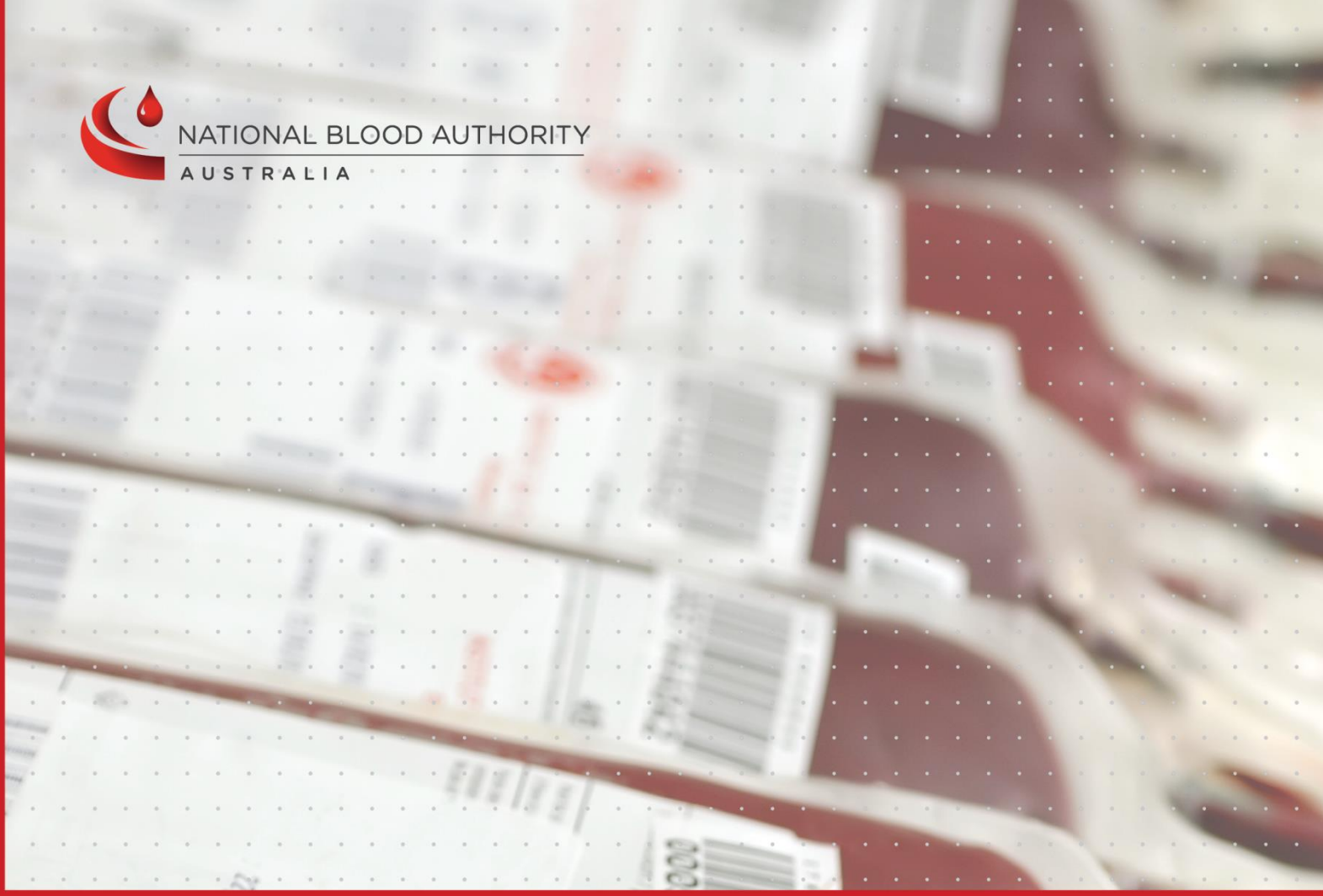
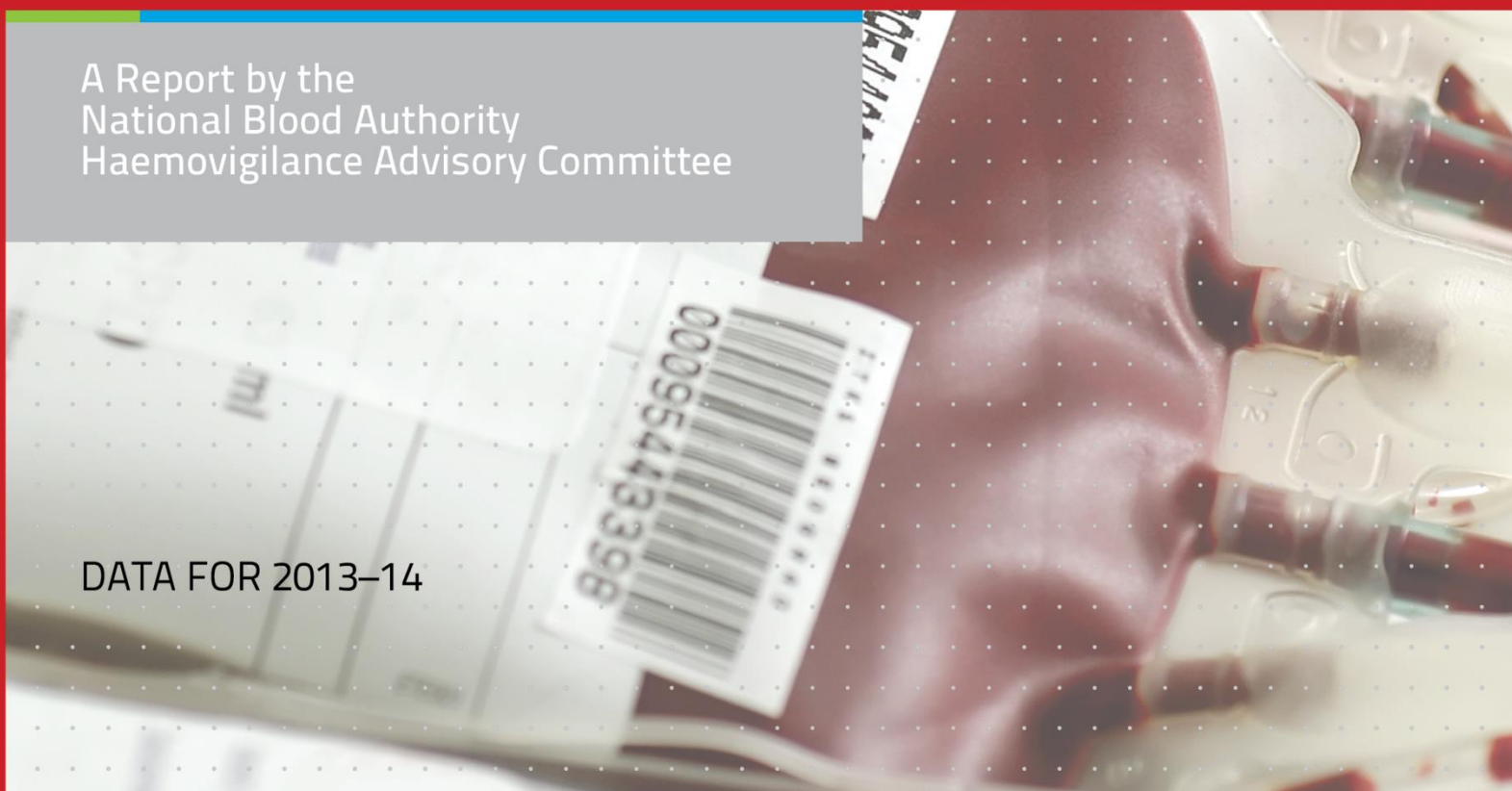
NATIONAL BLOOD AUTHORITY
AUSTRALIA



AUSTRALIAN HAEMOVIGILANCE REPORT

A Report by the
National Blood Authority
Haemovigilance Advisory Committee



DATA FOR 2013–14

Australian Haemovigilance Report, Data for 2013–14 published by the National Blood Authority.

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This report is available online at http://www.blood.gov.au/haemovigilance-reporting

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- All the adverse events in this report are reported cases rather than confirmed cases. The TRALI and TTI data is not reconciled with the Blood Service.
- Data contributions vary across years and between states/territories.
- Data is under-reported for private health service providers and some adverse events such as transfusion-associated circulatory overload.
- Near misses and denominator data are not collected and reported at national level.
- The adverse events definitions used for the reporting are not consistent with the current ISBT definitions; therefore the data cannot be properly analysed and compared at national level and international level.
- There is no detailed data on Australian practices to monitor improvement over time.

MESSAGE FROM THE GENERAL MANAGER OF THE NATIONAL BLOOD AUTHORITY

On behalf of the National Blood Authority (NBA), I am pleased to present the fifth Australian Haemovigilance Report. This report provides information on transfusion-related and donation-related adverse events between July 2013 and June 2014.

Haemovigilance is an important tool to improve the effective and appropriate management of blood and blood products, and to ensure the safety of Australians receiving and donating blood. The National Safety and Quality Health Service Standard 7 on Blood and Blood Products (NSQHS Standard 7) requires health service organisations to participate in relevant haemovigilance activities conducted at state or national level.

To ensure patient safety in blood transfusion, the NBA embarked on a program to develop Patient Blood Management Guidelines for fresh blood. Six modules have now been published and the first one is under review. The published modules cover critical bleeding/massive transfusion, perioperative, medical, critical care, obstetrics and maternity, neonatal and paediatrics.

Improvements in the appropriate use of fresh blood products and reduction in wastage continue to reduce demand for blood products. The 2014–15 demand for red cells decreased by 5 per cent and platelets by around 2 per cent. This brought the total reduction in red cell demand over the last three years to 18 per cent, realising significant improvements in patient outcomes and financial savings in excess of $78 million. In contrast, general hospital activities have increased by over 15 per cent in the same period.

Australia continues to develop capacity in haemovigilance data collection and reporting:

- The Australian Commission on Safety and Quality in Health Care (ACSQHC) with the NBA is conducting the review of NSQHS Standard 7. The public consultation on the revised standard has concluded and the implementation of the new Standard is expected in 2017–18.
- Governments have implemented a Strategic Framework for the National Haemovigilance Program to support and enhance haemovigilance activities, define haemovigilance roles and responsibilities within Australia and identify data collection and reporting obligations at local, state/territory and national levels.
- The NBA and Haemovigilance Advisory Committee (HAC) have redeveloped and published the Australian Haemovigilance Minimum Data Set (AHMDS), previously known as the Australian National Haemovigilance Data Dictionary (ANHDD).
- The NBA has assisted QLD and WA to develop and implement haemovigilance data collection forms. QLD Health has used the forms to collect and report 2013–14 data. WA is using the forms to collect haemovigilance data for 2015–16.
- The NBA is working closely with HAC and key stakeholders to develop and implement a Work Plan and other tools to promote haemovigilance in Australia. The Blood Service is developing guidance and a chart for the recognition and management of serious adverse events.

This fifth report is a valuable resource for assisting in understanding the risks associated with transfusion and donation in Australia. I would like to offer sincere thanks to all contributing parties for their dedication and hard work promoting safety and quality in the Australian blood sector.

Michael Stone
Acting General Manager
National Blood Authority

EXECUTIVE SUMMARY

This is the Australian Haemovigilance Report 2016 (Data for 2013-14). It provides an overview of blood transfusion and donation-related adverse events in Australia, and data and information on fresh blood product issues to health service organisations. This report also makes 11 key recommendations in four areas:

1. national blood quality and safety initiatives
2. reducing human errors
3. data standards
4. reporting capacity.

Reporting of haemovigilance data to the national haemovigilance program is voluntary and data validation is lacking in Australia. When using the data from this report it is important to note that it has quality issues in relation to data completeness, standardisation and relevance as described in Part 02. For example:

- All the adverse events in this report are reported cases rather than confirmed cases. The TRALI and TTI data is not reconciled with the Blood Service.
- Data contributions vary across years and between states/territories.
- Data is under-reported for private health service providers and some adverse events such as transfusion-associated circulatory overload.
- Near misses and denominator data are not collected and reported at national level.
- The adverse events definitions used for the reporting are not fully in line with the current ISBT definitions; therefore the data cannot be properly analysed and compared at national level and international level.
- There is no detailed data on Australian practices to monitor improvement over time.

Key findings

1. Fresh blood components have become increasingly safe as a result of stringent donor screening and selection policies and increasingly sensitive and selective product testing in Australia. There have been no transfusion-related deaths reported since 2009–10.
2. In the 11 years to 2013–14, the NBA's expenditure on fresh blood products increased from $247.8 million to $583 million. Key drivers of this increase are price increases, demand changes and the introduction of government-approved quality and safety measures.
3. There has been a reduction in demand for red blood cells and platelets over the last three years as a result of reported improvements in appropriate use and reduced wastage.
4. In 2013-14 there were 617 transfusion-related adverse events reported to the national haemovigilance program. NSW provided around 35% with SA and QLD around 25% each. This represented an increase from the number of events reported in 2012-13 (429).
5. From 2010–11 to 2013–14 there were 2,243 transfusion-related adverse events of 10 different types reported to the national haemovigilance program. NSW reported the highest number of adverse events (789), followed by SA (609) and QLD (470). QLD did not contribute 2012–13 data due to the cessation of the QLD haemovigilance system QiiT, however has contributed 2013–14 data, following the introduction of the QLD Haemovigilance Data Collection Forms. WA did not contribute data for this period.
6. The most frequently reported adverse events are febrile non-haemolytic transfusion reactions (FNHTR) and allergic reactions, representing 53.9% and 24.3% of all reports (2,243) respectively for 2010–11 to 2013–14. The Australian data for transfusion-associated circulatory overload (TACO), transfusion-related acute lung injury (TRALI), and delayed haemolytic transfusion reaction (DHTR) may indicate that these adverse events are under-reported when compared internationally.
7. 210 out of 2,243 transfusion-related events were classified as serious adverse events. TACO and allergic reaction were the most commonly reported serious adverse events, representing 23.8% and 22.9% of

all serious events respectively (210). TRALI accounted for only 1.4% of serious events, likely due to the implementation of TRALI risk reduction strategies in Australia, such as the use of male only plasma donors.

