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Australia

2021-22

AUSTRALIAN HAEMOVIGILANCE REPORT

Australian Haemovigilance Report, Data for 2021-22 published by the National Blood Authority.

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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 13th Australian Haemovigilance Report (2021-22). One hundred and twenty nine hospitals (96 public hospitals and 33 private hospitals) reported adverse events for 2021-22. 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 659 adverse events and 75 transfusion-related serious adverse events (SAE) to the national haemovigilance program in 2021-22.

A transfusion related serious adverse event 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 109 adverse events and 29 transfusion-related SAEs that represented 27% of their total reported adverse events, whereas New South Wales (NSW) reported 87 adverse events and 13 transfusion-related SAEs, representing 15% of the total adverse events reported.

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

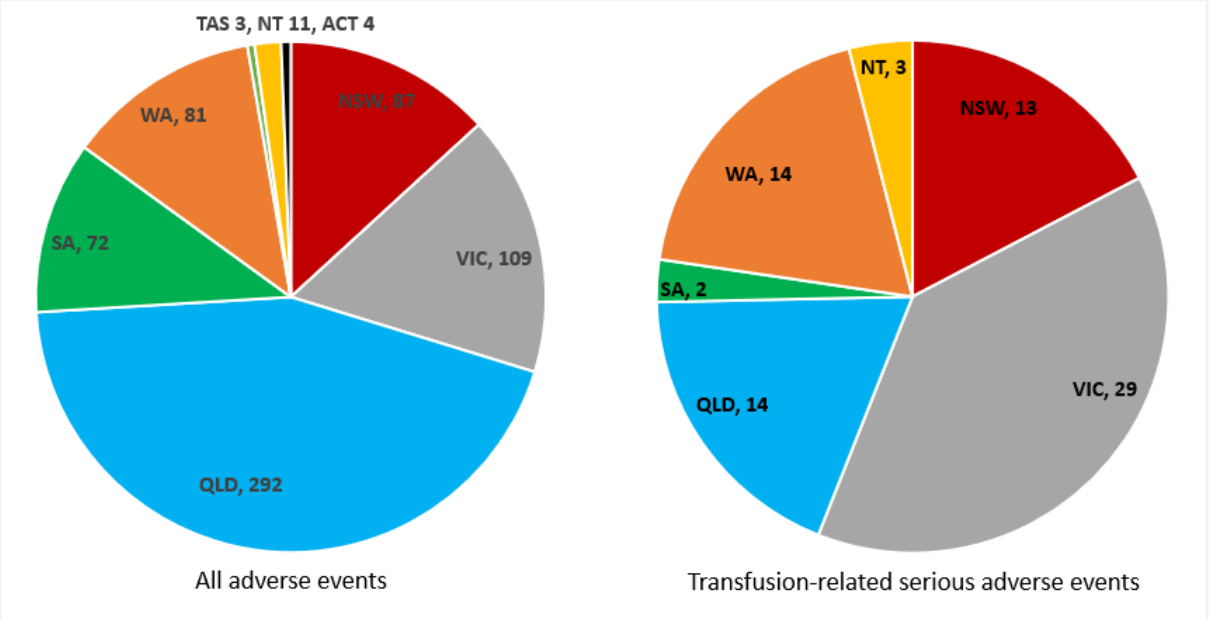

Figure 1: Number of transfusion-related serious adverse events and all adverse events by state and territory

The number of febrile non-haemolytic transfusion reaction (FNHTR) events was 38% of the total reported adverse events (251 of 659), but they were 12% of the total transfusion-related SAEs (9 of 75). Anaphylactic reactions represented 4% of the total reported adverse events (27 of 659), but were 21% of the total transfusion-related SAEs (16 of 75).

Figure 2 shows transfusion-related SAES by event.

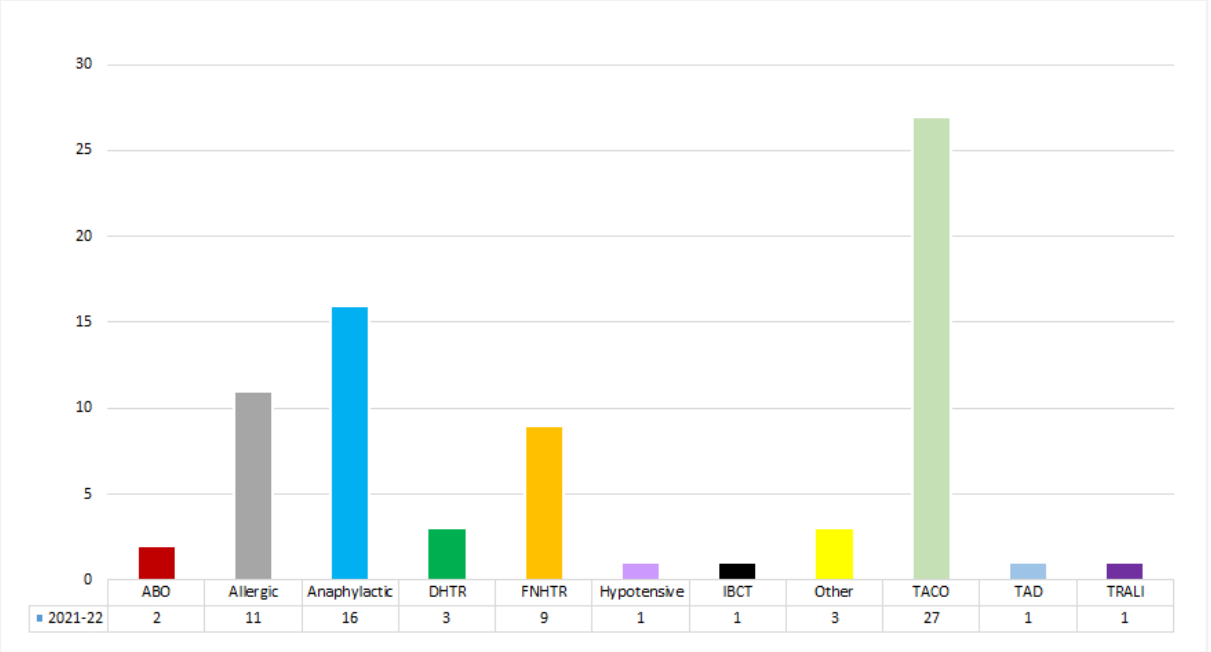

Figure 2: Number of transfusion-related serious adverse events

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 2.6, with Australian Capital Territory (ACT) and Tasmania (TAS) under 1 and Queensland (QLD) at 5.5.

