NATIONAL BLOOD AUTHORITY
AUSTRALIA

AUSTRALIAN HAEMOVIGILANCE REPORT

Data for 2023-24

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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 2023-24 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 2014-15 to 2023-24. One in ten (643 out of 6,475) of all reported transfusion adverse events are SAEs. The percentage of reported life-threatening and SAEs has dropped from 14% in 2016-17 to 9% in 2023-24.

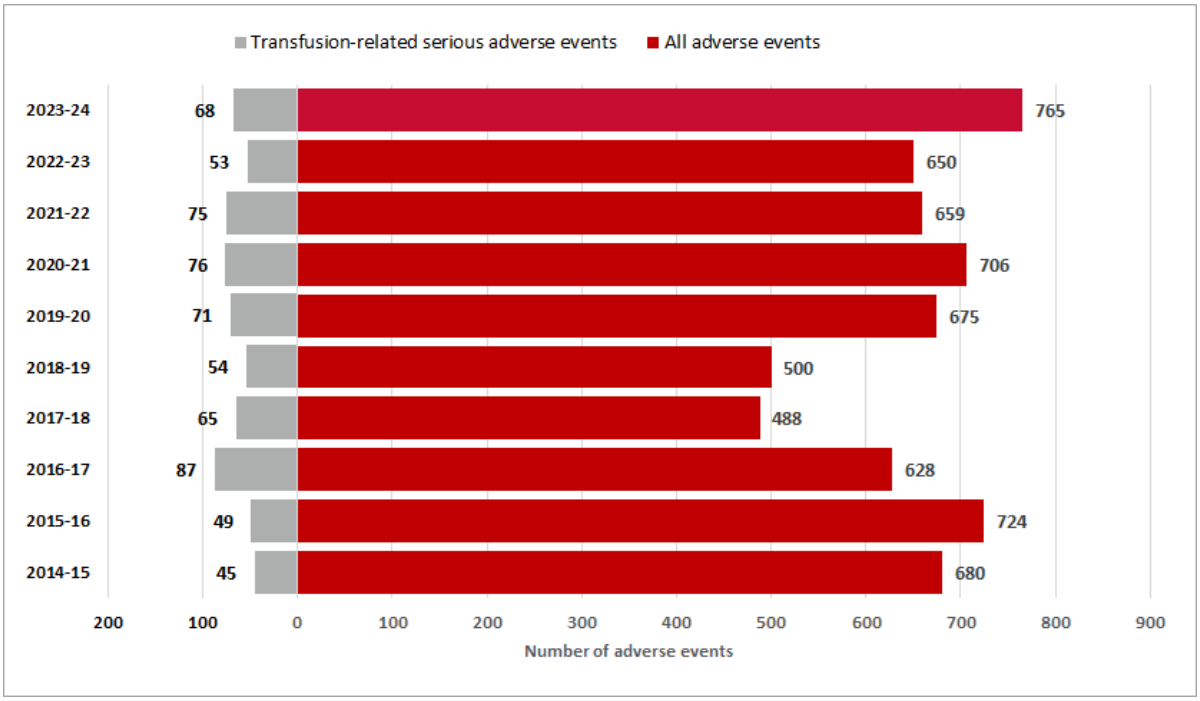


Figure 1: All reported adverse events and transfusion-related serious adverse events, 2014-15 to 2023-24

Figure 2 shows the percentage of all reported adverse events by year from 2019-20 to 2023-24. Febrile non-haemolytic transfusion reaction (FNHTR) and allergic reactions accounted for 62.3% of all reported adverse events (2,153 of 3,455). Transfusion-associated circulatory overload (TACO) and anaphylactic reactions accounted for 10.7% (369 of 3,455) and 3.1% (107 of 3,455) of all adverse events respectively. Refer to **Appendix 1 Table 3** for detailed adverse event data from 2019-20 to 2023-24.

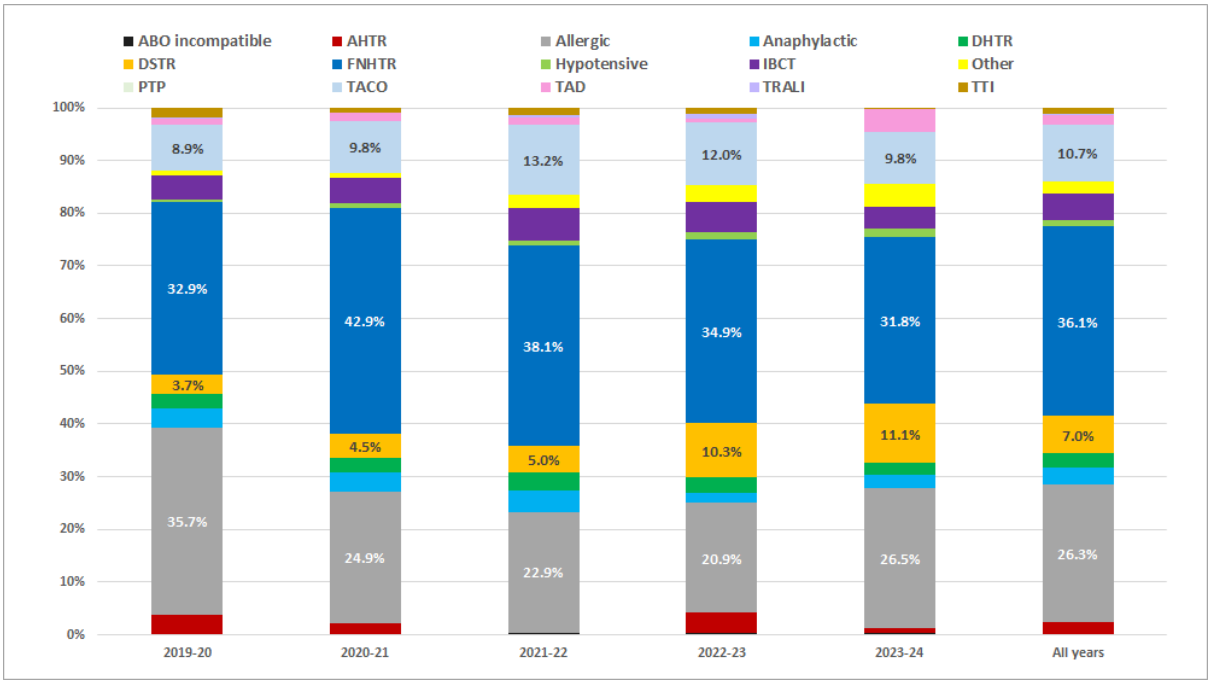


Figure 2: Percentage of all reported adverse events by year, 2019-20 to 2023-24

Figure 3 shows that TACO and anaphylactic reactions accounted for 52.8% of total transfusion-related SAEs (181 of 343). FNHTR and allergic reactions accounted for 28.9% of total transfusion-related SAEs (99 of 343). Refer to **Appendix 1 Table 4** for detailed transfusion-related SAE data from 2019-20 to 2023-24.

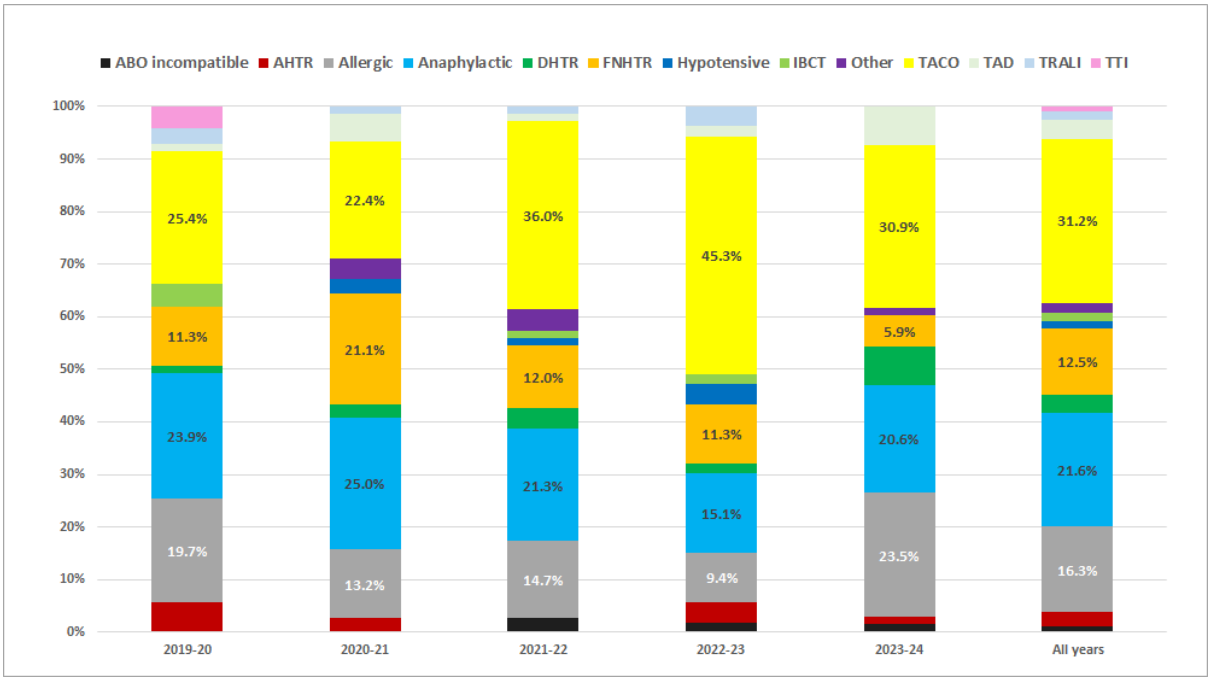


Figure 3: Percentage of transfusion-related serious adverse events by year, 2019-20 to 2023-24

Figure 4 shows the number of all reported adverse events by hospital type from 2019-20 to 2023-24. Public hospitals reported 88% of adverse events (3,032 of 3,455), compared with 12% reported by private hospitals (423 of 3,455).

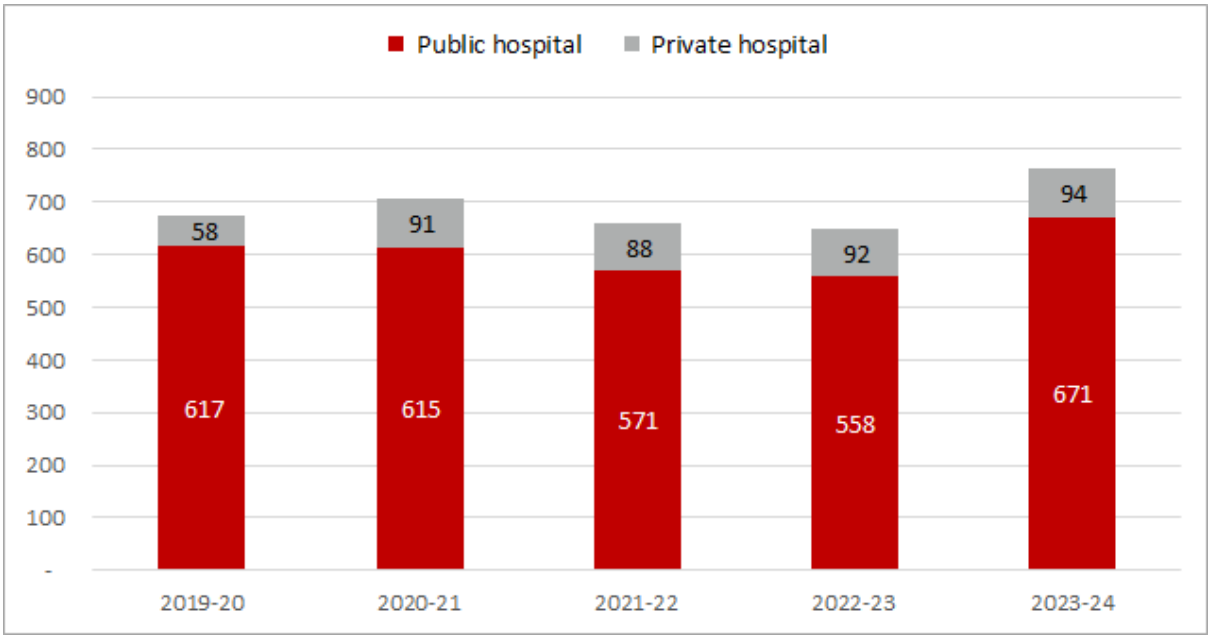


Figure 4: All reported adverse events by hospital type, 2019-20 to 2023-24

Figure 5 shows all reported adverse events and SAEs by state and territory from 2019-20 to 2023-24. Queensland (QLD) reported the most adverse events (1,459 of 3,455 or 42%). Victoria (VIC) reported the most SAEs (113 of 343 or 33%).

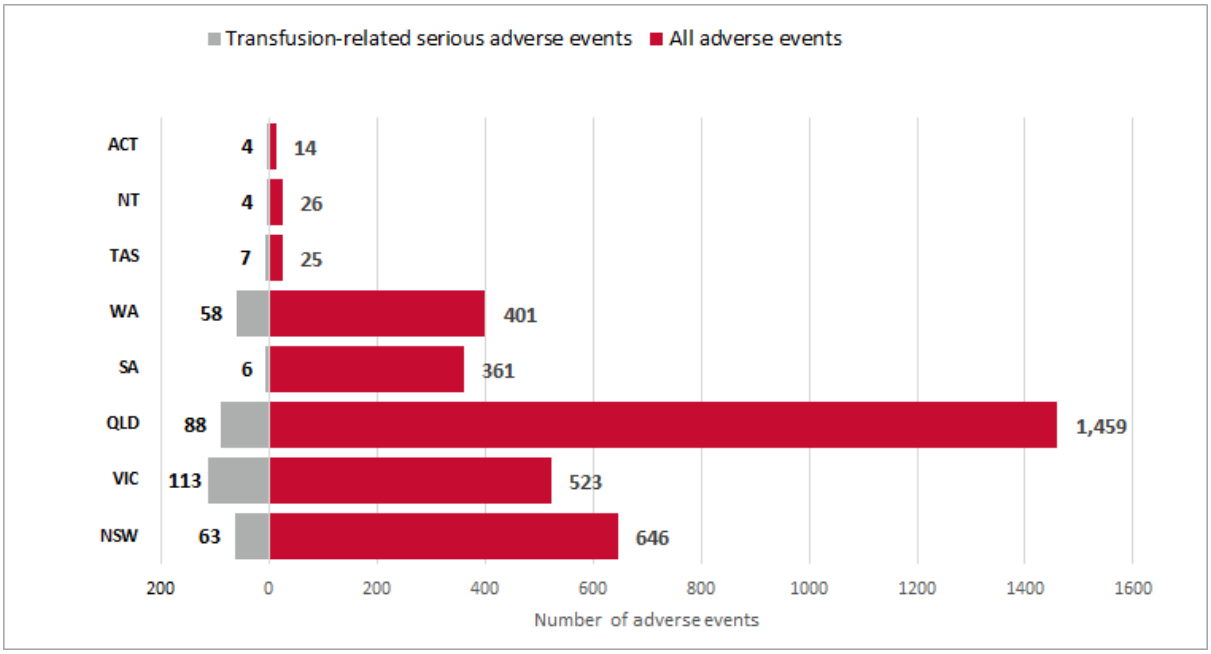


Figure 5: Number of adverse events and transfusion-related serious adverse events by state and territory, 2019-20 to 2023-24

TACO is the leading cause of SAEs in Australia and is 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 2024 Annual SHOT Report.

TACO Risk Assessment		YES	NO
	Does the patient have any of the following?: diagnosis of 'heart failure', congestive cardiac failure (CCF), left ventricular dysfunction, aortic stenosis, or any other heart valve disease		
	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 a low serum albumin level?		
	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 red cell transfusion: ensure appropriate indication and volume is prescribed (adults)

Indication code for transfusion	Target Hb	Dosing advice
Acute anaemia (R2)	Post-transfusion target Hb 70 - 90g/L	Body weight dosing (max 2 units)
Acute anaemia (R3: with acute MI/ACS)	Post-transfusion target Hb 80 - 100g/L	Body weight dosing (max 2 units)
Severe symptomatic chronic anaemia (R7)	No target Hb - minimum transfusion	Usually single unit only
Regular transfusion programme (R4)	Individualised target Hb	Body weight dosing (max 2 units)

Other measures to mitigate TACO: ASSIGN ACTION AS APPROPRIATE	TICK
Review patient after each unit (red cells) and review symptoms of anaemia. Is further transfusion necessary?	
Measure the fluid balance	
Consider a prophylactic diuretic (where appropriate/not contraindicated)	
Monitor the 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:	

TACO=transfusion-associated circulatory overload; MI=myocardial infarction; ACS=acute coronary syndrome; Hb=haemoglobin

SECTION 1

Australian Haemovigilance Data

Introduction

From 2019-20 to 2023-24, 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, followed by platelets and fresh frozen plasma (FFP).