8. Human errors continue to contribute to transfusion-related adverse events. For example, incorrect blood component transfused (IBCT) contributed to 7.5% of serious events.
9. The majority of serious allergic and anaphylactic reactions were related to the transfusion of fresh frozen plasma and platelets.
10. Around half of the serious events involved patients aged 65 and above. Around 30.5% of serious events were related to transfusions between 7pm and 7am.
11. In 2013–14 there were a total of 1.3 million donations, including 0.78 million whole blood donations, 0.48 million plasmapheresis donations and 0.04 million plateletpheresis donations.
12. There were 34,778 donation-related events reported in 2013–14. The reporting rate of serious donation-related events was 8.5 per 10,000 donations in 2013–14.
13. The frequency of adverse events was found to be higher in younger and female blood donors, especially those under the age of 20 years.

Recommendations

This 2016 report makes 12 recommendations, including eight recommendations from the last report and four new or revised recommendations. Please note the sixth recommendation of 'Review and redevelop the Australian National Haemovigilance Data Dictionary' from the last report has been delivered and replaced by 'Implement the Australian Haemovigilance Minimum Data Set' in this report. The NBA and HAC have developed a Work Plan for 2015–17 to guide the implementation of the recommendations in the following areas.

National blood quality and safety initiatives

1. Promote the recognition and management of transfusion-related adverse events.
2. Implement programs at the national, state and local health service provider levels to improve reporting of serious adverse events.

Reducing human errors

3. Clinical staff should comply with national guidelines on sample collection and administration of blood and blood products.
4. Promote the application of technological adjuncts such as portable barcode readers and/or radio-frequency identification scanners to reduce the scope for error.
5. Develop tools to encourage alignment of prescribing practice with clinical guidelines.

Data standards

6. Implement the Australian Haemovigilance Minimum Data Set (AHMDS).
7. Provide tools for health service providers on the application of the AHMDS and reporting of haemovigilance data.
8. Continue to include donor vigilance data in national haemovigilance reporting.
9. Consider including near misses in national haemovigilance reporting.
10. Include relevant data in national haemovigilance reporting.

Reporting capacity

11. Implement the Strategic Framework for the National Haemovigilance Program.
12. Maintain and improve existing capacities for haemovigilance data reporting.

PART 01 HAEMOVIGILANCE IN AUSTRALIA

Haemovigilance definitions

International Haemovigilance Network

'A set of surveillance procedures covering the whole transfusion chain (from the collection of blood and its components to the follow up of recipients), intended to collect and assess information on unexpected or undesirable effects resulting from the therapeutic use of labile blood products, and to prevent their occurrence or recurrence'.

World Health Organization

'Haemovigilance is required to identify and prevent occurrence or recurrence of transfusion related unwanted events, to increase the safety, efficacy and efficiency of blood transfusion, covering all activities of the transfusion chain from donor to recipient.
The system should include monitoring, identification, reporting, investigation and analysis of adverse events near-misses and reactions related to transfusion and manufacturing.'

Why conduct haemovigilance in Australia?

It is widely acknowledged that haemovigilance is an important tool to improve the effective and appropriate management of blood and blood products, and to ensure the safety of people receiving and donating blood.

The NBA, under the *National Blood Authority Act 2003*, plays a key role in promoting transfusion appropriateness, safety and blood management in Australia.

The NSQHS Standard 7 requires (section 7.3) that health organisations ensure blood and blood product adverse events are included in the incidents management and investigation system. The ACSQHC with the NBA is currently conducting the review of NSQHS Standard 7.

The Statement on National Stewardship Expectations for the Supply of Blood and Blood Products outlines measures that Health Ministers expect all health providers to adopt within their organisations. This includes the requirement to manage blood and blood products in ways that ensure transfusion-related adverse event information is collected and managed according to jurisdictional requirements.

National haemovigilance program and HAC

In Australia the rationale for setting up a national haemovigilance program is to enable transfusion practice and product improvements through the aggregation and review of state, territory and health organisation data to:

- identify contributory and comparator factors and
- place Australian transfusion risks into an international perspective.

The Australian national haemovigilance program was established in 2009. The Haemovigilance Advisory Committee (HAC) was established under the national blood arrangements to inform and guide the national haemovigilance program. The HAC comprises members with expertise and knowledge in the health sector, blood management and quality and safety. This group provides advice to governments on adverse event reporting originating from state and territory and other health service organisations and on national

transfusion safety priorities. The committee also oversees the national reporting and governance frameworks.

Strategic Framework for National Haemovigilance Program

The Strategic Framework for the National Haemovigilance Program (Strategic Framework) was developed and endorsed by the Jurisdictional Blood Committee in September 2014. The Strategic Framework redefines the scope of national haemovigilance arrangements to emphasise activities that contribute to national standardisation, and support the states and territories in their collections. There is no national IT system for haemovigilance in Australia.

The roles and responsibilities for haemovigilance within Australia are described in Figure 1.

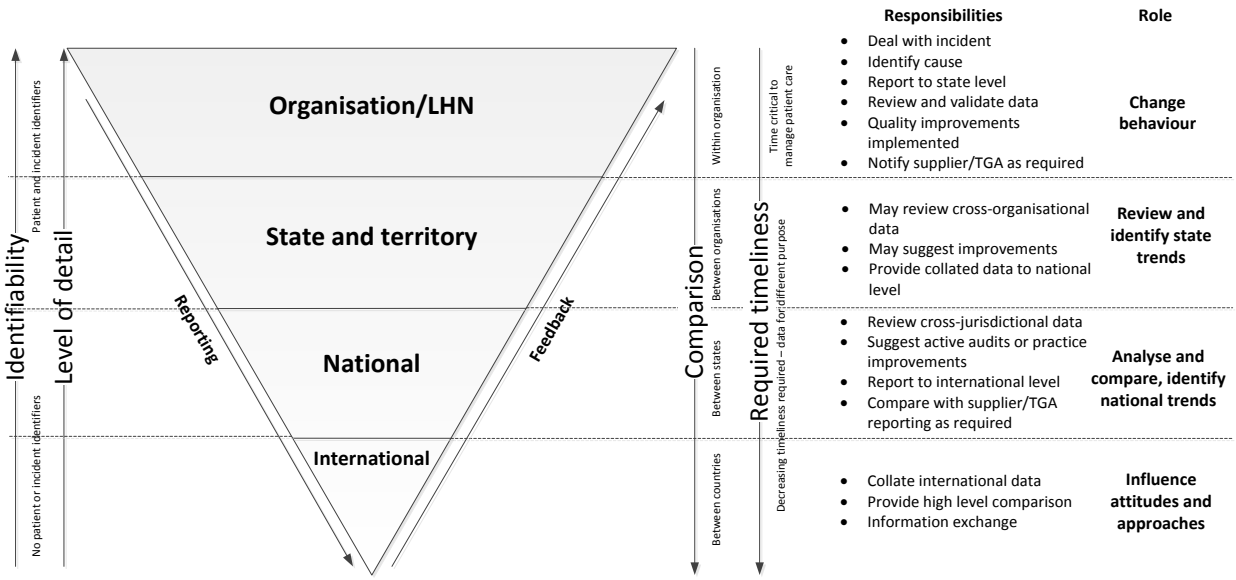

Figure 1: Haemovigilance roles and responsibilities

National haemovigilance reporting process

In Australia, haemovigilance is undertaken at local or state/territory level, supported by local data collection and reporting processes. At present there is no agreed national system for collection. Data is collected at the local or state/territory level and the local area has responsibility for the review of reported incidents to assess the validity and imputability of the incident with respect to whether it was reported correctly, the seriousness of the incident, and assessment of the cause of the incident being related to the transfusion. Some states and territories/local organisations provide their data to Serious Transfusion Incident Reporting (STIR) to conduct this review, while others manage this process themselves, or do not do a review outside of the local level. Following local review, selected data is aggregated and provided to the NBA for national analysis and reports. For more information about the reporting process, please refer to the Strategic Framework (http://www.blood.gov.au/document/strategic-framework-national-haemovigilance-program-pdf).

Haemovigilance Work Plan

To facilitate the implementation of the Strategic Framework and address the major shortcomings of the data, a detailed Work Plan was agreed by the HAC in 2015–16. The Work Plan includes a list of national tools, guidance and projects to improve haemovigilance in Australia. The NBA and HAC will work closely with the Blood Service, Australian & New Zealand Society of Blood Transfusion (ANZSBT), Therapeutic Goods Administration (TGA), state and territory departments of health and other key stakeholders to implement the Work Plan and improve data quality and transfusion safety.

Table 1 is a list of actions that were completed in 2014-15.

Table 1: Haemovigilance actions completed in 2014-15

Data Issue	Action	Progress
Data quality and completeness	Review NSQHS Standard 7	The ACSQHC with the NBA has started the review of Standard 7.
	Develop and implement the Strategic Framework for the National Haemovigilance Program	The Strategic Framework has been published on the NBA Website.
	Develop education and training tools	The NBA has developed and implemented the National Blood Sector Education and Training Strategy 2013–2016.
	Develop and publish clinical audit tools	The NBA has developed clinical audit tools for massive transfusion and red blood cell and these are available on the NBA website.
	Develop and publish transfusion-related case studies	The NBA has published case studies in previous Australian haemovigilance reports.
Data standardisation	Review and redevelop the AHMDS	The NBA has reviewed and redeveloped the data definitions to enable the consistent collection, validation and reporting of national haemovigilance data.
	Develop haemovigilance data collection forms and guidance	The NBA, in conjunction with QLD and WA, has developed data collection tools.
Data coverage	Continue to include donor vigilance data in national haemovigilance reporting	The Blood Service has provided the donor vigilance data for three Australian haemovigilance reports.

For more information about haemovigilance in Australia, please refer to the NBA website at: http://www.blood.gov.au/haemovigilance-reporting.

PART 02 HAEMOVIGILANCE DATA 2013–14

Since 2008, the NBA has collected haemovigilance data received from states and territories and published four Australian haemovigilance reports. This is the fifth national Australian Haemovigilance Report.

This report includes validated adverse event data from state level systems, including the NSW Health Incident Information Management System (IIMS), SA Health Safety Learning System (SLS) and VIC's Blood Matters STIR program. STIR also supports haemovigilance in TAS, ACT and the NT. QLD contributed data collected through new collections forms developed in conjunction with the NBA.

This report details transfusion-related adverse events reported for 2013–14. This summary section also reproduces cumulative data for all adverse events and serious adverse events from 2010–11 to 2013–14 for comparative purposes. The 2008–09 and 2009–10 data have been excluded from analysis because the data was largely incomplete whilst jurisdictions were establishing reporting processes.

It is important to note that all the adverse events are reported events and the data has quality issues in relation to completeness, standardisation and relevance due to the voluntary nature of reporting and lack of data validation in Australia.

Summary of findings for 2013–14

Table 2 shows that 617 events were reported to the national haemovigilance program in 2013–14. Most events were reported by NSW, SA and QLD, accounting for 84.8% of the total reports. ACT reported zero events and WA did not contribute data.

It is important to note that:

- STIR uses a higher level temperature threshold for the reporting of FNHTR. This may have resulted in a number of FNHTRs which would otherwise have been reportable to the national haemovigilance program being excluded for VIC, NT, TAS and ACT.
- All TTIs were suspected but not confirmed bacterial infections.

Table 2: Adverse events by state, 2013–14

	FNHTR	Allergic reaction	IBCT	TACO	TTI	Anaphylactic	DHTR	AHTR	PTP	TRALI	All reports	
											Total	Per cent
NSW	133	45	12	5	8	8	4	1	0	2	218	35.3%
SA	102	39	3	5	4	0	0	1	0	0	154	25.0%
QLD	79	28	6	5	13	3	6	4	6	1	151	24.5%
VIC	22	27	11	13	2	8	1	2	0	0	86	13.9%
NT	1	4	1	0	0	0	1	0	0	0	7	1.1%
TAS	0	1	0	0	0	0	0	0	0	0	1	0.2%
ACT	0	0	0	0	0	0	0	0	0	0	0	0.0%
Total	**337**	**144**	**33**	**28**	**27**	**19**	**12**	**8**	**6**	**3**	**617**	**100.0%**

Notes

1. ACT reported zero adverse events
2. WA did not contribute data
3. All TTIs were suspected but not confirmed bacterial infections

Table 3 details the number of adverse events by imputability score for 2013–14:

- 92.2% of the reported events had specified imputability scores.
- 87.1% of the events were possible, likely or confirmed to be related to the blood transfusion.
- 13.3% of the events were confirmed to be related to the blood transfusion.
- 5.2% of the events were classified as unlikely to be related to the blood transfusion.

Table 3: Adverse events by imputability score, 2013–14

Event Type	Excluded / Unlikely	Possible	Likely / Probable	Confirmed / Certain	N/A /Not assessable	Total	Per Cent
FNHTR	14	223	67	12	21	337	54.6%
Allergic reaction	2	29	70	37	6	144	23.3%
IBCT	2	2	0	13	16	33	5.3%
TACO	0	14	12	2	0	28	4.5%
TTI	10	7	2	6	2	27	4.4%
Anaphylactic	0	3	11	5	0	19	3.1%
DHTR	1	2	1	7	1	12	1.9%
AHTR	2	3	2	0	1	8	1.3%
PTP	1	3	2	0	0	6	1.0%
TRALI	0	0	2	0	1	3	0.5%
Total	**32**	**286**	**169**	**82**	**48**	**617**	
Per cent	**5.2%**	**46.4%**	**27.4%**	**13.3%**	**7.8%**	**100.0%**	

Notes

1. ACT reported zero adverse events
2. WA did not contribute data
3. All TTIs were suspected but not confirmed bacterial infections

Table 4 details the numbers of adverse events by blood product reported for 2013–14:

- Red blood cells were the products most often implicated in adverse events for 2013–14, accounting for 70.7% of the reports, followed by platelets (18.0%) and fresh frozen plasma (10.4%).
- Only a very small proportion of adverse events were related to the transfusion of cryoprecipitate and cryodepleted plasma.

