NATIONAL BLOOD AUTHORITY
AUSTRALIA

AUSTRALIAN HAEMOVIGILANCE REPORT

A Report by the
National Blood Authority
Haemovigilance Advisory Committee

DATA FOR **2011-12** AND **2012-13**

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When using data from this report it is important to note that information and data is not complete. Haemovigilance reporting by health service organisations is voluntary at both state and territory and national levels. For those states and territories that have reported, the number of health service organisations is unknown. For example in one jurisdiction there were no private hospitals reporting and only public hospitals in major cities. NSW (prior to 2011-12) and WA are excluded from the analysis due to the unavailability of component data for these two states. QLD data is unavailable for 2012–13. NT and ACT did not report in 2008-09.

MESSAGE FROM THE GENERAL MANAGER OF THE NATIONAL BLOOD AUTHORITY

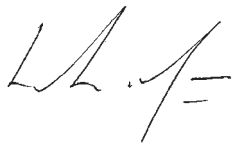
On behalf of the National Blood Authority (NBA), I am pleased to present the fourth Australian Haemovigilance Report. This report provides information on transfusion-related adverse events between July 2011 and June 2013 and donation-related adverse events between July 2012 and June 2013. It is a valuable resource for clinical communities and governments.

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 Australians receiving and donating blood. In January 2013 the National Safety and Quality Health Service (NSQHS) Standards were implemented, including Standard 7 Blood and Blood Products (NSQHS Standard 7), which requires health service organisations to participate in relevant haemovigilance activities conducted at state or national level.

To ensure that patients are not unnecessarily exposed to the risks associated with transfusion the NBA embarked on a program to develop Patient Blood Management Guidelines for fresh blood. Five of the six proposed modules have now been published and the sixth is in progress. The published modules cover critical bleeding/massive transfusion, perioperative, medical, critical care and obstetrics and maternity. Improvements in the appropriate use of fresh blood products and reduction in wastage have resulted in a commensurate reduction in demand. In 2013–14 the demand for red blood cells decreased by more than eight per cent and platelets decreased by three per cent compared with the previous year.

The states and territories continue to develop their haemovigilance capacity and consistent and complete data is crucial to providing vital feedback to clinical staff to improve patient outcomes. 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. To further promote haemovigilance activities in Australia, the NBA will work closely with its Haemovigilance Advisory Committee (HAC) and key stakeholders to develop tools to support haemovigilance in Australia.

This fourth 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.



Leigh McJames
General Manager
National Blood Authority

EXECUTIVE SUMMARY

This is the fourth national Australian Haemovigilance Report. It provides an overview of blood transfusion and donation-related adverse events in Australia, and recent data and information on fresh blood product issues. The report also delivers 10 key recommendations in the areas of:

- national blood quality and safety initiatives
- reducing human errors
- data standards
- reporting capacity.

Haemovigilance data for 2011–12 and 2012–13

The NBA National Haemovigilance Program and HAC continue to support the development and alignment of state level reporting systems with the recommended national haemovigilance dataset and Australian National Haemovigilance Data Dictionary.

This report includes validated adverse event data from state level systems, including the New South Wales (NSW) Health Incident Information Management System (IIMS), Victoria's (VIC) Blood Matters Serious Transfusion Incident Reporting (STIR) program, Queensland's (QLD) Incidents in Transfusion program (QiiT) and South Australia's (SA) Health Safety Learning System. STIR also supports haemovigilance in Tasmania (TAS), the Australian Capital Territory (ACT) and the Northern Territory (NT). NSW has improved its haemovigilance reporting capacity since the last report and provided detailed and validated adverse event data (such as imputability and outcome severity data) for this report. QiiT provided 2011–12 data only due to the system being decommissioned in 2013. Western Australia (WA) is the only jurisdiction not contributing to the national dataset for this report.

There were 2,251 adverse events reported to the National Haemovigilance Program from 2008–09 to 2012–13. The number of reports increased from 294 in 2008–09 to 615 in 2011–12, mainly due to the improved adverse event reporting from NSW, however this dropped in 2012-13 to 429 due to QLD not providing any reports for that year. The most frequently reported adverse events are febrile non-haemolytic transfusion reactions (FNHTR) and severe allergic reactions, representing 52.6% and 25.4% of all reports respectively. The first three confirmed cases of post-transfusion purpura (PTP) were reported in 2009–10 and 2010–11.

Adverse event	2011–12	2012–13	All reports	
			Number	Per cent
FNHTR	320	231	551	52.8%
Allergic reaction	147	111	258	24.7%
IBCT	62	43	105	10.1%
TACO	27	17	44	4.2%
Anaphylactoid or anaphylactic reaction	16	13	29	2.8%
TTI	12	5	17	1.6%
DHTR	17	6	23	2.2%
AHTR	10	2	12	1.1%
TRALI	4	1	5	0.5%
PTP	-	-	-	0.0%
Total number of reports	**615**	**429**	**1,044**	**100.0%**

Notes

1. All TTIs were bacterial infections and these were reported cases but not necessarily confirmed.
2. Limited adverse event data available for NSW for 2008–09 and 2009–10. NSW only provided detailed data (such as blood products, outcome severity and imputability score) for 2011–12 and 2012–13.
3. Adverse event data unavailable for ACT and NT for 2008–09, and QLD for 2012–13.
4. Adverse event data unavailable for WA.

Donor vigilance data for 2012–13

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. This report includes donor vigilance data contributed by the Australian Red Cross Blood Service (Blood Service).

During 2012–13, there were a total of 1.32 million donations, including 0.86 million whole blood donations, 0.43 million plasma donations and 0.04 million platelet donations. There were 33,208 event reports in 2012–13, with only 1,056 of these classified as serious adverse events. The overall reported rate of donation-related adverse events was 1:40 in 2012–13. The frequency of adverse events was found to be higher in younger and female blood donors, especially those under the age of 20 years.

Fresh blood product issue data

There were 2.3 million components of fresh blood products issued in Australia in 2011–12 (1.2 million) and 2012–13 (1.1 million). Red blood cells (RBC) accounted for about two-thirds of all issues. The demand for RBCs decreased (most likely due to improved patient blood management and better inventory management), from 36.4 units per 1000 population in 2009–10 to 33.3 units per 1000 population in 2012-13. The demand for fresh frozen plasma (FFP) also decreased during the same period, from 7.4 to 6.4 units per 1000 population. In contrast, the demand for platelets, cryoprecipitate units and cryodepleted plasma rose over the four years to 2012–13.

In the ten years to 2012–13, the NBA's expenditure on fresh blood products increased from $243.4 million to $549.3 million. Of this, $171.9 million was due to price increases, averaging 7.8% per year. $67.2 million was due to an increase in the overall demand for fresh products over the 10 year period, averaging 3.1% a year. A further $66.8 million was a consequence of the introduction of government-approved quality and safety measures (such as the universal leucodepletion of platelets and red cells), averaging 3.1% a year.

The Australian and international data shows, despite an ageing population, the demand for RBC has started declining around the world most likely due to the improved usage of blood by health professionals.

Recommendations

The 2013 report made 10 recommendations. Nine of these recommendations remain relevant in this report and one has been amended. The ninth recommendation of 'Conduct a scoping exercise for a national haemovigilance system' has been completed and the Strategic Framework for the National Haemovigilance Program was the result of this exercise. The NBA and HAC have developed a three-year Haemovigilance Action Plan 2013–16 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 hospital levels to improve reporting of serious adverse events.

Reducing human errors

3. Compliance by clinical staff 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. Review and re-develop the Australian National Haemovigilance Data Dictionary.
7. Provide tools for hospitals on the application of the Australian National Haemovigilance Data Dictionary and reporting of haemovigilance data.
8. Continue to include donor vigilance data in national haemovigilance reporting.

Reporting capacity

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

HAEMOVIGILANCE DATA FOR 2011–12 AND 2012–13

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PART 01 HAEMOVIGILANCE DATA FOR 2011–12 AND 2012–13

Introduction

The transfusion of blood and blood components is a core part of healthcare service delivery to patients. While the use of blood and blood components can be lifesaving, there are also risks associated with transfusion. In Australia, the risk of transmission of infectious disease (such as HIV, hepatitis B and C) through blood transfusions has reduced significantly in recent years through improved manufacturing and laboratory processes. However, in common with other developed countries, the non-infectious risks of transfusion, especially those related to human errors, continue to occur and affect patients' safety and health.

The mechanisms to ensure the safety of transfusions in Australia include:

- clinical transfusion guidelines to direct transfusion practices
- state and territory audit systems to monitor guideline compliance
- jurisdictional and national transfusion education initiatives to train and update clinical staff on best transfusion practices
- development of a national patient blood management program to create leadership for the appropriate use of blood and blood products
- a National Haemovigilance Program which monitors, through state and territory haemovigilance systems, the occurrence of transfusion-related serious adverse events in patients.

Surveillance of adverse transfusion events is the cornerstone of haemovigilance systems. The World Health Organization (WHO) states that:

> *'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.'*[1]

However, there are many ways in which haemovigilance is defined. A founding definition of haemovigilance was set out in Directive 2002/98/EC of the European Parliament,[2] setting standards of quality and safety for the collection, testing, processing, storage and distribution of human blood and blood components:

> *'A set of organised surveillance procedures relating to serious adverse or unexpected events or reactions in donors or recipients, and the epidemiological follow-up of donors'.*

The International Haemovigilance Network (IHN)[3] definition is the most widely used:

> *'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.'*[4]

Haemovigilance is now universally recognised as an integral part of safety in blood transfusion, and increasing attention is being paid to haemovigilance in many countries. The WHO Global Database on Blood Safety Summary

Report 2011[5] indicates that a national haemovigilance system was present in 13% of low-income countries, 30% of middle-income countries and 78% of high-income countries (data based on 106 responding countries). National haemovigilance systems provide an evidence base for the improvement of transfusion practice that displays the real risks and hazards of transfusion in a given community/country and allows for the dissemination of these findings and the instigation of appropriate actions, including educational processes to prevent recurrence.

Available Australian haemovigilance data for 2011–12 and 2012–13

The NBA established a National Haemovigilance Program and the HAC to support the continued development and alignment of jurisdictional haemovigilance reporting systems with the recommended national haemovigilance dataset. The Australian National Haemovigilance Data Dictionary (ANHDD) was developed by the HAC to standardise the data for the national haemovigilance dataset. The ANHDD is in its third iteration and is under continuous review.

Figure 1 shows a representation of the jurisdictions contributing haemovigilance data to the current report. Validated jurisdictional-level data was submitted by NSW, VIC, QLD, SA, TAS, the ACT and the NT. QLD contributed 2011–12 data only. WA is the only jurisdiction which did not contribute to the national dataset for the reporting period 1 July 2011 to 30 June 2013.

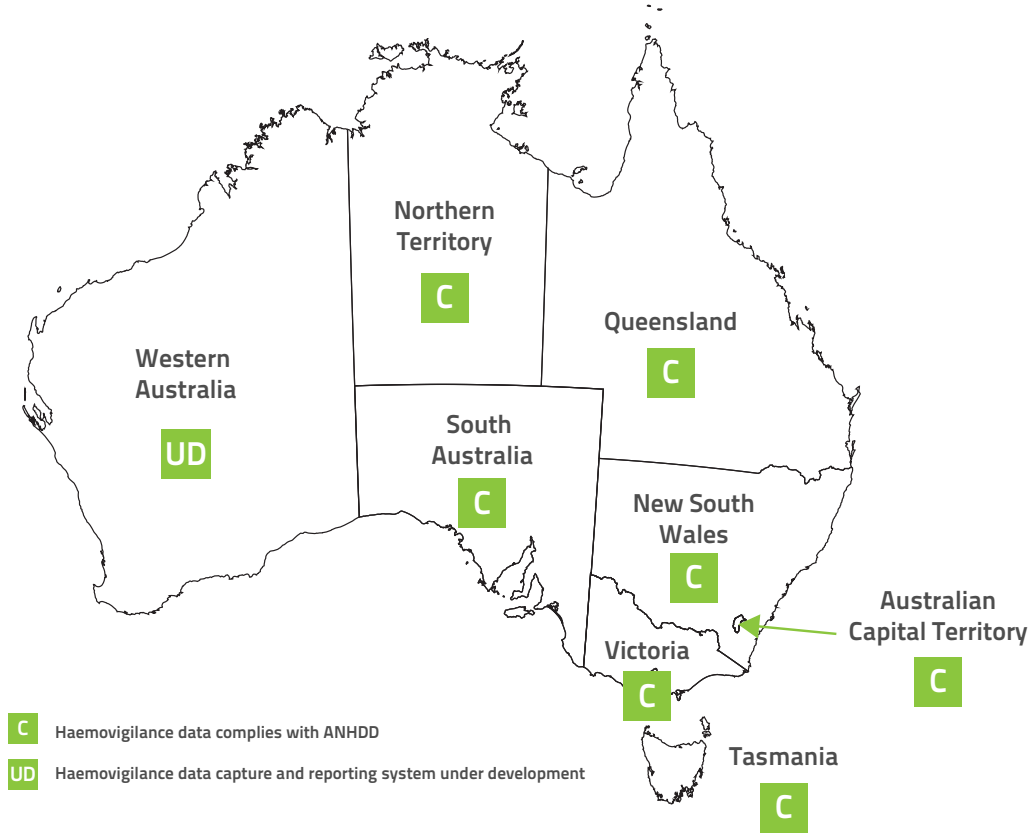


Figure 1: Jurisdictions contributing haemovigilance data to this report

Note: QLD contributed 2011–12 data only.

Victoria, Tasmania, Australian Capital Territory and Northern Territory

- VIC and TAS have supplied validated state level haemovigilance data to the National Haemovigilance Program since 2008–09 and the ACT and NT have contributed since 2009–10. The data provided by these states and territories is fully compliant with the data elements specified in the ANHDD.

South Australia

- The SA BloodSafe program has supplied validated state level haemovigilance data to the National Haemovigilance Program since 2008–09. SA recently made the ANHDD data elements such as age, sex and date of birth mandatory in the Datix Safety Learning System (SLS) to improve the completeness of data for national haemovigilance reporting.

Queensland

- The QLD Blood Management Program (QBMP) supplied validated jurisdictional-level haemovigilance data (QiiT) from 2008–09 to 2011–12; however there were a number of definitional and conceptual differences in the data. There was a discrepancy between the age categories used for QiiT and the national dataset. Table 1 shows the transformation used to map the QiiT age categories to those of the ANHDD. The decision was taken to align the ranges with a bias towards increasing the age category. For example, the 20–29 years QiiT category has been coded as 25–34 years in the national haemovigilance dataset. This allowed re-coding of the 28 day–1 year QiiT category and aligned with the concept that transfusion is more likely associated with increased age. De-identification of patient data at the QiiT level made it impractical to recode every incident from the original patient records according to national haemovigilance dataset standards.

Table 1: Transformation of age categories between QiiT and ANHDD standards

QiiT patient age	Re-coded to the national haemovigilance dataset patient age
28 days–1 year	0–4 years
1–4 years	0–4 years
5–9 years	5–14 years
10–19 years	15–24 years
20–29 years	25–34 years
30–39 years	35–44 years
40–49 years	45–54 years
50–59 years	55–64 years
60–69 years	65–74 years
70–79 years	75 years or older
> 80 years	75 years or older

- The ongoing supply of QLD data to the National Haemovigilance Program has now become a major issue due to the cessation of the centralised haemovigilance system (QiiT). As a result, QLD 2012–13 data was not available for this report. The NBA has provided assistance to QLD Health to develop the Haemovigilance Data Collection Tool. QLD Heath has used the tool to improve reporting capacity for future reports.

New South Wales

- NSW has contributed to the National Haemovigilance Program by performing a targeted analysis of transfusion-related adverse events as reported in IIMS since 2008–09. However, the IIMS is not a specific haemovigilance reporting system and many important data fields required by the national haemovigilance dataset are lacking for national level reporting. As a result, the NSW data provided for the previous reports was not comparable with the data provided by other states and territories. NSW has improved the haemovigilance reporting capacity since the last report and provided detailed and validated state level data (such as imputability and outcome severity data) for this report.

Western Australia

- Adverse event data in WA is collected and analysed on an individual hospital or health service basis and was not contributed to this or previous reports. WA is developing a reporting tool and process for the collection of haemovigilance data aligned with the ANHDD. Implementation is intended to facilitate the generation of state-level haemovigilance reports and provision of WA data for national reporting.

Data quality

States and territories are primarily responsible for the quality of adverse event data provided to the National Haemovigilance Program. Transfusion-related adverse events should be validated at the local level. Standards for validation are developed by local institutions in conjunction with health departments. Reports of serious adverse events may go through a secondary validation process within the state and territory haemovigilance programs and health department quality units to ensure data accuracy and completeness. State and territory haemovigilance representatives, on behalf of health departments, will aggregate and de-identify data and send periodic reports to the NBA. The NBA checks the validity and completeness of the reported values. 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 is variation between states and territories in the quality and completeness of adverse event data reported to the National Haemovigilance Program due to the voluntary nature of reporting. Data is not complete for every reported adverse event in the national dataset and even missing for some data elements:
  - NSW, VIC, QLD, SA, TAS, ACT and NT supplied validated data.
  - WA did not contribute data.
  - QLD data is unavailable for 2012–13.
  - Sex and facility location data is unavailable for NSW.
  - Time of transfusion data is unavailable for NSW and SA.
  - Contributory factors are not identified for most of the adverse events reported by QLD and SA.
- The adverse events definitions standardised in the ANHDD are consistent with the IHN/ISBT definitions.
- 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.
- 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.
- Near miss data is not presented in the report. However, some states and territories, such as VIC, SA, ACT, NT and NSW, have started to collect near miss events in their systems.
- With regard to denominator data, national information on the total number of fresh blood components transfused has not been collected and reported. The NBA, states and territories are addressing this through data linkage exercises external to the National Haemovigilance Program.

Overview of reported serious transfusion related adverse events

Transfusion risks

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. The infectious risks associated with transfusion are now very small. When considering the significance of specific risks, it is often useful to compare them to the risks associated with everyday living. The transfusion risk according to the Blood Service is high for allergic reaction, FNHTR and TACO; however it is very low for the other adverse events when compared to everyday risks (refer to Calman scale in Table 2 and transfusion risks in Table 3). For example, the chances of acquiring bacterial sepsis from a red cell transfusion are equivalent to the chances of death from a train accident according to the Calman chart risk per one year in Table 2.

Table 2: The Calman chart for explaining risk (United Kingdom; risk per one year) [6]

Risk Level	UK risk per one year
Negligible	< 1:1,000,000 such as death from a lightning strike
Minimal	1:100,000–1:1,000,000 such as death from a train accident
Very low	1:10,000–1:100,000 such as death from an accident at work
Low	1:1,000–1:10,000 such as death from a road accident
High	> 1:1,000 such as transmission of chickenpox to susceptible household contacts

Table 3: Transfusion risks (Blood Service; risk per unit transfused unless specified) [7]

Adverse reactions	Risk per unit transfused (unless specified)	Calman rating
Allergic reaction	1–3% of transfusions	High
Febrile non haemolytic reaction	0.1–1% of transfusions with universal leucocyte depletion. Most frequently in patients previously alloimmunised by transfusion or pregnancy.	High
Transfusion-associated circulatory overload	Up to 1% of patients receiving transfusions	High
Bacterial sepsis, relating to: –Platelets –Red cells	 At least 1:75,000 At least 1:500,000	 Very low Minimal
Haemolytic reactions: –Delayed –Acute –Fatal	 1:2,500–1:11,000 1:76,000 less than 1:1 million	 Low to very low Very low Negligible
Anaphylactic reaction	1:20,000–1:50,000	Very low
Transfusion-related acute lung injury	1:1,200–1:190,000	Low to minimal
Transfusion-associated graft versus host disease	Rare	Negligible
Post-transfusion purpura	Rare	Negligible

Summary of main findings and results

This report details transfusion-related adverse events reported for 2011–12 and 2012–13. This summary section also reproduces data for 2008–09, 2009–10 and 2010–11 (from the previous Australian Haemovigilance Report) for comparative purposes.

Table 4 shows the number of adverse events reported (independent of assigned imputability) to the National Haemovigilance Program for the five financial years 2008–09 to 2012–13. The relative incidence of the adverse events is comparable to the data of many other developed countries, with a majority of febrile reactions and allergic reactions. DHTR, AHTR, TRALI, TTI and PTP all present with very low to minimal prevalence in patients. Human errors continue to contribute to adverse events (discussed further in the section on Contributory factors).

Table 4: Australian adverse event data, 2008–09 to 2012–13

Adverse event	2008–09	2009–10	2010–11	2011–12	2012–13	All reports	
						Number	Per cent
FNHTR	154	158	321	320	231	1,184	52.6%
Allergic reaction	87	84	142	147	111	571	25.4%
IBCT	22	23	30	62	43	180	8.0%
TACO	6	12	24	27	17	86	3.8%
Anaphylactoid or anaphylactic reaction	8	12	33	16	13	82	3.6%
TTI	3	18	11	12	5	49	2.2%
DHTR	4	8	10	17	6	45	2.0%
AHTR	7	6	2	10	2	27	1.2%
TRALI	3	8	8	4	1	24	1.1%
PTP	-	2	1	-	-	3	0.1%
Total reports	**294**	**331**	**582**	**615**	**429**	**2,251**	**100.0%**

Notes

1. All TTIs were bacterial infections and these were reported cases but not necessarily confirmed.
2. Limited adverse event data available for NSW for 2008–09 and 2009–10. NSW only provided detailed data (such as blood products, outcome severity and imputability score) for 2011–12 and 2012–13.
3. Adverse event data unavailable for ACT and NT for 2008–09, and QLD for 2012–13.
4. Adverse event data unavailable for WA.

There were 2,251 reports of adverse events to the National Haemovigilance Program from 2008–09 to 2012–13 (Table 4). The improved reporting from NSW significantly contributed to the increase in the number of reports, from 294 in 2008–09 to 615 in 2011–12, however this dropped in 2012-13 to 429 due to QLD not providing any reports for that year. The most frequently reported adverse events are FNHTR and severe allergic reactions, representing 52.6% and 25.4% of all reports respectively. No PTP cases were reported for the collection period of this report. The Australian data for TACO, TRALI, and DHTR indicates that these adverse events are suspected to be under-reported.

From 2008–09 to 2012–13, 2,019 reports specified the blood products involved (Figure 2). Blood product information is unknown for 23 reports and not provided for 209 reports which were all contributed by NSW for 2009–10 and 2010–11. Red blood cells were the products most often implicated in adverse events for the last three financial years, accounting for 71.9% of the reports (1,451 of 2,019). Only a very small proportion of adverse events were related to the transfusion of whole blood (rarely used in Australia), cryoprecipitate and cryodepleted plasma. WA and NSW (prior to 2011-12) are excluded from the analysis due to the unavailability of blood component data for these two states.

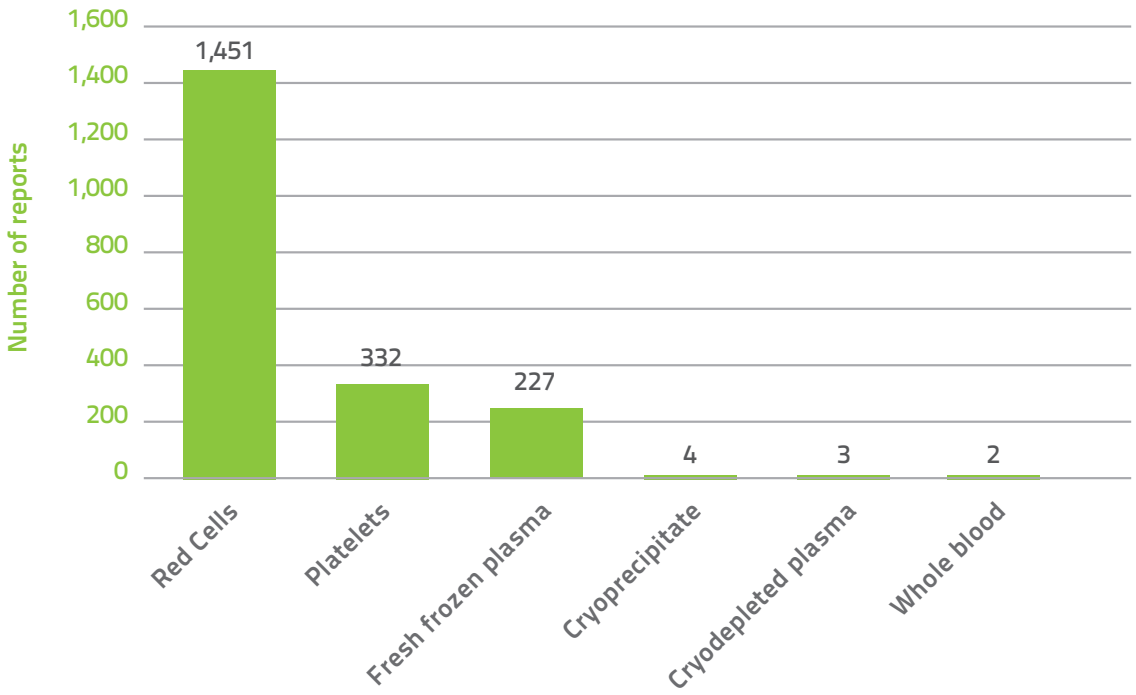


Figure 2: Blood products implicated in serious adverse events, 2008–09 to 2012–13

Notes:

1. Blood product data unavailable for NSW from 2008–09 to 2010–11, ACT and NT for 2008–09, and QLD for 2012–13.
2. Blood product data unavailable for WA.
3. Unknown products excluded from analysis.

Table 5 details the numbers of adverse events by blood product reported for 2008–09 to 2012–13. Table 6 details the Clinical outcome severity data reported by adverse events for 2008–09 to 2012–13.

Two cases of death (TACO and allergic reaction) were reported to National Haemovigilance Program in 2008–09. The number of adverse events reported with life threatening severity also dropped, from a total of 30 in 2008–09 to 10 in 2011–12 and 4 in 2012–13. Improved transfusion practice and better management of adverse events may contribute to the reduction of reported deaths and life threatening cases in Australia. In contrast, the cases with severe morbidity rose from 11 in 2008–09 to 55 in 2011–12 due to the increased reporting for most adverse events, but dropped to 42 in 2012–13 due to the unavailability of QLD data. The cases with minor morbidity had an increase from 33 in 2008–09 to 471 in 2011–12, most likely due to increased awareness of collecting and reporting non-serious adverse events such as FNHTRs and minor allergic reactions; and then dropped to 323 in 2012–13 due to the unavailability of QLD data.

Table 5: Numbers of adverse events by blood product, 2008–09 to 2012–13

Adverse event/year	Whole blood	Red blood cells	Platelets	Fresh frozen plasma	Cryodepleted plasma	Cryoprecipitate	Unknown	Total
FNHTR								
2008–09	-	134	15	2	-	-	3	154
2009–10	-	143	14	1	-	-	-	158
2010–11	-	170	27	3	-	-	121	321
2011–12	-	294	26	-	-	-	-	320
2012–13	1	201	24	5	-	-	-	231
Allergic reaction								
2008–09	-	40	19	27	-	1	-	87
2009–10	-	30	27	25	1	1	-	84
2010–11	-	33	27	41	1	-	40	142
2011–12	-	56	54	36	-	1	-	147
2012–13	-	42	35	34	-	-	-	111
IBCT								
2008–09	-	14	1	3	-	-	4	22
2009–10	1	16	5	-	-	-	1	23
2010–11	-	18	4	3	-	-	5	30
2011–12	-	49	2	10	1	-	-	62
2012–13	-	28	9	6	-	-	-	43
Anaphylactic								
2008–09	-	1	2	2	1	-	2	8
2009–10	-	5	1	1	-	-	5	12
2010–11	-	13	3	9	-	-	8	33
2011–12	-	6	5	5	-	-	-	16
2012–13	-	5	4	4	-	-	-	13
TACO								
2008–09	-	2	-	1	-	-	3	6
2009–10	-	8	-	-	-	-	4	12
2010–11	-	10	-	4	-	-	10	24
2011–12	-	25	1	1	-	-	-	27
2012–13	-	17	-	-	-	-	-	17
DHTR								
2008–09	-	1	3	-	-	-	-	4
2009–10	-	8	-	-	-	-	-	8
2010–11	-	6	-	1	-	-	3	10
2011–12	-	16	1	-	-	-	-	17
2012–13	-	6	-	-	-	-	-	6

Adverse event/year	Whole blood	Red blood cells	Platelets	Fresh frozen plasma	Cryodepleted plasma	Cryoprecipitate	Unknown	Total
Bacterial TTI								
2008–09	-	1	1	-	-	-	1	3
2009–10	-	2	5	-	-	-	11	18
2010–11	-	4	5	-	-	-	2	11
2011–12	-	6	6	-	-	-	-	12
2012–13	-	2	3	-	-	-	-	5
TRALI								
2008–09	-	1	-	1	-	-	1	3
2009–10	-	2	1	2	-	-	3	8
2010–11	-	5	-	-	-	-	3	8
2011–12	-	2	2	-	-	-	-	4
2012–13	-	1	-	-	-	-	-	1
AHTR								
2008–09	-	7	-	-	-	-	-	7
2009–10	-	6	-	-	-	-	-	6
2010–11	-	1	-	-	-	-	1	2
2011–12	-	10	-	-	-	-	-	10
2012–13	-	2	-	-	-	-	-	2
PTP								
2009–10	-	2	-	-	-	-	-	2
2010–11	-	-	-	-	-	-	1	1
Total	**2**	**1,451**	**332**	**227**	**4**	**3**	**232**	**2,251**

Notes

1. Blood product data unavailable for WA.
2. Blood product data unavailable for ACT and NT for 2008–09, NSW from 2008–09 to 2010–11, and QLD for 2012–13

Table 6: Clinical outcome severity data by adverse event, 2008–09 to 2012–13

	FNHTR	Allergic reaction	IBCT	Anaphylactic	TACO	DHTR	Bacterial TTI	AHTR	TRALI	PTP	Total
Death											
2008–09	-	1	-	-	1	-	-	-	-	-	2
2009–10	-	-	-	-	-	-	-	-	-	-	-
2010–11	-	-	-	-	-	-	-	-	-	-	-
2011–12	-	-	-	-	-	-	-	-	-	-	-
2012–13	-	-	-	-	-	-	-	-	-	-	-
Life threatening											
2008–09	5	16	1	3	-	-	1	2	2	-	30
2009–10	-	1	-	2	-	1	-	-	1	-	5
2010–11	-	-	1	1	1	-	1	-	-	-	4
2011–12	1	2	-	3	3	-	-	1	-	-	10
2012–13	-	-	1	3	-	-	-	-	-	-	4
Severe morbidity											
2008–09	3	8	-	-	-	-	-	-	-	-	11
2009–10	6	4	2	4	3	3	1	5	2	1	31
2010–11	12	9	2	6	9	1	2	1	3	-	45
2011–12	8	13	5	5	13	7	-	3	1	-	55
2012–13	12	10	4	5	9	1	1	-	-	-	42
Minor morbidity											
2008–09	14	16	2	1	-	-	-	-	-	-	33
2009–10	122	58	13	1	5	4	2	1	1	1	208
2010–11	184	87	8	15	4	5	3	-	2	-	308
2011–12	306	128	2	7	10	9	1	6	2	-	471
2012–13	202	96	7	5	8	1	1	2	1	-	323
No morbidity											
2008–09	77	29	17	3	1	4	1	4	-	-	136
2009–10	29	21	8	-	-	-	4	-	1	-	63
2010–11	9	7	14	2	-	1	3	-	-	-	36
2011–12	4	4	24	1	-	1	7	-	-	-	41
2012–13	9	5	16	-	-	2	-	-	-	-	32
Outcome not available											
2008–09	55	17	2	1	4	-	1	1	1	-	82
2009–10	1	-	0	5	4	-	11	-	3	0	24
2010–11	116	39	5	9	10	3	2	1	3	1	189
2011–12	1	-	31	-	1	-	4	-	1	-	38
2012–13	8	-	15	-	-	2	3	-	-	-	28
Total	**1,184**	**571**	**180**	**82**	**86**	**45**	**49**	**27**	**24**	**3**	**2,251**

Notes

1. Clinical outcome severity data unavailable for ACT and NT for 2008–09, NSW from 2008–09 to 2010–11, and QLD for 2012–13.
2. Clinical outcome severity data unavailable for WA.