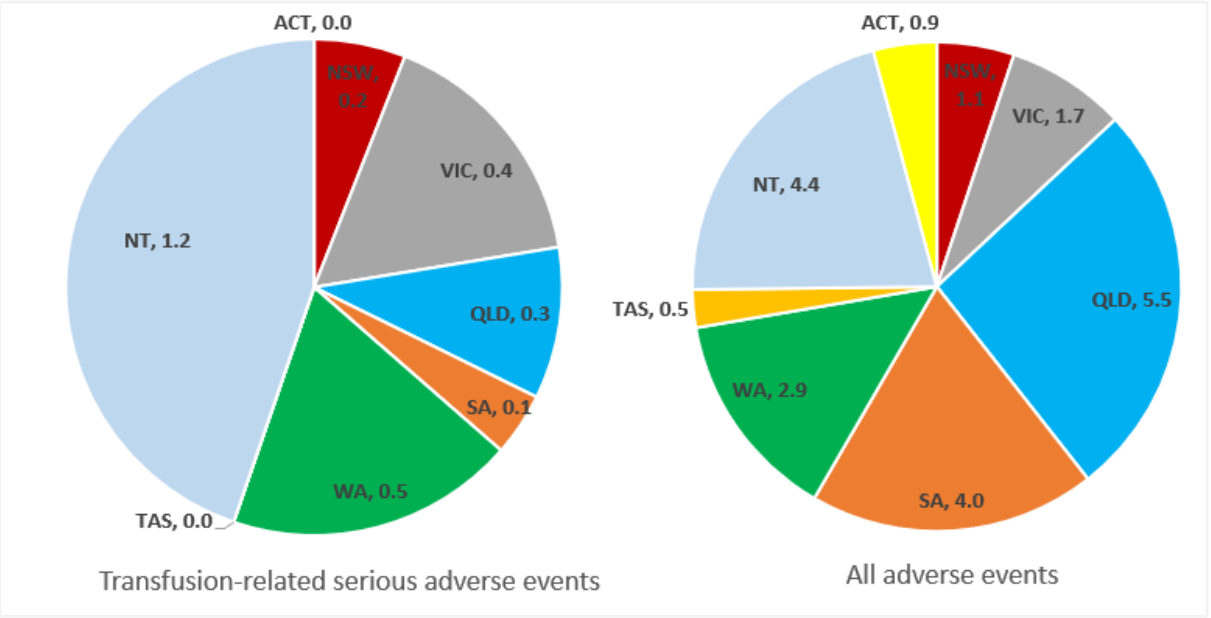

Figure 3: Rate per 100,000 populations for transfusion-related serious adverse events and all adverse events by state and territory

SECTION 1

Australian Haemovigilance Data

July 2021– June 2022

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 fourteen years.

- All states and territories except QLD reported the data in line with the NBA 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 2021-22 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.

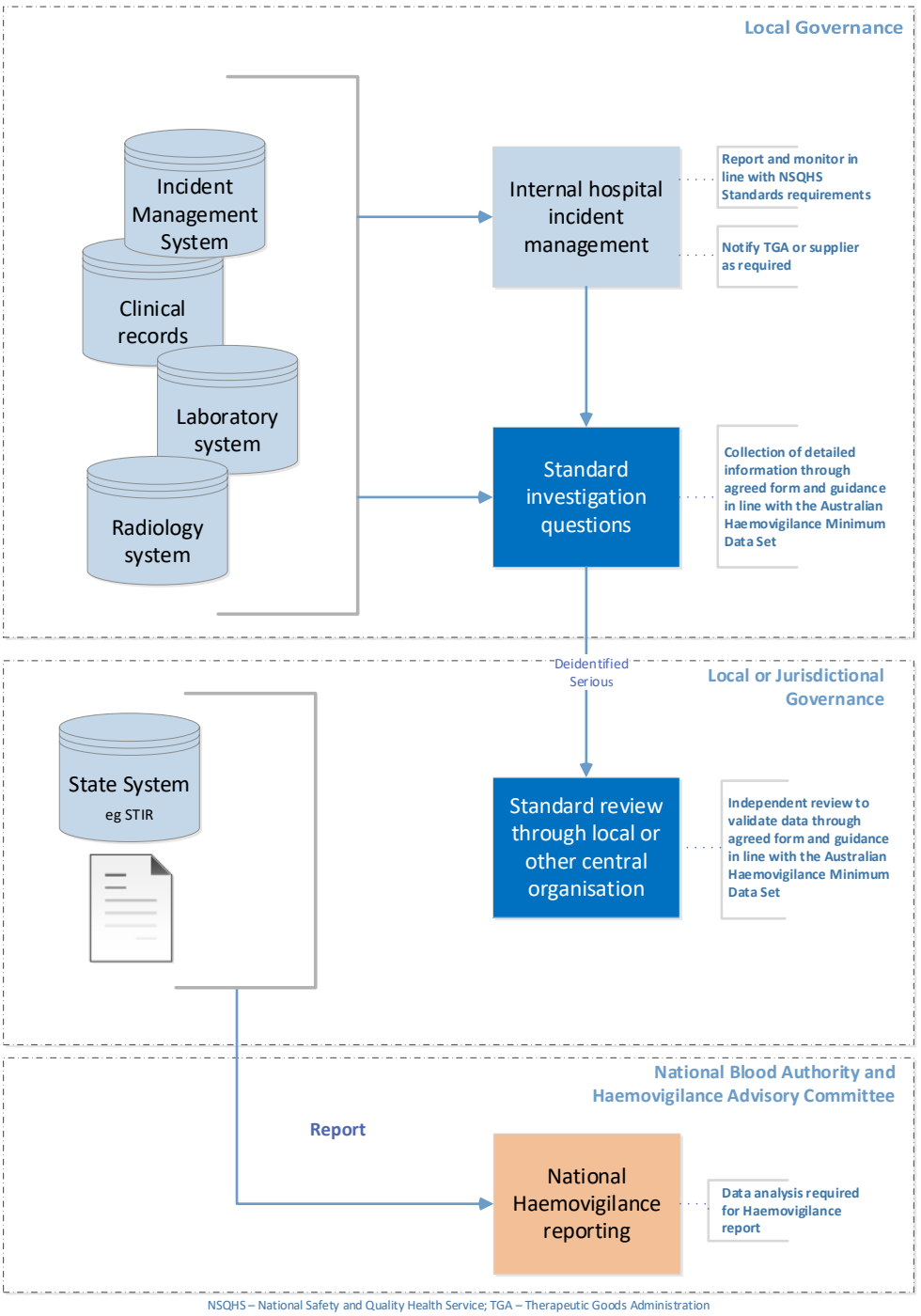

Figure 4: Reporting adverse events and haemovigilance in Australia

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

- NSW, VIC, QLD, South Australia (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 the 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.

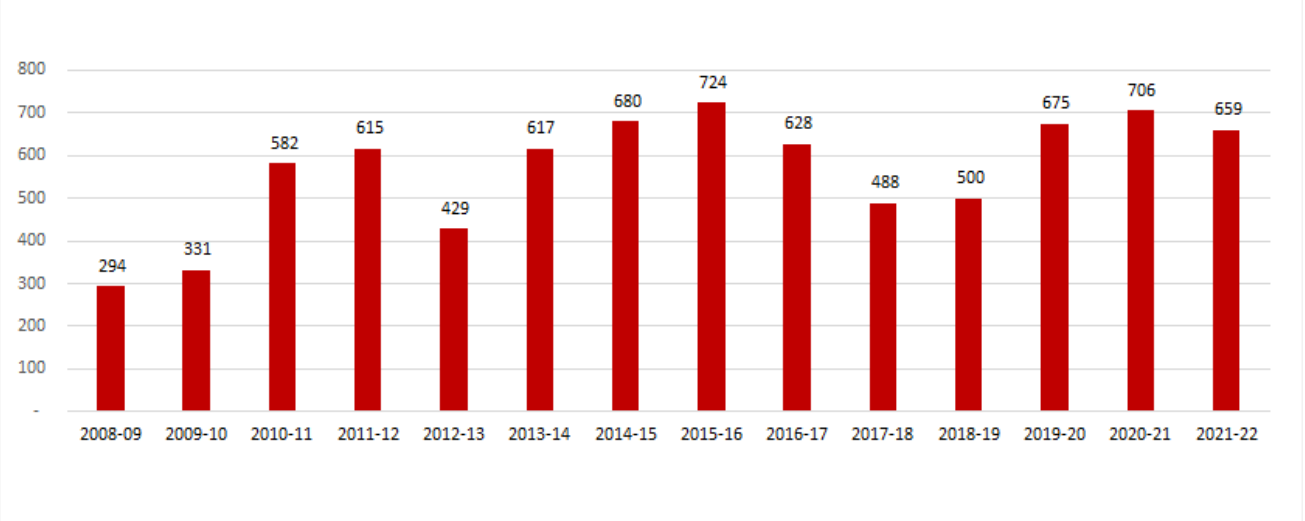

Figure 5: All reported adverse events, 2008-09 to 2021-22

The report presents the data and analysis for all adverse events for five years from 2017-18 to 2021-22, and for 2021-22 only.