Table 1: Issues by fresh blood products, 2019-20 to 2023-24

	Number of issues					% of issues				
	2019-20	2020-21	2021-22	2022-23	2023-24	2019-20	2020-21	2021-22	2022-23	2023-24
RBC	629,609	659,611	663,530	686,730	703,596	65.3%	65.0%	65.7%	65.4%	65.0%
Platelets	138,210	145,056	140,504	147,893	155,143	14.3%	14.3%	13.9%	14.1%	14.3%
Fresh frozen plasma	85,314	85,151	82,552	87,608	86,386	8.8%	8.4%	8.2%	8.3%	8.0%
Cryoprecipitate	106,818	119,477	119,275	122,760	132,371	11.1%	11.8%	11.8%	11.7%	12.2%
Cryo-depleted plasma	4,263	6,032	3,713	4,798	4,879	0.4%	0.6%	0.4%	0.5%	0.5%
All products	**964,214**	**1,015,327**	**1,009,574**	**1,049,789**	**1,082,375**	**100%**	**100%**	**100%**	**100%**	**100%**

Note: Data from Australian Red Cross Lifeblood for fresh blood products issued to Australian Health Providers under contract to the NBA

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 2019-20 to 2023-24, and for 2023-24 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.

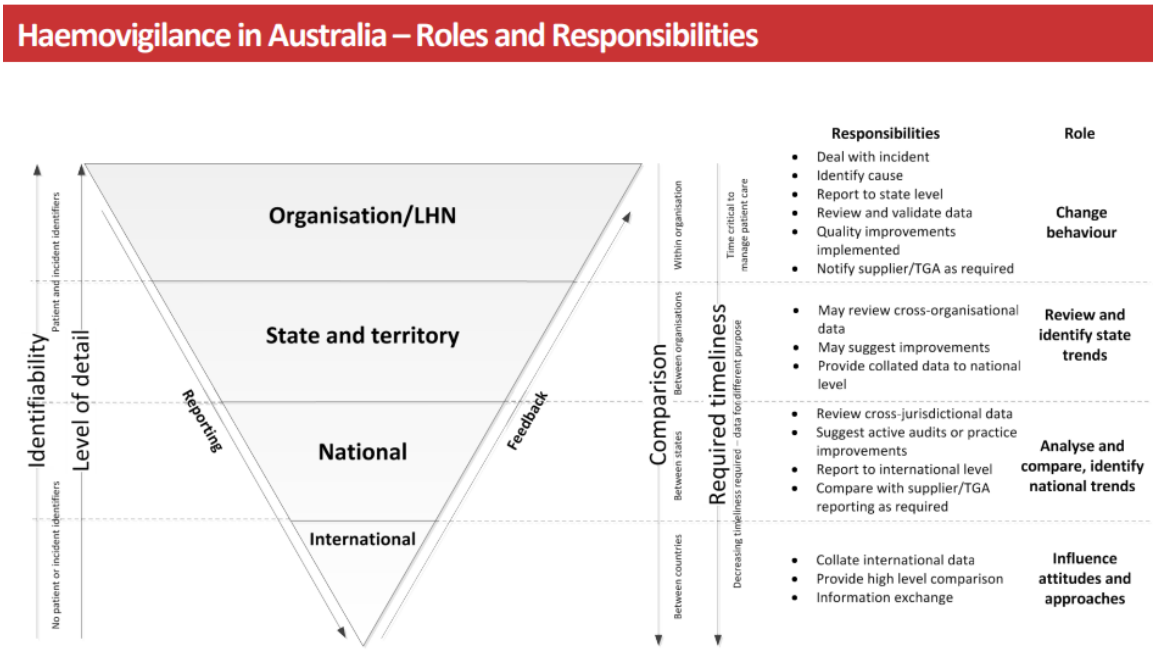
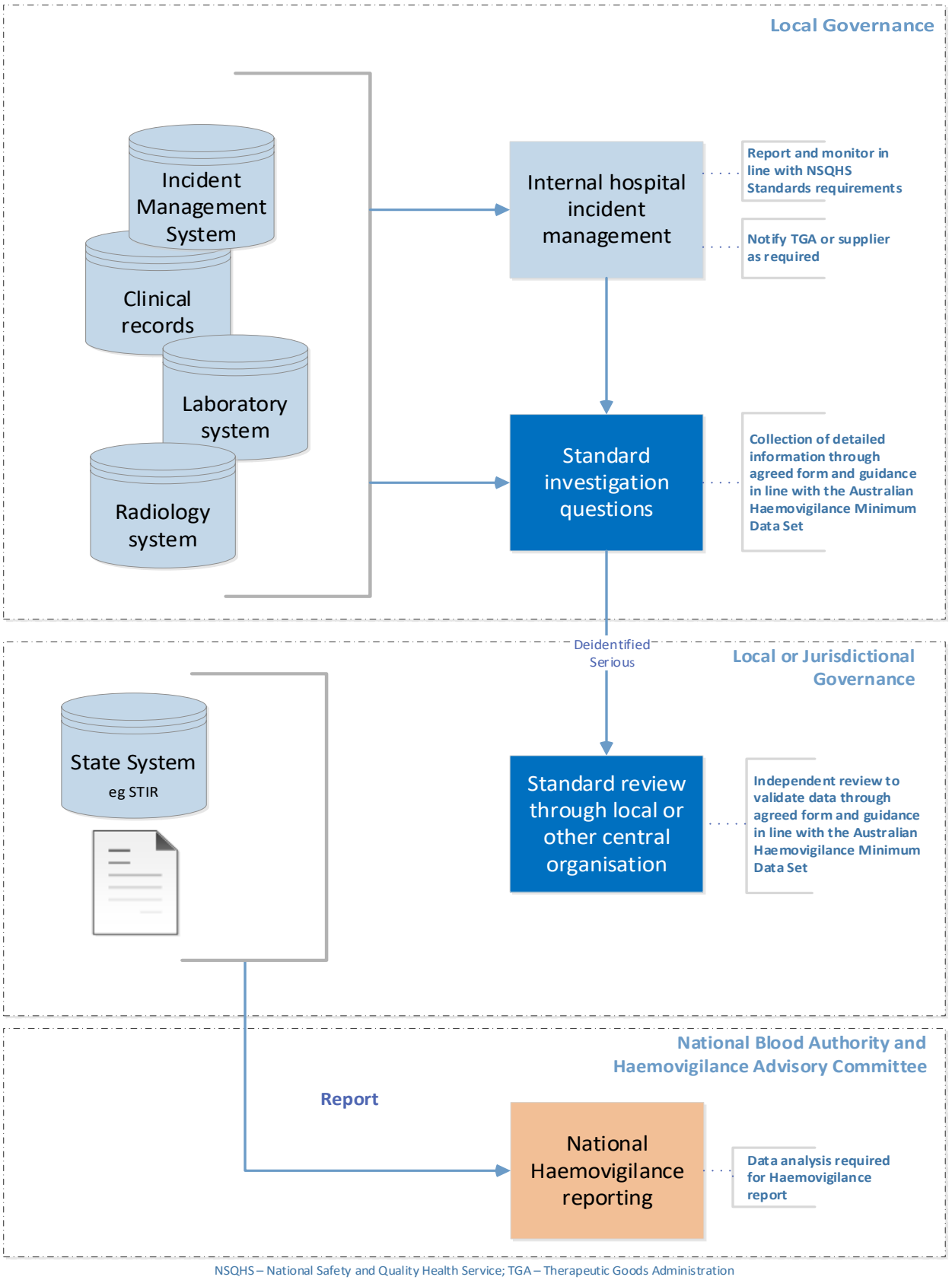


Figure 6: Haemovigilance in Australia – Roles and Responsibilities

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.
- All states and territories have contributed data to the NBA since 2015-16. However, the level of details 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 2023-24 transfusion-transmitted infection (TTI) data have been verified with the states and territories.
- 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.
- QLD has consistently reported a disproportionately higher number of transfusion-related adverse events, particularly FNHTRs, compared to other Australian jurisdictions. This difference stems primarily from QLD's comprehensive haemovigilance reporting coverage across both its public and private hospital sectors, and its inclusive practice of reporting non-serious FNHTRs. The AHMDS does not explicitly prohibit the submission of non-serious FNHTRs for national reporting. Other jurisdictions typically limit their national reporting to only serious FNHTRs.

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. The majority of participating and reporting hospitals are public. 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 hospitals 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.

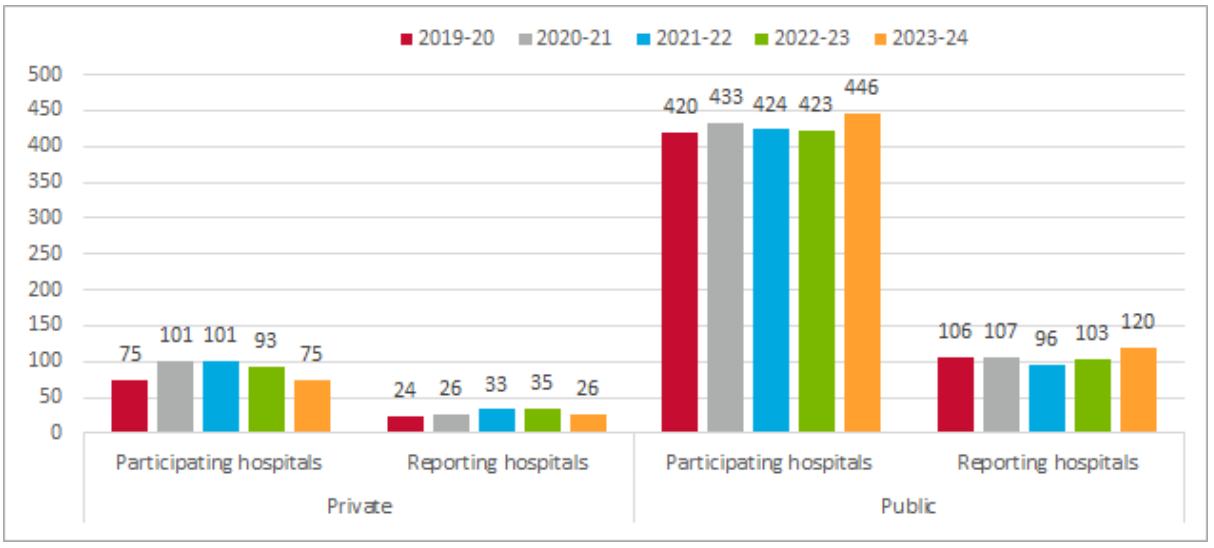
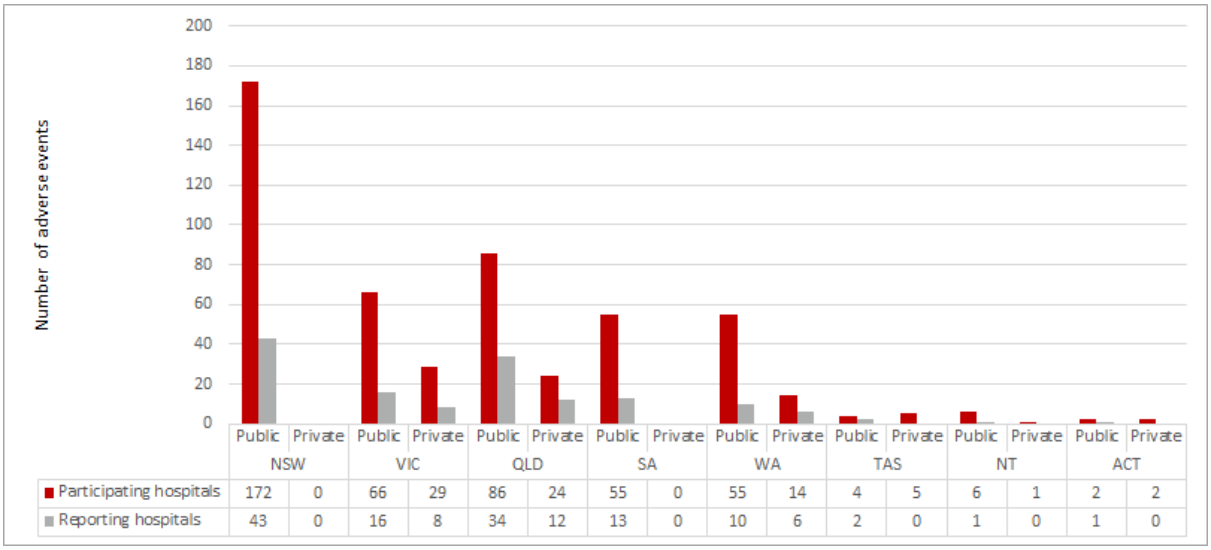


Figure 8: Number of participating and reporting hospitals by public/private and state/territory, 2019-20 to 2023-24

Figure 9 presents hospital participating and reporting data for states and territories in 2023-24. A total of 521 hospitals participated in national haemovigilance reporting, including 446 public hospitals and 75 private hospitals. Of these, 28% of participating hospitals (146 hospitals) reported adverse events, comprising 120 public hospitals and 26 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, 5.2 adverse events per hospital were reported for 2023-24. This varied between states and territories, ranging from 1.0 in NT to 6.5 in QLD in **Figure 10.**



	Public	Private	Public	Private	Public	Private	Public	Private	Public	Private	Public	Private	Public	Private	Public	Private
	NSW		VIC		QLD		SA		WA		TAS		NT		ACT	
Participating hospitals	172	0	66	29	86	24	55	0	55	14	4	5	6	1	2	2
Reporting hospitals	43	0	16	8	34	12	13	0	10	6	2	0	1	0	1	0

Figure 9: Number of participating and reporting hospitals by public/private and state/territory, 2023-24