Febrile non-haemolytic transfusion reactions (FNHTR)

2011–12 Data Summary (n=320)					
Age		**Sex**		**Day of Transfusion**	
0–4 years	5	Male	114	Week day	246
5–14 years	7	Female	93	Weekend	74
15–24 years	7	Uncategorised	113		
25–34 years	15	**Facility Location**		**Time of Transfusion**	
35–44 years	18	Major City	162	Between 7am and 7pm	92
45–54 years	28	Inner Regional	47	Between 7pm and 7am	32
55–64 years	45	Outer Regional	7	Unknown	196
65–74 years	70	Remote	1		
75+ years	122	Very Remote	-		
Not specified	3	Uncategorised	103		
Clinical Outcome Severity		**Imputability**		**Blood Component**	
Death	-	Excluded/Unlikely	20	Whole blood	-
Life threatening	1	Possible	90	Red cells	294
Severe morbidity	8	Likely/Probable	182	Platelets	26
Minor morbidity	306	Confirmed/Certain	5	Fresh Frozen Plasma	-
No morbidity	4	Not assessable	23	Cryoprecipitate	-
Outcome not available	1			Cryodepleted plasma	-

2012–13 Data Summary (n=231)					
Age		**Sex**		**Day of Transfusion**	
0–4 years	3	Male	62	Week day	178
5–14 years	6	Female	49	Weekend	53
15–24 years	8	Uncategorised	120		
25–34 years	12	**Facility Location**		**Time of Transfusion**	
35–44 years	21	Major City	112	Between 7am and 7pm	15
45–54 years	27	Inner Regional	-	Between 7pm and 7am	10
55–64 years	36	Outer Regional	4	Unknown	206
65–74 years	54	Remote	-		
75+ years	58	Very Remote	-		
Not specified	6	Uncategorised	115		
Clinical Outcome Severity		**Imputability**		**Blood Component**	
Death	-	Excluded/Unlikely	4	Whole blood	1
Life threatening	-	Possible	123	Red cells	201
Severe morbidity	12	Likely/Probable	83	Platelets	24
Minor morbidity	202	Confirmed/Certain	-	Fresh Frozen Plasma	5
No morbidity	9	Not assessable	21	Cryoprecipitate	-
Outcome not available	8			Cryodepleted plasma	-

Notes
1. QLD data is unavailable for 2012–13.
2. Sex and facility location data is unavailable for NSW.
3. Time of transfusion data is unavailable for NSW and SA.
4. Data is unavailable for WA.
5. Uncategorised refers to those reports where no data was provided.

FNHTR (see Appendix II: Definitions in haemovigilance) is the most common transfusion-related adverse event reported in Australia. The incidence rates for FNHTR have been reported at less than 1% with current methods that use single-donor apheresis units and leucoreduced products.[8,9] In combined financial years 2011–12 and 2012–13, 551 FNHTRs were reported to the National Haemovigilance Program, accounting for more than half (52.8%) of the total reports (1,044) for this period.

In the five financial years to 2012–13:

- The number of FNHTRs more than doubled, from 154 in 2008–09 to 321 in 2010–11 and 320 in 2011–12, mainly due to increased reporting of this event from NSW, QLD and SA. The number of FNHTRs dropped in 2012–13 due to the unavailability of QLD data.
- Despite the increase in the number of reported FNHTRs, the number of cases reporting life threatening severity dropped from five in 2008-09 to one (imputability=likely/probable) in 2011–12 and zero in 2012–13.
- The number of reports of minor morbidity had an increase from 14 in 2008–09 to 306 in 2011–12. This may indicate an increased awareness of collecting and reporting FNHTR events at a hospital level and a state level, and inclusion of NSW data. The number dropped in 2012–13, due to the unavailability of QLD data.
- The number of reports of outcome not available dropped from 55 in 2008–09 to 1 in 2011–12 and 8 in 2012–13.
- The majority of cases were related to red cell transfusion.

The lack of SA and NSW data for transfusion time and NSW data for sex and facility location contributed to the increased numbers of unknown/uncategorised cases for these categories in 2011–12 and 2012–13.

In the period 2011–12 and 2012–13, around 49.0% of FNHTRs (270) were assigned an imputability score of likely/probable or confirmed/certain, including 12 cases with severe morbidity and one case with life threatening severity.

Table 7: FNHTR clinical outcome severity by imputability, 2011–12 and 2012–13

Clinical Outcome Severity	Imputability					Total
	Excluded / Unlikely	Possible	Likely / Probable	Confirmed / Certain	N/A / Not assessable	
Life threatening						
2011–12	-	-	1	-	-	1
2012–13	-	-	-	-	-	-
Severe morbidity						
2011–12	-	3	5	-	-	8
2012–13	-	5	7	-	-	12
Minor morbidity						
2011–12	20	85	174	5	22	306
2012–13	4	106	72	-	20	202
No morbidity						
2011–12	-	2	2	-	-	4
2012–13	-	5	4	-	-	9
Outcome not available						
2011–12	-	-	-	-	1	1
2012–13	-	7	-	-	1	8
Total	**24**	**213**	**265**	**5**	**44**	**551**

Notes

1. Outcome severity and imputability data unavailable for QLD for 2012–13.
2. Outcome severity and imputability data unavailable for WA.

The current definition of FNHTR used by the HAC aligns with the definitions used by the IHN and the ISBT Working Party on Haemovigilance. However, there is still some divergence between the definitions in use. The VIC STIR system uses a higher temperature threshold than specified by the ANHDD; STIR specifies a fever >38.5°C or a change of 1.5°C above baseline to reflect more severe adverse events. This STIR definition matches that of the New Zealand Blood National Haemovigilance Programme. This results in some FNHTR incidents that are reportable to the National Haemovigilance Program being screened out by STIR.

Clinically confounding factors may complicate diagnosis and reporting of FNHTR. Difficulties with diagnosis and the burden of reporting for this common event may justify higher reporting thresholds. The ISBT suggests that for the purpose of international comparisons, only the most severe cases of FNHTR should be reported (fever ≥39°C oral or equivalent and a change of ≥2°C from pre-transfusion value; chills/rigors).

Clinical recommendation

The ANZSBT Guidelines for the Administration of Blood Products recommends that a temperature rise to ≥38°C or ≥1°C above baseline (if baseline ≥37°C) should prompt the interruption (stopping) of the transfusion and a clinical assessment of the patient.[10]

The Blood Service provides guidance on the recognition, investigation and management of FNHTR.[11]

- **When to suspect this adverse reaction?**
  Patients present with an unexpected temperature rise (≥38°C or ≥1°C above baseline, if baseline ≥37°C) during or shortly after transfusion. This is usually an isolated finding. Occasionally the fever is accompanied by chills.
  Chills, rigors, increased respiratory rate, change in blood pressure, anxiety and a headache may accompany this reaction but occur in several more serious transfusion reactions also, the most serious being acute haemolytic reaction, transfusion associated sepsis and TRALI. FNHTR is a diagnosis of exclusion. This occurs in 0.1% to 1% of transfusions with leucocyte depletion.
- **Usual causes?**
  Cytokine accumulation during storage of cellular components (especially in platelet units) is thought to be the most common event leading to symptoms of FNHTRs. Cytokines are released by white cells and pre-storage leucodepletion has reduced this risk.
  FNHTR is also caused by the presence of recipient antibodies (raised as a result of previous transfusions or pregnancies) reacting to donor human leucocyte antigens (HLA) or other antigens. These antigens are present on donor lymphocytes, granulocytes, or platelets.
- **Investigation**
  Clinically assess the transfused patient for fever, chills, rigors and headache.
  Acute haemolytic reaction may need exclusion.
  Direct antiglobulin test (DAT), blood count and repeat ABO grouping may be indicated.
  Consider investigations for transfusion associated sepsis.
  In patients with repeated FNHTR, investigation for HLA antibodies may be useful.
- **What to do?**
  Stop transfusion immediately and follow other steps for managing suspected transfusion reactions.
  Treat the fever with an antipyretic. However, avoid aspirin in thrombocytopenic and paediatric patients.
  Consider and exclude other causes, as fever alone may be the first manifestation of a life threatening reaction.
  Rule out acute haemolytic reaction, transfusion associated sepsis and TRALI.
  Recommencement of the transfusion, at a slow rate, is possible if other causes of a fever have been excluded.

Allergic reactions

2011–12 Data Summary (n=147)					
Age		**Sex**		**Day of Transfusion**	
0–4 years	6	Male	67	Week day	126
5–14 years	9	Female	53	Weekend	21
15–24 years	12	Uncategorised	27		
25–34 years	9	**Facility Location**		**Time of Transfusion**	
35–44 years	12	Major City	103	Between 7am and 7pm	63
45–54 years	19	Inner Regional	16	Between 7pm and 7am	10
55–64 years	29	Outer Regional	2	Unknown	74
65–74 years	24	Remote	-		
75+ years	26	Very Remote	-		
Not specified	1	Uncategorised	26		
Clinical Outcome Severity		**Imputability**		**Blood Component**	
Death	-	Excluded/Unlikely	1	Whole blood	-
Life threatening	2	Possible	20	Red cells	56
Severe morbidity	13	Likely/Probable	89	Platelets	54
Minor morbidity	128	Confirmed/Certain	35	Fresh Frozen Plasma	36
No morbidity	4	Not assessable	2	Cryoprecipitate	1
Outcome not available	-		-	Cryodepleted plasma	-

2012–13 Data Summary (n=111)					
Age		**Sex**		**Day of Transfusion**	
0–4 years	9	Male	43	Week day	91
5–14 years	5	Female	38	Weekend	20
15–24 years	11	Uncategorised	30		
25–34 years	14	**Facility Location**		**Time of Transfusion**	
35–44 years	7	Major City	75	Between 7am and 7pm	19
45–54 years	10	Inner Regional	2	Between 7pm and 7am	5
55–64 years	16	Outer Regional	5	Unknown	87
65–74 years	14	Remote	-		
75+ years	21	Very Remote	-		
Not specified	4	Uncategorised	29		
Clinical Outcome Severity		**Imputability**		**Blood Component**	
Death	-	Excluded/Unlikely	3	Whole blood	-
Life threatening	-	Possible	13	Red cells	42
Severe morbidity	10	Likely/Probable	77	Platelets	35
Minor morbidity	96	Confirmed/Certain	7	Fresh Frozen Plasma	34
No morbidity	5	Not assessable	11	Cryoprecipitate	-
Outcome not available	-			Cryodepleted plasma	-

Notes

1. QLD data is unavailable for 2012–13.
2. Sex and facility location data is unavailable for NSW.
3. Time of transfusion data is unavailable for NSW and SA.
4. Data is unavailable for WA.
5. Uncategorised refers to those reports where no data was provided.

Allergic reactions (see Appendix II: Definitions in haemovigilance) are the second most common transfusion-related adverse events reported in Australia. In combined financial years 2011–12 and 2012–13, 258 allergic reactions were reported to the National Haemovigilance Program, accounting for 24.7% of the reports (1,044) for this period. The number of allergic reactions dropped from 147 in 2011–12 to 111 in 2012–13 due to the unavailability of QLD data.

In the five financial years to 2012–13:

- The number of severe allergic reactions reported rose by 69.0% from 87 in 2008–09 to 147 in 2011–12, mainly due to increased reporting of this event from NSW, QLD and SA. The number of allergic reactions dropped in 2012–13 due to the unavailability of QLD data.
- There was one reported death in 2008–09 and no reported deaths from 2009–10 to 2012–13. The number of cases reported with life threatening severity dropped from 16 in 2008–09 to 2 in 2011–12 and 0 in 2012–13.
- The number of cases reported with minor morbidity increased from 16 in 2008–09 to 128 due to the inclusion of NSW data in 2011–12 and dropped to 96 in 2012-13 (likely due to the unavailability of QLD data).

The lack of SA and NSW data for transfusion time and NSW data for facility location contributed to large numbers of unknown/uncategorised cases for two categories in 2011–12 and 2012–13.

In the period 2011–12 to 2012–13, 80.6% of cases (208) were assigned an imputability score of likely/probable or confirmed/certain, including 20 cases with severe morbidity and two with life threatening severity. The confirmed case of life threatening severity was related to the transfusion of red cells.

Table 8: Severe allergic reaction clinical outcome severity by imputability, 2011–12 and 2012–13

Clinical Outcome Severity	Imputability					Total
	Excluded / Unlikely	Possible	Likely / Probable	Confirmed/ Certain	N/A / Not assessable	
Death						
2011–12	-	-	-	-	-	-
2012–13	-	-	-	-	-	-
Life threatening						
2011–12	-	-	1	1	-	2
2012–13	-	-	-	-	-	-
Severe morbidity						
2011–12	-	1	9	3	-	13
2012–13	-	1	7	1	1	10
Minor morbidity						
2011–12	1	19	77	29	2	128
2012–13	3	12	67	4	10	96
No morbidity						
2011–12	-	-	2	2	-	4
2012–13	-	-	3	2	-	5
Outcome not available						
2011–12	-	-	-	-	-	-
2012–13	-	-	-	-	-	-
Total	**4**	**33**	**166**	**42**	**13**	**258**

Notes

1. Outcome severity and imputability data unavailable for QLD for 2012–13.
2. Outcome severity and imputability data unavailable for WA.

Symptoms of allergic reactions may include urticaria (hives), oedema, pruritis, and angioedema. Urticarial reactions are presumably due to soluble antigens in the donor unit to which the recipient has been previously sensitised, and are typically dose-dependent.

Allergic reactions are a common complication of blood transfusion. Leucoreduction has no effect on decreasing incidence rates,[12] suggesting that cytokines released from white blood cells during storage are likely not responsible. Unless the patient has a history of transfusion-related severe allergic reactions, these incidents are difficult to predict.

Clinical recommendation

The Blood Service provides guidance on the recognition, investigation and management of severe allergic reactions.[13]

- **When to suspect these adverse reactions?**
  This reaction can range from one lesion to widespread urticarial lesions. This is commonly the only symptom but may be associated with mild upper respiratory symptoms, nausea, vomiting, abdominal cramps or diarrhoea. This occurs in 1–3% of transfusions.
- **Usual causes?**
  Hypersensitivity to allergens or plasma proteins in the transfused unit.
- **Investigation**
  Generally no investigations are required.
  If there is more than simple urticaria, haemolysis should be excluded: DAT, blood count and repeat ABO grouping may be indicated.
- **What to do?**
  Stop transfusion immediately and follow other steps for managing suspected transfusion reactions.
  Antihistamines may be given and once the reaction subsides, continue transfusion at a slow rate and complete within 4 hours of commencement.
  Consult a haematologist before administering additional blood packs.
  Consider premedication and/or washed red cells if the patient has recurrent allergic reactions to transfusion.

Anaphylactic or anaphylactoid reactions

2011–12 Data Summary (n=16)					
Age		**Sex**		**Day of Transfusion**	
0–4 years	-	Male	8	Week day	10
5–14 years	-	Female	7	Weekend	6
15–24 years	2	Uncategorised	1		
25–34 years	1	**Facility Location**		**Time of Transfusion**	
35–44 years	2	Major City	12	Between 7am and 7pm	11
45–54 years	2	Inner Regional	4	Between 7pm and 7am	2
55–64 years	2	Outer Regional	-	Unknown	3
65–74 years	3	Remote	-		
75+ years	4	Very Remote	-		
Not specified	-	Uncategorised			
Clinical Outcome Severity		**Imputability**		**Blood Component**	
Death	-	Excluded/Unlikely	-	Whole blood	-
Life threatening	3	Possible	3	Red cells	6
Severe morbidity	5	Likely/Probable	6	Platelets	5
Minor morbidity	7	Confirmed/Certain	7	Fresh Frozen Plasma	5
No morbidity	1	Not assessable	-	Cryoprecipitate	-
Outcome not available	-			Cryodepleted plasma	-

2012–13 Data Summary (n=13)					
Age		**Sex**		**Day of Transfusion**	
0–4 years	-	Male	1	Week day	13
5–14 years	-	Female	5	Weekend	-
15–24 years	1	Uncategorised	7		
25–34 years	2	**Facility Location**		**Time of Transfusion**	
35–44 years	3	Major City	5	Between 7am and 7pm	3
45–54 years	1	Inner Regional	1	Between 7pm and 7am	2
55–64 years	2	Outer Regional	-	Unknown	8
65–74 years	2	Remote	-		
75+ years	2	Very Remote	-		
Not specified	-	Uncategorised	7		
Clinical Outcome Severity		**Imputability**		**Blood Component**	
Death	-	Excluded/Unlikely	-	Whole blood	-
Life threatening	3	Possible	4	Red cells	5
Severe morbidity	5	Likely/Probable	9	Platelets	4
Minor morbidity	5	Confirmed/Certain	-	Fresh Frozen Plasma	4
No morbidity	-	Not assessable	-	Cryoprecipitate	-
Outcome not available	-			Cryodepleted plasma	-

Notes

1. QLD data is unavailable for 2012–13.
2. Sex and facility location data is unavailable for NSW.
3. Time of transfusion data is unavailable for NSW and SA.
4. Data is unavailable for WA.
5. Uncategorised refers to those reports where no data was provided.

An anaphylactic reaction involves a severe, life threatening, generalised or systemic hypersensitivity reaction characterised by rapidly developing airway and/or breathing and/or circulation problems usually associated with skin and mucosal changes.[14]

From 2011–12 to 2012–13, there were 29 reports of anaphylactic or anaphylactoid reactions to the National Haemovigilance Program, accounting for 2.8% of all reports (1,044) for this period. The number of cases rose from 8 in 2008–09 to 33 in 2010–11 and then dropped to 16 in 2011–12. It dropped further in 2012–13 due to the unavailability of QLD data.

In the period 2011–12 to 2012–13, 22 out of 29 cases were assigned an imputability score of likely/probable or confirmed/certain, including five cases of life threatening severity and seven cases with severe morbidity. Two confirmed cases of life threatening severity were related to the transfusion of platelets and red cells respectively.

Table 9: Anaphylactic or anaphylactoid reactions clinical outcome severity by imputability, 2011–12 and 2012–13

Clinical Outcome Severity	Imputability					Total
	Excluded / Unlikely	Possible	Likely / Probable	Confirmed/ Certain	N/A / Not assessable	
Death						
2011–12	-	-	-	-	-	-
2012–13	-	-	-	-	-	-
Life threatening						
2011–12	-	-	1	2	-	3
2012–13	-	1	2	-	-	3
Severe morbidity						
2011–12	-	1	3	1	-	5
2012–13	-	2	3	-	-	5
Minor morbidity						
2011–12	-	2	2	3	-	7
2012–13	-	1	4	-	-	5
No morbidity						
2011–12	-	-	-	1	-	1
2012–13	-	-	-	-	-	-
Outcome not available						
2011–12	-	-	-	-	-	-
2012–13	-	-	-	-	-	-
Total	**-**	**7**	**15**	**7**	**-**	**29**

Notes
1. Outcome severity and imputability data unavailable for QLD for 2012–13.
2. Outcome severity and imputability data unavailable for WA.

Anaphylaxis is an acute hypersensitivity reaction that can present as, or rapidly progress to, a severe life threatening reaction.[15] Anaphylactoid reactions are clinically indistinguishable from anaphylaxis reactions, but differ in their immune mechanism. Distinguishing between anaphylaxis and anaphylactoid reactions is impossible on the basis of clinical signs and symptoms alone; a clinical definition cannot differentiate between the two.

This position is consistent with suggestions for a revised nomenclature for allergy, issued by the European Academy of Allergy and Clinical Immunology (EAACI) and World Allergy Organization referring to anaphylactoid reactions simply as 'non-allergic anaphylaxis'.[16,17,18] Diagnosis of anaphylactic and anaphylactoid reactions can be difficult, and an international symposium recently acknowledged that a widely accepted definition of anaphylaxis is lacking, which contributes to the wide variation in standards of diagnosis and management.[18]

Clinical recommendation

The Blood Service provides guidance on the recognition, investigation and management of anaphylactic reactions.[19]

- **When to suspect these adverse reactions?**
  Reactions usually begin within 1 to 45 minutes after the start of the transfusion.
  Patients present with a sudden onset of severe hypotension, cough, bronchospasm (respiratory distress and wheezing), laryngospasm, angioedema, urticaria, nausea, abdominal cramps, vomiting, diarrhoea, shock and loss of consciousness. This may be a fatal reaction.
  This occurs in 1:20,000 to 1:50,000 of transfusions.
- **Usual causes?**
  Anaphylactic transfusion reactions can occur when IgE antibody in the patient interacts with an allergen, usually a plasma protein in the blood component.
  The following mechanisms have been implicated in anaphylactic reactions:
  - IgA-deficient patients who have anti-IgA antibodies
  - patient antibodies to plasma proteins (such as IgG, albumin, haptoglobin, transferrin, C3, C4 or cytokines)
  - transfusing an allergen to a sensitised patient (for example, penicillin or nuts consumed by a donor)
  - rarely the transfusion of IgE antibodies from a donor to an allergen present in the recipient.
- **Investigation**
  Anaphylaxis usually has a typical clinical presentation. Occasionally the differential diagnosis is acute haemolysis.
  DAT, blood count and repeat ABO grouping may be indicated.
  Check the recipient's pretransfusion sample for IgA deficiency and presence of anti-IgA antibodies.
- **What to do?**
  Stop transfusion immediately and follow other steps for managing suspected transfusion reactions. This may become a medical emergency.
  Maintain open airway and intravenous line, support blood pressure.
  Administer supplemental oxygen, antihistamines, adrenaline and corticosteroids as required, resuscitation may also be necessary.
  Consult a haematologist before administering additional blood packs. To prevent recurrent anaphyaxis the following options may be considered:
  - pre-medication with steroids and antihistamine
  - if patient is IgA deficient with anti-IgA, the use of IgA-deficient or washed blood components is recommended.

Acute haemolytic transfusion reactions (other than ABO incompatibility)

2011–12 Data Summary (n=10)					
Age		**Sex**		**Day of Transfusion**	
0–4 years	-	Male	4	Week day	6
5–14 years	-	Female	5	Weekend	4
15–24 years	-	Uncategorised	1		
25–34 years	-	**Facility Location**		**Time of Transfusion**	
35–44 years	-	Major City	9	Between 7am and 7pm	6
45–54 years	1	Inner Regional	1	Between 7pm and 7am	1
55–64 years	2	Outer Regional	-	Unknown	3
65–74 years	4	Remote	-		
75+ years	3	Very Remote	-		
Not specified	-	Uncategorised	-		
Clinical Outcome Severity		**Imputability**		**Blood Component**	
Death	-	Excluded/Unlikely	-	Whole blood	-
Life threatening	1	Possible	-	Red cells	10
Severe morbidity	3	Likely/Probable	5	Platelets	-
Minor morbidity	6	Confirmed/Certain	4	Fresh Frozen Plasma	-
No morbidity	-	Not assessable	1	Cryoprecipitate	-
Outcome not available	-			Cryodepleted plasma	-

2012–13 Data Summary (n=2)					
Age		**Sex**		**Day of Transfusion**	
0–4 years	-	Male	-	Week day	2
5–14 years	-	Female	-	Weekend	-
15–24 years	-	Uncategorised	2		
25–34 years	-	**Facility Location**		**Time of Transfusion**	
35–44 years	-	Major City	1	Between 7am and 7pm	-
45–54 years	-	Inner Regional	-	Between 7pm and 7am	-
55–64 years	-	Outer Regional	-	Unknown	2
65–74 years	1	Remote	-		
75+ years	1	Very Remote	-		
Not specified	-	Uncategorised	1		
Clinical Outcome Severity		**Imputability**		**Blood Component**	
Death	-	Excluded/Unlikely	-	Whole blood	-
Life threatening	-	Possible	-	Red cells	2
Severe morbidity	-	Likely/Probable	1	Platelets	-
Minor morbidity	2	Confirmed/Certain	-	Fresh Frozen Plasma	-
No morbidity	-	Not assessable	1	Cryoprecipitate	-
Outcome not available	-			Cryodepleted plasma	-

Notes

1. QLD data is unavailable for 2012–13.
2. Sex and facility location data is unavailable for NSW.
3. Time of transfusion data is unavailable for NSW and SA.
4. Data is unavailable for WA.
5. Uncategorised refers to those reports where no data was provided.

Acute haemolytic transfusion reactions (AHTR) occur by definition within 24 hours of transfusion. 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 incorrect blood component transfused (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.

From 2011–12 to 2012–13, there were 12 reports to the National Haemovigilance Program, with three cases of severe morbidity and one case of life threatening severity imputed as confirmed/certain. All cases were related to RBC transfusion. The National Haemovigilance Program has not gathered data on the particular red cell antibodies associated with haemolytic transfusion reactions.

Clinical recommendation

The Blood Service provides guidance on the recognition, investigation and management of anaphylactic reactions.[20]

- **When to suspect these adverse reactions?**
  It characteristically begins with an increase in temperature and pulse rate.
  Symptoms may include chills, rigors, dyspnoea, chest and/or flank pain, discomfort at infusion site, sense of dread, abnormal bleeding and may progress rapidly to shock.
  Instability of blood pressure is frequently seen. Transfused patients develop oliguria, haemoglobinuria and haemoglobinaemia.
- **Usual causes?**
  Acute haemolytic transfusion reactions occur at an incidence of 1:76,000 transfusions and may be associated with:
  - ABO/Rh mismatch patient antibodies to plasma proteins (such as IgG, albumin, haptoglobin, transferrin, C3, C4 or cytokines)
  - red cell alloantibodies (non-ABO) as a result of patient immunisation from previous pregnancy or transfusion
  - rare cases when Group O donor platelets with high titres of anti-A and/or anti-B are transfused to a non-Group O recipient.
- **Investigation**
  Clinically assess patients for common features of haemolysis occurring within 24 hours of transfusion.
  Check clerical records, such as ABO typing of patient and unit.
  Repeat patient ABO grouping in both pre- and post-transfusion samples.
- **What to do?**
  Stop transfusion immediately and follow other steps for managing suspected transfusion reactions. Seek urgent medical assistance. Maintain blood pressure and renal output.
  Induce diuresis with intravenous fluids and diuretics.
  This may become a medical emergency so support blood pressure and maintain an open airway.

Delayed haemolytic transfusion reactions (DHTR)

2011–12 Data Summary (n=17)					
Age		**Sex**		**Day of Transfusion**	
0–4 years	-	Male	5	Week day	11
5–14 years	-	Female	12	Weekend	6
15–24 years	-	Uncategorised			
25–34 years	2	**Facility Location**		**Time of Transfusion**	
35–44 years	1	Major City	14	Between 7am and 7pm	11
45–54 years	3	Inner Regional	-	Between 7pm and 7am	4
55–64 years	5	Outer Regional	3	Unknown	2
65–74 years	3	Remote	-		
75+ years	3	Very Remote	-		
Not specified	-	Uncategorised	-		
Clinical Outcome Severity		**Imputability**		**Blood Component**	
Death	-	Excluded/Unlikely	-	Whole blood	-
Life threatening	-	Possible	-	Red cells	16
Severe morbidity	7	Likely/Probable	-	Platelets	1
Minor morbidity	9	Confirmed/Certain	4	Fresh Frozen Plasma	-
No morbidity	1	Not assessable	13	Cryoprecipitate	-
Outcome not available	-			Cryodepleted plasma	-

2012–13 Data Summary (n=6)					
Age		**Sex**		**Day of Transfusion**	
0–4 years	-	Male	-	Week day	5
5–14 years	-	Female	3	Weekend	1
15–24 years	-	Uncategorised	3		
25–34 years	-	**Facility Location**		**Time of Transfusion**	
35–44 years	1	Major City	3	Between 7am and 7pm	2
45–54 years	2	Inner Regional	-	Between 7pm and 7am	1
55–64 years	1	Outer Regional	-	Unknown	3
65–74 years	1	Remote	-		
75+ years	1	Very Remote	-		
Not specified	-	Uncategorised	3		
Clinical Outcome Severity		**Imputability**		**Blood Component**	
Death	-	Excluded/Unlikely	-	Whole blood	-
Life threatening	-	Possible	2	Red cells	6
Severe morbidity	1	Likely/Probable	1	Platelets	-
Minor morbidity	1	Confirmed/Certain	3	Fresh Frozen Plasma	-
No morbidity	2	Not assessable	-	Cryoprecipitate	-
Outcome not available	2			Cryodepleted plasma	-

Notes

1. QLD data is unavailable for 2012–13.
2. Sex and facility location data is unavailable for NSW.
3. Time of transfusion data is unavailable for NSW and SA.
4. Data is unavailable for WA.
5. Uncategorised refers to those reports where no data was provided.

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. From 2011–12 to 2012–13, there were 23 reports of DHTR to the National Haemovigilance Program, accounting for 2.2% of all reports (1,044) for this period.

In the five financial years to 2012–13:

- The number of DHTRs increased from 4 in 2008–09 to 17 in 2011–12 and then dropped to 6 in 2012–13 (mainly due to the unavailability of QLD data).
- The majority of cases were related to red cell transfusion.
- The majority of affected patients were females.

DHTR are relatively common when compared with acute haemolytic transfusion reactions, but may be difficult to diagnose and easily missed as presentation may be remote (in time and place) from the causal transfusion. UK data has suggested that DHTR were responsible for 10.2% of all serious transfusion-related hazards between 1996 and 2003.[21] Researchers have observed that DHTRs are probably under-reported and under-recognised in the UK.[22]

The current figures for Australia imply that DHTR may be severely under-recognised and/or under-reported. The National Haemovigilance Program does not currently gather data on the specific antibodies associated with haemolytic transfusion reactions.

