NATIONAL BLOOD AUTHORITY
AUSTRALIA

AUSTRALIAN HAEMOVIGILANCE REPORT

Data for 2022-23

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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. 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.

A sentinel event is a particular type of serious incident that is wholly preventable and has caused serious harm to, or the death of, a patient. Refer to the NBA website at Transfusion-related adverse events | National Blood Authority for further information. In 2022-23 there were no sentinel events reported.

All adverse events in this report are reported adverse events regardless of imputability scores and outcome severities.

A transfusion-related serious adverse event (SAE) in this report is an adverse 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. SAE is a subset of all adverse events.

Figure 1 shows all transfusion adverse events and SAEs reported to the national haemoviglance program from 2013-14 to 2022-23. One in ten (629 out of 6,327) of all reported transfusion adverse events are SAEs. The percentage of reported life threatening and SAEs is the lowest since 2016-17.

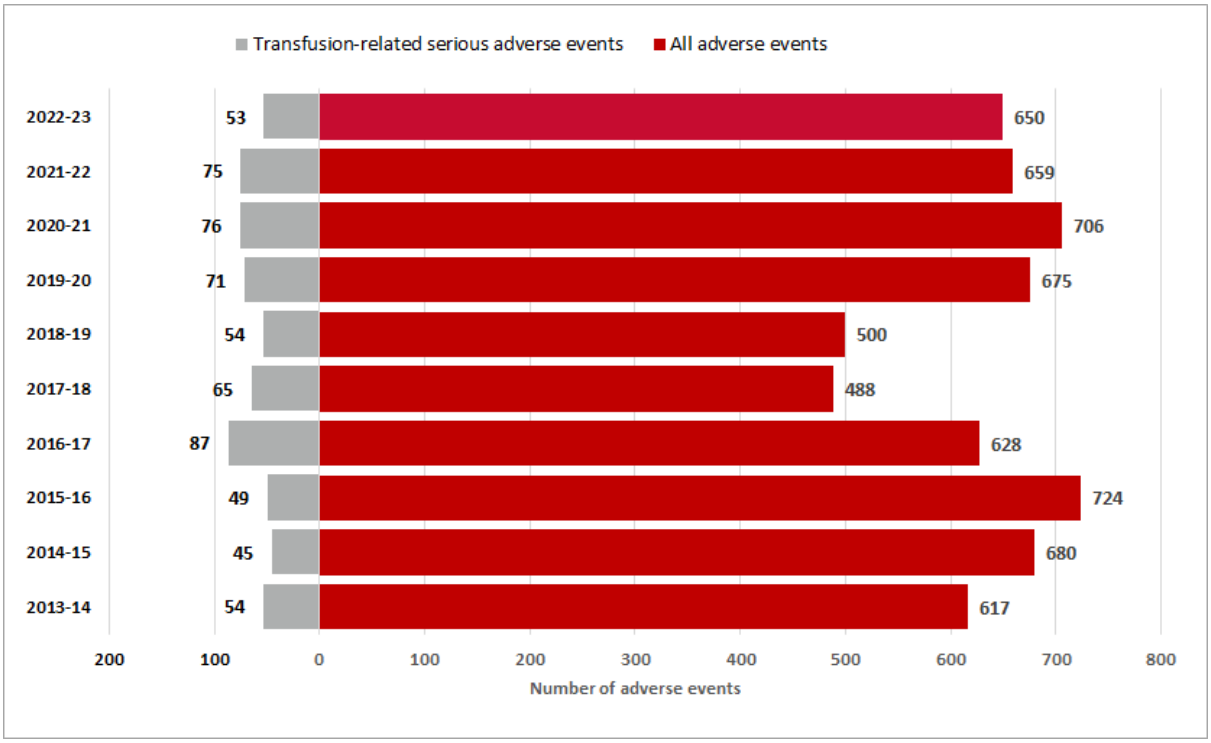


Figure 1: All reported adverse events and transfusion-related serious adverse events, 2013-14 to 2022-23

Figure 2 shows the percentage of all reported adverse events by year from 2018-19 to 2022-23. Febrile non-haemolytic transfusion reaction (FNHTR) and allergic reactions accounted for 64.4% of all reported adverse events (2,055 of 3,190). Transfusion-associated circulatory

overload (TACO) and anaphylactic reactions accounted for 10.5% (366) and 3.7% (117 of 3,190) of all adverse events respectively. Refer to **Appendix 1 Table 3** for detailed adverse event data from 2018-19 to 2022-23.

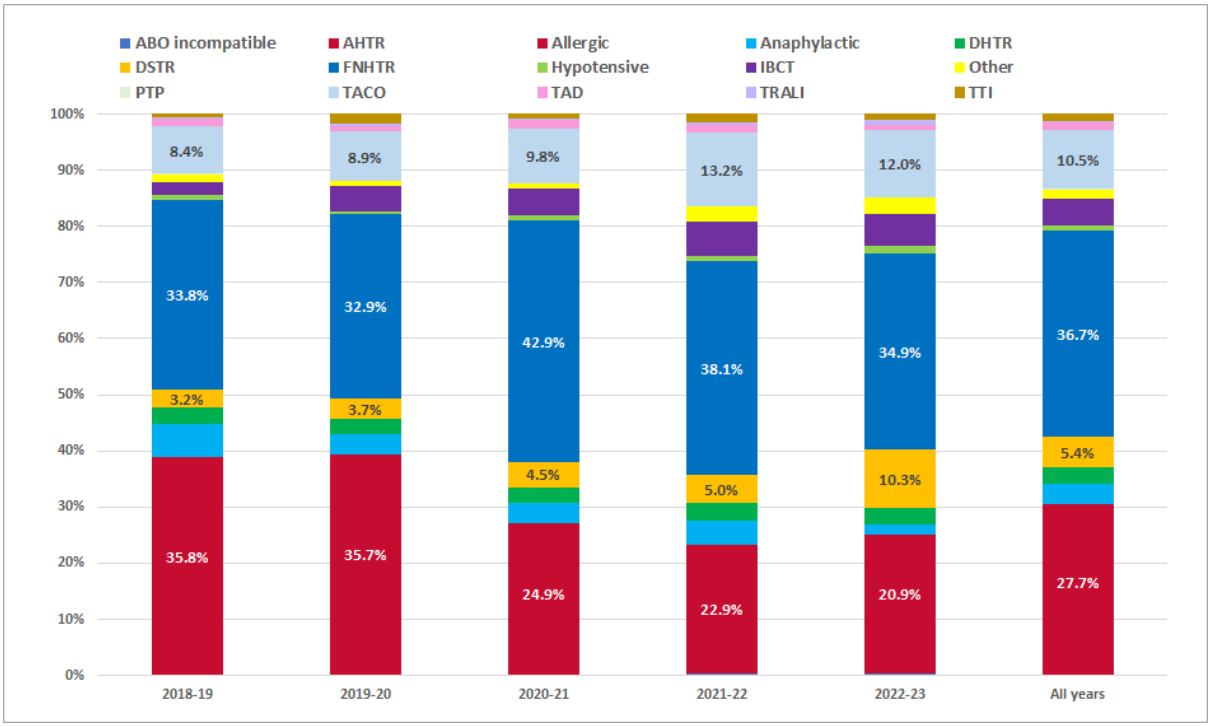


Figure 2: Percentage of all reported adverse events by year, 2018-19 to 2022-23

Figure 3 shows that TACO and anaphylactic reactions accounted for 56.2% of total transfusion-related SAEs (185 of 329). FNHTR and allergic reactions accounted for 26.7% of total transfusion-related SAEs (88 of 329). Refer to **Appendix 1 Table 4** for detailed transfusion-related SAE data from 2018-19 to 2022-23.

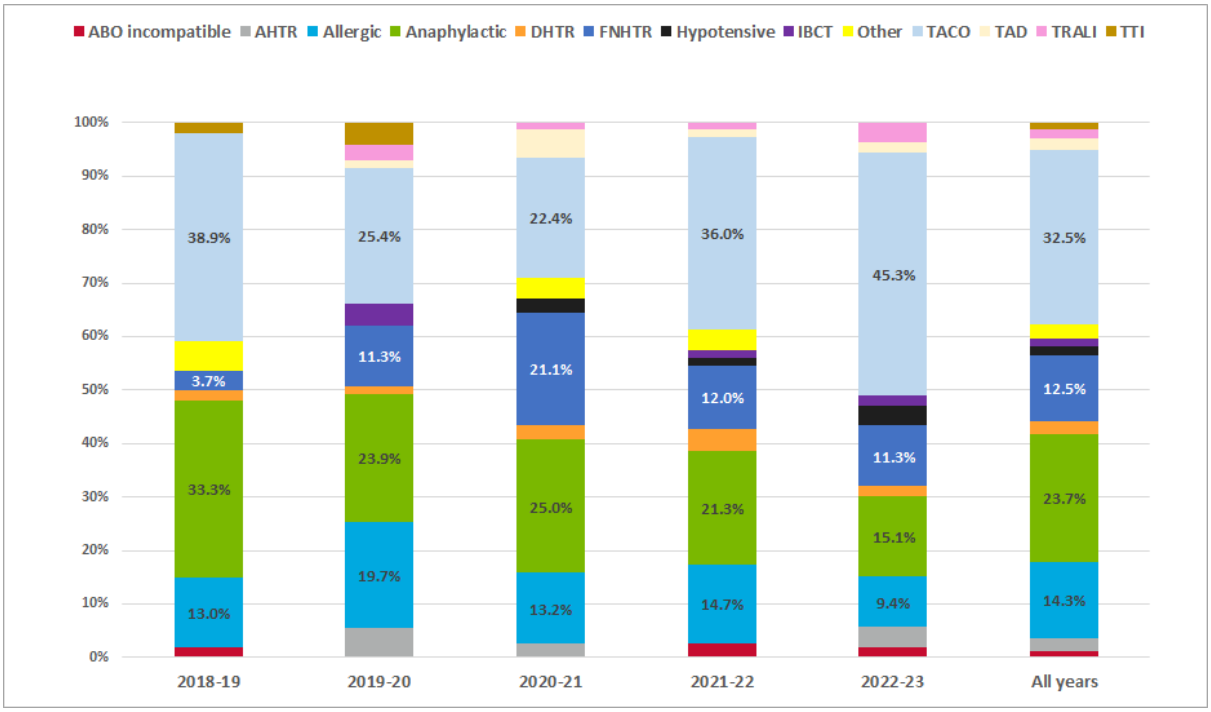


Figure 3: Percentage of transfusion-related serious adverse events by year, 2018-19 to 2022-23

Figure 4 shows the number of all reported adverse events by hospital type from 2018-19 to 2022-23. 86% (2,790 of 3,190) adverse events were reported by public hospitals when compared with 14% (400 of 3,190) by private hospitals.

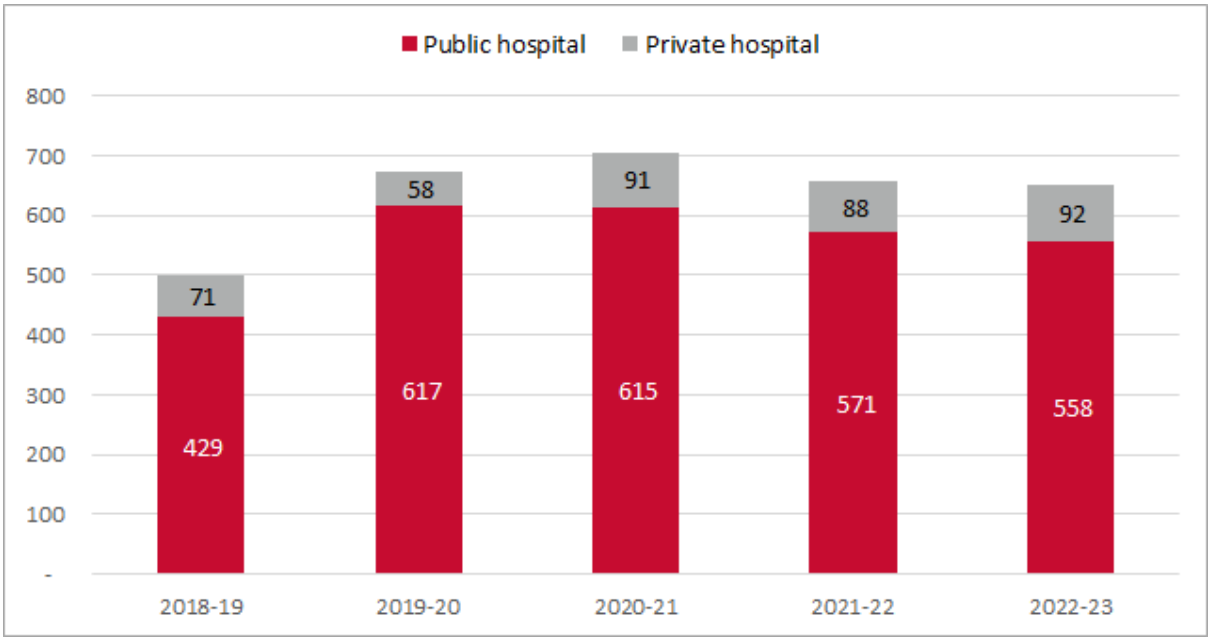


Figure 4: All reported adverse events by hospital type, 2018-19 to 2022-23

Figure 5 shows all reported transfusion adverse events and SAEs by state and territory from 2018-19 to 2022-23. Queensland (QLD) reported the most adverse events (1,394 of 3,190 or 44%). Victoria (VIC) reported the most SAEs (121 of 329 or 37%).

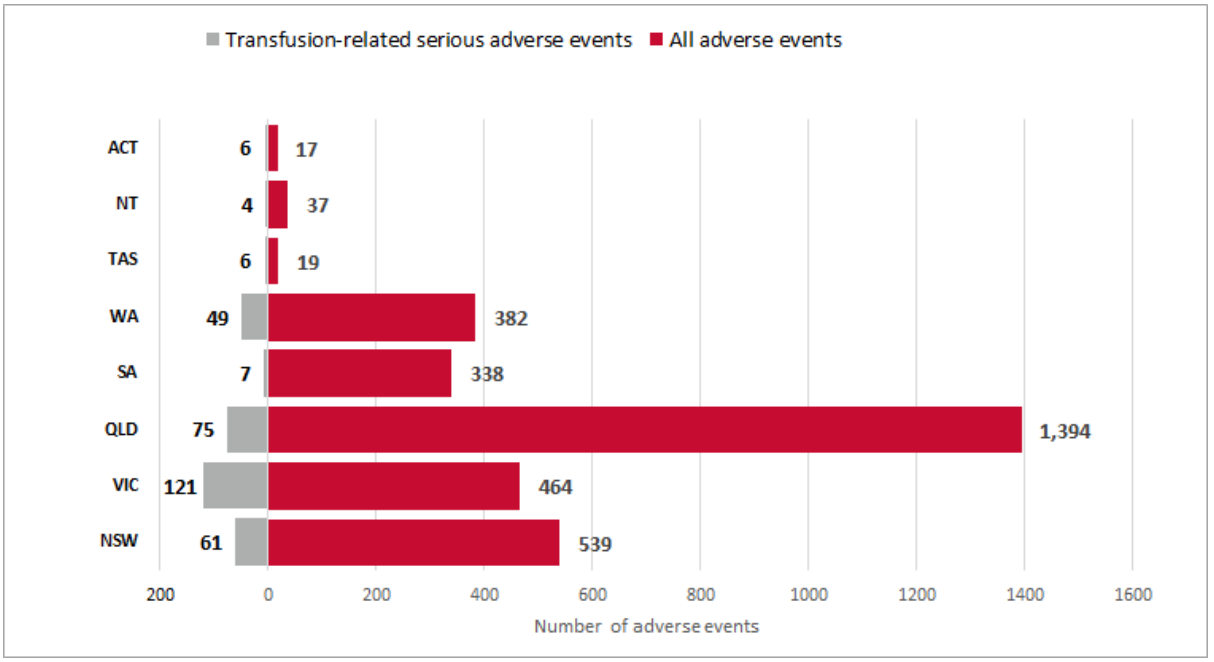
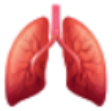


Figure 5: Number of adverse events and transfusion-related serious adverse events by state and territory, 2018-19 to 2022-23

TACO is the leading cause of SAEs in Australia and is also responsible for most deaths in the United Kingdom (UK). The UK Serious Hazards of Transfusion (SHOT) has developed a TACO checklist (also known as the pre-transfusion risk assessment), to help identify patients at risk of developing TACO during or after a blood transfusion. It involves assessing various risk factors and clinical signs to determine the likelihood of TACO. The checklist image below is taken from the 2023 Annual SHOT Report.

TACO Risk Assessment		YES	NO
	Does the patient have any of the following: diagnosis of 'heart failure', congestive cardiac failure (CCF), severe aortic stenosis, or moderate to severe left ventricular dysfunction?		
	Is the patient on a regular diuretic?		
	Does the patient have severe anaemia?		
	Is the patient known to have pulmonary oedema?		
	Does the patient have respiratory symptoms of undiagnosed cause?		
	Is the fluid balance clinically significantly positive?		
	Is the patient receiving intravenous fluids (or received them in the previous 24 hours)?		
	Is there any peripheral oedema?		
	Does the patient have hypoalbuminaemia?		
	Does the patient have significant renal impairment?		

If Risks Identified	YES	NO
Review the need for transfusion (do the benefits outweigh the risks)?		
Can the transfusion be safely deferred until the issue is investigated, treated or resolved?		