Table 5 details the number of reported adverse events by clinical outcome severity for 2013–14:

- No deaths were reported in 2013–14.
- 4.5% of events were classified as life-threatening which means the patient may have required major intervention following the transfusion such as vasopressors, intubation and/or intensive care.
- 4.5% of events were classified as severe morbidity which means the patient may have required hospitalisation or prolongation of hospitalisation as a result of the event.
- 74.2% of reported events were classified as minor morbidity which means the patient may have required medical intervention but had no permanent damage or impairment of a body function.
- 13.0% of events were classified as no morbidity which means there were no ill/clinical effects to the patient.

Table 4: Adverse events by blood product, 2013–14

Adverse event	Red blood cells	Platelets	Fresh frozen plasma	Cryodepleted	Cryoprecipitate	Unknown	Total
FNHTR	306	22	7	0	0	2	337
Allergic reaction	45	52	45	1	1	0	144
IBCT	22	5	5	1	0	0	33
TACO	26	1	1	0	0	0	28
TTI	8	19	0	0	0	0	27
Anaphylactic	7	8	4	0	0	0	19
DHTR	11	1	0	0	0	0	12
AHTR	7	1	0	0	0	0	8
PTP	1	2	2	1	0	0	6
TRALI	3	0	0	0	0	0	3
Total	**436**	**111**	**64**	**3**	**1**	**2**	**617**
Per cent	**70.7%**	**18.0%**	**10.4%**	**0.5%**	**0.2%**	**0.3%**	**100.0%**

Notes
1. ACT reported zero adverse events
2. WA did not contribute data
3. All TTIs were suspected but not confirmed bacterial infections

Table 5: Adverse events by clinical outcome severity, 2013–14

Adverse event	Death	Life-threatening	Severe morbidity	Minor morbidity	No morbidity	Outcome not available	Total
FNHTR	0	0	8	289	35	5	337
Allergic reaction	0	9	6	118	9	2	144
IBCT	0	0	0	3	20	10	33
TACO	0	8	8	10	1	1	28
TTI	0	0	0	14	8	5	27
Anaphylactic	0	9	4	6	0	0	19
DHTR	0	0	1	8	3	0	12
AHTR	0	1	0	6	1	0	8
PTP	0	1	0	2	3	0	6
TRALI	0	0	1	2	0	0	3
Total	**0**	**28**	**28**	**458**	**80**	**23**	**617**
Per cent	**0.0%**	**4.5%**	**4.5%**	**74.2%**	**13.0%**	**3.7%**	**100.0%**

Notes
1. ACT reported zero adverse events
2. WA did not contribute data
3. All TTIs were suspected but not confirmed bacterial infections

Table 6 shows the number of serious adverse events for 2013–14. ‘Serious adverse event’ in this report means that an event is possible or likely/probable, or confirmed/certain to be related to the blood

transfusion and results in severe morbidity or a life-threatening outcome or death to a patient. Previous haemovigilance reports did not include analysis of serious adverse events.

In 2013–14:

- 54 adverse events were classified as serious (8.8% of all reported events).
- 36 (68.6%) serious events were likely or confirmed to be related to the blood transfusion.
- Four life-threatening and six severe morbidity events were confirmed to be related to the blood transfusion.

Table 6: Serious adverse events by outcome severity and imputability score, 2013–14

	Death	Life-threatening	Severe morbidity	All reports	
				Total	Per cent
Possible	0	9	9	18	33.3%
Likely/Probable	0	15	11	26	48.1%
Confirmed/Certain	0	4	6	10	18.5%
Total	**0**	**28**	**26**	**54**	**100.0%**

Notes

1. Not assessable and excluded/unlikely imputability scores are not included in the analysis
2. Outcome severity with unknown outcomes, minor and no morbidities are not included in the analysis
3. ACT reported zero adverse events
4. WA did not contribute data

Cumulative results for 2010–11 to 2013–14

From 2010–11 to 2013–14, there were 2,243 reports of adverse events to the national haemovigilance program (see Table 7). The 2008–09 and 2009–10 data were excluded from analysis because the data was largely incomplete whilst jurisdictions were establishing reporting processes for these two years.

Most events were reported by NSW, SA and QLD, accounting for 83.3% of the total reports for this period:

- NSW reported the highest number of events among all the states and territories.
- QLD did not contribute any data for 2012–13 due to the cessation of the QLD haemovigilance system. QLD contributed data in 2013–14 through the use of haemovigilance data collection forms.
- ACT reported zero adverse events for 2010–11 and 2013–14.
- WA did not contribute data for the entire period.

Table 7: Adverse events by state, 2010–11 to 2013–14

	2010–11	2011–12	2012–13	2013–14	All reports	
					Number	Per cent
NSW	186	191	194	218	789	35.2%
SA	147	151	157	154	609	27.2%
QLD	142	177	0	151	470	21.0%
VIC	97	81	59	86	323	14.4%
NT	5	9	11	7	32	1.4%
TAS	5	2	4	1	12	0.5%
ACT	0	4	4	0	8	0.4%
All reports	**582**	**615**	**429**	**617**	**2,243**	**100.0%**

Notes

1. NSW did not report detailed data (such as blood products, outcome severity and imputability score) for 2010–11
2. ACT reported zero adverse events for 2010-11 and 2013–14
3. QLD did not contribute data for 2012–13
4. WA did not contribute data

Table 8 shows that from 2010–11 to 2013–14:

- The most frequently reported adverse events were FNHTRs and allergic reactions, representing 53.9% and 24.3% of all reports respectively.
- Seven PTP cases, including six cases in 2013–14, were reported to the national haemovigilance program.
- It is suspected that in Australia, TACO, TRALI, and DHTR are under-reported when comparing the transfusion risks of these three adverse events with the other commonly reported adverse events. For example: the transfusion risks suggest that TACO is as common as FNHTR, however the number of TACO events reported to the national haemovigilance program is much lower than that of FNHTR events (96 versus 1,209).
- Human errors continue to contribute to the occurrence of adverse events. For example, IBCT contributed to 7.5% of all reported events. Human errors are discussed further in the contributory factors section.

Please note that some FNHTR events reportable to the national haemovigilance program may have been screened out by STIR for VIC, NT, TAS and ACT due to the use of a higher level temperature threshold for the reporting of FNHTR. All TTIs were suspected but not confirmed bacterial infections.

Table 8: Australian adverse event data, 2010–11 to 2013–14

Adverse event	2010–11	2011–12	2012–13	2013–14	All reports		Transfusion risk per unit transfused
					Number	Per cent	(unless specified)
FNHTR	321	320	231	337	1,209	53.9%	0.1–1% of transfusions with universal leucocyte depletion
Allergic reaction	142	147	111	144	544	24.3%	1–3% of transfusion of plasma containing components
IBCT	30	62	43	33	168	7.5%	Not available
TACO	24	27	17	28	96	4.3%	<1% of transfused patients
TTI	11	12	5	27	55	2.5%	1:75,000 platelet transfusions 1:500,000 red cell transfusions
Anaphylactic	33	16	13	19	81	3.6%	1:20,000–1:50,000
DHTR	10	17	6	12	45	2.0%	1:2,500–1:11,000
AHTR	2	10	2	8	22	1.0%	1:76,000
PTP	1	-	-	6	7	0.3%	Rare
TRALI	8	4	1	3	16	0.7%	1:1,200–1:190,000 transfusions
All reports	**582**	**615**	**429**	**617**	**2,243**	**100.0%**	

Notes

1. NSW did not report detailed data (such as blood products, outcome severity and imputability score) for 2010–11
2. ACT reported zero adverse events for 2010-11 and 2013–14
3. QLD did not contribute data for 2012–13
4. WA did not contribute data
5. All TTIs were suspected but not confirmed bacterial infections

Serious adverse events

Among the 2,243 adverse events reported to the national haemovigilance program, around one in ten events (210) were classified as serious adverse events. TACO and allergic reaction were the most commonly reported serious adverse events, representing 23.8% and 22.9% of all serious events respectively (210). The percentage of serious events was very low for TRALI (1.4%), likely due to the implementation of the TRALI risk reduction strategies in Australia such as the use of male only plasma.

Table 9: Serious adverse events, 2010–11 to 2013–14

	2010–11	2011–12	2012–13	2013–14	All reports	
					Total	Per cent
TACO	10	16	8	16	50	23.8%
Allergic reaction	9	15	9	15	48	22.9%
FNHTR	12	9	12	7	40	19.0%
Anaphylactic	7	8	8	13	36	17.1%
IBCT	3	4	5	0	12	5.7%
DHTR	1	7	1	1	10	4.8%
AHTR	1	4	0	1	6	2.9%
TTI	3	0	1	0	4	1.9%
TRALI	2	1	0	0	3	1.4%
PTP	0	0	0	1	1	0.5%
All reports	**48**	**64**	**44**	**54**	**210**	**100.0%**

Notes

1. NSW did not report detailed data (such as blood products, outcome severity and imputability score) for 2010–11
2. ACT reported zero adverse events for 2010-11 and 2013–14
3. QLD did not contribute data for 2012–13
4. WA did not contribute data
5. All TTIs were suspected but not confirmed bacterial infections

Table 10 details the numbers of serious adverse events by blood product reported from 2010–11 to 2013-14:

- Red blood cells were the products most often implicated in serious events for this period, accounting for 63.8% of the reports, followed by fresh frozen plasma (19.0%) and platelets (17.1%).
- The majority of serious allergic and anaphylactic reactions were related to the transfusion of fresh frozen plasma and platelets.

Table 10: Serious adverse events by product, 2010–11 to 2013–14

	Red Cells	Fresh Frozen Plasma	Platelets
TACO	47	3	0
Allergic reaction	13	20	15
FNHTR	30	1	9
Anaphylactic	10	15	11
IBCT	11	1	0
DHTR	10	0	0
AHTR	6	0	0
TTI	4	0	0
TRALI	3	0	0
PTP	0	0	1
All reports	**134**	**40**	**36**
Per cent	**63.8%**	**19.0%**	**17.1%**

Notes

1. NSW did not report detailed data (such as blood products, outcome severity and imputability score) for 2010–11
2. ACT reported zero adverse events for 2010-11 and 2013–14
3. QLD did not contribute data for 2012–13
4. WA did not contribute data
5. All TTIs were suspected but not confirmed bacterial infections

Table 11 shows that 30.5% of serious events were related to transfusions between 7pm and 7am. The ANZSBT *Guideline for the Administration of Blood Products*[1] and British Committee for Standards in Haematology (BCSH) *Guideline on the Administration of Blood Components 2009*[2] both recommend that overnight/out-of-hours transfusion should be avoided unless clinically indicated.

The Annual SHOT Report 2014[3] recommended that:

- Transfusions should be given with the same attention to patient observations whatever the time of day or night.
- Transfusions at night must proceed where there is a clear clinical indication, and may be given as long as the staffing is sufficient to permit transfusion according to the standards defined in the BCSH Guideline on Administration of Blood Components 2009. These standards include adequate pre-transfusion assessment, observations at 15 minutes after the start of each component and regular visual observation throughout the transfusion.
- Decisions to transfuse should not be made simply on the basis of the haemoglobin result, but taking into account the full medical history, the patient's current medical condition and the wishes of the patient. Junior medical staff should review the patient, consult the case notes and take advice from senior medical staff before deciding to transfuse at night, particularly when the team concerned are not familiar with the patient's case and are not responsible for the overall management plan.

Table 11: Serious adverse events by transfusion time, 2010–11 to 2013–14

	2010–11	2011–12	2012–13	2013–14	All reports	
					Total	Per cent
Between 7am and 7pm	35	34	16	20	105	50.0%
Between 7pm and 7am	10	22	11	21	64	30.5%
Not reported	3	8	17	13	41	19.5%
All reports	**48**	**64**	**44**	**54**	**210**	**100.0%**

Notes

1. SA did not report transfusion time data from 2011–12 to 2013–14
2. NSW did not report detailed data (such as blood products, outcome severity and imputability score) for 2010–11
3. ACT reported zero adverse events for 2010-11 and 2013–14
4. QLD did not contribute data for 2012–13
5. WA did not contribute data

Table 12 details the data for serious events by week day/weekend for 2010–11 to 2013–14. Around 25.7% of serious events were related to weekend transfusion.

Table 12: Serious adverse events by week day/weekend, 2010–11 to 2013–14

	2010–11	2011–12	2012–13	2013–14	All reports	
					Total	Per cent
Week day	37	43	36	40	156	74.3%
Weekend	11	21	8	14	54	25.7%
Not reported	0	0	0	0	0	0.0%
All reports	**48**	**64**	**44**	**54**	**210**	**100.0%**

Notes

1. NSW did not report detailed data (such as blood products, outcome severity and imputability score) for 2010–11
2. ACT reported zero adverse events for 2010-11 and 2013–14
3. QLD did not contribute data for 2012–13
4. WA did not contribute data

Table 13 shows the number of serious events by age group from 2010–11 to 2013–14. Around half of the serious events involved patients aged 65 and above.

Table 13: Serious adverse events by age group, 2010–11 to 2013–14

	2010–11	2011–12	2012–13	2013–14	All reports	
					Total	Per cent
0–4 years	2	2	1	0	5	2.4%
5–14 years	0	3	2	3	8	3.8%
15–24 years	7	3	4	2	16	7.6%
25–34 years	0	3	3	2	8	3.8%
35–44 years	2	3	6	5	16	7.6%
45–54 years	5	4	3	4	16	7.6%
55–64 years	6	16	5	10	37	17.6%
65–74 years	9	16	8	8	41	19.5%
75 years or older	14	14	12	18	58	27.6%
Not stated	3	0	0	2	5	2.4%
All reports	**48**	**64**	**44**	**54**	**210**	**100.0%**

Notes

1. NSW did not report detailed data (such as blood products, outcome severity and imputability score) for 2010–11
2. ACT reported zero adverse events for 2010-11 and 2013–14
3. QLD did not contribute data for 2012–13
4. WA did not contribute data

Data quality for 2013-14

Reporting of haemovigilance data to the national haemovigilance program is voluntary in Australia. States and territories are primarily responsible for the quality of adverse event data provided to the national haemovigilance program according to each jurisdiction's review and reporting requirements.

