NATIONAL BLOOD AUTHORITY
AUSTRALIA

AUSTRALIAN HAEMOVIGILANCE REPORT

A Report by the
National Blood Authority
Haemovigilance Advisory
Committee

DATA FOR
2009-10 AND 2010-11

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PART 03 DONOR VIGILANCE was contributed by the Australian Red Cross Blood Service.

MESSAGE FROM THE GENERAL MANAGER OF THE NATIONAL BLOOD AUTHORITY

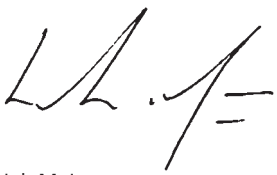
On behalf of the National Blood Authority (NBA), I am pleased to present the third Australian Haemovigilance Report. This report provides information on transfusion-related adverse events between July 2009 and June 2011 and donation-related adverse events between July 2011 and June 2012. It is a valuable resource for the clinical community and for governments.

Significant progress has occurred in the blood sector since the second Australian Haemovigilance Report. 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. The NBA and blood sector stakeholders assisted the Australian Commission on Safety and Quality in Health Care (ACSQHC) to develop National Safety and Quality Health Service (NSQHS) Standard 7 - Blood and Blood Products. The intention of this standard is to ensure that the patients who receive blood and blood products do so appropriately and safely; haemovigilance is a key feature of the standard.

Nationally consistent and complete data, and the validation of incident reports, are crucial to haemovigilance activities. The NBA is currently conducting work to scope a national haemovigilance system which would support and enhance these activities. The scoping exercise will deliver a full understanding of the requirements and management options for a national system, and will result in a business case that will be presented to governments at the Jurisdictional Blood Committee.

To further promote haemovigilance activities in Australia, the NBA intends to extend the scope of the National Haemovigilance Program to all blood and blood products that are supplied and distributed under the National Blood Agreement, including fresh blood, plasma derived and recombinant products.

The third 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 third 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 and usage. The report also delivers 10 key recommendations in the areas of:

- National blood quality and safety initiatives
- Reducing human errors
- Data standards
- Reporting capacity.

Donor vigilance data for 2011-12

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 a new section to present the donor vigilance data contributed by the Australian Red Cross Blood Service (Blood Service).

During 2011-12, there was a total of 1.3 million donations, including 0.9 million whole blood donations, 0.36 million plasma donations and 0.04 million platelet donations. There were 29,525 event reports in 2011-12, with only 704 of these classified as serious adverse events. The overall reported ratio of donation-related adverse events was 1:45 in 2011-12. 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 and usage data

There were 2.3 million components of fresh blood products issued in Australia in 2009-10 and 2010-11. Red blood cells (RBC) accounted for about two-thirds of all issues. The demand for RBC over the last few years has been slowing due to improvements in appropriate use; the issues of RBC per 1000 population decreased from 36.31 in 2007-08 to 36.09 in 2010-11. The demand for fresh frozen plasma (FFP) also decreased during the same period. In contrast, the demand for platelets and cryoprecipitate units rose steadily over the past four years to 2010-11.

The Australian and international data shows, despite an ageing population, the demand for RBC may not increase as much as predicted in other studies and further deceases in surgical RBC use may be achievable. However, the ageing population is likely to increase demand for medical (as opposed to surgical) use of fresh blood components.

Haemovigilance data for 2009-10 and 2010-11

The NBA National Haemovigilance Program and Haemovigilance Advisory Committee (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 (ANHDD).

This report includes validated adverse event data from state level systems, including the BloodSafe program in South Australia (SA), Queensland's (QLD) Incidents in Transfusion program (QiiT was decommissioned in 2013 due to the restructure of Queensland's public health system) and Victoria's (VIC) Blood Matters Serious Transfusion Incident Reporting (STIR) program. STIR also supports haemovigilance in Tasmania (TAS), the Australian Capital Territory (ACT) and the Northern Territory (NT). New South Wales (NSW) also provided limited non-validated haemovigilance data for 2009-11. Western Australia (WA) is the only jurisdiction not contributing to the national dataset for the reporting period of this report from July 2009 to June 2011.

There were 1207 adverse events reported to the National Haemovigilance Program from 2008-09 to 2010-11. The number of reports increased significantly from 294 in 2008-09 to 582 in 2010-11 likely due to the improved adverse event reporting from NSW and other states and territories. The most frequently reported adverse events are febrile non-haemolytic transfusion reactions (FNHTR) and severe allergic reactions, representing 52% and 26% of all reports respectively. The first three confirmed cases of post-transfusion purpura (PTP) were reported in 2009-10 and 2010-11. The data for transfusion-associated circulatory overload (TACO), transfusion-related acute lung injury (TRALI), and delayed haemolytic transfusion reaction (DHTR) indicates that these adverse events remain largely under-reported. Despite the large increase in the number of reports, there were no deaths caused by transfusion-related adverse events in 2009-10 and 2010-11; there were 2 such deaths in 2008-09. The number of life threatening cases also dropped significantly for most adverse event types during the same period.

Adverse event	2008-09	2009-10	2010-11	All reports	
				Number	Per cent
FNHTR	154	158	321	633	52.4%
Severe allergic reaction	87	84	142	313	25.9%
IBCT	22	23	30	75	6.2%
Anaphylactoid or anaphylactic reaction	8	12	33	53	4.4%
TACO	6	12	24	42	3.5%
DHTR	4	8	10	22	1.8%
TTI	3	18	11	32	2.7%
AHTR	7	6	2	15	1.2%
TRALI	3	8	8	19	1.6%
PTP		2	1	3	0.2%
Total number of reports	**294**	**331**	**582**	**1207**	**100%**

Source: NBA

Recommendations

The NBA, in conjunction with the HAC, makes 10 recommendations in this report 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

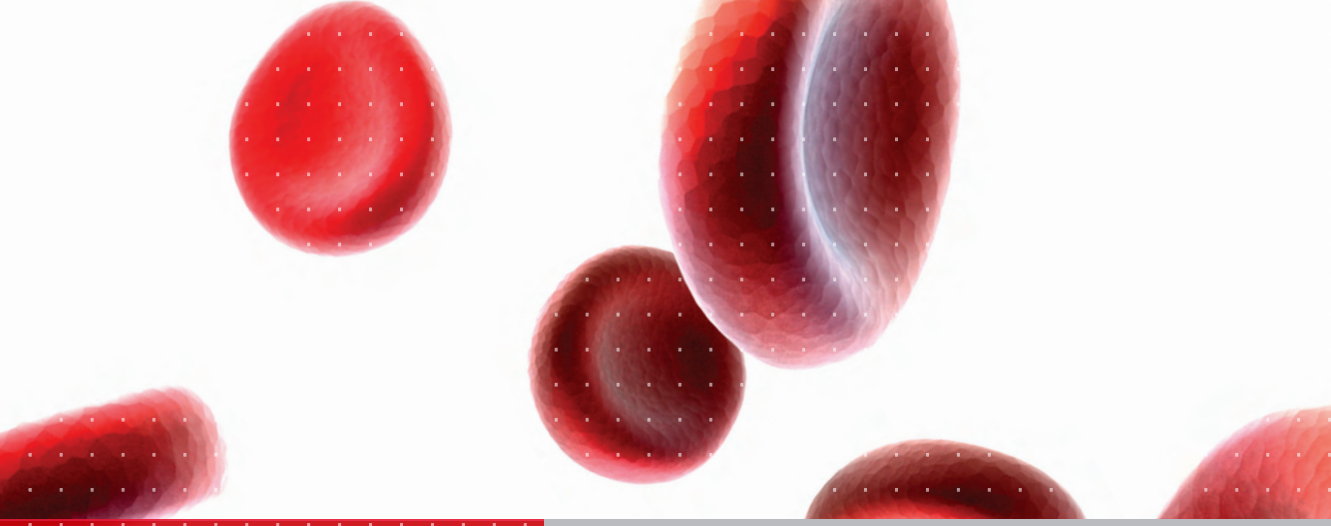
Data standards

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. Conduct a scoping exercise for a national haemovigilance system
10. Maintain and improve existing capacities for haemovigilance data reporting.

BLOOD USE AND HAEMOVIGILANCE SYSTEMS



PART 01

PART 01
BLOOD USE AND HAEMOVIGILANCE SYSTEMS

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 their 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 educational 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. 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[1], 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)[2] definition is the one most widely used and it states:

> ***'A set of surveillance procedures covering the whole transfusion chain (from the collection of blood and its components to the followup 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.[3] '***

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 World Health Organization (WHO) Global Database on Blood Safety Summary Report 2011[4] 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 reccurrence.

Trends in blood product issue and usage in Australia

All developed countries are facing increased demand for blood and blood products. Ageing populations and decreased donations contribute to competing supply and demand pressures for blood resources.[5]

Blood products collected and issued

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 in accordance with government policies in the National Blood Agreement and *National Blood Authority Act 2003.*

The NBA coordinates the purchase and supply of blood and blood products on behalf of all Australian governments. 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.

Table 1: Fresh blood products issued in Australia, 2009-10 and 2010-11

2009-10	RBC	Platelets	FFP	Cryoprecipitate	Cryodepleted plasma
	Units	Units	Units	Units	Units
NSW	247,432	35,192	57,923	25,333	2,351
VIC	207,004	33,043	32,887	17,432	1,675
QLD	169,139	35,958	38,405	9,074	5,446
WA	68,044	8,915	12,722	5,809	1,129
SA	71,226	9,661	14,566	1,539	633
TAS	15,235	2,792	1,503	1,472	0
ACT	12,535	2,066	2,234	1,409	133
NT	5,278	868	574	281	0
Australia	**795,892**	**128,495**	**160,814**	**62,349**	**11,367**
2010-11					
	Units	Units	Units	Units	Units
NSW	252,792	38,191	57,384	28,472	5,729
VIC	207,828	33,959	35,182	18,524	2,699
QLD	167,051	37,167	39,418	9,428	3,430
WA	66,012	9,139	10,771	6,436	669
SA	71,782	10,168	12,522	3,402	390
TAS	15,715	3,267	1,748	1,891	48
ACT	13,346	1,804	2,487	1,677	322
NT	6,047	1,010	1,026	258	595
Australia	**800,571**	**134,704**	**160,538**	**70,088**	**13,882**

Source: NBA

Notes

1. FFP=Fresh frozen plasma
2. RBC=Red blood cell

From 2009-10 to 2010-11, there were about 2.3 million components of fresh blood products issued in Australia. The demand for red blood cells remained high, accounting for about two-thirds of all issues. The demand for blood components varied across states and territories. NSW accounted for about 32% of all issues, followed by VIC (25%) and QLD (22%). NT accounted for less than 1% of all issues.

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.

The following tables (Table 2, Table 3) and figures (Figure 1, Figure 2) show that:

- From 2007-08 to 2010-11, the number of red cell issues increased by 4.1%, from 768,919 in 2007-08 to 800,571 in 2010-11. In contrast, the issues of red cell per 1000 population decreased slightly from 36.31 in 2007-08 to 36.09 in 2010-11.
- Demand for platelets and cryoprecipitate units rose steadily over the past four years to 2010-11. Cryoprecipitate is increasingly used in the treatment of massive bleeding and this may drive an increase in demand in the coming years.
- Demand for cryodepleted plasma units dropped to 11,872 in 2009-10 and then rose again to 13,882 in 2010-11. It remains difficult to forecast the demand for this blood component because this product is used episodically in a very small number of patients with thrombotic thrombocytopenic purpura.

Table 2: Fresh blood products issued in Australia, 2007-08 to 2010-11

Blood component	2007-08	2008-09	2009-10	2010-11
RBC units	768,919	793,480	795,892	800,571
Platelets (adult equivalent doses)	116,665	118,248	128,495	134,704
Fresh frozen plasma units	144,987	152,689	160,814	160,538
Cryoprecipitate units	53,459	59,267	64,734	70,102
Cryodepleted plasma units	14,888	15,430	11,872	13,882

Source: NBA

Note: RBC=Red blood cell

Table 3: Fresh blood products issued per 1000 population, 2007-08 to 2010-11

Blood component	2007-08	2008-09	2009-10	2010-11
RBC units	36.31	36.76	36.29	36.09
Platelets (adult equivalent doses)	4.80	5.48	5.86	6.07
Fresh frozen plasma units	6.85	7.07	7.33	7.24
Cryoprecipitate	2.52	2.75	2.95	3.16
Cryodepleted plasma units	0.70	0.71	0.54	0.63

Source: NBA

Notes

1. RBC=Red blood cell
2. ABS population data[6] for December quarter 2007, 2008, 2009 and 2010 are used for the calculation of figures in this table.

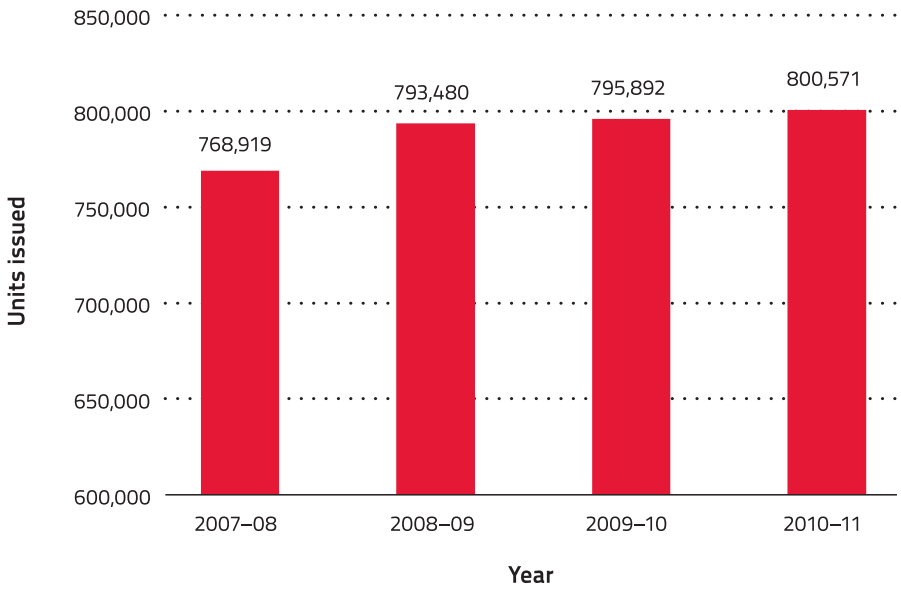


Figure 1: Total red blood cell issues in Australia, 2007-08 to 2010-11

Source: NBA

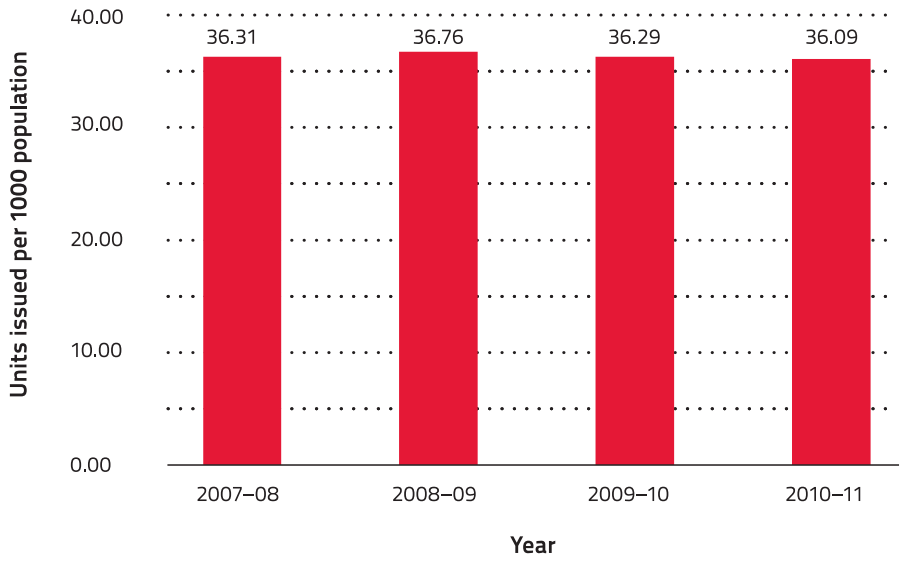


Figure 2: Total red blood cell issues per 1000 population, 2007-08 to 2010-11

Source: NBA

Demographics of blood use

Australia's population continues to rise at a slow pace increasing by 1.4% during the year ended 30 June 2011. The growth rate has been declining since the peak of 2.2% for the calendar year ended 31 December 2008.[7] Increases in population will inevitably result in increased future demand for health care services, including blood and blood components.