If Proceeding with Transfusion: Assign Actions	TICK
Body weight dosing for red cells	
Transfuse a single unit (red cells) and review symptoms	
Measure fluid balance	
Prophylactic diuretic prescribed (where appropriate/not contraindicated)	
Monitor vital signs closely, including oxygen saturation	

Name (PRINT):		**Due to the differences in adult and neonatal physiology, babies may have a different risk for TACO. Calculate the dose by weight and observe the notes above.**
Role:		
Date:	**Time (24hr):**	
Signature:		

SECTION 1

Australian Haemovigilance Data

Introduction

From 2018-19 to 2022-23, there were around one million units of fresh blood products issued in Australia each year. Red blood cells (RBC) and platelets accounted for around 65% and 14% of all issues respectively. RBCs are associated with the highest number of adverse events when compared with the other products, followed by platelets and fresh frozen plasma (FFP).

Table 1: Issues by fresh blood products, 2018-19 to 2022-23

	Number of issues					% of issues				
	2018-19	2019-20	2020-21	2021-22	2022-23	2018-19	2019-20	2020-21	2021-22	2022-23
RBC	629,377	629,609	659,611	663,530	686,730	64.6%	65.3%	65.0%	65.7%	65.4%
Platelets	136,446	138,210	145,056	140,504	147,893	14.0%	14.3%	14.3%	13.9%	14.1%
Fresh frozen plasma	96,264	85,314	85,151	82,552	87,608	9.9%	8.8%	8.4%	8.2%	8.3%
Cryoprecipitate	106,542	106,818	119,477	119,275	122,760	10.9%	11.1%	11.8%	11.8%	11.7%
Cryo-depleted plasma	6,287	4,263	6,032	3,713	4,798	0.6%	0.4%	0.6%	0.4%	0.5%
All products	**974,916**	**964,214**	**1,015,327**	**1,009,574**	**1,049,789**	**100%**	**100%**	**100%**	**100%**	**100%**

The national haemovigilance program receives reports from states and territories for adverse events related to the transfusion of fresh blood products. States and territories use different haemovigilance reporting processes which may lead to inconsistencies in reporting and recording of adverse events in the national haemovigilance program.

Aggregated haemovigilance data, supplied through State and Territory Departments of Health, are analysed for national trends and other indicators. Reports also refer to the national data in the context of previous national haemovigilance data. The function of national haemovigilance reports is to identify the incidence and causes of voluntarily reported adverse transfusion events and make recommendations for national quality and safety investments that can lead to genuine improvements in patient safety outcomes in Australia. National haemovigilance reports are issued by the NBA after advice from the Haemovigilance Advisory Committee (HAC). It is desirable to publish national reports annually.

The report presents the data and analysis for all adverse events for five years from 2018-19 to 2022-23, and for 2022-23 only.

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, the seriousness of the incident, and assessment of the cause of the incident being related to the transfusion.
The roles and responsibilities within Australia are depicted below in **Figure 6**, together with the data collection and reporting obligations at each level.

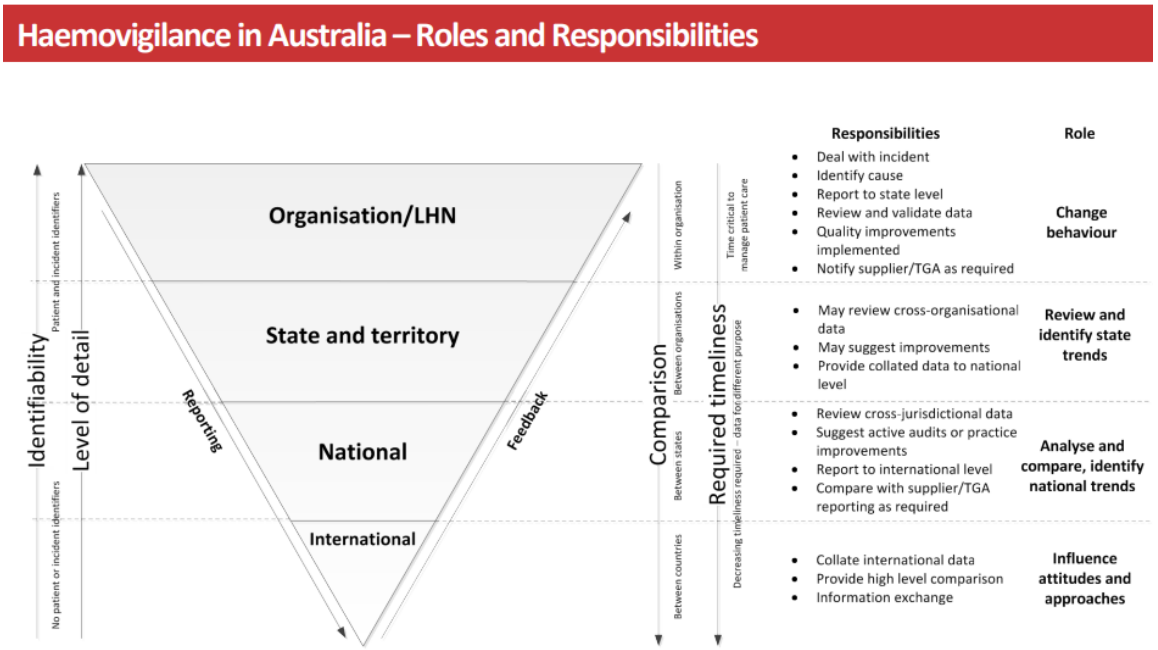
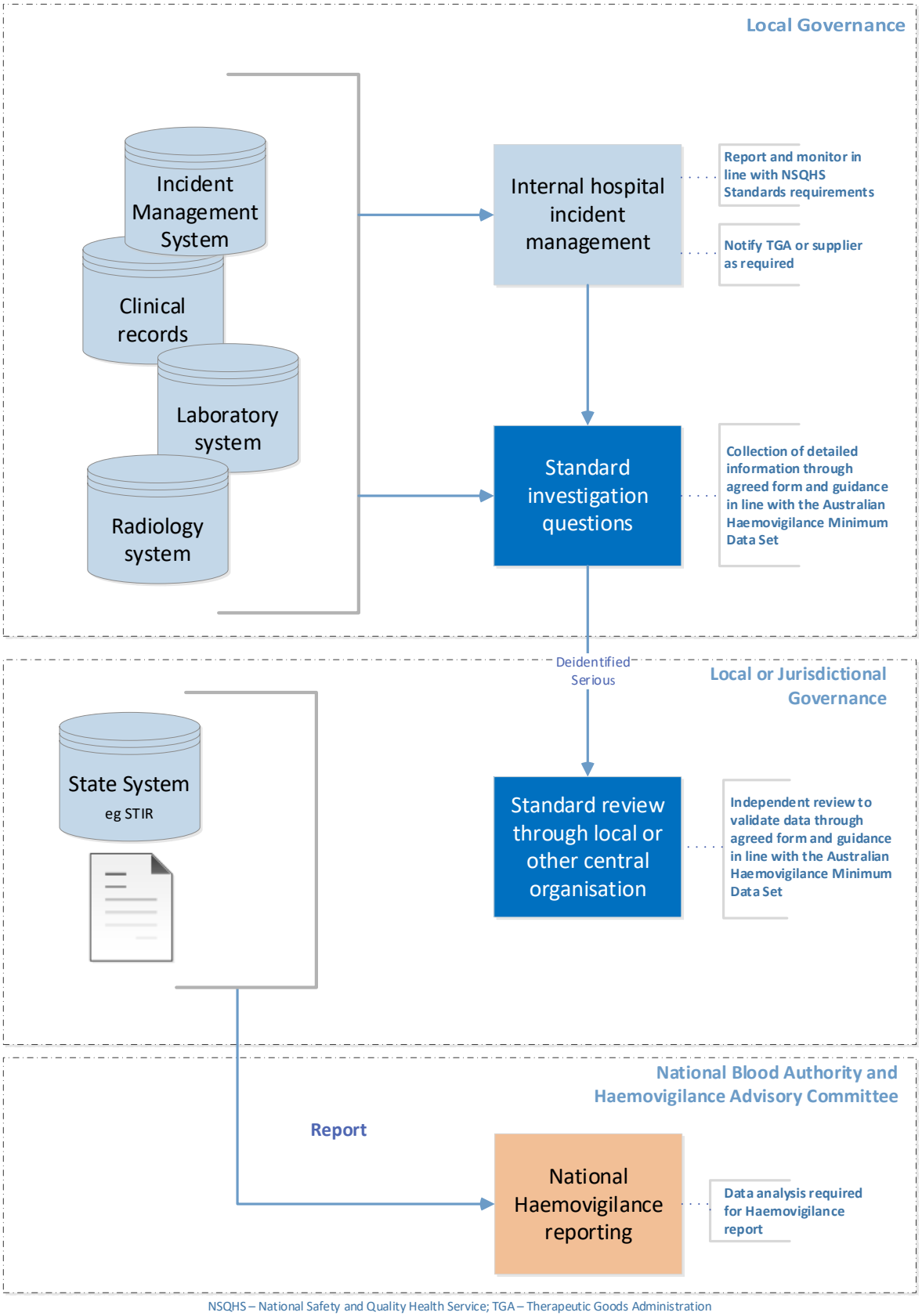


Figure 6: Haemovigilance in Australia – Roles and Responsibilities

Northern Territory (NT), ACT, VIC and Tasmania (TAS) provide their data to STIR (Serious Transfusion Incident Reporting system managed by Blood Matters in Victoria) 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 as shown in **Figure 7**.

Figure 7: Reporting adverse events and haemovigilance in Australia



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

Caveats and Assumptions

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 3** of the 2010 NHDD and 2015 AHMDS align with those used by the International Haemovigilance Network (IHN) and International Society Blood Transfusion (ISBT) unless otherwise stated. However, it is not expected that they are applied rigorously.
- All states and territories have contributed data to the NBA since 2015-16. However, the level and data provided vary across years and between states and territories. Some report only serious adverse events while others report all adverse events as per the AHMDS.
- 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 2022-23 transfusion-transmitted infection (TTI) data have been verified with the states and territories. TTIs reported do not specify any infections.
- STIR system reports serious adverse events and excludes non-transfusion related adverse events.
- The number of adverse events per transfusion rate is unavailable as the number of transfusions is not reported.

Hospital participation in haemovigilance reporting

Since 2019-20, the NBA has been collecting data from states and territories on participating and reporting hospitals.

- A participating hospital is a hospital that participates in state or territory haemovigilance reporting that reports zero or more adverse events.
- A reporting hospital is a participating hospital that reports one or more adverse events.

Figure 8 illustrates the differences in participation and reporting between public and private hospitals at the national level. Most participating and reporting hospitals are public. While the number of private hospitals contributing data has slightly increased from 2019-20 to 2022-23 in accordance with the National Safety and Quality Health Service (NSQHS) Blood Management Standard, private hospitals continue to under report transfusion adverse events in Australia. The NBA is collaborating with HAC to engage with the private sector in haemovigilance reporting through a consultancy initiative as part of the NBA's broad private sector engagement strategy.

In Australia there are 1,335 declared facilities to be a hospital, consistent with Section 121 of the Private Health Insurance Act 2007. Of this there are 636 private and 699 public hospitals. Some of these hospitals receive blood and blood products, directly from our suppliers, through pathology providers and through transfer arrangements. Further work on determining the number of hospitals that receive and transfuse blood and blood products is being undertaken.

Refer to **Appendix 1 Table 6** and **Table 7** for further information for the state and public/private differences.

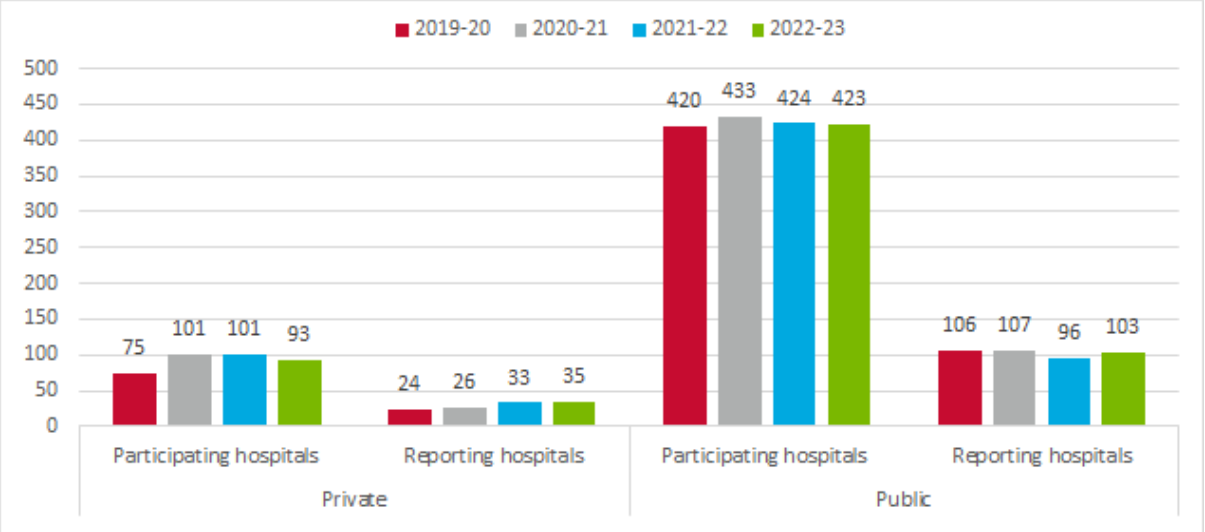
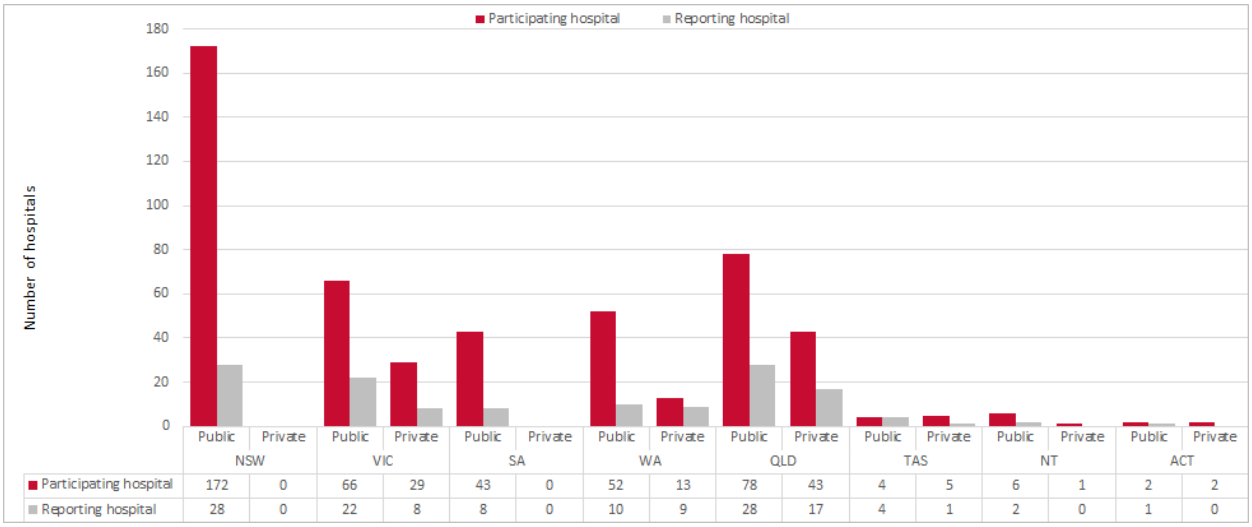


Figure 8: Number of participating and reporting hospitals by public/private and state/territory, 2019-20 to 2022-23

Figure 9 presents hospital participating and reporting data for states and territories in 2022-23. A total of 516 hospitals participated in national haemovigilance reporting, including 423 public hospitals and 93 private hospitals. Of these, 27% (138 hospitals) reported adverse events, comprising 103 public hospitals and 35 private hospitals. Four states (VIC, QLD, WA and TAS) reported adverse events for private hospitals. QLD had the highest number of reporting and participating hospitals for private hospitals. However, private hospitals in NSW and SA did not participate in national haemovigilance reporting. Nationally, 4.7 adverse events per hospital were reported for 2022-23. This varied between states and territories, ranging from 1.0 in ACT to 8.4 in SA in **Figure *10*.**



	NSW		VIC		SA		WA		QLD		TAS		NT		ACT	
	Public	Private	Public	Private	Public	Private	Public	Private	Public	Private	Public	Private	Public	Private	Public	Private
Participating hospital	172	0	66	29	43	0	52	13	78	43	4	5	6	1	2	2
Reporting hospital	28	0	22	8	8	0	10	9	28	17	4	1	2	0	1	0

Figure 9: Number of participating and reporting hospitals by public/private and state/territory, 2022-23