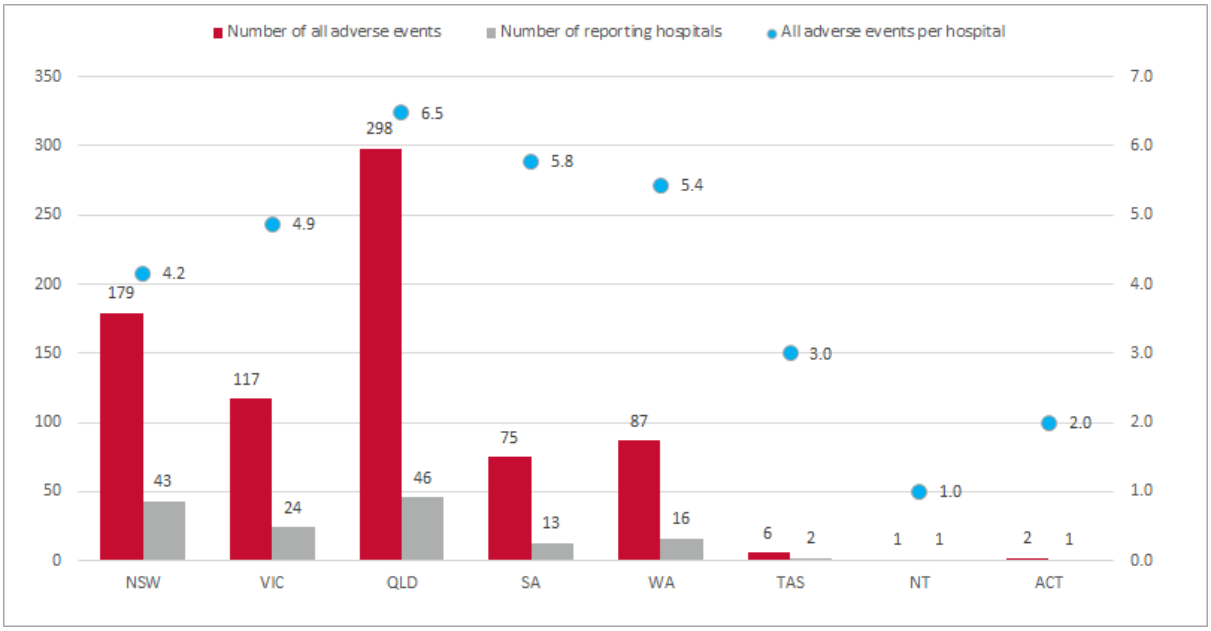


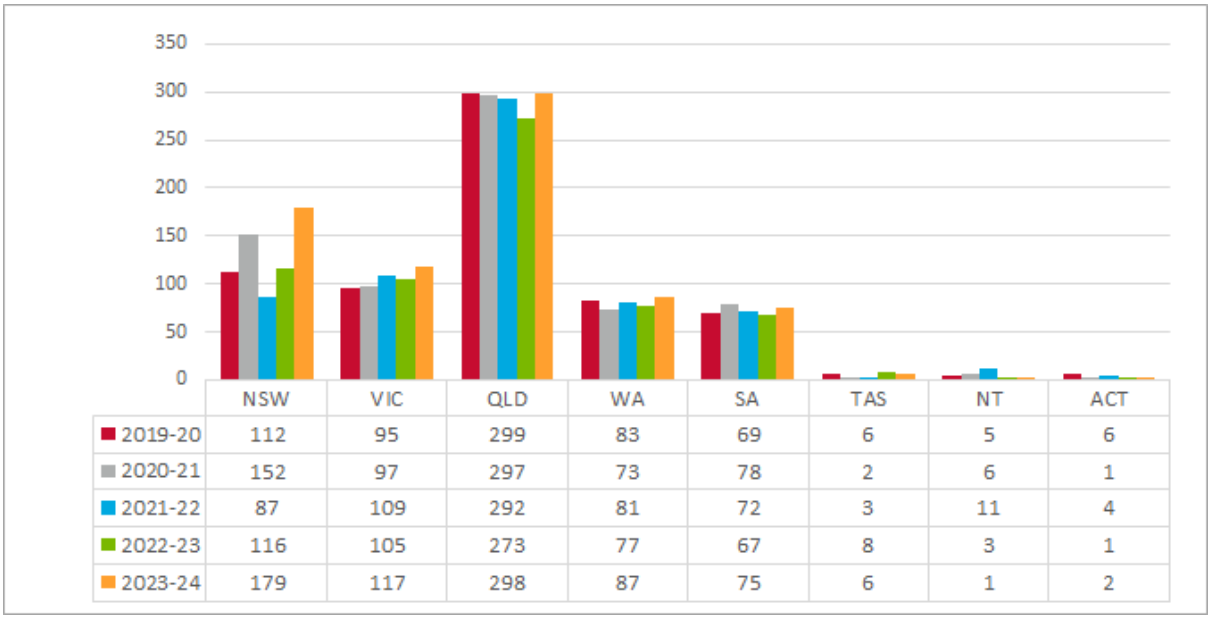
Figure 10: Number of adverse events per hospital by state/territory, 2023-24

Results for all adverse events, 2019-20 to 2023-24

This section presents the data and key results for all reported adverse events between 2019-20 and 2023-24.

Eight states and territories reported 3,455 transfusion adverse events of 15 different types to the National Haemovigilance Program events between 2019-20 and 2023-24.

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 2019-20 to 2023-24 and **Appendix 2 Table 17** for the detailed state adverse event data for 2023-24.



	NSW	VIC	QLD	WA	SA	TAS	NT	ACT
2019-20	112	95	299	83	69	6	5	6
2020-21	152	97	297	73	78	2	6	1
2021-22	87	109	292	81	72	3	11	4
2022-23	116	105	273	77	67	8	3	1
2023-24	179	117	298	87	75	6	1	2

Figure 11: All adverse events by state, 2019-20 to 2023-24

Figure 12 illustrates that adverse events reported for female patients increased from 267 in 2019-20 to 418 in 2023-24, while those for unknown sex declined from 87 in 2019-20 to 5 in 2023-24.

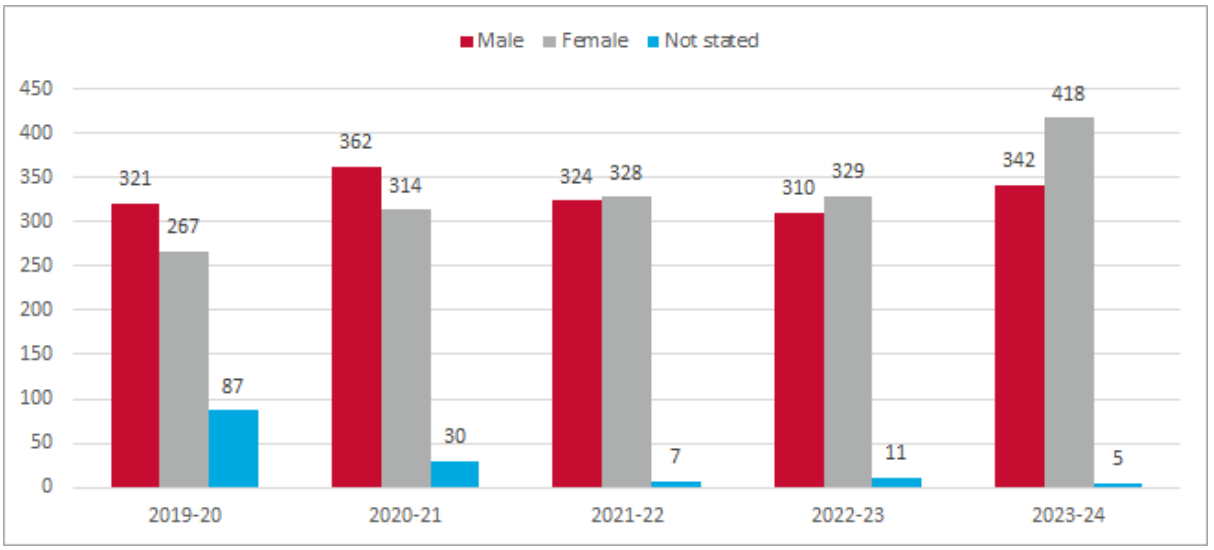


Figure 12: All adverse events by sex, 2019-20 to 2023-24

Thirty per cent (1,021 of 3,455) 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 2019-20 to 2023-24.

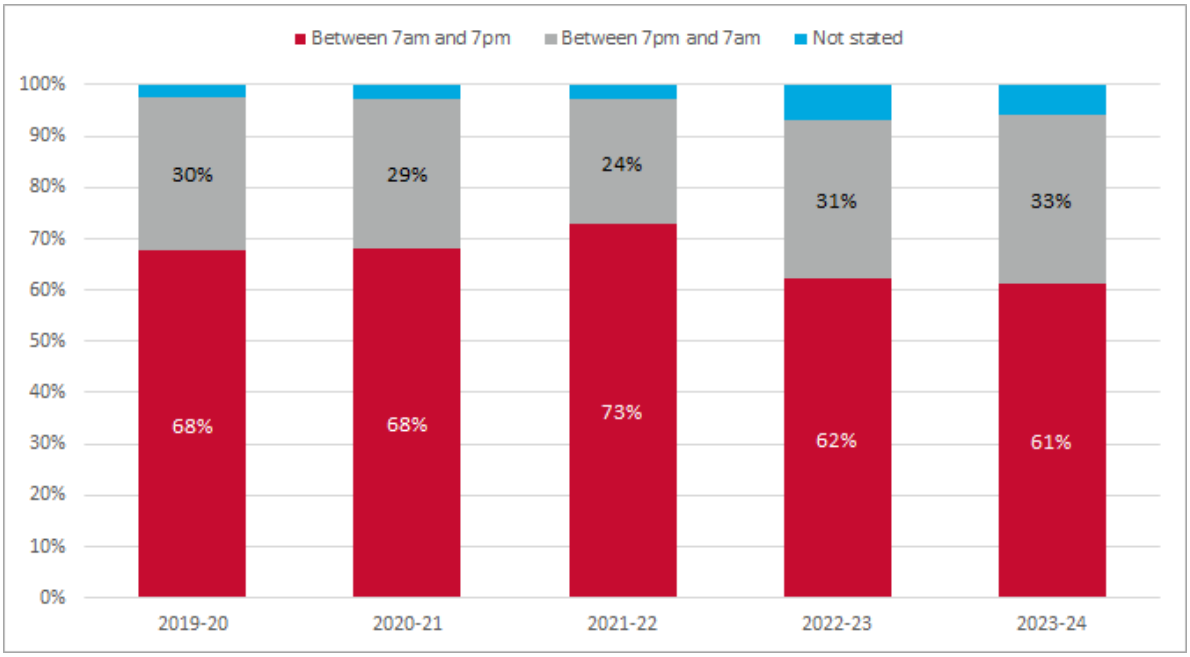


Figure 13: All adverse events by transfusion time, 2019-20 to 2023-24

Figure 14 presents that 22% (754 of 3,455) of reported adverse events occurred during weekend transfusions. Refer to **Appendix 1 Table 10** for detailed transfusion weekday/weekend data from 2019-20 to 2023-24.

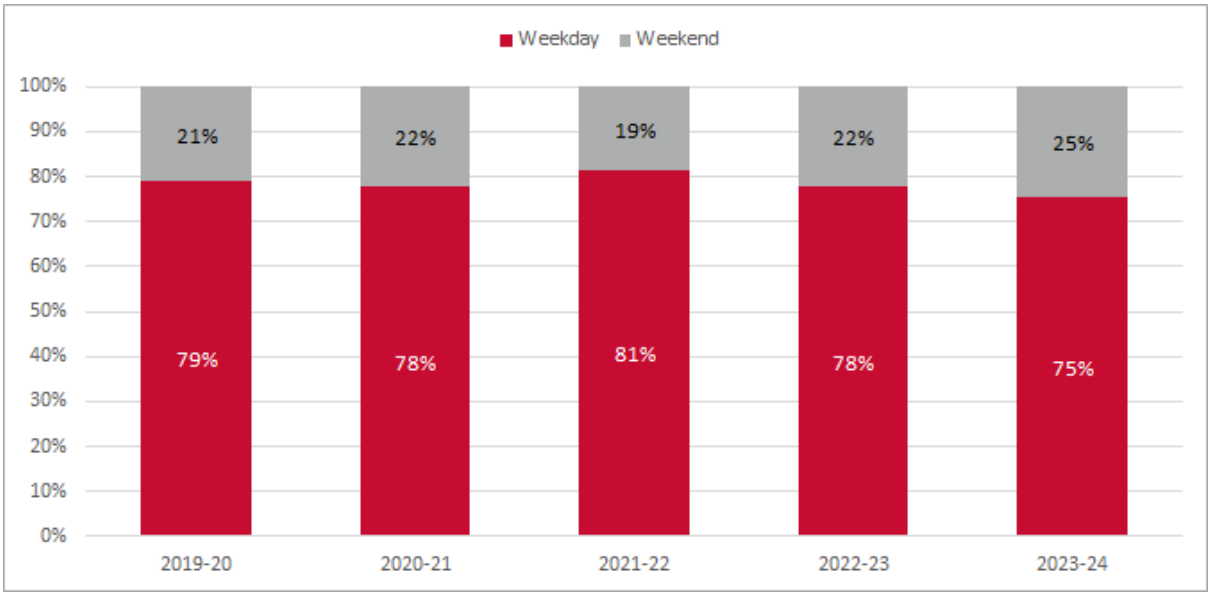


Figure 14: All adverse events by weekday/weekend, 2019-20 to 2023-24

Figure 15 shows that 76% (2,622 of 3,455) of reported adverse events occurred in major cities across Australia. Refer to **Appendix 1 Table 11 Parts 1 to 3** detailed remoteness data from 2019-20 to 2023-24.

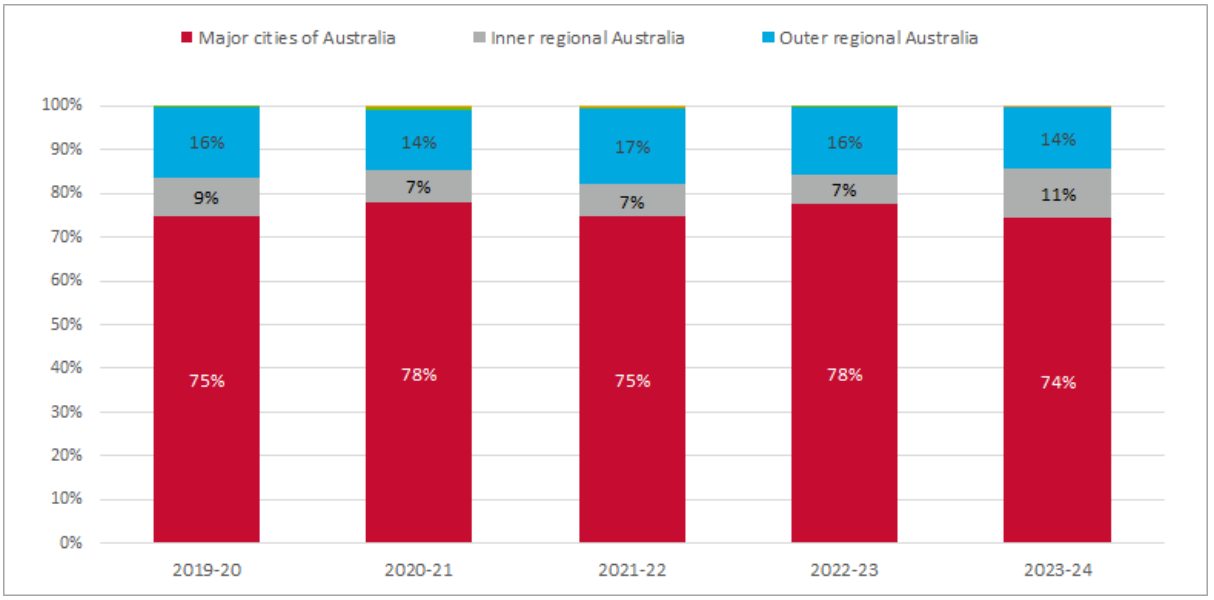


Figure 15: All adverse events by remoteness, 2019-20 to 2023-24

Figure 16 shows that the proportion of reported blood transfusion adverse events (imputability = definite, probable, possible) increased from 75% in 2022-23 to 86% in 2023-24. Refer to **Appendix 1 Table 13 Parts 1 to 3** for detailed imputability score data from 2019-20 to 2023-24.

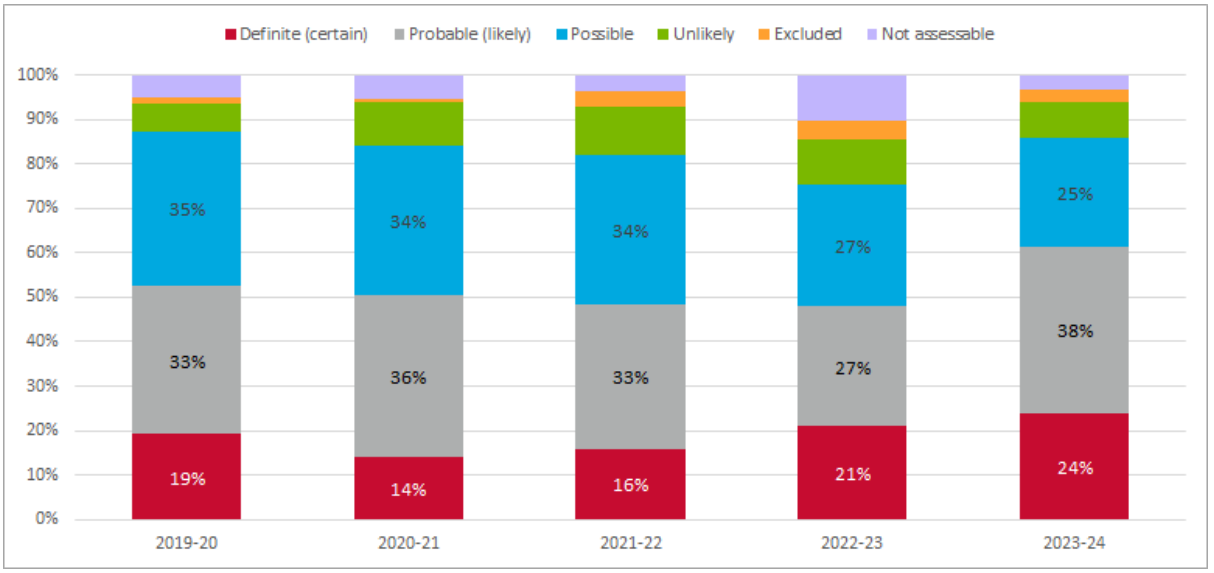


Figure 16: All adverse events by imputability score, 2019-20 to 2023-24

On average, death, life-threatening conditions, and severe morbidity events accounted for 11.2% 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 other four years. 0.3% (12 of 3,455) reported adverse events were related to death. Refer to **Appendix 1 Table 14 Parts 1 to 3** for detailed clinical outcome severity data from 2019-20 to 2023-24.

