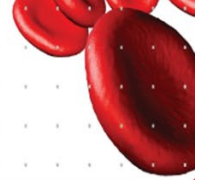


Table 2c: 2020-21 specific apheresis-related donor adverse event rates per 10,000 donations

	Plasmapheresis	Plateletpheresis	Total Apheresis
Citrate reaction ⁺	136.64	368.01	143.49
Haemolysis	0.50	0.00	0.49
Infiltration	46.02	55.52	46.31
Omitted anticoagulant	0.26	5.25	0.41

⁺ *The majority of citrate reactions are mild*

Overview of major trends

Whole blood

Total adverse event rates for whole blood in 2020-21 decreased significantly by 7.9% from 321.76 per 10,000 donations in 2019-20 to 296.35 per 10,000 donations. The decrease is attributed primarily to the decrease observed in vasovagal reaction rates (225.03 to 200.51 per 10,000 donations).

Apheresis

Total adverse event rates for plasmapheresis increased from 455.08 per 10,000 donations in 2019-20 to 524.36 per 10,000 in 2020-21. This is primarily attributed to the completed rollout of the new plasma platform and the previously reported increases in minor phlebotomy-related events and mild citrate reactions.

In May 2019 Lifeblood introduced a new platform to collect plasma. In 2020-21 almost all plasma donations were made on the new machines, compared with 58% in the 2019-20 period. One of the benefits of the newer technology is that it removes smaller volumes of blood in each draw cycle, reducing the chance of vasovagal events. The vasovagal rate, which has previously been shown to be lower than the previous platform, further decreased in 2020-21 (Refer 3.3 below).

As the new platform draws smaller volumes at any one time, more cycles are required to achieve the target volume, which results in greater potential for the needle to move position. This has translated to an increase in phlebotomy-related events in the last two financial years. Importantly, this increase represents minor events, with the rate of events requiring outside medical care similar to those observed on the original platform. Lifeblood has introduced a number of initiatives to manage this increase in phlebotomy events, following which, there has been a significant rate reduction in both haematoma (182.31 to 156.85 per 10,000 donations) and painful arm (71.67 to 60.63 per 10,000 donations). Infiltration rates on the new platform have continued to increase in the last year (42.59 to 46.90 per 10,000 donations), but this has been associated with a significant reduction in the rate of events requiring outside medical care. This is considered to be related to staff education initiatives which has resulted in heightened awareness and earlier identification and management of symptoms, improving outcomes for donors.

An increase in mild citrate reactions has also been observed on the new machine and is considered a temporary side effect that relates to the higher flow rate on the return of red cells. Importantly the majority of reactions resolve quickly. Citrate reaction rates on the new machine have remained reasonably steady since early 2020.

3.3 Vasovagal events

Vasovagal events are the most common donor adverse event if considered across all donation categories. Independent risk factors for vasovagal events are (donation) inexperience, younger age, and being female. This is demonstrated in Figure 1 below. The vasovagal rate for new female donors was similar for whole blood and plasma on the new plasma machine (796.03 vs 847.45 per 10,000); For new male donors, the rate was significantly higher if donating plasma (537.57 vs 602.11 per 10,000).