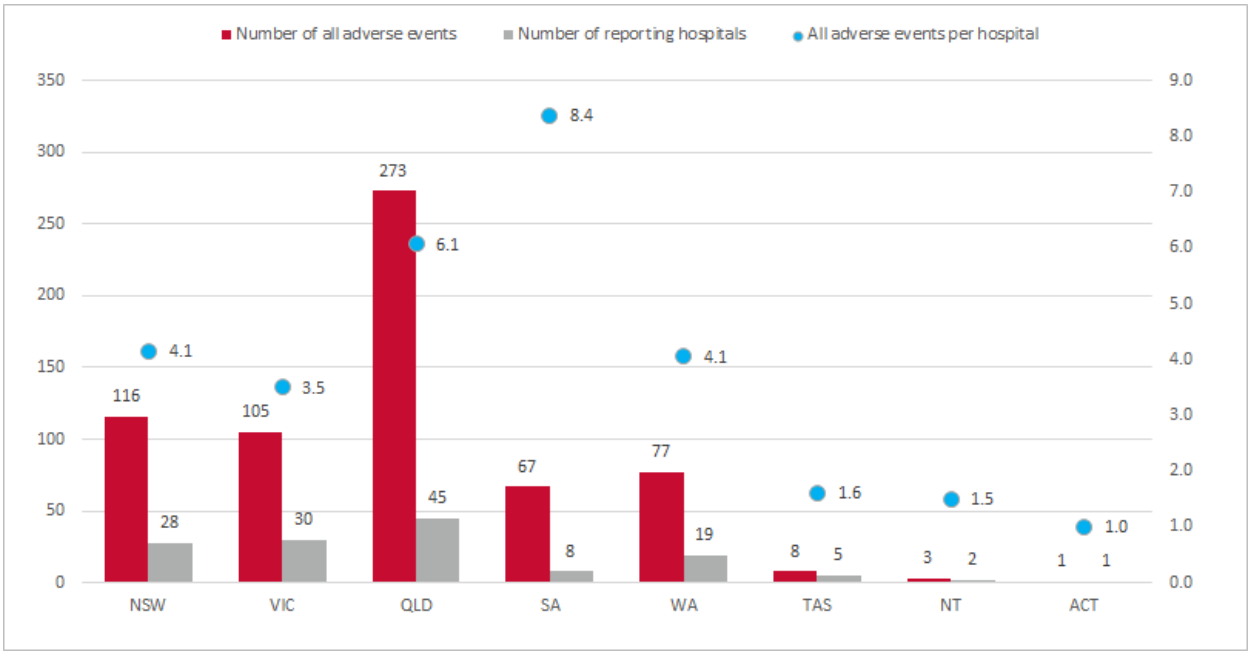


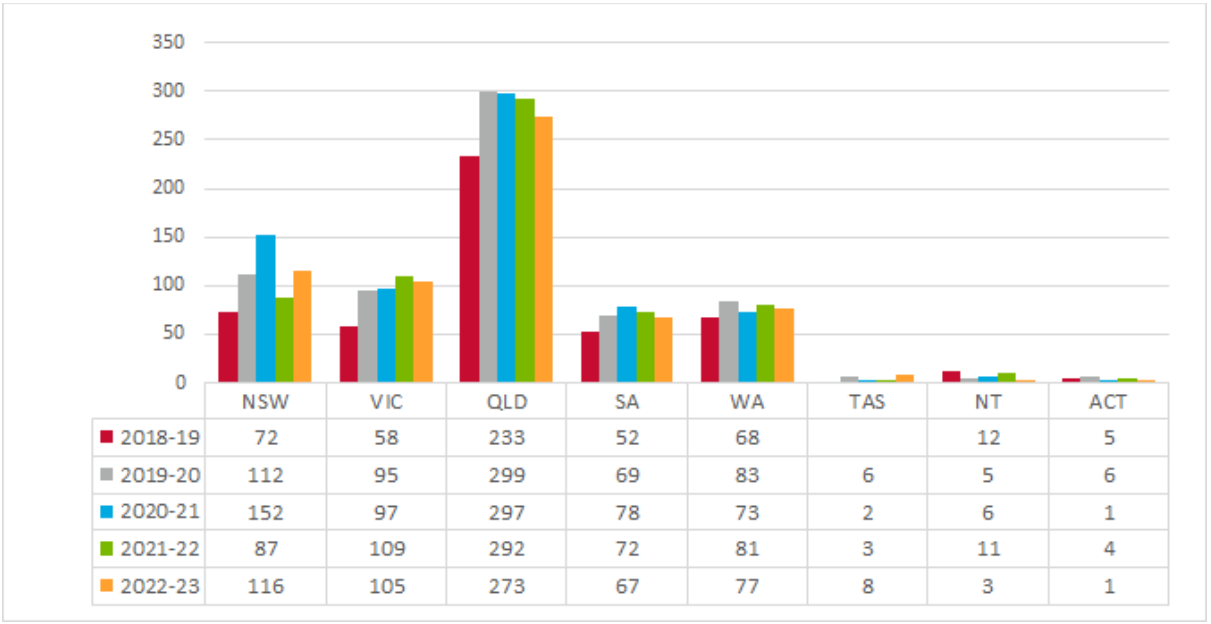
Figure 10: Number of adverse events per hospital by state/territory, 2022-23

Results for all adverse events, 2018-19 to 2022-23

This section presents the data and key results for all reported adverse events between 2018-19 and 2022-23.

Eight states and territories reported 3,190 transfusion adverse events of 15 different types to the National Haemovigilance Program between 2018-19 and 2022-23. QLD reported the highest number of adverse events, followed by NSW and VIC.

Figure 11 shows that QLD had reported the most adverse events over five years, followed by NSW and VIC. Refer to **Appendix 1 Table 8** for detailed state data from 2018-19 to 2022-23 and **Appendix 2 Table 17** for the detailed state adverse event data for 2022-23.



	NSW	VIC	QLD	SA	WA	TAS	NT	ACT
2018-19	72	58	233	52	68		12	5
2019-20	112	95	299	69	83	6	5	6
2020-21	152	97	297	78	73	2	6	1
2021-22	87	109	292	72	81	3	11	4
2022-23	116	105	273	67	77	8	3	1

Figure 11: All adverse events by state, 2018-19 to 2022-23

Figure 12 illustrates that adverse events reported for female patients increased from 215 in 2018-19 to 329 in 2022-23, while those for unknown sex declined from 62 in 2018-19 to 11 in 2022-23.

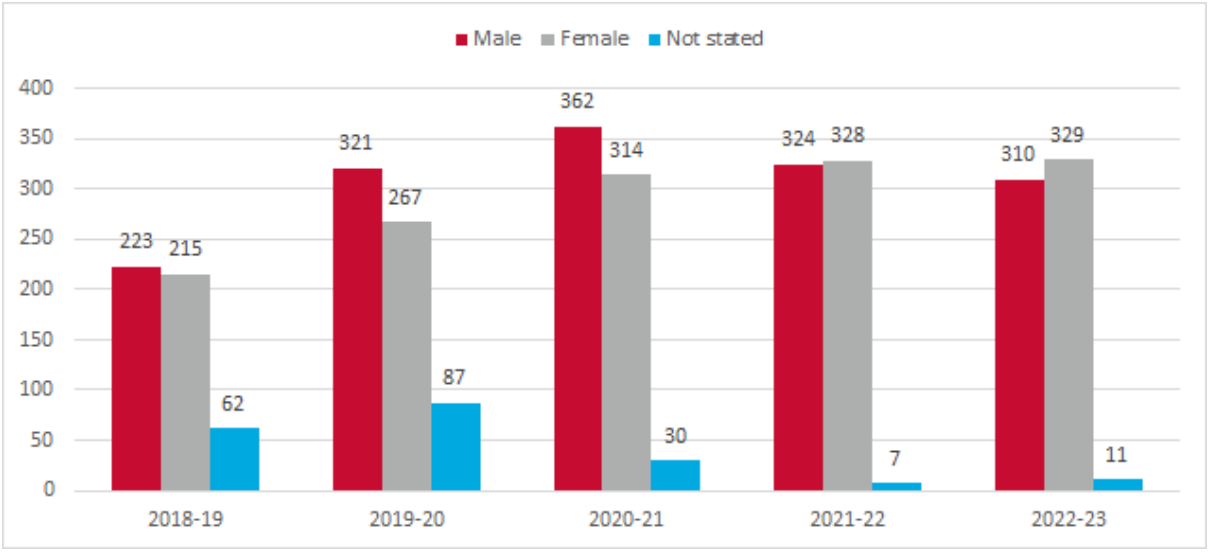


Figure 12: All adverse events by sex, 2018-19 to 2022-23

Twenty-eight per cent (907 of 3,190) of reported adverse events were linked to overnight transfusions **in Figure 13**. Various reactions are equally likely to occur at different times of day but more likely to be detected during better staffed hours. Some outcomes are under reported as they happen after a patient leaves hospital and the total transfusion rates are not reported. Refer to **Appendix 1 Table 9 Part 1 and 2** for further information for detailed transfusion time data from 2018-19 to 2022-23.

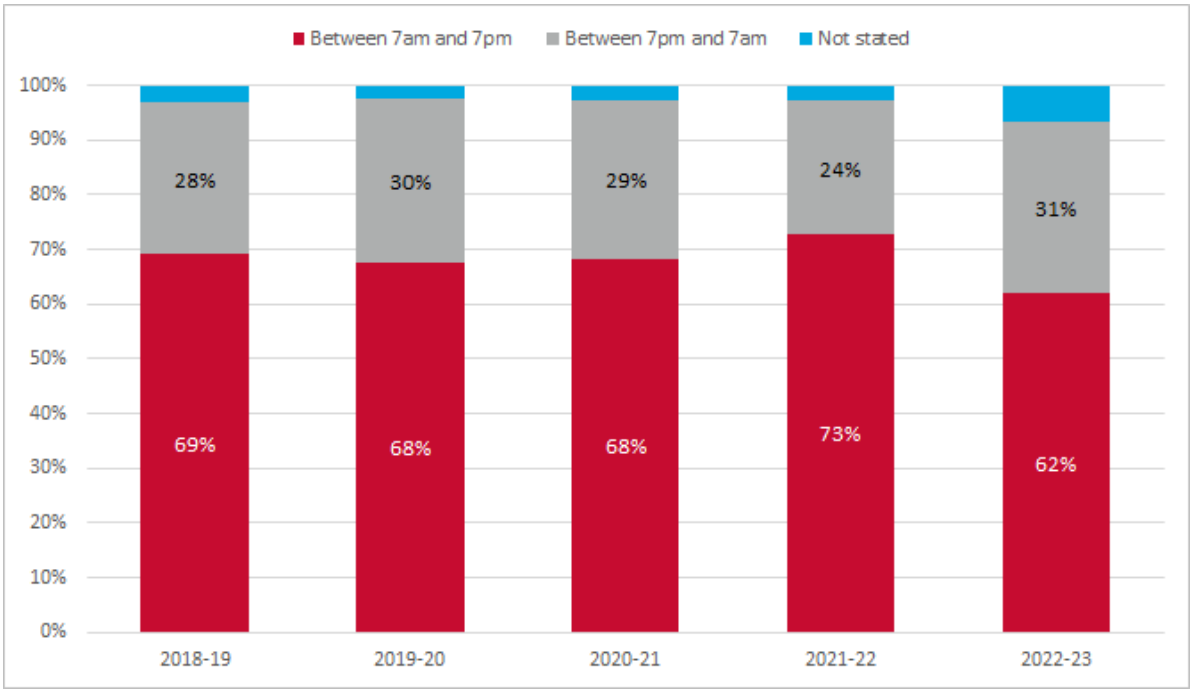


Figure 13: All adverse events by transfusion time, 2018-19 to 2022-23

Figure 14 presents that 21% (654 of 3,190) of reported adverse events occurred during weekend transfusions. Refer to **Appendix 1 Table 10** for detailed transfusion weekday/weekend data from 2018-19 to 2022-23.

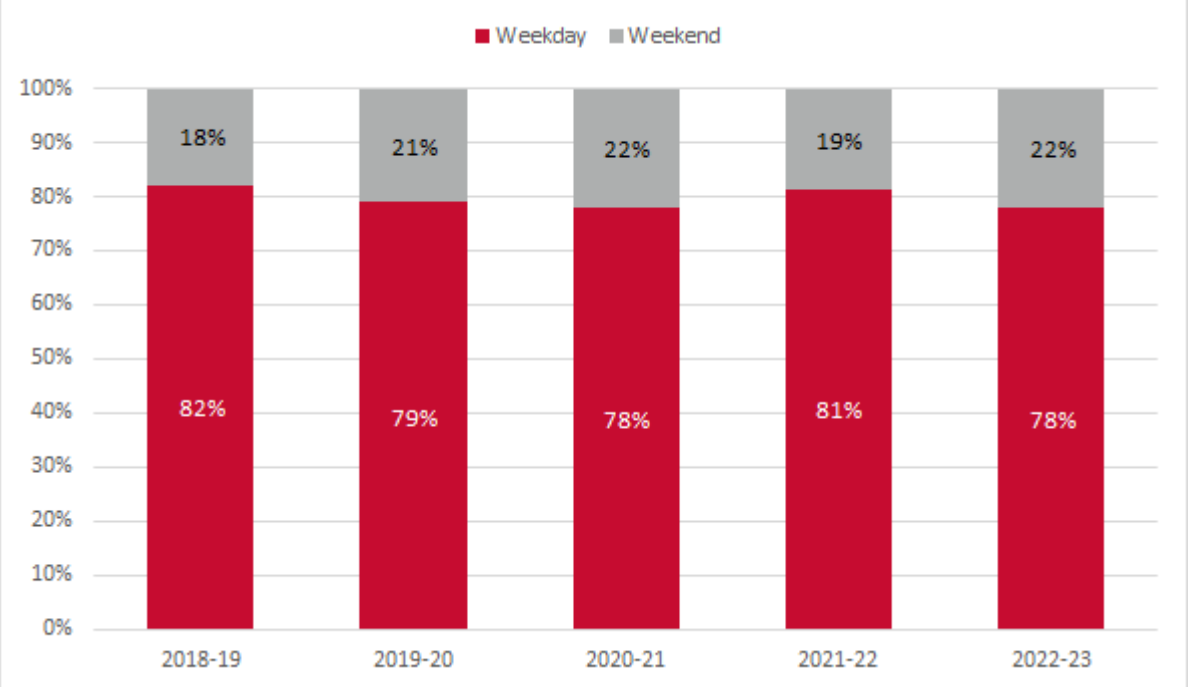


Figure 14: All adverse events by weekday/weekend, 2018-19 to 2022-23

Figure 15 shows that 76% (2,418 of 3,190) of adverse events occurred in major cities across Australia. Refer to **Appendix 1 Table 11 Parts 1 to 3** detailed remoteness data from 2018-19 to 2022-23.

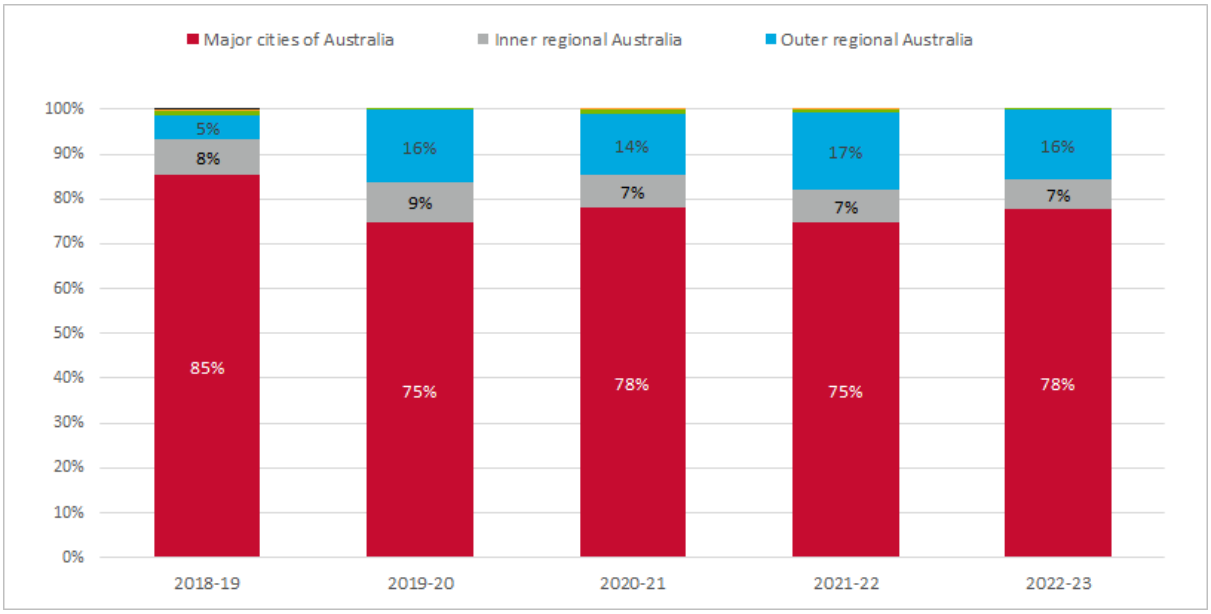


Figure 15: All adverse events by remoteness, 2018-19 to 2022-23

Figure 16 shows that the proportion of reported blood transfusion adverse events (imputability = definite, probable, possible) declined over five years, from 88% in 2018-19 to 75% in 2022-23. Refer to **Appendix 1 Table 13 Parts 1 to 3** for detailed imputability score data from 2018-19 to 2022-23.

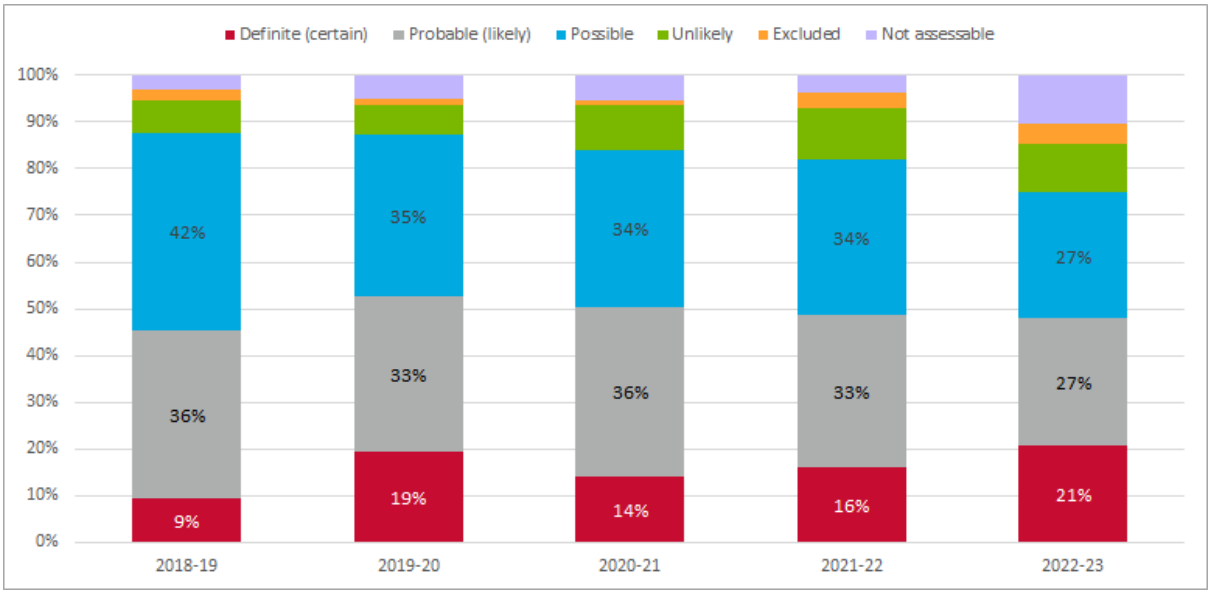


Figure 16: All adverse events by imputability score, 2018-19 to 2022-23

On average, death, life-threatening conditions, and severe morbidity events accounted for 11.5% of all reports in **Figure 17**. The percentage of life-threatening and severe morbidity cases was at its lowest in 2022-23, compared to the previous four years. 0.3% (8 of 3,190) reported adverse events were related to death. Refer to **Appendix 1 Table 14 Parts 1 to 3** for detailed clinical outcome severity data from 2018-19 to 2022-23.