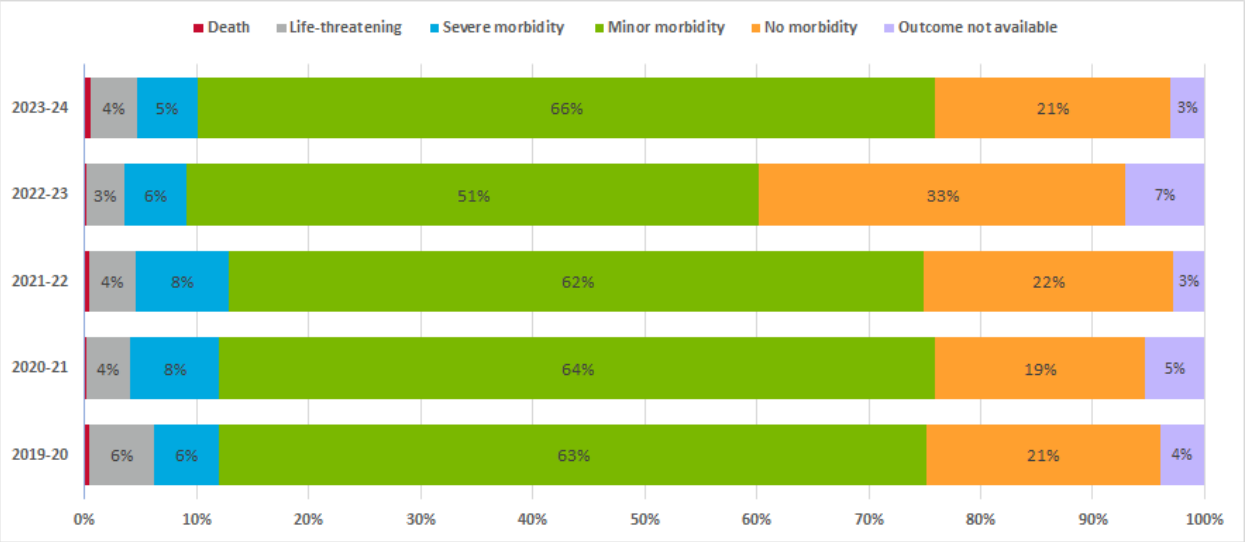


Figure 17: All adverse events by clinical outcome severity, 2019-20 to 2023-24

Figure 18 illustrates that the percentage of RBC transfusion adverse events reported increased over four years from 2019-20 to 2022-23. In contrast, platelet and FFP transfusion adverse events declined during the same period. On average, the proportion of RBC and FFP transfusion adverse events aligns 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 2019-20 to 2023-24.

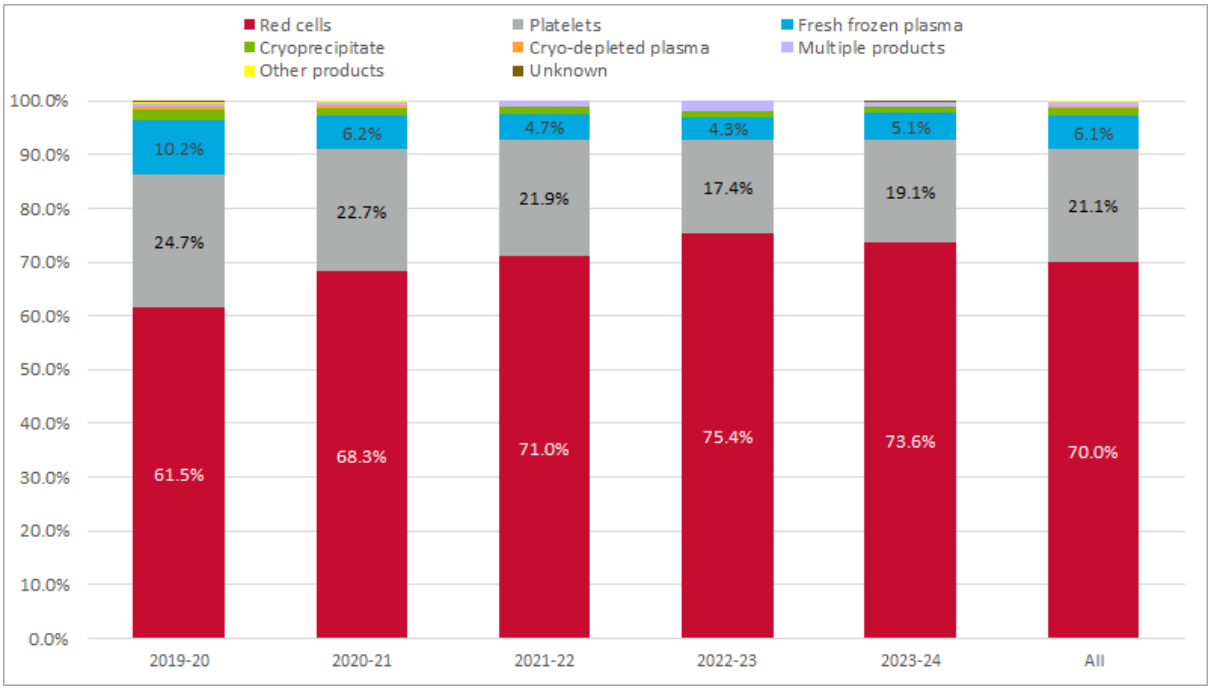


Figure 18: All adverse events by product, 2019-20 to 2023-24

Further 5-year trend data (2019-20 to 2023-24) is presented in **Appendix 1**. 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.

Results for all adverse events, 2023-24

This section presents the data and key results for all reported adverse events for 2023-24. There were 765 total reported adverse events for 2023-24 spanning 13 different event types, across 146 hospitals.

Figure 19 and **Figure 20** show:

- more adverse events were reported for females than males except in the 55 to 74 age groups
- 22% (76 cases) more adverse events were reported for females than males
- 13 more reports of Delayed serologic transfusion reactions (DSTR) and 12 more reports of allergic reaction and Transfusion-Associated Dyspnoea (TAD) 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.

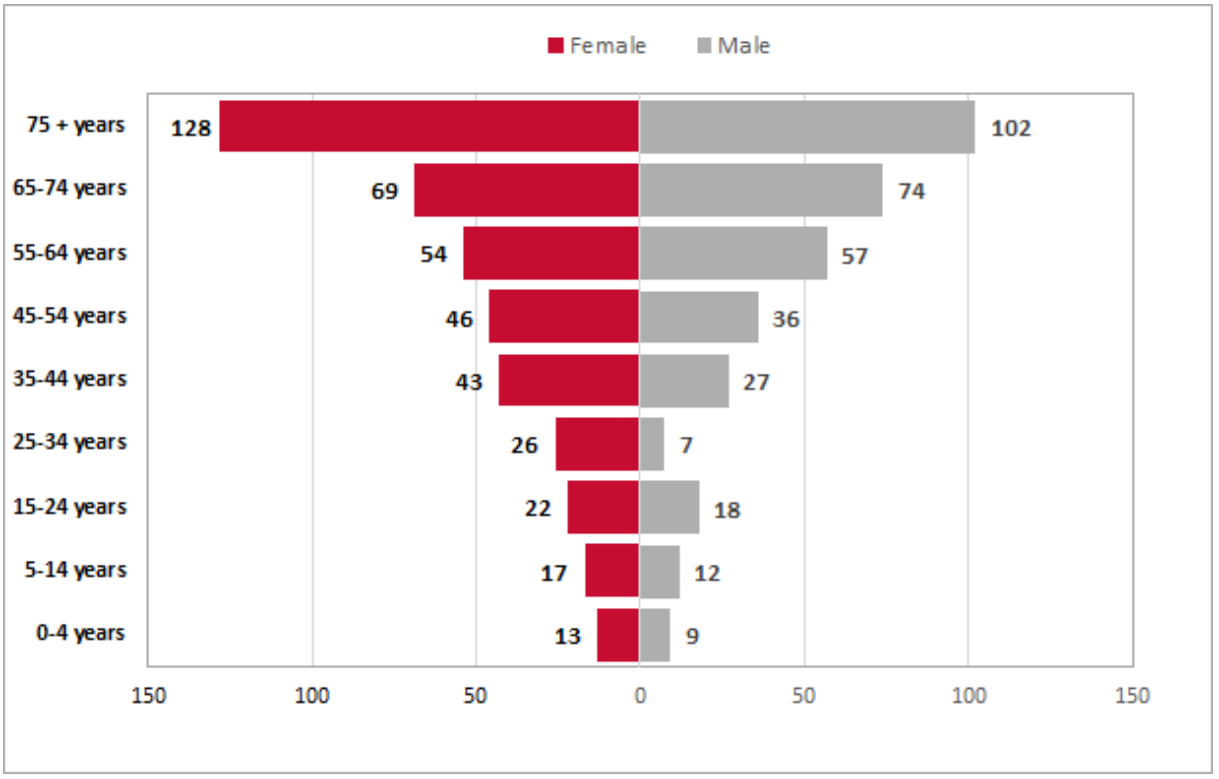


Figure 19: All adverse events by age and sex, 2023-24
Note: The data excludes unspecified sex

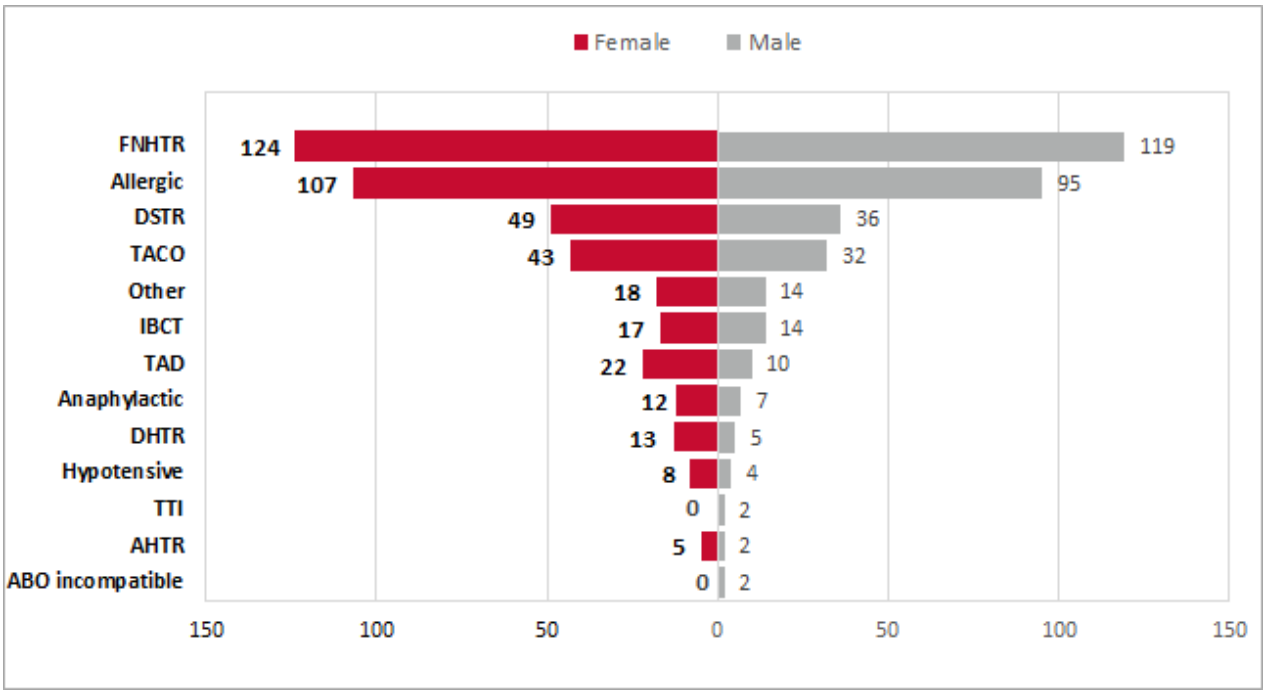


Figure 20: All adverse events by sex, 2023-24
Note: The data excludes unspecified sex

Figure 21 presents the proportion of adverse events across different age groups for 2023–24. 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 under-five (18%) and over 75 age groups (16%) compared to other age groups. DSTR accounted for 16% of reported adverse events in the 65-74 age group. Refer to **Appendix 2 Table 18** for detailed age group data for 2023-24.

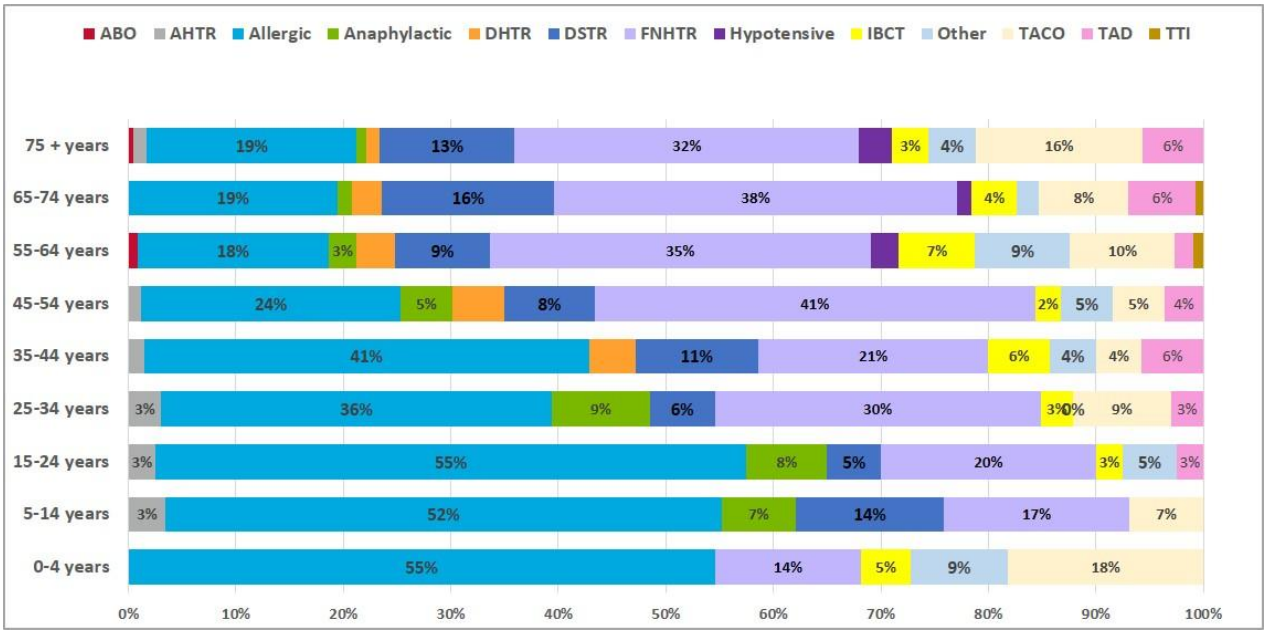


Figure 21: Percentage of all adverse events by age group, 2023-24

Figure 22 and **Figure 23** show:

- one third (252 of 765) of adverse events occurred during overnight transfusions (7pm to 7am)

- more TACO, Incorrect blood component transfused (IBCT) and 'Other' adverse events occurred during overnight transfusions compared to daytime
- one in four (189 of 765) adverse events took place over weekends, with 33% of TACO and TAD and 39% of DSTR 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 2023-24.

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.'