Results for all adverse events, 2017-18 to 2021-22

This section presents the data and key results for all adverse events from 2017-18 to 2021-22.

Table 1 shows that:

- five states and territories, VIC, WA, TAS, NT and ACT reported an increase in adverse events in 2021-22
- the adverse event rate per 100,000 population ranges from 0.53 for TAS to 5.55 for QLD in 2021-22

Table 1: All adverse events by state, 2017-18 to 2021-22

	2017-18	2018-19	2019-20	2020-21	2021-22	2021-22		
						Percent	Rate per 100,000 population	% change from 2020-21
NSW	61	72	112	152	87	13.2%	1.07	-42.8%
VIC	57	58	95	97	109	16.5%	1.66	12.4%
QLD	202	233	299	297	292	44.3%	5.55	-1.7%
SA	61	52	69	78	72	10.9%	3.99	-7.7%
WA	85	68	83	73	81	12.3%	2.93	11.0%
TAS	11	0	6	2	3	0.5%	0.53	50.0%
NT	2	12	5	6	11	1.7%	4.41	83.3%
ACT	9	5	6	1	4	0.6%	0.88	300.0%
Total	**488**	**500**	**675**	**706**	**659**	**100%**	**2.56**	**-6.7%**

Notes

1. **The population data is from the ABS 3101.0 - Australian Demographic Statistics, Dec 2021**
2. **The use of different haemovigilance reporting processes across the jurisdictions may lead to data inconsistencies.**

Table 2 shows that:

- the most common adverse events reported are FNHTR and Allergic and total 61% of the total reported adverse events in 2021-22
- 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, 2017-18 to 2021-22

	2017-18	2018-19	2019-20	2020-21	2021-22	2021-22			Incidence* (unless specified)
						Percent	Rate per 100,000 population	% of change from 2020-21	
ABO	2	1	1	0	2	0.3%	0.01	-	1:40,000
AHTR	8	15	24	16	1	0.2%	0.00	-93.8%	1:76,000
Allergic	107	179	241	176	151	22.9%	0.59	-14.2%	1–3% of transfusion of plasma containing components
Anaphylactic	20	29	24	25	27	4.1%	0.10	8.0%	Not available
DHTR	19	15	18	20	22	3.3%	0.09	10.0%	1:2,500–11,000 or 1:71,667
DSTR	10	16	25	32	33	5.0%	0.13	3.1%	Not available
FNHTR	210	169	222	303	251	38.1%	0.97	-17.2%	0.1–1% of transfusions with universal leucocyte depletion
Hypotensive	6	4	3	7	6	0.9%	0.02	-14.3%	Not available
IBCT	23	11	31	34	40	6.1%	0.16	17.6%	1:20,000–50,000 transfusions
Other	12	7	5	5	18	2.7%	0.07	260.0%	Not available
PTP	1	1	0	1	0	0.0%	-	-100.0%	Rare
TACO	52	42	60	69	87	13.2%	0.34	26.1%	Approximately 1% of transfused patients
TAD	0	7	7	11	9	1.4%	0.03	-18.2%	Not available
TRALI	3	1	2	1	3	0.5%	0.01	200.0%	1:1,200–1:190,000 transfusions
TTI	15	3	12	6	9	1.4%	0.03	50.0%	1:100,000 platelet transfusions
									1:500,000 red cell transfusions
Total	**488**	**500**	**675**	**706**	**659**	**100%**	**2.56**	**-6.7%**	

Notes

1. **The population data is from the ABS 3101.0 - Australian Demographic Statistics, Dec 2021**
2. ***Australian Red Cross Lifeblood (2020), Blood Component Information: An extension of blood component labels**

Table 3 shows that 86.6% events were reported by public hospitals. There was a decrease of reporting from both public and private hospitals in 2021-22. For more information, refer to the **Hospital participation in haemovigilance reporting** section.

Table 3: All adverse events by hospital type, 2017-18 to 2021-22

	2017-18	2018-19	2019-20	2020-21	2021-22	2021-22		
						Percent	Rate per 100,000 population	% change from 2020-21
Public hospital	454	429	617	615	571	86.6%	2.22	-7.2%
Private hospitals	34	71	58	91	88	13.4%	0.34	-3.3%
Total hospitals	**488**	**500**	**675**	**706**	**659**	**100%**	**2.57**	**-6.7%**

Note: The population data is from the ABS 3101.0 - Australian Demographic Statistics, Dec 2021

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 'Administration of product' doubled in 2021-22 from 2020-21.

Table 4: Contributory factors for all adverse events, 2017-18 to 2021-22

Summary Data	2017-18	2018-19	2019-20	2020-21	2021-22	% change from 2020-21
None identified	171	245	330	346	179	-48.3%
Product characteristic	193	182	174	161	187	16.1%
Transfusion in emergency setting	13	19	24	16	28	75.0%
Deliberate clinical decision	29	40	46	57	110	93.0%
Prescribing/ordering	12	5	5	18	18	0.0%
Specimen collection/labelling	1	3	2	4	1	-75.0%
Laboratory (testing/dispensing)	13	9	16	18	30	66.7%
Transport, storage, handling	1	1	1	2	2	0.0%
Administration of product	42	10	64	60	121	101.7%
Indications do not meet guidelines	8	5	6	13	18	38.5%
Procedure did not adhere to hospital transfusion guidelines	19	9	7	22	44	100.0%
Other	53	48	81	99	181	82.8%

Results for all adverse events, 2021-22

This section presents the data and key results for all reported adverse events for 2021-22.

Table 5 shows that the percentages of red blood cell (RBC) issued from the 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%) when compared with the population percentage and RBC issue percentage. This is due to reported FNHTRs events at 174. The use of different haemovigilance reporting processes across the jurisdictions may lead to these data inconsistencies.