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 4.7 years over the last two decades, from 32.4 years at 30 June 1991 to 37.1 years at 30 June 2011. Between 30 June 2010 and 2011 the median age rose slightly from 36.9 to 37.1. Over the next several decades, population ageing is projected to have significant implications for Australia including increased demands on the health system.[8]

Australia enjoys one of the highest life expectancies in the world. In 2009 it was ranked fifth overall at 81.6 among Organisation for Economic Co-operation and Development (OECD) countries after Japan (83.0 years), Switzerland (82.3), Italy (82.0) and Spain (81.8).[9]

In the 12 months to 30 June 2010, the number of people aged 65 years and over in Australia increased by 97,600 people, representing a 2.4% increase. The proportion of the population aged 65 years and over increased from 11.3% to 13.7% between 30 June 1991 and 30 June 2011. In the 12 months to 30 June 2011, the number of people aged 85 years and over increased by 20,900 people (5.3%) to reach 415,400. Over the two decades to 30 June 2011, the number of people aged 85 years and over increased by 169% compared with a total population growth of 31% for the same period.[6]

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[10] 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.

Figure 3 shows that the majority of red cell transfusion procedures in 2008-09 and 2009-10 occurred in patients aged 65 years and over. A similar trend was also observed for the other blood components (Table 4, Table 5) for the same period.

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:[11]

- 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.

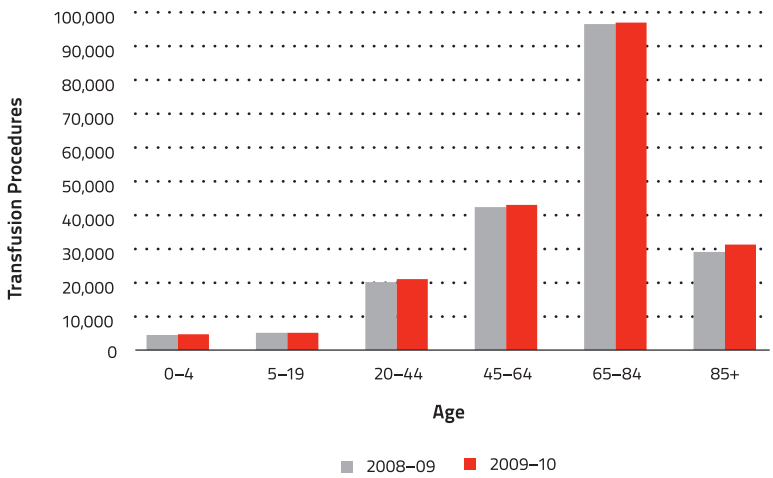


Figure 3: Red cell transfusions by patient age, 2008-09 and 2009-10

Source: AIHW National Hospital Morbidity Database

Table 4: ICD-10-AM / ACHI transfusion procedures by patient age, 2008-09

	Number of Procedures						Percentage of Procedures					
Transfusion of	0-4yrs	5-19yrs	20-44yrs	45-64yrs	65-84yrs	85+	0-4yrs	5-19yrs	20-44yrs	45-64yrs	65-84yrs	85+
Whole blood	76	276	1,937	548	456	150	2%	8%	56%	16%	13%	4%
Red blood cells	4,430	5,030	20,070	42,276	96,516	29,092	2%	3%	10%	21%	49%	15%
Platelets	1,708	1,786	3,450	9,242	11,618	1,091	6%	6%	12%	32%	40%	4%
Leukocytes	1	2	4	40	10	2	2%	3%	7%	68%	17%	3%
Autologous blood	145	207	419	3,084	4,338	290	2%	2%	5%	36%	51%	3%
Other serum	1,825	1,123	4,899	12,677	17,857	2,912	4%	3%	12%	31%	43%	7%
Blood expander	22	73	838	2,028	3,329	516	0%	1%	12%	30%	49%	8%
Other substance	1,378	4,034	10,328	20,480	18,635	1,535	2%	7%	18%	36%	33%	3%

Source: AIHW National Hospital Morbidity Database

Notes

1. ICD-10-AM=International Classification of Diseases 10th revision Australian Modification
2. ACHI=Australian Classification of Health Interventions

Table 5: ICD-10-AM / ACHI transfusion procedures by patient age, 2009-10

	Number of Procedures						Percentage of Procedures					
Transfusion of	0-4yrs	5-19yrs	20-44yrs	45-64yrs	65-84yrs	85+	0-4yrs	5-19yrs	20-44yrs	45-64yrs	65-84yrs	85+
Whole blood	121	291	1,944	502	306	136	4%	9%	59%	15%	9%	4%
Red blood cells	4,609	5,137	20,981	43,018	97,041	31,311	2%	3%	10%	21%	48%	15%
Platelets	1,785	1,966	3,820	9,789	13,166	1,425	6%	6%	12%	31%	41%	4%
Leukocytes	15	7	21	26	24	3	16%	7%	22%	27%	25%	3%
Autologous blood	126	197	482	3,363	4,760	308	1%	2%	5%	36%	52%	3%
Other serum	2,056	1,260	5,543	14,160	19,446	3,186	5%	3%	12%	31%	43%	7%
Blood expander	9	46	670	1,771	2,645	460	0%	1%	12%	32%	47%	8%
Other substance	1,629	4,186	11,103	22,191	21,694	1,756	3%	7%	18%	35%	35%	3%

Source: AIHW National Hospital Morbidity Database

Notes

1. ICD-10-AM=International Classification of Diseases 10th revision Australian Modification
2. ACHI=Australian Classification of Health Interventions

Clinical blood usage

A number of international studies have been undertaken examining changes in red cell usage over time, with particular focus on the impact of an ageing population.[12,13,14] As elderly patients are the main users of blood components, concerns have been raised that an ageing population may result in an increased demand for blood components.

- Borkent-Raven et al.[15] developed two models to describe and predict the national demand for RBC in the Netherlands. The first model was based on demography only (age and sex) and predicted an increase of 23% in RBC demand from 2008 to 2015. Interestingly, after incorporating both demographic changes and clinical RBC use, the second model predicted a decrease of 8% over the same period.

- Tinegate et al.[16] reported on surveys examining the changing patterns of red cell use in 1999, 2004 and 2009 in the North of England. The authors found, despite an increase in the mean age of the recipients of red cells from 62.7 years in 1999 to 63.2 years in 2009, there was an overall reduction of RBC transfusion rate, from 45.5 units per 100,000 population in 1999 to 36 in 2009. 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.

- An Australian red cell linkage program examined red cell use in SA public hospitals.[17] The study showed a reduction in the surgical use of RBC. About one third of RBC was used for surgical indications and one half was used for medical indications for 2008-09. The most common medical indication was haematology, accounting for about one quarter of total RBC use. This report also presented a slight decrease in the issues of red cell per 1000 population in Australia, from 36.76 in 2008-09 to 36.09 in 2010-11.

The above studies show, despite an ageing population, the RBC demand may not increase as much as predicted by other studies and further deceases in surgical RBC use may be achievable. However, a total increase in population numbers where that population is also ageing is likely to demand more blood for medical use. As a substantial user of RBCs and blood products, clinical haematology should be a target for best practice initiatives.

These results are consistent with similar studies undertaken by groups in other developed countries with similar ageing population profiles. The Blood Service 'Bloodhound' study[18] showed a similar age profile for Australian patients receiving red cell transfusions, with the median age of recipients being 69 years. The Bloodhound study following the fate of 5,052 RBC units indicated that for 53.4% of blood units the urgency of the surgical procedure and the urgency of transfusion was less than 24 hours. Only a small proportion was shown to support elective surgery.

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:[18]

- 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
- 6.5% where the indication was unknown
- just under 10% of transfused red blood cells were used to support elective surgery or non-urgent medical conditions.

Epidemiological information from the United States, England, Australia and Denmark suggests that the relationship between the disease or surgical procedure and the use of blood components was similar between these developed countries.[11] The use of red blood cells in cardiovascular surgery predominated. Neoplasms and digestive disorders were also common. Neoplasms, including those relating to haematology, were the main cause of platelet use, but cardiovascular surgery was also important. In all countries, plasma was largely used in cardiovascular surgery. Two countries provided data relating to the number of units per transfusion episode including information relating to massive transfusion. In Australia, red cell use of ≥50 units per episode was largely associated with multi-trauma patients.

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 II: Definitions in haemovigilance) but is seen as part of the professional duty of care for patient safety. Health service organisations have been recommended by the national government to participate in relevant haemovigilance activities conducted either locally or at state or national level from 1 January 2013. 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 that are captured in many other haemovigilance systems around the world. 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.

In order to help national haemovigilance programs to collect comparable international data, the International Society for Blood Transfusion (ISBT) has developed standard definitions for non-infectious adverse transfusion reactions.[19] The HAC has adopted these definitions and included them in the Australian National Haemovigilance Data Dictionary for national reporting.

The objectives of a national haemovigilance system are to provide an evidence base for improvement of transfusion practice, to know what the real risks and hazards of transfusion are in a given community and country, to disseminate these findings and to take appropriate actions including the instigation of appropriate education processes to prevent reccurrence.[20] Similarly haemovigilance data also provide a basis for the wider consideration of product, system and procedural changes that further advance transfusion safety and appropriateness.

The NBA is undertaking the realisation of these objectives through the following initiatives:

- the National Haemovigilance Program
- 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.

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).

Transfusion-related adverse events are investigated and reported according to local arrangements in each state and territory. A range of staff gather and validate haemovigilance data, including transfusion nurses and other clinical staff, haematologists and other medical specialists, hospital transfusion committees, hospital quality and safety units/managers and pathology quality and safety units/managers.

Serious human errors and incidents are thoroughly investigated at the local level using detailed analytical techniques such as root cause analysis (RCA) to ensure that clinicians and hospital directors fully understand the sequence of events. These procedures already form part of ordinary hospital quality management structures and are also applicable to transfusion practice and transfusion-related adverse events.

Transfusion adverse events are validated locally to properly determine whether they are transfusion-related or not and then imputability scores are allocated. Standards for validation are developed by local institutions in conjunction with health department oversight. Reports of serious adverse events may go through a secondary validation process within the state and territory haemovigilance programs and Department of Health Quality Units to ensure data accuracy and completeness. State and territory haemovigilance representatives, on behalf of health departments, aggregate and de-identify the data and send periodic reports

to the NBA. Agreed additional de-identified data concerning the patient, facility, event and implicated blood component will accompany each report, as will an imputability (causality) score, assigned by the reporting jurisdiction.

New South Wales

NSW Health has supported a series of initiatives over the past decade to enhance the quality and safety of transfusion practice in NSW public hospitals. The current transfusion practice improvement program 'Blood Watch' was launched under the auspices of the Clinical Excellence Commission (CEC) in 2006, in collaboration with NSW Health. The primary goal of Blood Watch is to improve the safety and quality of fresh blood component transfusion in all NSW public hospitals through a range of strategies including system redesign, risk controls, education, training and ongoing monitoring and feedback.

All NSW public hospitals use a centralised incident reporting system, the Incident Information Management System (IIMS; based on Adverse Incidents Monitoring System (AIMS), iSOFT Group Ltd) as their only incident reporting tool. IIMS was implemented in all NSW public health facilities in May 2005. The system is designed to allow healthcare professionals to report incidents, including near misses and risks to patient and staff safety. Reporting of incidents and near misses is mandated in the Incident Management Policy Directive PD2007-061.[21]

IIMS includes a specific reporting category for incidents involving blood and blood products which allows the notifier to select the type of blood product involved and the nature of the problem. IIMS also has fields designed to capture a wide range of general incident reporting information, and a free text description of the risk/incident.

Blood/blood product category incidents are included in routine IIMS reports of patterns and trends in reported incidents. In order to derive additional information regarding adverse transfusion events, the CEC performs a targeted analysis of the free text description of adverse events provided within the blood/blood product category of IIMS reports.

All severe adverse events (sentinel events) are subject to RCA investigation. The key lessons derived from the analysis of both severe and less severe events are analysed and strategies to reduce these incidents are developed.

The IIMS system is currently being reviewed. Capacity to report against the ANHDD data items is planned to be incorporated in specifications for its redevelopment.

A key focus in NSW in relation to reducing adverse events associated with transfusion has been to reduce inappropriate transfusion. Since the commencement of the Blood Watch program there has been a 10% reduction in red blood cell transfusions for inpatients in NSW public hospitals. A major focus for the program in 2010 was improving all aspects of identification, treatment and reporting of transfusion-related adverse events.

NSW data is presented in Appendix IV.

Victoria

The STIR system is part of the Blood Matters program.[22] Blood Matters is a collaborative effort between the Department of Health and the Blood Service. 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).

Reporting to STIR is voluntary in VIC. STIR collects haemovigilance data on events from participating public and private hospitals in Victoria and now includes participation from hospitals in TAS, ACT and NT. Victorian public hospitals report clinical incidents into a state-wide reporting system, Victorian Health Incident Management System (VHIMS) which includes blood-related incidents. VHIMS future enhancements will assist with blood incident reporting to align with the STIR criteria, and reduce double reporting for public hospitals in VIC.

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.

The electronic system used to manage incident reporting data as part of STIR has been developed within the Blood Matters program. Hospitals 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 initial and second level reports are submitted electronically by email from the reporting health service using the web-based eForm for notification and the investigation. With recent advancements in the STIR system, both forms are imported into the database through a semi-automated process, which has reduced time for the health service and the Blood Matters staff, and provided more timely

review and follow up. No information identifying the reporting institution or patient is maintained in the STIR database or visible at review.

In 2009-11, 43 hospitals from VIC, ACT, NT and TAS reported 404 events. Based on information from the Victorian Admitted Episode Dataset, it is estimated for VIC that hospitals which have agreed to report (public and private) represent approximately 85% of the total blood transfusion activity. From 2006-11 clinical incidents events - acute transfusion reactions - comprise 50% 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.

Hospitals are expected to review and validate data prior to submission to STIR. In most institutions this occurs through review by the hospital transfusion committee or senior medical officer. In addition to hospital level validation, the STIR program validates incident data. This includes review, classification and assessment of imputability rating by an expert panel comprised of medical and nursing clinicians and laboratory scientists. If the STIR expert panel rating differs from the hospital's assessment both are recorded, with the STIR rating treated as the primary record. This review 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 an RCA approach for these events is reviewed by the STIR expert group, with comments and recommendations provided back to reporting hospitals through the sentinel event program.

Aggregate information from STIR is presented to BMAC and used to develop policies, recommendations and educational resources for VIC hospitals. STIR reports for 2006-07, 2008-09 and 2009-11 are available at the Blood Matters website http://www.health.vic.gov.au/bloodmatters/tools/stir.htm. Experiences and data from STIR are regularly shared at conferences, workshops and hospital meetings. In the 2009-11 period 22 formal presentations were given locally (hospital transfusion committees, metropolitan and regional workshops), nationally (Haematology Society of Australia and New Zealand, Australian & New Zealand Society of Blood, Australian Society of Thrombosis and Haemostasis annual scientific meetings and Blood Service Transfusion Update) and internationally (IHN meetings).

Working within established clinical governance structures such as transfusion committees, the availability of transfusion nurses and rural transfusion trainers in Victorian hospitals has been recognised as an important element in supporting developments in transfusion practice improvement, including adverse event reporting, investigation and participation in haemovigilance activities. The emphasis on haemovigilance has been reinforced with the implementation of the NSQHS Standard 7 for hospital accreditation.

Queensland

Until early 2013, a centralised haemovigilance system was operational across Queensland Health. In this system, data validation and analysis was undertaken by clinicians employed within a corporate division of Queensland Health. The data presented in this report, for 2009-10 and 2010-11, was a product of this centralised haemovigilance system.

After the 2012 restructure of the QLD public health system, Hospital and Health Services (HHSs) were established and are responsible for the quality and safety of clinical services. The continuation of the centralised haemovigilance system was not consistent with the Department of Health's new system manager role and this system ceased in 2013. The QLD haemovigilance system was adapted in line with these new structural arrangements, in which:

- HHSs and licensed private health facilities will continue to report incidents and, as required by NSQHS Standard 7, will 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 spreadsheet
  - reviewing and validating haemovigilance data
  - providing de-identified haemovigilance data for state and national haemovigilance reports.
- the Department of Health will:
  - facilitate the availability of a tool (spreadsheet, database) for the consistent collection of haemovigilance data
  - develop and maintain a guideline on haemovigilance data collection and analysis
  - work with an expert group to develop annual/biennial haemovigilance reports
  - coordinate data provision from HHSs and licensed private health facilities to the NBA for national haemovigilance reporting.

Western Australia

WA Health is implementing patient blood management (PBM) as a standard of care state-wide. The rationale for the introduction of the program includes: the potential to reduce unnecessary patient exposure to the risks associated with avoidable transfusions and the consequent benefits to patients and the blood budget (estimated to be up to five per cent of the WA public healthcare budget); reduced pressure on demand for blood which is expected to increase with the ageing population; a desire to improve informed consent; and growing knowledge of the limitations and potential adverse outcomes with transfusion.

Given the concurrent development of new NSQHS accreditation standards to include

transfusion practice, informed transfusion consent and a commitment to improving the appropriateness of transfusion practice, the WA PBM program is an effective strategy to address WA's multiple responsibilities with regard to blood transfusion. The WA PBM program comprises:

- multiple education and communication strategies for:
  - consumers to facilitate patient consent and access to PBM
  - healthcare providers to actively participate in program development
- establishing effective data collection and monitoring systems to facilitate evaluation and continuous practice improvement and risk management
- building a strong guiding coalition of champions to change the paradigm and realign institutional culture to more appropriate patient-focused blood management
- developing and implementing PBM clinical policies, procedures and guidelines to facilitate the peri-operative 'Three-Pillar-Strategy' of PBM, including the development of an anaemia identification and management program
- mechanisms to propose and conduct outcomes research in PBM via the WA Data Linkage System
- benchmarking locally and with already committed international centres of excellence.