Current national level haemovigilance reporting in Australia does not consider the delay period between the transfusion and the reaction. This may be addressed in future reporting. UK data reported the interval in days between the implicated transfusion and clinical signs or symptoms of a DHTR to have a median of 8 days with a range of 2 to 18 days. Anti-Jk(a) is the single most common red cell specifically implicated in both acute and delayed reactions.[23] Treatment of DHTR remains challenging. Immunosuppressive medication has been reported to be useful by some but not by others. The mainstay of treatment is to minimise RBC transfusions as much as possible.[24]

Clinical recommendation

The Blood Service provides guidance on the recognition, investigation and management of DHTRs.[25]

- **When to suspect these adverse reactions?**
  Patients may present with unexplained fever and anaemia usually 2 to 14 days after transfusion of a red cell component.
  The patient may also have jaundice, high bilirubin, high liver function tests (LDH), reticulocytosis, spherocytosis, positive antibody screen and a positive DAT.
  It occurs in 1:2,500 to 1:11,000 of transfusions.
- **Usual causes?**
  After transfusion, transplantation or pregnancy, a patient may make an antibody to a red cell antigen that they lack. If the patient is later exposed to a red cell transfusion which expresses this antigen a DHTR may occur.
  DHTRs may also occur with transfusion transmitted malaria and babesiosis.
  The clinical severity of a DHTR depends on the immunogenicity or dose of the antigen. Blood group antibodies associated with DHTRs include those of the Kidd, Duffy, Kell and MNS systems, in order of decreasing frequency.
- **Investigation**
  Request a DAT, antibody screen, LDH and markers of haemolysis (eg serum haptoglobin, bilirubin).
- **What to do?**
  Most delayed haemolytic reactions have a benign course and require no treatment however life threatening haemolysis with severe anaemia and renal failure may occur.
  If an antibody is identified, you may request antigen-negative blood if further transfusion is needed.

Transfusion-associated circulatory overload (TACO)

2011–12 Data Summary (n=27)					
Age		**Sex**		**Day of Transfusion**	
0–4 years	-	Male	10	Week day	16
5–14 years	1	Female	11	Weekend	11
15–24 years	1	Uncategorised	6		
25–34 years	-	**Facility Location**		**Time of Transfusion**	
35–44 years	2	Major City	20	Between 7am and 7pm	3
45–54 years	1	Inner Regional	-	Between 7pm and 7am	14
55–64 years	3	Outer Regional	1	Unknown	10
65–74 years	6	Remote	-		
75+ years	13	Very Remote	-		
Not specified	-	Uncategorised	6		
Clinical Outcome Severity		**Imputability**		**Blood Component**	
Death	-	Excluded/Unlikely	-	Whole blood	-
Life threatening	3	Possible	6	Red cells	25
Severe morbidity	13	Likely/Probable	18	Platelets	1
Minor morbidity	10	Confirmed/Certain	2	Fresh Frozen Plasma	1
No morbidity	-	Not assessable	1	Cryoprecipitate	-
Outcome not available	1			Cryodepleted plasma	-

2012–13 Data Summary (n=17)					
Age		**Sex**		**Day of Transfusion**	
0–4 years	-	Male	6	Week day	12
5–14 years	-	Female	8	Weekend	5
15–24 years	2	Uncategorised	3		
25–34 years	-	**Facility Location**		**Time of Transfusion**	
35–44 years	-	Major City	12	Between 7am and 7pm	4
45–54 years	-	Inner Regional	1	Between 7pm and 7am	5
55–64 years	1	Outer Regional	1	Unknown	8
65–74 years	1	Remote	-		
75+ years	13	Very Remote	-		
Not specified	-	Uncategorised	3		
Clinical Outcome Severity		**Imputability**		**Blood Component**	
Death	-	Excluded/Unlikely	-	Whole blood	-
Life threatening	-	Possible	6	Red cells	17
Severe morbidity	9	Likely/Probable	10	Platelets	-
Minor morbidity	8	Confirmed/Certain	-	Fresh Frozen Plasma	-
No morbidity	-	Not assessable	1	Cryoprecipitate	-
Outcome not available	-			Cryodepleted plasma	-

Notes

1. QLD data is unavailable for 2012–13.
2. Sex and facility location data is unavailable for NSW.
3. Time of transfusion data is unavailable for NSW and SA.
4. Data is unavailable for WA.
5. Uncategorised refers to those reports where no data was provided.

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

From 2011–12 to 2012–13, there were 44 reports of TACO to the National Haemovigilance Program, accounting for 4.2% of all reports (1,044) for this period. The number of cases rose from 6 in 2008–09 to 27 in 2011–12. The number of reported cases dropped in 2012–13 due to the unavailability of QLD data. One death was reported in 2008–09 and there have been no deaths reported since then. The majority of cases were related to red cell transfusion. The reported figures also indicate that patients aged 65 and above are at high risk of TACO and this is consistent with international findings.

In the period 2011–12 to 2012–13, 30 out of 44 cases were assigned an imputability score of likely/probable or confirmed/certain, including 15 cases with severe morbidity. Three cases with life threatening severity were reported in 2011–12 but none of the cases was confirmed to be related to blood transfusion.

Table 10: TACO clinical outcome severity by imputability, 2011–12 and 2012–13

Clinical Outcome Severity	Imputability					Total
	Excluded / Unlikely	Possible	Likely / Probable	Confirmed/ Certain	N/A / Not assessable	
Death						
2011–12	-	-	-	-	-	-
2012–13	-	-	-	-	-	-
Life threatening						
2011–12	-	1	2	-	-	3
2012–13	-	-	-	-	-	-
Severe morbidity						
2011–12	-	2	10	1	-	13
2012–13	-	4	4	-	1	9
Minor morbidity						
2011–12	-	3	5	1	1	10
2012–13	-	2	6	-	-	8
No morbidity						
2011–12	-	-	-	-	-	-
2012–13	-	-	-	-	-	-
Outcome not available						
2011–12	-	-	1	-	-	1
2012–13	-	-	-	-	-	-
Total	**-**	**12**	**28**	**2**	**2**	**44**

Notes

1. Outcome severity and imputability data unavailable for QLD for 2012–13.
2. Outcome severity and imputability data unavailable for WA.

Patients at the highest risk for TACO include those younger than three and those older than 60 years of age, particularly those with underlying cardiac dysfunction.[26] TACO can occur after relatively small volumes of red blood cells (one unit or less) are transfused to these patients. To avoid this complication, transfusion speed and volume must be monitored very carefully.

Published TACO incident estimates have ranged from approximates of 0.0003% to 8% of transfusions depending upon patient population and reporting method.[27] These rates suggest that TACO is as common an adverse event as FNHTR. However, the number of TACO events (44) reported to the National Haemovigilance Program in 2011–12 and 2012–13 is much lower than that of FNHTR (531). The reasons for the under-reporting of TACO in Australia may relate to a combination of factors:

- Circulatory overload from fluid infusion (including blood transfusion) is common in elderly patients and patients with heart failure and managed along similar lines—TACO is seen as a complication of fluid infusion rather than blood transfusion.
- Hospital staff view it as a routine medical management issue (fluids management), rather than an adverse event following transfusion hence do not see the need to report it.
- It is common but routinely managed, and as such it is unlikely to be reported.

TACO is one of the leading causes of potentially avoidable mortality and major morbidity associated with blood transfusions in many countries including the UK, the Netherlands, the US and Canada (refer to Appendix I: International Context for details).

Increased awareness of TACO by clinical staff is needed as this adverse event is common, potentially lethal and, in many cases, avoidable.

Clinical recommendation

The ANZSBT Guidelines for the Administration of Blood Products recommends that children less than 30kg should have the volume of blood prescribed in mL and the volume should be calculated on the child's weight and the desired haemoglobin to prevent TACO.[10]

The NBA PBM Guidelines Module 3: Medical has a practice point on the management of TACO.

PRACTICE POINT – heart failure	
PP7	In all patients with heart failure, there is an increased risk of transfusion-associated circulatory overload. This needs to be considered in all transfusion decisions. Where indicated, transfusion should be of a single unit of RBC followed by reassessment of clinical efficacy and fluid status. For further guidance on how to manage patients with heart failure, refer to general medical or ACS sections, as appropriate (R1, R3, PP3–PP6).

The Blood Service provides guidance on the recognition, investigation and management of TACO.[28]

- **When to suspect this adverse reaction?**
  The clinical features of TACO can include dyspnoea, orthopnea, cyanosis, tachycardia, increased blood pressure and pulmonary oedema and may develop within 1 to 2 hours of transfusion.
  TACO occurs in less than 1% of patients receiving transfusions. Patients over 60 years of age, infants and severely anaemic patients are particularly susceptible.
- **Usual causes?**
  This is usually due to rapid or massive transfusion of blood in patients with diminished cardiac reserve or chronic anaemia.
- **Investigation**
  TACO is frequently confused with TRALI as a key feature of both is pulmonary oedema and it is possible for these complications to occur concurrently. Hypertension is a constant feature in TACO whereas it is infrequent and transient in TRALI.
  Perform a chest X-ray and if septal lines, cephalisation and enlarged vascular pedicles (>65 mm) are present, these findings are more consistent with circulatory overload.
  Clinically assess patients for distended neck veins, S3 murmur on cardiac examination and peripheral oedema as these are also consistent with circulatory overload.
- **What to do**
  Stop transfusion immediately and follow steps for managing suspected transfusion reactions.
  Place the patient in an upright position and treat symptoms with oxygen, diuretics and other cardiac failure therapy.
  In susceptible patients at risk for TACO (paediatric patients, patients with severe anaemia and patients with congestive heart failure), transfusion should be administered slowly and consideration given to use of a diuretic.

Transfusion-related acute lung injury (TRALI)

2011–12 Data Summary (n=4)					
Age		**Sex**		**Day of Transfusion**	
0–4 years	-	Male	2	Week day	3
5–14 years	-	Female	1	Weekend	1
15–24 years	-	Uncategorised	1		
25–34 years	-	**Facility Location**		**Time of Transfusion**	
35–44 years	1	Major City	2	Between 7am and 7pm	1
45–54 years	1	Inner Regional	1	Between 7pm and 7am	1
55–64 years	1	Outer Regional	-	Unknown	2
65–74 years	-	Remote	-		
75+ years	1	Very Remote	-		
Not specified	-	Uncategorised	1		
Clinical Outcome Severity		**Imputability**		**Blood Component**	
Death	-	Excluded/Unlikely	-	Whole blood	-
Life threatening	-	Possible	2	Red cells	2
Severe morbidity	1	Likely/Probable	-	Platelets	2
Minor morbidity	2	Confirmed/Certain	-	Fresh Frozen Plasma	-
No morbidity	1	Not assessable	2	Cryoprecipitate	-
Outcome not available	-			Cryodepleted plasma	-

2012–13 Data Summary (n=1)					
Age		**Sex**		**Day of Transfusion**	
0–4 years	-	Male	-	Week day	-
5–14 years	-	Female	1	Weekend	1
15–24 years	-	Uncategorised	-		
25–34 years	-	**Facility Location**		**Time of Transfusion**	
35–44 years	1	Major City	1	Between 7am and 7pm	-
45–54 years	-	Inner Regional	-	Between 7pm and 7am	-
55–64 years	-	Outer Regional	-	Unknown	1
65–74 years	-	Remote	-		
75+ years	-	Very Remote	-		
Not specified	-	Uncategorised	-		
Clinical Outcome Severity		**Imputability**		**Blood Component**	
Death	-	Excluded/Unlikely	-	Whole blood	-
Life threatening	-	Possible	1	Red cells	1
Severe morbidity	-	Likely/Probable	-	Platelets	-
Minor morbidity	1	Confirmed/Certain	-	Fresh Frozen Plasma	-
No morbidity	-	Not assessable	-	Cryoprecipitate	-
Outcome not available	-			Cryodepleted plasma	-

Notes
1. QLD data is unavailable for 2012–13.
2. Sex and facility location data is unavailable for NSW.
3. Time of transfusion data is unavailable for NSW and SA.
4. Data is unavailable for WA.
5. Uncategorised refers to those reports where no data was provided.

TRALI is a serious transfusion-associated adverse event leading to pulmonary oedema and respiratory distress. From 2011–12 to 2012–13, there were five suspected cases of TRALI reported to the National Haemovigilance Program, accounting for 0.5% of all reports (1,044). The number of cases reporting life threatening severity dropped from two in 2008–09 to zero in 2011–12 and 2012–13.

TRALI is the common cause of mortality and morbidity in patients who receive blood components, particularly plasma-containing components. Female donors were implicated in these cases. Countries such as Australia, the UK and New Zealand Blood Service have introduced risk reduction strategies to reduce the TRALI cases.

- From July 2007, the Blood Service commenced deferring blood donors implicated in confirmed TRALI cases, suspending pooled platelets in platelet additive solution and introducing male-only plasma. The supply of 100% male plasma was achieved in 2012. With current levels of TRALI reporting it is impossible to comment on any potential impact of this policy on the incidence of TRALI in Australia.
- All UK Blood Services moved to 100% FFP from male donors, suspension of platelet pools and preferably recruitment of male apheresis platelet donors. The newly recruited female platelet donors are screened for HLA or human neutrophil antigen (HNA) antibodies and rested after pregnancies. With the introduction of these strategies, the number of TRALI cases has decreased from a peak of 36 suspected cases (seven deaths) in 2003 to 11 suspected cases (no deaths) in 2012.[29]
- The New Zealand Blood Service has reduced the risk of TRALI through implementing clinical FFP from only male donors in 2008, HLA antibody screening of female plateletpheresis donors in July 2012, and extending the male only policy to include cryoprecipitate and cryodepleted plasma by the end of 2013.[30] The number of TRALI cases has decreased from 10 in 2005 to 2 in 2012.

Clinical recommendation

The ANZSBT Guidelines for the Administration of Blood Products identify that TRALI can occur unpredictably and progress rapidly, therefore further indicating the need for close observation throughout the transfusion. TRALIs must be reported to the institution's incident reporting system and reviewed by the hospital transfusion committee or other defined governance committee.

The Blood Service provides guidance on the recognition, investigation and management of TRALI.[31]

- **When to suspect this adverse reaction?**
  Acute onset of fever, chills, dyspnoea, tachypnoea, tachycardia, hypotension, hypoxaemia and noncardiogenic bilateral pulmonary oedema leading to respiratory failure during or within 6 hours of transfusion.
  TRALI has been implicated in transfusion of unfractionated plasma-containing components (red cells, platelets and plasma).
  Its incidence is variably reported between 1:1,200 to 1:190,000 transfusions with estimates around 1:10,000 most commonly reported.
- **Usual causes?**
  The most widely held pathogenesis theory is that HLA or HNA antibodies found in the donor's plasma are directed against the recipient's leucocyte antigen.
  The antigen-antibody reaction activates neutrophils in the lung microcirculation, releasing oxidases and proteases that damage blood vessels and make them leak. Biological response modifiers, such as biologically active lipids can accumulate in some cellular components during storage and may also induce TRALI in susceptible patients.
- **Investigation**
  TRALI has many clinical features in common with fluid overload or cardiogenic pulmonary oedema and careful clinical assessment is required.
  Acute haemolytic reaction or transfusion associated sepsis may have similar initial clinical findings. DAT, blood count and repeat ABO grouping may be indicated.
  Once TRALI is clinically suspected, test the donor and recipient serum for HLA and HNA antibodies and perform an HLA type on the recipient as demonstration of these antibodies supports diagnosis. TRALI testing is specialised and contact with the Blood Service is necessary.
  Chest X-ray will show bilateral interstitial infiltrates.
- **What to do?**
  Stop transfusion immediately and follow other steps for managing suspected transfusion reactions.
  Provide cardiovascular and airway support. Administer supplemental oxygen and employ ventilation as necessary. Diuretics are not beneficial.
  This may become a medical emergency; support blood pressure and maintain an open airway.
  Notify your Transfusion Service Provider to contact the Blood Service so related components from the same donor can be quarantined and tested to prevent TRALI in other recipients.

Transfusion transmitted infections (TTI)

2011–12 Data Summary (n=12)					
Age		**Sex**		**Day of Transfusion**	
0–4 years	1	Male	5	Week day	12
5–14 years	-	Female	3	Weekend	-
15–24 years	-	Uncategorised	4		
25–34 years	-	**Facility Location**		**Time of Transfusion**	
35–44 years	1	Major City	7	Between 7am and 7pm	4
45–54 years	1	Inner Regional	1	Between 7pm and 7am	2
55–64 years	1	Outer Regional	-	Unknown	6
65–74 years	3	Remote	-		
75+ years	5	Very Remote	-		
Not specified	-	Uncategorised	4		
Clinical Outcome Severity		**Imputability**		**Blood Component**	
Death	-	Excluded/Unlikely	1	Whole blood	-
Life threatening	-	Possible	5	Red cells	6
Severe morbidity	-	Likely/Probable	-	Platelets	6
Minor morbidity	1	Confirmed/Certain	2	Fresh Frozen Plasma	-
No morbidity	7	Not assessable	4	Cryoprecipitate	-
Outcome not available	4			Cryodepleted plasma	-

2012–13 Data Summary (n=5)					
Age		**Sex**		**Day of Transfusion**	
0–4 years	-	Male	-	Week day	4
5–14 years	-	Female	1	Weekend	1
15–24 years	-	Uncategorised	4		
25–34 years	1	**Facility Location**		**Time of Transfusion**	
35–44 years	-	Major City	-	Between 7am and 7pm	-
45–54 years	1	Inner Regional	1	Between 7pm and 7am	1
55–64 years	-	Outer Regional	-	Unknown	4
65–74 years	1	Remote	-		
75+ years	2	Very Remote	-		
Not specified	-	Uncategorised	4		
Clinical Outcome Severity		**Imputability**		**Blood Component**	
Death	-	Excluded/Unlikely	-	Whole blood	-
Life threatening	-	Possible	-	Red cells	2
Severe morbidity	1	Likely/Probable	1	Platelets	3
Minor morbidity	1	Confirmed/Certain	1	Fresh Frozen Plasma	-
No morbidity	-	Not assessable	3	Cryoprecipitate	-
Outcome not available	3			Cryodepleted plasma	-

Notes

1. QLD data is unavailable for 2012–13.
2. Sex and facility location data is unavailable for NSW.
3. Time of transfusion data is unavailable for NSW and SA.
4. Data is unavailable for WA.
5. Uncategorised refers to those reports where no data was provided.

The National Haemovigilance Program allows the reporting of four distinct TTI categories: bacterial, viral, parasitic and other (such as Creutzfeldt-Jakob disease).

From 2011–12 to 2012–13, there were 17 suspected cases of TTI reported to the National Haemovigilance Program, all of which were related to bacterial infections. Only three cases reported were confirmed to be TTIs, with two 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. There was an increase in the reports of suspected TTI from 3 in 2008–09 to 18 in 2009–10, and a decrease to 12 in 2011–12. The number of TTI dropped further in 2012–13 due to the unavailability of QLD data.

Table 11: TTI clinical outcome severity by imputability, 2011–12 and 2012–13

Clinical Outcome Severity	Imputability					Total
	Excluded / Unlikely	Possible	Likely / Probable	Confirmed/ Certain	N/A / Not assessable	
Death						
2011–12	-	-	-	-	-	-
2012–13	-	-	-	-	-	-
Life threatening						
2011–12	-	-	-	-	-	-
2012–13	-	-	-	-	-	-
Severe morbidity						
2011–12	-	-	-	-	-	-
2012–13	-	-	-	1	-	1
Minor morbidity						
2011–12	-	1	-	-	-	1
2012–13	-	-	1	-	-	1
No morbidity						
2011–12	1	4	-	2	-	7
2012–13	-	-	-	-	-	-
Outcome not available						
2011–12	-	-	-	-	4	4
2012–13	-	-	-	-	3	3
Total	**1**	**5**	**1**	**3**	**7**	**17**

Notes

1. Outcome severity and imputability data unavailable for QLD for 2012–13.
2. Outcome severity and imputability data unavailable for WA.

In Australia, the mandatory tests provided by the Blood Service for all blood donations are for ABO and Rh(D) blood groups, red cell antibodies, and the following infections: human immunodeficiency virus (HIV) I and II, hepatitis B and C, human T-lymphotrophic virus (HTLV) I and II, and syphilis. The Blood Service also performs a test for reported residence in, or travel to, an area with malaria. Test results are checked before blood components are released for clinical use or further manufacture. Only donations that have satisfactory blood group results, are non-reactive for infectious disease screening and meet other defined specifications are released. If an infectious disease screening test is confirmed reactive, the donation is destroyed. The Blood Service notifies donors of any abnormal results on infectious disease and red cell antibody screening once testing is completed, usually within 2 weeks. The donor is advised about the health implications of positive tests.

The viral risk estimates presented in the following table have recently been revised based on Blood Service data from 1 January 2012 to 31 December 2013. These estimates are updated annually. The risk of viral TTI in Australia is exceedingly low. The predicted risk of transmission per unit transfused for HIV, HCV, HTLV and malaria remains substantially less than the 1 in 1 million threshold considered as 'negligible'. The risk for HBV remains very low but has increased to approximately 1 in 468,000 per unit transfused due to the introduction of a more sensible

test for HBV DNA. The actual risk of HBV transmission would be predicted to have declined from the point of the new test's implementation in August 2013. To date there have been no reported cases of vCJD in Australia.

Table 12: 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.

Australia and many developed countries have developed effective strategies to reduce the bacterial contamination of blood components.

In Australia, 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 were no confirmed severe cases (such as death, life threatening or severe morbidity) related to platelet transfusion reported in Australia from 2008–09 to 2012–13.

Bacteria screening for platelet donations was rolled out in the UK's National Health Service Blood and Transplant (NHSBT) in 2011. Strategies to reduce the bacterial contamination of blood components are under continual review in the UK.[23] There were two undetermined cases of bacterial TTIs reported to the UK SHOT Program in 2012 and no proven cases in 2013, indicating that bacterial and viral screening is effective in improving the safety of the UK blood supply.

Clinical recommendation

The Blood Service provides guidance on the recognition, investigation and management of transfusion associated sepsis. [32]

- **When to suspect this adverse reaction?**
  Clinical features of transfusion associated sepsis suggesting the possibility of bacterial contamination and/ or endotoxin reaction may include rigors, high fever, severe chills, hypotension, tachycardia, nausea and vomiting, dyspnoea, or circulatory collapse during or soon after transfusion.
  In severe cases, the patient may develop shock with accompanying renal failure and disseminated intravascular coagulation (DIC). This reaction may be fatal.
  Bacterial infections are reported to occur in at least 1:75,000 platelet transfusions and at least 1:500,000 red cell transfusions. Bacterial infection is more common with:
  - platelets (as these are stored at room temperature)
  - previously frozen components thawed by immersion in a water bath
  - red cell components stored for several weeks.
- **Usual causes?**
  Blood components may be contaminated by:
  - bacteria from the donor's skin during the collection procedure
  - unrecognised bacteraemia in the donor
  - contamination from the environment
  - contamination during the preparation of components
  - contamination of ports during the thawing of frozen products in a water bath
  - both gram-positive and gram-negative organisms have been implicated in transfusion associated sepsis with serious morbidity and mortality occurring most frequently with gram-negative bacteria
  - organisms capable of multiplying at low temperatures and those using citrate as a nutrient are most often associated with red cell contamination, especially Yersinia enterocolitica.

- **Investigation**
  Request for blood cultures from the patient, and perform culture and Gram Stain on the remainder of the blood component.
  The key to diagnosing transfusion related sepsis is culturing the same organism from the patient and component.
  Keep the blood bag and giving set (sealed) for further investigation.
- **What to do?**
  Stop transfusion immediately and follow other steps for managing suspected transfusion reactions. Start broad-spectrum antibiotics once cultures have been taken, including cover for staphylococcal infections.
  Provide cardiovascular support.
  Send blood pack to the Transfusion Service Provider for urgent culture and Gram Stain.
  Advise Transfusion Service Provider to notify the Blood Service to ensure quarantining and testing of related components from the same donation/donor.

Case study 1: Transfusion transmitted bacterial infection

A 43 year old female with acute myeloid leukaemia required platelet transfusion for severe thrombocytopenia (platelet count of $5x10^9$/L) following a recent stem cell transplant. Approximately 30 minutes after the commencement of transfusion with a 4 day old leucodepleted pooled platelet concentrate she experienced fever, rigors, distress and vomiting. A transfusion reaction was suspected and the platelet transfusion was ceased. Blood cultures were taken and the patient was commenced on empirical antibiotic therapy with meropenem and vancomycin. The patient had been previously well and bacterial cultures performed several days earlier were negative.

A suspected transfusion transmitted bacterial infection was reported to the hospital blood bank and the Blood Service. The Blood Service immediately initiated a recall of the other components manufactured from the whole blood donations.

Gram stain of the implicated residual platelet component showed Gram positive cocci. Bacterial cultures from the patient and from the residual platelet component were both positive for Staphylococcus aureus.

The Blood Service performs bacterial contamination screening on all platelet components at 24 hours post manufacture and platelets are supplied culture negative to date. Review of the bacterial contamination screening testing of the implicated pooled platelet was negative after 7 days of culture. The red cell and plasma components from the 4 whole blood donations were able to be recalled for culture; they were all negative. The 4 donors were contacted to determine if they remained well post donation; no factors relating to bacterial infection were identified.

This is a high probability case of transfusion transmitted bacterial infection as the patient and residual platelet component cultures were both positive for the same organism following transfusion.

Platelet components are the most likely product to be contaminated due to their storage conditions at room temperature, neutral pH and high glucose concentration. There have been three cases of transfusion transmitted bacterial infection associated with platelets since the implementation of routine bacterial contamination testing of platelets by the Blood Service in April 2008. Implicated organisms included Staphylococcal species, which are well known skin contaminants, and Bacillus species which are an environmental contaminant. In all these cases the bacterial contamination screening performed by the Blood Service was negative after 7 days of culture representing a false negative culture. False negative culture results can occur because the level of bacterial contamination at 24 hours post manufacture can be very low.

This case illustrates the need for treating clinicians to consider the possibility of transfusion transmitted bacterial infection when patients develop symptoms consistent with a severe transfusion reaction during or shortly after transfusion. Suspected transfusion transmitted bacterial infections should be immediately reported to the Blood Service to allow timely recall of other implicated blood components to reduce the risk of other patient harm. A prompt Gram stain on the implicated pack will also assist in the prompt diagnosis and in the targeting of antibiotic therapy.

Incorrect blood component transfused (IBCT)

2011–12 Data Summary (n=62)					
Age		**Sex**		**Day of Transfusion**	
0–4 years	5	Male	3	Week day	48
5–14 years	-	Female	8	Weekend	14
15–24 years	-	Uncategorised	51		
25–34 years	4	**Facility Location**		**Time of Transfusion**	
35–44 years	1	Major City	4	Between 7am and 7pm	9
45–54 years	5	Inner Regional	4	Between 7pm and 7am	1
55–64 years	13	Outer Regional	1	Unknown	52
65–74 years	14	Remote	1		
75+ years	15	Very Remote	1		
Not specified	5	Uncategorised	51		
Clinical Outcome Severity		**Imputability**		**Blood Component**	
Death	-	Excluded/Unlikely	-	Whole blood	-
Life threatening	-	Possible	1	Red cells	49
Severe morbidity	5	Likely/Probable	-	Platelets	2
Minor morbidity	2	Confirmed/Certain	7	Fresh Frozen Plasma	10
No morbidity	24	Not assessable	54	Cryoprecipitate	-
Outcome not available	31			Cryodepleted plasma	1

2012–13 Data Summary (n=43)					
Age		**Sex**		**Day of Transfusion**	
0–4 years	6	Male	6	Week day	34
5–14 years	2	Female	5	Weekend	9
15–24 years	2	Uncategorised	32		
25–34 years	3	**Facility Location**		**Time of Transfusion**	
35–44 years	1	Major City	9	Between 7am and 7pm	6
45–54 years	6	Inner Regional	1	Between 7pm and 7am	5
55–64 years	6	Outer Regional	-	Unknown	32
65–74 years	7	Remote	1		
75+ years	8	Very Remote	-		
Not specified	2	Uncategorised	32		
Clinical Outcome Severity		**Imputability**		**Blood Component**	
Death	-	Excluded/Unlikely	-	Whole blood	-
Life threatening	1	Possible	-	Red cells	28
Severe morbidity	4	Likely/Probable	-	Platelets	9
Minor morbidity	7	Confirmed/Certain	12	Fresh Frozen Plasma	6
No morbidity	16	Not assessable	31	Cryoprecipitate	-
Outcome not available	15			Cryodepleted plasma	-

Notes
1. QLD data is unavailable for 2012–13.
2. Sex and facility location data is unavailable for NSW.
3. Time of transfusion data is unavailable for NSW and SA.
4. Data is unavailable for WA.
5. Uncategorised refers to those reports where no data was provided.

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.

From 2011–12 to 2012–13:

- There were 105 reports of IBCT to the National Haemovigilance Program, accounting for 10.1% of all reports (1,044) for this period.
- The number of cases dropped in 2012–13 due to the unavailability of QLD data.
- The majority of cases were related to red cell transfusion.
- The majority of cases (85 out of 105) were not assessed for imputability scores and NSW reported most of the cases (82).
- The life threatening case reported in 2012–13 was confirmed to be related to the transfusion of red cells.

Table 13: IBCT clinical outcome severity by imputability, 2011–12 and 2012–13

Clinical Outcome Severity	Imputability					Total
	Excluded / Unlikely	Possible	Likely / Probable	Confirmed/ Certain	N/A / Not assessable	
Death						
2011–12	-	-	-	-	-	-
2012–13	-	-	-	-	-	-
Life threatening						
2011–12	-	-	-	-	-	-
2012–13	-	-	-	1	-	1
Severe morbidity						
2011–12	-	1	-	3	1	5
2012–13	-	-	-	4	-	4
Minor morbidity						
2011–12	-	-	-	1	1	2
2012–13	-	-	-	5	2	7
No morbidity						
2011–12	-	-	-	3	21	24
2012–13	-	-	-	2	14	16
Outcome not available						
2011–12	-	-	-	-	31	31
2012–13	-	-	-	-	15	15
Total	**-**	**1**	**-**	**19**	**85**	**105**

Notes

1. Outcome severity and imputability data unavailable for QLD for 2012–13.
2. Outcome severity and imputability data unavailable for WA.

Table 14 details the contributory factors for reported IBCT events for 2008–09 to 2012–13:

- In 2008–09, 'prescribing/ordering' was the most frequent factor that contributed to IBCT adverse events.
- For 2009–10 and 2010–11, the most frequently cited contributory factors were 'prescribing/ordering', 'specimen collection/labelling', 'administration of product', and 'procedure did not adhere to hospital transfusing guidelines'.
- 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'.

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 14: Contributory factors cited in IBCT, 2008–09 to 2012–13

Contributory Factor	2008–09	2009–10	2010–11	2011–12	2012–13
None identified	-	-	-	9	-
Product characteristic	3	-	4	-	-
Transfusion in emergency setting	-	1	4	2	6
Deliberate clinical decision	5	3	-	1	-
Prescribing/ordering	13	12	5	7	-
Specimen collection/labelling	7	12	11	7	11
Laboratory (testing/dispensing)	8	7	5	24	22
Transport, storage, handling	-	1	-	1	1
Administration of product	5	12	8	5	9
Procedure did not adhere to hospital transfusion guidelines	2	13	14	1	-
Indications did not meet hospital transfusion guidelines	6	5	2	12	27
Other	4	5	8	4	12

Haemovigilance data and clinical studies cite three major areas of human error that jeopardise safe transfusion:

- accurate patient identification and proper labelling of pre-transfusion specimens
- appropriate decision-making regarding the clinical use of blood components
- accurate bedside verification that the correct blood is to be given to the intended recipient.