Transfusion-related adverse events should be validated at the local level. Standards for validation are developed by local health services in conjunction with health departments. Reports of serious adverse events may go through a secondary validation process within state and territory haemovigilance programs and health department quality units to ensure data accuracy and completeness. State and territory health departments aggregate and de-identify data, and send periodic reports to the NBA. The NBA checks the completeness of the reported values against the national definitions. Potential errors are queried with states and territories. Corrections and resubmissions may be made in response to the data queries. The NBA does not adjust data to account for possible missing or incorrect values.

There are four major issues in relation to national haemovigilance data collection, validation and reporting.

1. Data quality and completeness
   The existing haemovigilance and incident systems are organised at state level. The participation in these systems is voluntary for most states and territories and each jurisdiction has different requirements for adverse event reporting and review. This has led to variation in the quality and completeness of adverse event data reported to the national haemovigilance program for this report.
   - NSW, VIC, QLD, SA, TAS, NT and ACT contributed validated data according to the reporting requirements of these states and territories.
   - ACT reported zero adverse events.
   - WA did not contribute data.
   - NSW did not report sex and facility location data.
   - SA did not report time of transfusion data.
   - QLD and SA did not report contributory factors data for most of the adverse events.
   - In line with internationally reported trends, the Australian national haemovigilance dataset suggests that some adverse events, such as TACO, TRALI, and DHTR, are under-reported.
   - Limited numbers of private health service providers reported data to the national haemovigilance program. For those states and territories that have reported, the numbers of public and private health service organisations are unknown to the NBA.
   - Transfusion near misses are collected at state level for VIC, SA, TAS, ACT, NT and NSW; but not reported and analysed for trends at national level.
   - The denominator data, for example total number of fresh blood components transfused, has not been collected and reported.
   - A report is included for each adverse event, not for each patient. Patients who experienced a transfusion-related adverse event more than once may be associated with more than one report.
2. Data standardisation
   The adverse event definitions used for the national reporting are not consistent with the current ISBT definitions; therefore the data cannot be properly analysed and compared at national level and international level.
3. Data relevance
   There are no detailed data on Australian practices to monitor improvement over time.
4. Data integration
   The adverse event data reported to the national haemovigilance program is not integrated with the data reported to the Blood Service, TGA and clinical pathology laboratory data. It is impossible to determine if the adverse events (such as TRALI and TTI) reported to the national haemovigilance program are confirmed cases and if the Blood Service is being notified of all adverse events where it needs to take immediate action.

The NBA, states and territories are addressing the above data quality issues through the implementation of the Strategic Framework and Work Plan for the national haemovigilance program. For example:

- The NBA and HAC have revised the haemovigilance definitions to be in line with the ISBT definitions and published the new definitions in the AHMDS in 2016. A transition plan will be developed to support states and territories to implement the AHMDS.
- The NBA, WA and QLD have developed haemovigilance data collection tools to support both public and private health service providers to collect and report adverse events to state/territory and national haemovigilance programs.
- The NBA and HAC will develop guidance on how to run an independent haemovigilance review at national, state, LHN/HHS and health service provider level.
- The NBA and HAC will develop and publish audit tools to improve haemovigilance reporting.
- The HAC will establish working groups in 2016–17 to facilitate and evaluate the implementation of the AHMDS and improve data analysis for the next report.
- The Blood Service is developing the Guidance on Recognition and Management of Acute Transfusion Related Adverse Events.
- The Blood Service is working with states/territories on the reconciliation process for adverse event data.
- The NBA and HAC will consider including near-misses and Anti-D data in the national reporting.

Febrile non-haemolytic transfusion reaction (FNHTR)

2013–14 Data Summary (n=337)					
Age		**Sex**		**Day of Transfusion**	
0–4 years	1	Male	109	Week day	263
5–14 years	3	Female	93	Weekend	74
15–24 years	7	Not reported	135		
25–34 years	12	**Facility Location**		**Time of Transfusion**	
35–44 years	23	Major City	167	Between 7am and 7pm	139
45–54 years	27	Inner Regional	21	Between 7pm and 7am	82
55–64 years	61	Outer Regional	16	Not reported	116
65–74 years	78	Remote	0		
75+ years	119	Very Remote	0		
Not specified	6	Not reported	133		
Clinical Outcome Severity		**Imputability**		**Blood Component**	
Death	0	Excluded/Unlikely	14	Whole blood	0
Life-threatening	0	Possible	223	Red cells	306
Severe morbidity	8	Likely/Probable	67	Platelets	22
Minor morbidity	289	Confirmed/Certain	12	Fresh Frozen Plasma	7
No morbidity	35	Not assessable	21	Cryoprecipitate	0
Outcome not available	5			Cryodepleted plasma	0
				Not reported	2

Notes
1. NSW did not report sex and facility location data
2. NSW and SA did not report time of transfusion data
3. ACT reported zero adverse events
4. WA did not contribute data

FNHTR is the most common transfusion-related adverse event reported in Australia. In 2013–14:

- 337 FNHTRs were reported to the national haemovigilance program, accounting for more than half (54.6%) of the total reports (617) for this period.
- Around 23.4% of FNHTRs (79) were assigned an imputability score of likely/probable or confirmed/certain, including one case with severe morbidity.

Table 14: FNHTR clinical outcome severity by imputability, 2013–14

Clinical Outcome Severity	Imputability					Total
	Excluded / Unlikely	Possible	Likely / Probable	Confirmed / Certain	N/A /Not assessable	
Life-threatening	0	0	0	0	0	0
Severe morbidity	0	6	0	1	1	8
Minor morbidity	12	192	61	11	13	289
No morbidity	2	24	5	0	4	35
Outcome not available	0	1	1	0	3	5
Total	**14**	**223**	**67**	**12**	**21**	**337**

Note: WA did not contribute data

Allergic reaction

2013–14 Data Summary (n=144)					
Age		**Sex**		**Day of Transfusion**	
0–4 years	2	Male	54	Week day	123
5–14 years	11	Female	45	Weekend	21
15–24 years	7	Not reported	45		
25–34 years	7	**Facility Location**		**Time of Transfusion**	
35–44 years	18	Major City	83	Between 7am and 7pm	71
45–54 years	15	Inner Regional	8	Between 7pm and 7am	27
55–64 years	29	Outer Regional	8	Not reported	46
65–74 years	31	Remote	0		
75+ years	23	Very Remote	0		
Not specified	1	Not reported	45		
Clinical Outcome Severity		**Imputability**		**Blood Component**	
Death	0	Excluded/Unlikely	2	Whole blood	0
Life-threatening	9	Possible	29	Red cells	45
Severe morbidity	6	Likely/Probable	70	Platelets	52
Minor morbidity	118	Confirmed/Certain	37	Fresh Frozen Plasma	45
No morbidity	9	Not assessable	6	Cryoprecipitate	1
Outcome not available	2			Cryodepleted plasma	1

Notes

1. NSW did not report sex and facility location data
2. NSW and SA did not report time of transfusion data
3. ACT reported zero adverse events
4. WA did not contribute data

Allergic reactions are the second most common transfusion-related adverse events reported in Australia. In 2013–14:

- 144 allergic reactions were reported to the national haemovigilance program, accounting for 23.3% of the reports (617) for this period.
- 74.3% of cases (107) were assigned an imputability score of likely/probable or confirmed/certain, including six cases with severe morbidity and eight with life-threatening severity.
- The two confirmed cases of life-threatening severity were related to the transfusion of red cells and fresh frozen plasma respectively.

Table 15: Allergic reaction clinical outcome severity by imputability, 2013–14

Clinical Outcome Severity	Imputability					Total
	Excluded / Unlikely	Possible	Likely / Probable	Confirmed / Certain	N/A /Not assessable	
Life-threatening	0	1	6	2	0	9
Severe morbidity	0	0	4	2	0	6
Minor morbidity	2	25	55	30	6	118
No morbidity	0	3	3	3	0	9
Outcome not available	0	0	2	0	0	2
Total	**2**	**29**	**70**	**37**	**6**	**144**

Note: WA did not contribute data

Incorrect blood component transfused (IBCT)

2013–14 Data Summary (n=33)					
Age		**Sex**		**Day of Transfusion**	
0–4 years	2	Male	10	Week day	26
5–14 years	0	Female	11	Weekend	7
15–24 years	1	Not reported	12		
25–34 years	2	**Facility Location**		**Time of Transfusion**	
35–44 years	3	Major City	18	Between 7am and 7pm	17
45–54 years	3	Inner Regional	1	Between 7pm and 7am	10
55–64 years	5	Outer Regional	2	Not reported	6
65–74 years	7	Remote	0		
75+ years	10	Very Remote	0		
Not specified	0	Not reported	12		
Clinical Outcome Severity		**Imputability**		**Blood Component**	
Death	0	Excluded/Unlikely	2	Whole blood	0
Life-threatening	0	Possible	2	Red cells	22
Severe morbidity	0	Likely/Probable	0	Platelets	5
Minor morbidity	3	Confirmed/Certain	13	Fresh Frozen Plasma	5
No morbidity	20	Not assessable	16	Cryoprecipitate	0
Outcome not available	10			Cryodepleted plasma	1

Notes

1. NSW did not report sex and facility location data
2. NSW and SA did not report time of transfusion data
3. ACT reported zero adverse events
4. WA did not contribute data

IBCT occurs when a patient receives a blood component intended for another patient or a blood component where special requirements (such as CMV-negative or irradiated component) are not met. It should be noted that adverse events attributed to transfusion of ABO incompatible components are included in this category. Such events could equally be described as acute haemolytic transfusion reactions, but are included here because the key failure is IBCT. Transfusion of ABO incompatible components to a patient is considered a 'sentinel event' and is also subject to other reporting requirements.

In 2013–14, there were 33 IBCTs reported to the national haemovigilance program, accounting for 5.3% of all reports (617) for this period. All IBCTs were non-serious events and no life-threatening or severe morbidity cases were reported.

Table 16: IBCT clinical outcome severity by imputability, 2013–14

Clinical Outcome Severity	Imputability					Total
	Excluded / Unlikely	Possible	Likely / Probable	Confirmed / Certain	N/A /Not assessable	
Life-threatening	0	0	0	0	0	0
Severe morbidity	0	0	0	0	0	0
Minor morbidity	0	0	0	3	0	3
No morbidity	2	2	0	10	6	20
Outcome not available	0	0	0	0	10	10
Total	**2**	**2**	**0**	**13**	**16**	**33**

Note: WA did not contribute data

Table 17 details the contributory factors for reported IBCT events for 2010–11 to 2013–14:

- For 2010–11, the most frequently cited contributory factors were 'procedure did not adhere to hospital transfusing guidelines' and 'specimen collection/labelling'.
- For 2011–12 and 2012–13, the most frequent factors that contributed to IBCT events were 'laboratory (testing/dispensing)' and 'indications did not meet hospital transfusion guidelines'.
- For 2013–14, the most frequent factors that contributed to IBCT events were 'indications did not meet hospital transfusion guidelines' and 'prescribing/ordering'.

This reported data highlights the range of problems that contribute to IBCT events, and the key observation for IBCT is that staff should conform to local facility guidelines for prescribing, labelling, laboratory testing and transfusing.

Table 17: Contributory factors cited in IBCT, 2010–11 to 2013–14

Contributory Factor	2010–11	2011–12	2012–13	2013-14
None identified	0	9	0	1
Product characteristic	4	0	0	0
Transfusion in emergency setting	4	2	6	3
Deliberate clinical decision	0	1	0	0
Prescribing/ordering	5	7	0	14
Specimen collection/labelling	11	7	11	0
Laboratory (testing/dispensing)	5	24	22	12
Transport, storage, handling	0	1	1	1
Administration of product	8	5	9	10
Indications did not meet hospital transfusion guidelines	2	12	27	15
Procedure did not adhere to hospital transfusion guidelines	14	1	0	3
Other	8	4	12	12

Notes

1. Contributory factors are not identified for the adverse events reported by QLD and SA
2. WA did not contribute data
3. ACT reported zero adverse events

Transfusion-associated circulatory overload (TACO)

2013–14 Data Summary (n=28)					
Age		**Sex**		**Day of Transfusion**	
0–4 years	0	Male	12	Week day	23
5–14 years	0	Female	11	Weekend	5
15–24 years	1	Not reported	5		
25–34 years	1	**Facility Location**		**Time of Transfusion**	
35–44 years	1	Major City	20	Between 7am and 7pm	11
45–54 years	2	Inner Regional	2	Between 7pm and 7am	11
55–64 years	3	Outer Regional	1	Not reported	6
65–74 years	3	Remote	0		
75+ years	16	Very Remote	0		
Not specified	1	Not reported	5		
Clinical Outcome Severity		**Imputability**		**Blood Component**	
Death	0	Excluded/Unlikely	0	Whole blood	0
Life-threatening	8	Possible	14	Red cells	26
Severe morbidity	8	Likely/Probable	12	Platelets	1
Minor morbidity	10	Confirmed/Certain	2	Fresh Frozen Plasma	1
No morbidity	1	Not assessable	0	Cryoprecipitate	0
Outcome not available	1			Cryodepleted plasma	0

Notes

1. NSW did not report sex and facility location data
2. NSW and SA did not report time of transfusion data
3. ACT reported zero adverse events
4. WA did not contribute data

Over-transfusion and rapid transfusion of blood components, especially to patients with reduced cardiopulmonary reserve capacity (children and the elderly) can lead to overload of the circulatory system, termed TACO.

In 2013–14:

- 28 TACO cases were reported to the national haemovigilance program, accounting for 4.5% of all reports (617) for this period.
- 16 out of 28 events (57.1%) occurred in patients aged 75 and above.
- Most cases were related to red cell transfusions.
- 14 out of 28 cases (50%) were assigned an imputability score of likely/probable or confirmed/certain, including four life-threatening cases and five severe morbidity cases.

The reported figures indicate that patients aged 75 and above are at higher risk of TACO. This is consistent with international findings.