WA has finalised the business requirements and tender processes for a new Clinical Incident Monitoring System (CIMS), which is anticipated to include haemovigilance modules. To date, individual hospital-based transfusion committees monitor activities, and investigate transfusion-related incidents in their institutions. The new CIMS will continue to see case review and imputability elements of haemovigilance built into the individual health service programs and where necessary, escalated for a state-wide response.

South Australia

Haemovigilance data in SA is collected and analysed on an individual hospital or health service basis. The haemovigilance data submission from SA is limited to adverse events reported from across the SA public health system, also known as SA Health. The private sector utilises various incident management systems which are reviewed internally via safety and quality and/or transfusion committees. The Blood Service encourages adverse reaction reporting but primarily receives notification of serious adverse events such as TRALI and suspected bacterial contamination. Product related incidents are predominantly reported through SA Pathology to the Blood Service and may not be captured in hospital-based adverse event systems. SA Health mandates reporting of ABO related haemolytic transfusion reactions through a separate sentinel event reporting process covering public and private hospitals. The reliability of data on reported incidents is dependent on the staff member recognising that a significant adverse event has occurred.

On 1 July 2010, SA Health clinical incident reporting transitioned from AIMS (iSOFT Group Ltd) to Datix Safety Learning System (SLS). SLS is an electronic system for reporting and managing incidents and consumer feedback across the public sector with the capacity for online reporting in addition to reporting via a contact centre. Online reporting has been embraced by hospital staff and the contact centre has since ceased operations. SLS supports:

- electronic reporting of incidents with data available centrally for analysis
- voluntary reporting of patient related incidents and near misses across SA Health, and
- incident investigation and related continuous quality improvement activities.

Designated staff can receive automatic email notifications on transfusion events for their work area when an incident is logged, allowing follow up in real time. Automatic notifications of transfusion events are escalated to management levels within SA Health, depending on the Safety Assessment Code (SAC). BloodSafe Transfusion Nurse Consultants (TNC) are notified of all incidents classified under 'transfusion of blood related problem'. Individual incidents and types of incidents are reviewed and analysed to identify trends and areas of risk.

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 should improve, over time, as user knowledge of the software increases and the system evolves as a result of suggested system changes.

Elements of the ANHDD were incorporated into SLS; however, certain fields such as age, sex, date of birth are not mandatory. A single reaction investigation and reporting form has been introduced across SA Health; however, there are no consensus definitions which are aligned with the ANHDD and the form does not capture severity ratings or imputability. SAC scores and free text fields within SLS can aid in the interpretation of events but analysis can be subjective and resource intensive. SA Health does not currently maintain a transfusion specific jurisdictional expert group but significant events will be referred to general hospital or SA Health committees for review.

The system for the investigation, review and management of reported blood and blood component incidents/adverse events in SA is robust 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.

BloodSafe, SA's transfusion practice improvement program, continues to make a significant contribution towards blood transfusion safety and quality improvement. BloodSafe TNC's work 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.

SA Health has established a regular reporting and linkage process to monitor fresh blood component utilisation by inpatients. The data linkage will contribute to system understanding of the total volume of components transfused by hospitals.

BloodSafe eLearning Australia is now embedded across SA Health as the main educational tool for hospital staff. It is anticipated that this will result in improvements in the recognition of previously under-reported serious adverse events such as TACO and TRALI.

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. The Electronic Incident Management System (EIMS, 'Risk MonitorPro' rL Solutions) is used at local and state-wide levels to report and manage health care incidents as a key component of quality improvement. Department of Health and Human Services is currently scoping a replacement EIMS for the state. Recognising the importance of standardisation of data and related processes, the project team has sought input from the Tasmanian Blood Management Group in the classification design with the key objective of capturing data and supplementing national haemovigilance/NBA reporting in relation to management of safety events.

EIMS currently provides all public hospitals in TAS with a consistent, standard approach to incident reporting. All incidents are followed up and Serious Assessment Code 1 and 2 incidents are referred to a Serious Incident Panel. Blood related incidents represent approximately 1.4% of the total number of incidents reported.

Reporting to STIR is a separate process from EIMS as the two systems are not aligned. A key issue for Tasmania is reporting to a national database. Given that STIR and EIMS are not a good match it appears that provision of information via STIR is the most practical option. It is hoped that the new system will support the extraction of data directly to the STIR system.

Reporting to EIMS is voluntary. However, all Tasmanian public sector hospitals and health facilities use EIMS incident reporting. 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, however they do not contribute data to EIMS or STIR. Private hospitals have indicated an interest in contributing towards a state-wide and national database.

Transfusion-related incidents in the public sector are entered into EIMS with follow up incidents according to type and severity. Many haemovigilance activities are coordinated by Blood Transfusion Nurses with positions now in place at each of the four major Tasmanian public hospitals. 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. Blood Transfusion Nurses were funded following commencement of the national blood arrangements in order to contribute to jurisdictional requirements of the National Blood Agreement.

Recent initiatives include engagement of rural health facilities with activities undertaken on a regional basis and an ongoing accreditation process in place to designate facilities that have the necessary systems in place to safely transfuse blood. There has also been further engagement with the private hospital sector through education by blood nurses, adoption of forms that are consistent between the public and private sector in each region, and private sector participation on the Blood Transfusion Committee.

Future haemovigilance strategies include:

- aiming to streamline data provision to STIR through direct extraction from the planned new statewide incident reporting and management system
- having a consistent suite of incidents reported to EIMS and STIR by all public facilities
- further engagement of the private sector in haemovigilance activities.

Australian Capital Territory

The ACT is a small jurisdiction with a population of 371,000 people, although the complete catchment covers an extensive area of south-eastern NSW with a total catchment population of over 540,000. The ACT is serviced by two public and four private hospitals that transfuse blood and blood products. These facilities provide transfusion services to their consumers through three pathology providers.

The ACT Health Directorate (the Directorate) is aligned to the Statement on National Stewardship Expectations for the Supply of Blood and Blood Products and adheres to the Statement's Stewardship Principle in regard to collation and management of haemovigilance data. This has been facilitated through the Directorate's cross-jurisdictional collaboration with Blood Matters, VIC. As part of this program the Directorate participates in the STIR system. The ACT's public hospitals use the Riskman general incident reporting system to collect haemovigilance data. The private hospitals currently collect and benchmark their haemovigilance data through their internal organisational quality and risk management systems.

The Canberra Hospital is the region's major public hospital with approximately 600 beds, operating as an acute care tertiary referral centre and a teaching hospital affiliated with the Australian National University.

In addition to adverse event data reporting, the Canberra Hospital regularly participates in clinical transfusion audits conducted by Blood Matters (such as Comparative audit of blood transfusion policy and practice 2011) in addition to local audits and reviews focusing on areas of risk including patient identification, consent, documentation and storage and handling.

ACT data, released for the national haemovigilance report, is validated through a process of review and re-assessment of imputability rating by an expert STIR panel comprised of medical and nursing clinicians and laboratory scientists (including a representative from the ACT). Although the de-identified data is held and reported back to the ACT by STIR, the ACT reports into the National Haemovigilance Program depending on its own assessment.

The ACT being a small jurisdiction has allowed the Directorate's Transfusion Nurse to promote and sustain a jurisdictional approach to haemovigilance in the ACT, aligning transfusion practice across the ACT with national and international guidelines.

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 eLearning Australia program is promoted as critical training for all staff involved in the transfusion chain, at all hospitals across the ACT. Since 2007, the ACT has recorded 3607 registrations to the program.

Additionally, the Directorate convenes a local blood sector stakeholder group called the Appropriate Use of Blood Reference Group (AUBRG) which has broad-based membership from a variety of stakeholders including the NBA, the Blood Service and clinical representation from each of the hospitals and pathology providers across both the public and private health sectors.

The Directorate has hosted an annual Transfusion Champions Forum since 2009 which has brought together nurses and other health professionals with aims to:

- improve knowledge in relation to blood transfusion safety and quality across the ACT
- enhance clinical care in accordance with best practice
- support the development of strategies to mitigate against the significant risks associated with transfusion.

These forums have also been well supported by guest presenters from the NBA, the Blood Service, VIC Blood Matters and the NSW Clinical Excellence Commission.

This forum was the initiating platform for the ACT Transfusion Champions Network.

The aims of this network are to:

- enhance clinical care in accordance with best practice with a focus on transfusion of blood and blood products and documentation within relevant clinical areas
- ensure relevant accreditation criteria are met as outlined in both EQuIP 5: 1.5.5 and the NSQHS Standard 7 in all relevant clinical areas
- identify risks associated with transfusion practice in the Transfusion Champions' clinical areas and ensure reporting to the Transfusion Nurse and clinical managers
- promulgate information and quality improvement activities associated with transfusion

- assist Clinical Development Nurses with competency assessments associated with transfusion
- assist with clinical audits pertaining to transfusion practice.

Future plans for haemovigilance in the ACT include:

- working towards a data linkage platform for blood and blood products
- radio frequency identification (RFID), supporting positive patient identification for transfusion as well as enhancing the visibility of blood and blood products within the clinical environment
- alignment and further promulgation of the PBM suite of national guidelines.

Northern Territory

The NT Department of Health has established a comprehensive haemovigilance system over the last five years. The system includes:

- transfusion reaction reports
- RiskMan electronic incident management system
- Transfusion Incident Review Group (TIRG)
- NT Transfusion Committee (NTTC)
- participation in STIR
- transfusion education and training
- clinical auditing
- a full time Transfusion Nurse Consultant.

All NT Network Hospitals use the RiskMan electronic incident management system. All staff members have access to report incidents on RiskMan. Therefore any clinical staff can generate the initial report. Members of the TIRG are alerted by email when a transfusion-related incident is reported on RiskMan. There are four broad transfusion incident categories on RiskMan: administration, transfusion reaction, blood product, and documentation, with each having further sub-categories. The RiskMan system flags any transfusion incidents which meet the STIR criteria. If this occurs, a blood management extension is generated which captures additional information and produces a printable initial STIR report.

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. Reporting of transfusion reactions increased 300% with the introduction of the Transfusion Reaction Report in 2010.

The categories of RiskMan incidents which are reportable to STIR, and therefore generate the blood management extension, are:

- Incorrect blood component transfused
  It is recommended that an RCA be performed for this category of event
- Acute transfusion reaction (including anaphylaxis)
  Incidents occurring < 24 hours following transfusion
- Delayed transfusion reaction
  Incidents occurring > 24 hours following transfusion
- Transfusion-associated graft versus host disease (TA-GVHD)
- TRALI
- PTP
- Bacterial/other infection
- Post-transfusion viral infection
- WBIT
- Other near miss incident.

The TIRG is an expert group which meets monthly to review all transfusion-related incidents occurring in NT Network Hospitals. The group collates and analyses transfusion incident data; ensures serious transfusion incidents are investigated appropriately; coordinates RCA if required; ensures transfusion incidents which meet the STIR criteria are reported to Blood Matters; makes recommendations for transfusion practice improvement; and reports quarterly to the NT Transfusion Committee. The Transfusion Nurse Consultant submits the initial STIR report electronically or by email, and the second level STIR report and investigations are completed by either Transfusion Nurse Consultant or a Hospital Quality Coordinator. The Transfusion Nurse Consultant is the chair of the Transfusion Incident Review Group and provides clinical leadership in haemovigilance across all five NT Network Hospitals.

Since 2010, all five NT Network Hospitals have participated in voluntary reporting to the Blood Matters VIC STIR system. In 2011, a Memorandum of Understanding (MOU) between the VIC Department of Health and the NT Department of Health for the Blood Matters: Better Safer Transfusion Program was finalised. The MOU sets out three schedules covering serious transfusion incident reporting data, clinical audits and bi-annual education forums. All major blood users in VIC, TAS, the ACT and the NT voluntarily report to STIR. Aggregate haemovigilance data is presented in STIR annual reports and is submitted directly to the NBA.

The NTTC, established in 2009, meets quarterly to provide a forum for the review and improvement of blood transfusion services, and to ensure the delivery and use of safe, high quality and cost effective blood.

The NTTC objectives include:

- monitoring, reviewing and improving transfusion practices relating to appropriate use of blood and blood products, wastage, expiry and adverse events
- assisting in the development and review of transfusion policies, protocols and guidelines
- promoting communication and collaboration between: all staff involved in the transfusion process; executive staff; blood and blood product suppliers; and local and national blood user groups
- promoting the education and training of all staff involved in the transfusion process
- ensuring internal and external emergency planning incorporates appropriate provision of transfusion services.

In 2012, the BloodSafe eLearning Australia courses became mandatory for all NT clinical staff involved in the transfusion process. Doctors, nurses and midwives are required to complete the Clinical Transfusion Practice course; phlebotomists are required to complete the Collecting Blood Specimens course; and patient care attendants who transport blood as part of their duties are required to complete the Transporting Blood course. The courses are to be completed on commencement of employment and yearly thereafter. The Clinical Transfusion Practice course includes a module on transfusion reactions.

The Northern Territory has participated in several clinical audits conducted by the ANZSBT and VIC Blood Matters, including the ANZSBT Survey of Transfusion Consent Practices 2009, Blood Matters Comparative Audit of Blood Transfusion Policy and Practice 2011 and Blood Matters Audit of Consent for Blood Transfusion 2012. In addition, regular internal audits are conducted to provide data on current transfusion practices and to identify areas of practice which may need improving.

Future directions in Australian haemovigilance

Donor vigilance

Although blood donation is generally safe, a variety of risks and complications exist, the most common being vasovagal reactions, bruising and citrate-related events. Iron deficiency is a longer term risk of donation. In recent decades, extensive efforts have significantly improved recipient and product safety, but there is still potential to further optimise donor care. 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.

Standard international definitions are available for surveillance purposes[i]. A recent comprehensive review[23] on adverse events addresses all types of blood donation including whole blood, plasma, platelet, peripheral blood stem cell, leucocyte and bone marrow donation. It outlines strategies for the prevention and treatment of these events and gives a blueprint for future research in this field.

Donor vigilance in Australia is accomplished by the Blood Service with the exception of those donations not collected by the Blood Service, including peripheral blood stem cell, leucocyte and bone marrow donations. Whilst the Blood Service has collected, analysed and reported on donor vigilance data for many years, national data is included in this report for the first time (see PART 03 DONOR VIGILANCE).

Adverse event reporting for non-fresh products

The subject of 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 factor and other products.

i http://www.ihnorg.com/isbt/donorvigilancewp/

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 the NSQHS Standard 7[ii] 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[iii].

The TGA maintains a reporting service for adverse events or defects in medicines in Australia. Information on TGA reporting can be found on the TGA's website[iv] and reports can be submitted in various ways. Each year the TGA receives more than 12,000 reports of suspected adverse events associated with medicines and vaccines. About 40% of these reports come via pharmaceutical companies, and the remainder are reported directly to the TGA by general practitioners (about 15% of all reports), hospitals (20%) and specialists, community pharmacists, state and territory health departments and consumers.

Products for haemophilia and bleeding disorders

The Australian Bleeding Disorders Registry (ABDR)[v] 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 (this reporting is additional to the statutory requirement to report to the TGA):

- 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.

ii http://www.blood.gov.au/nationalstandard
iii http://www.tga.gov.au/
iv http://www.tga.gov.au/safety/problemmedicine.htm
v http://www.blood.gov.au/abdr

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 condition and eligibility criteria
- increasing the manufacture of IVIg in Australia
- importing IVIg from overseas.