Table 5: All adverse events by state, 2021-22

	ABO	AHTR	Allergic	Anaphylactic	DHTR	DSTR	FNHTR	Hypotensive	IBCT	Other	TACO	TAD	TRALI	TTI	All reports		Population	Red blood cell issues
															Total	Percent	Percent	Percent
NSW	0	0	27	8	2	0	22	3	17	0	3	5	0	0	87	13.2%	31.4%	31.2%
VIC	1	0	10	7	6	20	24	1	10	3	27	0	0	0	109	16.5%	25.5%	26.9%
QLD	1	0	53	10	12	0	174	0	1	0	30	0	2	9	292	44.3%	20.4%	20.7%
SA	0	0	31	0	1	0	4	0	9	12	14	1	0	0	72	10.9%	7.0%	8.2%
WA	0	0	28	1	1	13	20	2	1	2	10	2	1	0	81	12.3%	10.7%	8.7%
TAS	0	0	0	0	0	0	3	0	0	0	0	0	0	0	3	0.5%	2.2%	2.0%
NT	0	1	2	1	0	0	2	0	2	1	2	0	0	0	11	1.7%	1.0%	0.7%
ACT	0	0	0	0	0	0	2	0	0	0	1	1	0	0	4	0.6%	1.8%	1.5%
Total	**2**	**1**	**151**	**27**	**22**	**33**	**251**	**6**	**40**	**18**	**87**	**9**	**3**	**9**	**659**	**100%**	**100%**	**100%**

Note: The population data is from the ABS 3101.0 - Australian Demographic Statistics, Dec 2021

Table 6 shows that 82% (539) of reported adverse events (imputability=possible, likely, and definite) are related to blood transfusion in 2021-22.

Table 6: All adverse events by imputability score, 2021-22

Adverse event	Excluded	Unlikely	Possible	Probable (likely)	Definite (certain)	Not assessable	Total	Percent
ABO	0	0	0	0	2	0	2	0.3%
AHTR	0	0	0	0	1	0	1	0.2%
Allergic	4	9	35	80	21	2	151	22.9%
Anaphylactic	1	0	2	17	6	1	27	4.1%
DHTR	0	0	5	5	11	1	22	3.3%
DSTR	0	0	0	9	24	0	33	5.0%
FNHTR	12	58	126	50	2	3	251	38.1%
Hypotensive	0	1	3	1	1	0	6	0.9%
IBCT	1	0	2	2	26	9	40	6.1%
Other	0	0	14	2	1	1	18	2.7%
TACO	1	2	28	43	9	4	87	13.2%
TAD	0	0	4	3	1	1	9	1.4%
TRALI	0	0	2	1	0	0	3	0.5%
TTI	3	1	0	2	0	3	9	1.4%
Total	**22**	**71**	**221**	**215**	**105**	**25**	**659**	
Percent	**3.3%**	**10.8%**	**33.5%**	**32.6%**	**15.9%**	**3.8%**	**100.0%**	

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

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

- three reported deaths with one TACO death possibly related to transfusion
- life-threatening and severe morbidity events accounted for 12% of total reports
- 62% of reported adverse events related to minor morbidities.

Table 7: All adverse events by clinical outcome severity, 2021-22

Adverse event	Death	Life-threatening	Severe morbidity	Minor morbidity	No morbidity	Outcome not available	Total
ABO	0	0	2	0	0	0	2
AHTR	0	0	0	1	0	0	1
Allergic	0	3	10	117	18	3	151
Anaphylactic	0	11	5	8	3	0	27
DHTR	0	0	3	11	7	1	22
DSTR	0	0	0	3	30	0	33
FNHTR	1	2	11	193	39	5	251
Hypotensive	0	0	2	3	1	0	6
IBCT	0	0	1	4	27	8	40
Other	1	1	2	6	8	0	18
TACO	1	9	17	53	5	2	87
TAD	0	1	1	7	0	0	9
TRALI	0	0	1	2	0	0	3
TTI	0	0	0	1	8	0	9
Total	**3**	**27**	**55**	**409**	**146**	**19**	**659**
Percent	**0.5%**	**4.1%**	**8.3%**	**62.1%**	**22.2%**	**2.9%**	**100%**

Table 8 shows a breakdown of all adverse events by imputability score and outcome for 2021-22. 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, 2021-22

Adverse event	Death	Life-threatening	Severe morbidity	Minor morbidity	No morbidity	Outcome not available	Total
Excluded or unlikely	**1**	**0**	**7**	**65**	**18**	**2**	**93**
Allergic	0	0	2	9	2	0	**13**
Anaphylactic	0	0	0	0	1	0	**1**
FNHTR	1	0	4	54	9	2	**70**
Hypotensive	0	0	1	0	0	0	**1**
IBCT	0	0	0	0	1	0	**1**
TACO	0	0	0	2	1	0	**3**
TTI	0	0	0	0	4	0	**4**
Possible	**1**	**6**	**11**	**161**	**38**	**4**	**221**
Allergic	0	1	1	23	8	2	**35**
Anaphylactic	0	1	0	1	0	0	**2**
DHTR	0	0	1	4	0	0	**5**
FNHTR	0	1	5	100	18	2	**126**
Hypotensive	0	0	0	2	1	0	**3**
IBCT	0	0	0	2	0	0	**2**
Other	0	0	1	5	8	0	**14**
TACO	1	3	3	18	3	0	**28**
TAD	0	0	0	4	0	0	**4**
TRALI	0	0	0	2	0	0	**2**
Probable (likely)	**0**	**12**	**24**	**149**	**28**	**2**	**215**
Allergic	0	2	5	65	8	0	**80**
Anaphylactic	0	4	5	7	1	0	**17**
DHTR	0	0	1	2	1	1	**5**
DSTR	0	0	0	2	7	0	**9**
FNHTR	0	1	2	38	8	1	**50**
Hypotensive	0	0	1	0	0	0	**1**
IBCT	0	0	0	0	2	0	**2**
Other	0	0	1	1	0	0	**2**
TACO	0	5	7	31	0	0	**43**
TAD	0	0	1	2	0	0	**3**
TRALI	0	0	1	0	0	0	**1**
TTI	0	0	0	1	1	0	**2**
Definite (certain)	**0**	**8**	**13**	**32**	**50**	**2**	**105**
ABO	0	0	2	0	0	0	**2**
AHTR	0	0	0	1	0	0	**1**
Allergic	0	0	2	19	0	0	**21**
Anaphylactic	0	6	0	0	0	0	**6**
DHTR	0	0	1	5	5	0	**11**
DSTR	0	0	0	1	23	0	**24**
FNHTR	0	0	0	1	1	0	**2**
Hypotensive	0	0	0	1	0	0	**1**
IBCT	0	0	1	2	21	2	**26**
Other	0	1	0	0	0	0	**1**
TACO	0	1	7	1	0	0	**9**
TAD	0	0	0	1	0	0	**1**
Not assessable	**1**	**1**	**0**	**2**	**12**	**9**	**25**
Allergic	0	0	0	1	0	1	**2**
Anaphylactic	0	0	0	0	1	0	**1**
DHTR	0	0	0	0	1	0	**1**
FNHTR	0	0	0	0	3	0	**3**
IBCT	0	0	0	0	3	6	**9**
Other	1	0	0	0	0	0	**1**
TACO	0	0	0	1	1	2	**4**
TAD	0	1	0	0	0	0	**1**
TTI	0	0	0	0	3	0	**3**
Total	**3**	**27**	**55**	**409**	**146**	**19**	**659**

Table 9 highlights that 71% 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 2021-22, followed by platelets (13%) and fresh frozen plasma (8%).