The SHOT UK scheme showed that approximately 70% of IBCT event errors took place in clinical areas, the most frequent error being failure of the final patient ID check at bedside.

IBCT represents failure of the hospital system, which needs to be identified and subsequently corrected to prevent similar events happening in the future. For this reason, the recent Standard 7 Blood and Blood Products of the National Safety and Quality Health Service Standards (NSQHS Standard 7) states that adverse blood and blood product incidents should be reported to and reviewed by the highest level of governance in the health service organisation. The Australian Haemovigilance Report 2013 delivered several recommendations on reducing human errors:

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

The case study below demonstrates:

- an IBCT can occur as result of a series of process failures
- the multi-disciplinary nature of the transfusion process and the importance of education across all disciplines
- the importance of adhering to health service policy and procedures at all times
- 2D barcoding and patient safety software can reduce human errors.

Case study 2: Incorrect blood product was given to patient due to a series of process failures

Description

A 96 year old man was admitted with a fractured neck of femur, scheduled for surgery that afternoon. The patient's international normalised ratio (INR) was elevated at 1.6, and the decision was made to treat this elevated level with a unit of FFP prior to surgery.

The medical officer (MO) went to the laboratory to collect the unit of FFP. On arrival the scientist pointed to where the FFP was located and requested the MO to sign the unit out of the laboratory in the blood register. The unit collected by the MO was allocated for another patient and labelling not yet completed. The MO signed the unit out against his patient details in the blood register without checking the product details matched. He then took the unit to the ward.

On return to the ward the MO handed the FFP to the nurse caring for the patient, who was unaware of the request for transfusion. The nurse noted the lack of paperwork accompanying the FFP and sent the patient services attendant (PSA), with the unit, back to the laboratory to collect the appropriate paperwork.

The PSA returned and stated that there was no paperwork for this FFP unit and that it did not need to be checked, although the laboratory staff stated they did not speak to the PSA regarding the FFP.

The nurses on the ward took the word of the PSA that they did not need the paper work, and checked the FFP to the patient. The unit was group O, the patient's blood group was group A, therefore making this an incompatible transfusion. The staff were unaware of this at the time as both medical and nursing staff were under the impression that O was the universal group for FFP as well as red cells.

Later the laboratory staff noted the FFP for the patient was still in the fridge and when they checked the register realised the error. They immediately rang the ward; however the product had already been administered.

As a result the patient had a mild rise in bilirubin, and his procedure was delayed as a precaution and to monitor the patient for further sequelae.

Recommendations from the health service

- All staff who collect blood and blood products from the laboratory must be trained and have knowledge of correct processes for blood collection, including taking appropriate documentation to identify the patient and the product required.
- Staff collecting blood and blood products must collect from the collection fridge where all products are labelled and ready for collection, and not collect directly from the laboratory.
- Education of all medical and nursing staff regarding the appropriate use of FFP and the compatibility of blood groups for FFP, including the use of I-transfuse factsheet 'I need to know about Fresh Frozen Plasma' http://www.transfusion.com.au/fact_sheets.

Summary

This case study demonstrates that serious errors often occur as a result of a series of process failures rather than a single event failure. It also demonstrates the multi-disciplinary nature of the transfusion process and the importance of education across all disciplines. This event also highlights the importance of adhering to health service policy and procedures at all times.

The use of patient safety software and 2D barcoding to identify patient and product can also assist in the reduction of errors in which mis-identification of either the patient or the product occurs and should be considered in all areas involved in transfusion.

Contributory factors

Table 15: Contributory factors cited in adverse events, 2011-12 to 2012-13

Summary Data	2011–12	2012–13
Contributory Factors	**Number of reports**	**Number of reports**
None identified	351	148
Product characteristic	186	191
*Transfusion in emergency setting	8	11
*Deliberate clinical decision	1	-
*Prescribing/ordering	9	-
*Specimen collection/labelling	7	11
*Laboratory (testing/dispensing)	24	22
*Transport, storage, handling	1	2
*Administration of product	16	46
*Indications do not meet guidelines	6	-
*Procedure did not adhere to hospital transfusion guidelines	12	29
Other	13	15

Notes

1. QLD data is unavailable for 2012–13.
2. Contributory factors are not identified for most of the adverse events reported by QLD and SA.
3. Contributory factor data is unavailable for WA.
4. * refers to 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. Definitions for contributory factors can be found in Table 39 in Appendix II: Definitions in haemovigilance. It should be noted that:

- These categories are not mutually exclusive and more than one contributory factor may be associated with an adverse event.
- Most factors are related to human errors which could 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 and NSW, have collected near miss events in their systems. All states and territories will be required to collect and report near miss data through the implementation of NSQHS Standard 7.[33]

The data in this report shows:

- The most frequent contributory factor was 'product characteristic', accounting for 186 adverse events in 2011–12 and 191 in 2012–13. 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 67 adverse event reports (10.9%) that cited one or more preventable contributory factors other than 'product characteristic' for 2011–12 and 85 reports (19.8%) for 2012–13. The most common contributory factors cited were 'administration of product', 'laboratory (testing/dispensing)', and 'procedure did not adhere to hospital transfusion guidelines'.
- Despite the unavailability of QLD data for 2012–13, 'administration of product' remained a factor in 2012–13 and the number of reports increased to 46 from 16 in 2011–12.
- Table 16 and Table 17 show that 'administration of product' impacted:
  - 25 severe allergic reactions with 5 in 2011–12 and 20 in 2012–13
  - 19 FNHTRs with 3 in 2011–12 and 16 in 2012–13
  - 14 IBCT adverse events with 5 in 2011–12 and 9 in 2012–13

  - 2 anaphylactic or anaphylactoid reactions in 2011–12
  - 2 TACOs with 1 in 2011–12 and 1 in 2012–13.
- The clinical outcome severities related to 'administration of product' included:
  - 6 cases reporting severe morbidity with 3 in 2011–12 and 3 in 2012–13
  - 52 cases reporting minor morbidity with 11 in 2011–12 and 41 in 2012–13
  - 2 cases reporting no morbidity in 2012–13.
- 'Laboratory (testing/dispensing) contributed to 46 events with 24 in 2011–12 and 22 in 2012–13 and was related to 5 severe morbidity cases with 3 in 2011–12 and 2 in 2012–13.
- 'Procedure did not adhere to hospital transfusion guidelines' was related to one severe morbidity case in 2011–12 and one life threatening case and one severe morbidity case in 2012–13.

A key observation from the data is the need for clinical staff to conform to their local facility guidelines for transfusing. NSQHS Standard 7 recommends that the facility guidelines should be consistent with the following national evidence-based guidelines:

- ANZSBT Guidelines for the Administration of Blood Products 2nd ed
- ANZSBT Guidelines for Pre-Transfusion Laboratory Practice
- Australian Red Cross Blood Service Blood Component Information Circular
- Australian Red Cross Blood Service Blood Components and Products
- Australian Standard for Medical Refrigeration Equipment—For the Storage of Blood and Blood Products
- BloodSafe eLearning Australia module on Transporting Blood
- National Pathology Accreditation Advisory Council Requirement for Transfusion Laboratory Practice
- NBA PBM Guidelines.

Despite the improvement of national and local facility guidelines for transfusing, human errors continue to contribute significantly to transfusion-related risks to patients in Australia and other developed countries. The VIC STIR program reported[34] that human error related adverse events, including IBCT, WBIT and near miss events, accounted for 46% of all reports (404) during 2009–11. The SHOT Annual Report 2011[23] reported that procedural or human errors, including IBCT, inappropriate and unnecessary transfusion, handling and storage errors and ABO incompatible red cell transfusions, represented 51% (5,031) of the cumulative number of cases (9,925) reviewed from 1996–97 to 2010–11.

NSQHS Standard 7 (Action 7.2.1) recommended the following strategies to reduce the risk of human error:

- Identify the risks associated with transfusion, particularly risks relating to human errors.
- Redesign the system to reduce the potential for patient harm.
- Regularly and comprehensively review systems for effective and appropriate prescribing, sample collection, cross-matching, transport and storage, and product administration to identify and address weaknesses that create the potential for error and patient harm.

This Australian Haemovigilance Report 2013 delivered a recommendation to reconsider the definitions in the ANHDD, including those for contributory factors.

Table 16: Contributory factors cited by adverse event and by clinical outcome severity, 2011–12

Contributory Factors	Adverse event									Clinical outcome severity					
	FNHTR	Allergic	IBCT	Anaphylactic / Anaphylactoid	AHTR (not ABO)	TACO	DHTR	TTI Bacterial	TRALI	Outcome not available	No morbidity	Minor morbidity	Severe morbidity	Life threatening	Death
None identified	177	103	9	11	10	17	15	6	3	3	16	296	30	6	-
Product characteristic	140	38	-	3	-	1	1	2	1	2	6	160	17	1	-
Transfusion in emergency setting	3	1	2	-	-	2	-	-	-	2	1	1	4	-	-
Deliberate clinical decision	-	-	1	-	-	-	-	-	-	1	-	-	-	-	-
Prescribing/ordering	-	-	7	1	-	1	-	-	-	5	2	1	1	-	-
Specimen collection/labelling	-	-	7	-	-	-	-	-	-	2	1	1	3	-	-
Laboratory (testing/dispensing)	-	-	24	-	-	-	-	-	-	6	13	2	3	-	-
Transport, storage, handling	-	-	1	-	-	-	-	-	-	-	1	-	-	-	-
Administration of product	3	5	5	2	-	1	-	-	-	2	-	11	3	-	-
Indications do not meet guidelines	-	3	1	1	-	1	-	-	-	-	1	3	1	1	-
Procedure did not adhere to hospital transfusion guidelines	-	-	12	-	-	-	-	-	-	7	3	1	1	-	-
Other	1	-	4	-	-	4	-	4	-	6	-	2	3	2	-

Notes

1. Contributory factors are not identified for most of the adverse events reported by QLD and SA for 2011–12.
2. Contributory factor data is unavailable for WA for 2011–12.

Table 17: Contributory factors cited by adverse event and by clinical outcome severity, 2012–13

Contributory Factors	Adverse event									Clinical outcome severity					
	FNHTR	Allergic	IBCT	Anaphylactic / Anaphylactoid	AHTR (not ABO)	TACO	DHTR	TTI Bacterial	TRALI	Outcome not available	No morbidity	Minor morbidity	Severe morbidity	Life threatening	Death
None identified	72	48	-	3	2	14	6	2	1	2	6	125	14	1	-
Product characteristic	141	40	-	10	-	-	-	-	-	8	9	149	23	2	-
Transfusion in emergency setting	-	4	6	-	-	-	-	-	-	3	2	3	2	-	-
Deliberate clinical decision	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Prescribing/ordering	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Specimen collection/labelling	-	-	11	-	-	-	-	-	-	-	2	5	4	-	-
Laboratory (testing/dispensing)	-	-	22	-	-	-	-	-	-	8	8	4	2	-	-
Transport, storage, handling	1	-	1	-	-	-	-	-	-	-	1	1	-	-	-
Administration of product	16	20	9	-	-	1	-	-	-	-	2	41	3	-	-
Indications do not meet guidelines	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Procedure did not adhere to hospital transfusion guidelines	-	1	27	-	-	1	-	-	-	11	10	6	1	1	-
Other	-	-	12	-	-	-	-	3	-	3	3	5	4	-	-

Notes

1. Contributory factors are not identified for most of the adverse events reported by SA for 2012–13.
2. Contributory factor data is unavailable for QLD and WA for 2012–13.

RECOMMENDATIONS

> 02

CONTENTS

PART 02 RECOMMENDATIONS

The 2013 report made 10 recommendations. Nine of these recommendations remain relevant in this report and one has been amended. The ninth recommendation of 'Conduct a scoping exercise for a national haemovigilance system' has been completed and the Strategic Framework for the National Haemovigilance Program was the result of this exercise. The NBA and HAC have developed a three-year Haemovigilance Action Plan from 2013–14 to 2015–16 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 hospital 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. Review and re-develop the Australian National Haemovigilance Data Dictionary.
7. Provide tools for hospitals on the application of Australian National Haemovigilance Data Dictionary and reporting of haemovigilance data.
8. Continue to include donor vigilance data in national haemovigilance reporting.

Reporting capacity

9. Implement the Strategic Framework for the National Haemovigilance Program.
10. 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 and TRALI, 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 hospital transfusion practice and incident reporting with the NSQHS Standard 7.

Table 18: 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; Hospital Administrators; Hospital 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 Guidance redeveloped by the working group the Guidance published, distributed and evaluated by the NBA An eLearning module based on the Guidance developed
2	Implement programs at the national, state and local hospital levels to improve reporting of serious adverse events	NBA; JBC; State and territory departments of health; Hospital Administrators; Hospital 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 Guidance implemented The eLearning module developed and used by JMOs Reporting rates increased

Reducing human errors

Human errors continue to contribute significantly to 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 19: 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; Hospitals (Admin, HTC or equivalent)	NBA to promote or provide tools that allow states and territories to ensure hospitals 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 hospitals 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; hospitals	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 Barcoding Policy revised and published on the NBA web in 2014–15 Strategies and case studies developed for the implementation of the Barcoding Policy in 2015–16 Increased use of 2D barcode technology
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 ANHDD will be revised/reviewed in 2014–15, and published/distributed in 2015–16. The NBA will develop a set of other tools for hospitals from 2015–16 to assist with the application of the data dictionary and improve haemovigilance data collection and reporting. The haemovigilance report will continue to include donor vigilance data.

Table 20: Recommendations on data standards

	Recommendation	Who is Responsible	Proposed Strategy	How that will be measured
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	ANHDD revised/reviewed in 2014–15 and published/distributed in 2015–16
7	Provide tools for hospitals on the application of the Australian Haemovigilance Data Dictionary and reporting of haemovigilance data	NBA; HAC; State and territory Quality and Safety Units; Hospital Administrators; state and territory departments of health	NBA, assisted by states and territories, to develop and distribute tools to support hospitals for national haemovigilance reporting NBA to inform hospitals on the availability and use of tools	The following tools developed and used from 2014–15 to 2015 –16: ▪ Haemovigilance data collection forms and guidance ▪ The Guidance on Recognition and Management of Acute Transfusion-Related Adverse Events ▪ National guidance for informed patient consent ▪ Blood and blood product prescription form ▪ Clinical audit tools ▪ Transfusion related case studies ▪ Educational and training tools The number of public and private facilities submitting data to the National Haemovigilance Program increased
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 publish and report on donor vigilance data regularly

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.

The NBA, assisted by state and territory health departments and the JBC, developed the Strategic Framework for the National Haemovigilance Program as part of the scoping exercise described in the 2013 report. The Strategic Framework has been endorsed by the JBC and published on the NBA website. The NBA has developed a communication plan for the Strategic Framework. The NBA will work in collaboration with HAC and key stakeholders to develop a work plan to support the implementation of the Strategic Framework. States and territories should continue to maintain existing systems and improve capacities for haemovigilance data reporting.

Table 21: Recommendations on reporting capacity

	Recommendation	Who is Responsible	Proposed Strategy	How that will be measured
9	Implement the Strategic Framework for the National Haemovigilance Program	NBA; HAC; State and territory departments of health; Blood Service; Hospitals; 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 2015–16 The timeliness and completion of Haemovigilance reporting improved at national, state and local levels
10	Maintain and improve existing capacities for haemovigilance data reporting	NBA; HAC; State and territory departments of health Blood Service; Hospitals; 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

DONOR VIGILANCE

03

CONTENTS

Review of donor adverse events 2012–13

PART 03
DONOR VIGILANCE

The data contained in this report has been collected and the report compiled by the Blood Service using data gathered from adverse events reported via the Donor Adverse Event (DAE) database. Collection staff are responsible for the immediate management of adverse reactions which occur at the blood donor centre and for registration of these adverse events. Medical Services staff are responsible for registering events which are reported to the Blood Service after the donor has left the donor centre. Events are classified by a centralised team according to standard definitions which are largely based on definitions endorsed by the International Society of Blood Transfusion (ISBT) Haemovigilance Working Party. Donors are followed up by Medical Services staff according to the type and severity of reaction reported (refer to Appendix III: Definition of Donor Adverse Events). Donor haemovigilance data and trends are regularly monitored by the Donor and Product Safety Advisory Committee and the Blood Service Clinical Governance Committee to evaluate the impact of changes in donor selection criteria, donation processes and interventions to improve donor safety. There is also regular reporting to the Blood Service Executive and Board.

Review of donor adverse events 2012–13

Whilst blood donation is generally a very safe process, there are recognised donor complications which can occur. Donor haemovigilance systems permit monitoring of donor safety and evaluation of the success of interventions designed to further improve donor safety. International benchmarking of donor adverse events is important but not straightforward because of different adverse event definitions, different collection processes and probably most importantly differences in reporting compliance. Estimates of adverse event incidence in blood donors based on published international studies range considerably from 5% to 33%[35,36] and based on these rates Australia benchmarks favourably.

During 2012–13 there were a total of 1,322,883 donations, including 858,594 whole blood donations, 427,945 plasmapheresis donations and 36,344 plateletpheresis donations. Total donation associated events and serious donation-related events are shown in Figure 3 below.

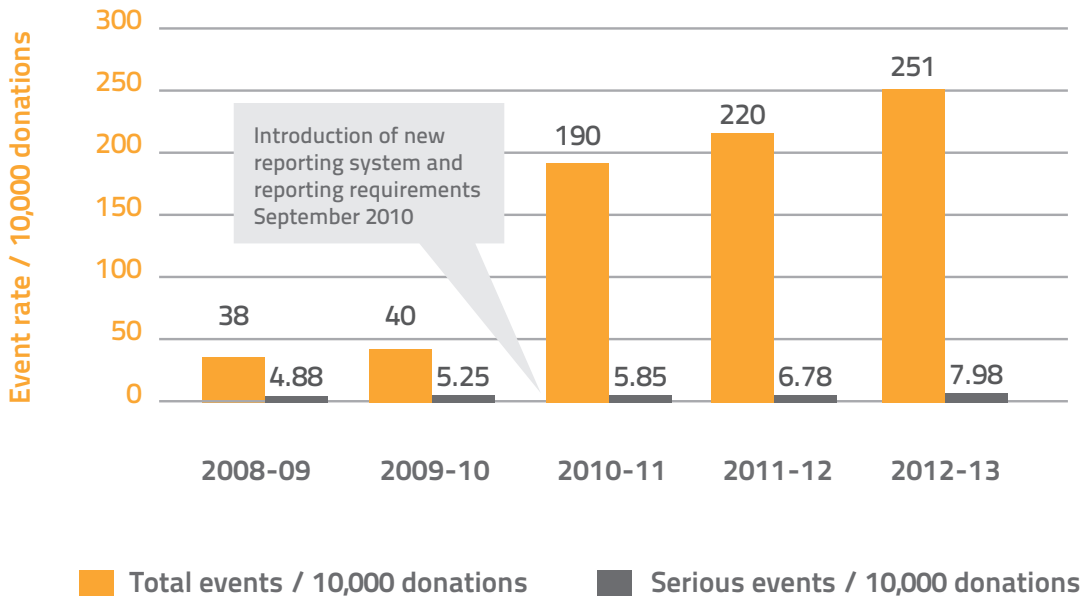


Figure 3: Total donation associated events and serious donation-related events 2008–09 to 2012–13

There were 33,208 adverse events reported with the vast majority of these being classified as mild, such as the donor feeling faint for a few minutes. Adverse events can occur during and after 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. Serious adverse events are those events where the donor requires external medical or hospital referral for the management of the adverse event and such events may be either immediate or delayed. The overall reported rate of donation-related adverse events was 1:40 in 2012–13.

The Blood Service has implemented a number of strategies to enhance reporting compliance by donors as well as donor centre and Medical Services staff. In November 2012, new standard operating procedures were introduced in which reporting requirements for adverse events changed to include the mandatory reporting of all citrate related reactions in apheresis donors. This change coincided with the roll-out of e-learning modules to all Collections and Medical Services staff to improve their understanding of the causes of adverse reactions, to enhance recognition and management of adverse reactions, and to emphasise the importance of adverse events reporting. Since January 2011 a donor wellness check has been in place whereby every time a donor returns to donate they are asked whether they experienced any problems related to their previous donation. Following this there has been a sustained increase in the number of delayed vasovagal reactions reported. The rate of delayed events for all collection types has increased by approximately 50%. The impact of this reporting can be seen in Table 22 and Figure 4.

Table 22: Impact of the donor wellness question—incidence of delayed vasovagal reactions

	Prior to the introduction of the wellness question	After the introduction of the wellness question		
	1/10/10–31/1/11	1/2/11–30/6/11	1/7/11–30/6/12	1/7/12–30/6/13
Whole Blood	0.17%	0.21%	0.26%	0.30%
Plasma	0.05%	0.10%	0.13%	0.14%
Platelets	0.06%	0.09%	0.10%	0.14%

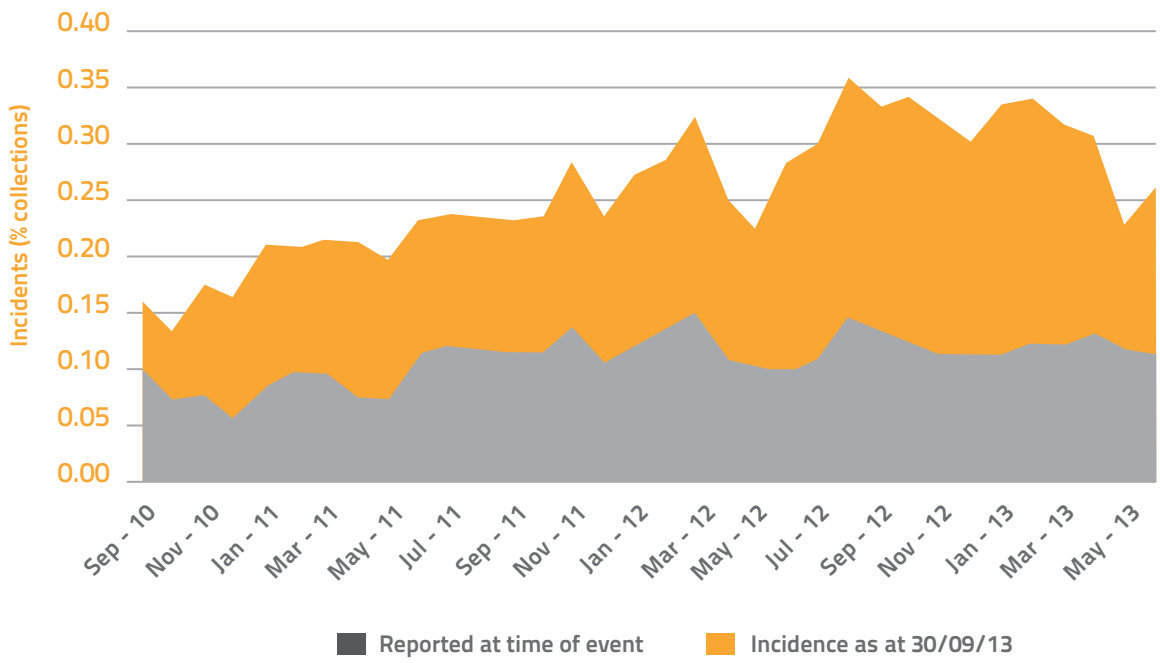


Figure 4: Impact of donor wellness question—whole blood delayed vasovagal reactions September 2010–June 2013

Note: Includes events occurring between 1/7/12 and 30/6/13, but reported up until 30/9/13

Table 23 shows the rate of adverse events by donation type, and the rate per 10,000 donations for 2012-13.

Table 23: Donor adverse events per procedure, 2012–13

Procedure	Total Donations	Donations with Events	Frequency	Rate / 10,000 Donations
Whole Blood	858,594	26,450	1:32	308
All apheresis procedures	464,289	6,758	1:69	146
Plasmapheresis	*427,945*	*5,127*	*1:83*	*120*
Plasmapheresis	*36,344*	*1,631*	*1:22*	*449*
Total procedures	**1,322,883**	**33,208**	**1:40**	**251**

Vasovagal reactions and bruising/haematoma are the most frequent complications associated with blood donation. Plasmapheresis donations are associated with the lowest frequency of adverse reactions, and platelet donations with the highest frequency. The incidence of the different types of adverse events for all donations is shown in Table 24.

Table 24: Donation associated events by category and frequency, 2012–13

Donor Event	Number	% Total Events	Frequency	Rate / 10,000 Donations
Immediate vasovagal	25,711	77.42%	1:51	194
Delayed vasovagal	3,278	9.87%	1:404	25
Chest pain	56	0.17%	1:23,623	0.4
Citrate reaction*	468	1.41%	1:992	10
Haematoma	1,473	4.44%	1:898	11
Painful arm	620	1.87%	1:2,134	5
Nerve irritation	201	0.61%	1:6,582	2
Nerve injury	170	0.51%	1:7,782	1
Arterial puncture	39	0.12%	1:33,920	0.3
Delayed bleeding	34	0.10%	1:38,908	0.3
Thrombophlebitis	34	0.10%	1:38,908	0.3
Tendon damage	9	0.03%	1:146,987	0.1
Allergy	50	0.15%	1:26,458	0.4
Other injuries**	1,065	3.21%	1:1,241	8
Total	**33,208**	**100.00%**	**1:40**	**251**

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.

Serious complications of blood donation

Serious complications related to blood donation are 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 2012–13 there were 451 hospital referrals and 605 general practitioner (GP) referrals for donation-related complications (Table 25). There were no donation associated deaths. The commonest reason for both hospital and GP referral was slow recovery from a vasovagal reaction; nerve irritation due to a large haematoma was the commonest reason for referral for phlebotomy injury, followed by painful arm following donation (Table 26). Table 27 details donor complication rates by severity per 10,000 donations 2012–13.

Table 25: Summary of external medical referrals, 2012–13

	Number of hospital referrals	Incidence of hospital referrals (% total collections)	Number of GP referrals	Incidence of GP referrals (% total collections)
Whole Blood	331	0.039	446	0.052
Plasmapheresis	101	0.024	140	0.033
Plateletpheresis	19	0.052	19	0.052
Total	**451**	**0.034**	**605**	**0.046**

Table 26: Reasons for external medical referrals, 2012–13

	Number of hospital referrals	Incidence of hospital referrals (% total collections)	Number of GP referrals	Incidence of GP referrals (% total collections)
Vasovagal Reactions	396	0.030	255	0.019
Phlebotomy Injuries	15	0.001	274	0.021
Chest Pain	16	0.001	19	0.001
Other*	24	0.002	57	0.004
Total	**451**	**0.034**	**605**	**0.046**

Note: * Other includes injuries sustained during a faint, such as head injuries, fractures and dental injuries, and also constitutional symptoms such as extreme fatigue and palpitations on minimal exertion experienced by some donors in the days immediately following blood donation.

Table 27: Donor complications by type and severity per 10,000 donations, 2012–13

			Rate per 10,000 donations		
			Whole Blood	Plasmapheresis	Plateletpheresis
			(n=858,594)	(n=427,945)	(n=36,344)
Complications related to blood outside blood vessels	Haematoma and bruising	Moderate	5.22	4.58	9.91
		Severe	0.75	0.61	2.2
	Arterial puncture	Moderate	0.01	0.16	0.00
		Severe	0.06	0.02	0.00
	Delayed bleeding	Mild	0.23	0.28	0.28
		Moderate	0.02	0.00	0.00
Pain/soft tissue injury	Nerve irritation	Moderate	0.63	0.3	0.83
		Severe	0.24	0.09	0.00
	Nerve injury	Moderate	0.42	0.3	0.55
		Severe	0.4	0.21	0.00
	Tendon damage	Moderate	0.02	0.00	0.00
		Severe	0.08	0.00	0.00
	Painful arm	Moderate	1.37	0.58	0.83
		Severe	0.58	0.61	0.28
Other complications with local symptoms	Thrombophlebitis	Moderate	0.04	0.02	0.00
		Severe	0.16	0.12	0.00
	Allergic reaction (localised)	Mild	0.19	0.09	0.28
		Moderate	0.10	0.05	0.00
Immediate vasovagal reaction	Without injury	Mild	190.71	50.38	140.6
		Moderate	43.47	10.96	39.62
		Severe	21.86	6.73	13.38
	With injury	Moderate	0.05	0.07	0.55
		Severe	1.09	0.02	1.93
Delayed vasovagal reaction	Without injury	Mild	7.85	3.69	3.03
		Moderate	6.00	3.25	3.58
		Severe	15.62	7.20	7.43
	With injury	Moderate	0.02	0.00	0.00
		Severe	0.96	0.16	0.28
Apheresis related complications	Citrate reaction		-	4.95	70.99
	Haemolysis		-	0.16	0.00

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, especially those under the age of 20 years. 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 14 donations. This trend is consistent with international published data.[37,38] Safety and wellbeing of youth donors is a key area of focus for the Blood Service. There is a steady reduction in the likelihood of a donation reaction with increasing age (see Table 28 below).

Table 28: Adverse donation reactions in male donors by age, including odds ratio, 2012–13

Age group	Number of events	Total donors in age group	Frequency	Rate/1000 donations	Odds ratio (95% CI)
16–17yrs	1,265	17,975	1:14	70.38	5.1054 (4.8093 - 5.4198)
18–20yrs	1,207	29,941	1:25	40.31	3.0125 (2.8419 - 3.1933)
21–23yrs	1,063	32,106	1:30	33.11	2.4219 (2.2778 - 2.5751)
24–30yrs	2,208	79,977	1:36	27.61	2.2009 (2.1047 - 2.3014)
31–40yrs	1,680	102,119	1:61	16.45	1.2262 (1.1679 - 1.2874)
41–50yrs	1,206	144,297	1:120	8.36	0.623 (0.5908 - 0.6569)
51–60yrs	958	187,052	1:195	5.12	0.3715 (0.3511 - 0.3931)
61–70yrs	458	122,149	1:267	3.75	0.2791 (0.2577 - 0.3023)
71+	22	13,690	1:622	1.61	0.1591 (0.1147 - 0.2208)
Total	**10,067**	**729,306**	**1:72**	**13.80**	

Table 29: Adverse donation reactions in female donors by age, including odds ratio, 2012–13

Age group	Number of events	Total donors in age group	Frequency	Rate/1000 donations	Odds ratio (95% CI)
16–17yrs	2,725	22,067	1:80	123.49	4.3722 (4.1913 - 4.5607)
18–20yrs	2,580	32,402	1:13	79.62	2.665 (2.5555 - 2.7792)
21–23yrs	2,217	36,498	1:16	60.74	1.9849 (1.8994 - 2.0742)
24–30yrs	3,501	76,385	1:22	45.83	1.5296 (1.4759 - 1.5852)
31–40yrs	2,271	80,623	1:36	28.17	0.8963 (0.8599 - 0.9343)
41–50yrs	1,951	112,654	1:58	17.32	0.5426 (0.5199 - 0.5662)
51–60yrs	2,305	140,209	1:61	16.44	0.4877 (0.4686 - 0.5076)
61–70yrs	1,286	85,449	1:66	15.05	0.4417 (0.4189 - 0.4657)
71+	86	7,216	1:84	11.92	0.3635 (0.2973 - 0.4443)
Total	**18,922**	**593,503**	**1:31**	**31.88**	

Performance in relation to international blood services

There are significant challenges in benchmarking Australia's adverse events rate with event rates reported by international blood services as a result of variations in the classification of donation associated events and also because of variations in reporting requirements between blood services and variable compliance with these requirements. Estimates of adverse event incidence in blood donors based on published international studies range from 5 to 33%[35,36] and based on these rates the Blood Service benchmarks favourably. However there remains considerable value in benchmarking initiatives to reduce adverse events. For this reason the Blood Service regularly benchmarks with blood services in America, Canada, Europe and Asia Pacific. Taking into consideration the significant challenges identified above, the focus is primarily on the review of strategies and initiatives being implemented to reduce adverse event rates and the impact of such interventions on local adverse event trends, rather than a comparison of absolute adverse event rates. The Blood Service is participating in work led by the ISBT Haemovigilance Working Party to improve the comparability of absolute adverse event rates.