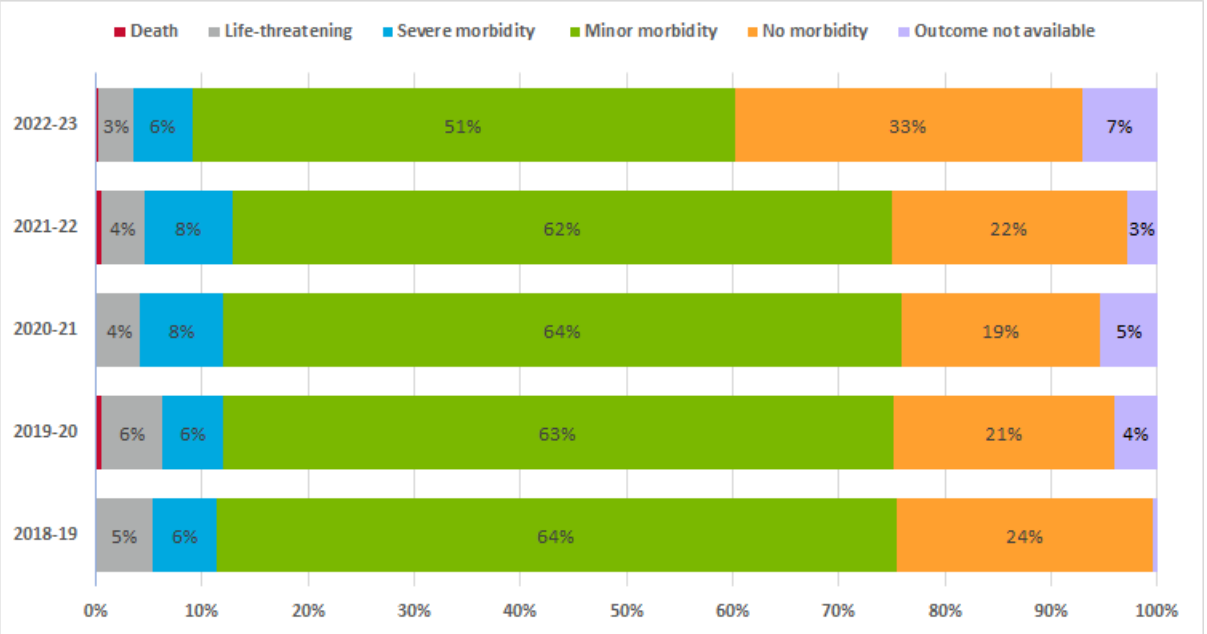


Figure 17: All adverse events by clinical outcome severity, 2018-19 to 2022-23

Figure 18 illustrates that the percentage of RBC transfusion adverse events reported increased over five years. In contrast, platelet and FFP transfusion adverse events declined during the same period. On average, the proportion of RBC and FFP transfusion adverse align closely with the corresponding percentage of issues in **Table 1**. However, the proportion of platelet transfusion adverse events exceeds the percentage of issues. Refer to **Appendix 1 Table 16** for detailed product data from 2018-19 to 2022-23.

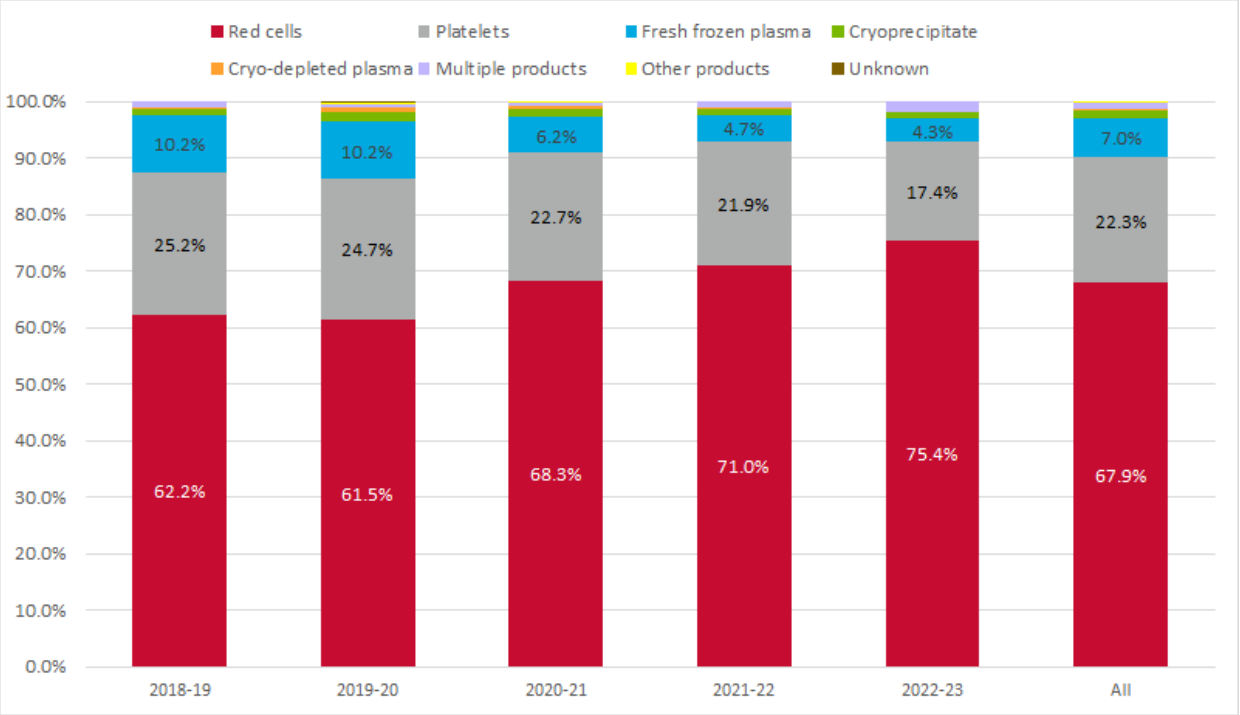


Figure 18: All adverse events by product, 2018-19 to 2022-23

States and territories report data on factors contributing to each adverse event where applicable. One adverse event might be associated with more than one contributory factors.

Further 5-year trend data (2018-19 to 2022-23) is presented in **Appendix 1**.

Results for all adverse events, 2022-23

This section presents the data and key results for all reported adverse events for 2022-23. There were 650 total reported adverse events for 2022-23 spanning 14 different event types, across 138 hospitals.

Figure 19 and **Figure 20** show:

- more adverse events were reported for females than males except in the under 15 and over 55 age groups
- 6.1% (19 cases) more adverse events were reported for females than males
- 38 more reports of allergic reactions were reported for female patients
- transfusion rates are not reported as part of the data set
- limitations in haemovigilance reporting for children under 18 exist due to the broad Australian Bureau of Statistics (ABS) age group classifications.

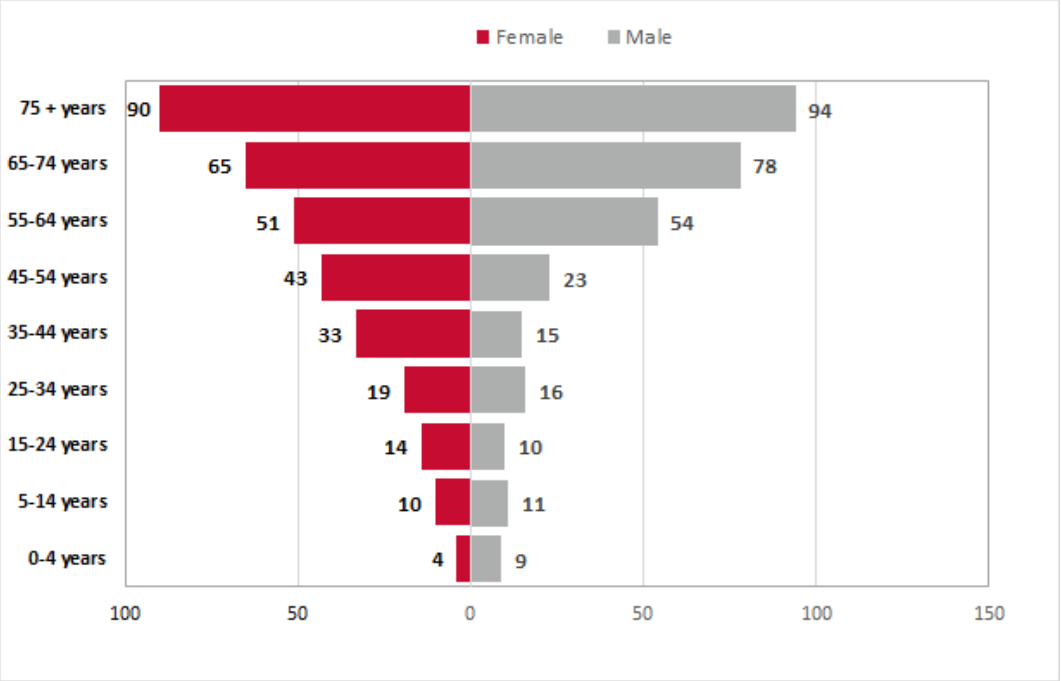


Figure 19: All adverse events by age and sex, 2022-23

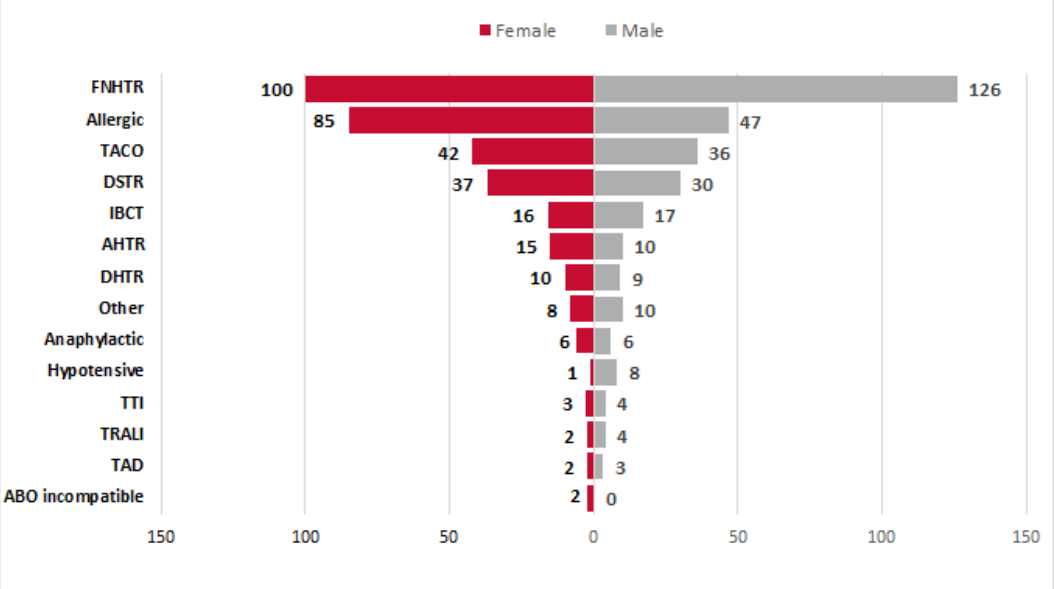


Figure 20: All adverse events by sex, 2022-23

Figure 21 presents the proportion of adverse events across different age groups for 2022–23. Allergic reactions were the most reported adverse events in the 5 to 44 age groups. In contrast, FNHTR is the most reported in the remaining age groups. TACO was notably more prevalent in the 5-14 (24%) and 65+ age groups (17% and 15%) compared to other age groups. Delayed serologic transfusion reactions (DSTR) accounted for 18% of reported adverse events in the 75+ age group and 17% in the 35-44 age group. Refer to **Appendix 2 Table 18** for detailed age group data for 2022-23.

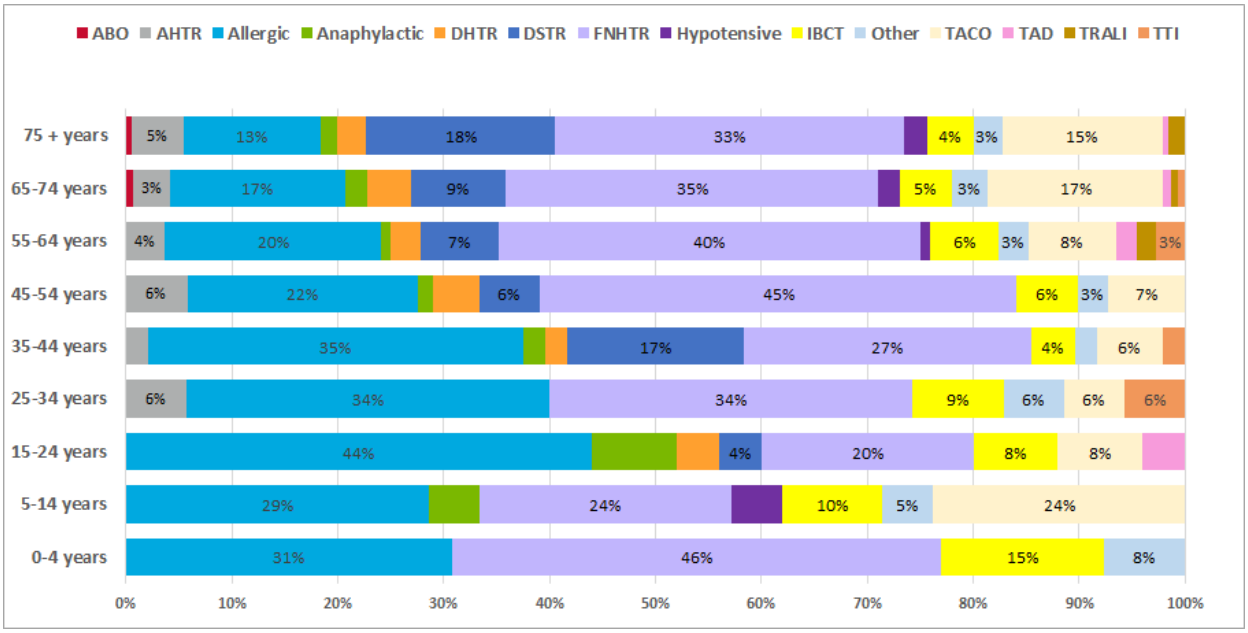


Figure 21: Percentage of all adverse events by age group, 2022-23

Figure 22 and **Figure 23** show:

- 31% (202 of 650) of adverse events occurred during overnight transfusions (7pm to 7am).
- more TACO, Transfusion-Associated Dyspnoea (TAD), and 'Other' adverse events occurred during overnight transfusions compared to daytime
- 22% (143 of 650) of adverse events took place over weekends, with around one-third of DSTRs and Transfusion-Related Acute Lung Injury (TRALI) cases occurring during weekends

Refer to **Appendix 1 Table 9 and Table 10**, **and Appendix 2 Table 19** for detailed transfusion time and day data for 2022-23.

ANZSBT Guideline for the Administration of Blood Products (3rd Edition) recommends that 'Transfusion must only take place when it is appropriately resourced; that is, where enough trained staff are available to monitor the patient, the patient can be observed and emergency medical support is readily available. Overnight or out-of-hours transfusion should be avoided unless clinically indicated.'