Table 9: All adverse events by blood product, 2021-22

Adverse event	Red cells	Platelets	Fresh frozen plasma	Cryoprecipitate	Cryo-depleted Plasma	Multiple products	Total
ABO	2	0	0	0	0	0	2
AHTR	1	0	0	0	0	0	1
Allergic	51	73	18	4	1	4	151
Anaphylactic	9	9	8	1	0	0	27
DHTR	22	0	0	0	0	0	22
DSTR	31	2	0	0	0	0	33
FNHTR	212	36	3	0	0	0	251
Hypotensive	3	3	0	0	0	0	6
IBCT	33	3	1	2	0	1	40
Other	18	0	0	0	0	0	18
TACO	77	8	1	0	0	1	87
TAD	6	3	0	0	0	0	9
TRALI	1	1	0	0	0	1	3
TTI	2	6	0	1	0	0	9
Total	**468**	**144**	**31**	**8**	**1**	**7**	**659**
Percent	**71.0%**	**21.9%**	**4.7%**	**1.2%**	**0.2%**	**1.1%**	**100%**

Table 10 shows that 0.6% (4) more adverse events were reported for females than males, and 10 more reports for IBCT were female.

Table 10: All adverse events by sex, 2021-22

Adverse event	Male	Female	Not reported	Total
ABO	2	0	0	2
AHTR	0	1	0	1
Allergic	79	71	1	151
Anaphylactic	11	16	0	27
DHTR	8	14	0	22
DSTR	13	20	0	33
FNHTR	124	127	0	251
Hypotensive	3	3	0	6
IBCT	13	23	4	40
Other	11	7	0	18
TACO	48	37	2	87
TAD	4	5	0	9
TRALI	3	0	0	3
TTI	5	4	0	9
Total	**324**	**328**	**7**	**659**
Percent	**49.2%**	**49.8%**	**1.1%**	**100%**

Table 11 shows more adverse events reported for females than males except the 5-14, 45-54 and 65-74 age groups.

Table 11: All adverse events by age and sex, 2021-22

Adverse event	Male	Female	Not reported	Total
0–4 years	7	9	0	16
5–14 years	13	6	0	19
15–24 years	15	17	0	32
25–34 years	21	22	1	44
35–44 years	19	38	0	57
45–54 years	34	29	0	63
55–64 years	52	53	3	108
65–74 years	86	63	0	149
75 years or older	77	91	3	171
Total	**324**	**328**	**7**	**659**
Percent	**49.2%**	**49.8%**	**1.1%**	**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, 2021-22

	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
ABO	2	0	0	0	0	2	0	0	0	0	0	0	0	0	2	2
AHTR	0	0	0	0	0	0	0	0	1	0	1	0	0	0	1	1
Allergic	84	9	17	0	0	110	20	0	5	0	25	1	0	1	136	151
Anaphylactic	14	0	3	0	0	17	4	0	0	0	4	4	0	4	25	27
DHTR	7	1	3	0	0	11	4	0	1	0	5	0	0	0	16	22
DSTR	16	1	0	0	0	17	11	1	0	0	12	0	0	0	29	33
FNHTR	100	17	42	0	1	160	26	1	7	0	34	1	0	1	195	251
Hypotensive	3	0	0	0	0	3	1	0	0	0	1	1	0	1	5	6
IBCT	17	0	0	1	0	18	4	0	0	1	5	1	3	4	27	40
Other	8	1	0	0	0	9	2	0	0	0	2	0	0	0	11	18
TACO	33	5	4	0	0	42	21	1	4	0	26	2	0	2	70	87
TAD	5	0	0	0	0	5	2	0	0	0	2	0	0	0	7	9
TRALI	1	0	0	0	0	1	1	0	1	0	2	0	0	0	3	3
TTI	5	0	4	0	0	9	0	0	0	0	0	0	0	0	9	9
Total	**295**	**34**	**73**	**1**	**1**	**404**	**96**	**3**	**19**	**1**	**119**	**10**	**3**	**13**	**536**	**659**

Table 13: All adverse events by time and weekend and remoteness area, 2021-22

	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
ABO	0	0	0	0	0	0	0	0	0	0	0	0	2
AHTR	0	0	0	0	0	0	0	0	0	0	0	0	1
Allergic	7	0	2	0	9	4	0	1	5	1	1	15	151
Anaphylactic	2	0	0	0	2	0	0	0	0	0	0	2	27
DHTR	2	0	1	0	3	3	0	0	3	0	0	6	22
DSTR	1	0	0	0	1	3	0	0	3	0	0	4	33
FNHTR	23	3	13	1	40	9	4	2	15	1	1	56	251
Hypotensive	1	0	0	0	1	0	0	0	0	0	0	1	6
IBCT	4	1	0	0	5	5	0	0	5	3	3	13	40
Other	3	0	1	0	4	2	0	0	2	1	1	7	18
TACO	8	0	1	0	9	7	0	1	8	0	0	17	87
TAD	1	1	0	0	2	0	0	0	0	0	0	2	9
TRALI	0	0	0	0	0	0	0	0	0	0	0	0	3
TTI	0	0	0	0	0	0	0	0	0	0	0	0	9
Total	**52**	**5**	**18**	**1**	**76**	**33**	**4**	**4**	**41**	**6**	**6**	**123**	**659**

Table 14 shows a breakdown of reported contributory factors by adverse event and outcome severity for 2021-22.

- 'Product characteristic' was reported to be associated 14 out of 27 of 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
- 37% (10 out of 27) of life-threatening cases had no identified contributory factors
- 25% (14 out of 55) of severity morbidity cases had no identified contributory factors
- 19% (179 out of 919) of contributory factors were not identified.

Table 14: Contributory factors by adverse event and by clinical outcome severity, 2021-22

Contributory Factors	Adverse event														Clinical outcome severity					
	ABO	AHTR	Allergic	Anaphylactic	DHTR	DSTR	FNHTR	Hypotensive	IBCT	Other	TACO	TAD	TRALI	TTI	Outcome not available	No morbidity	Minor morbidity	Severe morbidity	Life-threatening	Death
None identified	0	1	45	6	7	15	65	0	0	3	26	2	0	9	4	52	99	14	10	0
Product characteristic	0	0	58	11	5	16	61	4	4	1	16	5	1	5	7	47	101	17	14	1
Transfusion in emergency setting	0	0	5	0	3	2	2	0	12	1	3	0	0	0	2	12	10	3	0	1
Deliberate clinical decision	0	0	33	8	1	2	29	4	16	0	11	5	1	0	7	30	54	16	2	1
Prescribing/ordering	0	0	0	0	0	0	0	0	12	0	6	0	0	0	3	9	4	2	0	0
Specimen collection/labelling	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0	1	0	0	0	0
Laboratory (testing/dispensing)	0	1	1	0	0	0	0	0	27	0	0	0	0	1	7	17	5	1	0	0
Transport, storage, handling	0	0	0	0	0	0	1	0	1	0	0	0	0	0	0	1	1	0	0	0
Administration of product	1	0	30	6	5	0	43	0	13	2	15	0	1	5	3	19	88	8	2	1
Indications do not meet guidelines	0	0	2	1	0	1	2	0	8	0	4	0	0	0	1	7	7	0	3	0
Procedure did not adhere to hospital transfusion guidelines	2	0	2	0	0	0	12	0	23	1	4	0	0	0	2	21	17	4	0	0
Other	1	0	28	6	4	0	93	2	10	5	26	1	3	2	4	22	135	17	3	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 2021-22. Participating Hospital is a hospital that participates in State or Territory Haemovigilance Reporting that reports zero or more adverse events. Reporting Hospital is a participating hospital that reports one or more adverse events.