Interventions directed at reducing the risk of adverse events

1. Donor education via http://donateblood.com.au and on the Donor Questionnaire Form provides advice on preparation for blood donation (pre-donation salty snacks and adequate fluid intake) and 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)
2. Provision of specific information cards to donors at the time of an adverse event detailing immediate management and preventative actions relevant to subsequent donations
3. Permanent deferral of donors with significant risk of recurrence of serious adverse reactions
4. 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
5. Using a stepwise approach to increasing collection volume for plasmapheresis donors donating plasma for fractionation based on nomograms* for per cent Total Blood Volume
6. Using a stepwise approach for plasmapheresis donors donating Clinical Fresh Frozen Plasma with end saline, also based on a nomogram for Total Blood Volume
7. Using a "whole blood nomogram" with reduced volume whole blood collection for donors with low total blood volume
8. Use of specific guidelines for managing young donors – females under 20 years of age are not recruited to plasma donation
9. Provision of pre-donation oral calcium supplements for plateletpheresis donors to reduce the frequency and severity of citrate reactions
10. Communication with comparable international blood services to ensure 'best practice' protocols
11. 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
12. Implementation of initiatives to reduce the risk of iron deficiency associated with blood donation, including supporting research to identify other potential mitigation measures
13. External review and approval of donor selection guidelines and collection protocols by the TGA.

Note: *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 two values.

Planned initiatives directed at reducing the risk of adverse events

14. Youth donors (aged 16 and 17 years) will be restricted to one donation per annum from 1 January 2014 to reduce the risk of iron deficiency and number of vasovagal reactions
15. Pain experienced during a difficult phlebotomy does contribute to vasovagal reactions. A trial involving the use of vein visualisation technology conducted in 2013–14 and the impact on donor adverse event rates will be analysed
16. Two pilots of iron supplementation to reduce the risk of iron deficiency associated with blood donation commenced in 2013–14.

Case study 3: Delayed vasovagal reaction in a regular blood donor

The donor, a 53 year old woman, contacted the Blood Service approximately 6 hours after a whole blood donation to report that she had fainted 5 hours after donation, and continued to feel light-headed and weak.

The donor was in good health and was not taking any medication. She had been a blood donor for 14 years and had made 33 uneventful donations. On the day of donation she had eaten breakfast and lunch and had drunk 4-5 glasses of water and a cup of tea during the morning prior to her 2pm appointment. This was no different from her usual pre-donation preparation. She reported on her questionnaire and at interview that she was feeling healthy and well, and had no recent illnesses. The donor weighed 69kg and her height was 166cm (estimated total blood volume 4.1L). Her pre-donation blood pressure was 138/82mmHg and her pre-donation capillary Hb was 136g/L.

The donation commenced at 2.21pm and 471mL of whole blood was collected in 8 minutes. She felt well immediately following donation, and after resting briefly on the couch, she went to the refreshment area where she drank one glass of cordial and ate a muffin. She remained in the refreshment area for about 5 minutes. Following donation she went shopping for about 2 hours and then travelled home by bus. She felt well throughout this time. Her only fluid consumption after leaving the blood donor centre was a half a glass of water consumed whilst she was preparing the evening meal.

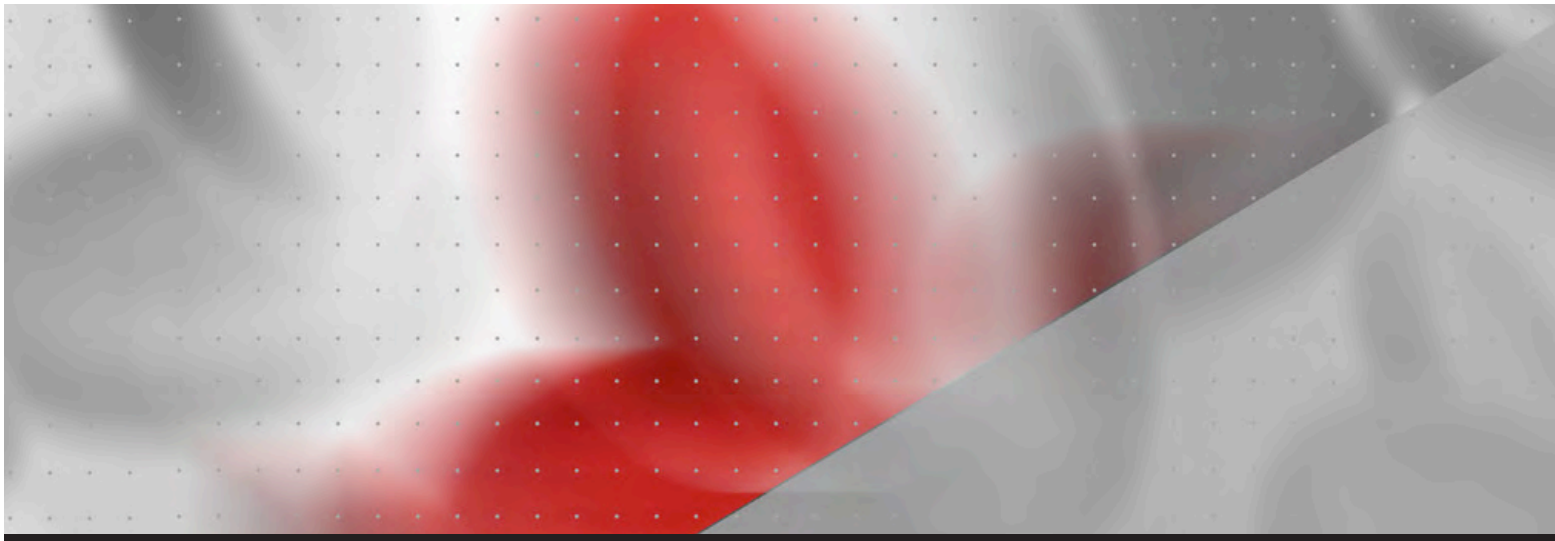
The donor started feeling unwell immediately following her evening meal during which she had drunk approximately half a glass of red wine. She fainted when she stood up to go to the bathroom. Her partner informed her that she was unconscious for "about 30 seconds". Immediately after regaining consciousness she attempted to move to a chair, and she fainted again. She remained on the floor for about 20 minutes and then moved to a chair. It was at this stage she contacted the Blood Service Medical Officer.

The Medical Officer advised the donor to remain semi-recumbent, to attempt to drink at least 2 glasses of cold water over the next 20 minutes, and instructed the donor in the use of applied muscle tension (repeated contraction of the thigh muscles which reduces peripheral venous pooling associated with vasovagal reactions and enhances venous return). She was advised to increase her intake of cool fluids over the next 3 hours, and to avoid hot baths or showers and was advised that she must not drive for at least the next 8 hours.

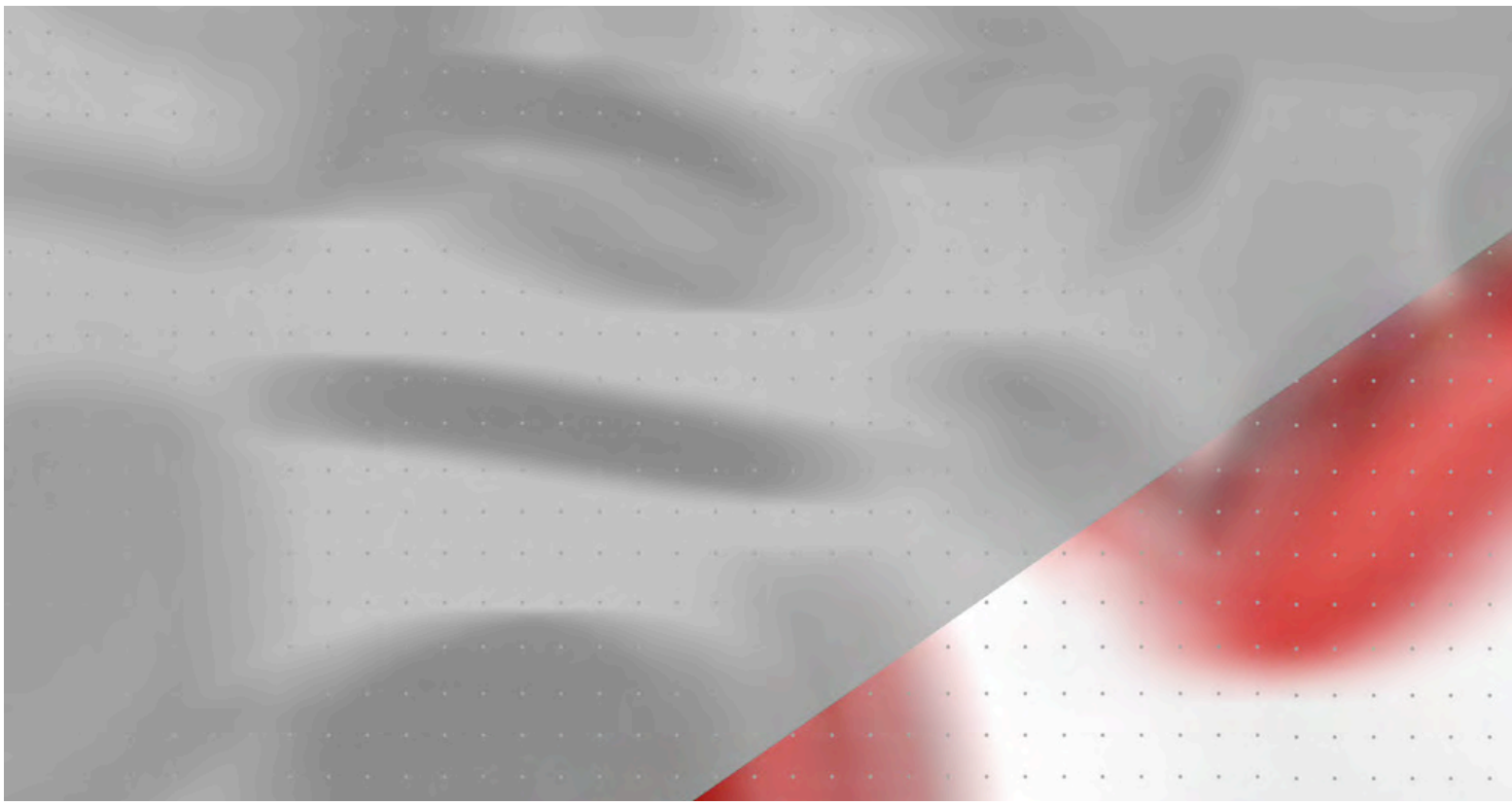
At follow up the next day, the donor reported that her symptoms of dizziness and sweating had resolved rapidly after she had used applied muscle tension; she had complied with the advice to drink additional cold, non-alcoholic fluids, and felt "back to normal" within 90 minutes.

Delayed vasovagal reaction is a well-recognised complication of blood donation, occurring in 0.34% of whole blood donors. It is thought that they occur as a result of failure of the donor's normal compensatory reflexes to respond to the volume loss associated with donation. Inadequate fluid intake post donation, prolonged standing, high environmental temperature, and alcohol ingestion all increase the risk of a delayed vasovagal reaction. Delayed reactions occur more frequently in female donors than in male donors (incidence 0.58% in females compared to 0.10% in male donors) and are more likely to be associated with loss of consciousness than immediate vasovagal reactions. Unlike immediate vasovagal reactions, the risk of a delayed reaction is not significantly higher in first time and inexperienced donors compared to experienced and older donors. It is possible that experienced donors are less vigilant about following advice to increase their fluid intake following donation, thereby increasing the risk of a delayed reaction.

Donors are provided with information on the risk of delayed reactions and advice on prevention, in particular advice on maintaining post donation fluid intake, and avoidance of known precipitants such as overheating, prolonged standing and drinking alcohol.



PREVIOUS AUSTRALIAN HAEMOVIGILANCE REPORT PERFORMANCE



04

CONTENTS

PART 04
PREVIOUS AUSTRALIAN HAEMOVIGILANCE REPORT PERFORMANCE

Scorecard – Performance to date

The 2013 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 those strategies to be delivered against each recommendation.

National blood quality and safety initiatives

Table 30: Progress against the national blood quality and safety initiatives recommendations of the Australian Haemovigilance Report 2013

	Recommendations from 2013 report	Who is responsible?	Proposed strategy from 2013 report	Outcomes
1	Promote the recognition and management of transfusion-related adverse events	NBA; JBC; State and territory Departments of Health; Hospital educators; Relevant professional Colleges and Societies	The NBA will develop and publish a document 'Guidance on Recognition and Management of Acute Transfusion-Related Adverse Events'	The NBA is developing the Guidance on Recognition and Management of Acute Transfusion-Related Adverse Events
2	Implement programs at the national, state and local hospital levels to improve reporting of serious adverse events	NBA; JBC; State and territory Departments of Health; Hospital educators; Relevant professional Colleges and Societies	The NBA and HAC will continue to engage with state and territory Departments of Health, hospital educators, and relevant professional Colleges and Societies as part of the ongoing Haemovigilance and Stewardship programs	The NBA will publish and distribute the above guidance document in 2015-16

Reducing human errors

Table 31: Progress against the human errors recommendations of the Australian Haemovigilance Report 2013

	Recommendations from 2013 report	Who is responsible?	Proposed strategy from 2013 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; Hospitals	Hospitals should ensure staff include regular Continued Professional Development to revise: ▪ ANZSBT Guidelines for the Administration of Blood Products ▪ ANZSBT Guidelines for Pre-Transfusion Laboratory Practice	The number of avoidable human errors should decline; however this is difficult to determine because near miss data may be collected for local reporting but not for national reporting
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	NBA and jurisdictions to continue to support the research and use of barcode technology and patient safety software to improve the bedside check of patient, blood and blood product identifications	The NBA has refined the National Policy on Barcoding for Blood and Blood Products
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	NBA is collaborating with the stakeholders to promote and develop a national reference set of tools

Data standards

Table 32: Progress against the data standards recommendations of the Australian Haemovigilance Report 2013

	Recommendations from 2013 report	Who is responsible?	Proposed strategy from 2013 report	Outcomes
6	Review and re-develop the Australian National Haemovigilance Data Dictionary	HAC; NBA	HAC to endorse a revised data dictionary and definitions	The ANHDD has been redeveloped The revised ANHDD will be published and distributed in 2015
7	Provide tools for hospitals on the application of Australian National Haemovigilance Data Dictionary and reporting of haemovigilance data	NBA; State and territory Quality and Safety Units; Hospital Administrators	NBA to inform hospitals on the availability and use of ANHDD NBA to support hospitals to provide a minimum set of data in a spread sheet or other tool for the national haemovigilance reporting	The NBA has helped QLD Health and WA to develop the Haemovigilance Data Collection Tool The NBA is refining the Tool and will publish it in 2015
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

Reporting capacity

Table 33: Progress against the reporting capacity recommendations of the Australian Haemovigilance Report 2013

	Recommendations from 2013 report	Who is responsible?	Proposed strategy from 2013 report	Outcomes
9	Conduct a scoping exercise for a national haemovigilance system	NBA; HAC; State and territory Departments of Health; Blood Service; Hospitals; Pathology providers; JBC	NBA to work in collaboration with state and territory health departments to investigate the feasibility of establishing a national haemovigilance system	Strategic Framework for the National Haemovigilance Program developed and endorsed by JBC
10	Maintain and improve existing capacities for haemovigilance data reporting	NBA; HAC; States and territories; Blood Service; Hospitals; Pathology providers; JBC	States and territories to consider means to improve existing mechanisms for reporting haemovigilance data	Reporting capacity improved for NSW QLD reporting capacity decreased but the Haemovigilance Data Collection Tool is being developed to improve this WA has also adopted a Data Collection Tool to facilitate haemovigilance data collection and reporting from 2015-16 The number of private hospitals submitting data to the National Haemovigilance Program remains low

Future directions in Australian haemovigilance

Adverse event reporting for non-fresh products

This report is confined to haemovigilance with respect to fresh blood components, such as red blood cells, platelets, fresh frozen plasma, cryodepleted plasma and cryoprecipitate. The Australian medical community also makes significant use of many plasma and recombinant products.

A range of valuable products is manufactured from plasma through the process of fractionation, in which different proteins found in blood plasma are separated, purified and concentrated into distinct therapeutic products. Most plasma derived products supplied in Australia are manufactured from plasma collected by the Blood Service and fractionated by CSL Behring. Some are imported.

Alternative recombinant product versions of plasma derived products are also available. These are manufactured by the expression of equivalent proteins from genetically engineered cell lines.

Important plasma and recombinant products are:

- intravenous and subcutaneous immunoglobulin
- hyperimmune immunoglobulin products
- albumin products
- clotting factors and other products.

Health professionals are required to report adverse events that occur as a result of administration of all blood and blood products. It is a requirement under NSQHS Standard 7[33] to report all adverse events into that facility's incident management and investigation system, as well as to the state and/or national haemovigilance system. As plasma and recombinant products are classified as medicines, reports of adverse events are directed to the TGA.[39]

The TGA maintains a reporting service for adverse events or defects in medicines in Australia. The reporting is mandatory for sponsors (serious adverse events only) and voluntary for other groups such as hospitals and general practitioners. The TGA publishes annual adverse event statistics. In 2013, the TGA receives over 17,500 adverse event reports of which 55% were by sponsors, 4% by general practitioners and 10% by hospitals. The TGA also publishes the adverse event data received through the Database of Adverse Event Notifications. Information on TGA reporting can be found on the TGA's website[40] and reports can be submitted in various ways.

Products for haemophilia and bleeding disorders

The Australian Bleeding Disorders Registry (ABDR)[41] was introduced in December 2008. The ABDR was further developed (to Version 4) in August 2012. A patient self-recording module, MyABDR, was launched in February 2014.

The ABDR is a clinical registry for patients in Australia with bleeding disorders. It is administered by the NBA, and used on a daily basis by clinicians in all Australian haemophilia treatment centres to assist in managing the treatment of people with bleeding disorders and to gain a better understanding of the incidence and prevalence of bleeding disorders.

The ABDR includes information on the following types of adverse events:

- an allergic or acute reaction possibly linked to a treatment administered to the patient
- a transfusion transmitted infection possibly linked to a treatment administered to the patient
- a malignancy possibly acquired from a treatment administered to the patient
- thrombosis possibly caused by a treatment administered to the patient
- the development of an inhibitor possibly caused by a treatment administered to the patient
- death of the patient possibly linked to a treatment administered to the patient
- poor efficacy or other adverse events possibly linked to a treatment administered to the patient.

The NBA produces ABDR annual reports and adverse event reporting will become more prominent as the dataset matures.

Intravenous immunoglobulin (IVIg)

Intravenous immunoglobulin (IVIg) is a fractionated blood product made from pooled human plasma. It is registered for use in Australia for the treatment of a number of diseases where immunoglobulin replacement or immune modulation therapy is indicated. IVIg is used to treat a growing number of unregistered indications where there is some evidence for its utility. IVIg is a life-saving therapy in appropriately selected patients and clinical circumstances.

Since the 1980s, the demand for IVIg has greatly increased, both internationally and in Australia. In the late 1990s, worldwide shortages prompted action by Australian governments to ensure that IVIg was available for those patients most in need. Since that time, strategies to ensure supply have included:

- rationalising the use of IVIg by specifying conditions and limiting IVIg access under the national blood arrangements to those patients meeting the specified conditions and eligibility criteria
- increasing the manufacture of IVIg in Australia
- importing IVIg from overseas.

The continual significant annual growth in IVIg usage, the high cost of IVIg products and the potential for supply shortages have all maintained the focus of Australian governments on ensuring use remains consistent with an evidence-based approach and that IVIg is able to be accessed under the National Blood Arrangements for those patients with the greatest clinical need.

The *Criteria for the clinical use of intravenous immunoglobulin*[42] in Australia describes current arrangements for access to IVIg funded under the national blood arrangements and the conditions for its use. The criteria have been developed to help clinicians and medical professionals identify the conditions and circumstances for which the use of IVIg is appropriate and funded.

The TGA collects information from hospitals and general practitioners on IVIg-related adverse reactions occurring in Australia. The NBA may work with the TGA on the inclusion of such data in future reports.

FRESH BLOOD PRODUCT USE AND HAEMOVIGILANCE SYSTEMS

05

CONTENTS

PART 05 FRESH BLOOD PRODUCT USE AND HAEMOVIGILANCE SYSTEMS

Trends in fresh blood product issues in Australia

In line with many developed countries Australia has made increasing progress towards improving the efficiency of blood utilisation and clinical transfusion practice. Transfusion-related clinical practice improvement programs in a number of states and territories have continued to develop in areas such as appropriate use of blood, clinical governance, haemovigilance and ongoing education of clinical and associated health care professionals.

Fresh blood products issued

The NBA coordinates the purchase and supply of blood and blood products on behalf of all Australian governments in accordance with government policies in the National Blood Agreement and *National Blood Authority Act 2003.*

In Australia, blood is voluntarily donated free from financial incentive. The Blood Service collects and processes blood and distributes blood products to Australian health providers. The Blood Service is funded by all Australian governments through the NBA which contracts the Blood Service under a Deed of Agreement.

The Therapeutic Goods Administration (TGA) regulates blood and plasma manufacturing activities and monitors any serious adverse transfusion events that may be product-related.

From 2011–12 to 2012–13, there were about 2.3 million components of fresh blood products issued in Australia. The demand for RBC remained high, accounting for about two-thirds of all issues. The demand for blood products varied across states and territories. NSW accounted for 32.5% of all issues, followed by VIC (25.4%) and QLD (21.2%). NT accounted for less than 1.0% of all issues.

Table 34: Fresh blood products issued in Australia, 2011–12 and 2012–13

2011–12	RBC	Platelets	FFP	Cryoprecipitate	Cryodepleted plasma
	Units	Units	Units	Units	Units
NSW	256,926	39,074	57,385	31,354	4,578
VIC	207,225	33,127	35,927	19,370	2,134
QLD	166,235	36,567	38,529	10,872	3,296
WA	65,742	9,356	9,944	7,654	815
SA	69,500	10,122	12,338	4,652	686
TAS	15,370	3,275	1,829	2,453	988
ACT	13,965	1,747	2,149	1,298	1,229
NT	6,333	882	923	446	30
Australia	**801,295**	**134,149**	**159,024**	**78,099**	**13,756**

2012–13	RBC	Platelets	FFP	Cryoprecipitate	Cryodepleted plasma
	Units	Units	Units	Units	Units
NSW	241,982	39,570	54,509	29,100	3,905
VIC	203,374	33,271	33,965	21,515	2,976
QLD	155,301	34,742	31,594	13,551	4,442
WA	64,064	10,200	9,450	10,618	2,390
SA	66,311	11,521	12,797	6,080	1,733
TAS	14,478	2,912	1,901	2,372	532
ACT	12,839	1,537	2,378	2,051	436
NT	5,194	824	1,047	405	261
Australia	**763,542**	**134,576**	**147,641**	**85,692**	**16,675**

Notes
1. FFP=Fresh frozen plasma
2. RBC=Red blood cell
3. Totals may not add up due to rounding.

The following tables and figures show that:

- The demand for RBC declined by 4.7%, from 801,295 in 2011–12 to 763,542 in 2012–13. The issues of RBC per 1000 population also dropped from 35.6 per 1000 population in 2011–12 to 33.3 in 2012–13. The decline in RBC demand is likely to demonstrate initial successes in programs to improve appropriate use and reduce wastage.
- The platelet demand in 2012–13 was consistent with the demand in 2011–12 with only 0.3% growth. In contrast, the issues of platelets per 1000 population decreased slightly from 6.0% in 2010–11 to 5.9% in 2012–13. The constrained growth is again likely to be the result of the initial success of programs to improve appropriate use and reduce wastage.
- The demand for FFP decreased by 7.2% from 2011-12 to 2012-13.
- The demand for cryoprecipitate units rose steadily over the past four years to 2012–13. Cryoprecipitate is increasingly used in the treatment of massive bleeding and this may drive an increase in demand in the coming years.
- The demand for cryodepleted plasma units increased by 21.2%, from to 13,756 in 2010–11 to 16,675 in 2012–13 after a slight decrease between 2010–11 and 2011–12. It remains difficult to forecast the demand for this blood product because this product is used episodically in a very small number of patients with thrombotic thrombocytopenic purpura.

Declining demand for RBC was also reported by other countries including the United Kingdom (UK), New Zealand (NZ) and the Netherlands during similar periods.

- RBC issues declined by 5.5% from 2011 to 2013 in the UK.
- The transfusion rate for RBC decreased by 8.9% from 2010 to 2012 in NZ.
- A declining trend of about 7% in the number of distributed RBCs was seen in the Netherlands from 2010 to 2012.

Table 35: Fresh blood products issued in Australia, 2009–10 to 2012–13

Fresh blood product	2009–10	2010–11	2011–12	2012–13
RBC	795,892	800,570	801,295	763,542
Platelets	128,495	134,705	134,149	134,576
Fresh frozen plasma	160,813	160,537	159,024	147,641
Cryoprecipitate	64,734	70,102	78,099	85,692
Cryodepleted plasma	11,872	13,882	13,756	16,675

Note: RBC=Red blood cell

Table 36: Fresh blood products issued per 1000 population, 2009–10 to 2012–13

Fresh blood product	2009–10	2010–11	2011–12	2012–13
RBC	36.4	36.1	35.6	33.3
Platelets	5.9	6.1	6.0	5.9
Fresh frozen plasma	7.4	7.2	7.1	6.4
Cryoprecipitate	3.0	3.2	3.5	3.7
Cryodepleted plasma	0.5	0.6	0.6	0.7

Notes
1. RBC=Red blood cell
2. ABS population data[43] for December quarters 2009, 2010, 2011 and 2012 are used for the calculation of figures in this table.

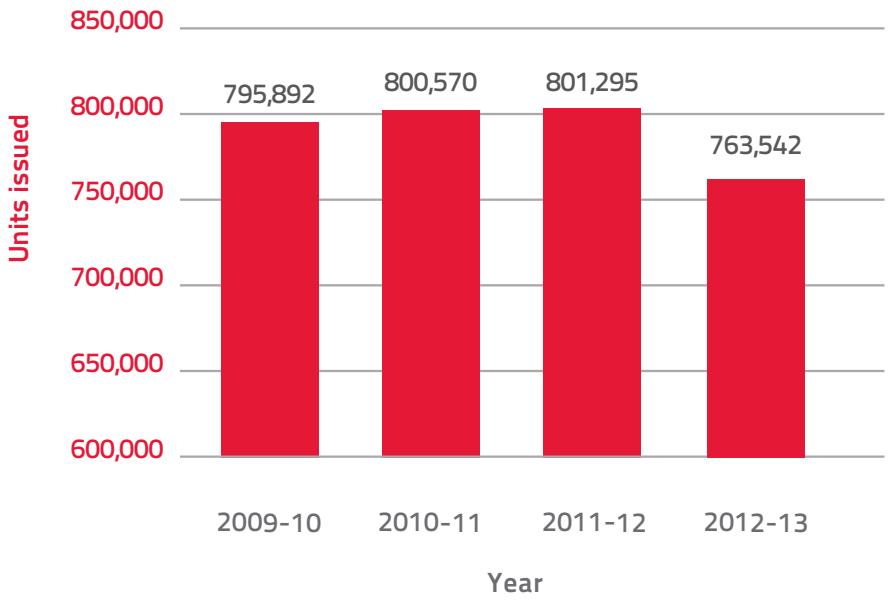


Figure 5: Total red blood cell issues in Australia, 2009–10 to 2012–13

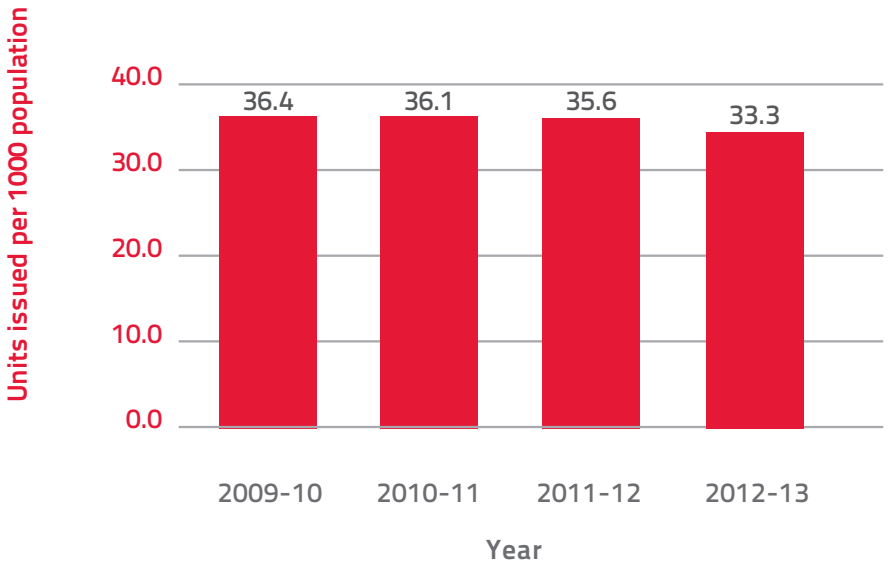


Figure 6: Total red blood cell issues per 1000 population, 2009–10 to 2012–13

Demographics of blood use

Australia's population grew by 1.8% to 23,130,900 during the year ended 30 June 2013. The growth rate has declined since the peak of 2.2% for the calendar year ended 31 December 2008.[44] Increases in population will inevitably result in increased future demand for health care services.