Table 18: TACO clinical outcome severity by imputability, 2013–14

Clinical Outcome Severity	Imputability					Total
	Excluded / Unlikely	Possible	Likely / Probable	Confirmed / Certain	N/A /Not assessable	
Life-threatening	0	4	4	0	0	8
Severe morbidity	0	3	4	1	0	8
Minor morbidity	0	5	4	1	0	10
No morbidity	0	1	0	0	0	1
Outcome not available	0	1	0	0	0	1
Total	**0**	**14**	**12**	**2**	**0**	**28**

Note: WA did not contribute data

Transfusion-transmitted infection (TTI)

2013–14 Data Summary (n=27)					
Age		**Sex**		**Day of Transfusion**	
0–4 years	3	Male	12	Week day	21
5–14 years	0	Female	7	Weekend	6
15–24 years	1	Not reported	8		
25–34 years	4	**Facility Location**		**Time of Transfusion**	
35–44 years	1	Major City	10	Between 7am and 7pm	14
45–54 years	4	Inner Regional	5	Between 7pm and 7am	4
55–64 years	3	Outer Regional	4	Not reported	9
65–74 years	3	Remote	0		
75+ years	8	Very Remote	0		
Not specified	0	Not reported	8		
Clinical Outcome Severity		**Imputability**		**Blood Component**	
Death	0	Excluded/Unlikely	10	Whole blood	0
Life-threatening	0	Possible	7	Red cells	8
Severe morbidity	0	Likely/Probable	2	Platelets	19
Minor morbidity	14	Confirmed/Certain	6	Fresh Frozen Plasma	0
No morbidity	8	Not assessable	2	Cryoprecipitate	0
Outcome not available	5			Cryodepleted plasma	0

Notes

1. NSW did not report sex and facility location data
2. NSW and SA did not report time of transfusion data
3. ACT reported zero adverse events
4. WA did not contribute data

The national haemovigilance program allows the reporting of four TTI categories: bacterial, viral, parasitic and other (such as Creutzfeldt-Jakob disease); however the TTI definition is not clear and some cases might not be confirmed according to the national definition. This has affected the quality of the reported TTI data. The NBA and HAC will review the TTI definition and reporting process with a view to improving future TTI reporting.

In 2013–14:

- All TTI reports were non-serious events.
- Six cases were confirmed to be TTI, with five related to the transfusion of platelets and one related to the transfusion of red cells.
- There were no reports of any TTI resulting from viral or parasitically contaminated components.
- All of the 27 TTI events reported to the national haemovigilance program were suspected to be related to bacterial infections.

Table 19: TTI clinical outcome severity by imputability, 2013–14

Clinical Outcome Severity	Imputability					Total
	Excluded / Unlikely	Possible	Likely / Probable	Confirmed / Certain	N/A /Not assessable	
Life-threatening	0	0	0	0	0	0
Severe morbidity	0	0	0	0	0	0
Minor morbidity	3	4	2	5	0	14
No morbidity	7	0	0	1	0	8
Outcome not available	0	3	0	0	2	5
Total	**10**	**7**	**2**	**6**	**2**	**27**

Note: WA did not contribute data

Table 20 details the residual risk estimates for TTIs. Australia has developed effective strategies to reduce the bacterial contamination of blood components. The major components of the management strategies for TTI include the pre-donation questionnaire, identification of factors associated with TTI risk, skin disinfection prior to needle insertion, use of diversion pouches in collection kits to minimise the risk of bacterial infection and screening for antibody, antigen and viral nucleic acids. In April 2008, the Blood Service commenced pre-release bacterial contamination screening of 100% of platelet components. As a result, there have been no confirmed severe cases (such as death, life-threatening or severe morbidity) related to platelet transfusion reported in Australia since 2008–09.

Table 20: Blood Service residual risk estimates for transfusion-transmitted infections

Agent and testing standard	Window Period (Days)	Estimate of residual risk 'per unit'
HIV (antibody/ /p24Ag + NAT)	5.9	Less than 1 in 1 million
HCV (antibody + NAT)	2.6	Less than 1 in 1 million
HBV (HBsAg + NAT)	15.1	Approximately 1 in 468,000
HTLV I & II (antibody)	51	Less than 1 in 1 million
Variant Creutzfeldt-Jakob Disease (vCJD) [No testing]	Not available	Possible. Not yet reported in Australia.
Malaria (antibody)	7–14	Less than 1 in 1 million

Notes

1. The risk estimates for HIV, HCV and HBV are based on Blood Service data from 1 January 2012 to 31 December 2013
2. The HTLV estimates are based on data for the period 1 January 2010 to 31 December 2013

Anaphylactic or anaphylactoid reaction

2013–14 Data Summary (n=19)					
Age		**Sex**		**Day of Transfusion**	
0–4 years	0	Male	6	Week day	13
5–14 years	1	Female	5	Weekend	6
15–24 years	0	Not reported	8		
25–34 years	1	**Facility Location**		**Time of Transfusion**	
35–44 years	1	Major City	10	Between 7am and 7pm	9
45–54 years	2	Inner Regional	1	Between 7pm and 7am	8
55–64 years	4	Outer Regional	0	Not reported	2
65–74 years	3	Remote	0		
75+ years	6	Very Remote	0		
Not specified	1	Not reported	8		
Clinical Outcome Severity		**Imputability**		**Blood Component**	
Death	0	Excluded/Unlikely	0	Whole blood	0
Life-threatening	9	Possible	3	Red cells	7
Severe morbidity	4	Likely/Probable	11	Platelets	8
Minor morbidity	6	Confirmed/Certain	5	Fresh Frozen Plasma	4
No morbidity	0	Not assessable	0	Cryoprecipitate	0
Outcome not available	0			Cryodepleted plasma	0

Notes

1. NSW did not report sex and facility location data
2. NSW and SA did not report time of transfusion data
3. ACT reported zero adverse events
4. WA did not contribute data

In 2013–14:

- 19 anaphylactic or anaphylactoid reactions were reported to the national haemovigilance program, accounting for 3.1% of all reports (617) for this period.
- The majority of cases (16 out of 19) were assigned an imputability score of likely/probable or confirmed/certain, including six cases of life-threatening severity and four cases with severe morbidity.
- Two confirmed cases of life-threatening severity were related to the transfusion of platelets.

Table 21: Anaphylactic or anaphylactoid reactions clinical outcome severity by imputability, 2013–14

Clinical Outcome Severity	Imputability					Total
	Excluded / Unlikely	Possible	Likely / Probable	Confirmed / Certain	N/A /Not assessable	
Life-threatening	0	3	4	2	0	9
Severe morbidity	0	0	3	1	0	4
Minor morbidity	0	0	4	2	0	6
No morbidity	0	0	0	0	0	0
Outcome not available	0	0	0	0	0	0
Total	**0**	**3**	**11**	**5**	**0**	**19**

Note: WA did not contribute data

Delayed haemolytic transfusion reaction (DHTR)

2013–14 Data Summary (n=12)					
Age		**Sex**		**Day of Transfusion**	
0–4 years	0	Male	6	Week day	10
5–14 years	0	Female	2	Weekend	2
15–24 years	0	Not reported	4		
25–34 years	0	**Facility Location**		**Time of Transfusion**	
35–44 years	1	Major City	2	Between 7am and 7pm	6
45–54 years	3	Inner Regional	0	Between 7pm and 7am	4
55–64 years	2	Outer Regional	6	Not reported	2
65–74 years	4	Remote	0		
75+ years	2	Very Remote	0		
Not specified		Not reported	4		
Clinical Outcome Severity		**Imputability**		**Blood Component**	
Death	0	Excluded/Unlikely	1	Whole blood	0
Life-threatening	0	Possible	2	Red cells	11
Severe morbidity	1	Likely/Probable	1	Platelets	1
Minor morbidity	8	Confirmed/Certain	7	Fresh Frozen Plasma	0
No morbidity	3	Not assessable	1	Cryoprecipitate	0
Outcome not available	0			Cryodepleted plasma	0

Notes

1. NSW did not report sex and facility location data
2. NSW and SA did not report time of transfusion data
3. ACT reported zero adverse events
4. WA did not contribute data

In contrast to AHTR, delayed haemolytic transfusion reactions (DHTR) are triggered by the production or re-emergence of antibodies following transfusion and therefore are not generally detectable at the time of pre-transfusion compatibility testing. In 2013–14, there were 12 reports of DHTR to the national haemovigilance program, accounting for 1.9% of all reports (617) for this period. The majority of DHTR cases were related to red cell transfusion.

Acute haemolytic transfusion reaction (other than ABO incompatibility) (AHTR)

2013–14 Data Summary (n=8)					
Age		**Sex**		**Day of Transfusion**	
0–4 years	0	Male	2	Week day	7
5–14 years	0	Female	5	Weekend	1
15–24 years	0	Not reported	1		
25–34 years	1	**Facility Location**		**Time of Transfusion**	
35–44 years	0	Major City	3	Between 7am and 7pm	2
45–54 years	2	Inner Regional	3	Between 7pm and 7am	5
55–64 years	2	Outer Regional	1	Not reported	1
65–74 years	2	Remote	0		
75+ years	1	Very Remote	0		
Not specified	0	Not reported	1		
Clinical Outcome Severity		**Imputability**		**Blood Component**	
Death	0	Excluded/Unlikely	2	Whole blood	0
Life-threatening	1	Possible	3	Red cells	7
Severe morbidity	0	Likely/Probable	2	Platelets	1
Minor morbidity	6	Confirmed/Certain	0	Fresh Frozen Plasma	0
No morbidity	1	Not assessable	1	Cryoprecipitate	0
Outcome not available	0			Cryodepleted plasma	0

Notes

1. NSW did not report sex and facility location data
2. NSW and SA did not report time of transfusion data
3. ACT reported zero adverse events
4. WA did not contribute data

AHTR occurs by definition within 24 hours of transfusion. AHTR was defined as IHTR (intermediate haemolytic transfusion reaction) in the National Haemovigilance Data Dictionary 2010. Diagnosis of an AHTR can be difficult, as reactions are often seen in patients with concurrent illnesses that may have other causes for their symptoms.

Adverse events attributed to transfusion of ABO incompatible components can cause AHTRs, but are categorised as IBCT as that is the key error. Transfusion of ABO incompatible components to a patient is considered a ‘sentinel event’ and is subject to other reporting requirements in addition to the national haemovigilance program. The national haemovigilance program has not gathered data on the particular red cell antibodies associated with haemolytic transfusion reactions.

In 2013–14:

- Eight AHTRs were reported to the national haemovigilance program, with one case of life-threatening severity imputed as possible.
- Five cases occurred between 7pm and 7am.
- Seven cases were related to red blood cell transfusion.

Post transfusion purpura (PTP)

2013–14 Data Summary (n=6)					
Age		**Sex**		**Day of Transfusion**	
0–4 years	0	Male	2	Week day	6
5–14 years	0	Female	4	Weekend	0
15–24 years	1	Not reported	0		
25–34 years	1	**Facility Location**		**Time of Transfusion**	
35–44 years	0	Major City	6	Between 7am and 7pm	0
45–54 years	0	Inner Regional	0	Between 7pm and 7am	0
55–64 years	2	Outer Regional	0	Not reported	0
65–74 years	2	Remote	0		
75+ years	0	Very Remote	0		
Not specified	0	Not reported	0		
Clinical Outcome Severity		**Imputability**		**Blood Component**	
Death	0	Excluded/Unlikely	1	Whole blood	0
Life-threatening	1	Possible	3	Red cells	1
Severe morbidity	0	Likely/Probable	2	Platelets	2
Minor morbidity	2	Confirmed/Certain	0	Fresh Frozen Plasma	2
No morbidity	3	Not assessable	0	Cryoprecipitate	0
Outcome not available	0			Cryodepleted plasma	1

Notes

1. NSW did not report sex and facility location data
2. NSW and SA did not report time of transfusion data
3. ACT reported zero adverse events
4. WA did not contribute data

Post-transfusion purpura (PTP) is a rare delayed transfusion reaction where a patient develops dramatic, sudden and self-limiting thrombocytopenia 7 to 10 days after a blood transfusion. Bleeding from mucous membranes and the gastrointestinal and urinary tracts is common. Mortality is rare but if it occurs may be due to intracranial haemorrhage. In the four financial years to 2013–14:

- There were seven cases of PTP reported to the national haemovigilance program, with one for 2010–11 and six for 2013–14.
- Most reported PTPs were non severe cases. The only life-threatening case for 2013–14 was categorised as likely to be related to platelet transfusion.
- Most PTP patients (6 out of 7) were females.

Transfusion-related acute lung injury (TRALI)

2013–14 Data Summary (n=3)					
Age		**Sex**		**Day of Transfusion**	
0–4 years	0	Male	1	Week day	3
5–14 years	0	Female	0	Weekend	0
15–24 years	0	Not reported	2		
25–34 years	0	**Facility Location**		**Time of Transfusion**	
35–44 years	1	Major City	1	Between 7am and 7pm	1
45–54 years	0	Inner Regional	0	Between 7pm and 7am	2
55–64 years	0	Outer Regional	0	Not reported	0
65–74 years	0	Remote	0		
75+ years	2	Very Remote	0		
Not specified		Not reported	2		
Clinical Outcome Severity		**Imputability**		**Blood Component**	
Death	0	Excluded/Unlikely	0	Whole blood	0
Life-threatening	0	Possible	0	Red cells	3
Severe morbidity	1	Likely/Probable	2	Platelets	0
Minor morbidity	2	Confirmed/Certain	0	Fresh Frozen Plasma	0
No morbidity	0	Not assessable	1	Cryoprecipitate	0
Outcome not available	0			Cryodepleted plasma	0

Notes

1. NSW did not report sex and facility location data
2. NSW and SA did not report time of transfusion data
3. ACT reported zero adverse events
4. WA did not contribute data

TRALI is a serious transfusion-associated adverse event leading to pulmonary oedema and respiratory distress. In 2012–13, there were three suspected cases of TRALI reported to the national haemovigilance program, accounting for 0.5% of all reports (617).