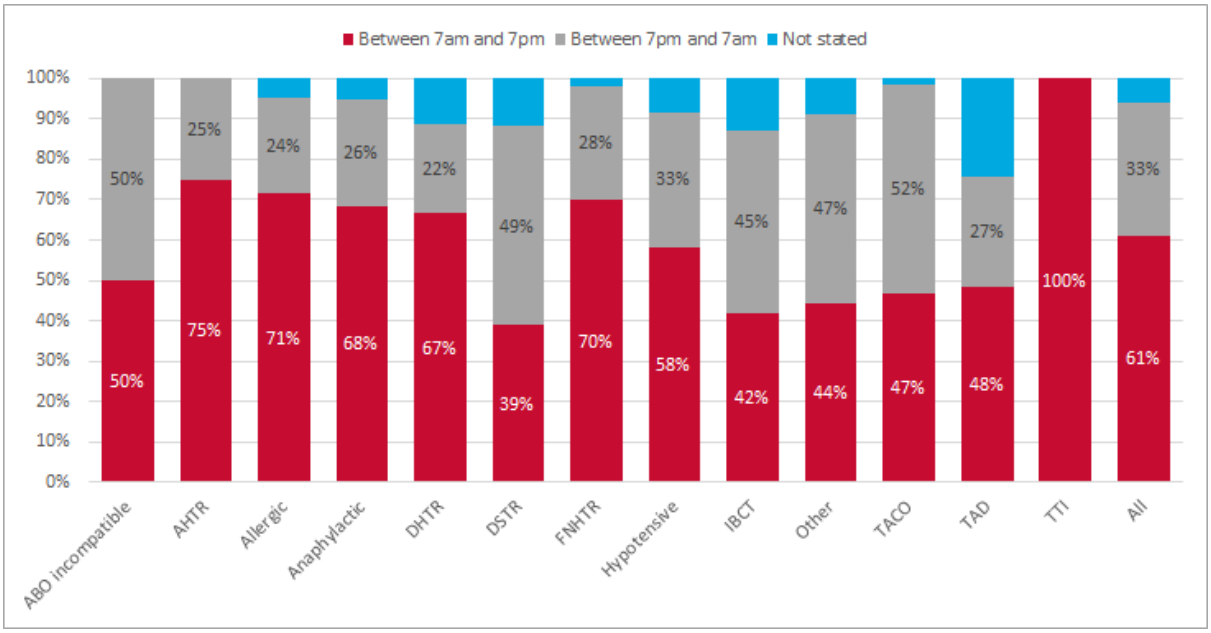


Figure 22: All adverse events by transfusion time, 2023-24

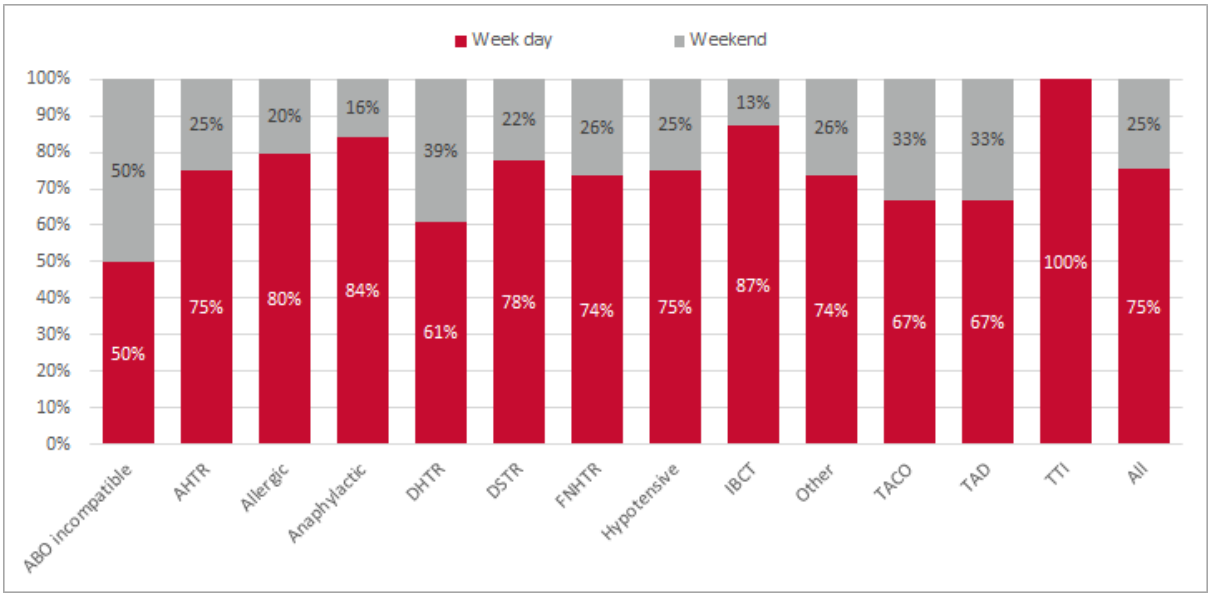


Figure 23: All adverse events by weekday/weekend, 2023-24

Figure 24 shows that 569 of 765 (74.4%) 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 2023-24.

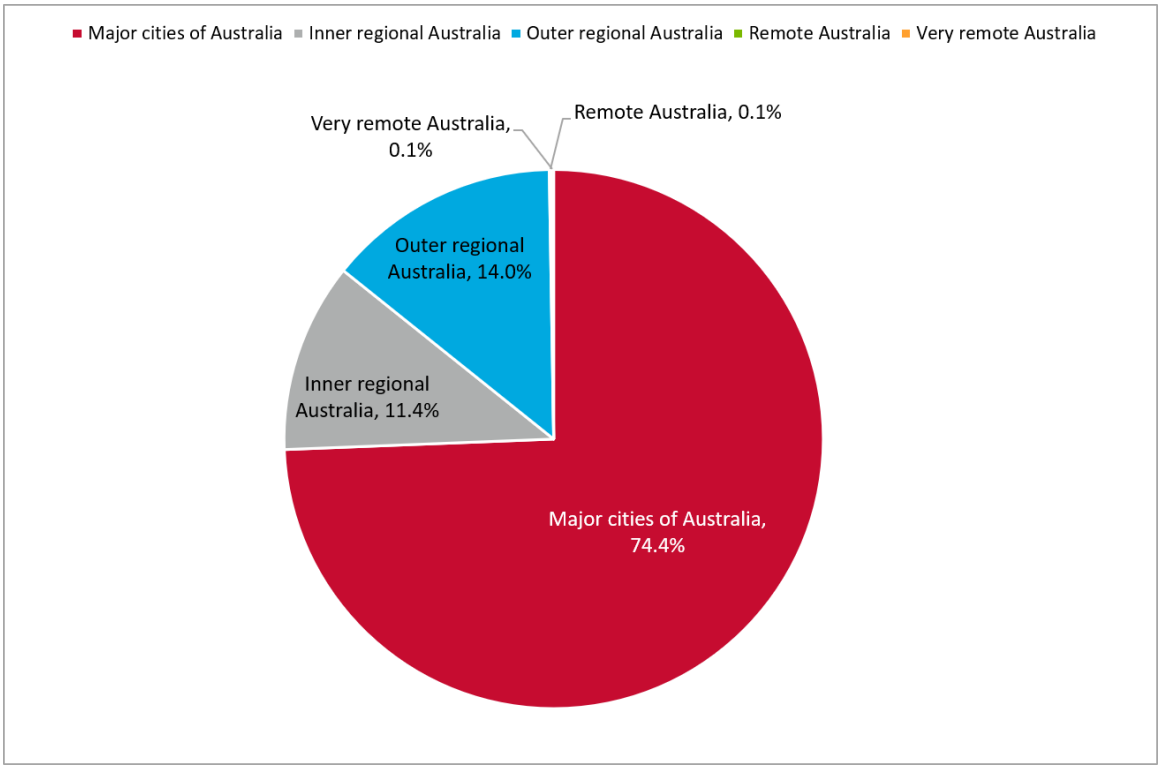


Figure 24: Percentage of adverse events by remoteness, 2023-24

Figure 25 shows that 86% (658 of 765) of reported adverse events were definitely, probably, or possibly related to blood transfusions for 2023-24.

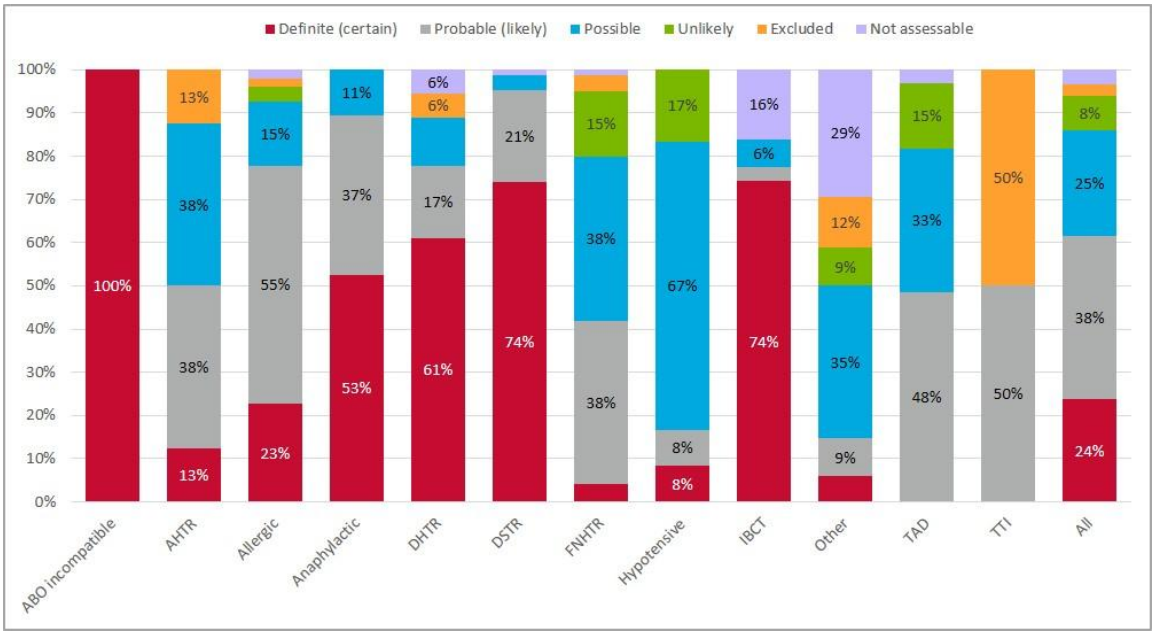


Figure 25: Percentage of adverse events by imputability score, 2023-24

Refer to **Appendix 1 Table 13** for detailed imputability score data for 2023-24.

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

- two hypotensive, one TAD and one 'Other' related deaths were reported
- life-threatening and severe morbidity adverse events accounted for 10% of total reports
- 87% of reported adverse events related to minor or no morbidity.

Table 2: All adverse events by clinical outcome severity, 2023-24

	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	1	0	1	0	0	2	0%	50%	0%	50%	0%	0%
AHTR	0	1	0	4	2	1	8	0%	13%	0%	50%	25%	13%
Allergic	0	5	11	157	27	3	203	0%	2%	5%	77%	13%	1%
Anaphylactic	0	11	3	3	0	2	19	0%	58%	16%	16%	0%	11%
DHTR	0	0	5	8	5	0	18	0%	0%	28%	44%	28%	0%
DSTR	0	0	0	12	73	0	85	0%	0%	0%	14%	86%	0%
FNHTR	0	2	4	216	20	1	243	0%	1%	2%	89%	8%	0%
Hypotensive	2	0	0	10	0	0	12	17%	0%	0%	83%	0%	0%
IBCT	0	0	0	7	16	8	31	0%	0%	0%	23%	52%	26%
Other	1	1	1	12	11	8	34	3%	3%	3%	35%	32%	24%
TACO	0	11	12	48	3	1	75	0%	15%	16%	64%	4%	1%
TAD	1	0	5	24	3	0	33	3%	0%	15%	73%	9%	0%
TTI	0	0	0	2	0	0	2	0%	0%	0%	100%	0%	0%
All	**4**	**32**	**41**	**504**	**160**	**24**	**765**	**1%**	**4%**	**5%**	**66%**	**21%**	**3%**

Figure 26 highlights that

- 38.2% of RBC transfusion adverse events and 16.4% of platelet transfusion adverse events were FNHTRs.
- 67.8% of platelet-related adverse events and 71.8% of FFP-related adverse events were allergic reactions
- 15.1% of RBC transfusion adverse events were DSTR cases.

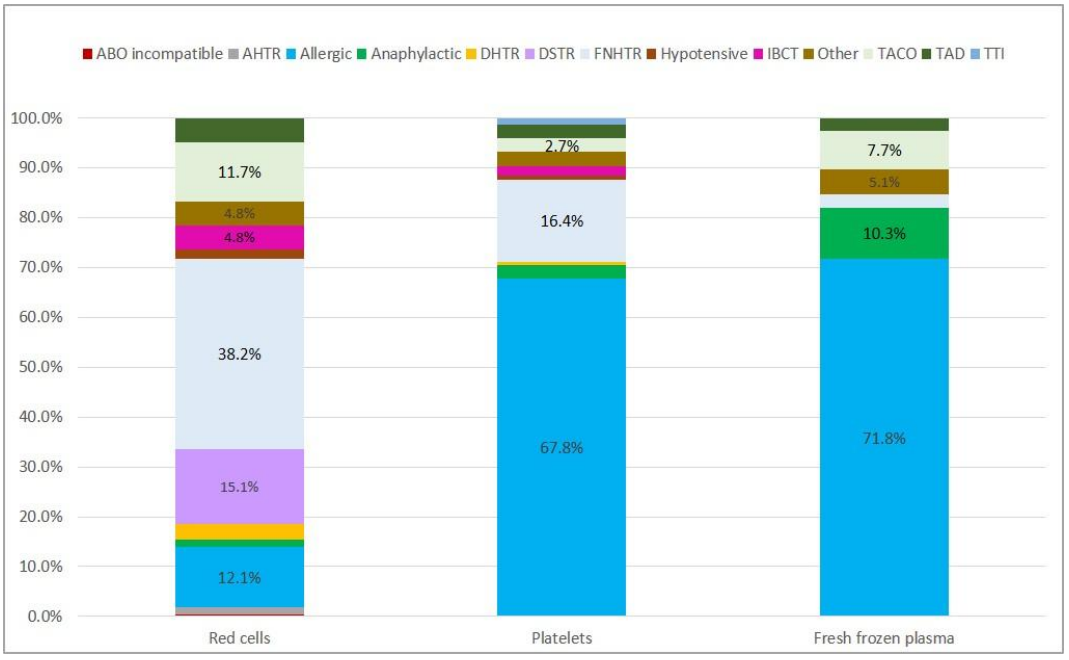


Figure 26: Percentage of products by adverse event, 2023-24

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 2019-20 to 2023-24

This section presents further data for adverse events from 2019-20 to 2023-24, in support of the data in the previous sections.

Table 3: Number of all adverse events, 2019-20 to 2023-24

Adverse Event	2019-20	2020-21	2021-22	2022-23	2023-24	Total	% of total adverse events
ABO incompatible	1	0	2	2	2	**7**	**0.2%**
AHTR	24	16	1	25	8	**74**	**2.1%**
Allergic	241	176	151	136	203	**907**	**26.3%**
Anaphylactic	24	25	27	12	19	**107**	**3.1%**
DHTR	18	20	22	19	18	**97**	**2.8%**
DSTR	25	32	33	67	85	**242**	**7.0%**
FNHTR	222	303	251	227	243	**1,246**	**36.1%**
Hypotensive	3	7	6	9	12	**37**	**1.1%**
IBCT	31	34	40	37	31	**173**	**5.0%**
Other	5	5	18	20	34	**82**	**2.4%**
PTP	0	1	0	0	0	**1**	**0.0%**
TACO	60	69	87	78	75	**369**	**10.7%**
TAD	7	11	9	5	33	**65**	**1.9%**
TRALI	**2**	**1**	**3**	**6**	**0**	**12**	**0%**
TTI	12	6	9	7	2	**36**	**1.0%**
Total	**675**	**706**	**659**	**650**	**765**	**3,455**	**100%**

Table 4: Number of transfusion-related serious adverse events, 2019-20 to 2023-24

Adverse Event	2019-20	2020-21	2021-22	2022-23	2023-24	Total	% of total adverse events
ABO incompatible	0	0	2	1	1	**4**	**1.2%**
AHTR	4	2		2	1	**9**	**2.6%**
Allergic	14	10	11	5	16	**56**	**16.3%**
Anaphylactic	17	19	16	8	14	**74**	**21.6%**
DHTR	1	2	3	1	5	**12**	**3.5%**
FNHTR	8	16	9	6	4	**43**	**12.5%**
Hypotensive	0	2	1	2	0	**5**	**1.5%**
IBCT	3	0	1	1	0	**5**	**1.5%**
Other	0	3	3	0	1	**7**	**2.0%**
TACO	18	17	27	24	21	**107**	**31.2%**
TAD	1	4	1	1	5	**12**	**3.5%**
TRALI	2	1	1	2	0	**6**	**1.7%**
TTI	3	0	0	0	0	**3**	**0.9%**
Total	**71**	**76**	**75**	**53**	**68**	**343**	**100%**

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

Table 5 shows that 88% of events were reported by public hospitals. There was an increase in reporting from both public and private hospitals in 2023-24. **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, 2019-20 to 2023-24