Australia's population, similar to that of most developed countries, is ageing as a result of sustained low birth rates and increasing life expectancy. This is resulting in proportionally fewer children (less than 15 years of age) in the population. The median age (the age at which half the population is older and half is younger) of the Australian population increased by 4.3 years over the last two decades, from 33.0 years at 30 June 1993 to 37.3 years at 30 June 2013. Between 30 June 2012 and 30 June 2013 the median age remained steady at 37.3 years. Over the next several decades, population ageing is projected to have significant implications for Australia in many spheres, including increased demands and spending on the health system.[44]

Australia enjoys one of the highest life expectancies in the world. In 2012 it was ranked sixth overall at 82.1 among Organisation for Economic Co-operation and Development (OECD) countries after Japan (83.2 years), Iceland (83.0), Switzerland (82.8), Spain (82.5) and Italy (82.3).[46]

In the 12 months to 30 June 2013, the number of people aged 65 years and over in Australia increased by 120,100 people, representing a 3.7% increase. The proportion of the population aged 65 years and over increased from 11.6% to 14.4% between 30 June 1993 and 30 June 2013. This is projected to increase more rapidly over the next decade, as further cohorts of baby boomers turn 65. In the 12 months to 30 June 2013, the number of people aged 85 years and over increased by 19,300 (4.6%) to reach 439,600. Over the two decades to 30 June 2013, the number of people aged 85 years and over increased by 159% compared with a total population growth of 31% for the same period.[8]

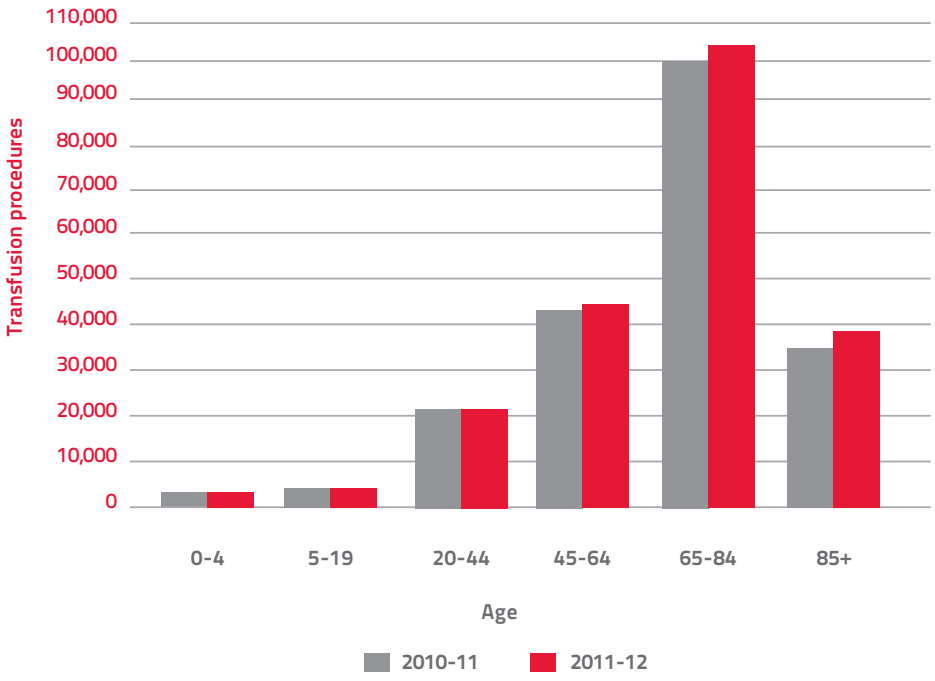
The rise in the elderly population of Australia has a tangible effect on the nation's blood supply needs. There is a correlation between patient age and blood component use and this is illustrated by a range of data available from the Australian Institute of Health and Welfare (AIHW).

The AIHW publishes data relating to transfusion of blood and immunoglobulin on an annual basis. There are, however, a number of limitations[47] with respect to the analysis and the potential use of this data for blood supply demand planning:

- there is a 12 month delay before the data becomes available in the public domain
- information is only collected for patients who have been admitted to hospital
- information collected only relates to the number of transfusion procedures for blood and immunoglobulin. No information is collected regarding the actual number of units of blood components or plasma derived blood products transfused during each of these transfusion procedures
- other than for red blood cells, platelets and perhaps whole blood, the other sub-coded data cannot be related to any specific blood component or plasma derived blood product such as 'coagulation factors', 'blood expanders', and 'other serum'
- differences in coding and reporting practices across hospitals and jurisdictions are likely to affect the quality of the data collected and may result in some under-reporting.

Despite the limitations, the AIHW data provides some insight into Australian transfusion trends.

As shown in Figure 7 below, the majority of RBC transfusion procedures in 2010–11 and 2011–12 occurred in patients aged 65 years and over. A similar trend was also observed for other blood products (Table 37, Table 38) for the same period.



Source: AIHW National Hospital Morbidity Database

Figure 7: RBC transfusions by patient age, 2010–11 and 2011–12

This phenomenon is not unique to Australia. Epidemiological information from the United States, England, and Denmark highlighted similar age and sex distributions of transfused patients: [48]

- most of the red cell components were transfused to older recipients
- the distribution between men and women was approximately equal
- the distribution for platelets was over a wider age range
- the distribution for plasma was also directed to the elderly.

Table 37: ACHI transfusion procedures by patient age, 2010–11

	Number of Procedures						Percentage of Procedures					
Administration of	0–4yrs	5–19yrs	20–44yrs	45–64yrs	65–84yrs	85+	0–4yrs	5–19yrs	20–44yrs	45–64yrs	65–84yrs	85+
RBC	4,539	5,208	21,234	43,994	100,789	33,064	2%	2%	10%	21%	48%	16%
Platelets	1,865	2,026	4,049	10,177	14,680	1,702	5%	6%	12%	29%	43%	5%
Leukocytes	9	12	12	46	36	3	8%	10%	10%	39%	31%	3%
Autologous blood	106	205	452	3,323	4,880	327	1%	2%	5%	36%	53%	4%
Other serum	2,182	1,349	6,009	15,679	21,732	3,794	4%	3%	12%	31%	43%	7%
Blood expander	10	13	310	728	1,084	232	0%	1%	13%	31%	46%	10%
Other substance	1,631	4,176	11,511	24,012	24,275	2,276	2%	6%	17%	35%	36%	3%

Note: ACHI=Australian Classification of Health Interventions
Source: AIHW National Hospital Morbidity Database

Table 38: ACHI transfusion procedures by patient age, 2011–12

	Number of Procedures						Percentage of Procedures					
Administration of	0–4yrs	5–19yrs	20–44yrs	45–64yrs	65–84yrs	85+	0–4yrs	5–19yrs	20–44yrs	45–64yrs	65–84yrs	85+
RBC	4,678	5,373	21,522	44,808	104,535	35,157	2%	2%	10%	21%	48%	16%
Platelets	1,950	2,208	3,715	10,756	15,574	1,756	5%	6%	10%	30%	43%	5%
Leukocytes	8	10	14	32	24	1	9%	11%	16%	36%	27%	1%
Autologous blood	142	241	538	3,310	5,384	369	1%	2%	5%	33%	54%	4%
Other serum	2,325	1,535	6,161	16,564	23,011	4,039	4%	3%	11%	31%	43%	8%
Blood expander	11	15	314	473	827	174	1%	1%	17%	26%	46%	10%
Other substance	1,691	4,432	12,286	25,945	27,699	2,763	2%	6%	16%	35%	37%	4%

Note: ACHI=Australian Classification of Health Interventions
Source: AIHW National Hospital Morbidity Database

Clinical use of RBC

An Australian red cell linkage program examined red cell use in SA public hospitals.[49] The study showed a reduction in the surgical use of RBC from 2007 to 2009. About a third of RBC was used for surgical indications and half was used for medical indications in 2008–09. The most common medical indication was haematology, accounting for about one quarter of total RBC use.

The Blood Service 'Bloodhound' study[50] showed approximately one-third of tagged red blood cells were used to support surgery, one-third for haematology/oncology and one-third for other medical and miscellaneous indications. The breakdown of the clinical indications for transfusion was as follows:

- 33.6% for haematological and oncological conditions
- 27.8% for surgical specialities (including cardiothoracic 5.6%, orthopaedic 9.8%, vascular 2.3%, solid organ transplantation 2.3% and other 9.5%)
- 13.5% for other medical conditions (including gastroenterology 8.7%, nephrology 2.8%, paediatric specific indications 0.1% and other 1.9%)
- 12.7% for unspecified anaemia
- 3.8% for obstetrics and gynaecology
- 2.1% for trauma.

These Australian results are consistent with the similar studies undertaken by other countries. Tinegate et al[51] reported on surveys examining the changing patterns of red blood cell use in 1999, 2004 and 2009 in the North of England. The authors found that the surgical use of RBC also dropped significantly from 41% in 1999 to 29% in 2009, solely to the recipients aged 50 to 80 years. In contrast, the medical use of RBC (64% of RBC use in 2009) had not changed significantly over 10 years. The most common medical use of RBC was haematology, accounting for 28% of total RBC use in 2009.

Appropriate use of blood in Australia

There has been an increased focus on appropriate use of fresh blood products in Australia in recent years. The 2010 Australian Health Ministers' Conference Statement for National Stewardship Expectations on the Supply of Blood and Blood Products (Stewardship Statement) requires that blood should be managed in ways to ensure all blood products are used in a clinically appropriate manner in accordance with relevant professional guidelines and standards. The NBA has developed Patient Blood Management (PBM) Guidelines and carried out a range of implementation activities in relation to the PBM Guidelines to improve the appropriate use of fresh blood products.

PBM Guidelines

The NBA has published five modules of the PBM Guidelines:

- Module 1: Critical Bleeding/Massive Transfusion
- Module 2: Perioperative
- Module 3: Medical
- Module 4: Critical Care
- Module 5: Obstetrics and Maternity

Over 100,000 copies of the first four PBM modules have been either issued in hard copy or downloaded in over 60 countries. They provide evidence based guidance on optimisation of the patient's own blood, non-transfusion strategies to minimise blood loss and bleeding and strategies to manage anaemia. In early 2015, the NBA published Module 5: Obstetrics and Maternity. Module 6: Paediatric and Neonatal is currently being developed by the Clinical/Consumer Reference Group. Module 6 will be released for public consultation on 2 September 2015 and will be published in 2016.

Implementation of PBM Guidelines

In 2013–14, the NBA carried out a range of activities to improve appropriate use through PBM as defined in the JBC-approved National Blood and Blood Product Wastage Reduction Strategy 2013–2017 and the National Patient Blood Management Guidelines Implementation Strategy 2013–2017.

Best practice tools

The NBA intensified its development of best practice tools to support health providers to implement improvements in the management and use of blood and blood products, including development of:

- guidance for the implementation of a PBM program (not yet completed)
- materials for the implementation of a single unit transfusion policy
- guidance for the provision of intraoperative cell salvage
- a guidance module for inter-hospital transfers as part of the Managing Blood and Blood Product Inventory Guidelines for Australian Health Providers
- guidance on acute transfusion reaction, recognition and management chart (not yet completed)
- red blood cell and massive transfusion protocol clinical audit tools (not yet completed)
- a case study on preoperative anaemia identification, assessment and management
- a case study on the Prince Charles Hospital implementing point of care testing
- promotional products for use within hospitals to raise awareness of wastage of blood and blood products.

Promotional and communication activities

With the increased focus on appropriate use of fresh blood products, opportunities to promote the guidelines and NBA's key messages at conferences and sector events were leveraged in 2013–14.

Through trade stands, presentations or conference advertising, NBA initiatives were promoted at the following key events:

- Australian Society of Anaesthetists National Scientific Congress, Canberra, September 2013
- Australian and New Zealand Intensive Care Society (ANZICS) Annual Scientific Meeting, Hobart, October 2013
- 2013 Annual Scientific Meetings of the Haematology Society of Australia and New Zealand, Australian & New Zealand Society of Blood Transfusion and the Australasian Society of Thrombosis and Haemostasis (HAA), Gold Coast, October 2013
- Australian Private Hospitals Association (APHA) 33rd National Congress, Melbourne, March 2014
- Combined Royal Australian College of Surgeons (RACS) Annual Scientific Congress and Australian and New Zealand College of Anaesthetists (ANZCA) Annual Scientific Meeting, Singapore, May 2014
- World Federation of Haemophilia Congress, Melbourne, May 2014
- Blood Service Transfusion Update, Melbourne, May 2014.

The NBA also sponsored a number of stand-alone events designed to improve awareness and understanding of improvements required in the management and use of blood and blood products:

- The NBA engaged the Australian Commission on Safety and Quality in Health Care (ACSQHC) to co-brand a series of National Blood Symposiums held in September 2013 in Sydney, Melbourne and Adelaide. The symposiums, attended in total by more than 650 health professionals, were focused on supporting the implementation of NSQHS Standard 7.
- The NBA joined the Western Australian Department of Health to co-sponsor the inaugural National Patient Blood Management Conference, titled "Patient Blood Management as a standard of care in Australia: Past, Present and Future". The conference agenda included presentations from a cross section of international, national and local experts. The conference was acclaimed by over 300 attendees as highly successful with a strong demand for further events focused on PBM.

Education and training

- **National Blood Sector Education and Training Strategy**
  In 2013-14, the NBA published the National Blood Sector Education and Training Strategy 2013–2016. The strategy outlines a plan to work with current education and training providers to address the growing demand for high quality, well-tailored education, training and health promotion materials to support the implementation of evidence-based practice and attainment of health service accreditation under the new standards.
- **BloodSafe eLearning Australia**
  BloodSafe eLearning Australia is funded by all Australian governments. The online site offers a range of courses relating to clinical transfusion practice including PBM, blood specimen collection and product handling. The suite of courses has proved to be very popular with 252,217 registered users and 65,284 new registrations in 2013–14. On average the site attracts about 5,500 new registrations and 10,500 course completions per month.
  There were 31 per cent repeat registered users during 2013–14 demonstrating that existing users continue to return to the site to participate in new educational offerings.
  The following enhancements were made to BloodSafe eLearning Australia during 2013–14:
  - release of two new modules, one on PBM and one on Perioperative which was based on the NBA's Perioperative module of the PBM Guidelines
  - update of the website at www.bloodsafelearning.org.au to improve access, including compatibility with mobile devices
  - Critical Bleeding and Postpartum Haemorrhage courses recognised as an emergency response activity for ANZCA Continuing Professional Development program
  - review of the Iron Deficiency Anaemia module in response to clinical feedback
  - commencement of the development of a new module based on Module 4 Medical of the PBM Guidelines.
- **National Safety and Quality Health Service Standards**
  As part of the National Health Reforms, the ACSQHC has developed the NSQHS Standards. These standards are intended to drive improvement in safety and quality for patients. They also provide a clear statement of the level of care consumers can expect from health services. Accreditation against the standards commenced in January 2013. The NBA is committed to supporting health service organisations to meet the requirements under NSQHS Standard 7. During 2013–14 the NBA worked with the Commission and other stakeholders to develop resources to support implementation of the Standard.

Research and development

In 2012–13 NBA worked with stakeholders to release the National Blood Research and Development Strategic Priorities 2013-2016. The purpose of the publication is to provide a useful resource to guide priority setting for research. It may be used by researchers to support funding requests, by identifying that their research aligns with priorities communicated by governments.

In 2013–14 the NBA partnered with the Transfusion Outcomes Research Collaborative (TORC) on a successful NHMRC project grant application to improve outcomes for patients with critical haemorrhage requiring massive transfusion. The project is consistent with the national research and development strategic priorities in that it seeks to:

- systematically measure and monitor transfusion practice and outcomes in patients with critical bleeding requiring massive transfusion. This will be achieved using data generated by the bi-national expansion of the Massive Transfusion Registry (MTR), which has already been successfully piloted at six Australian sites
- provide robust national data on blood utilisation for massive transfusion to inform blood supply planning and inventory management and thereby improve equity of access to blood products
- inform development of future clinical studies of patients with critical bleeding and provide a mechanism to support and measure translation of new findings into practice.

Australia's capacity to report haemovigilance data

Haemovigilance in Australia

Haemovigilance is a vital and integral part of modern transfusion medicine. In Australia, national haemovigilance reporting is voluntary (with the exception of sentinel events, see Appendix IV) but is seen as part of the professional duty of care for patient safety. The Australian government has recommended health service organisations participate in relevant haemovigilance activities conducted either locally or at state or national level from 1 January 2013 as part of NSQHS Standard 7.

Haemovigilance provides a very important source for identifying emerging trends in hazards related to blood transfusion. The quality of blood and blood products in Australia has reduced the recorded risks associated with the transfusion product itself. The major residual hazards of transfusion in Australia can be broadly divided into human errors and clinical reactions. In common with other OECD countries, such as the United Kingdom, New Zealand, Sweden and Canada, the risks to the safety of transfused patients in Australia have clearly been shown to occur predominantly in the hospital environment arising from human errors. For example, the majority of preventable transfusion errors and adverse events result from human error.

To support the continued development and alignment of state and territory haemovigilance and systems with the national reporting requirements, JBC endorsed the recommendations in the Initial Australian Haemovigilance Report 2008 and established a National Haemovigilance Program in 2008. The rationale for setting up the National Haemovigilance Program was to:

- enable transfusion practice improvements
- enable product improvements
- identify contributory and comparator factors
- place Australian transfusion risks into an international perspective.

The National Haemovigilance Program is implemented through the following initiatives:

- the HAC
- maintaining a national haemovigilance database and the ANHDD
- publishing Australian haemovigilance reports
- participating in IHN
- promoting and reporting Australian haemovigilance at local, national and international forums
- integrating the activities and output from the National Haemovigilance Program with relevant linked NBA activities including the development of patient blood management clinical practice guidelines, national educational initiatives, and developing the national patient blood management program.

In addition to the National Haemovigilance Program, haemovigilance is also supported at a national level by bodies involved in education and practice improvement, production of guidelines, product and service standards and accreditation:

- Australian Commission on Safety and Quality in Health Care (ACSQHC)
- Australia and New Zealand Society for Blood Transfusion (ANZSBT)
- Australian Association of Pathology Practices (AAPP)
- Australian Council on Health Care (ACHS)
- Australian Haemophilia Centre Directors' Organisation (ACHDO)
- Australian Nursing Federation (ANF)
- Australian Private Hospitals Association (APHA)
- Australian Red Cross Blood Service (Blood Service)
- Australian Society of Blood Transfusion (ASBT)
- BloodSafe eLearning Australia
- Clinical Excellence Commission (CEC)
- National Association of Testing Authorities (NATA)
- National Coalition of Public Pathology (NCOPP)
- National Health and Medical Research Council (NHMRC)
- National Pathology Accreditation Advisory Council (NPAAC)
- Royal College of Pathologists of Australasia (RCPA)
- Therapeutic Goods Administration (TGA).

The NSQHS Standard 7 requires that health organisations ensure blood and blood product adverse events are included in the incidents management and investigation system:

- 7.3.1 Reporting on blood and blood product incidents is included in regular incident reports
- 7.3.2 Adverse blood and blood product incidents are reported to and reviewed by the highest level of governance in the health service organisation
- 7.3.3 Health service organisations participate in relevant haemovigilance activities conducted by the organisation or at state or national level.

The Stewardship Statement outlines measures that Health Ministers expect all health providers to adopt within their organisation. 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.

Case study 4: STIR end to end process for haemovigilance

Background

The Blood Matters Serious Transfusion Incident Reporting (STIR) system is the only standalone haemovigilance system in Australia. It receives voluntary reporting of blood related incidents and near misses from public and private health services in Victoria, Tasmania, the Australian Capital Territory and the Northern Territory using a semi-automated process. All cases reported to the STIR undergo an independent review/validation process to determine classification and assignment of imputability and severity. This review/validation is considered one of STIR's strengths, but it is time-intensive and adds complexity to the process.

STIR end to end process

To better understand the STIR System and identify areas for improvement, the STIR and NBA analysed the STIR haemovigilance review and reporting activities and produced a STIR end to end process map (Figure 8) which identified the following five steps.

Step 1: Assessing adverse events

The Health Service Quality and Safety Representative (Q&S Rep) reviews and investigates incidents reported to the Incident Management System prior to notification to STIR.

Step 2: Notification to STIR

The Q&S Rep notifies STIR of the incident through the completion and submission of an eForm linked on the Blood Matters website (https://stir.transfusion.com.au/).

Step 3: STIR investigation of reported adverse events

The STIR Secretariat conducts a scope assessment for the reported incident. The STIR Secretariat emails a relevant investigation form for the in-scope incident to the Q&S Rep for completion. The investigation form provides more detail about the incident such as product involved, where and when it occurred, contributing factors and outcome for the patient. The Q&S Rep is requested to complete the form within four weeks and return the form electronically to the STIR for review. The STIR Data Manager (DM) enters the de-identified data into an Access database.

Step 4: Validation/review of severity, imputability and causality

This step is the fundamental component of the STIR system. This process includes the review and validation of the incident by expert reviewers who volunteer their time. The review validates reports, and enables recommendations and tools to be developed to help health services understand and better manage serious transfusion reactions. The reported incident may undergo three levels of review:

- **Initial review**
  The STIR DM extracts the 15 earliest unreviewed adverse events from the Access database and copies the records into a review tool. A reviewer is selected to conduct the initial review. If the reviewer changes severity, imputability/causality or disagrees with the health service assessment of type of reaction the event will be flagged for further review.
  The STIR DM merges the review data into a database and then conducts a consensus review to determine whether or not the report is available for feedback or requires further specialist or group review.
- **Specialist review**
  If the reviewer comes to a different assessment of the severity or imputability/causality or type of reaction, the report is referred to a specialist reviewer. The STIR DM extracts a subset of up to 15 records that requires specialist review and copies the records into a specialist review tool. A Specialist reviewer is selected to conduct the review. Following review the STIR DM merges the reviewed data into a database and then conducts a consensus review to determine whether or not the report is available for feedback or requires further group review.
- **Expert group review**
  If, after specialist review, consensus is not achieved then the event will be reviewed by the STIR Expert group. This is the final review to address all the issues for the records from previous review process(s). The reports will be available for feedback after this process.

Step 5: STIR feedback

The Blood Matters program publishes STIR de-identified aggregated reports and STIR sends summary reports to all reporting health services every six months for quality improvement purposes.

Conclusion

Haemovigilance reporting is now a national requirement for health services. The STIR expert case review process currently involves multiple business areas and includes detailed pathways to resolve the more complex cases. Analysis of data and feedback informs and assists health services to improve transfusion practice, meet reporting requirements and comply with the NSQHS Standard 7. Mapping the business process helps to demystify these pathways and identify areas for improvement, including future strengthening of the system and potential efficiencies.

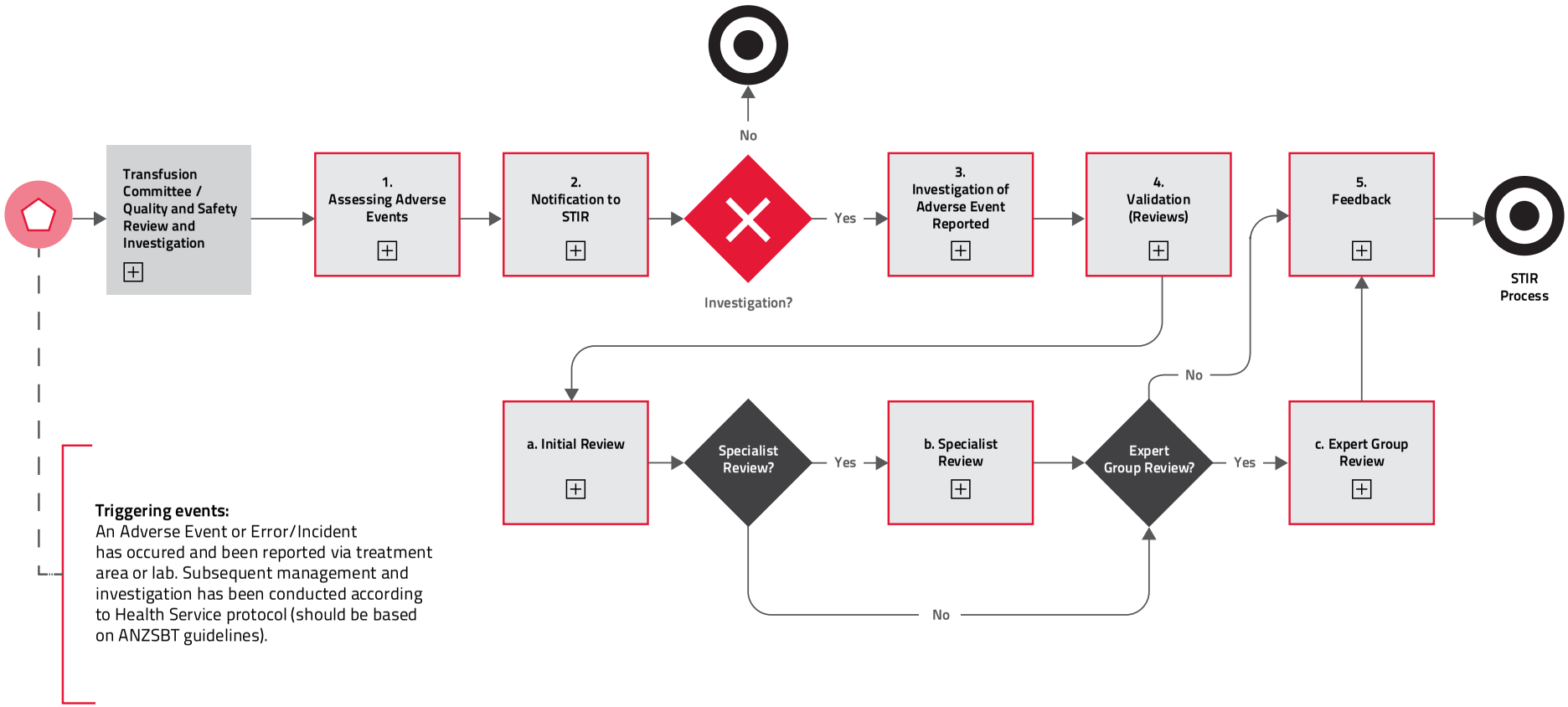


Figure 8: Serious Transfusion Incident Reporting (STIR) end to end process, 2012–13

New South Wales

NSW is the most populous state in Australia with a population of just under 7.5 million in 2012–13. Supporting this population are over 200 public hospitals, a large percentage of which transfuse blood and blood products, as well as over 100 private facilities. Usage of fresh blood products in NSW accounts for approximately 30% of the National issue.

In 2006, the NSW Clinical Excellence Commission (CEC), in collaboration with NSW Health, launched the Blood Watch program to implement and support transfusion medicine improvements in NSW public hospitals. The Blood Watch Program provides a mechanism for system analysis and design related to the clinical use of blood and blood products, a key function of which is the review and analysis of haemovigilance-related information and data.

NSW public hospitals use a centralised incident reporting platform to report incidents and near miss events, including those related to the clinical handling, management and administration of blood and blood products. The current platform used is the Incident Information Management System (IIMS).

In keeping with the principles outlined in the National Haemovigilance Program, incidents and events are reported, investigated and managed locally, and the information is used within the context of an overall health system defined by the mandatory NSW Policy Directive PD2014_004 Incident Management. Incident management processes and system level analysis is undertaken at the state level by the Patient Safety team as a function of the CEC.

The definitions of transfusion-related incidents and adverse outcomes contained within IIMS pre-date those outlined in the ANHDD. Data extracted, once de-identified, requires review and re-classification prior to submission for inclusion in the National Haemovigilance Report. This is undertaken on a bi-annual basis by the Blood Watch Program team and an expert clinical review group.

As IIMS contains entries relating to the clinical elements of the transfusion chain, as well as adverse outcomes from all blood and blood products (not just fresh products), only a small number of relevant incidents entered, approximately 15% are mapped and submitted for the National Haemovigilance report. All haemovigilance incidents are aggregated at the state level and are used to inform risk, identify opportunities for local improvements, and inform state wide improvement opportunities (such as the implementation in 2012 of the mandatory requirement for health care workers involved in transfusion to complete BloodSafe eLearning).

Learnings from the bi-annual review of the IIMS data, as well as the national haemovigilance reports and other international programs such as the Serious Hazards of Transfusion (SHOT) program in the UK, are currently being used to inform the build of the upgrade to the NSW reporting system. The upgrade, and new centralised reporting system, is planned for release in 2016.

An expert working group has been convened to support the development of the haemovigilance business rules for the new system. Work has progressed on ensuring the ability to capture data for inclusion in the national reporting program, in compliance with the ANHDD, whilst maintaining and supporting the ongoing reporting of all haemovigilance incidents that currently inform the system in NSW.

Victoria

Blood Matters is a collaborative between the Department of Health and the Blood Service with the goal of improving transfusion quality, safety and appropriateness of blood and blood products. The STIR system is one part of the Blood Matters program. Governance of the STIR system is provided by an expert group of clinicians with an interest in adverse event management and transfusion improvement, along with assistance from the Blood Matters secretariat, and it reports to the Blood Matters Advisory Committee (BMAC). STIR is a voluntary reporting system that collects haemovigilance data on events from participating public and private health services in VIC, ACT and NT (through memorandums of understanding). Victorian public health services report clinical incidents into a state wide reporting system, the Victorian Health Incident Management System (VHIMS) which includes blood-related incidents. Categories of events reportable to STIR are classified as either clinical or procedural.

Clinical:

- acute transfusion reaction (including anaphylaxis)
- delayed transfusion reaction
- transfusion-associated graft versus host disease
- TRALI
- TACO
- PTP
- post-transfusion viral infection
- bacterial/other infection.

Procedural:

- IBCT
- wrong blood in tube (WBIT)
- other near miss events.

In 2015 data collection will be expanded to include events related to cell salvage and Rh(D) Immunoglobulin.

The electronic system used to manage incident reporting data as part of STIR has been developed within the Blood Matters program. Health services submit an initial electronic notification through a web eForm to the STIR office. The STIR office then provides a detailed follow-up investigation form tailored to the type of event notified. This second level reporting by health services collects additional relevant detailed information specific to the event type, and is reported using an electronic Word form. Both forms are imported into the database through a semi-automated process, providing timely review and follow up. Confidentiality is maintained by collection of limited patient information (such as age and gender only) and health services are identified by a code only known by the STIR office, which is not included in the expert review process.

From February 2006 to 30 June 2013, STIR received 1,207 notifications of transfusion episodes resulting in 1,221 adverse events and incidents, with 55 health services reporting at least one event. In 2011–13, 43 health services from VIC, ACT, NT and TAS reported 356 events. Based on information from the Victorian Admitted Episode Dataset, it is estimated for VIC that health services which have agreed to report (public and private) represent approximately 90% of the total blood transfusion activity. From 2006–13 clinical incidents events (acute transfusion reactions) comprise 49% of the reports. Procedural events account for approximately 43% of the events, and include incorrect blood component transfused (including transfusion of a unit intended for another patient, or which did not meet a patient's individual requirements, such as failure to provide irradiated components), 'wrong blood in tube' events and other 'near miss' events.

Reports are expected to be reviewed prior to submission to STIR. In most health services this occurs through review by the transfusion committee (or similar) or senior medical officer. The STIR program validates incident data through expert review. STIR review includes classification and assessment of imputability and severity rating. The expert review group is comprised of medical, nursing and scientific staff with an expertise and interest in transfusion. The review process is a key strength of the STIR program; it provides validity to the data submitted and recommendations for improved practice. ABO incompatible blood transfusions are also reportable to the Victorian sentinel event program, and a root cause analysis (RCA) approach for these events is reviewed by the STIR expert group, with comments and recommendations provided back to reporting health services through the sentinel event program.