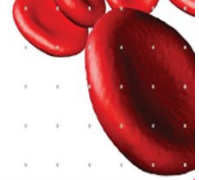
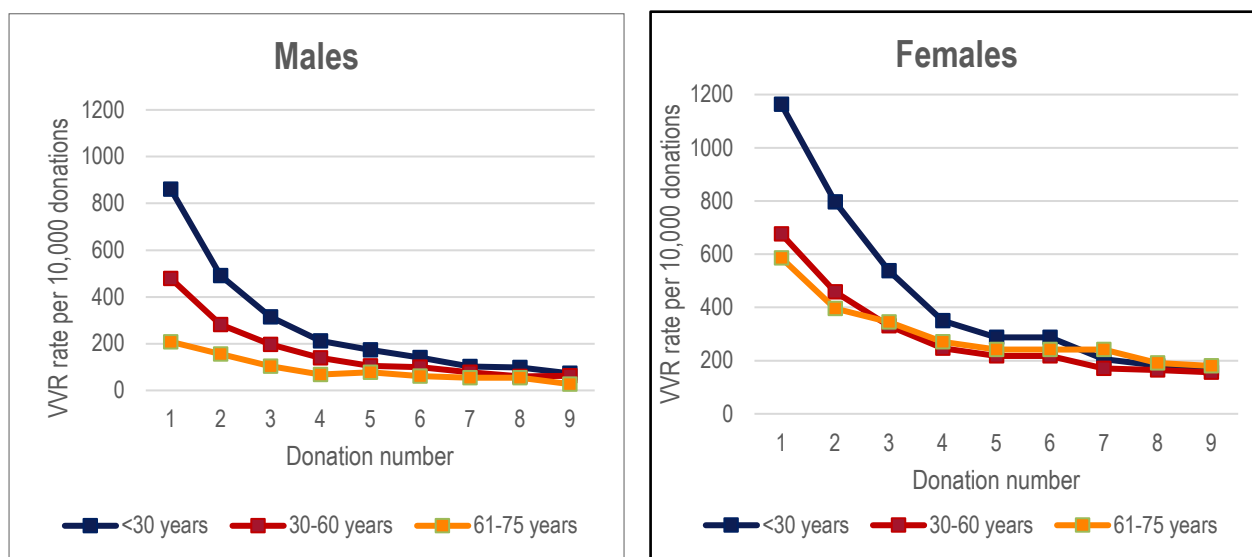


Figure 1: Vasovagal rate per 10,000 donations by age group and donation experience



The overall rate of vasovagal events across all donation categories for 2020-21 was 149.55 per 10,000 donations; significantly reduced from 2019-20 (166.24 per 10,000). This is the net effect of the reduction across all donation types; 4%, 8.8% and 17.6% for whole blood, plasmapheresis and plateletpheresis respectively, after adjustments for gender, new or returned⁴ donor status and age status less than 30 years or 30 years and over.

In 2020-21, approximately 90% of all vasovagal reactions occurred in the donor centre. These events were less likely to be associated with loss of consciousness (6.8% vs 15.9%), and those sustaining loss of consciousness had a lower rate of injury if the event occurred on-site (3.51% vs 11.43%).

Overall, the rate of vasovagal events associated with loss of consciousness has reduced significantly since 2019-20 (11.64 vs 12.96⁵ per 10,000 donations). There has been no significant change in the rate of vasovagal events associated with injury (0.65 vs 0.59 per 10,000 donations)

In 2020-21, there were 77 reports (0.47 per 10,000 donations) of vasovagal reactions occurring whilst driving, 42 apheresis and 35 whole blood donors. The rate of vasovagal events whilst driving (with and without loss of consciousness) was slightly up from 0.35 in 2019-20, but not statistically higher (p=0.10). Vasovagal events whilst driving have the potential for serious harm. There was one report of donor injury associated with a motor vehicle accident. The donor made a full recovery.

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.

3.4 Outside medical care

Outside medical care is an event that requires care from an external health professional including hospital, General Practitioner and/or ambulance. In 2020-21, the overall rate for events requiring outside medical care was 6.67 per 10,000 (Table 3); not significantly different from the previous year (7.03 per 10,000)⁶. Vasovagal reactions are the most common event associated with the requirement for outside medical care.

⁴ This does not include adjustment for experience within the returned cohort itself

⁵ Rate updated from 13.61 in previous report due to error

⁶ Outside medical care included "other health care" attendances for the first time in 2020-21. The 2019-20 comparison rate has been updated to include this category.