Contributory factors

Table 22: Contributory factors cited in adverse events, 2013–14

Summary Data	
Contributory Factors	Number of reports
None identified	277
Product characteristic	267
*Transfusion in emergency setting	3
*Deliberate clinical decision	6
*Prescribing/ordering	14
*Specimen collection/labelling	0
*Laboratory (testing/dispensing)	13
*Transport, storage, handling	1
*Administration of product	28
*Indications do not meet guidelines	8
*Procedure did not adhere to hospital transfusion guidelines	21
Other	21

Notes

1. Contributory factors are not identified for most of the adverse events reported by QLD and SA
2. WA did not contribute data
3. ACT reported zero adverse events
4. * refers to potentially avoidable human errors

The national haemovigilance program requests that states and territories report data on factors contributing to each adverse event where applicable. The contributory factor categories defined seek to mirror key stages of the transfusion chain. It should be noted that:

- These categories are not mutually exclusive and more than one contributory factor may be associated with an adverse event.
- Contributory factors include human errors which could potentially have been avoided.
- Contributory factors are not identified for most of the adverse events reported by QLD and SA.
- Near miss data is not presented in the report. However, some states and territories, such as VIC, SA, ACT, NT, TAS and NSW, have collected near miss events in their systems.

The data in this report shows:

- The most frequent contributory factor was ‘product characteristic’, accounting for 267 adverse events in 2013–14. A blood component may contribute to an adverse reaction due to an inherent but not necessarily faulty characteristic, such as an allergic or immunological reaction to a component. Individual patient characteristics play an important role in this factor. Patients with previous transfusions and pregnancies are at increased risk of FNHTR, allergic and anaphylactic reactions. Since this factor is related to both individual patient characteristics and component characteristics, the current terminology and definition may not be appropriate and could lead to confusion for data collectors and users.
- There were 73 adverse event reports (11.8%) that cited one or more preventable contributory factors for 2013–14. The most common avoidable contributory factors cited were ‘administration of product’ (28 reports) and ‘procedure did not adhere to hospital transfusion guidelines’ (21 reports).

- Table 23 shows that events during the 'administration of product' impacted:
  - 10 IBCTs
  - 8 FNHTRs
  - 3 TTIs
  - 2 severe allergic reactions
  - 2 AHTRs
  - 1 anaphylactic or anaphylactoid reaction
  - 1 TACO
  - 1 TRALI
- The clinical outcome severities related to 'administration of product' included:
  - 1 life-threatening case
  - 2 severe morbidity cases
  - 14 minor morbidity cases
  - 7 no morbidity cases
  - 4 outcome not available cases.

A key observation from the data is the need for clinical staff to conform to their local facility guidelines for transfusing.

Table 23: Contributory factors cited by adverse event and by clinical outcome severity, 2013–14

Contributory Factors	Adverse event										Clinical outcome severity					
	FNHTR	Allergic reaction	IBCT	TACO	TTI Bacterial	Anaphylactic / Anaphylactoid	DHTR	AHTR (not ABO)	PTP	TRALI	Outcome not available	No morbidity	Minor morbidity	Severe morbidity	Life-threatening	Death
None identified	163	59	1	24	12	1	5	6	6	0	6	21	230	11	9	0
Product characteristic	158	78	0	0	9	17	4	0	0	1	4	36	197	13	17	0
Transfusion in emergency setting	0	0	3	0	0	0	0	0	0	0	0	2	1	0	0	0
Deliberate clinical decision	4	2	0	0	0	0	0	0	0	0	0	0	6	0	0	0
Prescribing/ordering	0	0	14	0	0	0	0	0	0	0	3	10	1	0	0	0
Specimen collection/labelling	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Laboratory (testing/dispensing)	0	0	12	0	1	0	0	0	0	0	4	6	3	0	0	0
Transport, storage, handling	0	0	1	0	0	0	0	0	0	0	0	1	0	0	0	0
Administration of product	8	2	10	1	3	1	0	2	0	1	4	7	14	2	1	0
Indications do not meet guidelines	0	2	3	2	0	1	0	0	0	0	3	0	2	1	2	0
Procedure did not adhere to hospital transfusion guidelines	4	0	15	1	1	0	0	0	0	0	5	13	3	0	0	0
Other	1	4	12	0	0	0	3	0	0	1	4	8	7	2	0	0

Notes

1. Contributory factors are not reported for most of the adverse events reported by QLD and SA
2. ACT reported zero adverse events
3. WA did not contribute data

PART 03 DONOR VIGILANCE DATA 2013–14

Executive summary

Whilst blood donation is generally a safe process, there are recognised donor complications which can occur. Donor vigilance is the systematic monitoring of adverse reactions and incidents in blood donor care with a view to improving quality and safety for blood donors.

Between 1 July 2013 and 30 June 2014 there were a total of 1.3 million donations, including 0.78 million whole blood donations, 0.48 million plasmapheresis donations and 0.04 million plateletpheresis donations. There were 34,778 adverse events reported. The overall reported rate of donation-related adverse events has increased from 251/10,000 donations for the previous 12 months to 267/10,000 donations. Despite this increase, the rate of adverse events remains within the previously established control limits of 2.68%.

The increase in overall adverse events for 2013-14 largely reflects improved capture and reporting of adverse events, rather than deterioration in donor safety as a result of the following changes:

- In November 2013 a new system for reporting adverse donation events was introduced. This has permitted the reporting of more than one type of adverse event for each donation, such as a vasovagal reaction associated with a phlebotomy injury. As a result of this change there has been an increase in phlebotomy injuries being captured since this time.
- Since October 2012 all citrate reactions were captured - prior to this, only severe citrate reactions were reported. The impact of this change is seen for the full 12 months in 2013-14.

In 2013-14 Australia has contributed to a joint initiative by the ISBT, the International Haemovigilance Network (IHN) and the American Association of Blood Banks (AABB) to standardise donor haemovigilance definitions internationally. Agreement has now been reached on standard definitions and from 2014-15 these new internationally agreed definitions will be used for donor haemovigilance reporting. This will provide the capacity to benchmark Australian performance with blood services internationally.

Data is accurate at the time of publication. Data from previous years has been updated to include additional events which were not known by the Blood Service to have occurred because reporting from the donor was delayed.

Donation adverse event trends

Donor haemovigilance systems permit monitoring of donor safety and evaluation of the impact of changes in donation procedures and of the success of interventions designed to further improve donor safety. The Blood Service has actively sought to improve the effectiveness of its haemovigilance system, and in 2010 moved from a paper based manual system to an electronic system which permits real-time reporting. Changes in the reporting requirements and reporting system have resulted in improved understanding of the true impacts of blood donation on the safety of donors.

In September 2010 an electronic donor adverse events database was introduced. This was associated with an increase in the number of events reported because reporting requirements expanded to include all donor reactions, not just severe reactions. In January 2011 a donor wellness check was introduced whereby every time a donor presents to donate they are asked whether they experienced any problems related to their previous donation. The main purpose of the donor wellness check is to identify delayed donor reactions. Following the introduction of the donor wellness check there was a significant increase

in the reporting of delayed events associated with all donation types. The significant increase in plateletpheresis reactions and modest increase in plasmapheresis donor reactions in 2012-13 reflects the introduction of reporting for all citrate reactions, regardless of severity from October 2012.

In November 2013 a new system for reporting adverse donation events was introduced. This has permitted the reporting of more than one type of donation reaction for each donation. Previously collections centre staff reported the most significant event (mostly faints and pre-faints) experienced by a donor; now faints and pre-faints which are associated with phlebotomy-related problems such as pain and bruising have both fainting and the phlebotomy injury reported, rather than just the faint. This change has resulted in an increase in phlebotomy injuries reported over the past 12 months (as detailed in Table 24 below).

Table 24: Total number of collections by donation type, 2010–11 to 2013–14

Collections	2010–11	2011–12	2012–13	2013–14
Whole Blood	999,038	945,900	858,594	783,346
All apheresis procedures	352,730	396,983	464,289	518,579
Plasmapheresis	313,775	357,701	427,945	482,857
Plateletpheresis	38,955	39,282	36,344	35,722
Total collections	**1,351,768**	**1,342,883**	**1,322,883**	**1,301,925**

There were 34,778 adverse events reported in 2013–14. The most frequently reported reaction to blood donation is vasovagal reaction, where the donor experiences dizziness, sweating and nausea; in a small proportion of donors the reaction is associated with loss of consciousness. Vasovagal reactions can occur during or after the donation (sometimes as long as 6-8 hours following the donation). Events which occur in the donor centre are termed immediate events. Events which occur after the donor has left the donor centre are classified as delayed events.

Immediate vasovagal reactions are the most commonly reported adverse donation reactions, with an incidence of 1.8%. 11% of immediate reactions are associated with loss of consciousness; the majority of donors experience dizziness or light headedness, which may be associated with sweating, nausea and weakness. Delayed vasovagal reactions are less common than immediate reactions occurring in 0.17% of donors. 60% of delayed reactions are associated with loss of consciousness, which represents a significant risk to the donor who is not under observation at the time of the event.

The other major category of adverse event is related to local complications at the donation site caused by the needle. The most frequent phlebotomy injuries include bruising and local pain; less frequent local complications include local thrombosis and arterial puncture. Donors who are slow to recover from vasovagal reactions (with symptoms lasting more than one hour) and donors who have fainted and sustained an injury may require hospital treatment. The overall reported rate of donation-related adverse events was 1:37 in 2013–14.

Total donation-associated events and serious donation-related events are shown in Figure 2 below.

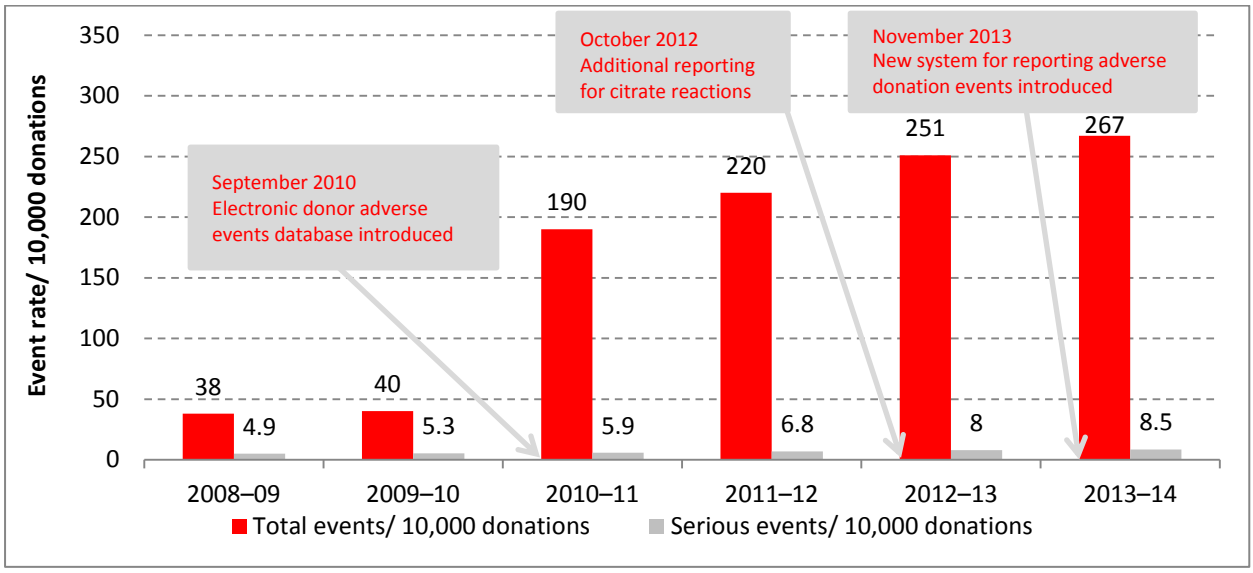

Figure 2: Total donation-associated events and serious donation-related events 2008–09 to 2013–14

The incidence of the different types of adverse events for all donations is shown in Table 25**.**

Table 25: Adverse donor reaction rate by category, 2010–11 to 2013–14 (per 10,000 donations)

Donor Event	2010–11	2011–12	2012–13	2013–14
Immediate vasovagal	118.1	180	194	176
Delayed vasovagal	7	21	25	27
Chest Pain	0.3	0.4	0.4	0.7
Citrate Reaction*	1.1	2	10	31
Haematoma	5.3	8	11	13
Painful Arm	2	3	5	11
Nerve Irritation/Injury	2	3	3	4
Arterial Puncture	0.3	0.4	0.3	0.2
Delayed Bleeding	0.2	0.3	0.3	0.6
Thrombophlebitis	0.1	0.2	0.3	0.3
Tendon injury	0	0.02	0.1	0.03
Allergy	0.4	0.1	0.4	0.6
Other Injuries**	1.2	2	8	3
Total	**190**	**220**	**251**	**267**

Notes

1. *Calculated for apheresis collections only
2. ** includes injuries sustained in falls during fainting, headaches during and after donation, cramps, palpitations or awareness of heart beat, nausea or abdominal pain during or immediately following procedure, onset of wheeze or asthma during donation, prolonged fatigue following donation

The increase in citrate reactions since 2013 is the result of increased reporting of these events. Since January 2013, reporting of citrate reactions of all severities has been required. Before this, only severe reactions were reported.

Adverse events by donation type:

1. Whole Blood – the rate of adverse reactions is stable overall. There has been a small decrease in the number of vasovagal reactions as a result of the policy change limiting donation by young donors to a single donation per year. However there has been an increase in the number of phlebotomy injuries reported since the ability to capture more than one adverse event at each donation has been possible. There has been no change in donation protocols.
2. Plasmapheresis – roll out of new apheresis software commenced in April 2014 and was completed by the end of July 2014. This resulted in a change in the collection protocol such that 250ml of normal saline is administered after the second return as opposed to after the first return. This change has been associated with an increase in mild and moderate donor reactions; however the incidence of delayed reactions has decreased since the new software was introduced. This is pleasing as delayed reactions are more likely to be associated with donor injury.
3. There has also been an increase in the number of mild citrate reactions (as a result of changes to reporting requirements) and phlebotomy injuries (as a result of changes in the ability to report more than one event at each donation, as previously discussed).
4. Plateletpheresis – the increase in reported reactions is almost entirely due to comprehensive reporting of all citrate reactions. To reduce the likelihood of citrate reactions, all plateletpheresis donors are offered oral calcium supplements immediately prior to donation; in addition, the website now contains advice to donors on appropriate dietary preparation for 24 hours prior to donation. Plasmapheresis donations are associated with the lowest frequency of adverse reactions, and platelet donations with the highest frequency, as detailed in Table 26 and Table 27 below.

The rate of bruising and haematoma is significantly higher in platelet donors as a result of the increased dose of anticoagulant administered during the procedure and the longer duration of plateletpheresis procedures compared to whole blood or plasmapheresis.