Aggregate information from STIR is presented to BMAC and used to develop recommendations and educational resources for health services. All STIR reports from 2006 onwards are available on the Blood Matters website http://www.health.vic.gov.au/bloodmatters/tools/stir.htm. STIR regularly shares experiences and data locally, nationally and internationally at conferences, workshops and meetings. The implementation of the National Standards for accreditation has reinforced the importance of recognising, reacting to, and reporting transfusion adverse events. Having staff dedicated to support NSQHS Standard 7 increases awareness of and engagement with haemovigilance activities.

Queensland

QLD is a large and highly decentralised State, with an estimated resident population of 4.708 million in March 2014.[53] The State's use of blood and blood products is mostly provided across 16 Hospital and Health Services and 105 licensed private health facilities.

Queensland Health had a centralised haemovigilance system until early 2013. Under this system, data validation and analysis was conducted by clinicians in a corporate division of Queensland Health. The data presented in this report, for 2011–12, was a product of this centralised haemovigilance system.

The Queensland haemovigilance system was adapted in line with the new structural arrangements for public health services in QLD. Under these arrangements, Health Hospital and Health Services (HHSs) and licensed private health facilities continue to report incidents and, as required by NSQHS Standard 7, implement local haemovigilance activities, which may include:

- completing follow up forms in response to blood-related incidents reported in local incident monitoring systems
- entering haemovigilance data in a standardised spreadsheet
- reviewing and validating haemovigilance data
- providing de-identified haemovigilance data for state and national haemovigilance reports.

In major hospitals with transfusion nurses, haemovigilance-related quality improvement activities are being implemented. Some hospitals without transfusion nurses have given the responsibility for monitoring and implementing haemovigilance activities to local patient safety officers.

Local action is supported by a guideline on haemovigilance data collection and analysis and a suite of tools (electronic haemovigilance forms and spreadsheet), to facilitate consistency in haemovigilance reporting and analysis processes across QLD. The Department of Health will coordinate data provision from health facilities to the NBA for national haemovigilance reporting.

Future plans for haemovigilance in QLD are to include haemovigilance reporting in the new statewide incident reporting system being developed by Queensland Health for use by HHSs.

Western Australia

WA is a jurisdiction with an estimated population of 2.5 million people that covers an area comprising some 2.5 million square kilometres. Approximately three quarters of the State's population reside in the greater Perth metropolitan area. Western Australia is serviced by both public and private hospitals that transfuse blood and blood products. These include a number of tertiary and major private hospitals located in the Perth metropolitan area and a network of general and regional public hospitals located in the metropolitan area and across rural WA. Several larger regional centres are also serviced by private hospital providers.

WA Health acknowledges the Statement on National Stewardship Expectations for the Supply of Blood and Blood Products including requirements for transfusion-related adverse event information to be collected and managed as part of appropriate stewardship of blood products and patient and product safety.

Currently, haemovigilance data in WA is collected and analysed on an individual hospital or health service basis. In WA public hospitals, transfusion-related incidents and adverse events are investigated at the individual hospital level and data collected and reported to hospital transfusion or blood management committees and/or hospital safety and quality committees. This can include collection of data and reporting on near miss events. Product-related reactions may also be reported through the state public pathology provider PathWest to the Blood Service.

Transfusion-related incidents and reactions may be classified according to defined outcome severity with incidents rated as major or severe requiring review by the highest governance level of the hospital. In WA public hospitals, clinical

incidents classified as Severity Assessment Code 1 (SAC1), which includes sentinel events, or SAC2 are mandated to be reported via the WA Health Clinical Incident Management System DATIX CIMS. This online system operates across all public sector hospitals and health facilities providing a state-wide platform for the notification and management of health care incidents.

Private hospitals currently collect their haemovigilance data through their internal organisational quality and risk management systems. In WA, private licensed health care facilities are required to report all clinical incidents rated as SAC1 to the WA Department of Health. Transfusion-related incidents and adverse events are reviewed internally by hospital safety and quality and/or transfusion committees. Product-related reactions may be reported through private pathology providers to the Blood Service.

Depending on the hospital, investigation of transfusion-related adverse events and collection of data for internal hospital reporting is undertaken by a variety of staff. These include hospital transfusion and PBM nurses, transfusion coordinators, laboratory scientists and consultant medical staff. These individuals provide leadership in the area of haemovigilance by maintaining systems for the investigation, review and management of transfusion-related adverse events, providing education for hospital staff and aligning transfusion practice with relevant national clinical guidelines and the NSQHS Standard 7.

The BloodSafe e-Learning program is promoted as an important training and education program for staff involved in transfusion in WA hospitals. WA also continues to promote the principles of PBM as a standard of care state-wide. Although formalised programs are changing in 2015, the standard of care/change in practice continues throughout the state and WA remains a resource for PBM excellence. PBM is the essence of evidence based practice regarding anaemia diagnosis, treatment and avoidance of unnecessary transfusion.

In early 2015, WA established a State Haemovigilance Committee. The Committee has broad representation from public and private sectors. A role of the Committee is to assist WA with decision making and implementation of a local model for haemovigilance. This includes consideration of a reporting tool and process, accessible state-wide, for the collection of haemovigilance data aligned with ANHDD. Implementation is intended to facilitate the generation of state-level haemovigilance reports and provision of WA data for national reporting as well as meeting the requirements of NSQHS Standard 7.

South Australia

SA has a population of 1.7 million which accounts for approximately 7.09% of the national population. SA is serviced by the nine public metropolitan hospitals and network of country hospitals and health services comprising SA Health, and the private sector. The laboratories supporting these sites are SA Pathology (comprising 7 metropolitan and 9 regional public laboratories) and four private pathology providers.

SA Health continues to use the online Datix Safety Learning System (SLS) for reporting and managing incidents and consumer feedback across the public sector. The ANHDD was taken into consideration during the development of the SLS to facilitate national haemovigilance reporting in addition to meeting general hospital requirements. The quality of the data in SLS has improved since its implementation as a consequence of increased user knowledge of the software and improvements in reporting options. Alignment with the ANHDD has improved with the recent inclusion of mandatory fields for age, sex and date of birth for all adverse events. However, review of SAC scores and free text fields is still required to interpret events and assign an ANHDD classification to each incident reported.

The private sector utilises various incident management systems which are reviewed internally via safety and quality and/or transfusion committees. At present, there is no combined registry of public and private transfusion-related adverse events.

The collection and analysis of haemovigilance data in SA is undertaken on an individual hospital/health service basis. BloodSafe Transfusion Nurse Consultants, who cover the major metropolitan hospitals and country regions, receive notification of all incidents classified under 'transfusion of blood-related problems' and participate in the reporting, review, investigation and follow-up of adverse and near-miss events.

SLS reports are generated for the hospital Blood Management Committee to inform activities in the Transfusion Quality Improvement program, including monitoring organisation-wide risk. SA Pathology is advised of blood and blood product incidents via the completion and submission of the SA Pathology Notification of Transfusion Reaction form as well as via the SLS notification system. SA Pathology is responsible for reporting to the Blood Service where appropriate. The national haemovigilance data submission from SA is limited to adverse events reported from across SA Health.

The SA Department for Health and Ageing mandates reporting of haemolytic blood transfusion reaction resulting from ABO incompatibility sentinel events through a separate sentinel event reporting process encompassing both public and private hospitals. All actual SAC1 incidents must be escalated to the Chief Executive Officer of the Local Hospital Network (LHN). In addition, SAC1 and 2 incidents are reviewed by the local Incident Review Panel or the Mortality Review committee. Recommendations arising from such reviews are directed to the relevant Blood Management Committee Chair for further action.

SA Health does not currently maintain a transfusion specific jurisdictional expert group whose role is to review, classify and assess adverse events, and validate data. Significant events are referred to general hospital or SA Health committees for review. The BloodSafe program and staff, however, continue to make a significant contribution towards blood transfusion safety and quality improvement. The work of BloodSafe Transfusion Nurse Consultants in public and private hospitals is aimed at:

- promoting the appropriate use of blood and blood products
- providing education on the safe administration of blood and blood products
- conducting audits of appropriate use of blood and blood products and
- developing tools to assist in the management, prescribing and administration of blood and blood products.

There are currently a number of haemovigilance-related activities underway that are focused on system, education and quality improvement:

- The Department has been monitoring the utilisation of red blood cells by inpatients since 2006 through the SA Blood Utilisation Study. The information from this study has been incorporated into a Reporting Tool which allows major metropolitan hospitals to better understand their red cell usage patterns.
- The Enterprise Patient Administration System (EPAS) currently being implemented across SA Health requires the development of blood and blood product transfusion orders sets. A transfusion working group is providing expert medical, scientific and nursing input into the prescribing and ordering requirements for blood and blood products. Key factors in the development include clinician friendly order sets meeting current national transfusion guidelines and legislative requirements.
- The BloodSafe Transfusion Nurse Consultants are conducting audits to monitor variability in ordering practices and compliance with Standard 7 haemovigilance activities as part of each hospital's Transfusion Quality Improvement program.
- A BloodSafe guide for Transfusion Nurses is under development, the aim of which is to ensure a standardised and consistent procedure for investigating, documenting and reporting transfusion-related incidents.
- The SA Blood Management Council has recommended that all medical, nursing, and support staff complete training provided by BloodSafe eLearning Australia with the aim of improving the recognition and reporting of adverse events.

The system for the investigation, review and management of reported blood and blood component incidents/adverse events in SA is considered effective due to the collaborative efforts of the SA Department for Health and Ageing, the Blood Service, the SA BloodSafe Program and pathology services. Some reporting gaps remain in terms of both the completeness of individual reports and the overall system coverage across SA Health.

Future plans for haemovigilance in SA include:

- development of EPAS order sets/pathways for the investigation and management of serious transfusion-related adverse events, critical bleeding and antenatal
- further engagement of the private sector in haemovigilance activities.

Tasmania

In TAS, quality and safety activities are undertaken by the blood transfusion team at each major public hospital supported by the Hospital Transfusion Committee (HTC) and local safety and quality governance. TAS is a participant in the Victorian Haemovigilance Program: 'Blood Matters'. This includes reporting to the STIR system, which is administered by the Victorian Department of Health. Tasmanian hospitals are active participants in STIR and have two representatives on the STIR Expert Group.

A state-wide incident reporting system operates across all public sector hospitals and health facilities. In 2013-14 the Electronic Incident Management System (EIMS) was replaced by the Safety Learning and Reporting System (SLRS). The new system is used at local and state-wide levels to report and manage all health care incidents as a critical component of quality improvement. When the scoping process for the replacement system was undertaken it was hoped that the new system would support direct capture and transfer of data to the STIR system but this has not been possible. Reporting to STIR remains a separate reporting process as the two systems are not aligned. Data is reported back to TAS by STIR and following review of the annual data TAS authorises STIR to report Tasmanian data to the NBA for the purposes of the National Haemovigilance Program. The provision of Tasmanian data to STIR remains the most practical option for reporting at a national level.

Reporting to SLRS is a mandatory requirement in all Tasmanian public sector hospitals. SLRS provides all public hospitals with a consistent, standard approach to incident reporting. Blood-related incidents represent approximately 1.4% of the total number of incidents reported. It is estimated that the private hospitals in TAS represent approximately 10% of the total transfusion activity in the state. All private hospitals record incidents, including blood-related incidents, to their own risk management systems, and recently some private hospitals have commenced reporting to STIR.

Many haemovigilance activities are coordinated by Blood Transfusion Nurses with positions now in place at each of the four major Tasmanian public hospitals. Blood Transfusion Nurses were funded following commencement of the national blood arrangements in order to contribute to jurisdictional requirements of the National Blood Agreement. The role of these positions includes education of clinical staff, development of policies and guidelines, conduct of audits of blood product utilisation and incident reporting and monitoring. Nursing staff undertake the required training in transfusion practice in order to meet the mandatory competency requirements. There is considerable clinical commitment to haemovigilance in TAS which is reflected in local governance and activities, participation in STIR and involvement in national clinical committees. There are good links with the Blood Service regarding haemovigilance activities.

Recent initiatives include representation from the major private hospitals on the state-wide Blood Management Group, strong promotion of the BloodSafe e-Learning program as an essential training component for all hospital staff involved in transfusion and the introduction of the Single Unit Policy.

Future haemovigilance strategies include:

- further engagement of the private sector in haemovigilance activities
- inclusion of haemovigilance reporting as a standing item on the agenda for the state-wide Blood Management Group meetings.

Australian Capital Territory

The ACT is a small jurisdiction with a population of 384,000 people, although the complete catchment covers an extensive area of south-eastern NSW that encompasses a total population of well over 500,000. The ACT is serviced by 2 public and 4 private hospitals that transfuse blood and blood products.

ACT Health aligns well to the Stewardship Statement's principle in regards to collating and managing haemovigilance data. This has been facilitated through the ACT's cross-jurisdictional collaboration with Blood Matters, Victoria and has enabled participation by ACT in the Blood Matters STIR system. The ACT's public hospitals use the RiskMan general incident reporting system to collect haemovigilance data. The reporting is mandatory if an incident is identified as a sentinel incident. Incidents are classified according to the defined severity of the outcome. The incidents rated as major or extreme outcome will require review by the highest governance level of the hospital. The system captures blood and blood product-related incidents including near misses. The classification of the incidents aligns with the STIR criteria and ANHDD.

The private hospitals currently collect and benchmark their haemovigilance data through their internal organisational quality and risk management systems.

ACT haemovigilance data, once released for the national haemovigilance report has already undergone a robust validation through a process of review and re-assessment of imputability ratings by an expert STIR panel comprised of medical and nursing clinicians and laboratory scientists (including a clinical expert from the ACT). Although the de-identified data are held and reported back to the ACT by STIR, the ACT reports into the National Blood Authority's (NBA) national haemovigilance program depending on its own assessment.

The ACT Transfusion Nurse endeavours to promote and sustain a jurisdictional approach to haemovigilance across the entire ACT health sector and has been instrumental in aligning transfusion practice across the Territory with the NBA's Patient Blood Management Guidelines and the NSQHS Standard 7.

The Transfusion Nurse provides clinical leadership in the area of haemovigilance by maintaining a robust system for the investigation, review and management of transfusion-related adverse events, providing education for staff and patients across the ACT, and the development and implementation of clinical policy aligned to national guidelines.

The BloodSafe e-Learning program is strongly promoted as a fundamental and essential training component for all staff involved in the transfusion chain at all hospitals across the ACT.

Future plans for haemovigilance in the ACT include:

- introduction of the Single Unit Policy for ACT Health during 2014–15
- working towards a robust data linkage platform for all blood and blood product usage
- alignment and further promulgation of the Patient Blood Management suite of national guidelines.

Northern Territory

The Northern Territory Government (NTG) health services' haemovigilance system includes the following elements:

- RiskMan electronic incident management system
- Transfusion reaction reports
- Transfusion Incident Review Group (TIRG)
- Blood Matters STIR system.

All NTG hospitals use a centralised incident reporting system, the RiskMan electronic incident management system, as the only incident reporting tool. The NT Health Incident Management Policy and NT Health Incident Management Guide require NTG health staff to report all incidents and near-miss events on RiskMan.

RiskMan has a specific classification for blood transfusion incidents. There are five categories under the blood transfusion classification: administration, transfusion reaction, blood product, documentation and massive transfusion, with additional sub-categories. The RiskMan system flags any transfusion incidents which are reportable to STIR. If an incident is reportable to STIR, a blood management extension is generated. The blood management extension captures the additional information required for an initial STIR report. Incidents reportable to STIR are:

- acute transfusion reaction
- delayed transfusion reaction
- transfusion-associated graft versus host disease
- transfusion-related acute lung injury
- transfusion-associated circulatory overload
- post-transfusion purpura
- post-transfusion viral infection
- bacterial/other infection
- incorrect blood component transfused
- wrong blood in tube.

The NT transfusion clinical nurse consultant (CNC) submits initial STIR reports electronically or by email, and the second level STIR reports and investigations are completed by either the transfusion CNC or a hospital quality coordinator.

In NTG hospitals a transfusion reaction report is issued with all fresh blood components. If a transfusion reaction occurs, the transfusion reaction report is completed in addition to the RiskMan report. A copy of the transfusion reaction report is sent to the laboratory with any requested specimens.

The TIRG is an expert group consisting of medical, quality, nursing and scientific representatives. The group meets monthly to review all transfusion-related incidents. TIRG members are alerted by email when a transfusion-related incident is reported on RiskMan. The group:

- collates and analyses transfusion incident data
- ensures serious transfusion incidents are investigated appropriately
- coordinates RCAs if required
- ensures transfusion incidents which meet the STIR criteria are reported to Blood Matters
- makes recommendations for transfusion practice improvement.

The TIRG reports quarterly to the NT Transfusion Committee. The five NTG hospitals participate in voluntary haemovigilance reporting to the Blood Matters STIR system through a memorandum of understanding between the Victorian Department of Health and the NT Department of Health. Each event reported to STIR is reviewed by the STIR expert group which is comprised of medical, nursing and scientific staff with expertise in transfusion (including a medical expert from the NT). Aggregate de-identified haemovigilance data is presented in STIR annual reports and is submitted directly to the NBA.

The transfusion CNC is the chair of the TIRG and provides clinical leadership in haemovigilance across all five NTG hospitals. The transfusion CNC also coordinates transfusion education for clinical staff and is responsible for developing and maintaining local guidelines which align with international and national standards, including the Australian Commission on Safety and Quality in Health Care National Safety and Quality Health Service (NSQHS) Standards. The NT executive sponsor for NSQHS Standard 7 works closely with the transfusion CNC and the NT Transfusion Committee to strengthen the NT focus on blood safety.

APPENDIX I: INTERNATIONAL CONTEXT

The first haemovigilance system[54] in Europe was initiated in France in 1994, in large part as a reaction to the human immunodeficiency virus scandal in the 1980s and early 1990s. Other European countries followed this initiative, notably the SHOT program in the UK in 1996. The French and UK systems are the most mature and continue to provide insightful data and contribute to the global improvement of quality of care. Subsequent to the adoption and implementation of the European Blood Directive (2002/98/EC) and three additional implementing directives (2004/33/EC, 2005/61/EC and 2005/62/EC), nearly all European Union countries, and many other countries internationally, have established haemovigilance systems.

The current haemovigilance systems show significant differences related to what is reported (such as all versus serious adverse events) and how the system is organised (such as voluntary versus mandatory reporting). The majority of the serious adverse reactions and events reported to the systems occurred in hospitals and the majority of preventable adverse reactions are due to human errors. Data from the UK SHOT program has drawn attention to the fact that about 50% of adverse events are due to administrative errors. Various corrective actions and success measures have improved the safety of blood products and quality of transfusion practice. One key example is the use of male only donor plasma, which has resulted in a significant reduction of TRALIs in many countries such as the UK, the Netherlands, France, Canada, Australia and New Zealand.

International Haemovigilance Network

Communication between haemovigilance systems is organised through the IHN,[55] which was formed in 2009 from the European Haemovigilance Network. The IHN provides a forum for sharing best practice and benchmarking data, as well as providing a resource for existing and new haemovigilance systems. The network started with five member countries from Europe and grew to 28, including seven from outside Europe. It now has 32 international members and six more countries are in the application stage.

International haemovigilance seminar

The IHN holds annual haemovigilance seminars for member countries and researchers. The 16th International Haemovigilance Seminar (IHS) was held in Barcelona in March 2013. The seminar covered all aspects of haemovigilance from blood donation and blood processing to blood transfusion and optimal blood use. The key topics included education and training to improve transfusion safety, audits in blood transfusion, donor selection and release criteria for cellular therapy products and the vigilance of medical devices. The meeting papers and presentations are available from the IHS website.[57]

International haemovigilance database

The IHN has established a web based international haemovigilance database—International Surveillance of Transfusion-Associated Reactions and Events (ISTARE). The goal of ISTARE is to maximise donor and recipient safety by sharing haemovigilance data and improving preventive measures throughout the world. As a member of IHN, the NBA participates in and reports on Australian haemovigilance data to the ISTARE. From 2006 to 2012, the ISTARE received 121 reports from 25 countries: 0.4% of these reports were fatal; 4.2% were life threatening; 20.0% were severe; 75.4% were non-severe.

Standard haemovigilance definitions

The INH is working in collaboration with the International Society of Blood Transfusion (ISBT) to standardise the definitions for adverse events and adverse reactions in patients. The definitions have been published in the document of Proposed Standard Definitions for Surveillance of Non-infectious Adverse Transfusion Reactions on the IHN and ISBT websites. The NBA is redeveloping the ANHDD to align with the ISBT and IHN definitions.

World Health Organization

The World Health Organization (WHO) supports haemovigilance at a global level, particularly in developing countries. The recent data from the WHO Global Database on Blood Safety showed that the number of countries which have a national haemovigilance system increased from 42 in 2004–05 to 57 in 2011.[59]

Guidance on national haemovigilance system

The WHO is drafting guidance on developing a national haemovigilance system based on output from the WHO Global Consultation on Haemovigilance 2012 and input from the IHN, ISBT and other organisations. The guidance will cover the following key elements of a national haemovigilance system:

- leadership and governance
- organisation and coordination of a haemovigilance system
- haemovigilance in the donation and provision of blood and blood products
- haemovigilance in clinical transfusion.

The guidance will include a check list to facilitate the implementation of these elements.

NOTIFY project

WHO, in collaboration with the Italian National Transplant Centre, created the NOTIFY project in 2010. The intent of the NOTIFY Library is to provide a comprehensive reference of types of serious adverse events and reactions and their underlying root causes related to medical products of human origin including organs, tissues and cells. The project has recently been extended to include adverse events related to blood and blood products.

The project also supports the development of taxonomy and case definitions. The NOTIFY library had created a taxonomy based on the European Union definitions of serious adverse reactions. The database of vigilance information collected by the project will be made publicly available on the WHO/CNT Global NOTIFY Library web site. [60]

Serious Hazards Of Transfusion

The UK SHOT program began in 1996. The evidence collected by SHOT has prompted changes in transfusion practice in the UK and contributed to the global improvement of quality and safety of care. Transfusion in the UK is very safe. The participation rate in SHOT by National Health Service organisations was 99.5% in 2013. 29 million components were issued in 2013 and very few deaths are related to transfusion. The estimated risks shown in the SHOT data are 1 in 322,580 components issued for death and 1 in 21,413 for major morbidity; the risk of transfusion-transmitted infection is much lower. Acute transfusion reactions and TACO carry the highest risk for morbidity and death. Despite the very useful information gained about transfusion reactions, the main risks remain human factors. The recommendations on reduction of errors through a 'back to basics' approach from the first annual SHOT report remain relevant today.[29,61]

Transfusion Reactions in Patients

The national haemovigilance system in the Netherlands, 'Transfusion Reactions in Patients' (TRIP), has reported annually since 2002. 98% of hospitals participated in the system in 2012. From 2006 to 2012, the total number of serious adverse reactions (imputability certain, probable or possible) was 123. The overall reporting rate is 4.0 per 1000 components reported issued for all adverse reactions and 0.16 per 1000 for serious adverse reactions. TACO accounted for the largest number of the serious reports and the administration of incorrect blood component remains a cause of avoidable morbidity in patients.

USA haemovigilance system

In the USA, it is obligatory to report all fatal transfusion reactions to the Food and Drug Administration (FDA), but no official national haemovigilance system was used until 2009. Initiated in 2006, the US Biovigilance Network is a public-private collaboration between the USA Department of Health and Human Services, including the Centers for Disease Control and Prevention, and organisations involved in blood collection, transfusion, tissue and organ transplantation.[64] The AABB Donor Hemovigilance Program is used to track and reduce the occurrence of adverse events associated with blood donation. Created through collaboration among the U.S. Department of Health and Human Services, the Armed Services Blood Program and the private sector — including AABB, America's

Blood Centers, the American Red Cross, Blood Systems, Inc. and hospital blood collection centers — the module allows participating facilities to enter data into a web-based electronic data collection system and to use that information to analyze their donor data and identify trends.[64]

The latest FDA annual report of transfusion fatalities indicates that the blood supply is safer today than at any time in history. Due to advances in donor screening, improved testing, automated data systems, and changes in transfusion medicine practices, the risks associated with blood transfusion continue to decrease in the USA. From fiscal year 2009 to 2013, 190 transfusion related deaths were reported. The most common cause of death is TRALI (74 deaths), followed by TACO (45 deaths), and bacterial infections (19 deaths).[65]

Transfusion Transmitted Injuries Surveillance System

The Transfusion Transmitted Injuries Surveillance System (TTISS) has been monitoring adverse reactions related to the transfusion of blood components in Canada since 2001. From 2006 to 2012:

- around 1.5 million transfusions of blood components were given in Canada each year
- around 80% of these transfusions were monitored by the TTISS network
- a total of 3,957 cases of transfusion-related adverse reactions were reported to the TTISS
- 41 transfusion-related deaths were reported and only one was definitely caused by transfusion
- other reports were either probably (n=12) or possibly (n=28) related to transfusion
- the leading causes of death were TRALI and TACO which accounted for 71% of the cases.[66]

APPENDIX II: DEFINITIONS IN HAEMOVIGILANCE

The following definitions and descriptions are used in the ANHDD.

Sentinel event

ABO incompatibility

The transfusion of ABO incompatible product(s) resulting in an acute haemolytic transfusion reaction. Generally major ABO red blood cell mismatches result in significant morbidity or mortality, but minor incompatibilities may be innocuous and not result in harm. Incompatible platelet and plasma transfusions may or may not result in haemolysis and harm.

Haemolytic transfusion reactions (HTR) are clinically suspected if one or more of the following is present in a temporal association with transfusion:

- fever and a variety of other symptoms (including dyspnoea, hypotension, tachycardia, flank or back pain)
- inadequate rise in post-transfusion Hb level
- drop in Hb level (≥2 g/dl within 24 hours)
- rise in LDH (≥50% within 24 hours)
- rise in bilirubin, haemoglobinuria or decrease in haptoglobin levels.

It should be noted that adverse events attributed to transfusion of ABO incompatible products are included in the Incorrect Blood Component Transfused (IBCT) category. Such events could equally be described as acute haemolytic transfusion reactions (AHTR), but the key failure is IBCT. Transfusion of ABO incompatible products to a patient is considered a 'sentinel event' and is also subject to other reporting channels outside the National Haemovigilance Program.

Other serious transfusion reactions and events

Febrile non-haemolytic transfusion reaction (FNHTR)

Presents with one or more of the following during or within 4 hours of transfusion without any other cause such as haemolytic transfusion reaction or infection:

- fever (≥38°C or change of ≥1°C from pre-transfusion level)
- chills
- cold
- rigor
- other symptoms of discomfort.

Allergic reaction

One or more of the following without hypotension, and within 24 hours of transfusion:

- rash
- allergic dyspnoea (stridor, cyanosis, wheezing)
- angioedema
- generalised pruritis
- urticaria.

Anaphylactic or anaphylactoid reaction

Allergic reaction with hypotension (drop in systolic BP ≥30mmHg) during or within 24 hours of transfusion or intractable hypotension or shock with loss of consciousness during transfusion, and without any indication of other cause.

Acute haemolytic transfusion reactions other than ABO incompatibility (AHTR)

Acute transfusion reactions occur within 24 hours of transfusion. They may have immune or non-immune aetiology.

Delayed haemolytic transfusion reaction (DHTR)

Occurs between 1 and 28 days post-transfusion, and is the result of other atypical red blood cell alloantibodies.

Transfusion-associated circulatory overload (TACO)

Features respiratory distress, tachycardia, increased blood pressure, typical signs of cardiogenic lung oedema in the chest x-ray, evidence of a positive fluid balance and/or a known compromised cardiac status during or within 12 hours after transfusion.

Transfusion-related acute lung injury (TRALI)

TRALI may be immune or non-immune. Serological confirmation is not required for diagnosis. Clinical TRALI features:

- acute respiratory distress and
- diffuse bilateral lung infiltrations in the lung radiograph and
- occurrence during or within 6 hours of completion of the transfusion and
- no evidence of transfusion-associated circulatory overload (TACO).

Transfusion transmitted infections (TTI)

Bacterial infection

Transfusion transmitted bacterial infection should be clinically suspected if:

- fever >39°C or a change of >2°C from pre-transfusion value and
- rigors and
- tachycardia >120 beats/min or a change of >40 beats/min from pre-transfusion value or a rise or drop of 30mmHg in systolic blood pressure within 4 hours of transfusion are present.

Possible transfusion transmitted bacterial infection:

- detection of bacteria by approved techniques in the transfused blood component but not in the recipient's blood or
- detection of bacteria in the recipient's blood following transfusion but not in the transfused blood component and no other reasons are ascertainable for the positive blood culture.

Confirmed transfusion transmitted bacterial infection:

- detection of the same bacterial strain in the recipient's blood and in the transfused blood product by approved techniques.

Viral infection

Following investigation, the recipient has evidence of infection post-transfusion and no clinical or laboratory evidence of infection prior to transfusion and either, at least one component received by the infected recipient was donated by a donor who had evidence of the same infection, or, at least one component received by the infected recipient was shown to have been contaminated with the virus. Reports should at least consider HIV, Hepatitis B, Hepatitis C and CMV.

Parasitic infection

Detection of the same parasite in the recipient's blood and parasite or specific antibodies in the donor blood.

Transfusion-associated graft versus host disease (TA-GVHD)

TA-GVHD clinically features the following 1–6 weeks post transfusion, with no other apparent cause:

- fever
- rash
- liver dysfunction
- diarrhoea and
- cytopenia.

TA-GVHD is confirmed by GVHD-typical biopsy and genetic analysis to show chimerism of donor and recipient lymphocytes.

Post-transfusion purpura (PTP)

Clinically features purpura and thrombocytopenia within 12 days of transfusion. PTP is confirmed by the detection of platelet specific antibodies (usually anti-HPA-1a) in the recipient's blood, and detection of the antithetical antigen on the donor platelets, or by a positive platelet X-match.

Incorrect blood component transfused (IBCT)

A patient receives a blood component destined for someone else, or receives a component not to specification. For instance, an immune compromised patient may require irradiated cellular products but receive ordinary banked blood instead. No distinction is made whether or not harm was done.