	2019-20	2020-21	2021-22	2022-23	2023-24	2023-24	
						% of total adverse events	% change from 2022-23
Public hospital	617	615	571	558	671	87.7%	20.3%
Private hospitals	58	91	88	92	94	12.3%	2.2%
Total hospitals	**675**	**706**	**659**	**650**	**765**	**100%**	**17.7%**

Table 6: Number of private participating and reporting hospitals by state/territory, 2019-20 to 2023-24

State	Hospital	2019-20	2020-21	2021-22	2022-23	2023-24
NSW	Participating hospitals	0	0	0	0	0
	Reporting hospitals	0	0	0	0	0
VIC	Participating hospitals	25	34	27	29	29
	Reporting hospitals	4	8	8	8	8
QLD	Participating hospitals	30	48	55	43	24
	Reporting hospitals	16	14	18	17	12
SA	Participating hospitals	0	0	0	0	0
	Reporting hospitals	0	0	0	0	0
WA	Participating hospitals	12	10	10	13	14
	Reporting hospitals	4	4	7	9	6
TAS	Participating hospitals	5	6	5	5	5
	Reporting hospitals	0	0	0	1	0
NT	Participating hospitals	0	0	1	1	1
	Reporting hospitals	0	0	0	0	0
ACT	Participating hospitals	3	3	3	2	2
	Reporting hospitals	0	0	0	0	0
Total	**Participating hospitals**	**75**	**101**	**101**	**93**	**75**
	Reporting hospitals	**24**	**26**	**33**	**35**	**26**

Table 7: Number of public participating and reporting hospitals by state/territory, 2019-20 to 2023-24

State	Hospital	2019-20	2020-21	2021-22	2022-23	2023-24
NSW	Participating hospitals	172	172	172	172	172
	Reporting hospitals	37	37	27	28	43
VIC	Participating hospitals	61	72	63	66	66
	Reporting hospitals	20	21	18	22	16
QLD	Participating hospitals	80	81	80	78	86
	Reporting hospitals	23	22	30	28	34
SA	Participating hospitals	43	43	43	43	55
	Reporting hospitals	10	8	8	8	13
WA	Participating hospitals	53	53	53	52	55
	Reporting hospitals	11	16	9	10	10
TAS	Participating hospitals	4	3	4	4	4
	Reporting hospitals	2	1	1	4	2
NT	Participating hospitals	5	6	6	6	6
	Reporting hospitals	2	1	2	2	1
ACT	Participating hospitals	2	3	3	2	2
	Reporting hospitals	1	1	1	1	1
Total	**Participating hospitals**	**420**	**433**	**424**	**423**	**446**
	Reporting hospitals	**106**	**107**	**96**	**103**	**120**

Table 8: All adverse events by state/territory, 2019-20 to 2023-24

	2019-20	2020-21	2021-22	2022-23	2023-24	2023-24	
						% of total adverse events	% change from 2022-23
NSW	112	152	87	116	179	23.4%	54.3%
VIC	95	97	109	105	117	15.3%	11.4%
QLD	299	297	292	273	298	39.0%	9.2%
SA	83	73	81	77	87	11.4%	13.0%
WA	69	78	72	67	75	9.8%	11.9%
TAS	6	2	3	8	6	0.8%	-25.0%
NT	5	6	11	3	1	0.1%	-66.7%
ACT	6	1	4	1	2	0.3%	100.0%
Total	**675**	**706**	**659**	**650**	**765**	**100%**	**17.7%**

Table 9: All adverse events by time, 2019-20 to 2023-24 – Part 1

	2019-20			2020-21			2021-22		
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	0	0	0	2	0	0
AHTR	19	4	1	14	2	0	0	1	0
Allergic	179	57	5	132	39	5	119	30	2
Anaphylactic	20	4	0	20	5	0	19	4	4
DHTR	10	7	1	11	9	0	14	8	0
DSTR	6	18	1	13	17	2	18	15	0
FNHTR	161	57	4	205	93	5	200	49	2
Hypotensive	1	2	0	4	3	0	4	1	1
IBCT	13	17	1	23	8	3	23	10	7
Other	3	2	0	5	0	0	13	4	1
PTP	0	0	0	0	0	1	0	0	0
TACO	34	25	1	41	25	3	51	34	2
TAD	3	4	0	8	3	0	7	2	0
TRALI	0	2	0	1	0	0	1	2	0
TTI	7	3	2	5	1	0	9	0	0
All	**457**	**202**	**16**	**482**	**205**	**19**	**480**	**160**	**19**

Table 9: All adverse events by transfusion time, 2019-20 to 2023-24 – Part 2

	2022-23			2023-24			
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	1	1	0	**7**
AHTR	21	2	2	6	2	0	**74**
Allergic	90	32	14	145	48	10	**907**
Anaphylactic	6	6	0	13	5	1	**107**
DHTR	10	6	3	12	4	2	**97**
DSTR	26	33	8	33	42	10	**242**
FNHTR	167	55	5	170	68	5	**1,246**
Hypotensive	5	3	1	7	4	1	**37**
IBCT	17	14	6	13	14	4	**173**
Other	4	14	2	15	16	3	**82**
PTP	0	0	0	0	0	0	**1**
TACO	44	31	3	35	39	1	**369**
TAD	2	3	0	16	9	8	**65**
TRALI	4	2	0	0	0	0	**12**
TTI	6	1	0	2	0	0	36
All	**404**	**202**	**44**	**468**	**252**	**45**	**3,455**

Table 10: All adverse events by weekday/weekend, 2019-20 to 2023-24

	2019-20		2020-21		2021-22		2022-23		2023-24		
Adverse Event	Weekday	Weekend	Weekday	Weekend	Weekday	Weekend	Weekday	Weekend	Weekday	Weekend	Total
ABO incompatible	1	0	0	0	2	0	2	0	1	1	**7**
AHTR	20	4	16	0	1	0	18	7	6	2	**74**
Allergic	194	47	138	38	136	15	118	18	162	41	**907**
Anaphylactic	20	4	18	7	25	2	10	2	16	3	**107**
DHTR	15	3	16	4	16	6	14	5	11	7	**97**
DSTR	19	6	29	3	29	4	45	22	66	19	**242**
FNHTR	172	50	223	80	195	56	176	51	179	64	**1,246**
Hypotensive	3	0	6	1	5	1	8	1	9	3	**37**
IBCT	23	8	26	8	27	13	29	8	27	4	**173**
Other	2	3	5	0	11	7	15	5	25	9	**82**
PTP	0	0	1	0	0	0	0	0	0	0	**1**
TACO	52	8	53	16	70	17	57	21	50	25	**369**
TAD	4	3	11	0	7	2	4	1	22	11	**65**
TRALI	1	1	1	0	3	0	4	2	0	0	**12**
TTI	7	5	6	0	9	0	7	0	2	0	**36**
All	**533**	**142**	**549**	**157**	**536**	**123**	**507**	**143**	**576**	**189**	**3,455**

Table 11: All adverse events by remoteness, 2019-20 to 2023-24 – Part 1

	2019-20				2020-21				
Adverse Event	Major cities of Australia	Inner regional Australia	Outer regional Australia	Remote Australia	Major cities of Australia	Inner regional Australia	Outer regional Australia	Remote Australia	Very remote Australia
ABO incompatible	1	0	0	0	0	0	0	0	0
AHTR	17	3	4	0	11	1	3	1	0
Allergic	196	16	29	0	148	10	17	1	0
Anaphylactic	19	3	2	0	21	2	2	0	0
DHTR	13	1	4	0	13	0	5	2	0
DSTR	25	0	0	0	32	0	0	0	0
FNHTR	142	19	61	0	216	25	60	2	0
Hypotensive	3	0	0	0	6	1	0	0	0
IBCT	23	8	0	0	28	5	0	1	0
Other	2	3	0	0	5	0	0	0	0
PTP	0	0	0	0	1	0	0	0	0
TACO	50	5	4	1	55	5	8	0	1
TAD	6	1	0	0	9	2	0	0	0
TRALI	2	0	0	0	1	0	0	0	0
TTI	6	1	5	0	5	0	1	0	0
All	**505**	**60**	**109**	**1**	**551**	**51**	**96**	**7**	**1**

Table 11: All adverse events by remoteness, 2019-20 to 2023-24 – Part 2

	2021-22					2022-23			
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
ABO incompatible	2	0	0	0	0	2	0	0	0
AHTR	0	0	1	0	0	24	0	1	0
Allergic	117	9	25	0	0	110	5	21	0
Anaphylactic	24	0	3	0	0	10	1	1	0
DHTR	16	1	5	0	0	11	1	7	0
DSTR	31	2	0	0	0	66	1	0	0
FNHTR	160	25	64	1	1	152	17	58	0
Hypotensive	6	0	0	0	0	5	4	0	0
IBCT	34	4	0	2	0	31	5	1	0
Other	16	1	1	0	0	17	0	3	0
PTP	0	0	0	0	0	0	0	0	0
TACO	71	6	10	0	0	66	5	6	1
TAD	8	1	0	0	0	4	1	0	0
TRALI	2	0	1	0	0	3	2	1	0
TTI	5	0	4	0	0	4	1	2	0
All	**492**	**49**	**114**	**3**	**1**	**505**	**43**	**101**	**1**

Table 11: All adverse events by remoteness, 2019-20 to 2023-24 – Part 3

2023-24						
Adverse Event	Major cities of Australia	Inner regional Australia	Outer regional Australia	Remote Australia	Very remote Australia	Total
ABO incompatible	2	0	0	0	0	**7**
AHTR	6	0	2	0	0	**74**
Allergic	162	15	26	0	0	**907**
Anaphylactic	17	0	2	0	0	**107**
DHTR	13	3	2	0	0	**97**
DSTR	76	7	2	0	0	**242**
FNHTR	157	34	50	1	1	**1,246**
Hypotensive	5	4	3	0	0	**37**
IBCT	23	5	3	0	0	**173**
Other	26	3	5	0	0	**82**
PTP	0	0	0	0	0	**1**
TACO	61	8	6	0	0	**369**
TAD	21	7	5	0	0	**65**
TRALI	0	0	0	0	0	**12**
TTI	0	1	1	0	0	**36**
All	**569**	**87**	**107**	**1**	**1**	**3,455**

Table 12: Issues by fresh blood product and remoteness, 2019-20 to 2023-24 – Part 1

	2019-20					2020-21				
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	504,308	84,018	34,347	4,946	1,923	528,958	87,494	36,192	5,029	1,874
Platelets	119,963	12,578	5,411	258	0	125,177	13,391	6,213	275	0
Fresh frozen plasma	75,848	6,672	2,413	298	67	74,861	7,225	2,694	305	63
Cryoprecipitate	95,466	7,606	3,523	194	29	107,114	8,233	3,901	194	35
Cryodepleted-depleted plasma	3,186	142	935	0	0	5,217	458	357	0	0
All	**798,771**	**111,016**	**46,629**	**5,696**	**2,019**	**841,327**	**116,801**	**49,357**	**5,803**	**1,972**

Table 12: Issues by fresh blood product and remoteness, 2019-20 to 2023-24 – Part 2

	2021-22					2022-23				
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	531,714	89,881	35,245	4,869	1,757	554,402	90,723	34,791	4,794	1,972
Platelets	121,218	12,784	6,175	326	1	127,838	13,317	6,497	239	2
Fresh frozen plasma	71,323	8,120	2,787	232	80	76,730	8,180	2,309	294	85
Cryoprecipitate	107,485	7,813	3,710	233	34	111,428	7,565	3,516	222	29
Cryodepleted-depleted plasma	2,999	344	370	0	0	4,542	73	183	0	0
All	**834,739**	**118,942**	**48,287**	**5,660**	**1,872**	**874,940**	**119,858**	**47,296**	**5,549**	**2,088**

Table 12: Issues by fresh blood product and remoteness, 2019-20 to 2023-24 – Part 3

2023-24						
Product	Major cities of Australia	Inner regional Australia	Outer regional Australia	Remote Australia	Very remote Australia	Total
RBC	567,040	95,247	34,654	4,722	1,933	3,342,833
Platelets	134,990	14,126	5,813	207	7	726,806
Fresh frozen plasma	76,450	7,283	2,293	278	82	426,972
Cryoprecipitate	120,668	8,407	3,066	185	45	600,701
Cryodepleted-depleted plasma	4,381	225	273	0	0	23685
All	**903,529**	**125,288**	**46,099**	**5,392**	**2,067**	**5,120,997**

Table 13: All adverse events by imputability score, 2019-20 to 2023-24 – Part 1

	2019-20						2020-21					
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	0	0	0	0	0	0
AHTR	6	6	8	1	0	3	2	11	2	0	0	1
Allergic	50	131	55	1	2	2	34	97	34	5	0	6
Anaphylactic	3	9	12	0	0	0	6	14	5	0	0	0
DHTR	10	4	4	0	0	0	12	4	3	0	0	1
DSTR	17	7	1	0	0	0	20	11	1	0	0	0
FNHTR	2	40	122	40	5	13	11	81	148	57	3	3
Hypotensive	0	0	2	0	0	1	0	2	4	0	0	1
IBCT	25	0	1	0	0	5	7	2	0	0	2	23
Other	1	0	4	0	0	0	0	0	4	0	1	0
PTP	0	0	0	0	0	0	0	0	0	0	0	1
TACO	13	23	19	1	0	4	6	31	26	4	1	1
TAD	0	2	3	0	0	2	1	3	5	2	0	0
TRALI	0	1	1	0	0	0	0	1	0	0	0	0
TTI	2	2	2	0	2	4	0	0	5	1	0	0
All	**130**	**225**	**234**	**43**	**9**	**34**	**99**	**257**	**237**	**69**	**7**	**37**

Table 13: All adverse events by imputability score, 2019-20 to 2023-24 – Part 2

	2021-22						2022-23					
Adverse Event	Definite (certain)	Probable (likely)	Possible	Unlikely	Excluded	Not assessable	Definite (certain)	Probable (likely)	Possible	Unlikely	Excluded	Not assessable
ABO incompatible	2	0	0	0	0	0	2	0	0	0	0	0
AHTR	1	0	0	0	0	0	6	2	3	0	1	13
Allergic	21	80	35	9	4	2	16	55	32	10	2	21
Anaphylactic	6	17	2	0	1	1	4	5	2	1	0	0
DHTR	11	5	5	0	0	1	10	7	0	0	0	2
DSTR	24	9	0	0	0	0	54	12	1	0	0	0
FNHTR	2	50	126	58	12	3	1	48	104	42	21	11
Hypotensive	1	1	3	1	0	0	1	2	3	0	0	3
IBCT	26	2	2	0	1	9	23	2	2	2	0	8
Other	1	2	14	0	0	1	0	3	9	4	0	4
PTP	0	0	0	0	0	0	0	0	0	0	0	0
TACO	9	43	28	2	1	4	18	35	18	2	1	4
TAD	1	3	4	0	0	1	1	3	0	1	0	0
TRALI	0	1	2	0	0	0	0	2	1	2	0	1
TTI	0	2	0	1	3	3	0	0	2	2	3	0
All	**105**	**215**	**221**	**71**	**22**	**25**	**136**	**176**	**177**	**66**	**28**	**67**

Table 13: All adverse events by imputability score, 2019-20 to 2023-24 – Part 3

	2023-24						
Adverse Event	Definite (certain)	Probable (likely)	Possible	Unlikely	Excluded	Not assessable	Total
ABO incompatible	2	0	0	0	0	0	**7**
AHTR	1	3	3	0	1	0	**74**
Allergic	46	112	30	7	4	4	**907**
Anaphylactic	10	7	2	0	0	0	**107**
DHTR	11	3	2	0	1	1	**97**
DSTR	63	18	3	0	0	1	**242**
FNHTR	10	92	92	37	9	3	**1,246**
Hypotensive	1	1	8	2	0	0	**37**
IBCT	23	1	2	0	0	5	**173**
Other	2	3	12	3	4	10	**82**
PTP	0	0	0	0	0	0	**1**
TACO	13	31	23	6	2	0	**369**
TAD	0	16	11	5	0	1	**65**
TRALI	0	0	0	0	0	0	**12**
TTI	0	1	0	0	1	0	**36**
All	**182**	**288**	**188**	**60**	**22**	**25**	**3,455**

Table 14: All adverse events by clinical outcome severity, 2019-20 to 2023-24 – Part 1