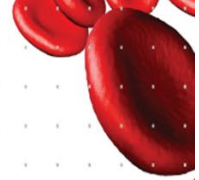


Table 3: Rates per 10,000 donations for all 2020-21 adverse events requiring outside medical care

	GP attendance*	Ambulance attendance^	Hospital attendance*	Other health care	Total
Whole Blood	3.45	0.77	2.93	0.04	7.18
Plasmapheresis	3.27	0.50	2.38	0.10	6.25
Plateletpheresis	4.50	1.13	1.13	0.00	6.75
Total	3.37	0.63	2.60	0.07	6.67

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

4. Conclusion

In 2020-21, there were more than 1.6 million donations. Of the 873,448 plasmapheresis donations, almost all were collected on the new plasma machines. Approximately 4.28% of donations were associated with at least one donor adverse event, although the vast majority were minor and resolved quickly, with only 0.07% of donations associated with an event requiring outside medical care. Considering all donations where an adverse event of any severity was reported; vasovagal events were reported in 34.7%, haematomas in 30.9% and citrate reactions in 18.6%.

There have been a number of rate improvements over the 2020-21 year including reduction in vasovagal rates across all donation types and reduction in haematoma and painful arm rates associated with the new plasma platform. The overall rate increase in plasmapheresis reflects the fully realised impact of the new machine, rather than a further increase in rates. Lifeblood has implemented a bundle of initiatives in the last 18 months which are considered to have contributed positively to improving safety for donors, both with respect to vasovagal and phlebotomy-related events.

Lifeblood's donor vigilance reporting system provides a transparent, sensitive and real-time approach to monitoring donor adverse events in the donor setting. The sensitive adverse event surveillance system supports our continuous improvement approach and together with staff, process and technology development and international consultation, Lifeblood strives to ensure that donating blood remains as safe as possible.

APPENDIX

Description of donor adverse events

Vasovagal reaction	This refers to feeling faint or fainting. Symptoms include dizziness, light-headedness and nausea. In some cases, the donor may faint (lose consciousness). These symptoms may be triggered by anxiety or pain and/or occur as a result of the reduction in blood volume. In many cases when donors feel faint or faint, there are multiple contributing factors.
Phlebotomy (needle)-related:	
Arterial puncture	Piercing of an artery with the donation needle. This may cause severe bruising because arterial blood is under high pressure
Cellulitis	Infection of the skin in the area of the needle insertion due to inadequate cleaning/sterilisation of the skin prior to needle insertion
Delayed bleeding	Bleeding from the needle site after leaving the donor centre
Haematoma	Bruising which may result from incorrect placement or dislodgment of the needle from the vein but may also occur as a normal side effect of removing the needle from the vein.
Nerve injury/irritation	Irritation or damage to a nerve. In most instances the report is consistent with nerve irritation which resolves quickly once the needle is removed.
Painful arm	A report of pain that is not otherwise associated with a diagnosis such as a haematoma or nerve injury.
Thrombophlebitis	Clot formation in the vein with surrounding inflammation
Other	
Anaphylaxis	More severe allergic reaction that includes symptoms such as wheeze, shortness of breath, rash, facial swelling.
Chest pain	Chest pain can occur in relation to a donation event or anxiety but is frequently non-donation related
Local allergic reaction	Local signs and symptoms such as redness, swelling and itch around the needle insertion site in response to products used in the donation process such as disinfectant wipes and tubing.
Apheresis specific events	
Citrate reaction	The anticoagulant solution contains citrate which binds calcium, temporarily reducing calcium levels in the blood. This can cause symptoms such as tingling around the mouth, a metallic taste in the mouth or altered sensation of hands and feet. In most cases symptoms are resolved with simple measures such as reducing the return flow rate, warming with blankets and calcium supplements. A severe reaction to citrate may cause generalised muscle contractions or spasms, seizures, palpitations (disturbance of heart rhythm), loss of consciousness, cardiac or respiratory arrest.
Infiltration	Leakage of blood and/or saline solution into the tissues may occur during a return cycle if the needle has moved partly or entirely out of the vein. This may cause swelling, pain, nerve irritation and/or bruising. Extensive swelling may compromise the blood flow.
Haemolysis	Damage to red cells may occur from a kink in the tubing or incorrect set up of the kit. If a significant amount of damaged red cells are returned, this may cause blood in the urine, fevers, back pain and short term kidney impairment.
Omitted anticoagulant	When the required dose of anticoagulant is not given to the donor. If there is insufficient mixing of blood with the anticoagulant solution, the blood may clot in the tubing. If clotted blood is returned it may cause symptoms associated with blocking of the blood vessels including dizziness, breathlessness, coughing, chest pain or limb swelling.