Table 26 below shows annual rates of all adverse events by donation type from 2010–11 to 2013–14.

Table 27 details donor complication rates by severity per 10,000 donations for 2013–14.

Table 26: Adverse donor event rate by procedure, 2010–11 to 2013–14 (per 10,000 donations)

Procedure	2010–11	2011–12	2012–13	2013–14
Whole Blood	168	265	308	307
Plasmapheresis	82	92	120	158
Plateletpheresis	177	288	449	935
All apheresis	90	111	146	212
Total procedures	**190**	**220**	**251**	**267**

Table 27: Donation-associated events by type and severity, 2013–14

			Rate per 10,000 donations		
			Whole Blood	Plasmapheresis	Plateletpheresis
			(n=783,346)	**(n=482,857)**	**(n=35,722)**
Complications related to blood outside vessels	Haematoma and bruising	Moderate	10.71	12.14	50.39
		Severe	0.75	0.83	1.12
	Arterial puncture	Moderate	0.27	0.00	0.00
		Severe	0.01	0.00	0.00
	Delayed bleeding	Mild	0.51	0.52	0.28
		Moderate	0.08	0.12	0.00

			Rate per 10,000 donations		
			Whole Blood	Plasmapheresis	Plateletpheresis
Pain/soft tissue injury	Nerve irritation	Moderate	3.40	2.57	2.24
		Severe	0.88	0.54	1.12
	Nerve injury	Moderate	0.00	0.04	0.00
		Severe	0.03	0.00	0.00
	Tendon damage	Moderate	10.23	9.49	18.20
		Severe	1.35	1.16	0.84
	Painful arm	Moderate	3.40	2.57	2.24
		Severe	0.88	0.54	1.12
Other complications with local symptoms	Thrombophlebitis	Moderate	0.09	0.06	0.00
		Severe	0.20	0.19	0.00
	Allergy (local)	Mild	0.31	0.56	0.28
		Moderate	0.06	0.04	0.00
Immediate vasovagal reaction	Without injury	Mild	158.92	44.92	148.93
		Moderate	59.93	16.05	62.71
		Severe	20.81	5.36	14.56
	With injury	Mild	0.00	0.00	0.00
		Moderate	0.03	0.00	0.28
		Severe	1.16	0.21	1.96
Delayed vasovagal reaction	Without injury	Mild	9.15	3.33	2.24
		Moderate	5.60	3.02	3.92
		Severe	16.84	7.91	11.20
	With injury	Mild	0.00	0.00	0.00
		Moderate	0.03	0.02	0.00
		Severe	1.57	0.35	1.12
Apheresis related complications	Citrate reaction		N/A	40.05	583.11
	Haemolysis		N/A	0.29	0.00

Serious complications of blood donation

Serious complications related to blood donation are defined as events resulting in any of the following:

- hospitalisation if it is attributable to the reaction, based on the evaluation of hospital medical staff
- attendance at a healthcare facility to manage a complication and to prevent ongoing impairment
- involvement in an accident (with or without significant injury) if the accident was probably or definitely related to the donation
- death following a donation complication if the death was probably, possibly or definitely related to the donation.

During 2013-2014 there were 492 donors who attended hospital and 735 who attended their general practitioner (GP) for donation-related complications (Table 28). There were no donation-associated deaths. The majority of hospital attendances are by donors directly referred from the donor centre, either because of an injury sustained in a fall during a vasovagal reaction or because a donor is very slow to recover from a vasovagal reaction. Donors experiencing chest pain are generally referred for assessment in the Emergency Department. 33 donors with chest pain were referred to hospital between July 2013 and June 2014 of whom 7 were admitted for cardiac investigations; all had been previously well but had risk factors for coronary disease; one donor required coronary stenting. Of the 33 donors

who were referred for chest pain where cardiac disease was excluded, the diagnosis was anxiety (in 22 donors) or no definitive diagnosis was made (for 11 donors). Most hospital attendances are brief presentations to the Emergency Department, and admission to hospital is rare. A number of donors self-refer to hospital following a delayed vasovagal reaction. Attendance at GPs is usually initiated by donors who have experienced a delayed faint, or more frequently, because of local symptoms caused by nerve irritation due to a large haematoma or painful arm following donation.

Table 28: Summary of external medical referrals, 2013–14

	Number of hospital referrals	Incidence of hospital referrals (% total collections)	Number of GP referrals	Incidence of GP referrals (% total collections)
Whole Blood	356	0.045	508	0.065
Plasmapheresis	120	0.025	205	0.042
Plateletpheresis	16	0.045	22	0.062
Total	**492**	**0.038**	**735**	**0.056**

Hospital referral rates have been stable over the past 4 years (refer to Table 29 below).

Table 29: The rate (per 10,000 donations) and total numbers of adverse donor reactions requiring hospital attendance, 2010-11 to 2013-14

	2010–11	2011–12	2012–13	2013–14
Whole Blood	3 (309)	4 (351)	4 (348)	5 (356)
Plasmapheresis	1 (37)	2 (65)	2 (105)	2 (120)
Plateletpheresis	2 (9)	3 (12)	5 (19)	4 (16)

Note: The figures in this table will not agree with those reported in the previous report due to the updated data on incidents that happened in previous years

The small increase in the rate of hospital attendance following 2011-12 is the result of improved reporting by donors to staff (a combination of the donor wellness question and improved follow up by medical officers as a result of the enhanced reporting via the electronic database). It also reflects a change in donor centre design – previously there was a dedicated “reaction room” in most small and medium donor centres where donors who had experienced a donation reaction could rest, sometimes for several hours, until they had recovered. New donor centres do not have this capacity; if a donor has not recovered from their reaction within a maximum of 90 minutes, they are generally referred to hospital.

Donor gender and age and adverse reactions to donation

The frequency of donation-associated events is higher in younger blood donors and in female blood donors. Donors up to the age of 30 years have a significantly higher risk of experiencing an adverse reaction than donors over the age of 30 years. There is a steady reduction in the likelihood of a donation reaction with increasing age (See Table 30 and Table 31 below). The frequency of reactions in 16-17 year old females is one in every eight donations, and in 16-17 year old males, one in every 13 donations. The majority of the donation reactions in younger donors are characterised by brief dizziness, associated with sweating and nausea, usually lasting for less than 15 minutes. This trend is consistent with international published data. The higher rate of adverse events in this age group prompted a policy change to limit donations from this age group to one donation per annum. Safety and wellbeing of youth donors is a key area of focus for the Blood Service.

Table 30: Adverse donation reactions in female donors by age, including odds ratio

Age group	Number of events	Total donors in age group	Frequency	Rate/1000 donations	Odds ratio (95% CI)
16–17yrs	1,866	14,868	1:8	126	3.8499 (3.6602 - 4.0495)
18–20yrs	2,776	32,718	1:12	85	2.5234 (2.4208 - 2.6302)
21–23yrs	2,554	38,209	1:15	67	1.9060 (1.8264 - 1.9890)
24–30yrs	4,080	78,241	1:19	52	1.4704 (1.4199 - 1.5226)
31–40yrs	2,796	77,943	1:28	36	0.9255 (0.8889 - 0.9637)
41–50yrs	2,899	105,275	1:36	28	0.6676 (0.6416 - 0.6946)
51–60yrs	3,179	132,205	1:42	24	0.5534 (0.5337 - 0.5760)
61–70yrs	1,600	83,897	1:52	19	0.4482 (0.4258 - 0.4719)
71+	117	8,055	1:69	15	0.3680 (0.3065 - 0.4420)
Total	**21,867**	**571,411**	**1:26**	**38**	

Table 31: Adverse donation reactions in male donors by age, including odds ratio

Age group	Number of events	Total donors in age group	Frequency	Rate/1000 donations	Odds ratio (95% CI)
16–17yrs	897	11,638	1:13	77	4.9049 (4.5712 - 5.2629)
18–20yrs	1,422	31,191	1:22	46	3.0827 (2.9133 - 3.2620)
21–23yrs	1,210	33,837	1:28	36	2.1725 (2.0456 - 2.3074)
24–30yrs	2,685	84,042	1:31	32	2.0453 (1.9676 - 2.1448)
31–40yrs	2,372	103,492	1:44	23	1.3732 (1.3127 - 1.4365)
41–50yrs	1,849	141,539	1:77	13	0.6920 (0.6585 - 0.7272)
51–60yrs	1,637	185,160	1:113	9	0.4229 (0.4014 - 0.4455)
61–70yrs	774	124,183	1:160	6	0.3073 (0.2857 - 0.3305)
71+	57	15,438	1:271	4	0.2026 (0.1561 - 0.2629)
Total	**12,903**	**730,520**	**1:57**	**18**	

Current interventions directed at improving the capture and reducing the risk of adverse events:

1. Donor centres have access to a donor adverse events dashboard which is updated on a daily basis – this provides real time feedback to donor centres on their performance, and enables benchmarking between donor centres with similar donor and collection characteristics, and provides immediate

feedback on those events which are notified after the donor leaves the donor centre. This improves staff awareness and focuses attention on preventative strategies.

2. Information provided to donors at donateblood.com.au, in donor centres and on the Donor Questionnaire Form provides plain English, simple advice on preparation for blood donation using evidence–based strategies such as pre-donation salty snacks and in-centre pre-donation fluid intake.
3. Provide plain English advice to donors on strategies to minimise the risk of a reaction during and after donation (use of applied muscle tension, rest and fluid intake, avoidance of strenuous physical activity and alcohol post donation). New approaches such as YouTube video clips are under consideration.
4. Provision of specific information cards to donors at the time of an adverse event detailing immediate management and preventative actions relevant to subsequent donations.
5. Permanent deferral of donors with significant risk of recurrence of serious adverse reactions.
6. Use of a mid-donation saline protocol for plasma donors which includes the administration of 500mL of saline to reduce the risk of vasovagal reactions.
7. Using a stepwise approach to increasing collection volume for plasmapheresis donors donating plasma for fractionation based on nomograms* for per cent Total Blood Volume.
8. Using a stepwise approach for plasmapheresis donors donating Clinical Fresh Frozen Plasma with end saline also based on a nomogram for Total Blood Volume.
9. Using a "whole blood nomogram" with reduced volume whole blood collection for donors with low total blood volume.
10. Implementation of specific guidelines for managing young donors – females less than 20 years of age are not recruited to plasma donation.
11. Youth donors (aged 16 and 17 years) have been restricted to one donation per annum from 1 January 2014 to reduce the risk of iron deficiency and number of vasovagal reactions.
12. Offering pre-donation oral calcium supplements for plateletpheresis donors to minimise the severity of citrate reactions.
13. Communication with comparable international blood services to ensure 'best practice' protocols.
14. Formal clinical governance processes including review of staff scope of practice and training, the conduct of clinical audits, robust data capture and analysis of adverse events, regular management and external review of donor adverse event trends with corrective action taken as required.
15. Pain experienced during a difficult phlebotomy contributes to vasovagal reactions. A trial involving the use of vein visualisation technology is being progressed at 2 sites in NSW.
16. External review and approval of donor selection guidelines and collection protocols by the Therapeutic Goods Administration.
17. Two pilots of iron supplementation to reduce the risk of iron deficiency associated with blood donation have commenced.
18. Progressing a number of research initiatives aimed at maintaining donor health and wellbeing and reducing the number and severity of donation adverse events.

*A nomogram is a chart or graph used to show relationships between several variables (such as height and weight) to enable a third value (the collection volume, which is based on the total blood volume) to be read directly at the intersection point of the first 2 values.

PART 04 SCORECARD – PERFORMANCE TO DATE

The 2015 report delivered 10 key recommendations in the areas of national blood quality and safety initiatives, reducing human errors, data standards and reporting capacity. The following provides an update on the status of the strategies to be delivered against each recommendation.

National blood quality and safety initiatives

Table 32: Progress against the national blood quality and safety initiatives recommendations of the Australian Haemovigilance Report 2015

	Recommendations from 2015 report	Who is responsible?	Proposed strategy from 2015 report	Outcomes
1	Promote the recognition and management of transfusion-related adverse events	National Education and Training Committee; NBA; JBC; State and territory departments of health; health service provider educators; Relevant professional Colleges and Societies	Establish a working group to rescope and redevelop the Guidance on Recognition and Management of Acute Transfusion-Related Adverse Events (the Guidance) Publish the Guidance on the NBA website and incorporate it into the eLearning module	The Blood Service will develop the Guidance as part of an education and training package for junior medical officers (JMOs) A project plan has been agreed between the Blood Service and NBA
2	Implement programs at the national, state and local health service provider levels to improve reporting of serious adverse events	NBA; JBC; State and territory departments of health; health service provider educators; Relevant professional Colleges and Societies	The NBA and HAC will continue to engage with key stakeholders as part of the ongoing national haemovigilance and stewardship programs The outcomes for Recommendations 6, 9 and 10 will also contribute to improving reporting of serious adverse events	The NBA will publish and distribute the Guidance (see above) in 2016–17

Reducing human errors

Table 33: Progress against the reducing human errors recommendations of the Australian Haemovigilance Report 2015

	Recommendations from 2015 report	Who is responsible?	Proposed strategy from 2015 report	Outcomes
3	Clinical staff should comply with national guidelines on sample collection and administration of blood and blood products	State and territory departments of health; health service providers	NBA to promote or provide tools that allow states and territories to ensure health service providers have policies, procedures or protocols that adhere to national guidelines such as ANZSBT Guidelines for the Administration of Blood Products and Guideline for Pre-Transfusion Laboratory Practice NBA to promote or provide tools that enable health service providers to ensure staff include regular continued professional development as part of their program, through resources such as BloodSafe eLearning Monitor and publish the number of human errors in national or state/territory reports	The number of avoidable human errors should decline; however this is difficult to determine because near miss data is currently not reported to a national body. Some jurisdictions do report locally The number of IBCT events reported should decline – this can be measured by haemovigilance data
4	Promote the application of technological adjuncts such as portable barcode readers and/or radio frequency identification scanners to reduce the scope for error	NBA; HAC; Quality and Safety organisations; Research Bodies	Implement the National Policy on Barcoding for Blood and Blood Products NBA to recommend strategies and develop case studies to support the implementation of the Barcoding Policy	The Barcode Specifications (previously known as National Policy on Barcoding for Blood and Blood Products), samples and other standard and guide information have been published on the NBA website The NBA is developing case studies with states/territories and health service providers
5	Develop tools to encourage alignment of prescribing practice with clinical guidelines	NBA; Blood Sector stakeholders	NBA to collaborate with relevant stakeholders to develop a national reference set of tools to assist with transfusion practice and clinical decision support	NBA is collaborating with stakeholders to promote and develop a national reference set of tools