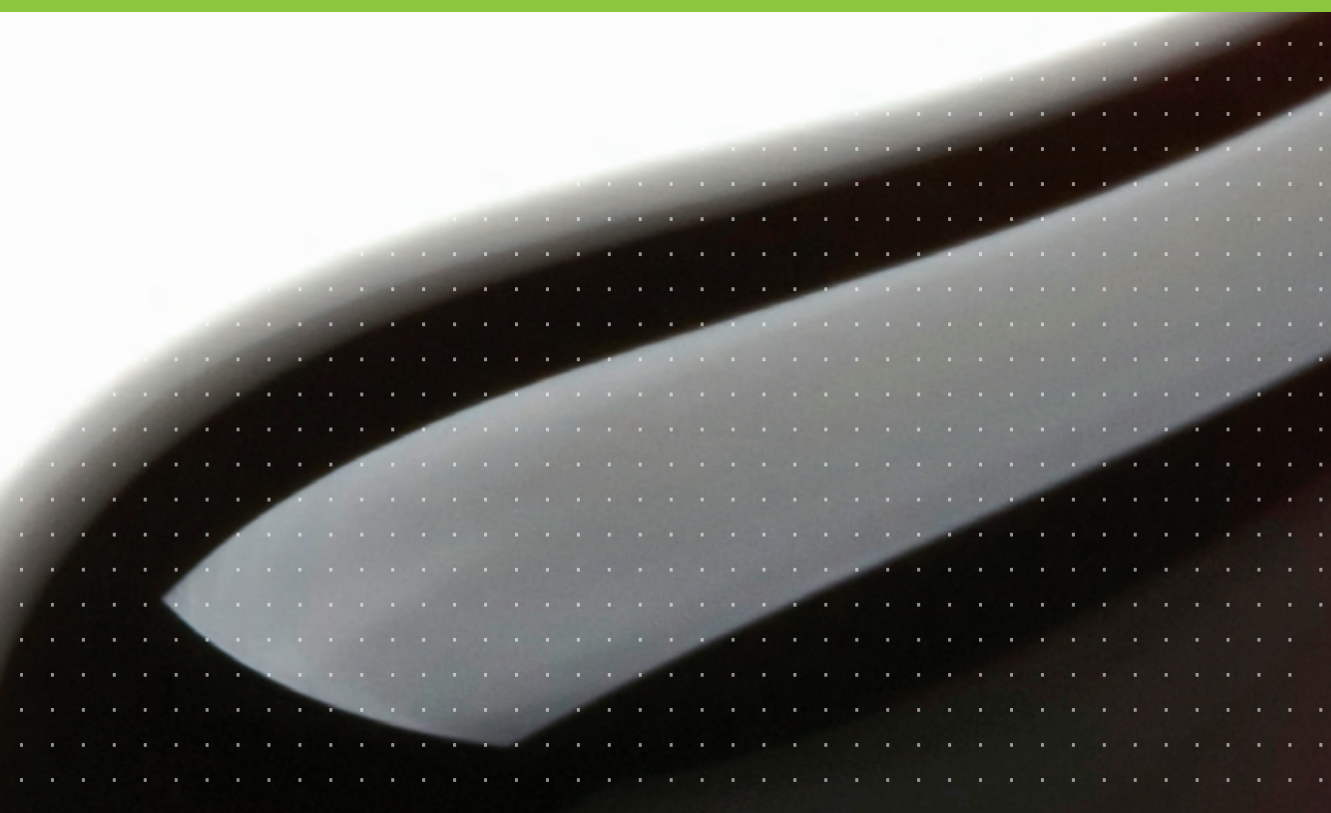
The continual significant annual growth in IVIg usage, the high cost of IVIg products and the potential for supply shortages have all maintained the focus of Australian governments on ensuring use remains consistent with an evidence-based approach and that IVIg is able to be accessed under the National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

The *Criteria for the clinical use of intravenous immunoglobulin*[vi] 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 health care professionals on IVIg-related adverse reactions occurring in Australia. The NBA may include data on IVIg-related adverse events in future reports.

vi http://www.blood.gov.au/ivigcriteria

PREVIOUS AUSTRALIAN HAEMOVIGILANCE DATA AND PERFORMANCE



PART 02

Initial Australian Haemovigilance Report 2008

Australian Haemovigilance Report 2010

Scorecard - Performance to date

PART 02
PREVIOUS AUSTRALIAN HAEMOVIGILANCE DATA AND PERFORMANCE

Initial Australian Haemovigilance Report 2008

The Initial Australian Haemovigilance Report 2008 presented a selection of the available information on transfusion-related adverse events reported in Australia over a period of three to five years before the report. It did not include haemovigilance data from individual hospitals or hospital networks, only information reported to and held at the state or territory level.

Data sources at that time included state and territory healthcare reporting systems, such as AIMS (used in the public health care sector of SA and WA), IIMS (used by all eight NSW area health services), STIR (used by the VIC Department of Human Services Quality Improvement Unit), RiskMan (used by ACT Health and a number of private healthcare organisations), and PRIME (Acclaim Safety Systems Ltd), which was the healthcare reporting facility for QLD Health. The 2008 report also made use of data from AIHW National Hospital Morbidity Database (NHMD).

A number of caveats applied to the adverse events data presented in the 2008 report, including:

- incomplete reporting of adverse events, meaning calculation of rates or frequencies of events was not possible
- differences in definitions and collection methods in each state or territory
- lack of validated data and imputability criteria, reducing the certainty of a causal link between transfusions and the reported adverse events
- data was collected over different reporting periods, further hindering comparability.

The reporting period and caveats associated with the 2008 report mean that the data is not directly comparable with the data of the current report. Any apparent differences in reporting rates of adverse events should be considered in the context of the significant improvements that have been made in Australian haemovigilance since the 2008 report, which aim to increase reporting and the quality of data reported.

The Initial Australian Haemovigilance Report 2008 made four broad recommendations:

- an enduring National Haemovigilance Program is established
- states and territories continue to align their reporting systems with an agreed dataset to create a comprehensive national minimum dataset
- states and territories progressively implement procedural training and process improvements in line with program reports and recommendations
- states and territories work collaboratively with clinical colleges, specialist societies and the Blood Service to scope, assess and where appropriate, promote a stronger awareness and adoption of comprehensive patient blood management strategies.

The first three recommendations were pursued through the establishment of an ongoing National Haemovigilance Program and the HAC to provide governance to haemovigilance at a national level in Australia. As an aid to procedural training and process improvements BloodSafe eLearning Australia was approved for funding by the Jurisdictional Blood Committee (JBC) as a suitable vehicle to deliver broad based education on appropriate and safe blood transfusion practices to a wide range of ancillary and professional health provider audiences over a three year period beginning in December 2009. To ensure that patients are not unnecessarily exposed to the risks associated with transfusion the NBA also embarked on a program to revise the NHMRC transfusion guidelines, and replace them with the publication of six modular PBM Guidelines. The fourth recommendation was addressed through the development of a National Patient Blood Management Program.

Australian Haemovigilance Report 2010

The 2010 report improved upon the standards of the Initial Australian Haemovigilance Report 2008 in a number of significant ways. The Australian Haemovigilance Report 2010 included validated data from state level haemovigilance programs including BloodSafe in SA, the QLD Incidents in Transfusion program and the VIC Blood Matters and STIR programs. The STIR program also provided data from the haemovigilance activities in TAS, the ACT and the NT. Limited data was included from the NSW Blood Watch program.

The 2010 report detailed serious adverse events reported (n=294) to the Australian National Haemovigilance Program for the 2008-09 period. The relative incidence of the adverse events was comparable to the data of many other developed countries, with a majority of FNHTR (n=154) and allergic reactions (n=87), some serious anaphylactic and anaphylactoid reactions (n=8), haemolytic transfusion reactions (AHTR n=7; DHTR n=4), TACO (n=6), TRALI (n=3) and TTI (n=3). There were 22 IBCT events reported.

Across all reported adverse events, there were 92 reports (31% of reports) that cited one or more contributory factors that could have been avoided. These included prescribing/ordering, specimen collection/labelling, laboratory (testing/dispensing), transport, storage, handling, administration of product, or adverse events where the clinical indications for transfusion did not meet the facilities' transfusion guidelines or where the transfusion procedures undertaken did not adhere to the facilities' transfusion procedures.

Data from the 2010 report is compatible with the new data presented in this report. Relevant observations and discussions have been included in the analyses presented in PART 04 HAEMOVIGILANCE DATA FOR 2009-10 AND 2010-11.

Scorecard - Performance to date

The 2010 report delivered 12 key recommendations in the areas of data quality, jurisdictional capacity to report haemovigilance data, prescribing practice, human errors, and national blood quality and safety initiatives. The following sections and tables summarise the progress made against the recommendations of the 2010 report.

Data

The 2010 report made four recommendations on the subject of data (Table 6).
Progress against these recommendations has been as follows:

- The national haemovigilance data has been extended to include the donor vigilance data from the Blood Service
- The quality of data has improved since the last report. However, some states were unable to allocate adequate resources to develop and improve their systems. As a result, the number of states and territories reporting validated data to the National Haemovigilance Program remains unchanged at six and the completeness of data is still an issue for these states
- The NBA and JBC have promoted and funded further development of BloodSafe eLearning Australia (https://www.bloodsafelearning.org.au/) as a national education tool to improve the recognition and management of serious adverse events, including TACO and TRALI
- The NBA has included the risk information for TACO and TRALI in PBM Guidelines
- The HAC has agreed to develop a Guidance on Recognition and Management of Acute Transfusion Reactions and Events
- The NBA is working with the data linkage programs in the states and territories to develop the systems and capability to enable the total number of components and patients transfused to be known
- The HAC will re-evaluate the national haemovigilance dataset, consider the inclusion of near miss reports and look at the definitions as part of the scoping exercise for a national haemovigilance system.

Table 6: Progress against data recommendations of Australian Haemovigilance Report 2010

	Recommendation from 2010 Report	Who is Responsible?	Proposed strategy from 2010 report	Outcomes
1	Jurisdictions to continue to develop their haemovigilance data capture and validation systems (which should include donor vigilance) to enhance the quality and completeness of data reported to the national dataset	NBA/JBC; State and territory Departments of Health; Blood Service; Private sector hospitals and private pathology providers	JBC to consider strategies for further development of haemovigilance systems State and territory Departments of Health to consider establishing ongoing funding for maintenance of haemovigilance systems if funding not already in place	The number of state and territories reporting validated data remains unchanged The completeness of data remains an issue for some states Donor vigilance data included in this report
2	Programs should be implemented at the national, state and local hospital levels to improve recognition and reporting of under reported serious adverse events such as TACO and TRALI	JBC; NBA; State and territory Departments of Health; Hospital Educators; Relevant professional Colleges and Societies	Incorporate TACO and TRALI into: ▪ SA BloodSafe eLearning ▪ Post Graduate Certificate in Transfusion Practice ▪ Junior Medical Officer (JMO) Education Include advice on risks of TACO and TRALI in PBM Guidelines	BloodSafe eLearning Australia NBA Patient Blood Management Guidelines Guidance on Recognition and Management of Acute Transfusion Reactions and Events is under development TACO is still largely under-reported
3	Develop the systems and capability to enable the total number of products and patients transfused to be known	JBC; NBA; State and territory Departments of Health; Blood Service; AIHW; Clinicians; Clinical Coders	States and territories to consider initiatives to: ▪ Use data linkage to determine the number of patients transfused in the public hospital system ▪ Improve the capture and utilisation of registry data	NSW, SA, WA and QLD have advanced their health data linkage capabilities and the resulting data and analysis on red cell use have been used to inform clinical practice at a state level The NBA is currently coordinating a Red Cell Data Linkage national minimum dataset to inform policy and decision making at a national level
4	HAC to discuss the definition and inclusion of near misses into the dataset	HAC; NBA; JBC; State and territory Departments of Health	HAC to discuss near miss definition in data dictionary Promote inclusion of near miss information in jurisdictional data systems	STIR has captured and reported near miss data at the state level since 2007 The HAC will re-evaluate the national haemovigilance dataset as part of the scoping exercise for a national haemovigilance system

Capacity

The 2010 report made two recommendations on the subject of capacity to report haemovigilance data (Table 7). Progress against these recommendations has been as follows:

- The NBA and blood sector stakeholders assisted the ACSQHS to develop NSQHS Standard 7. The primary aims of the NSQHS Standards are to protect the public from harm and to improve the quality of health service provision. They provide a quality assurance mechanism that tests whether relevant systems are in place to ensure minimum standards of safety and quality are met, and a quality improvement mechanism that allows health services to realise aspirational or developmental goals. The Standards are integral to the accreditation process as they determine how and against what an organisation's performance will be assessed. The Standards have been designed for use by all health services.
- NSQHS Standard 7 came into effect on 1 January 2013. From this date, accreditation against the standard became mandatory.
- Criteria 7.1, 7.3 and 7.6 under NSQHS Standard 7 require:
  - developing a governance system for safe and appropriate prescription, administration and management of blood and blood products
  - ensuring blood and blood product adverse events are included in the incidents management and investigation system
  - the clinical workforce documenting any adverse reactions to blood and blood products.
- The NBA is scoping the requirements for a national haemovigilance system. The NBA is working in collaboration with the VIC Blood Matters team with a view to extending collaboration across states and territories. If agreed by states and territories, such a system could supersede state and territory haemovigilance systems.

Table 7: Progress against capacity recommendations of Australian Haemovigilance Report 2010

	Recommendation from 2010 Report	Who is Responsible?	Proposed strategy from 2010 report	Outcomes
5	Jurisdictions to consider strategies to improve the timeliness and completeness of reporting	JBC; State and territory Departments of Health; State and territory Quality and Safety Units	JBC to investigate strategies to support further development of haemovigilance systems State and territory Departments of Health to consider establishing ongoing funding for maintenance of haemovigilance systems	NBA is scoping the requirements for a national haemovigilance system NSQHS Standard 7 - Blood and Blood Products
6	All transfusing hospitals should have transfusion governance arrangements in place	State and territory Departments of Health; State and territory Quality and Safety Units; Hospital Administrators	Jurisdictions to consider providing a directive to administrators responsible for transfusion institutions to establish haemovigilance governance arrangements	NSQHS Standard 7 - Blood and Blood Products

Prescribing

The 2010 report made two recommendations on the subject of prescribing blood and blood products (Table 8). Progress against these recommendations has been as follows:

- The NBA has published four modules of the PBM Guidelines:
  - Module 1 - Critical Bleeding/Massive Transfusion
  - Module 2 - Perioperative
  - Module 3 - Medical
  - Module 4 - Critical Care
- Two modules are in development:
  - Module 5 - Obstetrics
  - Module 6 - Paediatrics/Neonates
- The NBA Patient Blood Management Guidelines Module 2 - Perioperative [24] made the following recommendations on the red cell blood transfusions for patients with perioperative anaemia.

RECOMMENDATIONS – preoperative anaemia assessment	
R2 GRADE C	In patients undergoing cardiac surgery, preoperative anaemia should be identified, evaluated and managed to minimise RBC transfusion, which may be associated with an increased risk of morbidity, mortality, ICU length of stay and hospital length of stay (Grade C).
R3 GRADE C	In patients undergoing noncardiac surgery, preoperative anaemia should be identified, evaluated and managed to minimise RBC transfusion, which may be associated with an increased risk of morbidity, mortality, ICU length of stay and hospital length of stay (Grade C).

RECOMMENDATIONS – iron and erythropoiesis-stimulating agents	
R4 GRADE B	In surgical patients with, or at risk of, iron-deficiency anaemia, preoperative oral iron therapy is recommended (Grade B). Refer to the preoperative haemoglobin assessment and optimisation template [Appendix F] for further information on the optimal dosing strategy.
R5 GRADE A	In patients with preoperative anaemia, where an ESA is indicated, it must be combined with iron therapy (Grade A).
R6 GRADE B	In patients with postoperative anaemia, early oral iron therapy is not clinically effective; its routine use in this setting is not recommended (Grade B).

- Due to competing interests the NBA has not continued research on the specific elements that should be included on a blood order/prescription form to encourage alignment of prescribing with clinical guidelines. However, the NBA research and development priorities include characterisation of clinical decision making at the point of prescription, and development of strategies to support decision making.[vii]

Table 8: Progress against prescribing recommendations of Australian Haemovigilance Report 2010

	Recommendation from 2010 Report	Who is Responsible?	Proposed strategy from 2010 report	Outcomes
7	Continue to develop, publish and promulgate Patient Blood Management Guidelines	NBA; ANZSBT; NHMRC; Relevant professional Colleges and Societies	NBA to continue to work with professional Colleges and Societies and the NHMRC to publish PBM guidelines	Four PBM Guideline Modules published: ▪ Module 1 - Critical Bleeding/Massive Transfusion ▪ Module 2 - Perioperative ▪ Module 3 - Medical ▪ Module 4 - Critical Care Two further modules are currently under development
8	Research and publish the specific elements that should be included on a blood order/prescription form to encourage alignment of prescribing with clinical guidelines	NBA; Relevant professional Colleges and Societies	NBA to consider engaging relevant bodies to work with to develop a national blood order/prescription form	The current report expands this recommendation to develop tools to encourage alignment of prescribing practice with clinical guidelines

vii http://www.blood.gov.au/sites/default/files/documents/nba-research-and-development-priorities-2013-16.pdf

Procedural errors

The 2010 report made two recommendations on the subject of procedural errors during transfusions (Table 9). Progress against these recommendations has been as follows:

- The JBC promoted BloodSafe eLearning Australia as a main national education tool to improve clinical transfusion practice and patient blood management. The number of health care professionals registering with the BloodSafe eLearning Australia program continues to increase, with over 186,000 people from 1,000 Australian hospitals registered as of June 2013. The JBC has agreed to fund BloodSafe eLearning Australia to develop eLearning modules of the PBM Guidelines for Perioperative, Medical and Critical Care. The ACSQHC has also recommended using BloodSafe eLearning Australia to assist with the implementation of NSQHS Standard 7.
- The NBA supported research on barcode readers and radio-frequency identification technology in Australia. A recent pilot study conducted in a major metropolitan hospital demonstrates that 2D barcode technology and patient safety software significantly improve the bedside check of patient, blood and blood product identifications in an Australian setting.[25]

Table 9: Progress against recommendations of Australian Haemovigilance Report 2010 on procedural errors

	Recommendation from 2010 Report	Who is Responsible?	Proposed strategy from 2010 report	Outcomes
9	Reduce the potential for procedural errors through training, stringent application of standards, proficiency testing and accreditation	State and territory Departments of Health; Administration staff; Quality and Safety personnel; Hospital educators; Clinical staff	Standardised training and development Periodic proficiency testing Compliance with specimen labelling standards and patient identification, as prescribed by the NPAAC and the ANZSBT, and the ACHS accreditation standards required under EQuIP	BloodSafe eLearning Australia As of June 2013, there are over 186,000 users from 1,000 Australian hospitals registered with BloodSafe eLearning Australia BloodSafe eLearning Australia will develop modules for the PBM guidelines and assist with the implementation of NSQHS Standard 7
10	Research possible application of technological adjuncts such as portable barcode readers and/or radio-frequency identification scanners to reduce the scope for error	HAC; Quality and Safety organisations; Research Bodies	Jurisdictions and the NBA to encourage this research	A recent pilot study demonstrates that 2D barcode technology and patient safety-software significantly improves the bedside check of patient, blood and blood product identifications in an Australian setting

National blood quality and safety initiatives

The 2010 report made two recommendations on the subject of national blood quality and safety initiatives (Table 10). Progress against these recommendations has been as follows:

- Outcomes for these recommendations were pursued through the NBA's involvement in the development of NSQHS Standard 7.
- NSQHS Standard 7 came into effect on 1 January 2013.