- 526 hospitals participated in national haemovigilance reporting, including 424 public hospitals and 102 private hospitals
- 25% (129) participating hospitals reported adverse events, including 96 public hospitals and 33 private hospitals
- only three states (VIC, QLD and WA) reported adverse events for private hospitals, QLD had the highest number of reporting and participating hospitals for private hospitals
- private hospitals from NSW and SA did not participate in national haemovigilance reporting.

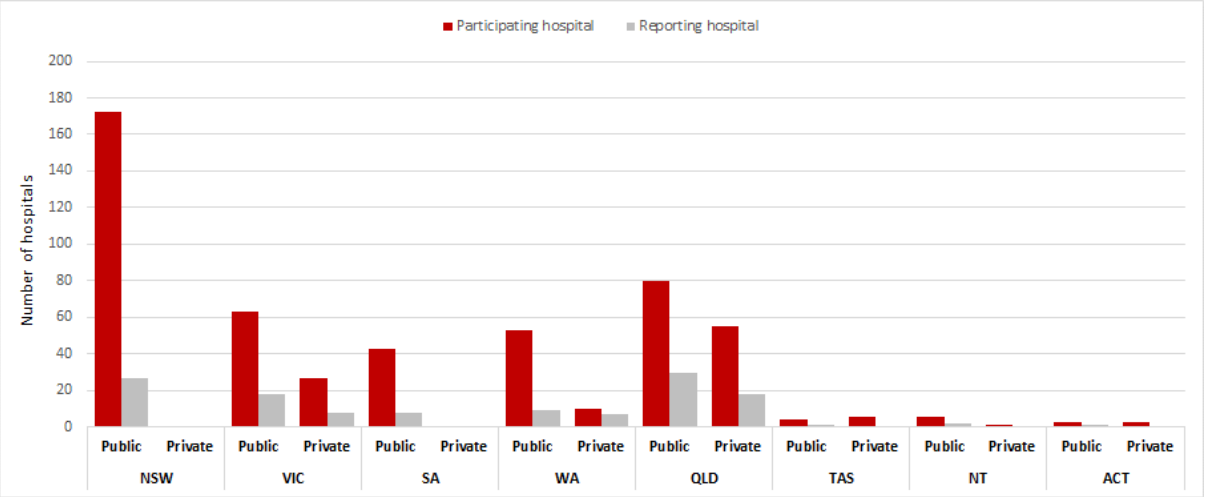

Figure 6: Number of participating and reporting hospitals by public/private and state/territory, 2021-22

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

Table 15: Number of participating and reporting hospitals by public/private and state/territory, 2021-22

		NSW	VIC	QLD	SA	WA	TAS	NT	ACT	Total
Participating hospitals	Public	172	63	80	43	53	4	6	3	424
	Private	0	27	55	0	10	5	1	3	101
Reporting hospitals	Public	27	18	30	8	9	1	2	1	96
	Private	0	8	18	0	7	0	0	0	33

Nationally, 5.1 adverse events per hospital were reported for 2021-22. This varied between states and territories, ranging from 3.0 in TAS to 9.0 in SA in **Table 16.**

Table 16: Number of adverse events per hospital by state/territory, 2021-22

	NSW	VIC	QLD	SA	WA	TAS	NT	ACT	Total
Number of reporting hospitals	**27**	**26**	**48**	**8**	**16**	**1**	**2**	**1**	**129**
Number of adverse events	**87**	**109**	**292**	**72**	**81**	**3**	**11**	**4**	**659**
Adverse events per hospital	**3.2**	**4.2**	**6.1**	**9.0**	**5.1**	**3.0**	**5.5**	**4.0**	**5.1**

Recommendations

This report restates the five recommendations made in the 2020-21 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.

The National Blood Research and Development Strategic Priorities 2022-27 highlights the need for research in haemovigilance and in particular “Priority 3: Reduce donor and patient adverse events”.

Description of adverse events from 2015 AHMDS

Adverse Event	Definition – Where possible this is the ISBT Definition
ABO incompatibility (ABO)	All cases where a blood component was transfused which was (unintentionally) ABO incompatible. Include all such events • even if only a small quantity of blood was transfused, and/or • if no adverse reaction occurred All cases are to be included, whether the first error occurred in the blood establishment, in the blood transfusion laboratory or in clinical areas. Note that these are a subgroup of the IBCT category. 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.
Acute haemolytic transfusion reaction (other than ABO incompatibility) (AHTR)	An AHTR has its onset within 24 hours of a transfusion. Clinical or laboratory features of haemolysis are present. 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. Common laboratory features are hemoglobinaemia, haemoglobinuria, decreased serum haptoglobin, unconjugated hyperbilirubinaemia, increased LDH and AST levels and decreased haemoglobin levels. Not all clinical or laboratory features are present in case of AHTR.
Allergic reaction (Allergic)	An allergic reaction may present only with mucocutaneous signs and symptoms during or within 4 hours of transfusion: • morbilliform rash with itching • urticaria • localised angioedema • oedema of lips, tongue and uvula • periorbital pruritus, erythema and oedema • conjunctival oedema This type of allergic reaction is called 'minor allergic reaction' in some haemovigilance systems.
Anaphylactoid or anaphylactic reaction (Anaphylactic)	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 pulmonary (dyspnoea, 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

Adverse Event	Definition – Where possible this is the ISBT Definition
	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)	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: • fever (≥38°C oral or equivalent and a change of ≥1°C from pre-transfusion value) • chills • rigors This may be accompanied by headache and nausea. FNHTR could be present in absence of fever (if chills or rigors without fever). 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: • fever (≥39°C oral or equivalent and a change of ≥2°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)	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 • the component was ABO compatible and/or • only a small quantity of blood was transfused and/or • there was no adverse reaction
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: • acute respiratory distress • tachycardia • increased blood pressure

Adverse Event	Definition – Where possible this is the ISBT Definition
	• 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: • 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:
	• Acute onset
	• Hypoxemia
	  ○ $Pa0_2$ / $Fi0_2$ < 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)
	• No temporal relationship to an alternative risk factor for ALI, during or within 6 hours of completion of transfusion.
	
	Alternate risk factors for ALI are:
	• Direct Lung Injury
	  ○ Aspiration
	  ○ Pneumonia
	  ○ Toxic inhalation
	  ○ Lung contusion
	  ○ Near drowning
	• Indirect lung injury
	  ○ Severe sepsis
	  ○ Shock
	  ○ Multiple trauma
	  ○ Burn injury
	  ○ Acute pancreatitis
	  ○ Cardiopulmonary bypass
	  ○ Drug overdose

Adverse Event	Definition – Where possible this is the ISBT Definition
	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. 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
Transfusion transmitted infection (TTI)	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. *Transfusion transmitted bacterial infection* Transfusion transmitted bacterial infection should be clinically suspected if: • fever >39°C or a change of >2°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 Possible transfusion transmitted bacterial infection: • detection of bacteria by approved techniques in the transfused blood component but not in the recipient's blood or • 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 • Confirmed transfusion transmitted bacterial infection: • detection of the same bacterial strain in the recipient's blood and in the transfused blood product by approved techniques *Transfusion transmitted viral infection* 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. *Transfusion transmitted parasitic infection* Detection of the same parasite in the recipient's blood and parasite or specific antibodies in the donor blood.

Australian Red Cross Lifeblood®

SECTION 2

Donor Safety Report

2021–22

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 2021-22 financial year. Events notified to Lifeblood by 31 July 2022 are included in the report.