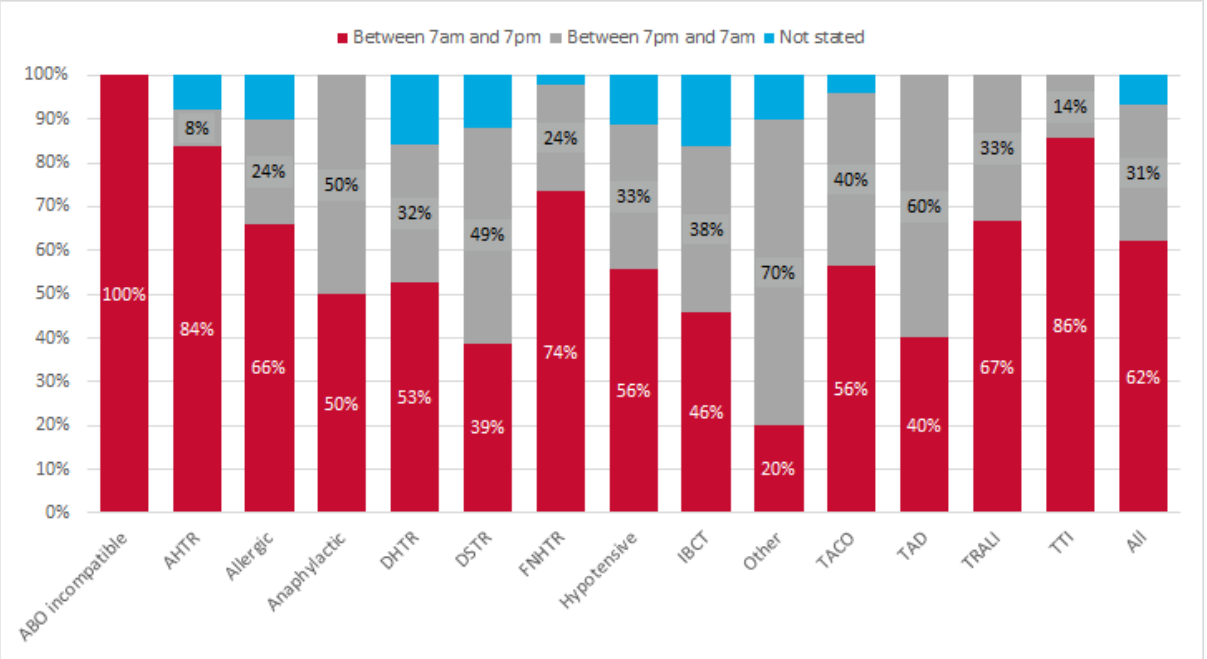


Figure 22: All adverse events by transfusion time, 2022-23

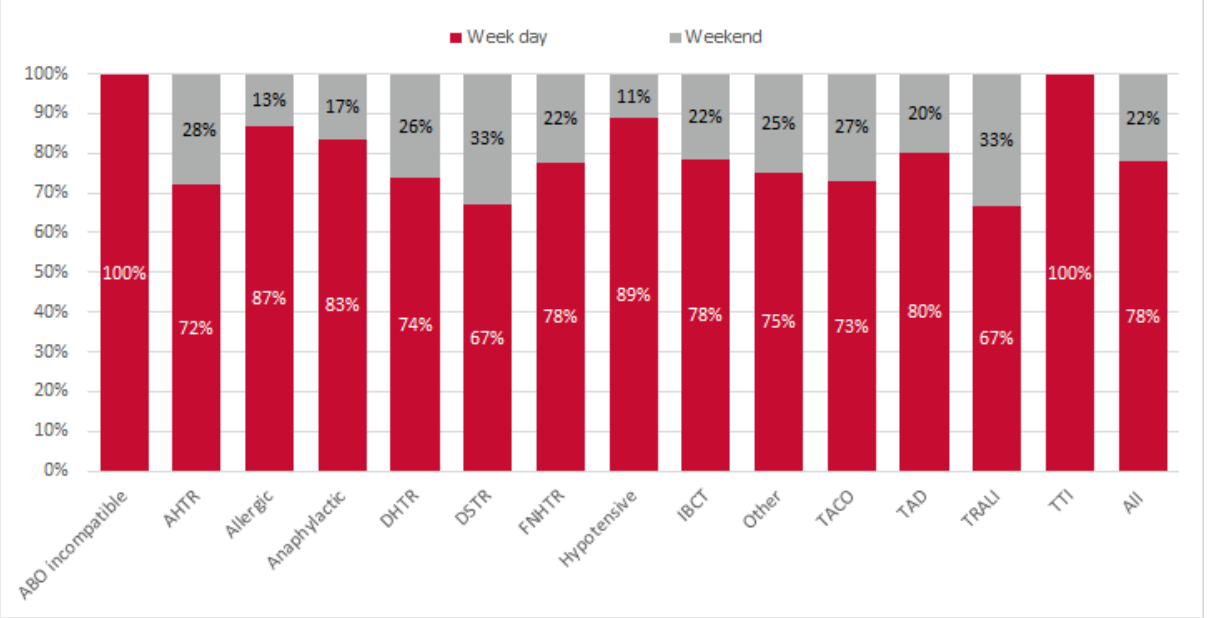


Figure 23: All adverse events by weekday/weekend, 2022-23

Figure 24 shows that 505 of 650 (77.7%) reported adverse events occurred in major cities, while only 0.2% occurred in remote areas. Refer to **Appendix 1 Table 11** for detailed remoteness data for 2022-23.

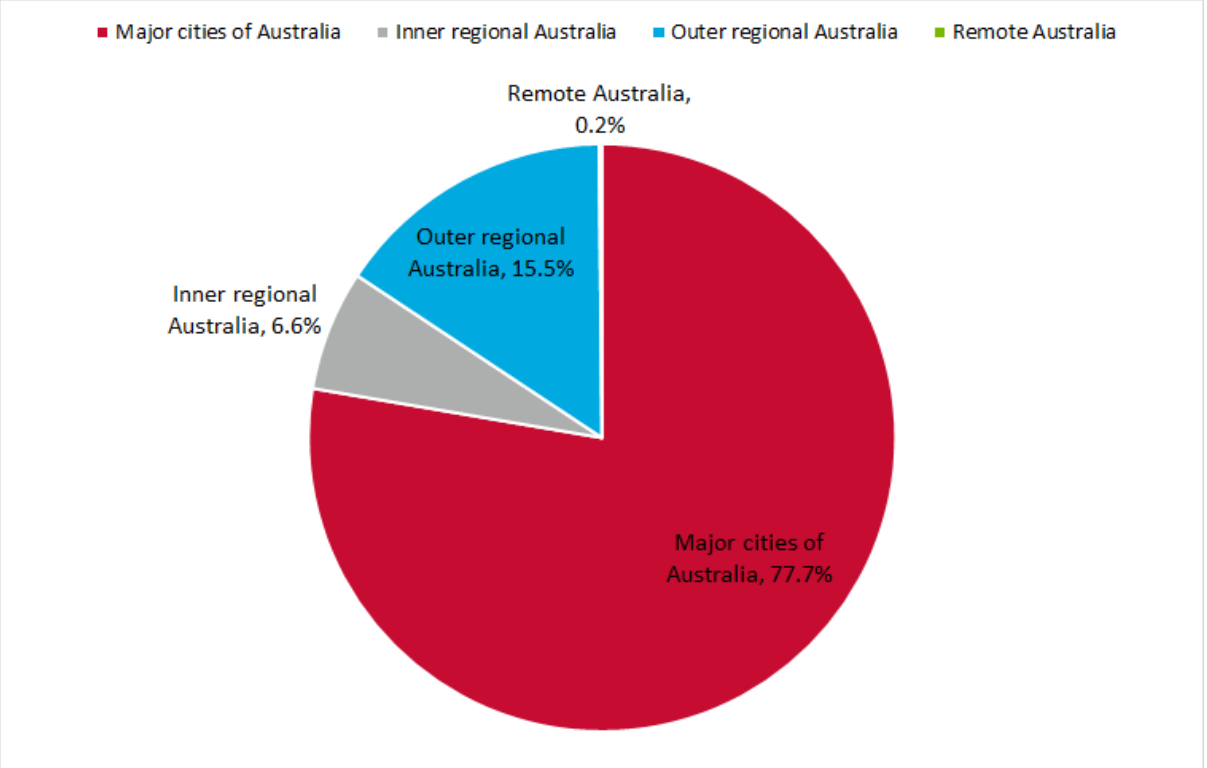


Figure 24: Percentage of adverse events by remoteness, 2022-23

Figure 25 shows that 75% (488 of 650) of reported adverse events were definitely, probably, or possibly related to blood transfusions for 2022-23.

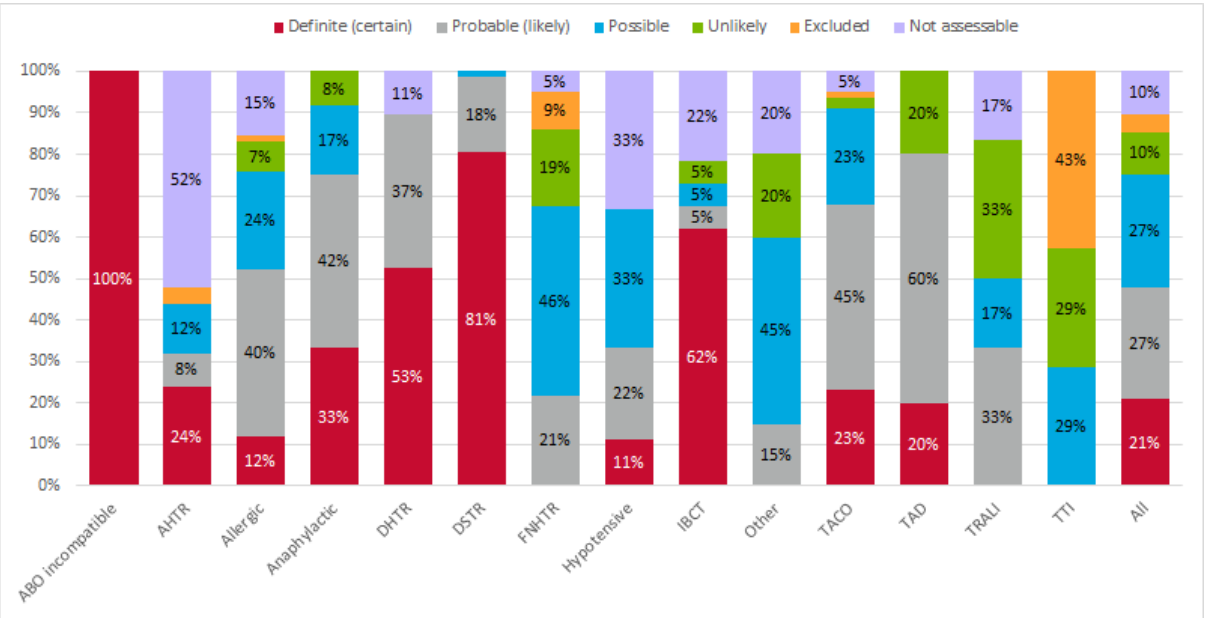


Figure 25: Percentage of adverse events by imputability score, 2022-23

Refer to **Appendix 1 Table 13** for detailed imputability score data for 2022-23.

A breakdown of adverse events by clinical outcome severity in **Table 2** shows:

- one TACO related death was reported, and no further information was provided
- life-threatening and severe morbidity adverse events accounted for 9% of total reports
- 84% of reported adverse events related to minor and no morbidities.

Table 2: All adverse events by clinical outcome severity, 2022-23

	Number of adverse events							% of adverse events					
Adverse Event	Death	Life-threatening	Severe morbidity	Minor morbidity	No morbidity	Outcome not available	Total	Death	Life-threatening	Severe morbidity	Minor morbidity	No morbidity	Outcome not available
ABO incompatible	0	0	1	1	0	0	2	0%	0%	50%	50%	0%	0%
AHTR	0	0	3	8	11	3	25	0%	0%	12%	32%	44%	12%
Allergic	0	2	4	81	40	9	136	0%	1%	3%	60%	29%	7%
Anaphylactic	0	6	3	3	0	0	12	0%	50%	25%	25%	0%	0%
DHTR	0	0	1	10	7	1	19	0%	0%	5%	53%	37%	5%
DSTR	0	0	0	0	59	8	67	0%	0%	0%	0%	88%	12%
FNHTR	0	0	7	161	54	5	227	0%	0%	3%	71%	24%	2%
Hypotensive	0	2	1	5	1	0	9	0%	22%	11%	56%	11%	0%
IBCT	0	0	1	6	18	12	37	0%	0%	3%	16%	49%	32%
Other	0	0	0	6	12	2	20	0%	0%	0%	30%	60%	10%
TACO	1	12	12	45	4	4	78	1%	15%	15%	58%	5%	5%
TAD	0	0	1	3	1	0	5	0%	0%	20%	60%	20%	0%
TRALI	0	0	2	0	2	2	6	0%	0%	33%	0%	33%	33%
TTI	0	0	0	3	4	0	7	0%	0%	0%	43%	57%	0%
All	**1**	**22**	**36**	**332**	**213**	**46**	**650**	**0%**	**3%**	**6%**	**51%**	**33%**	**7%**

Figure 26 highlights that

- 39.6% of RBC transfusion adverse events and 26.5% of platelet transfusion adverse events were FNHTRs.
- 48.7% of platelet-related adverse events and 82.1% of FFP-related adverse events were allergic reactions
- 14.5% of RBC transfusion adverse events were TACO cases.

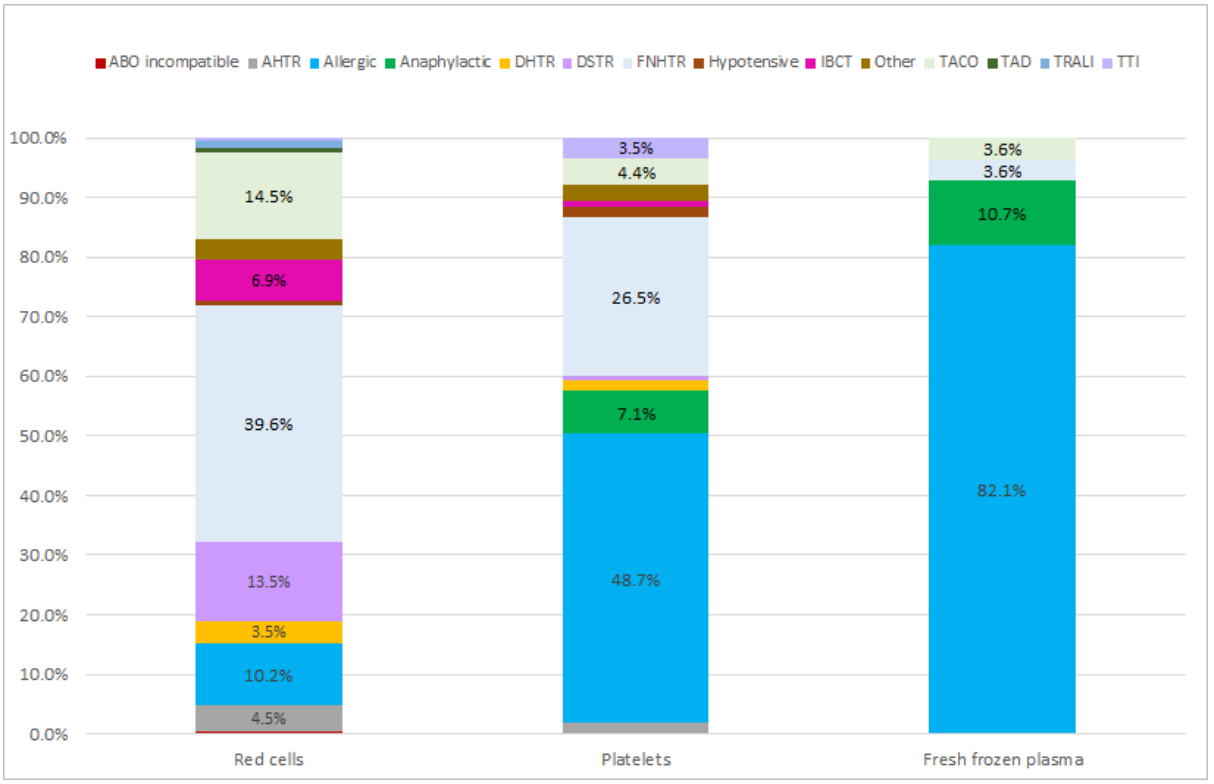


Figure 26: Percentage of products by adverse event, 2022-23

Recommendations

This report restates the five recommendations made in the 2021-22 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 new 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 at AHP level.

Private sector engagement

6. Engage with the private sector in haemovigilance reporting through a consultancy initiative.

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”.

Appendix 1: Trend Data for 2018-19 to 2022-23

This section presents further data for adverse events from 2018-19 to 2022-23, in support of the data in the previous sections. Note that the hospital participation in haemovigilance reporting includes four-year data from 2019-20 to 2022-23.

Table 3: Number of all adverse events, 2018-19 to 2022-23

Adverse Event	2018-19	2019-20	2020-21	2021-22	2022-23	Total	% of total adverse events
ABO incompatible	1	1	0	2	2	**6**	**0.2%**
AHTR	15	24	16	1	25	**81**	**2.5%**
Allergic	179	241	176	151	136	**883**	**27.7%**
Anaphylactic	29	24	25	27	12	**117**	**3.7%**
DHTR	15	18	20	22	19	**94**	**2.9%**
DSTR	16	25	32	33	67	**173**	**5.4%**
FNHTR	169	222	303	251	227	**1,172**	**36.7%**
Hypotensive	4	3	7	6	9	**29**	**0.9%**
IBCT	11	31	34	40	37	**153**	**4.8%**
Other	7	5	5	18	20	**55**	**1.7%**
PTP	1	0	1	0	0	**2**	**0.1%**
TACO	42	60	69	87	78	**336**	**10.5%**
TAD	7	7	11	9	5	**39**	**1.2%**
TRALI	**1**	**2**	**1**	**3**	**6**	**13**	**0%**
TTI	3	12	6	9	7	**37**	**1.2%**
Total	**500**	**675**	**706**	**659**	**650**	**3,190**	**100%**

Table 4: Number of transfusion-related serious adverse events, 2018-19 to 2022-23

Adverse Event	2018-19	2019-20	2020-21	2021-22	2022-23	Total	% of total adverse events
ABO incompatible	1	0	0	2	1	**4**	**1.2%**
AHTR	0	4	2	0	2	**8**	**2.4%**
Allergic	7	14	10	11	5	**47**	**14.3%**
Anaphylactic	18	17	19	16	8	**78**	**23.7%**
DHTR	1	1	2	3	1	**8**	**2.4%**
FNHTR	2	8	16	9	6	**41**	**12.5%**
Hypotensive	0	0	2	1	2	**5**	**1.5%**
IBCT	0	3	0	1	1	**5**	**1.5%**
Other	3	0	3	3	0	**9**	**2.7%**
TACO	21	18	17	27	24	**107**	**32.5%**
TAD	0	1	4	1	1	**7**	**2.1%**
TRALI	0	2	1	1	2	**6**	**1.8%**
TTI	1	3	0	0	0	**4**	**1.2%**
Total	**54**	**71**	**76**	**75**	**53**	**329**	**100%**

Note: The use of different haemovigilance reporting processes across the jurisdictions may lead to data inconsistencies.