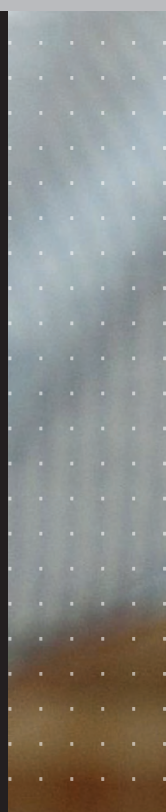
Table 10: Progress against recommendations of Australian Haemovigilance Report 2010 on national blood quality and safety initiatives

	Recommendation from 2010 Report	Who is Responsible?	Proposed strategy from 2010 report	Outcomes
11	Include Haemovigilance in Accreditation requirements	NBA; HAC; ACHS; NATA; RCPA; ACSQHC	NBA and HAC to continue to work with ACHS to monitor and improve accreditation requirements for haemovigilance	NSQHS Standard 7 developed and published Safety and Quality Improvement Guide for NSQHS Standard 7 developed and published
12	NBA, JBC and HAC to continue to engage with ACSQHC in the judicious development of indicators and standards relevant to the blood sector	NBA; JBC; HAC; ACSQHC	Provision of timely input as required by ACSQHC into the development of a Standard for Blood and Blood Products	NSQHS Standard 7 developed and published Safety and Quality Improvement Guide for NSQHS Standard 7 developed and published

DONOR VIGILANCE

PART 03

REVIEW OF DONOR ADVERSE EVENTS 2011-12



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. Collections staff who are responsible for the immediate management of adverse reactions which occur at the blood donor centre register such 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 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: Definitions 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 2011-12

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%-33%[26,27] and based on these rates Australia benchmarks favourably.

During 2011-12 there was a total of 1,342,883 donations, including 945,490 whole blood donations, 357,701 plasmapheresis donations and 39,282 plateletpheresis donations collected by the Blood Service. Total donation associated events and serious donation related events are shown in Figure 4 below.

There were 29,525 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 1:45 in 2011-12.

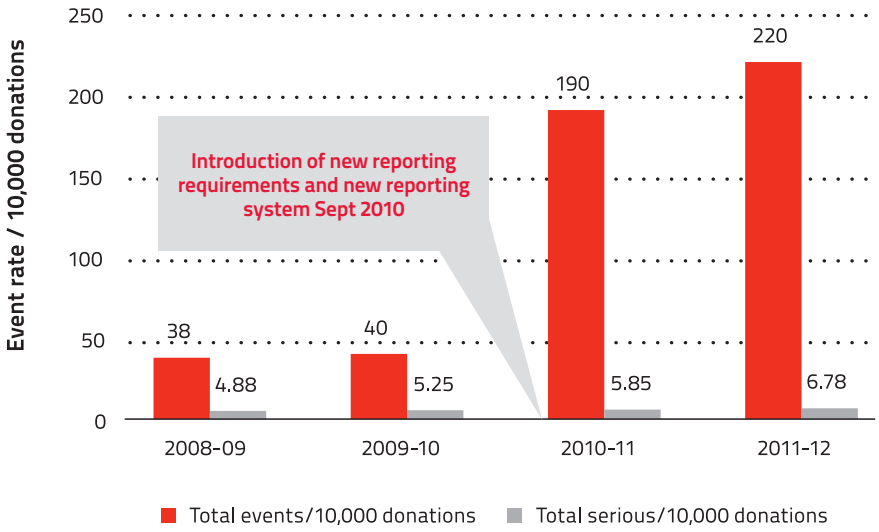


Figure 4: Total donation associated events and serious donation related events

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 September 2010, new standard operating procedures were introduced in which reporting requirements for adverse events changed to include the mandatory reporting of events classified as mild reactions are reported. This change in reporting requirements occurred concurrently with the introduction of an electronic reporting system to replace a paper-based system. In January 2011 a donor wellness check was introduced whereby every time a donor presents to donate they are asked whether they experienced any problems related to their previous donation. The main purpose of the donor wellness check is to identify delayed donor reactions.

In the 12 month period following the introduction of the donor wellness check there was nearly a 50% increase in the reporting of delayed events associated with whole blood donations and a 120% increase in the reporting of delayed events associated with plasma donations. These changes were associated with an apparent increase in reaction rates, as shown in Figure 4. Table 11 shows the impact of the introduction of the donor wellness question from 31 January 2011.

Table 12 shows the rate of adverse events by donation type, and the rate per 10,000 donations.

Table 11: Impact of the donor wellness question

	Prior to the introduction of the wellness question		After the introduction of the wellness question	
	Total Delayed events 1/10/10 - 31/1/11	Serious Delayed events 1/10/10 - 31/1/11	Total Delayed events 1/10/11 - 31/1/12	Serious Delayed events 1/10/11 - 31/1/12
Whole Blood	0.17%	0.03%	0.25%	0.03%
Plasma	0.05%	0.05%	0.11%	0.01%
Platelets	0.06%	0.03%	0.06%	0.02%

Table 12: Donor adverse events per procedure 2011-12

Procedure	Total Donations	Donations with Events	Frequency	Rate / 10,000 Donations
Whole Blood	945,900	25,110	1:38	265
Plasmapheresis	357,701	3,283	1:109	92
Plateletpheresis	39,282	1,131	1:35	288
All apheresis procedures	396,983	4,414	1:90	111
Total procedures	**1,342,883**	**29,524**	**1:45**	**220**

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 at 1:109, and platelet donations with the highest frequency at 1:35 (Table 12). The incidence of the different types of adverse events for all donations is shown in Table 13.

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 2011-12 there were 331 hospital referrals and 373 general practitioner (GP) referrals for donation-related complications (Table 14). There were no donation associated deaths. The most common reason for both hospital and GP referral is slow recovery from a vasovagal reaction. Nerve irritation due to a large haematoma was the most common reason for referral for phlebotomy injury, followed by painful arm after donation (Table 15). Table 16 details donor complication rates by severity per 10,000 donations 2011-12.

Table 13: Donation associated events by category and frequency for 2011-12

Donor Event	Number	% Total Events	Frequency	Rate / 10,000 Donations
Immediate vasovagal	24,225	82.05%	1:55	180
Delayed vasovagal	2,771	9.39%	1:485	21
Chest pain	48	0.16%	1:27,977	0.4
Citrate reaction*	233	0.79%	1:5,763	2
Haematoma	1,137	3.85%	1:1,181	8
Painful arm	431	1.46%	1:3,116	3
Nerve irritation	123	0.42%	1:10,918	1
Nerve injury	204	0.69%	1:6,583	2
Arterial puncture	50	0.17%	1:26,858	0.4
Delayed bleeding	39	0.13%	1:34,433	0.3
Thrombophlebitis	31	0.1%	1:43,319	0.2
Tendon damage	3	0.01%	1:447,628	0.02
Allergy	16	0.05%	1:83,930	0.1
Other injuries**	213	0.72%	1:6,305	2
Total	**29,524**	**-**	**1:45**	**219**

Notes:

1. *Calculated for apheresis collections only
2. **Includes severe headache during or immediately following donation (38 reports), generalised cramps (18 reports), palpitations/awareness of heart beat (17 reports), nausea and abdominal pain (10 reports), onset of wheeze/asthma during donation (8 reports), extreme fatigue following donation (7 reports)

Table 14: Summary of external medical referrals 2011-12

	Number of hospital referrals	Incidence of hospital referrals (% total collections)	Number of GP referrals	Incidence of GP referrals (% total collections)
Whole Blood	284	0.030	293	0.031
Plasmapheresis	37	0.010	65	0.018
Plateletpheresis	10	0.025	15	0.038
Total	**331**	**0.031**	**373**	**0.036**

Table 15: Reasons for external medical referrals 2011-12

	Number of hospital referrals	Incidence of hospital referrals (% total collections)	Number of GP referrals	Incidence of GP referrals (% total collections)
Vasovagal reactions	258	0.019	112	0.008
Phlebotomy Injuries	33	0.002	177	0.013
Chest Pain	17	0.001	20	0.001
Other*	23	0.002	64	0.005
Total	**331**	**0.025**	**373**	**0.028**

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 16: Donor complication rate by severity per 10,000 donations 2011-12

			Rate per 10,000 donations		
			Whole Blood	Plasmapheresis	Plateletpheresis
			(n=945,145)	(n=350,350)	(n=39,039)
Complications related to donation	Haematoma	Moderate	6.82	8.93	28.43
		Severe	0.47	0.29	1.54
	Arterial puncture	Moderate	0.45	0.09	0.00
		Severe	0.04	0.00	0.00
	Delayed bleeding	Mild	0.24	0.40	0.00
		Moderate	0.02	0.00	0.00
Pain/soft tissue injury	Nerve irritation	Moderate	0.79	0.86	1.28
		Severe	0.11	0.09	0.00
	Nerve injury	Moderate	1.34	0.94	0.77
		Severe	0.34	0.23	0.26
	Tendon damage	Mild	0.02	0.00	0.00
		Moderate	0.01	0.00	0.00
	Painful arm	Mild	0.87	1.37	2.31
		Moderate	1.94	1.71	1.02
		Severe	0.36	0.31	0.00
Other complications with local symptoms	Thrombophlebitis	Moderate	0.04	0.11	0.00
		Severe	0.16	0.17	0.00
	Allergy (local)	Mild	0.18	0.14	0.00
		Moderate	0.01	0.03	0.26
Immediate vasovagal reaction	Without injury	Mild	161.51	43.13	133.46
		Moderate	43.68	12.24	48.93
		Severe	19.72	5.71	9.99
	With injury	Mild	0.00	0.00	0.00
		Moderate	0.11	0.00	0.26
		Severe	0.61	0.17	0.77
Delayed vasovagal reaction	Without injury	Moderate	4.75	2.25	2.05
		Severe	10.18	3.94	3.07
	With injury	Moderate	0.01	0.03	0.00
		Severe	0.90	0.29	0.00
Apheresis related complications	Citrate reaction		0.00	1.54	45.85
	Haemolysis		0.00	0.03	0.00

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 (odds ratio 3.5 for 16-17 year males, and 6.3 for 16-17 year old females). This trend is consistent with international published data.[28, 29] Safety and well-being 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 Figure 5 and Figure 6). Refer to Appendix V for the supporting data for the calculation of the odds ratio.

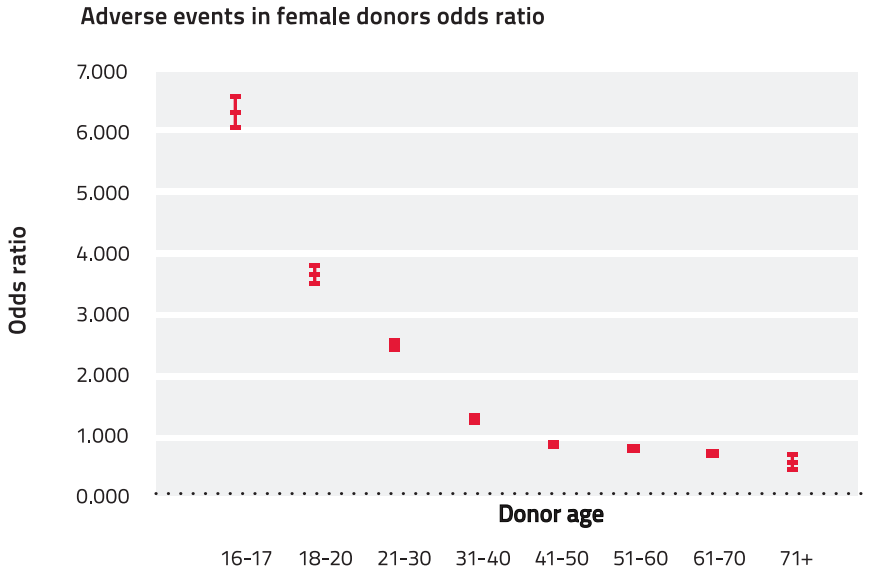


Figure 5: Odds ratio for vasovagal reactions associated with all donation types 2011-12 (females)

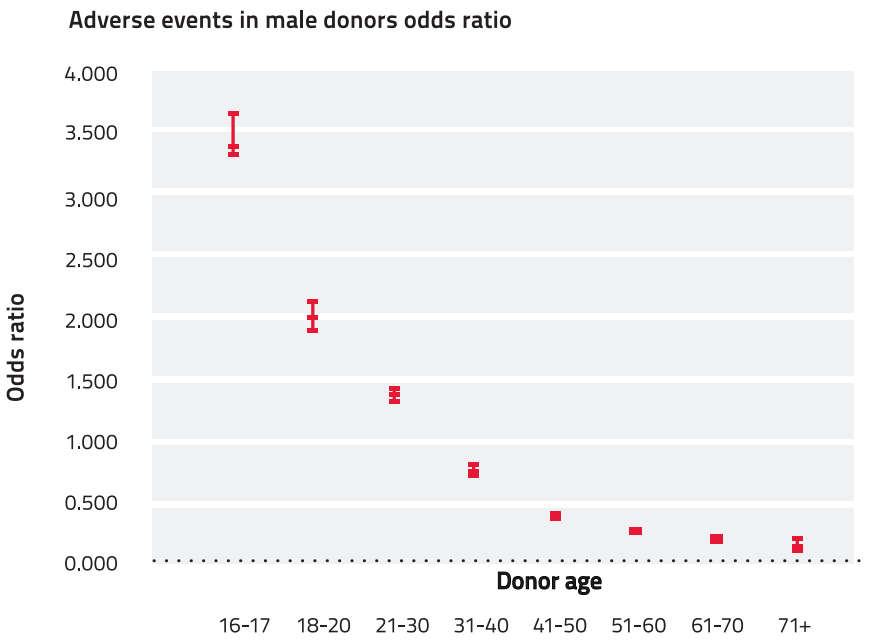


Figure 6: Odds ratio for vasovagal reactions associated with all donation types 2011-12 (males)

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%-33% and based on these rates we benchmark favourably. However there remains considerable value in benchmarking initiatives to reduce adverse events. For this reason the Blood Service regularly benchmarks with Blood Services across America, Canada, Europe and the Asia-Pacific region. 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[viii] 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 '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 prevent 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 Therapeutic Goods Administration.

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

HAEMOVIGILANCE DATA FOR 2009-10 AND 2010-11

PART 04

Available Australian haemovigilance data for 2009-10 and 2010-11

Overview of reported serious transfusion-related adverse events

Severe febrile non haemolytic transfusion reactions (FNHTR)

Allergic reactions (severe)

Anaphylactic and anaphylactoid reactions

Acute haemolytic transfusion reactions (other than ABO incompatibility)

Delayed haemolytic transfusion reactions (DHTR)

Transfusion-associated circulatory overload (TACO)

Transfusion transmitted infections (TTI)

Post transfusion purpura (PTP)

Incorrect blood component transfused (IBCT)

Contributory factors

PART 04
HAEMOVIGILANCE DATA FOR 2009-10 AND 2010-11

Available Australian haemovigilance data for 2009-10 and 2010-11

The NBA established a National Haemovigilance Program and HAC to support the continued development and alignment of jurisdictional haemovigilance reporting systems with the recommended national haemovigilance dataset. The 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.

Data source

Figure 7 shows a representation of the jurisdictions contributing haemovigilance data to the current report. Validated jurisdictional-level data was submitted by VIC, QLD, SA, TAS, the ACT and the NT. A small amount of relevant but incompatible data was submitted by NSW. WA is the only jurisdiction not contributing to the national dataset for the reporting period of this report from July 2009 to June 2011.