More than 1.59 million donations were collected in 2021-22. Approximately 4.12% of donations were associated with at least one donor adverse event. This is a 3.94%[1] decrease from the previous year and is primarily accounted for by the decrease in rates for plasma-related haematoma and mild citrate events and to a lesser extent vasovagal reactions. Thesereductions have been offset to some degree by an increase in rates for plasma-related infiltration events which has resulted from staff education aimed at improving the identificationof these cases.

Vasovagal symptoms (feeling faint or fainting) are the most common adverse event. These events are more common in younger donors, females and less experienced donors. In 2021-22there was a reduction in unadjusted vasovagal rates in all donation types. The adjusted rate for whole blood, which considered gender, age and donation experience[2], was significantly higher than in 2020-21 (2.28% difference), whilst the adjusted plasma rate for 2021-22 remained significantly lower than 2020-21 (3.59% difference). Whilst these changes are statistically significant, the differences are small in absolute terms and likely represent the normal variation that is seen across different time periods. Notwithstanding this, Lifeblood endeavours to understand factors contributing to significant changes, even if small, to ensurethat negative trends are identified and managed early, and improvements are acknowledged to enable reinforcement of strategies that are providing a positive impact on donor safety andexperience.

A number of factors other than donor demographics and donation experience may influence vasovagal rates, and in 2021-22 there were a number of initiatives that may have contributed to the reduction in plasma-related vasovagal rate. This includes improved donor compliance in response to targeted messaging for pre-donation fluid intake and in-centre applied muscle tensing exercises, staff phlebotomy excellence training, the change to a smaller gauge needle and experience with the plasma machines introduced from May 2019. The observed increasein the whole blood-related vasovagal rate may relate to donor risk perception and change in compliance with mitigation strategies and less experienced staff who may be more likely to report very minor symptoms.

The rate for outside medical care reduced significantly from 6.67 per 10,000 in 2020-21 to 5.30per 10,000 donations in 2021-22. This was primarily the result of the significant reduction in vasovagal events requiring outside medical care, which may be due to more serious vasovagalevents being prevented.

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 minutes3 from when the needle is inserted. This 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 46 minutes4 and a plateletpheresis donation 77 minutes5. Since 2015-16, plateletpheresis donations have been predominantly collected from males as a risk mitigation strategy for transfusion-related acute

approach to ensure donation is as safe as possible. This report provides a summary of adverse event rates for 2021-22 with an overview of changes from the previous four years. Events reported by 31 July 2022 are included in the report.

The type and rates of adverse events differ between the donation types. For instance, the higher rate of phlebotomy (needle)-related events in apheresis compared with whole blood 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 (refer to Appendix 1 for a description of adverse events). 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 relates to 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. Donor characteristics such as gender, age and donation experience also impact adverse event rates, particularly vasovagal risk, and in some cases adjusting for variation of these factors is required for more valid comparisons between time periods.

3. Cohort

A donation is included if a donation needle was inserted regardless of whether the collection was completed. The cohort numbers for the last five financial years are provided in Table 1.

Table 1: Number of donations in the denominator cohort from 2017-18 to 2021-22

Donation Type	2017-18	2018-19	2019-20	2020-21	2021-22
Whole Blood	700,546	703,986	701,475	724,121	739,624
Plasmapheresis	646,488	745,666	822,903	873,448	831,148
Plateletpheresis	27,782	29,127	27,501	26,657	22,484
Total	1,374,816	1,478,779	1,551,879	1,624,226	1,593,256

[3] Based on minimum collection of 450 mL for males and females 2021/22

[4] Based on minimum collection of 422 mL for females and 488 for males (excluding anticoagulant) 2021/22

[5] Based on collection of double-dose platelet 2021/22

4. Donor adverse events

4.1 Overview

Approximately 4.12% of donations were associated with at least one donor adverse event. Total donor adverse event rates per 10,000 donations from 2017-18 to 2021-22 are provided in Table 2a. Rates for individual events are provided in Table 2b and 2c.

Table 2a: Total donor adverse event rates per 10,000 donations for 2017-18 to 2021-22

Donation	2017-18	2018-19	2019-20	2020-21	2021-22	Change from 2020-21
Whole Blood	299.05	297.09	321.76	296.35	313.49	+5.78%
Plasmapheresis	261.60	324.13	455.08	524.36	490.95	-6.37%
Plateletpheresis	976.17	1,047.14	990.15	869.94	700.05	-19.53%
Total	295.12	325.50	404.30	428.38	411.52	-3.94%

Table 2b: Unique donor adverse event rates per 10,000 donations for 2021-22

Event type	Whole Blood	Plasmapheresis	Plateletpheresis	Total
Vasovagal Events				
All vasovagal events	195.17	103.80	104.07	146.22
Loss of consciousness	17.17	6.32	8.90	11.39
Phlebotomy Related				
Arterial puncture	0.51	0.23	0.00	0.36
Cellulitis	0.04	0.01	0.00	0.03
Delayed bleeding	1.69	1.97	1.33	1.83
Haematoma	83.34	156.19	237.95	123.53
Nerve injury/irritation	11.92	17.53	10.67	14.83
Other injury	0.51	0.99	0.00	0.75
Painful arm^	28.54	68.60	42.70	49.64
Thrombophlebitis	0.31	0.45	0.00	0.38
Other Event Type				
Anaphylaxis	0.01	0.00	0.00	0.01
Chest pain	0.58	0.72	2.22	0.68
Local allergic reaction	1.19	2.20	0.44	1.71
Other event/injury	1.24	1.90	3.56	1.62

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

Table 2c: Apheresis-specific event rates per 10,000 donations for 2021-22

Event type	Plasmapheresis	Plateletpheresis	Total
Citrate reaction+	107.35	288.65	112.12
Haemolysis	0.66	0.00	0.64
Infiltration	74.28	67.60	74.11
Omitted anticoagulant	0.24	1.78	0.28

+ *Plasma includes 312 moderate and 6 severe cases; Platelets includes 36 moderate and 0 severe cases.*

4.2 Overview or major trends

4.2.1 Whole blood

The total whole blood rate increased by 5.78% and was primarily related to the increase in haematoma rates from 64.22 to 83.34 per 10,000. The rate of haematoma events requiring outside medical care and the rates of delayed bleeding did not increase, suggesting the increase was mainly minor events and that identification and appropriate management of haematoma events is occurring in centre.

The vasovagal rate was 195.17 per 10,000 in 2021-22, 2.66% lower than in 2020-21, but the 2021-22 adjusted rate for age, gender and donor experience was 205.08, 2.28% higher than in 2020-21. The increase may relate to donor risk perception and compliance with mitigation strategies. Noting that our surveillance system is able to detect very small changes, this may also represent a normal variation between time periods.

4.2.2 Plasmapheresis

The 6.37% reduction in the total plasmapheresis rate was largely an effect of the rate reductionin haematoma events, mild citrate reactions and vasovagal symptoms. To some extent these were offset by increases in the infiltration rate.