ANNEX

State/territory haemovigilance process improvement

In 2020-21, state/territory departments of health continue to improve their process for haemovigilance data collection and reporting.

NSW

Based on patient identity issues recognised in the 2019-20 report, a safety information bulletin was published in June 2021- Patient identity checks before administration of blood products safety (<https://www.health.nsw.gov.au/sabs/Documents/2021-si-006.pdf>). System improvements are expected to be seen in the 2021-22 reporting period.

VIC

From 1 July 2020, STIR started accepting reports of RhD isoimmunisations and hypotensive transfusion reactions. From 1 January 2021, questions were added to several forms (wrong blood in tube, IBCT, near miss and RhD incident), relating to how an electronic medical record may have contributed to or been involved in these types of incidents.

QLD

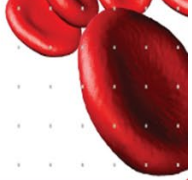
The strategies implemented across hospitals over the reporting period include blood management process improvement, haemovigilance and education activities such as:

- 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.
- Collaborating with Aboriginal and Torres Strait Islander communities to develop a 'yarning about blood'.
- Improving clinician access and decision-making with interfacing upgrades to the laboratory information system.
- Auditing compliance of the online blood management courses for nursing staff.
- Improving patient blood management of preoperative anaemia for telehealth surgical appointments.
- Removing the need for routine preoperative group and hold for primary hip and knee patients following a utilisation audit.
- Improving operating theatre blood storage processes assessed with an education quiz for anaesthetists and anaesthetic technicians.
- Reducing the risk of iatrogenic anaemia with changes to phlebotomy practice.
- Development of patient blood management medical education tools including short quiz for consultants and registrars and combined case study/quiz for new residents.
- Research activities including:
 - review of prothrombin complex concentrate use in cardiac surgery
 - identifying optimal haemoglobinHb optimisation targets prior to cardiac surgery
 - participating in the multicentre randomised control study in cryopreserved verses liquid platelet (CLIP2)

SA

There are currently several 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 NSQHS Standard 7 haemovigilance activities.
- The review of the Safety Learning System (SLS) to ensure it remains in line with the AHMDS 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 transfusion-related adverse events.

WA

The 2020-21 report from WA included a detailed analysis of the outcome severity rating associated with a transfusion-related adverse events. Despite patients experiencing symptomatic adverse reactions such as anaphylaxis requiring treatment with adrenaline, nebulisers, oxygen and/or additional intravenous fluids; some were assigned as no or minor morbidity. Education and awareness should reduce such occurrences.

2020-21 was the last year that hospitals were required to submit their data 6 monthly via an excel spreadsheet. As of 1 July 2021, hospitals can submit events via the REDCap online reporting tool as soon as all relevant information has been gathered. The online reporting tool also captures additional clinical data regarding the transfusion-related adverse events which will improve the quality of the data and help identify required changes.

TAS

Process improvements via internal adverse event reporting systems and governance.

NT

The occurrence of reported transfusion-related adverse events during the period of 2020 – 2021 has remained steady (5 x FNHTR and 1 x Allergic reaction) in comparison to the 2019 – 2020 data (2 x FNHTR, 1 x Allergic, 1 x TACO, and 1 x AHTR).

All of the reported transfusion-related adverse events 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.

ABBREVIATIONS

ABO	The human red cell ABO blood group system
ACT	Australian Capital Territory
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)

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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
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VIC Department of Health and Human Services Blood Matters Program
QLD Health
SA Health BloodSafe Program
WA Department of Health
TAS Department of Health and Human Services
ACT Health
NT Department of Health

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