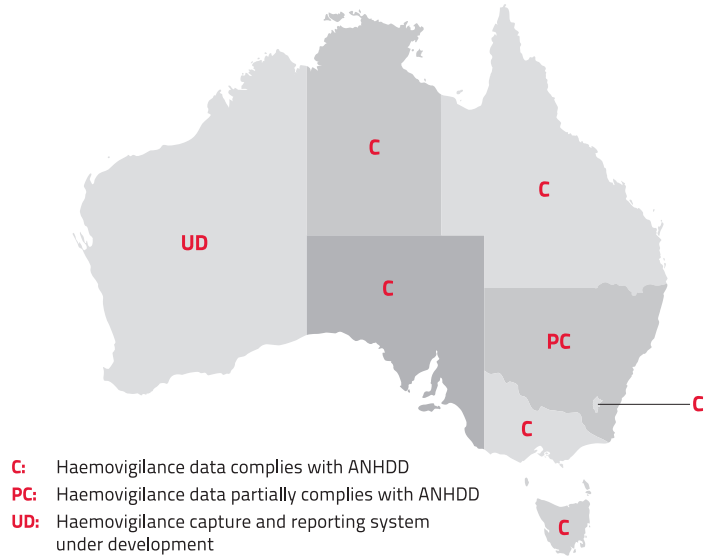


Figure 7: Jurisdictions contributing haemovigilance data to this report

Image adapted from Outline map of Australia (with state borders)

Victoria, Tasmania, Australian Capital Territory and Northern Territory

- VIC, TAS, ACT and NT supplied validated state level haemovigilance data to the National Haemovigilance Program. The transfusion-related adverse event data is fully compliant with the data elements specified in the ANHDD.

South Australia

- The SA BloodSafe program supplied validated state level haemovigilance data to the National Haemovigilance Program. SA Health clinical reporting transitioned from AIMS to Datix SLS in 2010. The ANHDD was incorporated into the development of SLS to facilitate national haemovigilance reporting. However, certain ANHDD data elements, such as age, sex and date of birth, are not mandatory for reporting and this has resulted in some missing data elements in this report.

Queensland

- The QLD Blood Management Program (QBMP) also supplied validated jurisdictional-level haemovigilance data (QiiT), 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 17 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.

- The QiiT has recently been decommissioned due to the restructure of Queensland's public health system. As a result, the ongoing supply of QLD data to the National Haemovigilance Program has now become a major issue. The NBA is working closely with Queensland Health on this issue. Meanwhile, NBA will advise transfusing hospitals on the use of ANHDD and reporting of haemovigilance data (see PART 05: RECOMMENDATIONS).

Table 17: Transformation of age categories between QiiT and ANHDD standards

QiiT Patient Age		National haemovigilance dataset Patient Age
28 days-1 year	was re-coded as	0-4 years
1-4 years	was re-coded as	0-4 years
5-9 years	was re-coded as	5-14 years
10-19 years	was re-coded as	15-24 years
20-29 years	was re-coded as	25-34 years
30-39 years	was re-coded as	35-44 years
40-49 years	was re-coded as	45-54 years
50-59 years	was re-coded as	55-64 years
60-69 years	was re-coded as	65-74 years
70-79 years	was re-coded as	75 years or older
> 80 years	was re-coded as	75 years or older

Source: NBA

New South Wales

- All NSW public hospitals use a centralised IIMS as their only incident reporting tool. IIMS is used to collect data and allows for the provision of reports on jurisdiction level haemovigilance incidents as one part of its broader incident information management function. It should be noted that the IIMS is not a specific haemovigilance reporting system, resulting in a lack of many important data fields required by the national haemovigilance dataset for national level reporting.
  The IIMS system is currently being reviewed. Capacity to report against the ANHDD data items is planned to be incorporated in the redevelopment specifications.
  The NSW data provided for 2009-10 and 2010-11 was not compatible with the reporting standards for this report. Relevant comment on NSW data is included in data discussions where appropriate, and the complete NSW data is presented in Appendix IV.

Western Australia

- WA did not contribute adverse event data to this or previous reports. WA is implementing PBM to address WA's multiple responsibilities in relation to blood transfusion. One component of the PBM program is to establish effective data collection and monitoring systems to facilitate evaluation and continuous practice improvement and risk management. WA has finalised the business requirements and tender processes for a new CIMS, which is anticipated to include haemovigilance modules.

Data quality

- 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.
- There is variation between states and territories in the quality and completeness of adverse event data reported to the National Haemovigilance Program: VIC, QLD, SA, TAS, ACT and NT supplied valid data; NSW supplied a small amount of relevant but incompatible data; WA did not contribute data.
- 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.
- It should be noted that the data is not complete for every reported adverse event in the national dataset. Data may be missing for some data elements, such as age, sex, time of transfusion, blood component and contributory factor. Where data elements are missing, the figures presented in the data summaries for each adverse event may be less than the total expected, or larger than the value expected for certain categories.
- 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. The report delivers a recommendation on redeveloping the ANHDD (see PART 05: RECOMMENDATIONS). This will include near miss data.
- With regard to denominator data, national information on the total number of fresh blood components transfused cannot be 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 estimates for most adverse reactions are very low when compared to everyday risks (refer to Calman scale in Table 18 and transfusion risks in Table 19). For example, the chances of acquiring bacterial sepsis from a red cell transfusion are equivalent to the chances of death from a train accident.

Table 18: The Calman chart for explaining risk (United Kingdom; risk per one year) [30]

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	1:1000 - 1:10,000 such as death from a road accident
High	> 1:1000 such as transmission of chickenpox to susceptible household contacts

Table 19: Transfusion risks [31]

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	At least 1:75,000	Very low
-Red cells	At least 1:500,000	Minimal
Haemolytic reactions:		
-Delayed	1:2,500 - 1:11,000	Low to very low
-Acute	1:76,000	Very low
-Fatal	less than 1:1 million	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

Table 20 shows the number of adverse events reported (independent of assigned imputability) to the National Haemovigilance Program for the three financial years 2008-09 to 2010-11. 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, page 117).

Summary of main findings and results

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

There were 1207 reports of adverse events to the National Haemovigilance Program from 2008-09 to 2010-11. The improved reporting from NSW significantly contributed to the increase in the number of reports, from 294 in 2008-09 to 582 in 2010-11. The most frequently reported adverse events are FNHTR and severe allergic reactions, representing 52% and 26% of all reports respectively. The Australian data for TACO, TRALI, and DHTR indicates that these adverse events remain largely under-reported.

Table 20: Australian adverse event data, 2008-09 to 2010-11

Adverse event	2008-09	2009-10	2010-11	All reports	
				Number	Per cent
FNHTR	154	158	321	633	52.4%
Severe allergic reaction	87	84	142	313	25.9%
IBCT	22	23	30	75	6.2%
Anaphylactoid or anaphylactic reaction	8	12	33	53	4.4%
TACO	6	12	24	42	3.5%
DHTR	4	8	10	22	1.8%
TTI	3	18	11	32	2.7%
AHTR	7	6	2	15	1.2%
TRALI	3	8	8	19	1.6%
PTP		2	1	3	0.2%
Total number of reports	**294**	**331**	**582**	**1207**	**100%**

Source: NBA

Notes

1. All TTIs were bacterial infections and these were reported cases but not necessarily confirmed.
2. Limited data from NSW for 2008-09 and 2009-10.

Red blood cells were the components most often implicated in adverse events for the last three financial years, accounting for 68.4% (683 of 998) of the reports from the VIC, QLD, SA, TAS, ACT and NT (Figure 8). The number of adverse events related to FFP transfusions increased from 29 reports in 2009-10 to 61 (41 severe allergic reactions) in 2010-11. In 23 events, the blood component type(s) was not specified. Only a very small proportion of adverse events were related to the transfusion of whole blood (rarely used in Australia), cryoprecipitate and cryodepleted plasma. Please note that WA and NSW are excluded from analysis due to the unavailability of blood component data for these two states.

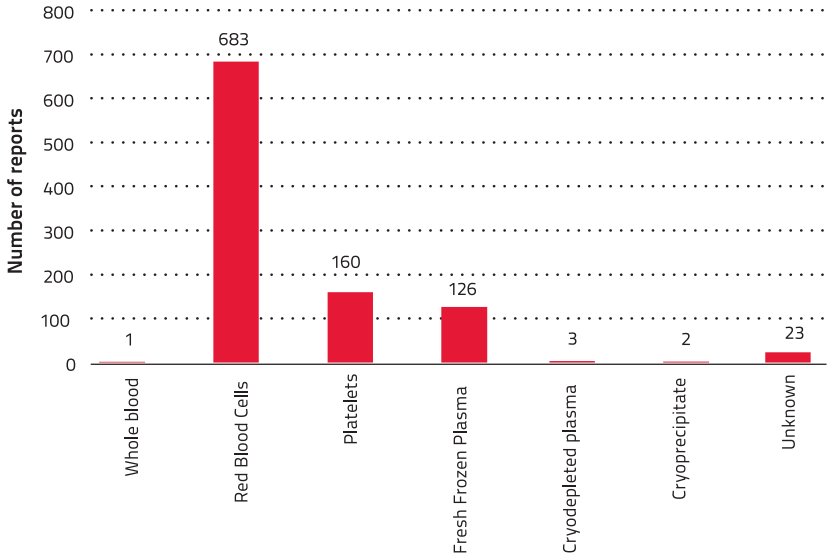


Figure 8: Blood components implicated in serious adverse events, 2008-09 to 2010-11

Source: NBA

Notes: Blood product component data unavailable for NSW and WA.

Table 21 details the numbers of adverse events by blood component and Table 22 details the mortality and morbidity data for 2008-11. Please note that WA and NSW are excluded from analysis due to the unavailability of blood component and outcome severity data for these two states.

Despite the increase in the number of reported events in 2009-10 and 2010-11, the number of deaths dropped from 2 in 2008-09 (1 death relating to allergic reaction and 1 death relating to TACO) to 0 in 2009-10 and 2010-11. The number of adverse events with life threatening severity also dropped significantly for most event types, FNHTR and severe allergic reaction particularly, from 30 in 2008-09 to 5 in 2009-10 and 4 in 2010-11. In contrast, the cases with severe morbidity rose from 11 in 2008-09 to 31 in 2009-10 and 45 in 2010-11. The cases with minor morbidity also had a large increase from 33 in 2008-09 to 208 in 2009-10 and 308 in 2010-11.

Table 21: Numbers of adverse events by blood component, 2008-09 to 2010-11

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	-	-	6	206
Allergic								
2008-09	-	40	19	27	-	1	-	87
2009-10	-	30	27	25	1	1	-	84
2010-11	-	33	27	41	1	-	1	103
IBCT								
2008-09	-	14	1	3	-	-	4	22
2009-10	1	16	5	-	-	-	1	23
2010-11	-	18	4	3	-	-	1	26
Anaphylactic								
2008-09	-	1	2	2	1	-	2	8
2009-10	-	5	1	1	-	-	-	7
2010-11	-	13	3	9	-	-	-	25
TACO								
2008-09	-	2	-	1	-	-	3	6
2009-10	-	8	-	-	-	-	-	8
2010-11	-	10	-	4	-	-	-	14
DHTR								
2008-09	-	1	3	-	-	-	-	4
2009-10	-	8	-	-	-	-	-	8
2010-11	-	6	-	1	-	-	-	7
Bacterial TTI								
2008-09	-	1	1	-	-	-	1	3
2009-10	-	2	5	-	-	-	-	7
2010-11	-	4	5	-	-	-	-	9
TRALI								
2008-09		1	-	1	-	-	1	3
2009-10	-	2	1	2	-	-	-	5
2010-11	-	5	-	-	-	-	-	5
AHTR								
2008-09	-	7	-	-	-	-	-	7
2009-10	-	6	-	-	-	-	-	6
2010-11	-	1	-	-	-	-	-	1
PTP								
2009-10	-	2	-	-	-	-	-	2
Total	**1**	**683**	**160**	**126**	**3**	**2**	**23**	**998**

Source: NBA

Notes

1. Table presents aggregate data from VIC, QLD, SA, TAS, ACT and NT.
2. Blood product component data unavailable for WA and NSW.

Table 22: Mortality and morbidity data, 2008-09 to 2010-11

	FNHTR	Allergic	IBCT	Anaphylactic	TACO	DHTR	Bacterial TTI	AHTR	TRALI	PTP	Total
Death											
2008-09	-	1	-	-	1	-	-	-	-	-	2
2009-10	-	-	-	-	-	-	-	-	-	-	-
2010-11	-	-	-	-	-	-	-	-	-	-	-
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
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
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
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
Outcome not available											
2008-09	55	17	2	1	4		1	1	1	-	82
2009-10	1	-	-		-		-	-	-	-	1
2010-11	1	-	1	1	-		-	-	-	-	3
Total	**518**	**274**	**71**	**40**	**28**	**19**	**19**	**14**	**13**	**2**	**998**

Source: NBA

Notes

1. Table presents aggregate data from VIC, QLD, SA, TAS, ACT and NT.
2. Outcome severity data unavailable for WA and NSW.

Severe febrile non-haemolytic transfusion reactions (FNHTR)

2009-10 Data Summary (n=158)					
Age		**Sex**		**Day of Transfusion**	
0-4 years	7	Male	34	Week day	121
5-14 years	4	Female	37	Weekend	37
15-24 years	3	Uncategorised	87	Unknown	-
25-34 years	5				
35-44 years	3	**Facility Location**		**Time of Transfusion**	
45--54 years	2	Major City	132	Between 7am and 7pm	55
55-64 years	9	Inner Regional	18	Between 7pm and 7am	17
65-74 years	8	Outer Regional	7	Unknown	86
75+ years	31	Remote	1		
Not specified	86	Very Remote	-		
Clinical Outcome Severity		**Imputability**		**Blood Component**	
Death	-	Excluded	5	Whole blood	-
Life threatening	-	Unlikely / Possible	44	Red cells	143
Severe morbidity	6	Likely / Probable	108	Platelets	14
Minor morbidity	122	Confirmed / Certain	1	Fresh Frozen Plasma	1
No morbidity	29	N/A / Not assessable	-	Cryoprecipitate	-
Outcome not available	1			Cryodepleted plasma	-
NSW					
Number of reports	-				

2010-11 Data Summary (n=321)					
Age		**Sex**		**Day of Transfusion**	
0-4 years	3	Male	54	Week day	159
5-14 years	3	Female	46	Weekend	47
15-24 years	5	Uncategorised	106	Unknown	-
25-34 years	9				
35-44 years	8	**Facility Location**		**Time of Transfusion**	
45--54 years	12	Major City	166	Between 7am and 7pm	77
55-64 years	10	Inner Regional	29	Between 7pm and 7am	29
65-74 years	23	Outer Regional	9	Unknown	100
75+ years	34	Remote	2		
Not specified	99	Very Remote	-		
Clinical Outcome Severity		**Imputability**		**Blood Component**	
Death	-	Excluded	15	Whole blood	-
Life threatening	-	Unlikely / Possible	47	Red cells	170
Severe morbidity	12	Likely / Probable	127	Platelets	27
Minor morbidity	184	Confirmed / Certain	11	Fresh Frozen Plasma	3
No morbidity	9	N/A / Not assessable	6	Cryoprecipitate	-
Outcome not available	1			Cryodepleted plasma	-
NSW					
Number of reports	115				

Source: NBA

Notes

1. Table presents aggregate data from VIC, QLD, SA, TAS, ACT and NT.
2. Age, sex and time of transfusion data is unavailable for SA.
3. Data element values (such as age, sex) missing for NSW.
4. Data unavailable for WA.

FNHTR (see Appendix II: Definitions in haemovigilance) are the most common transfusion-related adverse events 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.[32,33] In combined financial years 2008-09 through 2010-11, there were 633 FNHTRs reported to the National Haemovigilance Program, accounting for more than half (52%) of total reports (1207).

In the three financial years to 2010-11:

- The number of FNHTRs more than doubled, from 154 in 2008-09 to 321 in 2010-11, mainly due to increased reporting of this event from NSW and other states. There were no deaths associated with this event and the number of cases reporting life-threatening severity dropped from five in 2008-09 to zero in 2009-10 and 2010-11.
- The number of reports of minor morbidity had a large increase from 14 in 2008-09 to 188 in 2010-11. This may indicate an increased awareness of collecting and reporting FNHTR events at a hospital level and a state level, however there is still room for improvement in collection.
- The number of reports of outcome not available dropped significantly from 55 in 2008-09 to 1 in 2009-10 and 1 in 2010-11.
- The majority of cases were related to red cell transfusion.
- Data for age, sex, facility location, date and time of transfusion were all within expected distributions.
- The lack of SA data for age, sex and transfusion time attributed to the increased numbers of unknown/unspecified cases for these categories in 2009-10 and 2010-11.

In the period 2009-10 to 2010-11, around 68% of FNHTRs were assigned an imputability score of likely/probable or confirmed/certain, including seven cases with severe morbidity.