	2019-20						2020-21					
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	1	0	0	0	0	0	0	0	0
AHTR	0	3	1	18	2	0	0	1	1	13	1	0
Allergic	0	9	5	186	40	1	0	4	7	132	25	8
Anaphylactic	1	11	5	2	5	0	0	14	5	5	1	0
DHTR	0	0	1	12	4	1	0	0	2	10	8	0
DSTR	0	0	0	2	23	0	0	0	0	4	28	0
FNHTR	1	1	12	167	32	9	0	1	19	233	35	15
Hypotensive	0	0	0	1	1	1	0	0	2	3	0	2
IBCT	1	1	2	2	15	10	0	1	0	3	19	11
Other	0	0	0	1	4	0	0	2	1	1	1	0
PTP	0	0	0	0	0	0	0	0	1	0	0	0
TACO	0	8	12	31	8	1	1	4	13	42	7	2
TAD	0	1	0	3	2	1	0	1	4	3	3	0
TRALI	0	2	0	0	0	0	0	0	1	0	0	0
TTI	0	3	1	0	5	3	0	0	0	2	4	0
All	**3**	**39**	**39**	**426**	**141**	**27**	**1**	**28**	**56**	**451**	**132**	**38**

Table 14: All adverse events by clinical outcome severity, 2019-20 to 2023-24 – Part 2

	2021-22						2022-23					
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	2	0	0	0	0	0	1	1	0	0
AHTR	0	0	0	1	0	0	0	0	3	8	11	3
Allergic	0	3	10	117	18	3	0	2	4	81	40	9
Anaphylactic	0	11	5	8	3	0	0	6	3	3	0	0
DHTR	0	0	3	11	7	1	0	0	1	10	7	1
DSTR	0	0	0	3	30	0	0	0	0	0	59	8
FNHTR	1	2	11	193	39	5	0	0	7	161	54	5
Hypotensive	0	0	2	3	1	0	0	2	1	5	1	0
IBCT	0	0	1	4	27	8	0	0	1	6	18	12
Other	1	1	2	6	8	0	0	0	0	6	12	2
PTP	0	0	0	0	0	0	0	0	0	0	0	0
TACO	1	9	17	53	5	2	1	12	12	45	4	4
TAD	0	1	1	7	0	0	0	0	1	3	1	0
TRALI	0	0	1	2	0	0	0	0	2	0	2	2
TTI	0	0	0	1	8	0	0	0	0	3	4	0
All	**3**	**27**	**55**	**409**	**146**	**19**	**1**	**22**	**36**	**332**	**213**	**46**

Table 14: All adverse events by clinical outcome severity, 2019-20 to 2023-24 – Part 3

	2023-24						
Adverse Event	Death	Life-threatening	Severe morbidity	Minor morbidity	No morbidity	Outcome not available	Total
ABO incompatible	0	1	0	1	0	0	**7**
AHTR	0	1	0	4	2	1	**74**
Allergic	0	5	11	157	27	3	**907**
Anaphylactic	0	11	3	3	0	2	**107**
DHTR	0	0	5	8	5	0	**97**
DSTR	0	0	0	12	73	0	**242**
FNHTR	0	2	4	216	20	1	**1,246**
Hypotensive	2	0	0	10	0	0	**37**
IBCT	0	0	0	7	16	8	**173**
Other	1	1	1	12	11	8	**82**
PTP	0	0	0	0	0	0	**1**
TACO	0	11	12	48	3	1	**369**
TAD	1	0	5	24	3	0	**65**
TRALI	0	0	0	0	0	0	**12**
TTI	0	0	0	2	0	0	**36**
All	**4**	**32**	**41**	**504**	**160**	**24**	**3,455**

Table 15 highlights from 2019-20 to 2023-24 that:

- 44.5% (1,077 of 2,418) of RBC transfusion adverse events and 20.5% (150 of 730) of platelet transfusion adverse events were FNHTRs
- 56.6% (413 of 730) of platelet-related adverse events, 72.5% (153 of 211) of FFP-related adverse events, 65.2% (30 of 46) cryoprecipitate transfusion adverse events and 87.5% (7 of 8) cryo-depleted plasma transfusion adverse events were allergic reactions
- 13.6% (329 of 2,418) of RBC transfusion adverse events were TACOs
- 12.8% (27 of 211) of FFP transfusion adverse events were anaphylactic reactions.

Table 15: All adverse events by product, 2019-20 to 2023-24

	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	6	0	1	0	0	0.2%	0.0%	0.5%	0.0%	0.0%
AHTR	55	15	2	1	0	2.3%	2.1%	0.9%	2.2%	0.0%
Allergic	285	413	153	30	7	11.8%	56.6%	72.5%	65.2%	87.5%
Anaphylactic	30	43	27	4	0	1.2%	5.9%	12.8%	8.7%	0.0%
DHTR	91	5	0	0	0	3.8%	0.7%	0.0%	0.0%	0.0%
DSTR	237	5	0	0	0	9.8%	0.7%	0.0%	0.0%	0.0%
FNHTR	1,077	150	12	2	1	44.5%	20.5%	5.7%	4.3%	12.5%
Hypotensive	27	7	0	1	0	1.1%	1.0%	0.0%	2.2%	0.0%
IBCT	144	17	4	3	0	6.0%	2.3%	1.9%	6.5%	0.0%
Other	70	8	3	1	0	2.9%	1.1%	1.4%	2.2%	0.0%
PTP	1	0	0	0	0	0.0%	0.0%	0.0%	0.0%	0.0%
TACO	329	26	7	3	0	13.6%	3.6%	3.3%	6.5%	0.0%
TAD	51	11	2	0	0	2.1%	1.5%	0.9%	0.0%	0.0%
TRALI	9	2	0	0	0	0.4%	0.3%	0.0%	0.0%	0.0%
TTI	6	28	0	1	0	0.2%	3.8%	0.0%	2.2%	0.0%
Grand Total	**2,418**	**730**	**211**	**46**	**8**	**100%**	**100%**	**100%**	**100%**	**100%**

Table 16: All adverse events by product and year, 2019-20 to 2023-24

	Number of adverse events					% of adverse events				
	2019-20	2020-21	2021-22	2022-23	2023-24	2019-20	2019-20	2020-21	2021-22	2022-23
Red cells	415	482	468	490	563	62.2%	61.5%	68.3%	71.0%	75.4%
Platelets	167	160	144	113	146	25.2%	24.7%	22.7%	21.9%	17.4%
Fresh frozen plasma	69	44	31	28	39	10.2%	10.2%	6.2%	4.7%	4.3%
Cryoprecipitate	12	11	8	6	9	1.0%	1.8%	1.6%	1.2%	0.9%
Cryo-depleted plasma	4	3	1	0	0	0.4%	0.6%	0.4%	0.2%	0.0%
Multiple products	1	1	0	0	0	1.0%	0.7%	0.7%	1.1%	2.0%
Other products	5	5	7	13	7	0.0%	0.1%	0.1%	0.0%	0.0%
Unknown	2	0	0	0	1	0.0%	0.3%	0.0%	0.0%	0.0%
Total	**675**	**706**	**659**	**650**	**765**	**100%**	**100%**	**100%**	**100%**	**100%**

Appendix 2: Data for 2023-24

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 (39%) when compared with the population percentage and RBC issue percentage. This is due to reported FNHTRs events of 176. The use of different haemovigilance reporting processes across the jurisdictions may lead to these data inconsistencies.

Table 17: All adverse events by state, 2023-24

	ABO incompatible	AHTR	Allergic	Anaphylactic	DHTR	DSTR	FNHTR	Hypotensive	IBCT	Other	TACO	TAD	TTI	All reports		Red blood cell issue
														Total	% of total adverse events	Percent
NSW	0	0	50	4	3	12	35	10	15	18	11	20	1	179	23.4%	31.1%
VIC	1	0	14	7	5	49	4	2	12	0	23	0	0	117	15.3%	27.1%
QLD	1	4	76	2	6	0	176	0	1	0	31	0	1	298	39.0%	20.2%
SA	0	4	31	3	2	0	12	0	0	16	4	3	0	75	9.8%	8.3%
WA	0	0	30	2	2	24	12	0	1	0	6	10	0	87	11.4%	8.8%
TAS	0	0	2	0	0	0	4	0	0	0	0	0	0	6	0.8%	2.2%
NT	0	0	0	0	0	0	0	0	1	0	0	0	0	1	0.1%	0.7%
ACT	0	0	0	1		0	0	0	1	0	0	0	0	2	0.3%	1.6%
Total	**2**	**8**	**203**	**19**	**18**	**85**	**243**	**12**	**31**	**34**	**75**	**33**	**2**	**765**	**100%**	**100%**

Table 18: All adverse events by age group, 2023-24

	ABO incompatible	AHTR	Allergic	Anaphylactic	DHTR	DSTR	FNHTR	Hypotensive	IBCT	Other	TACO	TAD	TTI	Total
0-4 years	0	0	12	0	0	0	3	0	1	2	4	0	0	22
5-14 years	0	1	15	2	0	4	5	0	0	0	2	0	0	29
15-24 years	0	1	22	3	0	2	8	0	1	2	0	1	0	40
25-34 years	0	1	12	3	0	2	10	0	1	0	3	1	0	33
35-44 years	0	1	29	0	3	8	15	0	4	3	3	4	0	70
45-54 years	0	1	20	4	4	7	34	0	2	4	4	3	0	83
55-64 years	1	0	20	3	4	10	40	3	8	10	11	2	1	113
65-74 years	0	0	28	2	4	23	54	2	6	3	12	9	1	144
75 + years	1	3	45	2	3	29	74	7	8	10	36	13	0	231
Total	**2**	**8**	**203**	**19**	**18**	**85**	**243**	**12**	**31**	**34**	**75**	**33**	**2**	**765**

Table 19: All adverse events by transfusion day and time, 2023-24

	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	0	1	0	1	0	0	1	1	0	2
AHTR	4	2	0	2	0	0	6	2	0	8
Allergic	122	32	8	23	16	2	145	48	10	203
Anaphylactic	10	5	1	3	0	0	13	5	1	19
DHTR	7	3	1	5	1	1	12	4	2	18
DSTR	26	32	8	7	10	2	33	42	10	85
FNHTR	121	53	5	49	15	0	170	68	5	243
Hypotensive	4	4	1	3	0	0	7	4	1	12
IBCT	12	12	3	1	2	1	13	14	4	31
Other	11	11	3	4	5		15	16	3	34
TACO	26	24	0	9	15	1	35	39	1	75
TAD	12	3	7	4	6	1	16	9	8	33
TTI	2	0	0	0	0	0	2	0	0	2
Total	**357**	**182**	**37**	**111**	**70**	**8**	**468**	**252**	**45**	**765**
Percent	**46.7%**	**23.8%**	**4.8%**	**14.5%**	**9.2%**	**1.0%**	**61.2%**	**32.9%**	**5.9%**	**100%**

Table 20: All adverse events by blood product, 2023-24

	Number of adverse events							% of products					
Adverse Event	Red cells	Platelets	Fresh frozen plasma	Cryoprecipitate	Multiple products	Unknown	Total	Red cells	Platelets	Fresh frozen plasma	Cryoprecipitate	Multiple products	Unknown
ABO incompatible	2	0	0	0	0	0	2	0.4%	0.0%	0.0%	0.0%	0.0%	0.0%
AHTR	8	0	0	0	0	0	8	1.4%	0.0%	0.0%	0.0%	0.0%	0.0%
Allergic	68	99	28	5	3	0	203	12.1%	67.8%	71.8%	55.6%	42.9%	0.0%
Anaphylactic	9	4	4	0	2	0	19	1.6%	2.7%	10.3%	0.0%	28.6%	0.0%
DHTR	17	1	0	0	0	0	18	3.0%	0.7%	0.0%	0.0%	0.0%	0.0%
DSTR	85	0	0	0	0	0	85	15.1%	0.0%	0.0%	0.0%	0.0%	0.0%
FNHTR	215	24	1	2	0	1	243	38.2%	16.4%	2.6%	22.2%	0.0%	100.0%
Hypotensive	11	1	0	0	0	0	12	2.0%	0.7%	0.0%	0.0%	0.0%	0.0%
IBCT	27	3	0	0	1	0	31	4.8%	2.1%	0.0%	0.0%	14.3%	0.0%
Other	27	4	2	1	0	0	34	4.8%	2.7%	5.1%	11.1%	0.0%	0.0%
TACO	66	4	3	1	1	0	75	11.7%	2.7%	7.7%	11.1%	14.3%	0.0%
TAD	28	4	1	0	0	0	33	5.0%	2.7%	2.6%	0.0%	0.0%	0.0%
TTI	0	2	0	0	0	0	2	0.0%	1.4%	0.0%	0.0%	0.0%	0.0%
All	**563**	**146**	**39**	**9**	**7**	**1**	**765**	**100%**	**100%**	**100%**	**100%**	**100%**	**100%**

Table 21: Contributory factors by adverse event and by clinical outcome severity, 2023-24

Contributory factors	Adverse event													Clinical outcome severity					
	ABO incompatible	AHTR	Allergic	Anaphylactic	DHTR	DSTR	FNHTR	Hypotensive	IBCT	Other	TACO	TAD	TTI	Outcome not available	No morbidity	Minor morbidity	Severe morbidity	Life-threatening	Death
None identified	1	5	124	12	8	36	164	9	0	25	44	21	1	12	64	331	26	15	2
Product characteristic	0	0	33	6	4	44	33	1	11	0	10	6	1	3	47	86	4	9	0
Transfusion in emergency setting	1	0	4	0	2	3	9	2	12	0	2	4	0	4	8	22	1	2	2
Deliberate clinical decision	0	1	2	1	1	1	2	1	8	1	4	3	0	6	5	11	1	2	0
Prescribing/ordering	0	0	1	0	1	0	2	0	12	0	1	1	0	2	9	6	1	0	0
Specimen collection/labelling	0	0	0	0	0	0	1	0	0	0	0	1	0	0	2	0	0	0	0
Laboratory (testing/dispensing)	0	0	0	0	1	7	1	0	17	0	0	1	0	3	13	10	1	0	0
Transport, storage, handling	1	0	0	0	0	0	1	0	1	0	0	1	0	1	0	3	0	0	0
Administration of product	1	1	21	0	3	0	11	1	11	3	7	3	0	9	26	22	4	1	0
Indications do not meet guidelines	0	0	1	0	0	1	1	0	3	0	2	1	0	2	2	5	0	0	0
Procedure did not adhere to hospital transfusion guidelines	0	1	2	0	1	2	2	1	20	1	1	3	0	5	14	14	0	1	0
Other	0	1	20	1	3	0	29	0	13	6	8	2	1	4	16	53	5	6	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
	  ○ Acute pancreatitis

Adverse Event	Definition – Where possible this is the ISBT Definition
	○ 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 2023–24

Executive summary

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 2023-24 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 2023-24 there were 1,673,410 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 or operational significance, the analysis includes unadjusted and standardised[1] rates, the number of donations for one additional (or one less) event and trend data.

In 2023-24, approximately 3.64% of donations (n=60,870) were associated with at least one donor adverse event. Standardised analysis shows that the total adverse event rate for all donation types have generally improved or remained stable since 2022-23. With regard to unique events, there has been a significant reduction in haematoma and painful arm. The infiltration rate for plasmapheresis collections has increased with an additional event occurring every 1,844 donations. The rate of infiltration events requiring outside medical care is not significantly different, suggesting the increase is in more minor events.

Events that require outside medical care are considered a surrogate for more severe reactions. The unadjusted and standardised rate for outside medical care for both whole blood and plasma were significantly increased in 2023-24 compared with 2022-23. There were increases in outside medical care rates for both Vasovagal rates (VVRs) and non-apheresis phlebotomy-related events. Based on the three-year monthly trend data, the increase is considered a normal variation.

[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 rates1 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. Whilst standardising does not fully adjust for all possible variables, standardised rates allow for a more accurate comparison between time periods.