Table 5 shows that 86% of events were reported by public hospitals. There was a decrease in reporting from public hospitals and an increase in reporting from private hospitals in 2022-23. **Table 6** and **Table 7** show the number of private and public participating and reporting hospitals. Refer to the **Hospital participation in haemovigilance reporting** section for the definitions and information about participating and reporting hospitals.

Table 5: All adverse events by hospital type, 2018-19 to 2022-23

	2018-19	2019-20	2020-21	2021-22	2022-23	2022-23	
						% of total adverse events	% change from 2021-22
Public hospital	429	617	615	571	558	85.8%	-2.3%
Private hospitals	71	58	91	88	92	14.2%	4.5%
Total hospitals	**500**	**675**	**706**	**659**	**650**	**100%**	**-1.4%**

Table 6: Number of private participating and reporting hospitals by state/territory, 2019-20 to 2022-23

State	Hospital	2019-20	2020-21	2021-22	2022-23
NSW	Participating hospitals	0	0	0	0
	Reporting hospitals	0	0	0	0
VIC	Participating hospitals	25	34	27	29
	Reporting hospitals	4	8	8	8
QLD	Participating hospitals	30	48	55	43
	Reporting hospitals	16	14	18	17
SA	Participating hospitals	0	0	0	0
	Reporting hospitals	0	0	0	0
WA	Participating hospitals	12	10	10	13
	Reporting hospitals	4	4	7	9
TAS	Participating hospitals	5	6	5	5
	Reporting hospitals	0	0	0	1
NT	Participating hospitals	0	0	1	1
	Reporting hospitals	0	0	0	0
ACT	Participating hospitals	3	3	3	2
	Reporting hospitals	0	0	0	0
Total	**Participating hospitals**	**75**	**101**	**101**	**93**
	Reporting hospitals	**24**	**26**	**33**	**35**

Table 7: Number of public participating and reporting hospitals by state/territory, 2019-20 to 2022-23

State	Hospital	2019-20	2020-21	2021-22	2022-23
NSW	Participating hospitals	172	172	172	172
	Reporting hospitals	37	37	27	28
VIC	Participating hospitals	61	72	63	66
	Reporting hospitals	20	21	18	22
QLD	Participating hospitals	80	81	80	78
	Reporting hospitals	23	22	30	28
SA	Participating hospitals	43	43	43	43
	Reporting hospitals	10	8	8	8
WA	Participating hospitals	53	53	53	52
	Reporting hospitals	11	16	9	10
TAS	Participating hospitals	4	3	4	4
	Reporting hospitals	2	1	1	4
NT	Participating hospitals	5	6	6	6
	Reporting hospitals	2	1	2	2
ACT	Participating hospitals	2	3	3	2
	Reporting hospitals	1	1	1	1
Total	**Participating hospitals**	**420**	**433**	**424**	**423**
	Reporting hospitals	**106**	**107**	**96**	**103**

Table 8: All adverse events by state/territory, 2018-19 to 2022-23

	2018-19	2019-20	2020-21	2021-22	2022-23	2022-23	
						% of total adverse events	% change from 2021-22
NSW	72	112	152	87	116	17.8%	33.3%
VIC	58	95	97	109	105	16.2%	-3.7%
QLD	233	299	297	292	273	42.0%	-6.5%
SA	52	69	78	72	67	10.3%	-6.9%
WA	68	83	73	81	77	11.8%	-4.9%
TAS	0	6	2	3	8	1.2%	166.7%
NT	12	5	6	11	3	0.5%	-72.7%
ACT	5	6	1	4	1	0.2%	-75.0%
Total	**500**	**675**	**706**	**659**	**650**	**100%**	**-1.4%**

Table 9: All adverse events by time, 2018-19 to 2022-23 – Part 1

	2018-19			2019-20			2020-21		
Adverse Event	Between 7am and 7pm	Between 7pm and 7am	Not stated	Between 7am and 7pm	Between 7pm and 7am	Not stated	Between 7am and 7pm	Between 7pm and 7am	Not stated
ABO incompatible	1	0	0	1	0	0	0	0	0
AHTR	14	1	0	19	4	1	14	2	0
Allergic	144	31	4	179	57	5	132	39	5
Anaphylactic	16	12	1	20	4	0	20	5	0
DHTR	3	9	3	10	7	1	11	9	0
DSTR	6	5	5	6	18	1	13	17	2
FNHTR	115	52	2	161	57	4	205	93	5
Hypotensive	2	2	0	1	2	0	4	3	0
IBCT	6	4	1	13	17	1	23	8	3
Other	5	2	0	3	2	0	5	0	0
PTP	0	1	0	0	0	0	0	0	1
TACO	27	15	0	34	25	1	41	25	3
TAD	6	1	0	3	4	0	8	3	0
TRALI	1	0	0	0	2	0	1	0	0
TTI	0	3	0	7	3	2	5	1	0
All	**346**	**138**	**16**	**457**	**202**	**16**	**482**	**205**	**19**

Table 9: All adverse events by transfusion time, 2018-19 to 2022-23 – Part 2

	2021-22			2022-23			
Adverse Event	Between 7am and 7pm	Between 7pm and 7am	Not stated	Between 7am and 7pm	Between 7pm and 7am	Not stated	Total
ABO incompatible	2	0	0	2	0	0	**6**
AHTR	0	1	0	21	2	2	**81**
Allergic	119	30	2	90	32	14	**883**
Anaphylactic	19	4	4	6	6	0	**117**
DHTR	14	8	0	10	6	3	**94**
DSTR	18	15	0	26	33	8	**173**
FNHTR	200	49	2	167	55	5	**1,172**
Hypotensive	4	1	1	5	3	1	**29**
IBCT	23	10	7	17	14	6	**153**
Other	13	4	1	4	14	2	**55**
PTP	0	0	0	0	0	0	**2**
TACO	51	34	2	44	31	3	**336**
TAD	7	2	0	2	3	0	**39**
TRALI	1	2	0	4	2	0	**13**
TTI	9	0	0	6	1	0	**37**
All	**480**	**160**	**19**	**404**	**202**	**44**	**3,190**

Table 10: All adverse events by weekday/weekend, 2018-19 to 2022-23

	2018-19		2019-20		2020-21		2021-22		2022-23		
Adverse Event	Weekday	Weekend	Weekday	Weekend	Weekday	Weekend	Weekday	Weekend	Weekday	Weekend	Total
ABO incompatible	1	0	1	0	0	0	2	0	2	0	**6**
AHTR	13	2	20	4	16	0	1	0	18	7	**81**
Allergic	155	24	194	47	138	38	136	15	118	18	**883**
Anaphylactic	23	6	20	4	18	7	25	2	10	2	**117**
DHTR	13	2	15	3	16	4	16	6	14	5	**94**
DSTR	13	3	19	6	29	3	29	4	45	22	**173**
FNHTR	132	37	172	50	223	80	195	56	176	51	**1,172**
Hypotensive	2	2	3	0	6	1	5	1	8	1	**29**
IBCT	10	1	23	8	26	8	27	13	29	8	**153**
Other	7	0	2	3	5	0	11	7	15	5	**55**
PTP	1	0	0	0	1	0	0	0	0	0	**2**
TACO	34	8	52	8	53	16	70	17	57	21	**336**
TAD	5	2	4	3	11	0	7	2	4	1	**39**
TRALI	0	1	1	1	1	0	3	0	4	2	**13**
TTI	2	1	7	5	6	0	9	0	7	0	**37**
All	**411**	**89**	**533**	**142**	**549**	**157**	**536**	**123**	**507**	**143**	**3,190**

Table 11: All adverse events by remoteness, 2018-19 to 2022-23 – Part 1

	2018-19						2019-20			
Adverse Event	Major cities of Australia	Inner regional Australia	Outer regional Australia	Remote Australia	Very remote Australia	Not stated	Major cities of Australia	Inner regional Australia	Outer regional Australia	Remote Australia
ABO incompatible	1	0	0	0	0	0	1	0	0	0
AHTR	10	2	0	1	0	2	17	3	4	0
Allergic	123	5	6	0	0	45	196	16	29	0
Anaphylactic	20	2	0	0	0	7	19	3	2	0
DHTR	11	2	0	1	1	0	13	1	4	0
DSTR	15	1	0	0	0	0	25	0	0	0
FNHTR	130	13	14	3	0	9	142	19	61	0
Hypotensive	2	0	0	0	0	2	3	0	0	0
IBCT	6	3	1	0	0	1	23	8	0	0
Other	6	1	0	0	0	0	2	3	0	0
PTP	1	0	0	0	0	0	0	0	0	0
TACO	32	5	2	0	0	3	50	5	4	1
TAD	5	0	0	0	0	2	6	1	0	0
TRALI	1	0	0	0	0	0	2	0	0	0
TTI	2	0	0	0	0	1	6	1	5	0
All	**365**	**34**	**23**	**5**	**1**	**72**	**505**	**60**	**109**	**1**

Table 11: All adverse events by remoteness, 2018-19 to 2022-23 - Part 2

	2020-21					2021-22				
Adverse Event	Major cities of Australia	Inner regional Australia	Outer regional Australia	Remote Australia	Very remote Australia	Major cities of Australia	Inner regional Australia	Outer regional Australia	Remote Australia	Very remote Australia
ABO incompatible	0	0	0	0	0	2	0	0	0	0
AHTR	11	1	3	1	0	0	0	1	0	0
Allergic	148	10	17	1	0	117	9	25	0	0
Anaphylactic	21	2	2	0	0	24	0	3	0	0
DHTR	13	0	5	2	0	16	1	5	0	0
DSTR	32	0	0	0	0	31	2	0	0	0
FNHTR	216	25	60	2	0	160	25	64	1	1
Hypotensive	6	1	0	0	0	6	0	0	0	0
IBCT	28	5	0	1	0	34	4	0	2	0
Other	5	0	0	0	0	16	1	1	0	0
PTP	1	0	0	0	0	0	0	0	0	0
TACO	55	5	8	0	1	71	6	10	0	0
TAD	9	2	0	0	0	8	1	0	0	0
TRALI	1	0	0	0	0	2	0	1	0	0
TTI	5	0	1	0	0	5	0	4	0	0
All	**551**	**51**	**96**	**7**	**1**	**492**	**49**	**114**	**3**	**1**

Table 11: All adverse events by remoteness, 2018-19 to 2022-23 - Part 3

2022-23					
Adverse Event	Major cities of Australia	Inner regional Australia	Outer regional Australia	Remote Australia	Total
ABO incompatible	2	0	0	0	**6**
AHTR	24	0	1	0	**81**
Allergic	110	5	21	0	**883**
Anaphylactic	10	1	1	0	**117**
DHTR	11	1	7	0	**94**
DSTR	66	1	0	0	**173**
FNHTR	152	17	58	0	**1,172**
Hypotensive	5	4	0	0	**29**
IBCT	31	5	1	0	**153**
Other	17	0	3	0	**55**
PTP	0	0	0	0	**2**
TACO	66	5	6	1	**336**
TAD	4	1	0	0	**39**
TRALI	3	2	1	0	**13**
TTI	4	1	2	0	**37**
All	**505**	**43**	**101**	**1**	**3,190**

Table 12: Issues by fresh blood product and remoteness, 2018-19 to 2022-23– Part 1

	2018-19					2019-20				
Product	Major cities of Australia	Inner regional Australia	Outer regional Australia	Remote Australia	Very remote Australia	Major cities of Australia	Inner regional Australia	Outer regional Australia	Remote Australia	Very remote Australia
RBC	503,999	83,722	34,436	5,228	1,926	504,308	84,018	34,347	4,946	1,923
Platelets	118,425	11,753	5,950	314	4	119,963	12,578	5,411	258	0
Fresh frozen plasma	86,551	6,649	2,737	249	64	75,848	6,672	2,413	298	67
Cryoprecipitate	94,042	7,558	4,687	229	26	95,466	7,606	3,523	194	29
Cryodepleted-depleted plasma	5,807	18	462	0	0	3,186	142	935	0	0
All	**808,824**	**109,700**	**48,272**	**6,020**	**2,020**	**798,771**	**111,016**	**46,629**	**5,696**	**2,019**

Table 12: Issues by fresh blood product and remoteness, 2018-19 to 2022-23– Part 2

	2020-21					2021-22				
Product	Major cities of Australia	Inner regional Australia	Outer regional Australia	Remote Australia	Very remote Australia	Major cities of Australia	Inner regional Australia	Outer regional Australia	Remote Australia	Very remote Australia
RBC	528,958	87,494	36,192	5,029	1,874	531,714	89,881	35,245	4,869	1,757
Platelets	125,177	13,391	6,213	275	0	121,218	12,784	6,175	326	1
Fresh frozen plasma	74,861	7,225	2,694	305	63	71,323	8,120	2,787	232	80
Cryoprecipitate	107,114	8,233	3,901	194	35	107,485	7,813	3,710	233	34
Cryodepleted-depleted plasma	5,217	458	357	0	0	2,999	344	370	0	0
All	**841,327**	**116,801**	**49,357**	**5,803**	**1,972**	**834,739**	**118,942**	**48,287**	**5,660**	**1,872**

Table 12: Issues by fresh blood product and remoteness, 2018-19 to 2022-23– Part 3

2022-23						
Product	Major cities of Australia	Inner regional Australia	Outer regional Australia	Remote Australia	Very remote Australia	Total
RBC	554,402	90,723	34,791	4,794	1,972	3,268,548
Platelets	127,838	13,317	6,497	239	2	708,109
Fresh frozen plasma	76,730	8,180	2,309	294	85	436,836
Cryoprecipitate	111,428	7,565	3,516	222	29	574,872
Cryodepleted-depleted plasma	4,542	73	183	0	0	25093
All	**874,940**	**119,858**	**47,296**	**5,549**	**2,088**	**5,013,458**

Table 13: All adverse events by imputability score, 2018-19 to 2022-23 – Part 1

	2018-19						2019-20					
Adverse Event	Definite (certain)	Probable (likely)	Possible	Unlikely	Excluded	Not assessable	Definite (certain)	Probable (likely)	Possible	Unlikely	Excluded	Not assessable
ABO incompatible	1	0	0	0	0	0	1	0	0	0	0	0
AHTR	2	4	7	1	1	0	6	6	8	1	0	3
Allergic	6	94	66	7	2	4	50	131	55	1	2	2
Anaphylactic	11	11	7	0	0	0	3	9	12	0	0	0
DHTR	8	1	6	0	0	0	10	4	4	0	0	0
DSTR	10	2	3	0	0	1	17	7	1	0	0	0
FNHTR	2	39	92	26	6	4	2	40	122	40	5	13
Hypotensive	0	1	3	0	0	0	0	0	2	0	0	1
IBCT	4	2	0	0	1	4	25	0	1	0	0	5
Other	0	1	5	0	0	1	1	0	4	0	0	0
PTP	0	0	1	0	0	0	0	0	0	0	0	0
TACO	3	22	15	1	0	1	13	23	19	1	0	4
TAD	0	2	5	0	0	0	0	2	3	0	0	2
TRALI	0	0	0	0	1	0	0	1	1	0	0	0
TTI	0	1	2	0	0	0	2	2	2	0	2	4
All	**47**	**180**	**212**	**35**	**11**	**15**	**130**	**225**	**234**	**43**	**9**	**34**

Table 13: All adverse events by imputability score, 2018-19 to 2022-23 – Part 2

	2020-21						2021-22					
Adverse Event	Definite (certain)	Probable (likely)	Possible	Unlikely	Excluded	Not assessable	Definite (certain)	Probable (likely)	Possible	Unlikely	Excluded	Not assessable
ABO incompatible	0	0	0	0	0	0	2	0	0	0	0	0
AHTR	2	11	2	0	0	1	1	0	0	0	0	0
Allergic	34	97	34	5	0	6	21	80	35	9	4	2
Anaphylactic	6	14	5	0	0	0	6	17	2	0	1	1
DHTR	12	4	3	0	0	1	11	5	5	0	0	1
DSTR	20	11	1	0	0	0	24	9	0	0	0	0
FNHTR	11	81	148	57	3	3	2	50	126	58	12	3
Hypotensive	0	2	4	0	0	1	1	1	3	1	0	0
IBCT	7	2	0	0	2	23	26	2	2	0	1	9
Other	0	0	4	0	1	0	1	2	14	0	0	1
PTP	0	0	0	0	0	1	0	0	0	0	0	0
TACO	6	31	26	4	1	1	9	43	28	2	1	4
TAD	1	3	5	2	0	0	1	3	4	0	0	1
TRALI	0	1	0	0	0	0	0	1	2	0	0	0
TTI	0	0	5	1	0	0	0	2	0	1	3	3
All	**99**	**257**	**237**	**69**	**7**	**37**	**105**	**215**	**221**	**71**	**22**	**25**

Table 13: All adverse events by imputability score, 2018-19 to 2022-23 – Part 3

	2022-23						
Adverse Event	Definite (certain)	Probable (likely)	Possible	Unlikely	Excluded	Not assessable	Total
ABO incompatible	2	0	0	0	0	0	**6**
AHTR	6	2	3	0	1	13	**81**
Allergic	16	55	32	10	2	21	**883**
Anaphylactic	4	5	2	1	0	0	**117**
DHTR	10	7	0	0	0	2	**94**
DSTR	54	12	1	0	0	0	**173**
FNHTR	1	48	104	42	21	11	**1,172**
Hypotensive	1	2	3	0	0	3	**29**
IBCT	23	2	2	2	0	8	**153**
Other	0	3	9	4	0	4	**55**
PTP	0	0	0	0	0	0	**2**
TACO	18	35	18	2	1	4	**336**
TAD	1	3	0	1	0	0	**39**
TRALI	0	2	1	2	0	1	**13**
TTI	0	0	2	2	3	0	**37**
All	**136**	**176**	**177**	**66**	**28**	**67**	**3,190**