Table 23: FNHTR clinical outcome severity by imputability, 2009-10 and 2010-11

Clinical Outcome Severity	Imputability					Total
	Excluded	Unlikely / Possible	Likely / Probable	Confirmed / Certain	N/A / Not assessable	
Severe morbidity						
2009-10	-	5	1	-	-	6
2010-11	-	6	5	1	-	12
Minor morbidity						
2009-10	4	25	92	1	-	122
2010-11	15	38	118	9	4	184
No morbidity						
2009-10	-	14	15	-	-	29
2010-11	-	3	4	1	1	9
Outcome not available						
2009-10	1	-	-	-	-	1
2010-11	-	-	-	-	1	1
Total	**20**	**91**	**235**	**12**	**6**	**364**

Source: NBA

Notes

1. Table presents aggregate data from VIC, QLD, SA, TAS, ACT and NT.
2. Outcome severity and imputability data unavailable for WA and NSW.

The current definition of FNHTR used by the HAC in the ANHDD 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. Examples are described in the case studies below. Fever may also accompany other acute transfusion reactions, including acute haemolytic transfusion reactions, infusion of a bacterially contaminated blood component or TRALI. The diagnosis of FNHTR is generally a diagnosis of exclusion requiring a flexible approach.

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).

Case Study 1

Diagnosis of FNHTR in an elderly patient with hip replacement surgery

An elderly male was electively admitted for revision of his total hip replacement.

On the second day following his surgery, the patient had developed clinically significant anaemia. The patient advised that he was feeling very lethargic and felt a little dizzy when he sat up. On examination he appeared pale. His heart rate was elevated and he had postural hypotension. A sample of his blood was examined indicating his haemoglobin was 63g/L.

A transfusion of compatible red blood cells was ordered to treat his anaemia. A unit of compatible group A Rh(D) positive red blood cells was transfused over a period of 3 hours without any issue. Following reassessment, transfusion of a second unit of compatible A Rh(D) positive red blood cells was commenced. Approximately 15 minutes into the transfusion the nurse returned to the patient's room to check on his condition, at this time the patient reported feeling unwell and he was shaking with chills. His temperature had risen by 1.7°C to 38.5°C. The nurse stopped the transfusion and contacted the medical officer to review the patient. The patient was given an antipyretic medication and observed closely. The remaining red blood cells were sent back to the Transfusion Laboratory along with patient samples for testing.

The laboratory testing confirmed that the unit being transfused was blood group A Rh(D) positive and indeed compatible with the patient's own blood group. Testing confirmed that the patient was not suffering haemolysis (destruction of red blood cells) or bacteraemia (transfusion of a contaminated red cell unit). The patient's temperature and the chills resolved soon after the transfusion was ceased. He was discharged home as expected.

The conclusion of the hospital's Transfusion Service was that the patient had experienced a FNHTR.

Practice Notes

It is impossible to predict which patient may experience a FNHTR to transfusion. The causes are thought to be alloimmunisation to human leukocyte antigens or other antigens that accumulate during storage. Clinically, it is important to rule out other potentially more dangerous reactions such as acute haemolysis and bacteraemia. The fever often resolves after cessation of the transfusion or the administration of antipyretic medication. This type of reaction occurs in patients who have been alloimmunised by previous transfusion or pregnancy. The Australian Red Cross Blood Service introduced universal leucocyte depletion to aid in reducing the incidence of FNHTR.

Case Study 2

Difficulties with the diagnosis of FNHTR

A middle aged male underwent leg amputation complicated by bleeding with a background history of diabetes, liver disease and chronic pancreatitis.

He was afebrile 48 hours prior to transfusion although he was on multiple antibiotics for wound infection. Pre transfusion vital signs were BP: 90/60 mmHg, PR: 90 bpm, Temp: 36.2°C and RR: 14 bpm. He was transfused with a unit of red cells and at completion within 4 hours he developed high fever and rigors.

Vital signs post transfusion were BP: 110/70, PR: 118, Temp: 39.1 and RR: 21.

He was seen by the hospital medical officer within 30 minutes and was given hydrocortisone and promethazine. Blood cultures were taken from the patient and transfused blood unit and they proved negative after 5 days. Patient's Hb increased from 78 g/L to 88 g/L immediately after transfusion. The medical officer decided that no further investigation was required. However, the patient had a positive Direct Antiglobulin Test (DAT) before transfusion which remained positive post transfusion. Although his Hb dropped to 73 g/L two days after transfusion no test was done to exclude haemolysis.

Considerations

- Is this a typical FNHTR?
- Could this be a postoperative infection?
- Should further investigations have been carried out to exclude haemolytic transfusion reaction given the significant drop in Hb two days later?
- Was the management of this post-transfusion febrile episode appropriate?

Allergic reactions (severe)

2009-10 Data Summary (n=84)					
Age		**Sex**		**Day of Transfusion**	
0-4 years	3	Male	26	Week day	66
5-14 years	3	Female	25	Weekend	18
15-24 years	3	Uncategorised	33	Unknown	-
25-34 years	4				
35-44 years	5	**Facility Location**		**Time of Transfusion**	
45-54 years	10	Major City	74	Between 7am and 7pm	39
55-64 years	8	Inner Regional	7	Between 7pm and 7am	14
65-74 years	7	Outer Regional	1	Unknown	31
75+ years	8	Remote	1		
Not specified	33	Very Remote	1		
Clinical Outcome Severity		**Imputability**		**Blood Component**	
Death	-	Excluded	-	Whole blood	-
Life threatening	1	Unlikely / Possible	12	Red cells	30
Severe morbidity	4	Likely / Probable	59	Platelets	27
Minor morbidity	58	Confirmed / Certain	13	Fresh Frozen Plasma	25
No morbidity	21	N/A / Not assessable	-	Cryoprecipitate	1
Outcome not available	-			Cryodepleted plasma	-
NSW					
Number of reports	-				

2010-11 Data Summary (n=142)					
Age		**Sex**		**Day of Transfusion**	
0-4 years	4	Male	30	Week day	80
5-14 years	-	Female	34	Weekend	23
15-24 years	4	Uncategorised	39	Unknown	-
25-34 years	5				
35-44 years	2	**Facility Location**		**Time of Transfusion**	
45--54 years	12	Major City	80	Between 7am and 7pm	58
55-64 years	6	Inner Regional	20	Between 7pm and 7am	11
65-74 years	12	Outer Regional	3	Unknown	34
75+ years	21	Remote	-		
Not specified	37	Very Remote	-		
Clinical Outcome Severity		**Imputability**		**Blood Component**	
Death	-	Excluded	3	Whole blood	-
Life threatening	-	Unlikely / Possible	8	Red cells	33
Severe morbidity	9	Likely / Probable	68	Platelets	27
Minor morbidity	87	Confirmed / Certain	23	Fresh Frozen Plasma	41
No morbidity	7	N/A / Not assessable	1	Cryoprecipitate	1
Outcome not available	-			Cryodepleted plasma	-
NSW					
Number of reports	39				

Source: NBA

Notes

1. Table presents aggregate data from VIC, QLD, SA, TAS, ACT and NT.
2. Age, sex and time of transfusion data is unavailable for SA.
3. Data element values (such as age, sex) missing for NSW.
4. Data unavailable for WA.

Allergic reactions (see Appendix II: Definitions in haemovigilance) are the second most common transfusion-related adverse event reported in Australia. From 2008-09 to 2010-11, there were 313 reports to the National Haemovigilance Program, accounting for 26% of all reports (1207).

In the three financial years to 2010-11:

- The number of severe allergic reactions rose by 63 % from 87 in 2008-09 to 142 in 2010-11, mainly due to increased reporting of this event from NSW.
- There was one death in 2008-09 and no deaths in 2009-10 or 2010-11. The number of cases reporting life-threatening severity also dropped from 16 in 2008-09 to 1 in 2009-10 and 0 in 2010-11.
- The number of cases reporting minor morbidity increased from 16 in 2008-09 to 87 in 2010-11.

The lack of SA data for age, sex and transfusion time contributed to the large numbers of unknown/unspecified cases across these categories.

In the period 2009-10 to 2010-11, 87% of cases were assigned an imputability score of likely/probable or confirmed/certain, including 12 cases with severe morbidity. The only case with life threatening severity in 2009-10 was assigned an imputability score of unlikely/possible.

Table 24: Severe allergic reaction clinical outcome severity by imputability, 2009-10 and 2010-11

Clinical Outcome Severity	Imputability					Total
	Excluded	Unlikely / Possible	Likely / Probable	Confirmed / Certain	N/A / Not assessable	
Death						
2009-10	-	-	-	-	-	-
2010-11	-	-	-	-	-	-
Life threatening						
2009-10	-	1	-	-	-	1
2010-11	-	-	-	-	-	-
Severe morbidity						
2009-10	-	-	3	1	-	4
2010-11	-	1	6	2	-	9
Minor morbidity						
2009-10	-	7	39	12	-	58
2010-11	3	7	56	20	1	87
No morbidity						
2009-10	-	4	17	-	-	21
2010-11	-	-	6	1	-	7
Outcome not available						
2009-10	-	-	-	-	-	-
2010-11	-	-	-	-	-	-
Total	**3**	**20**	**127**	**36**	**1**	**187**

Source: NBA

Notes

1. Table presents aggregate data from VIC, QLD, SA, TAS, ACT and NT.
2. Outcome severity and imputability data unavailable for WA and NSW.

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. These reactions have historically been estimated to occur in 1-3% of transfusions. Leucoreduction has no effect on decreasing these rates[34], 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.

The management depends on the severity of the reaction, and consideration of other causes (such as latex or drug allergy) may be required. The following case studies illustrate the clinical presentation of a transfusion-related severe allergic reaction.

Case Study 3

Importance of rate of infusion in development and severity of allergic reactions

A middle-aged male, previously well, was receiving therapeutic plasma exchange (TPE) for thrombotic thrombocytopenic purpura (TTP). The patient was also receiving prednisolone. He had a background history of exercise-induced asthma, allergy to penicillin with rash and lip swelling, and to shellfish with rash.

Replacement fluid for his TPE was fresh frozen plasma (FFP). During his first TPE a reaction was reported in which he complained of breathlessness and chest tightness. Wheeze was noted on auscultation of his chest. This occurred after the first 2 units of FFP were exchanged. The reaction was treated with hydrocortisone, promethazine and salbutamol and the procedure ceased. His symptoms resolved rapidly. The reaction was reported to the hospital transfusion service. Chest x-ray (CXR) and IgA levels were normal. His reaction was most consistent with an allergic reaction to FFP.

For his second procedure he was premedicated with cetirizine and seretide. He tolerated the second procedure with further episodes of slight chest tightness which was relieved with salbutamol.

Prior to his third procedure the patient was given a premedication with cetirizine and seretide. During this procedure he developed an urticarial rash over the palms of his hands and cubital fossa without breathlessness, stridor or haemodynamic instability. The TPE was paused to administer promethazine and the rash resolved. The procedure was recommenced after approximately 30 minutes. The patient then developed more generalised urticaria over his arms and chest with hypotension (systolic BP 90). There was a Medical Emergency Team (MET) call review and the procedure was ceased. He was treated with hydrocortisone and promethazine. Approximately 30 minutes later there was a second MET call for hypotension (systolic BP 70), wheeze (O_2sat 100%) and ongoing urticarial rash. Adrenaline and salbutamol were administered. The patient was transferred to ICU for further treatment and monitoring during TPE.

Premedication was recommended for further TPE. Treatment was modified to include slow plasma infusions along with TPE using 4% albumin as replacement, with some FFP given towards the end of the procedure. He was also continued on steroids and was treated with rituximab in an attempt to avoid any risk of relapse due to his high risk of reactions to plasma therapy. He had no further reactions to FFP when it was infused at the slower rates.

Practice Notes

Severe allergic reactions can rarely be predicted before first presentation. However, there are a variety of strategies and premedications available to manage patients that are prone to reactions. It is vital that this information is included in the permanent patient records, and that the reaction is fully explained to the patient.

Case Study 4

Other possible causes of allergic reactions

A middle-aged female underwent urgent triple coronary artery bypass graft surgery complicated by early postoperative bleeding. She developed severe hypotension, tachycardia, skin rash and urticaria whilst she was receiving FFP (550 ml) in ICU. Her pre-transfusion vital signs were BP: 90/50mmHg, HR: 70 bpm, Temp: 36.1°C. She was sedated and ventilated. Her vital signs at the time of reaction were BP: 58/40, HR: 112 and Temp: 35.3. She was on the following medications before the reaction: ranitidine, ticarcillin/clavulinic acid, atorvastatin, hydrocortisone, perindopril, clopidogrel and metoprolol.

This reaction was treated by 'stat' doses of hydrocortisone and adrenaline and an infusion of noradrenaline was also commenced.

Investigations for this event showed normal IgA levels, no detectable anti-IgA antibodies on 2 consecutive tests 2 days apart, sinus tachycardia on ECG and troponin T levels were in the expected postoperative range.

The patient recovered well within 3 hours after the onset of reaction.

Considerations

- Was this an allergic reaction to FFP or a reaction to medications?
- Was the reaction exaggerated because of the effects of preoperative treatment with ACE inhibitor (perindopril)?
- Were the investigations sufficient to confirm or refute a transfusion reaction?
- Was the management of the reaction appropriate?

Anaphylactic and anaphylactoid reactions

2009-10 Data Summary (n=12)					
Age		**Sex**		**Day of Transfusion**	
0-4 years	-	Male	3	Week day	5
5-14 years	1	Female	4	Weekend	2
15-24 years	-	Uncategorised	-	Unknown	-
25-34 years	-				
35-44 years	-	**Facility Location**		**Time of Transfusion**	
45--54 years	1	Major City	7	Between 7am and 7pm	3
55-64 years	1	Inner Regional	-	Between 7pm and 7am	4
65-74 years	-	Outer Regional	-	Unknown	-
75+ years	4	Remote	-		
Not specified	-	Very Remote	-		
Clinical Outcome Severity		**Imputability**		**Blood Component**	
Death	-	Excluded	-	Whole blood	-
Life threatening	2	Unlikely / Possible	3	Red cells	5
Severe morbidity	4	Likely / Probable	1	Platelets	1
Minor morbidity	1	Confirmed / Certain	-	Fresh Frozen Plasma	1
No morbidity	-	N/A / Not assessable	3	Cryoprecipitate	-
Outcome not available	-			Cryodepleted plasma	-
NSW					
Number of reports	5				

2010-11 Data Summary (n=33)					
Age		**Sex**		**Day of Transfusion**	
0-4 years	-	Male	9	Week day	17
5-14 years	-	Female	5	Weekend	8
15-24 years	4	Uncategorised	11	Unknown	-
25-34 years	2				
35-44 years	1	**Facility Location**		**Time of Transfusion**	
45--54 years	3	Major City	22	Between 7am and 7pm	1
55-64 years	2	Inner Regional	2	Between 7pm and 7am	4
65-74 years	2	Outer Regional	1	Unknown	11
75+ years	-	Remote	-		
Not specified	11	Very Remote	-		
Clinical Outcome Severity		**Imputability**		**Blood Component**	
Death	-	Excluded	-	Whole blood	-
Life threatening	1	Unlikely / Possible	4	Red cells	13
Severe morbidity	6	Likely / Probable	16	Platelets	3
Minor morbidity	15	Confirmed / Certain	5	Fresh Frozen Plasma	9
No morbidity	2	N/A / Not assessable	-	Cryoprecipitate	-
Outcome not available	1			Cryodepleted plasma	-
NSW					
Number of reports	8				

Source: NBA

Notes

1. Table presents aggregate data from VIC, QLD, SA, TAS, ACT and NT.
2. Age, sex and time of transfusion data is unavailable for SA.
3. Data element values (such as age, sex) missing for NSW.
4. Data unavailable for WA.

In the three financial years 2008-09 to 2010-11, there were 53 reports of anaphylactic and anaphylactoid reactions to the National Haemovigilance Program, accounting for 4.4 % of all reports (1207). The number of cases rose from 8 in 2008-09 to 33 in 2010-2011. One life threatening case was confirmed to be related to fresh frozen plasma transfusion for 2010-11.

In the period 2009-10 to 2010-11, 22 out of 32 cases were assigned an imputability score of likely/probable or confirmed/certain, including one case of life threatening (confirmed/certain) and six cases with severe morbidity. Another two cases with life threatening severity were assigned an imputability score of unlikely/possible.

Table 25: Anaphylactic and anaphylactoid reactions clinical outcome severity by imputability, 2009-10 and 2010-11

Clinical Outcome Severity	Imputability					Total
	Excluded	Unlikely / Possible	Likely / Probable	Confirmed / Certain	N/A / Not assessable	
Death						
2009-10	-	-	-	-	-	-
2010-11	-	-	-	-	-	-
Life threatening						
2009-10	-	2	-	-	-	2
2010-11	-	-	-	1	-	1
Severe morbidity						
2009-10	-	-	1	-	3	4
2010-11	-	1	3	2	-	6
Minor morbidity						
2009-10	-	1	-	-	-	1
2010-11	-	1	12	2	-	15
No morbidity						
2009-10	-	-	-	-	-	-
2010-11	-	1	1	-	-	2
Outcome not available						
2009-10	-	-	-	-	-	-
2010-11	-	1	-	-	-	1
Total	**-**	**7**	**17**	**5**	**3**	**32**

Source: NBA

Notes

1. Table presents aggregate data from VIC, QLD, SA, TAS, ACT and NT.
2. Outcome severity and imputability data unavailable for WA and NSW.