Overview of total event rates by donation type

In 2023-24, approximately 3.64% of donations (n=60,870) were associated with at least one donor adverse event. Unadjusted figures showed that the total donor adverse event rate for each of the donation types in 2023-24 were significantly lower than in 2022-23 [Table 1]. Standardised data showed a significant reduction in the overall rate for whole blood and plasmapheresis, and no significant difference for plateletpheresis [Table 2, Figure 1]. 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 2023-24 to 2022-23		
Donation type	20-21	21-22	22-23	23-24	RR[2] (95% CI[3]; p value)	Number of donations for one additional event*	% Change in rate
Whole blood	297.56	315.31	286.83	273.59	0.95 (0.94-0.97; p<0.001)	-755	-4.62%
Plasmapheresis	525.55	493.82	475.36	432.91	0.91 (0.90-0.92; p<0.001)	-236	-8.93%
Plateletpheresis	870.66	704.12	760.61	707.78	0.93 (0.88-0.99; p=0.02)	-189	-6.95%
Total	429.57	413.92	392.50	363.75	0.93 (0.92-0.94; p<0.001)	-348	-7.33%

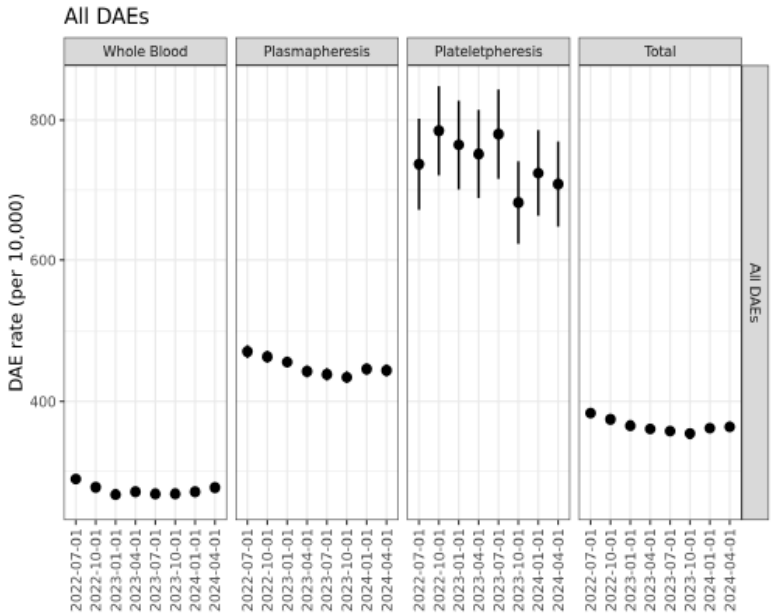
*a negative number indicates that the number of donations is for one less event

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

	Rate per 10,000 donations		Comparison 2023-24 to 2022-23		
Donation type	22-23	23-24	RR (95% CI; p value)	Number of donations for one additional event	% Change in rate
Whole blood	286.01	280.29	0.98 (0.96-1.00; p=0.03)	-1,750	-2.00%
Plasmapheresis	460.77	444.39	0.96 (0.95-0.98; p<0.001)	-611	-3.55%
Plateletpheresis	759.90	724.70	0.95 (0.90-1.01; p=0.12)	-284	-4.63%
Total	377.06	365.78	0.97 (0.96-0.98; p<0.001)	-886	-2.99%

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

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



[2] *Relative Risk*

[3] *Confidence Interval*

General trends for more common events by donation type

Whole blood (n=773,015)

The reduction in the unadjusted total rate for whole blood is primarily attributed to reductions in rates for vasovagal (174.1 vs 181.9 per 10,000), haematoma (72.5 vs 76.4 per 10,000) and painful arm (18.33 vs 20.6 per 10,000) Standardising demonstrated a significant relative risk reduction for haematoma and painful arm only, translating to one less event for every 3,059 and 5,194 whole blood donations respectively.

Plasmapheresis (n=873,395)

The reduction in the unadjusted total rate for plasmapheresis was a net effect of the rate reduction for vasovagal reactions (100.4 vs 112.7 per 10,000), haematoma (121.9 vs 132.1 per 10,000), painful arm (46.2 vs 55.8 per 10,000), nerve injury (17.1 vs 19.3 per 10,000) and mild citrate reactions (91.5 vs 110.3 per 10,000). This reduction was offset to a small degree by a rate increase in infiltration (86.03 vs 80.61 per 10,000). After standardising there were only significant rate reductions for haematoma, painful arm and mild citrate reactions, translating to one less event for every 1,285, 1,412 and 1,049 plasmapheresis donations respectively. The infiltration rate remained significantly higher in the standardised analysis (85.6 vs 78.4 per 10,000 donations), translating to one additional event for every 1,383 donations. The rate of infiltration events requiring outside medical care was not significantly different (0.77 vs 0.71 per 10,000) and suggests an increase in more minor events.

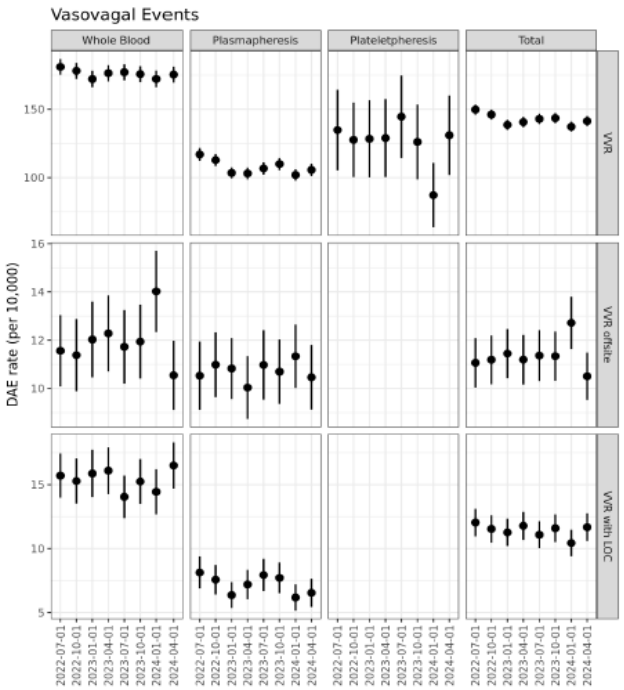
Plateletpheresis (n=27,000)

In 2023-24 there were rate reductions for vasovagal (106.3 vs 121.5 per 10,000), haematoma (188.5 vs 216.3 per 10,000), painful arm (27.4 vs 46.8 per 10,000) and mild citrate reactions (298.9 vs 319.4 per 10,000). This was offset to some degree by rate increases for nerve injury (12.6 vs 9.1 per 10,000) and infiltration (118.2 vs 100.3 per 10,000). On standardising, there were significant rate reductions for haematoma and painful arm, translating to one less event every 364 and 522 plateletpheresis donations respectively. The total infiltration rate did not reach significance when standardising (116.6 vs 98.6 per 10,000; p=0.05).

General trends for vasovagal subtype events

Figure 2 shows the two-year adjusted rates by donation type for (1) all vasovagal events, (2) those that occurred offsite and (3) those associated with Loss of consciousness (LOC). The only significant change was a reduction in offsite (delayed) VVRs associated with plateletpheresis (5.14 vs 10.29 per 10,000). VVRs requiring outside medical care, which is considered an indicator of a more serious event is discussed in the following section.

Figure 2: Unadjusted VVR rates by subgroup, donation type



Outside medical care

The rate for events requiring outside medical care is a surrogate for more serious events. Approximately 0.06% of donations had an event requiring external care (n=1,084). The total unadjusted and standardised rates were significantly higher for whole blood and plasma [Table 3 and 4]. The analysis of unique events was limited to unadjusted rates due to the small number of events requiring outside care. The main event contributing to this increase, was VVRs (4.06 vs 3.25 per 10,000; RR 1.25 95% CI: 1.11-1.40; p<0.001), noting that the effect was largest in whole blood, translating to an extra VVR event requiring outside medical care every 8,479 whole blood donations. There was also a significant increase in the proportion of phlebotomy-related events requiring outside medical care (0.95% vs 0.75% per 10,000; p=0.01).

Of events requiring outside medical care, 35.8% required a hospital attendance, 50.2% visited the GP and 10.7% received in-centre ambulance assessment. This represented a percentage point change of -5.4, -0.5 and +5.2 from 2022-23 respectively. Of the 1,084 events reported, vasovagal was reported in 62.6%, nerve injury in 10.1%, haematoma in 7.0%, infiltration in 6.3%, and chest pain in 6.3%.

With improved access to healthcare after the COVID pandemic, an increase in outside medical care could be expected. There is however, no definitive evidence this is occurring, with the Australian Healthcare index (August 2024) indicating that the community is cutting down on GP visits due to the rising cost of living. Based on the three-year monthly trend data the overall increase this year is consistent with a normal variation.

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

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

	Rate per 10,000 donations				Comparison 2023-24 to 2022-23		
Donation type	20-21	21-22	22-23	23-24	RR (95% CI; p value)	Number of donations for one additional event	% Change
Whole blood	7.22	5.87	5.44	7.10	1.31 (1.15-1.48; p<0.001)	+6,041	+30.57%
Plasmapheresis	6.31	4.87	4.79	6.00	1.25 (1.10-1.42; p<0.001)	+8,300	+25.13%
Plateletpheresis	6.75	4.45	3.93	4.07	1.04 (0.44-2.44; p=0.94)	+70,798	+3.59%
Total	6.72	5.33	5.08	6.48	1.28 (1.17-1.40; p<0.001)	+7,153	+27.56%

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

	Rate per 10,000 donations		Comparison 2023-24 to 2022-23		
Donation type	22-23	23-24	RR (95% CI; p value)	Number of donations for one additional event	% Change
Whole blood	5.31	7.01	1.32 (1.16-1.50; p<0.001)	+5,900	+31.91%
Plasmapheresis	4.45	5.75	1.29 (1.13-1.47; p<0.001)	+7,706	+29.17%
Plateletpheresis	3.79	3.95	1.04 (0.44-2.46; p=0.92)	+59,783	+4.42%
Total	4.88	6.36	1.30 (1.19-1.43; p<0.001)	+6,754	+30.37%

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

Conclusion

Overall, except for infiltration, unique adverse event rates are similar to, or improved, from the previous year. The rate for outside medical care significantly increased in 2023-24, particularly for VVR and (non-apheresis) phlebotomy events, translating to one additional event requiring outside medical care every 7,153 donations. It should be noted that the monthly trend data shows the two peaks coincided with two of our most significant marketing campaigns and suggests that donors may be more likely to come underprepared and/or the experience in centre is different at times of increased workflow. Strengthening messaging on preparation at times of large campaigns may help reduce this effect. With expected improved access to healthcare after the COVID pandemic, an increase in the outside medical care rate could occur. There is however no definitive evidence that this is a reset effect after restricted access to healthcare during the pandemic, and the overall increase in the outside medical care rate this year is consistent with a normal variation.

APPENDIX

Table 1: Unique adverse event rates for 2023-24 per 10,000 donations and unit change from 2022-23

Event type	Whole Blood		Plasmapheresis		Plateletpheresis		Total	
	Event (n)	Rate (change)	Event (n)	Rate (change)	Event (n)	Rate (change)	Event (n)	Rate (change)
Vasovagal events								
VVR	13,455	174.06 -7.84	8,769	100.4 -12.32	287	106.3 -15.23	22,511	134.52 -10.37
VVR with LOC	1,226	15.86 -0.76	608	6.96 -0.64	24	8.89 0.24	1,858	11.1 -0.69
Phlebotomy Related								
Arterial Puncture	37	0.48 0	6	0.07 -0.1	0	0 0	43	0.26 -0.05
Cellulitis	1	0.01 0	6	0.07 -0.05	0	0 0	7	0.04 -0.03
Delayed Bleeding	88	1.14 0	102	1.17 -0.36	2	0.74 0.35	192	1.15 -0.18
Haematoma	5,602	72.47 -3.9	10,650	121.94 -10.17	509	188.52 -27.79	16,761	100.16 -7.45
Nerve injury/irritation	935	12.1 0.23	1,494	17.11 -2.2	34	12.59 3.55	2,463	14.72 -0.99
Other phlebotomy injury	3	0.04 -0.54	8	0.09 -0.68	0	0 0	11	0.07 -0.61
Painful arm	1,417	18.33 -2.25	4,034	46.19 -9.64	74	27.41 -19.39	5,525	33.02 -6.35
Thrombophlebitis	37	0.48 0.04	65	0.74 0.29	2	0.74 -0.05	104	0.62 0.17
Other Event Type								
Anaphylaxis	0	0 0	1	0.01 -0.01	0	0 0	1	0.01 0.00
Chest Pain	35	0.45 -0.01	66	0.76 0.1	2	0.74 0.35	103	0.62 0.05
Local Allergic Reaction*	84	1.09 0.04	138	1.58 -0.41	1	0.37 -0.81	223	1.33 -0.21
Other event/injury	198	2.56 1.25	309	3.54 1.52	5	1.85 1.85	512	3.06 1.4

Table 2: Unique apheresis-specific adverse event rates for 2023-24 per 10,000 donations and unit change from 2022-23

Event type	Plasmapheresis		Plateletpheresis		Total	
	Event (n)	Rate (change)	Event (n)	Rate (change)	Event (n)	Rate (change)
Haemolysis	37	0.42 0.12	1	0.37 0.37	38	0.42 0.13
Infiltration	7,514	86.03 5.42	319	118.15 17.86	7,833	87 5.82
Mild Citrate Reaction	7,992	91.5 -18.77	807	298.89 -20.46	8,799	97.72 -18.61
Moderate/severe Citrate Reaction	398	4.56 0.35	47	17.41 -8.16	445	4.94 0.12
Omitted Anticoagulant	5	0.06 -0.08	3	1.11 0.72	8	0.09 -0.06

ANNEX 1 - State/territory haemovigilance process improvement

In 2023-24, state/territory departments of health continue to improve their process for haemovigilance data collection and reporting.

NSW

Brief description (one or two paragraphs) of the jurisdiction's progress since the last report and strategies moving forward.

Wrong Blood In Tube (WBIT) incidents:

- NSW Health mandated a new standardised pre-transfusion testing form in January 2024. Data from January – June 2024 demonstrates a decrease in the number of WBIT incidents reported since the new form was mandated.
- Further analysis will be undertaken to measure whether this represents a decrease in the rate of these incidents.
- As opportunities to refine the NSW Health incident management system for blood and blood products, Blood Watch will advocate for changes that support compliance with AHMDS.

VIC

Continue to provide Bulletins covering transfusion related issues, that come to light from data and the network, to help improve practice.

An annual report of all validated investigations is developed each financial year. This report contains case studies and recommendations for improved practice.

Currently reviewing many of our reporting forms to ensure we have the best information available and can meet AHMDS data requirements, without making the forms onerous for reporters to complete.

Ambulance Victoria are now one of the services that can report incidents and reactions to STIR. No reports at this time.

QLD

Haemovigilance strategies continue to be embedded in local processes, with a focus on sustaining improvements and maintaining engagement across relevant clinical and support teams. At the state level, a Patient Safety Communique will shortly be published and disseminated across Hospital and Health Services, related to ABO-incompatible transfusion incidents. The purpose of this Communique is to highlight the criticality of positive patient identification prior to commencing a blood transfusion, and to summarise lessons from blood transfusion-related clinical incidents (ABO-incompatible adverse events).

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

With introduction of new AHMDS in July 2025, WA Haemovigilance Program reporting via REDCap will be aligned with AHMDS 2025 allowing for simplified data extraction for NBA data requests.

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.

NT

The occurrence of reported transfusion reactions has decreased from 3 in the 2022 – 23 period (1 x TACO and 2 x FNHTR) to 1 in the 2023-24 period (1 x IBCT).

All reported transfusion reactions are investigated and reviewed 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. The above-mentioned transfusion incident was 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

ACT Health is preparing to roll out its ACT-wide Haemovigilance Framework (Framework) mid 2025. The Framework outlines the requirements for Haemovigilance reporting in the ACT and will be provided to each of the ACT's hospitals 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
EPAS	Enterprise Patient Administration System
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
SHOT	Serious Hazards of Transfusion
STIR	Serious Transfusion Incident Reporting
TACO	Transfusion-associated circulatory overload
TAD	Transfusion associated dyspnoea
TAS	Tasmania
TIRG	Transfusion Incident Review Group
TRALI	Transfusion-related acute lung injury
TTI	Transfusion-transmitted infection
VIC	Victoria
VVR	Vasovagal rate
WA	Western Australia
WBIT	Wrong Blood In Tube

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

Professor Erica Wood	NBA appointed HAC Chair
Mr Brett Aitken	Australian Private Hospitals Association
Mr Geoffrey Bartle	Consumer Representative
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
Associate Professor Lilon Bandler	NBA Patient Blood Management Advisory Committee Chair

Expert Advisors

Dr Heather Buchan	Australian Commission on Safety and Quality in Health Care
Dr Angela Gowland	Therapeutic Goods Administration
Dr Adrian Webster	Australian Institute of Health and Welfare

National Blood Authority

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Ms Suzie Cong	Senior Data Analyst, Data and Blood Services
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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 and Human Services
ACT Health
NT Department of Health

SECTION 2 – DONOR SAFETY REPORT was contributed by the Australian Red Cross Lifeblood


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