Table 14: All adverse events by clinical outcome severity, 2018-19 to 2022-23 – Part 1

	2018-19					2019-20					
Adverse Event	Life-threatening	Severe morbidity	Minor morbidity	No morbidity	Outcome not available	Death	Life-threatening	Severe morbidity	Minor morbidity	No morbidity	Outcome not available
ABO incompatible	0	1	0	0	0	0	0	0	1	0	0
AHTR	0	0	12	3	0	0	3	1	18	2	0
Allergic	2	6	129	42	0	0	9	5	186	40	1
Anaphylactic	12	6	7	4	0	1	11	5	2	5	0
DHTR	0	1	11	3	0	0	0	1	12	4	1
DSTR	0	0	4	12	0	0	0	0	2	23	0
FNHTR	1	3	127	38	0	1	1	12	167	32	9
Hypotensive	0	0	1	3	0	0	0	0	1	1	1
IBCT	0	0	1	10	0	1	1	2	2	15	10
Other	1	2	2	2	0	0	0	0	1	4	0
PTP	0	0	1	0	0	0	0	0	0	0	0
TACO	11	10	19	1	1	0	8	12	31	8	1
TAD	0	0	4	3	0	0	1	0	3	2	1
TRALI	0	0	0	0	1	0	2	0	0	0	0
TTI	0	1	2	0	0	0	3	1	0	5	3
All	**27**	**30**	**320**	**121**	**2**	**3**	**39**	**39**	**426**	**141**	**27**

Table 14: All adverse events by clinical outcome severity, 2018-19 to 2022-23 – Part 2

	2020-21						2021-22					
Adverse Event	Death	Life-threatening	Severe morbidity	Minor morbidity	No morbidity	Outcome not available	Death	Life-threatening	Severe morbidity	Minor morbidity	No morbidity	Outcome not available
ABO incompatible	0	0	0	0	0	0	0	0	2	0	0	0
AHTR	0	1	1	13	1	0	0	0	0	1	0	0
Allergic	0	4	7	132	25	8	0	3	10	117	18	3
Anaphylactic	0	14	5	5	1	0	0	11	5	8	3	0
DHTR	0	0	2	10	8	0	0	0	3	11	7	1
DSTR	0	0	0	4	28	0	0	0	0	3	30	0
FNHTR	0	1	19	233	35	15	1	2	11	193	39	5
Hypotensive	0	0	2	3	0	2	0	0	2	3	1	0
IBCT	0	1	0	3	19	11	0	0	1	4	27	8
Other	0	2	1	1	1	0	1	1	2	6	8	0
PTP	0	0	1	0	0	0	0	0	0	0	0	0
TACO	1	4	13	42	7	2	1	9	17	53	5	2
TAD	0	1	4	3	3	0	0	1	1	7	0	0
TRALI	0	0	1	0	0	0	0	0	1	2	0	0
TTI	0	0	0	2	4	0	0	0	0	1	8	0
All	**1**	**28**	**56**	**451**	**132**	**38**	**3**	**27**	**55**	**409**	**146**	**19**

Table 14: All adverse events by clinical outcome severity, 2018-19 to 2022-23 – Part 3

	2022-23						
Adverse Event	Death	Life-threatening	Severe morbidity	Minor morbidity	No morbidity	Outcome not available	Total
ABO incompatible	0	0	1	1	0	0	**6**
AHTR	0	0	3	8	11	3	**81**
Allergic	0	2	4	81	40	9	**883**
Anaphylactic	0	6	3	3	0	0	**117**
DHTR	0	0	1	10	7	1	**94**
DSTR	0	0	0	0	59	8	**173**
FNHTR	0	0	7	161	54	5	**1,172**
Hypotensive	0	2	1	5	1	0	**29**
IBCT	0	0	1	6	18	12	**153**
Other	0	0	0	6	12	2	**55**
PTP	0	0	0	0	0	0	**2**
TACO	1	12	12	45	4	4	**336**
TAD	0	0	1	3	1	0	**39**
TRALI	0	0	2	0	2	2	**13**
TTI	0	0	0	3	4	0	**37**
All	**1**	**22**	**36**	**332**	**213**	**46**	**3,190**

Table 15 highlights from 2018-19 to 2022-23 that:

- 46.6% (1,010 of 2,166) of RBC transfusion adverse events and 20.1% (143 of 710) of platelet transfusion adverse events were FNHTRs.
- 56.8% (403 of 710) of platelet-related adverse events, 72.6% (162 of 223) of FFP-related adverse events, 64.3% (27 of 42) cryoprecipitate transfusion adverse events and 90% (9 of 10) cryo-depleted plasma transfusion adverse events were allergic reactions
- 13.8% (299 of 2,166) of RBC transfusion adverse events were TACOs
- 13.5% (30 of 223) of FFP transfusion adverse events were anaphylactic reactions.

Table 15: All adverse events by product, 2018-19 to 2022-23

	Number of adverse events					% of adverse events				
	Red cells	Platelets	Fresh frozen plasma	Cryoprecipitate	Cryo-depleted plasma	Red cells	Platelets	Fresh frozen plasma	Cryoprecipitate	Cryo-depleted plasma
ABO incompatible	5	0	1	0	0	0.2%	0.0%	0.4%	0.0%	0.0%
AHTR	54	19	5	2	0	2.5%	2.7%	2.2%	4.8%	0.0%
Allergic	263	403	162	27	9	12.1%	56.8%	72.6%	64.3%	90.0%
Anaphylactic	31	50	30	4	0	1.4%	7.0%	13.5%	9.5%	0.0%
DHTR	89	4	0	0	0	4.1%	0.6%	0.0%	0.0%	0.0%
DSTR	168	5	0	0	0	7.8%	0.7%	0.0%	0.0%	0.0%
FNHTR	1,010	143	14	1	1	46.6%	20.1%	6.3%	2.4%	10.0%
Hypotensive	20	6	0	1	0	0.9%	0.8%	0.0%	2.4%	0.0%
IBCT	126	15	4	4	0	5.8%	2.1%	1.8%	9.5%	0.0%
Other	50	4	1	0	0	2.3%	0.6%	0.4%	0.0%	0.0%
PTP	2	0	0	0	0	0.1%	0.0%	0.0%	0.0%	0.0%
TACO	299	26	5	2	0	13.8%	3.7%	2.2%	4.8%	0.0%
TAD	30	7	1	0	0	1.4%	1.0%	0.4%	0.0%	0.0%
TRALI	10	2	0	0	0	0.5%	0.3%	0.0%	0.0%	0.0%
TTI	9	26	0	1	0	0.4%	3.7%	0.0%	2.4%	0.0%
All	**2,166**	**710**	**223**	**42**	**10**	**100%**	**100%**	**100%**	**100%**	**100%**

Table 16: All adverse events by product and year, 2018-19 to 2022-23

	Number of adverse events					% of adverse events				
	2018-19	2019-20	2020-21	2021-22	2022-23	2018-19	2019-20	2020-21	2021-22	2022-23
Red cells	311	415	482	468	490	62.2%	61.5%	68.3%	71.0%	75.4%
Platelets	126	167	160	144	113	25.2%	24.7%	22.7%	21.9%	17.4%
Fresh frozen plasma	51	69	44	31	28	10.2%	10.2%	6.2%	4.7%	4.3%
Cryoprecipitate	5	12	11	8	6	1.0%	1.8%	1.6%	1.2%	0.9%
Cryo-depleted plasma	2	4	3	1	0	0.4%	0.6%	0.4%	0.2%	0.0%
Multiple products	5	5	5	7	13	1.0%	0.7%	0.7%	1.1%	2.0%
Other products	0	1	1	0	0	0.0%	0.1%	0.1%	0.0%	0.0%
Unknown	0	2	0	0	0	0.0%	0.3%	0.0%	0.0%	0.0%
Total	**500**	**675**	**706**	**659**	**650**	**100%**	**100%**	**100%**	**100%**	**100%**

Appendix 2: Data for 2022-23

Table 17 shows that the percentages of RBC issued by 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 of 168. The use of different haemovigilance reporting processes across the jurisdictions may lead to these data inconsistencies.

Table 17: All adverse events by state, 2022-23

	ABO incompatible	AHTR	Allergic	Anaphylactic	DHTR	DSTR	FNHTR	Hypotensive	IBCT	Other	TACO	TAD	TRALI	TTI	All reports		Red blood cell issue
															Total	% of total adverse events	Percent
NSW	0	16	34	5	2	8	16	4	17	0	11	1	1	1	116	17.8%	31.1%
VIC	0	1	2	3	5	39	17	2	7	0	29	0	0	0	105	16.2%	27.2%
QLD	2	3	59	2	10	0	168	0	4	0	15	0	4	6	273	42.0%	20.3%
SA	0	0	23	0	2	0	4	2	8	19	8	1	0	0	67	10.3%	8.2%
WA	0	5	18	1	0	20	16	0	1	1	11	3	1	0	77	11.8%	8.9%
TAS	0	0	0	1	0	0	4	1	0	0	2	0	0	0	8	1.2%	2.1%
NT	0	0	0	0	0	0	2	0	0	0	1	0	0	0	3	0.5%	0.7%
ACT	0	0	0	0	0	0	0	0	0	0	1	0	0	0	1	0.2%	1.5%
Total	**2**	**25**	**136**	**12**	**19**	**67**	**227**	**9**	**37**	**20**	**78**	**5**	**6**	**7**	**650**	**100%**	**100%**

Table 18: All adverse events by age group, 2022-23

	ABO incompatible	AHTR	Allergic	Anaphylactic	DHTR	DSTR	FNHTR	Hypotensive	IBCT	Other	TACO	TAD	TRALI	TTI	Total
0-4 years	0	0	4	0	0	0	6	0	2	1	0	0	0	0	13
5-14 years	0	0	6	1	0	0	5	1	2	1	5	0	0	0	21
15-24 years	0	0	11	2	1	1	5	0	2	0	2	1	0	0	25
25-34 years	0	2	12	0	0	0	12	0	3	2	2	0	0	2	35
35-44 years	0	1	17	1	1	8	13	0	2	1	3	0	0	1	48
45-54 years	0	4	15	1	3	4	31	0	4	2	5	0	0	0	69
55-64 years	0	4	22	1	3	8	43	1	7	3	9	2	2	3	108
65-74 years	1	5	24	3	6	13	51	3	7	5	24	1	1	1	145
75 + years	1	9	24	3	5	33	61	4	8	5	28	1	3	0	185
Not stated	0	0	1	0	0	0	0	0	0	0	0	0	0	0	1
Total	**2**	**25**	**136**	**12**	**19**	**67**	**227**	**9**	**37**	**20**	**78**	**5**	**6**	**7**	**650**

Table 19: All adverse events by transfusion day and time, 2022-23

	Week day			Weekend			All days			
	Between 7am and 7pm	Between 7pm and 7am	Not stated	Between 7am and 7pm	Between 7pm and 7am	Not stated	Between 7am and 7pm	Between 7pm and 7am	Not stated	Total
ABO incompatible	2	0	0	0	0	0	2	0	0	2
AHTR	17	1	0	4	1	2	21	2	2	25
Allergic	80	25	13	10	7	1	90	32	14	136
Anaphylactic	6	4	0	0	2	0	6	6	0	12
DHTR	8	4	2	2	2	1	10	6	3	19
DSTR	20	20	5	6	13	3	26	33	8	67
FNHTR	129	42	5	38	13	0	167	55	5	227
Hypotensive	5	2	1	0	1	0	5	3	1	9
IBCT	12	11	6	5	3	0	17	14	6	37
Other	4	9	2	0	5	0	4	14	2	20
TACO	32	22	3	12	9	0	44	31	3	78
TAD	1	3	0	1	0	0	2	3	0	5
TRALI	2	2	0	2	0	0	4	2	0	6
TTI	6	1	0	0	0	0	6	1	0	7
Total	**324**	**146**	**37**	**80**	**56**	**7**	**404**	**202**	**44**	**650**
Percent	**49.8%**	**22.5%**	**5.7%**	**12.3%**	**8.6%**	**1.1%**	**62.2%**	**31.1%**	**6.8%**	**100%**

Table 20: All adverse events by blood product, 2022-23

	Number of adverse events						% of products				
Adverse Event	Red cells	Platelets	Fresh frozen plasma	Cryoprecipitate	Multiple products	Total	Red cells	Platelets	Fresh frozen plasma	Cryoprecipitate	Multiple products
ABO incompatible	2	0	0	0	0	2	0.4%	0.0%	0.0%	0.0%	0.0%
AHTR	22	2	0	0	1	25	4.5%	1.8%	0.0%	0.0%	7.7%
Allergic	50	55	23	4	4	136	10.2%	48.7%	82.1%	66.7%	30.8%
Anaphylactic	1	8	3	0	0	12	0.2%	7.1%	10.7%	0.0%	0.0%
DHTR	17	2	0	0	0	19	3.5%	1.8%	0.0%	0.0%	0.0%
DSTR	66	1	0	0	0	67	13.5%	0.9%	0.0%	0.0%	0.0%
FNHTR	194	30	1	0	2	227	39.6%	26.5%	3.6%	0.0%	15.4%
Hypotensive	4	2	0	1	2	9	0.8%	1.8%	0.0%	16.7%	15.4%
IBCT	34	1	0	0	2	37	6.9%	0.9%	0.0%	0.0%	15.4%
Other	17	3	0	0	0	20	3.5%	2.7%	0.0%	0.0%	0.0%
TACO	71	5	1	1	0	78	14.5%	4.4%	3.6%	16.7%	0.0%
TAD	4	0	0	0	1	5	0.8%	0.0%	0.0%	0.0%	7.7%
TRALI	6	0	0	0	0	6	1.2%	0.0%	0.0%	0.0%	0.0%
TTI	2	4	0	0	1	7	0.4%	3.5%	0.0%	0.0%	7.7%
All	**490**	**113**	**28**	**6**	**13**	**650**	**100%**	**100%**	**100%**	**100%**	**100%**

Table 21: Contributory factors by adverse event and by clinical outcome severity, 2022-23

Contributory factors	Adverse event														Clinical outcome severity					
	ABO incompatible	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	60	3	9	28	112	2	4	10	24	3	4	3	4	84	155	13	7	0
Product characteristic	0	21	51	8	9	38	48	6	13	1	26	2	1	2	27	97	82	11	8	1
Transfusion in emergency setting	0	1	2	0	0	1	4	1	9	2	3	0	0	0	4	8	8	1	2	0
Deliberate clinical decision	0	0	3	0	0	1	2	0	5	0	12	0	0	0	3	5	12	1	1	1
Prescribing/ordering	0	0	0	1	0	0	0	0	4	0	1	0	0	0	2	2	1	0	1	0
Specimen collection/labelling	1	0	0	0	0	0	0	0	2	0	0	0	0	0	1	2	0	0	0	0
Laboratory (testing/dispensing)	0	1	1	0	1	0	0	0	20	0	0	0	0	0	5	11	6	1	0	0
Transport, storage, handling	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Administration of product	0	0	19	0	1	0	47	1	6	3	11	0	1	1	8	17	57	6	2	0
Indications do not meet guidelines	0	0	1	1	0	2	1	0	5	0	1	0	0	0	3	4	2	0	2	0
Procedure did not adhere to hospital transfusion guidelines	1	0	1	0	0	0	1	0	14	0	3	0	0	0	4	10	4	2	0	0
Other	1	5	8	2	1	0	28	1	2	5	8	0	0	2	2	13	39	7	2	0

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

Appendix 3: 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 during specimen collection, in the transfusion laboratory or during administration 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. It is an 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.

Adverse Event	Definition – Where possible this is the ISBT Definition
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)	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 characterised 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.

Adverse Event	Definition – Where possible this is the ISBT Definition
Transfusion-associated circulatory overload (TACO)	TACO is characterised by any 4 of the following: • 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 characterised 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

Adverse Event	Definition – Where possible this is the ISBT Definition
	○ Acute pancreatitis ○ Cardiopulmonary bypass ○ Drug overdose 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 2022–23

Executive summary

Whilst blood donation is generally a safe process, there are recognised complications which can occur. Lifeblood's donor vigilance system monitors adverse events in blood donors that have a temporal relationship to blood donation. This report provides an overview of donor adverse event rates for the 2022-23 financial year, with data from the three previous years included for comparison. Events registered within 30 days of each reporting period are included in the analysis. The denominator cohort includes any donation where a needle-in attempt was registered in the National Blood Management System (NBMS), regardless of whether the donation was successful. In 2022-23 there were 1,635,893 donations meeting criteria for inclusion.

The analysis includes commentary on whether rate differences are statistically significant ($p<0.05$) from previous reporting periods. A statistical difference does not necessarily translate to a clinically significant change. Lifeblood's reporting process is very sensitive; the large cohort sizes enable even small differences to be detected. To assist in the interpretation of whether a statistical difference has clinical significance, the analysis includes unadjusted and standardised[1] rates, the number of donations for one additional (or one less) event and trend data.

In 2022-23, approximately 4% of donations (n=64,209) were associated with at least one donor adverse event. Standardised analysis shows that the total adverse event rate for each donation type, as well as individual rates for common events (including vasovagal, haematoma, painful arm and mild citrate reactions), have generally improved or remained stable since 2021-22. Specifically, there were improvements in phlebotomy injury rates which were considered clinically significant and considered the result of the implementation of the vein grading process in July 2022. The observed decrease in the whole blood vasovagal rate is considered to represent a normal variation. Of note, there has been an increase in the plateletpheresis infiltration rate which reflects mild events and is considered likely an impact of a reporting change.

Events that require outside medical care are considered a surrogate for more severe reactions. The standardised rate for whole blood events requiring outside medical care reduced significantly in 2022-23 compared with 2021-22. There were no significant differences in the rates for plasmapheresis or plateletpheresis.