Haematoma and infiltration

In May 2019 Lifeblood commenced the roll out of a new plasma machine. One of the benefits of the new machine is that it removes a smaller volume of blood each cycle, reducing the risk ofa fainting event. However, as more cycles are needed to collect the total volume, there is a higher chance of the needle moving. An increase in haematoma and infiltration rates were observed and which have previously been reported. In the last financial year there was a furtherincrease in infiltration rates from 46.02 to 74.28 per 10,000, and a concurrent decrease occurringin haematoma events from 183.02 to 156.19 per 10,000. Infiltration occurs when red cells or saline are reinfused into the extravascular space on a return cycle. As it is occurring under pressure, it almost always results in a haematoma, and the event may therefore be reported asa haematoma rather than infiltration. The rate changes for infiltration and haematoma observedin 2021-22 followed staff education sessions on identifying and managing infiltration, and hence the changes likely represent staff more accurately classifying infiltration events. The rate of infiltration events requiring outside medical care has not changed and supports that the increaseis in mild events.

Citrate reactions

An increase in the rate of mild citrate reactions was observed following the introduction of the new plasma machine in 2019-20. This increase was related to a higher return flow rate on the newer machine. The significant reduction observed in the mild citrate reaction rate in 2021-22 (136.64 to 107.35 per 10,000 donations), is possibly an effect of donors becoming more familiar with the machine and being less likely to report minor citrate-related symptoms on return visits as these symptoms resolve quickly and are generally well-tolerated.

Vasovagal symptoms

The rate for 2021-22 reduced significantly by 4.39% from 108.57 to 103.80 per 10,000. The adjusted rate was 104.67 per 10,000, similar to the unadjusted rate. The reduction in the vasovagal rate is likely to be multifactorial; donors are now more familiar with the current plasma machine, the day before hydration messaging and applied muscle tensing exercises were both imple mented in December 2020 and the roll-out of a smaller gauge needle was completed in June 2021. Together with Lifeblood's phlebotomy excellence training program, these initiativesall contribute to mitigating vasovagal reactions in plasma donors.

4.2.3 Platelets

The total adverse event rate for platelets decreased by 19.53% from 869.94 to 700.05 per 10,000. This was due primarily to reductions in rates for haematoma (328.62 to 237.95 per 10,000) and citrate events (368.01 to 288.65 per 10,000). These were offset in part by an increase in infiltration events (55.52 to 67.60 per 10,000). These changes are likely related to amore experienced cohort

of donors and also the staff training to improve identification and reporting of infiltration events, even if mild.

4.3 Vasovagal with loss of consciousness

Feeling faint is a common event. The overall vasovagal rate in 2021-22 was 146.22 per 10,000 donations. Fainting (loss of consciousness) is uncommon and occurred in 7.79% of these cases. Most reports of donors feeling faint occur whilst they are in centre (90.6%). Events occurring off-site are more likely to be associated with loss of consciousness (18.74% vs 6.63%)[6]. Overall, there was no significant change in the rate of vasovagal events associated with loss of consciousness (11.64 per 10,000 in 2020-21 vs 11.39 per 10,000 in 2021-22) or the rate of vasovagal events associated with injury (0.65 per 10,000 in 2020-21 vs 0.68 per 10,000 in 2021-22). Events in female donors accounted for 66.1% of events associated with loss of consciousness and 76.9% of events with injury, noting females account for 67.72% of all vasovagal events.

4.4 Events requiring outside medical care

Outside medical care is defined as an event that requires care from an external health professional including hospital, general practitioner, ambulance or other healthcare professional. The rate of events requiring outside medical care reduced in all donation categories. The overall rate for 2021-22 was 5.30 per 10,000, significantly lower compared with 6.67 per 10,000 in 2020-21 [Table 3]. Vasovagal reactions are associated with 61.9% of cases seeking outside medical care, with 24.5% of these associated with a second event that may be contributory (e.g. infiltration, painful arm).

Table 3: Rates for all events requiring outside medical care for 2021-22

Donation type	Total number of events	Rate per 10,000	Change in Rate per 10,000 from 2020-21
Whole Blood	433	5.85	-1.33
Plasmapheresis	402	4.84	-1.41
Plateletpheresis	10	4.45	-2.30
Total	845	5.30	-1.37

5. Conclusion

In 2021-22, there were 1.59 million donations. Approximately 4.12% of donations were associated with at least one donor adverse event. The vast majority of events were minor and resolved quickly, with only 0.05% of donations associated with an event requiring outside medical care. Lifeblood's sensitive and real-time donor vigilance surveillance system together with continuous development of our staff, process and technology, ensures that donating blood remains as safe as possible.

[6] 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 understate the proportion of eventsthat occur off-site overall and over-state the association between off-site events and loss of consciousnessand/or injury.

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.

APPENDIX

State/territory haemovigilance process improvement

In 2021-22, state/territory departments of health continue to improve their process for haemovigilance data collection and reporting.

NSW

NSW Health completed transition of the incident management system to the new Incident Management System (ims+) platform in November 2020. Therefore this reporting period is drawn from notifications entirely from the new ims+. Data capture improvements in this system assisted with assessing whether adverse events could be aligned to the AHMDS.

The reporting period includes peak periods of the COVID-19 Delta and Omicron waves. Beyond ims+, no new process improvements were introduced during this time.

There are system opportunities to support facility-based incident reviewers to document investigation outcomes that more reliably align with the AHMDS.

VIC

The Blood Matters Serious Transfusion Incident Reporting (STIR) expert group continue to review definitions for reporting to ensure they are consistent with National and International definitions for serious transfusion events.

STIR continue to work on ways of communicating back to reporters to ensure they understand the reasons for any changes to their notifications made by the expert group and to share information from the reports (Bulletins and annual reports).

QLD

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

- Encourage and promote staff to report all suspected adverse reactions into Riskman Incident Reporting System.
- Review, classification, and documentation of all reported adverse reactions by a Haemovigilance team consisting of Haematologist, Pathology Scientist and Transfusion Clinical Nurse Consultant (CNC).
- Continuation of participation in the National Haemovigilance Program as part of Standard 7 – Blood Management (Standard 7) and alignment with the national framework provided by the National NSQHS standards.
- Use of an established validity classification and assessment of imputability for initial assessment of all haemovigilance events which is then reviewed and confirmed with the Consultant Haematologist.
- Review of all haemovigilance incidents in a timely manner to ensure accurate reporting and management of events with feedback provided to the ward areas where necessary.

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 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

On 1 July 2021 WA commenced online reporting of haemovigilance events. In addition to the AHMDS, the online form also allows for the capture of clinical data surrounding the event. This data has been helpful for validation of reported events and overall improving the data quality.

In 2022-23 the WA Dept of Health is investigating the use of Power BI dashboards to display individual HSP haemovigilance data and state-wide trends. A small working group has been established to ensure the dashboards will be fit for purpose.

WA Health have also been monitoring trends involving platelets. We hope to be able to present some initial findings in the coming years.

NT

The occurrence of reported transfusion-related adverse events has increased from 6 in the 2020 – 2021 period (5 x FNHTR and 1 x Allergic reaction) to 11 in the 2021 – 2022 period (2 x IBCT, 2 x TACO, 2 x FNHTR, 1 x Anaphylaxis, 2 x Allergic, 1 x ATR ('Haemolytic'), and 1 x 'other'.

All the reported transfusion-related adverse event are investigated and discussed at the Transfusion Incident Review Group (TIRG) meetings, and when deemed appropriate, at the NT Transfusion Committee (NTTC) meetings. NT is part of the Blood Matters STIR reporting group. All the above 11 mentioned transfusion-related adverse events were reported to STIR.

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
CNC	Transfusion Clinical Nurse Consultant
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
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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
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