Definitions for contributory factors

Table 39: ANHDD definitions for contributory factors

Field Value	Explanatory note
None identified	No contributory factors have been attributed to the adverse event
Product characteristic	The product contributed to the reaction due to an inherent but not necessarily faulty characteristic (such as an allergic or anaphylactic reaction to a product; unknown significance of anti-HLA antibodies)
Transfusion in emergency setting	The transfusion was administered under emergency conditions
Deliberate clinical decision	The decision to transfuse was made with clinical forethought, and with due consideration of the possibility of a transfusion reaction
Prescribing/ordering	Event(s) during prescribing or ordering the product contributed to the transfusion reaction
Specimen collection/labelling	Event(s) during specimen collection or labelling contributed to the transfusion reaction
Laboratory (testing/dispensing)	Event(s) during laboratory pre-transfusion testing or dispensing of the product contributed to the transfusion reaction
Transport, storage, handling	Event(s) during the transport, storage or handling of the product contributed to the transfusion reaction
Administration of product	Event(s) during the administration of the product contributed to the transfusion reaction
Indications did not meet hospital transfusion guidelines	The clinical indications for transfusion did not meet hospital transfusion guidelines
Did not adhere to hospital transfusion procedures	The transfusion procedures did not adhere to hospital transfusion procedures
Other (specify)	Free-text field. Please specify the event(s) that contributed to the adverse transfusion reaction

Notes
1. Multiple entries allowed
2. At least one value to be returned

APPENDIX III: DEFINITIONS OF DONOR ADVERSE EVENTS

Table 40: Definitions of donor adverse events

Event Type	Definition	
Vasovagal	Vasovagal reaction is a reflex of the involuntary nervous system that causes the heart to slow down whilst causing the blood vessels in the legs to dilate (expand). The widening of these blood vessels causes blood to pool in the legs, reducing the amount of blood being supplied to the brain. When the brain is deprived of oxygen, a fainting episode is likely to occur.	
	Fainting is a loss of consciousness caused by a lack of blood supply to the brain, also known as syncope.	
	Pre-faint refers to symptoms such as dizziness, sweating, muffled hearing and nausea that can result from a vasovagal reaction. If these symptoms do not progress to loss of consciousness, the reaction can be termed 'pre-faint' or 'pre-syncope'.	
	Mild	A donor experiences symptoms lasting less than 15 minutes without fainting (loss of consciousness) or seizure.
	Moderate	A donor experiences symptoms lasting at least 15 minutes but less than 1 hour without fainting (loss of consciousness) or convulsions.
	Severe	A donor who faints experiencing loss of consciousness for ANY length of time with or without convulsions (seizures) or pre-faint symptoms that persist for more than 1 hour.
	Delayed	Donors who experience ANY of the signs and symptoms associated with vasovagal, pre-fainting and fainting ANYTIME AFTER they have left a Blood Service collection site. Events that occur in the refreshment area or bathroom of a Blood Service collection site are not classified as 'delayed'. There is a high rate of injury associated with delayed reactions as they can occur without warning up to 6 hours after the donation while the donor is travelling home, working or driving.
	Complicated	A donor experiences a fall or incident as a result of a vasovagal reaction causing injury. For example a donor may hit their head as they fall, lacerating their forehead and fracturing their jaw. These events can occur on- or off-site.
Haematoma	A bruise or haematoma is bleeding or a collection of blood under the skin. It is formed when blood leaks from the vein into the surrounding tissues. The following are reported: ▪ 5 centimetres in diameter or greater ▪ less than 5 centimetres in diameter, but associated with persistent pain or symptoms of nerve injury or irritation.	
Arterial puncture	When a needle is incorrectly inserted into the artery instead of the vein.	

Event Type	Definition
Extravasation	Occurs when a large volume of blood or fluid leaks under pressure, out of the vein wall into the surrounding tissue and forearm.
Compartment syndrome	Develops when leaked blood or fluid compresses nerves, blood vessels and muscle. An increase in pressure results in the decrease of blood supply to the muscle and tissue leading to necrosis (tissue death).
Nerve injury	Direct nerve injury or trauma occurs when the needle cuts or damages the nerve or the sheath of the nerve. Indirect nerve injury, trauma or irritation is caused by pressure from a bruise/haematoma or swelling pushing against the nerve.
Post donation thrombosis	Thrombosis is the formation of a blood clot. Post-donation thrombosis is the formation of a blood clot in a deep vein (such as the axillary vein) with very little inflammatory reaction in the vein wall.
Thrombophlebitis	Phlebitis is inflammation of a vein. Thrombophlebitis is inflammation of a vein associated with the formation of a blood clot.
Serious	Any event that requires external referral to a hospital, general practitioner or any other registered medical practitioner.

Source: Blood Service 2013

Table 41: Alignment of events between Australian and international categories

Australian Category Description	Relevant International Category
Air Embolism	Air Embolism
Allergic Reaction Mild	Generalised Allergic Reaction
Allergic/Anaphylactic Reaction—Progressive to Severe	Generalised Allergic Reaction
Allergic/Anaphylactic Reaction—Severe	Generalised Allergic Reaction
Arterial Puncture	Arterial Puncture
Cardiac Arrest	Other
Chest Pain	Other
Citrate Toxicity—Mild	Citrate Reaction
Citrate Toxicity—Moderate	Citrate Reaction
Citrate Toxicity—Severe	Citrate Reaction
Death of Donor	Other
Delayed Bleeding	Delayed Bleeding
Suspected Haemolysis	Haemolysis
Extravasation of Fluid / Compartment Syndrome	Other
Haematoma	Haematoma
Local Allergy	Allergy (Local)
Nerve Injury	Nerve Injury
Nerve Irritation	Nerve Irritation
Not Reportable Event	Not Reportable Event
Omitted Anticoagulant—Moderate	Other
Omitted Anticoagulant—Severe	Other
Other Injury	Other
Painful Arm	Painful Arm
Post Donation Thrombosis—Axillary Vein Involvement	Other
Post Donation Thrombosis—No Axillary Vein Involvement	Other
Tendon Injury	Tendon Injury
Thrombophlebitis	Thrombophlebitis
Vasovagal Reaction—Mild	Immediate Vasovagal Reaction
Vasovagal Reaction—Mild & Delayed	Delayed Vasovagal Reaction
Vasovagal Reaction—Moderate	Immediate Vasovagal Reaction
Vasovagal Reaction—Moderate & Complicated	Immediate Vasovagal Reaction with Injury
Vasovagal Reaction—Moderate & Delayed	Delayed Vasovagal Reaction
Vasovagal Reaction—Moderate & Delayed & Complicated	Delayed Vasovagal Reaction with Injury
Vasovagal Reaction—Severe	Immediate Vasovagal Reaction
Vasovagal Reaction—Severe & Complicated	Immediate Vasovagal Reaction with Injury
Vasovagal Reaction—Severe & Delayed	Delayed Vasovagal Reaction
Vasovagal Reaction—Severe & Delayed & Complicated	Delayed Vasovagal Reaction with Injury
Wrong Solution Administered	Other

Source: Blood Service 2013

APPENDIX IV: INCIDENT SEVERITY RATING AND REPORTING

New South Wales

All NSW public hospitals use the Incident Information Management System (IIMS) for clinical incident reporting. Entered incidents are rated for outcome severity at the local level using a Safety Assessment Code (SAC). There are four SAC ratings, ranging from SAC1 (extreme risk/harm) to SAC4 (low risk/harm).

There is a requirement that once confirmed as a SAC1 incident, a notification to the NSW Ministry of Health and the NSW CEC (a Reportable Incident Brief) must be attended within 24 hours, and the final report is to be submitted within 70 days. All SAC1 incidents are subject to a thorough RCA, to determine causality and identify opportunities to make services safer.

Incidents other than SAC1 are managed at the local level, and further collation and analysis is undertaken at the unit, hospital, Local Health District and State level to identify opportunities for local and state wide improvement.

Further information on Incident Management in NSW, including those related to blood and blood products, can be found in the NSW Health Incident Management Policy document at: http://www0.health.nsw.gov.au/policies/pd/2014/pdf/PD2014_004.pdf

Victoria

The Victorian public hospitals use the VHIMS for incident reporting. The outcome severity of an incident is measured by an Incident Severity Rating (ISR). The ISR is derived from the degree of impact, level of care and treatment required and has four ratings:

- ISR1: Severe/death
- ISR2: Moderate
- ISR3: Mild
- ISR4: No harm/near miss.

The STIR program collects and reviews transfusion related incident data for participating hospitals from VIC, TAS, NT and ACT.

Health services, on notification of an incident to STIR, provide a severity rating based on the VHIMS definition. Following expert review, a patient outcome is assigned that aligns with the ISR ratings. For the purpose of STIR, near miss and IBCT may be assigned a severity rating based on the realistic potential to result in unexpected death or permanent disabling injury.

To produce the clinical outcome severity required for the national haemovigilance reports as defined in the ANHDD, validated data is run through an algorithm based on the expert review severity rating and taking into consideration reported death and ICU admission due to transfusion (Figure 9).

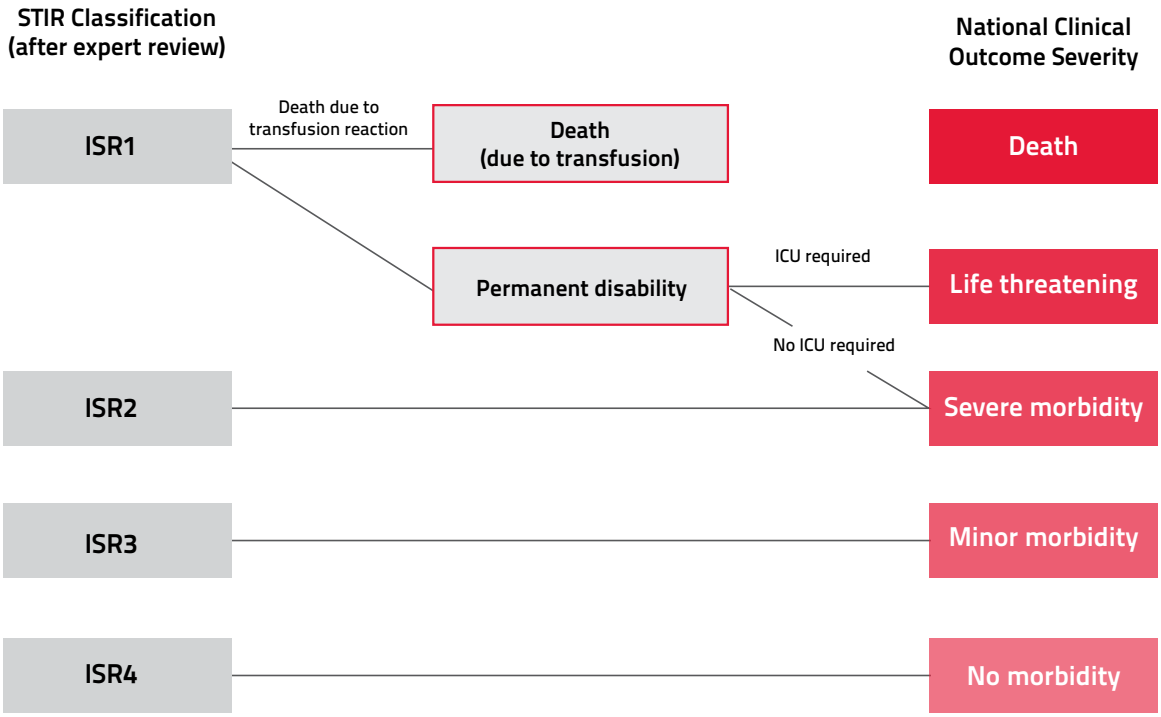


Figure 9: STIR classification and ANHDD clinical outcome severity

Reporting requirements for ISR incidents

ISR incidents and sentinel events

- Health services report all haemolytic blood transfusion reactions resulting from ABO incompatibility to the Department of Health Sentinel Event Program within three days of the incident occurring.
  Report templates are available at: http://www.health.vic.gov.au/clinrisk/sentinel/ser
- Heath services conduct RCA for each ISR1 incident or sentinel event.
- The final de-identified RCA summary report is provided to the department within 60 days of notification.
- The RCA findings should be documented on the RCA summary report which includes a Risk Reduction Action Plan (RRAP) and RCA Report Form.
- The Department of Health reviews and feeds back on submitted RCAs. The de-identified RCA and health service recommendations are also sent to the STIR Expert Group for review and comment with any additional recommendations reported back to the health service by the Department of Health.
- Health services are to confirm that they have completed the actions identified in the RRAP.
- The RRAP feedback report template documenting the completed actions is to be submitted to the Department of Health.

Other ISR incidents

- All other ISR1 and ISR2 incidents require a detailed investigation of the incident preferably using the in-depth case review methodology.
- The investigation of ISR3 and ISR4 incidents can be undertaken at the local level but management responsibility for the investigation or review process must be assigned.
- Reports and analysis of aggregate ISR3 and ISR4 incidents should be an agenda item for the ward, department or unit on a regular basis and are often reported to the hospital Transfusion Committee or equivalent.

Queensland

The QLD public hospitals use a clinical incident reporting system (PRIME) for clinical incident reporting. The incidents are identified and reported according to a SAC. The SAC is dependent on the consequence of the incident on the patient and has three scores:

- SAC1: Death or permanent loss of function
- SAC2: Patient with temporary loss of function
- SAC3: Patient with minor or no injury.

Queensland Health has implemented a joint NBA/QLD Tool to help both public and private hospitals with haemovigilance data collection and reporting. When reporting adverse transfusion events using the new tools, the events are assessed and scored for outcome severity using a Grading and a SAC rating. The four ratings of the Grading match closely to the SAC scores and align exactly with the clinical outcome severity defined in the ANHDD.

Table 42: QLD Grading, SAC, and ANHDD clinical outcome severity

Grading	SAC	ANHDD
Grade 0 No morbidity	SAC3	No morbidity
Grade 1 Minor morbidity	SAC3	Minor morbidity
Grade 2 Severe morbidity	SAC2	Severe morbidity
Grade 3 Life threatening	SAC1	Life threatening
Grade 4 Death	SAC1	Death
n/a Outcome not available		Outcome not available

Reporting requirements for SAC incidents, sentinel events and reportable events

Public health facilities

SAC1, sentinel and reportable events:

- Health services must report all SAC1 and sentinel events to the QLD Health Patient Safety Unit (PSU) within one business day of a service becoming aware of the incident.
- An analysis must be performed for the reported SAC1 and sentinel incidents.
- The analysis report shall be submitted to the PSU within 90 calendar days of the incident being reported.
- Mandatory formal open disclosure is activated and clinician disclosure performed for SAC1 events.
- Defined reportable event notifications must be sent to the Health Ombudsman within 15 business days under s26 of the *Health Ombudsman Act 2013.*
- Under the *Hospital and Health Boards Act 2011,* if RCA of a reportable event is conducted, documentation needs to be submitted to the commissioning authority that appointed the RCA team members as soon as is practical after completion of the report. The commissioning authority must provide the report to the Health Ombudsman as soon as is practical after receiving the report.

SAC2 and SAC3 incidents

- Hospital line managers work with their teams to identify and implement corrective actions rapidly, without requiring an elaborate process.
- Open disclosure is required if harm occurs.

Licensed private health facilities

Sentinel and reportable events

- Private health facilities are requested to report defined sentinel events to the Chief Health Officer within two working days of a service becoming aware of the incident.
- Defined reportable event notifications must be sent to the Health Ombudsman within 15 business days under s26 of the Health Ombudsman Act 2013.
- Under the Hospital and Health Boards Act 2011, if RCA of a reportable event is conducted, documentation needs to be submitted to the commissioning authority that appointed the RCA team members as soon as is practical after completion of the report. The commissioning authority must provide the report to the Chief Health Officer and the Health Ombudsman as soon as is practical after receiving the report.

Clinical incidents

- Hospital line managers work with their teams to identify and implement corrective actions rapidly, without requiring an elaborate process.
- Open disclosure is required if harm occurs.

South Australia

In SA, public hospitals use the Safety Learning System (SLS) for incident reporting. The outcome severity of an incident is classified using a SAC. The SAC rating (level 1 to 4) is derived from a matrix matching severity with likelihood of recurrence.

The SAC rating guides the level of investigation and management that is undertaken for each incident. SAC1 incidents require review and investigation, and include sentinel events, while incidents with a lower SAC rating (3 and 4) may be aggregated into common incident types and reviewed utilising the clinical practice improvement methodology to achieve system improvement.

- SAC1: Extreme risk
- SAC2: High risk
- SAC3: Medium risk
- SAC4: Low risk

The mappings from the SAC scores or SAC consequences to the outcome severity categories defined in the ANHDD are not straightforward. Comparison of the definitions used for SAC and the ANHDD highlight a number of differences. For example, a SAC consequence of 'moderate' does not map to the ANHDD definition of minor or severe morbidity. Similarly, a SAC sentinel event (extreme consequence) does not always result in a life threatening outcome or death as defined by the ANHDD.

In addition to clinical and patient outcomes, the SAC consequence classification also takes into account staff, visitor, financial and environmental factors related to the incident being reported. The process of preparing SA haemovigilance data for national reporting requires a senior data analyst to review the details of each individual incident reported, and consequently apply the most appropriate ANHDD definition, irrespective of the SAC score entered into SLS.

Reporting requirements for SAC incidents

SAC1 incidents including sentinel events

- All SAC1 incidents must be reported within 24 hours of knowledge of the event.
- SAC1 incidents confirmed by a manager are escalated to the Chief Executive Officer of the Local Health Network.
- Confirmed SAC1 incidents require a detailed and thorough investigation/review and a level 1 open disclosure response. RCA is conducted for the reported incidents.
- The Safety and Quality/Clinical Governance Unit must confirm the SAC1/Sentinel Event status of the incident.

Other SAC incidents

- RCA may be conducted for SAC2 incidents which fall into the definition of an adverse event. The outcome of the investigation should be entered into the SAC 1 investigation Panel of Safety Learning System.
- Investigation or review of SAC3 and SAC4 events are managed at a local level.

Western Australia

WA public hospitals and health services use the online DATIX CIMS for clinical incident notification and management. Incidents are measured by a SAC rating. The SAC is based on the actual or potential consequence to the patient. The SAC has three ratings. SAC1 incidents include sentinel events.

- SAC1: All clinical incidents/near misses where serious harm or death is/could be specifically caused by health care rather than the patient's underlying condition or illness.
- SAC2: All clinical incidents/near misses where moderate harm is/could be specifically caused by health care rather than the patient's underlying condition or illness.
- SAC3: All clinical incidents/near misses where minimal or no harm is/could be specifically caused by health care rather than the patient's underlying condition or illness.

While WA has not to-date contributed data to the national haemovigilance reports, the SAC ratings align with the clinical outcome severity defined in the ANHDD.

Table 43: WA SAC and ANHDD clinical outcome severity

SAC	ANHDD
SAC1	Death Life threatening
SAC2	Severe morbidity
SAC3	Minor morbidity No morbidity

Reporting requirements for SAC incidents

SAC1 incidents including sentinel events

- Notification of a SAC1 clinical incident is required to be submitted to DATIX CIMS (for public facilities) or equivalent (for private health facilities/organisations) by the end of the notifier's work day.
- Mandatory reporting of SAC1 clinical incidents into DATIX CIMS.
- Health services notify the WA Health Patient Safety Surveillance Unit (PSSU) of all SAC1 clinical incidents (including sentinel events) within seven working days of the event's occurrence.
    - Notification is via DATIX CIMS for public sites.
    - Private health facilities/organisations use the SAC1 Clinical Incident Notification Form (available at http://ww2.health.wa.gov.au/Corporate/Articles/S_T/Severity-assessment-codes).
- Appropriate investigation for the reported incident(s) is conducted. Findings from the investigation(s) are reported to the PSSU within 28 working days of the event notification.
- Health Services are required to implement and evaluate recommendations from clinical incident investigations within six months of completing the investigation report.
- Health Services are also required to provide report updates to the PSSU on completed and evaluated SAC1 clinical incident recommendations on a six monthly basis.

Other SAC incidents

- Health Services should have in place processes for the reporting and follow-up of SAC2 and SAC3 clinical incidents.
- For public health facilities there is mandatory reporting of SAC2 clinical incidents into DATIX CIMS
- SAC2 and SAC3 clinical incidents require the completion of investigation and actions taken within 60 working days of the clinical incident being notified.
- The completion of the clinical incident form (notification and investigation sections) may be submitted as the final report for SAC2 and SAC3 clinical incidents.

Further information on Clinical Incident Management in WA can be found in the WA Health Clinical Incident Management Policy document at: http://www.safetyandquality.health.wa.gov.au/clinical_incid_man/aims.cfm

Tasmania

In TAS, all public hospitals use the SRLS to report clinical incidents. Incidents including blood related incidents are classified using a SAC. The SAC is based on the immediate consequence of the event and the likelihood of recurrence of incidents. The SAC has four scores and SAC1 incidents include sentinel events. ABO incompatibility is a sentinel event for blood and blood products.

- SAC1: Extreme risk
- SAC2: High risk
- SAC3: Medium risk
- SAC4: Minimum risk

Tasmanian public hospitals also participate in the STIR Program for national haemovigilance reporting. Table 44 shows that the SAC aligns with the clinical outcome severity defined in the ANHDD. However, the mappings from the SAC scores to ANHDD categories are not straightforward because the SAC scores are difficult to interpret. In contrast, the consequence categories (serious, major, moderate, minor, minimum) which are used to calculate the SAC scores can be mapped to the ANHDD categories.

Table 44: Tasmanian SAC and ANHDD clinical outcome severity

SAC	ANHDD
SAC1	Death Life threatening
SAC2	Severe morbidity
SAC3	Minor morbidity
SAC4	No morbidity

Reporting requirements for SAC incidents

SAC1 and SAC2 incidents

- Health services report all SAC1 and SAC2 incidents within 24 hours of occurrence.
- The incidents are referred to a Weekly Incident Panel comprising staff from the Safety and Quality Unit. This panel decides whether the event should go before the Serious Incident Panel for review.

Other SAC incidents

- Health services provide a report on SAC3 and SAC4 incidents through routine Core Reports.
- SAC3 and SAC4 incidents, which used to be managed by the Transfusion Nurse Consultant, are now required to be managed by the Nurse Unit Manager of the area where the incident occurred.

Northern Territory

NTG hospitals use the RiskMan electronic incident management system for clinical incident reporting. RiskMan uses an ISR system to classify clinical incidents. There are five ISR score levels which measure the severity of the impact caused to the person affected following an incident, ISR1 being the highest or most severe (including sentinel events) and ISR5 being the lowest or insignificant (including near misses).

- ISR1 (catastrophic): Death or permanent loss or reduction of functioning and recovery is unlikely. Includes sentinel events.
- ISR2 (major): Significant harm or impact. Loss or reduction in functioning is temporary and full recovery is expected.
- ISR3 (moderate): Harm which may require a higher level of care or observation. No loss or reduction in function.
- ISR4 (minor): Harm is minimal. Additional level of care not required.
- ISR5 (insignificant): No harm. Includes near misses.

NTG hospitals also participate in the STIR Program for national haemovigilance reporting. Table 45 shows how the NT ISR system aligns with the clinical outcome severity defined in the ANHDD.

Table 45: NT ISR Scores and ANHDD clinical outcome severity

ISR	ANHDD
ISR1: Catastrophic	Death Life threatening
ISR2: Major	Severe morbidity
ISR3: Moderate	Minor morbidity
ISR4: Minor	Minor morbidity
ISR5: Insignificant	No morbidity

Reporting requirements for ISR incidents

ISR1: Catastrophic incidents including sentinel events

For both ISR1 and sentinel events, the Department of Health's Clinical Safety & Quality Branch must be notified as soon as practicable or at least within three days of the incident being identified.

All ISR1 incidents must be reviewed by the organisation to determine opportunities for system improvement. On identification of an ISR1 incident, a review using an appropriate methodology such as RCA is undertaken to explore causation and identify contributing factors, and the following notifications are made:

- The Chief Operating Officer/Executive Director commissions the RCA team and the review terms of reference.
- The summary report of the analysis is presented to the team involved with care of the patient. The outcomes are also presented or made available at relevant staff meetings to ensure staff are aware of the factors contributing to the incident and the action being taken to improve safety.
- The final de-identified RCA summary report is to be provided to the Clinical Safety & Quality Branch within 60 calendar days of notification.
- Recommendations from the RCA report are linked to the health service's risk register. This ensures continuity of monitoring of both the evaluation and effectiveness of the recommended actions as a corporate risk management strategy.

ISR2 incidents

All ISR2 incidents require a detailed analysis of the incident using an appropriate methodology such as in-depth case review, or a modified version of RCA. Responsibility for reporting ISR2 incident reviews is assigned to a designated senior manager in order to link into the health service safety and quality governance policies and procedures. All complete ISR2 case reviews must be submitted to the organisation's safety and quality committee for consideration.

ISR3, ISR4 and ISR5 incidents

The analysis of ISR3, ISR4 and ISR5 incidents can be undertaken at the local level but management responsibility for the analysis or review process must be assigned.

Australian Capital Territory

The ACT's public hospitals use the RiskMan general incident reporting system for clinical incident reporting. The system captures blood and blood product related incidents including near misses. The reported incidents are classified using an incident outcome rating (IOR). The IOR is based on the severity of outcome and has five ratings for clinical incidents:

- Extreme: Patient death
- Major: Major and permanent loss of function
- Moderate: Temporary loss of function
- Minor: Minor injury
- Insignificant: No injury.

Extreme incidents include sentinel events. A significant incident is an incident with an extreme or major outcome occurring in relation to Health Directorate services and care. Significant incidents require escalation.

The ACT's hospitals also participate in the STIR Program for national haemovigilance reporting. The IOR aligns with the clinical outcome severity defined in ANHDD (Table 46).

Table 46: ACT and ANHDD clinical outcome severity

Clinical outcome	ANHDD
Extreme	Death
Major	Life threatening Severe morbidity
Moderate	Minor morbidity
Minor	Minor morbidity
Insignificant	No morbidity

Reporting requirements for incidents

Significant incidents

- All significant incidents must be notified verbally to the Director General within 12 hours and an electronic incident report must be submitted through RiskMan within 1 working day of the incident occurring.
- All significant incidents undergo an in depth investigation by or after consultation with the Health Directorate's HealthCARE Improvement Division.
- A copy of the initial significant incident report will be sent to the relevant Executive Director.
- The Director General and/or Deputy Director General may provide feedback when a report is submitted.

Other incidents

- RiskMan is the electronic incident reporting system available to and accessible by all staff within ACT Health for notifying incidents. Staff are encouraged to notify incidents as soon as possible and practical following the incident.
- Managers are responsible for reviewing all incidents submitted by staff who report to them within 5 working days, undertaking local actions in a timely manner, and documenting these in RiskMan.

ABBREVIATIONS AND ACRONYMS

AAPP	Australian Association of Pathology Practices
ABDR	Australian Bleeding Disorders Registry
ABO	The human red cell ABO blood group system
ABS	Australian Bureau of Statistics
ACHI	Australian Classification of Health Interventions
ACSQHC	Australian Commission on Safety and Quality in Health Care
ACT	Australian Capital Territory
AHCDO	Australian Haemophilia Centre Directors' Organisation
AIHW	Australian Institute of Health and Welfare
AIMS	Advanced Incident Management System
ALI	Acute lung injury
ANF	Australian Nursing Federation
ANHDD	Australian National Haemovigilance Data Dictionary
ANZCA	Australian and New Zealand College of Anaesthetists
ANZSBT	Australian and New Zealand Society of Blood Transfusion
APHA	Australian Private Hospitals Association
ARCBS	Australian Red Cross Blood Service (Blood Service)
ASBT	Australian Society of Blood Transfusion
ASTH	Australian Society of Thrombosis and Haemostasis
BCSH	British Committee for Standards in Haematology
BeST	Better Safer Transfusion Program
BMAC	Blood Matters Advisory Committee
BP	Blood pressure
CCF	Congestive cardiac failure
CEC	Clinical Excellence Commission, New South Wales
CIMS	Clinical Incident Monitoring System
CMV	Cytomegalovirus
CNC	Clinical Nurse Consultant
CXR	Chest x-ray
DAT	Direct Antiglobulin Test
DHTR	Delayed haemolytic transfusion reaction
DIC	Disseminated intravascular coagulation

DM	Data Manager
EAACI	European Academy of Allergy and Clinical Immunology
EHN	European Haemovigilance Network (now IHN)
EIMS	Electronic Incident Management System
EPAS	Enterprise Patient Administration System
EQuIP	Evaluation and Quality Improvement Program
FDA	Food and Drug Administration, US
FFP	Fresh frozen plasma
FNHTR	Febrile non-haemolytic transfusion reaction
GI	Gastrointestinal
GP	General practitioner
HAC	Haemovigilance Advisory Committee
Hb	Haemoglobin
HCV	Hepatitis C Virus
HHS	Hospital and Health Service
HIT	Healthcare Incident Type
HIV	Human immunodeficiency virus
HLA	Human leucocyte antigen
HNA	Human neutrophil alloantigens
HPWG	Haemovigilance Project Working Group
HR	Heart rate
HTC	Hospital Transfusion Committee
HTLV	Human T-cell lymphotropic virus
HTR	Haemolytic transfusion reaction
IBCT	Incorrect blood component transfused
ICD-10-AM	International Classification of Diseases 10th revision Australian Modification
IHN	International Haemovigilance Network (previously EHN)
IIMS	Incident Information Management System
IOR	Incident outcome rating
ISBT	International Society for Blood Transfusion
ISTARE	International Surveillance of Transfusion-Associated Reactions and Events
JBC	Jurisdictional Blood Committee
JMO	Junior Medical Officer
LHN	Local Hospital Network
MB-FFP	Methylene blue treated fresh frozen plasma
MET	Medical Emergency Team

NBA	National Blood Authority
NCOPP	National Coalition of Public Pathology
NHMD	National Hospital Morbidity Database (AIHW)
NHMRC	National Health and Medical Research Council
NHSBT	National Health Service Blood and Transfusion
NPAAC	National Pathology Accreditation Advisory Council
NSQHS	National Safety and Quality Health Service
NSW	New South Wales
NT	Northern Territory
NTG	Northern Territory Government
NTTC	Northern Territory Transfusion Committee
OECD	Organisation for Economic Co-operation and Development
PBM	Patient Blood Management
PR	Pulse rate
PRIME	Queensland Health incident reporting system
PTP	Post transfusion purpura
Q&S	Quality and Safety
QBMP	Queensland Blood Management Program
QiiT	Queensland Incidents in Transfusion
QLD	Queensland
RACS	Royal Australian College of Surgeons
RBC	Red blood cell
RCA	Root cause analysis
RCPA	Royal College of Pathologists of Australasia
RFID	Radio Frequency Identification
RR	Respiratory rate
SA	South Australia
SAC	Safety Assessment Code
SHOT	Serious Hazards of Transfusion (UK)
SLS	Safety Learning System
STIR	Serious Transfusion Incident Reporting
TAS	Tasmania
TACO	Transfusion-associated circulatory overload
TA-GVHD	Transfusion-associated graft versus host disease
TGA	Therapeutic Goods Administration
TIRG	Transfusion Incident Review Group

TNC	Transfusion Nurse Consultant
TPE	Therapeutic plasma exchange
TRALI	Transfusion-related acute lung injury
TRIP	Transfusion Reaction in Patients
TTI	Transfusion transmitted infection
TTISS	Transfusion Transmitted Injuries Surveillance System
TTP	Thrombotic thrombocytopenic purpura
WA	Western Australia
WBIT	Wrong blood in tube
WHO	World Health Organization
VHIMS	Victorian Health Incident Management System
VIC	Victoria
UK	United Kingdom
USA	United States of America

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Queensland Health

SA Health BloodSafe Program

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