Data standards

Table 34: Progress against the data standards recommendations of the Australian Haemovigilance Report 2015

	Recommendations from 2015 report	Who is responsible?	Proposed strategy from 2015 report	Outcomes
6	Review and re-develop the Australian National Haemovigilance Data Dictionary	HAC; NBA	NBA to revise the ANHDD based on the NBA standard data element template The HAC to review and endorse the revised data dictionary and definitions NBA to publish and distribute the Dictionary	The revised ANHDD now called the Australian Haemovigilance Minimum Data Set (AHMDS) was reviewed by HAC in 2015 and published on the NBA website in 2016
7	Provide tools for health service providers on the application of the Australian National Haemovigilance Data Dictionary and reporting of haemovigilance data	NBA; State and territory Quality and Safety Units; health service provider administrators	NBA, assisted by states and territories, to develop and distribute tools to support health service providers for national haemovigilance reporting NBA to inform health service providers on the availability and use of tools	The NBA has helped QLD Health and WA to develop haemovigilance data collection tools in line with the AHMDS The NBA is refining the tools for publication in 2016
8	Continue to include donor vigilance data in national haemovigilance reporting	Blood Service; NBA	Blood Service to continue to improve the transparency of donor vigilance data	Donor vigilance data has been included in this report and will continue to be included in future reports The Blood Service may provide additional data after completing the reconciliation process with states and territories

Reporting capacity

Table 35: Progress against the reporting capacity recommendations of the Australian Haemovigilance Report 2015

	Recommendations from 2015 Report	Who is responsible?	Proposed strategy from 2015 report	Outcomes
9	Implement the Strategic Framework for the National Haemovigilance Program	NBA; HAC; State and territory departments of health; Blood Service; health service providers; pathology providers; JBC	NBA to work in collaboration with key stakeholders to develop/implement the Communication Plan and Work Plan to support the implementation of the Strategic Framework	Communication Plan and Work Plan under development to support the implementation of the Strategic Framework
10	Maintain and improve existing capacities for haemovigilance data reporting	NBA; HAC; States and territories; Blood Service; health service providers; pathology providers; JBC	NBA to investigate and consider other sources and types of reporting for national haemovigilance reporting	The NBA and HAC discussed establishing a national independent review group to provide further validation over adverse events reported by states/territories and health service providers QLD reporting capacity improved for both public and private health service providers due to the use of haemovigilance data collection forms WA adopted a data collection tool to facilitate haemovigilance data collection and reporting from 2015–16

PART 05 RECOMMENDATIONS

There are 12 recommendations in this report, including eight recommendations from the last report and four new or revised recommendations. Please note the sixth recommendation of 'Review and re-develop the Australian National Haemovigilance Data Dictionary' from the last report has been delivered and replaced by 'Implement the Australian Haemovigilance Minimum Data Set' in this report. The NBA and HAC have developed a Work Plan for 2015–17 to guide the implementation of the recommendations in the following areas.

National blood quality and safety initiatives

1. Promote the recognition and management of transfusion-related adverse events.
2. Implement programs at the national, state and local health service provider levels to improve reporting of serious adverse events.

Reducing human errors

3. Clinical staff should comply with national guidelines on sample collection and administration of blood and blood products.
4. Promote the application of technological adjuncts such as portable barcode readers and/or radio-frequency identification scanners to reduce the scope for error.
5. Develop tools to encourage alignment of prescribing practice with clinical guidelines.

Data standards

6. Implement the Australian Haemovigilance Minimum Data Set (AHMDS).
7. Provide tools for health service providers on the application of the AHMDS and reporting of haemovigilance data.
8. Continue to include donor vigilance data in national haemovigilance reporting.
9. Consider including near misses in national haemovigilance reporting.
10. Include relevant data in national haemovigilance reporting.

Reporting capacity

11. Implement the Strategic Framework for the National Haemovigilance Program.
12. Maintain and improve existing capacities for haemovigilance data reporting.

National blood quality and safety initiatives

Haemovigilance has become a more routine part of clinical practice in Australia. The data to date suggests a focus on those events that are most common (such as FNHTR and severe allergic reactions) and that cause the greatest numbers of severe patient outcomes (such as TACO and anaphylactic reactions).

In relative terms, the Australian data suggests that TACO, TRALI and DHTR which account for disproportionate numbers of life-threatening and severe morbidity events, are likely under-reported. National quality and safety initiatives should be developed with the aim of helping clinical staff to recognise and manage these events and support alignment of health service provider transfusion practice and incident reporting with the NSQHS Standard 7.

Table 36: Recommendations on national blood quality and safety initiatives

	Recommendation	Who is Responsible	Proposed Strategy	How that will be measured
1	Promote the recognition and management of transfusion-related adverse events	NBA; JBC; Blood Service; ANZSBT; State and territory departments of health; health service provider administrators; health service provider educators; Relevant professional Colleges and Societies	Blood Service to develop the Guidance on Recognition and Management of Acute Transfusion-Related Adverse Events (the Guidance) Publish the Guidance on the NBA and Blood Service websites and incorporate it into the eLearning module	The Guidance redeveloped by the Blood Service and reviewed by the HAC The Guidance published and evaluated by the NBA and Blood Service An eLearning module based on the Guidance developed
2	Implement programs at the national, state and local health service provider levels to improve reporting of serious adverse events	NBA; JBC; State and territory departments of health; health service provider administrators; health service provider educators; Relevant professional Colleges and Societies	Monitor and publish the reporting rates for acute transfusion-related adverse events on a regular basis Establish haemovigilance independent review group(s) at national, state or local levels to provide further validation over adverse events reported by health service providers Develop and implement guidance on how to run a haemovigilance independent review at national, state, LHN/HHS and health service provider level	Reporting rates increased Haemovigilance independent review group(s) established at national, state and local levels Independent review guidance developed and used

Reducing human errors

Human errors continue to contribute significantly to avoidable transfusion-related risks to patients. Further effort is required to ensure clinical staff comply with national guidelines on the collection and administration of blood and blood products. Data on 'near miss' events (an adverse event that is discovered before the start of a transfusion) would be useful to focus efforts to reduce human errors, and transfusing facilities are now required by NSQHS Standard 7 Safety and Quality Improvement Guide to record near-miss events in haemovigilance data. Research suggests that technological adjuncts such as portable barcode readers and/or radio-frequency identification scanners also reduce the scope for human errors. Clinical staff should also be supported in their efforts with tools such as a defined blood order/prescription form to encourage alignment of prescribing with clinical guidelines.

Table 37: Recommendations on reducing human errors

	Recommendation	Who is Responsible	Proposed Strategy	How that will be measured
3	Clinical staff should comply with national guidelines on sample collection and administration of blood and blood products	State and territory departments of health; health service providers (Admin, HTC or equivalent)	NBA to promote or provide tools that allow states and territories to ensure health service providers have policies, procedures or protocols that adhere to national guidelines such as ANZSBT Guidelines for the Administration of Blood Products and Guideline for Pre-Transfusion Laboratory Practice The NBA to promote or provide tools that enable health service providers to ensure staff include regular continued professional development as part of their program, through resources such as BloodSafe eLearning Monitor and publish the number of human errors in national or state/territory reports	Human errors captured and published in national or state/territory reports Decrease in the number of avoidable human errors
4	Promote the application of technological adjuncts such as portable barcode readers and/or radio-frequency identification scanners to reduce the scope for error	NBA; HAC; Quality and Safety organisations; Research bodies; health service providers	Implement the Barcode Specifications to improve product safety and patient safety NBA to develop case studies with states/territories and health service providers to support the implementation of the Barcode Specifications	Case studies developed in 2016–17 Increased use of 2D barcode technology by health service providers to prevent and reduce human errors

	Recommendation	Who is Responsible	Proposed Strategy	How that will be measured
5	Develop tools to encourage alignment of prescribing practice with clinical guidelines	NBA; Blood Sector stakeholders	NBA to collaborate with relevant stakeholders to develop a national reference set of tools to assist with transfusion practice and clinical decision support	Tools developed, published, distributed and evaluated on an ongoing basis

Data standards

Data standards should be revised and updated as haemovigilance matures in Australia. The Australian Haemovigilance Minimum Data Set (AHMDS), previously known as the Australian National Haemovigilance Data Dictionary (ANHDD) has been redeveloped and published in 2016. The NBA, HAC and states/territories are developing a set of tools including audit tools, guidance documents, data collection forms, and case studies from 2015–16 to assist with the application of the AHMDS and improve haemovigilance data collection and reporting. The haemovigilance report will continue to include donor vigilance data.

Table 38: Recommendations on data standards

	Recommendation	Who is Responsible	Proposed Strategy	How that will be measured
6	Implement the Australian Haemovigilance Minimum Data Set (AHMDS)	JBC; HAC; NBA; State and territory departments of health	NBA/HAC to work with the JBC and states/territories on the transition of AHMDS and the timing for the implementation NBA to develop a mapping document from the ANHDD to the AHMDS HAC to establish a working group to develop guidance for states/territories to implement the AHMDS	AHMDS and guidance implemented in 2016–17 subject to approval from the JBC
7	Provide tools for health service providers on the application of the AHMDS and reporting of haemovigilance data	NBA; HAC; State and territory Quality and Safety Units; health service provider administrators; state and territory departments of health; Blood Service	NBA/HAC, states and territories and Blood Service to develop and distribute tools to support health service providers for national haemovigilance reporting NBA to inform health service providers on the availability and use of tools	The following tools have been or will be developed or published in 2015–17: • AHMDS and guidance • Haemovigilance data collection forms and guidance • Clinical audit tools • Transfusion-related case studies • Educational and training tools Increased number of public and private facilities submitting data to national haemovigilance program

	Recommendation	Who is Responsible	Proposed Strategy	How that will be measured
8	Continue to include donor vigilance data in national haemovigilance reporting	Blood Service; NBA	Blood Service to continue to improve the transparency of donor vigilance data	Donor vigilance data included in future national haemovigilance reports The Blood Service will publish and report on donor vigilance data regularly
9	Consider including near misses in national haemovigilance reporting	NBA; HAC; JBC; State and territory Quality and Safety Units; health service providers; state and territory departments of health	JBC and NBA to provide a transition timetable to collect and include near misses for national reporting and AHMDS	Near-miss data included in future national haemovigilance reports
10	Include relevant data in national haemovigilance reporting	NBA; HAC; State and territory Quality and Safety Units; health service providers; state and territory departments of health	JBC and NBA to provide a transition timetable to define and collect relevant data such as Anti-D and Rh alloimmunisation data for national reporting	Relevant data such as Anti-D defined and included in future national haemovigilance reports

Reporting capacity

The mechanisms to collect, record, review and analyse haemovigilance data in Australia are fragmented. This allows varied approaches to data definitions and data validation processes, and has seen haemovigilance reporting develop at different rates in states and territories.

NBA/HAC and states and territories continue to improve capacities for haemovigilance data reporting after the Strategic Framework for the National Haemovigilance Program was endorsed by the JBC and published on the NBA website. The NBA and HAC have developed a Work Plan 2015–17 and will develop a Communication Plan to support the implementation of the Strategic Framework.

Table 39: Recommendations on reporting capacity

	Recommendation	Who is Responsible	Proposed Strategy	How that will be measured
11	Implement the Strategic Framework for the National Haemovigilance Program	NBA; HAC; State and territory departments of health; Blood Service; health service providers; Pathology providers; JBC	NBA to work in collaboration with key stakeholders to develop/implement the Communication Plan and Work Plan to support the implementation of the Strategic Framework	Communication Plan and Work Plan for the Strategic Framework implemented in 2016–17 The timeliness and completion of haemovigilance reporting improved at national, state and local levels

	Recommendation	Who is Responsible	Proposed Strategy	How that will be measured
12	Maintain and improve existing capacities for haemovigilance data reporting	NBA; HAC; State and territory departments of health Blood Service; health service providers; Pathology providers; JBC	NBA to investigate and consider other sources and types of reporting for national haemovigilance reporting	Number of public and private facilities submitting data to the national haemovigilance program increased Additional haemovigilance information included in future national haemovigilance reports if agreed

ABBREVIATIONS AND ACRONYMS

AABB	American Association of Blood Banks
ABO	The human red cell ABO blood group system
ACSQHC	Australian Commission on Safety and Quality in Health Care
ACT	Australian Capital Territory
AHMDS	Australian Haemovigilance Minimum Data Set
ANHDD	Australian National Haemovigilance Data Dictionary
ANZSBT	Australian and New Zealand Society of Blood Transfusion
BCSH	British Committee for Standards in Haematology
FNHTR	Febrile non-haemolytic transfusion reaction
GP	General practitioner
HAC	Haemovigilance Advisory Committee
IBCT	Incorrect blood component transfused
IHN	International Haemovigilance Network (previously EHN)
IIMS	Incident Information Management System
ISBT	International Society for Blood Transfusion
JBC	Jurisdictional Blood Committee
JMO	Junior Medical Officer
NBA	National Blood Authority
NSQHS	National Safety and Quality Health Service
NSW	New South Wales
NT	Northern Territory
PTP	Post transfusion purpura
QiiT	Queensland Incidents in Transfusion
QLD	Queensland
SA	South Australia
SHOT	Serious Hazards of Transfusion (UK)
SLS	Safety Learning System
STIR	Serious Transfusion Incident Reporting
TACO	Transfusion-associated circulatory overload
TAS	Tasmania
TGA	Therapeutic Goods Administration
TRALI	Transfusion-related acute lung injury
TTI	Transfusion-transmitted infection
UK	United Kingdom
VIC	Victoria
WA	Western Australia

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This report was prepared on behalf of the National Blood Authority and the Haemovigilance Advisory Committee by Ms Suzie Cong.

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