[1] The unadjusted rate is the crude (actual) frequency observed in the reporting period and reflects the actual donor population contributing to collections in that period. Standardised rates[1] are based on a set reference population (in this report, it is based on the July 2021 donor population) and adjust for factors that are known to influence the risk of adverse events, such as donor gender, age and donation experience. Standardised rates therefore enable a more accurate comparison between time periods and provide more of the context to how Lifeblood is performing from an operational perspective. Comparing standardised rates is particularly important in this report given the large intake of new donors who became eligible to donate following the removal of the geographical UK deferral on 25 July 2022. In the first 6 months of 2022-23, there were 25,537 new and 4,724 returned UK donors with a mean age of 49 and 58 respectively.

Overview of total event rates by donation type

In 2022-23, approximately 4% of donations (n=64,209) were associated with at least one donor adverse event. Unadjusted figures showed that the total donor adverse event rate for whole blood and plasmapheresis in 2022-23 was significantly lower than in 2021-22 and the rate for plateletpheresis, significantly higher than in 2021-22 [Table 1]. Standardised data similarly showed a significant reduction in the overall rate for whole blood and plasmapheresis, but in contrast demonstrated no significant difference for plateletpheresis [Table 2]. The rate of unique events by donation type are provided in the Appendix [Tables 1 and 2].

Table 1: Unadjusted total adverse event rates per 10,000 donations

	Rate per 10,000 donations				Comparison 2022-23 to 2021-22		
Donation type	**19-20**	**20-21**	**21-22**	**22-23**	**RR[2] (95% CI[3]; p value)**	**Number of donations for one additional event***	**% Change**
Whole blood	322.74	297.56	315.31	286.83	0.91 (0.89-0.93; p<0.001)	-351	-9.03%
Plasmapheresis	455.88	525.55	493.82	475.36	0.96 (0.95-0.98; p<0.001)	-542	-3.74%
Plateletpheresis	990.15	870.66	704.12	760.61	1.08 (1.01-1.15; p=0.02)	+177	+8.02%
Total	405.17	429.57	413.92	392.50	0.95 (0.94-0.96; p<0.001)	-467	-5.31%

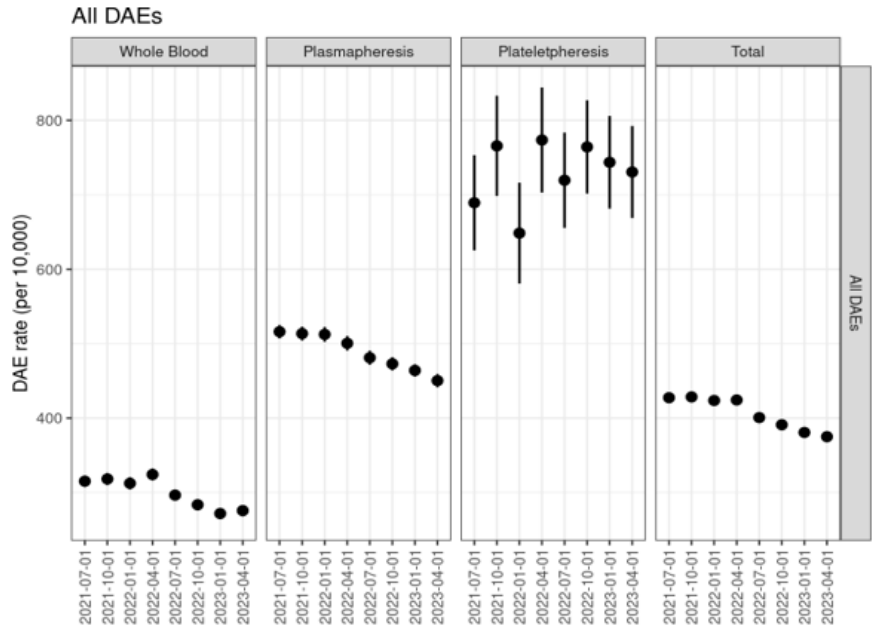
*a negative number indicates that the number of donations is for one less event
[2] Relative risk
[3] Confidence interval

Table 2: Standardised* total adverse event rates per 10,000 donations

	Rate per 10,000 donations		Comparison 2022-23 to 2021-22		
Donation type	**21-22**	**22-23**	**RR (95% CI; p value)**	**Number of donations for one additional event**	**% Change**
Whole blood	327.00	291.82	0.89 (0.88-0.91; p<0.001)	-284	-10.76%
Plasmapheresis	513.31	469.24	0.91 (0.90-0.93; p<0.001)	-227	-8.59%
Plateletpheresis	722.32	740.23	1.02 (0.96-1.09; p=0.45)	+558	+2.48%
Total	431.72	392.52	0.91 (0.90-0.92; p<0.001)	-255	-9.08%

*Variables used to calculate standardised rates: Donor age, gender, donation type, no. previous donations, and TB

Figure 1: Plot graph for quarterly standardized rates for total adverse events per 10,000 donations



General trends for more common events by donation type

Whole blood

The reduction in the unadjusted total rate for whole blood is primarily attributed to reductions in rates for vasovagal (181.9 vs 196.6 per 10,000), haematoma (76.4 vs 83.5 per 10,000) and painful arm (20.6 vs 28.3 per 10,000). Standardising demonstrated a significant relative risk reduction in each of these events in 2022-23, translating to one less vasovagal, haematoma and painful arm event, for every 637, 1,063 and 1,276 whole blood donations respectively.

Plasmapheresis

The reduction in the unadjusted total rate for plasmapheresis was a net effect of the rate reduction in haematoma (132.1 vs 157.1 per 10,000) and painful arm (55.8 vs 68.8 per 10,000), offset in part by a rate increase in vasovagal (112.7 vs 104.5 per 10,000), infiltration (80.6 vs 75.1 per 10,000) and mild citrate events (110.3 vs 103.7 per 10,000). After standardising there was no difference in infiltration rates or vasovagal rates. Standardising also demonstrated a significant relative risk reduction in haematoma, painful arm and mild citrate reactions in 2022- 23, translating to one less event for every 313, 680 and 1,939 plasmapheresis donations respectively.

Plateletpheresis

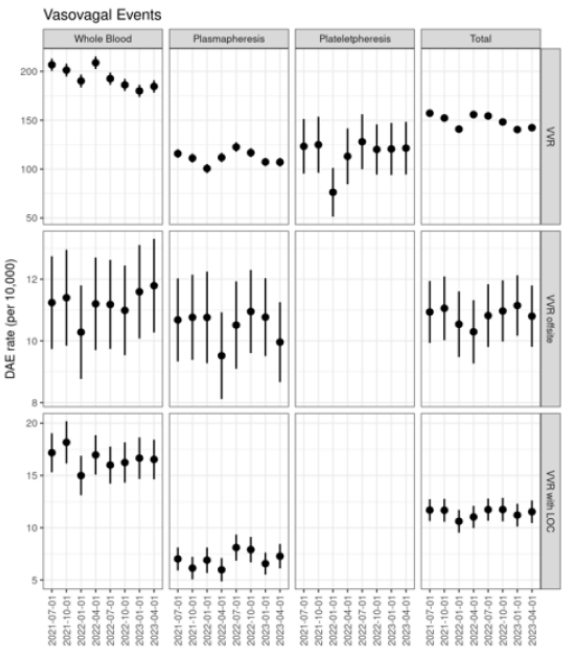
The increase in the unadjusted total rate for plateletpheresis primarily related to increases in vasovagal, citrate and infiltration rates, offset to some degree by a reduction in the haematoma rate. Standardising did not demonstrate a significant difference in vasovagal or citrate rates. The (standardised) relative risk of an infiltration event in 2022-23 was 1.42 (1.16-1.73; p<0.001) which translated to an additional event every 347 donations. There was one infiltration event requiring outside medical care in 2022-23, suggesting the increase was in mild events. The increase followed a change to the follow up process for infiltration events. It is likely this led to more infiltration events being identified and classified correctly, where previously they were reported as haematoma events. A similar effect was seen in plasmapheresis following education on infiltration in late 2020, which was plasmapheresis focussed. Whilst considered reporting-related, surveillance will continue, and a structured training program will be delivered aiming to improve expertise and consistency in plateletpheresis collection.

General trends for vasovagal subtype events

Figure 2 shows the two-year adjusted rate trend for all vasovagal events, those that occurred offsite and those associated with loss of consciousness (LOC). There was a significant increase in both the unadjusted (7.6 vs 6.3 per 10,000) and adjusted rates (7.6 vs 6.7 per 10,000) for plasmapheresis events associated with loss of consciousness. However, all things considered equal, these rates continue to remain lower than those observed in whole blood.

Whilst there was an increase in the unadjusted rate of offsite events for both whole blood and plasmapheresis, there was no difference once standardised. There was also no difference in the unadjusted rates for events requiring outside medical care for any donation type. Standardised rates for outside medical care were not analysed due to small event numbers.

Figure 2: Vasovagal event rate by donation type



Outside medical care

The rate for events requiring outside medical care is a surrogate for more serious events. The total unadjusted rate for each donation type was not significantly different to 2021-22 [Table 3]. The standardised rate showed a significant reduction in the rate for whole blood and the overall rate [Table 4]. The rate for outside medical is higher in newer donors and females and in particular increases with age after the age of 50. Of events requiring outside medical care across all donation types, 41.2%, 45.0% and 11.3% required a hospital attendance, GP visit and in-centre ambulance call respectively. Of the 831 events reported in 2022-23, vasovagal was reported in 64%, nerve injury in 10%, infiltration in 7.6%, haematoma in 6.3% and chest pain in 5.8%. Review of data to December 2022, showed the reduction in rates for outside medical care observed since 2019-20 reflect a reduction in Lifeblood referred GP and hospital attendances, rather than donor-initiated visits.

Table 3: Unadjusted adverse event rates for all events requiring outside medical care

	Rate per 10,000 donations				Comparison 2022-23 to 2021-22		
Donation type	19-20	20-21	21-22	22-23	RR (95% CI; p value)	Number of donations for one additional event	% Change
Whole blood	7.78	7.22	5.87	5.44	0.93 (0.81-1.06; p=0.27)	-23,334	-7.30%
Plasmapheresis	6.53	6.31	4.87	4.79	0.98 (0.86-1.13; p=0.82)	-128,256	-1.60%
Plateletpheresis	4.00	6.75	4.45	3.93	0.88 (0.37-2.12; p=0.78))	-19,411	-11.58%
Total	7.05	6.72	5.33	5.08	0.95 (0.87-1.05; p=0.33)	-40,177	-4.64%

Table 4: Standardised* total adverse event rates for all events requiring outside medical care

	Rate per 10,000 donations		Comparison 2022-23 to 2021-22		
Donation type	21-22	22-23	RR (95% CI; p value)	Number of donations for one additional event	% Change
Whole blood	5.90	5.11	0.87 (0.76-0.99; p=0.04)	-12,602	-13.44%
Plasmapheresis	4.97	4.42	0.89 (0.77-1.02; p=0.09)	-18,087	-11.13%
Plateletpheresis	4.54	3.69	0.81 (0.34-1.96; p=0.65)	-11,889	-18.55%
Total	5.39	4.72	0.88 (0.80-0.97; p<0.01)	-15,017	-12.36%

*Variables used to calculate standardised rates: Donor age, gender, donation type, no. previous donations, and TBV

Conclusion

In general, the adverse event rates are similar to, or improved, from the previous year. The decrease in phlebotomy injury rates are considered clinically significant and considered the result of the implementation of a process for vein grading in July 2022 which identified when it was appropriate for more experienced phlebotomist to undertake the venipuncture. As part of Lifeblood's continuous improvement in donor vigilance, in 2023-24, Lifeblood will commence the transition to a new severity classification that aligns with international reporting. This will improve our ability to report by event severity, target specific at-risk cohorts for mitigation strategies and improve capacity to benchmark against international blood services.

APPENDIX

Table 1: Unique adverse event rates for 2022-23 per 10,000 donations and unit change from 2021-22

Event type	Whole Blood n= 757,454		Plasmapheresis n= 853,012		Plateletpheresis n= 25,427		Total n=1,635,893	
	Event (n)	Rate (change)	Event (n)	Rate (change)	Event (n)	Rate (change)	Event (n)	Rate (change)
Vasovagal events								
VVR	13,778	181.90 -14.74	9,615	112.72 +8.19	309	121.52 +16.11	23,702	144.89 -2.41
VVR with LOC	1,259	16.62 -0.59	648	7.6 +1.27	22	8.65 -0.24	1,929	11.79 +0.37
Phlebotomy Related								
Arterial Puncture	36	0.48 -0.04	14	0.16 -0.06	0	0.00 0.00	50	0.31 -0.05
Cellulitis	1	0.01 -0.03	10	0.12 +0.11	0	0.00 0.00	11	0.07 +0.04
Delayed Bleeding	86	1.14 -0.55	130	1.52 -0.47	1	0.39 -0.94	217	1.33 -0.52
Haematoma	5,785	76.37 -7.10	11,269	132.11 -24.95	550	216.31 -23.0	17,604	107.61 -16.45
Nerve injury/irritation	899	11.87 -0.22	1,647	19.3 +1.57	23	9.05 -2.07	2,569	15.7 +0.68
Other phlebotomy injury	44	0.58 +0.07	66	0.77 -0.22	0	0.00 0.00	110	0.67 -0.09
Painful arm	1,559	20.58 -7.76	4,762	55.83 -12.97	119	46.8 +3.66	6,440	39.37 -10.29
Thrombophlebitis	33	0.44 +0.12	39	0.46 +0.01	2	0.79 +0.79	74	0.45 +0.08
Other Event Type								
Anaphylaxis	0	0.00 -0.01	2	0.02 +0.02	0	0.00 0.00	2	0.01 +0.01
Chest Pain	35	0.46 -0.12	56	0.66 -0.08	1	0.39 -1.83	92	0.56 -0.12
Local Allergic Reaction	79	1.04 -0.15	170	1.99 -0.21	3	1.18 +0.74	252	1.54 -0.17
Other event/injury	99	1.31 +0.06	172	2.02 +0.09	0	0.00 -3.56	271	1.66 +0.02

Table 2: Apheresis-specific rates per 10,000 donations and unit rate change from 2021-22.

Event type	Plasmapheresis n= 853,012		Plateletpheresis n= 25,427		Total n=878,439	
	Event (n)	Rate (change)	Event (n)	Rate (change)	Event (n)	Rate (change)
Haemolysis	26	0.30 -0.36	0	0.00 0.00	26	0.30 -0.35
Infiltration	6,876	80.61 +5.56	255	100.29 +32.23	7,131	81.18 +6.31
Mild Citrate Reaction	9,407	110.28 +6.59	812	319.35 +45.79	10,219	116.33 +8.17
Moderate/severe Citrate Reaction	359	4.21 +0.38	65	25.56 +9.55	424	4.83 +0.68
Omitted Anticoagulant	12	0.14 -0.10	1	0.39 -1.39	13	0.15 -0.13

ANNEX 1 - State/territory haemovigilance process improvement

In 2022-23, state/territory departments of health continue to improve their process for haemovigilance data collection and reporting.

NSW

The reporting period included periods of activity associated with the pandemic response, where there were limited opportunities for improvements. However, the following improvements are noted:

- No identified incidents related to Incorrect Blood Component Transfused to patients in the operating theatre. This was previously highlighted as a high-risk patient population. Safety Information 06/2021 Patient identity checks before administration of blood products
- NSW Health Pathology now report delayed serological transfusion reactions to the Incident Management System (ims+) and, are included in this NSW data submission.
- The CEC updated and published Information for staff managing: Transfusion related notifications in ims+ in September 2023, to assist facilities with their haemovigilance reporting requirements. Improvements in data quality will be evaluated with the 2023-24 data submission.

VIC

During 2023, STIR has commenced a review of all reporting forms to ensure adequate information for reviewers and validation.

Bulletins relating to wrong blood in tube events and the checking procedure for blood products to reduce incorrect blood component transfused events were published.

Interim reports, sent to submitting health services, have also been reviewed to clarify these reports for the finalised data reports.

QLD

The strategies implemented across 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 a Haematologist, Pathology Scientist and Transfusion Clinical Nurse Consultant (CNC).
- Continuation of participation in the National Haemovigilance Program as part of NSQHS Standard 7 – Blood Management (NSQHS Standard 7) and alignment with the national framework provided by the National Safety and Quality Health Service 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.

TAS

The Tasmanian Health Service Safety Learning and Reporting System records and ensures safety events, including blood safety events, are followed up and appropriately actioned.

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 adverse 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 health service provider 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 reactions has decreased from 11 in the 2021-22 period (2 x IBCT, 2 x TACO, 2 x FNHTR, 1 x Anaphylaxis, 2 x Allergic, 1 x ATR ('Haemolytic'), and 1 x 'other to 3 in the 2022 –23 period (1 x TACO and 2 x FNHTR).

All reported transfusion reactions are investigated and discussed at the Transfusion Incident Review Group (TIRG) meetings, and when deemed appropriate, at the NT Transfusion Committee (NTTC) meetings. NT is part of the Blood Matters STIR reporting group. All the above 3 mentioned transfusion reactions 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.

ACT

A draft ACT wide Haemovigilance Framework (Framework) has been developed. The Framework outlines the requirements for Haemovigilance reporting in the ACT and will be provided to each of the ACT's hospitals for broader consultation, along with an invitation to each hospital to formally contribute to the ACT's existing reporting process into the national haemovigilance program.

ANNEX 2 - 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

ANNEX 3 - Acknowledgements List

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. For further information refer to the NBA Website or strategic-framework-for-national-haemovigilance-program.pdf.

National Blood Authority Haemovigilance Advisory Committee (HAC)

Members

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

Expert Advisors

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Australian Government and State and Territory contributors

NSW Health Clinical Excellence Commission Blood Watch Program
VIC Department of Health and Human Services Blood Matters Program
QLD Health
SA Health BloodSafe Program
WA Department of Health
TAS Department of Health
ACT Health
NT Department of Health

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