Anaphylaxis is an acute hypersensitivity reaction that can present as, or rapidly progress to, a severe life-threatening reaction.[35] Anaphylactoid reactions are clinically indistinguishable from anaphylaxis reactions, but differ in their immune mechanism. A distinction between anaphylaxis and anaphylactoid reaction is impossible on the basis of clinical signs and symptoms alone; a clinical definition cannot differentiate between the two.

This position is consistent with recent 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'.[36, 37, 38] 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.[38]

The British Committee for Standards in Haematology (BCSH) has the following recommendations on the treatment of anaphylactic and anaphylactoid reactions in the UK:[39]

- adrenaline (epinephrine) is the first line drug in anaphylaxis
- antihistamine and hydrocortisone may have a role in shortening the anaphylactic reaction and preventing recurrence
- the history of patients who have experienced an anaphylactic reaction should be discussed with an allergist or immunologist, in keeping with UK resuscitation council guidelines.

Acute haemolytic transfusion reactions (other than ABO incompatibility)

2009-10 Data Summary (n=6)					
Age		**Sex**		**Day of Transfusion**	
0-4 years	-	Male	4	Week day	5
5-14 years	1	Female	2	Weekend	1
15-24 years	-	Uncategorised	-	Unknown	-
25-34 years	-				
35-44 years	-	**Facility Location**		**Time of Transfusion**	
45--54 years	-	Major City	5	Between 7am and 7pm	6
55-64 years	1	Inner Regional	1	Between 7pm and 7am	-
65-74 years	2	Outer Regional	-	Unknown	-
75+ years	2	Remote	-		
Not specified	-	Very Remote	-		
Clinical Outcome Severity		**Imputability**		**Blood Component**	
Death	-	Excluded	-	Whole blood	-
Life threatening	-	Unlikely / Possible	1	Red cells	6
Severe morbidity	5	Likely / Probable	1	Platelets	-
Minor morbidity	1	Confirmed / Certain	4	Fresh Frozen Plasma	-
No morbidity	-	N/A / Not assessable	-	Cryoprecipitate	-
Outcome not available	-			Cryodepleted plasma	-
NSW					
Number of reports	-				

2010-11 Data Summary (n=2)					
Age		**Sex**		**Day of Transfusion**	
0-4 years	-	Male	-	Week day	1
5-14 years	-	Female	1	Weekend	-
15-24 years	-	Uncategorised	-	Unknown	-
25-34 years	-				
35-44 years	-	**Facility Location**		**Time of Transfusion**	
45--54 years	-	Major City	1	Between 7am and 7pm	1
55-64 years	-	Inner Regional	-	Between 7pm and 7am	-
65-74 years	1	Outer Regional	-	Unknown	-
75+ years	-	Remote	-		
Not specified	-	Very Remote	-		
Clinical Outcome Severity		**Imputability**		**Blood Component**	
Death	-	Excluded	-	Whole blood	-
Life threatening	-	Unlikely / Possible	-	Red cells	1
Severe morbidity	1	Likely / Probable	-	Platelets	-
Minor morbidity	-	Confirmed / Certain	1	Fresh Frozen Plasma	-
No morbidity	-	N/A / Not assessable	-	Cryoprecipitate	-
Outcome not available	-			Cryodepleted plasma	-
NSW					
Number of reports	1				

Source: NBA

Notes

1. Table presents aggregate data from VIC, QLD, SA, TAS, ACT and NT.
2. Age, sex and time of transfusion data is unavailable for SA.
3. Data element values (such as age, sex) missing for NSW.
4. Data unavailable for WA.

Acute transfusion reactions occur by definition within 24 hours of transfusion. Diagnosis of an acute haemolytic transfusion reaction can be difficult, as reactions are often seen in patients with concurrent illnesses that may have other causes for their symptoms. The risk of acute haemolytic transfusion is low, estimated to be 1 in 76,000 transfusions (refer to transfusion risks in Table 19).

Adverse events attributed to transfusion of ABO incompatible components can cause acute haemolytic transfusion reactions, 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.

Acute transfusion reactions may have immune or non-immune aetiology; blood group serology usually shows abnormal results but absence of immunological findings does not exclude acute haemolytic transfusion reactions. These reactions may also be due to erythrocyte auto-antibodies in the recipient or to non-immunological factors like mechanical factors inducing haemolysis (including malfunction of a pump, of a blood warmer or use of hypotonic solutions).

From 2009-10 to 2010-11, there were 8 reports to the National Haemovigilance Program, with 6 cases reporting severe morbidity imputed as confirmed/certain or likely/probable. 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.

Case Study 5

Difficulties with the diagnosis of acute haemolytic transfusion reactions

An elderly male admitted with chronic renal failure with history of asthma, ischemic heart disease, recent myocardial infarction and PCI with stents implantation. He was on ventolin and symbicort inhalers and aspirin before transfusions. He received 5 units of red cells over 3 days and showed some reaction to the last blood unit. His pretransfusion vital signs were: BP: 132/98 mmHg, PR: 100 bpm, Temp: 37.1°C and RR: 18 bpm.

Posttransfusion observation showed BP: 150/100, PR: 120, Temp: 38.5 and RR: 34. The patient complained of dyspnoea and had rigors. He was given hydrocortisone and a stat IV dose of frusemide as his fluid balance was about one litre positive. There was consistently no increase in Hb levels, 57 g/L, despite receiving 5 units of red cells, however LDH was raised from 590 to 980U/L, pre- and posttransfusion DAT were positive, blood culture after transfusion was negative and there was microscopic haematuria. Haptoglobin was not checked after transfusion. Pretransfusion tests performed 2 days prior to transfusion were all correct and antibody screen and cross-match were done by the automated computer systems. Last transfused blood unit was found not compatible and antibody screen was positive (anti-Jk(a) antibody) on retesting of pretransfusion sample. Same tests after the reaction also showed similar results.

Considerations:

- Antibodies in the Kidd blood group system, such as anti-Jk(a) are notorious for causing acute haemolytic transfusion reactions.
- The negative pretransfusion antibody screen may have been a false negative because of a weak Jk(a) antibody.
- Should the possibility of haemolysis have been considered by clinicians earlier, given there was no increase in Hb whilst the patient was not bleeding?
- Is there a need for a national antibody registry for transfusion laboratories and an antibody alert card for patients?

Delayed haemolytic transfusion reactions (DHTR)

2009-10 Data Summary (n=8)					
Age		**Sex**		**Day of Transfusion**	
0-4 years	-	Male	2	Week day	7
5-14 years	-	Female	6	Weekend	1
15-24 years	-	Uncategorised	-	Unknown	-
25-34 years	1				
35-44 years	-	**Facility Location**		**Time of Transfusion**	
45--54 years	1	Major City	7	Between 7am and 7pm	4
55-64 years	3	Inner Regional	-	Between 7pm and 7am	4
65-74 years	2	Outer Regional	1	Unknown	-
75+ years	1	Remote	-		
Not specified	-	Very Remote	-		
Clinical Outcome Severity		**Imputability**		**Blood Component**	
Death	-	Excluded	-	Whole blood	-
Life threatening	1	Unlikely / Possible	1	Red cells	8
Severe morbidity	3	Likely / Probable	1	Platelets	-
Minor morbidity	4	Confirmed / Certain	5	Fresh Frozen Plasma	-
No morbidity	-	N/A / Not assessable	1	Cryoprecipitate	-
Outcome not available	-			Cryodepleted plasma	-
NSW					
Number of reports	-				

2010-11 Data Summary (n=10)					
Age		**Sex**		**Day of Transfusion**	
0-4 years	-	Male	1	Week day	6
5-14 years	-	Female	6	Weekend	1
15-24 years	1	Uncategorised	-	Unknown	-
25-34 years	2				
35-44 years	-	**Facility Location**		**Time of Transfusion**	
45--54 years	1	Major City	5	Between 7am and 7pm	5
55-64 years	2	Inner Regional	1	Between 7pm and 7am	2
65-74 years	1	Outer Regional	1	Unknown	-
75+ years	-	Remote	-		
Not specified	-	Very Remote	-		
Clinical Outcome Severity		**Imputability**		**Blood Component**	
Death	-	Excluded	-	Whole blood	-
Life threatening	-	Unlikely / Possible	1	Red cells	6
Severe morbidity	1	Likely / Probable	1	Platelets	-
Minor morbidity	5	Confirmed / Certain	5	Fresh Frozen Plasma	1
No morbidity	1	N/A / Not assessable	-	Cryoprecipitate	-
Outcome not available	-			Cryodepleted plasma	-
NSW					
Number of reports	3				

Source: NBA

Notes

1. Table presents aggregate data from VIC, QLD, SA, TAS, ACT and NT.
2. Age, sex and time of transfusion data is unavailable for SA.
3. Data element values (such as age, sex) missing for NSW.
4. Data unavailable for WA.

In contrast to the acute haemolytic transfusion reactions, DHTR are triggered by the production or re-emergence of antibodies following transfusion and therefore are not generally detectable at the time of pre-transfusion compatibility testing.

In the three financial years to 2010-11:

- there were 22 reports of DHTR to the National Haemovigilance Program, accounting for 1.8% of total reports (1207)
- there was one reported case of life-threatening severity in 2009-10 and this was assigned an imputability score of confirmed/certain
- the majority of cases were related to red cell transfusion
- the majority of 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.[40] Researchers have observed that DHTR are probably under-reported and under-recognised in the UK.[41]

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 antibody specificity implicated in both acute and delayed reactions.[42] 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.[43]

Transfusion-associated circulatory overload (TACO)

2009-10 Data Summary (n=12)					
Age		**Sex**		**Day of Transfusion**	
0-4 years	-	Male	2	Week day	6
5-14 years	-	Female	4	Weekend	2
15-24 years	-	Uncategorised	2	Unknown	-
25-34 years	-				
35-44 years	-	**Facility Location**		**Time of Transfusion**	
45--54 years	-	Major City	6	Between 7am and 7pm	6
55-64 years	1	Inner Regional	2	Between 7pm and 7am	-
65-74 years	-	Outer Regional	-	Unknown	2
75+ years	5	Remote	-		
Not specified	2	Very Remote	-		
Clinical Outcome Severity		**Imputability**		**Blood Component**	
Death	-	Excluded	1	Whole blood	-
Life threatening	-	Unlikely / Possible	4	Red cells	8
Severe morbidity	3	Likely / Probable	2	Platelets	-
Minor morbidity	5	Confirmed / Certain	-	Fresh Frozen Plasma	-
No morbidity	-	N/A / Not assessable	1	Cryoprecipitate	-
Outcome not available	-			Cryodepleted plasma	-
NSW					
Number of reports	4				

2010-11 Data Summary (n=24)					
Age		**Sex**		**Day of Transfusion**	
0-4 years	-	Male	7	Week day	11
5-14 years	-	Female	5	Weekend	3
15-24 years	-	Uncategorised	2	Unknown	-
25-34 years	-				
35-44 years	-	**Facility Location**		**Time of Transfusion**	
45--54 years	1	Major City	9	Between 7am and 7pm	7
55-64 years	-	Inner Regional	4	Between 7pm and 7am	5
65-74 years	4	Outer Regional	1	Unknown	2
75+ years	7	Remote	-		
Not specified	2	Very Remote	-		
Clinical Outcome Severity		**Imputability**		**Blood Component**	
Death	-	Excluded	-	Whole blood	-
Life threatening	1	Unlikely / Possible	6	Red cells	10
Severe morbidity	9	Likely / Probable	7	Platelets	-
Minor morbidity	4	Confirmed / Certain	1	Fresh Frozen Plasma	4
No morbidity	-	N/A / Not assessable	-	Cryoprecipitate	-
Outcome not available	-			Cryodepleted plasma	-
NSW					
Number of reports	10				

Source: NBA

Notes

1. Table presents aggregate data from VIC, QLD, SA, TAS, ACT and NT.
2. Age, sex and time of transfusion data is unavailable for SA.
3. Data element values (such as age, sex) missing for NSW.
4. Data unavailable for WA.

Transfusion of significant volumes 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.

In the last three financial years to 2010-11, there were 42 reports of TACO to the National Haemovigilance Program, accounting for 3.5% of total reports (1207). The number of cases rose from 6 in 2008-09 to 24 in 2010-11. One death occurred in 2008-09 and no deaths in 2009-10 or 2010-11. Only one case with life threatening severity was reported in 2010-11 but it was classified as unlikely/possible to be related to blood transfusion. The majority of cases were related to red cell transfusion. The figures also indicate that elderly patients aged 65 and above are at high risk of TACO and this is consistent with international findings.

In the period 2009-10 to 2010-11, 10 out of 22 cases were assigned an imputability score of likely/probable or confirmed/certain, including six cases with severe morbidity.

Table 26: TACO clinical outcome severity by imputability, 2009-10 and 2010-11

Clinical Outcome Severity	Imputability					Total
	Excluded	Unlikely / Possible	Likely / Probable	Confirmed / Certain	N/A / Not assessable	
Death						
2009-10	-	-	-	-	-	-
2010-11	-	-	-	-	-	-
Life threatening						
2009-10	-	-	-	-	-	-
2010-11	-	1	-	-	-	1
Severe morbidity						
2009-10	-	1	1	-	1	3
2010-11	-	4	4	1	-	9
Minor morbidity						
2009-10	1	3	1	-	-	5
2010-11		1	3			4
No morbidity						
2009-10	-	-	-	-	-	-
2010-11	-	-	-	-	-	-
Outcome not available						
2009-10	-	-	-	-	-	-
2010-11	-	-	-	-	-	-
Total	**1**	**10**	**9**	**1**	**1**	**22**

Source: NBA

Notes

1. Table presents aggregate data from VIC, QLD, SA, TAS, ACT and NT.
2. Outcome severity and imputability data unavailable for WA and NSW.

Patients at the highest risk for TACO include those younger than 3 and those older than 60 years of age, particularly those with underlying cardiac dysfunction.[44] 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.

At presentation, distinguishing TACO and TRALI can be particularly difficult. The clinical presentation is similar, and there are no diagnostic tests that reliably discriminate. Furthermore, a patient may simultaneously suffer both TACO and TRALI and this adds to the complexity. The therapy and management of the patient, and the implications for the donor, in the two different reactions are quite dissimilar.

TACO remains the leading cause of potentially avoidable mortality and major morbidity associated with blood transfusions in the UK. In 2011[42] the mortality rate was 0.7 per 1,000,000 components issued and the major morbidity rate was 8.1 per 1,000,000 components issued.

TACO incident estimates have ranged from approximates of 0.0003% to 8% of transfusions depending upon patient population and reporting method.[45] These rates suggest that TACO is as common an adverse event as FNHTR. However, the number of TACO events (36) reported to the National Haemovigilance Program in 2009-10 and 2010-11 is much lower than that of FNHTR (479). 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
- issues relating to reporting within hospitals and subsequent reporting to jurisdictional and national haemovigilance programs.

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

The NBA PBM Guidelines Module 3: Medical has a practice point on the recognition and 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 UK SHOT report also recommends that all measures must be taken to reduce the risk of TACO.[42] These include pre-transfusion clinical assessment to identify patients at increased risk of TACO in whom particular consideration should be given to the appropriateness of transfusion, the rate of transfusion and diuretic cover. Careful attention to fluid balance is essential and must be documented.

Case Study 6

Complexities of decision making in the transfusion process for an elderly patient with anaemia

An elderly male was admitted to the Emergency Department with significant anaemia for investigation. The patient had a history of atrial fibrillation (this condition was being managed with warfarin (an anticoagulant medication)), and congestive cardiac failure (CCF). He had been passing dark stools for the two days preceding his presentation. It was suspected that the patient was experiencing bleeding in his gastrointestinal (GI) tract, exacerbated by the anticoagulant therapy. Blood testing revealed that the patient had low haemoglobin of 85g/L and his INR (measurement of the warfarin effectiveness) was elevated at 2.9.

The decision was made to reverse the warfarin. Vitamin K and two units of FFP were ordered, to be followed by four units of red cells to correct the low haemoglobin. Diuretics were not prescribed at the time of the transfusion. During administration of the second unit of FFP the patient developed signs of a reaction and the transfusion was ceased. His blood pressure increased and he was dyspnoeic, with decreased oxygen saturation and development of a respiratory wheeze.

The patient was administered oxygen, ventolin nebuliser, diuretics and a chest xray and blood tests were performed. The patient responded well to the diuretics and oxygen, his symptoms were reduced. The chest xray showed signs of circulatory overload and his INR was closer to the normal range (still elevated at 1.5), his fibrinogen level was elevated to 4.4g/L and his Brain Natriuretic Peptide (BNP) level was significantly elevated to 682ng/L (reference range is <100ng/L). The patient recovered soon after this event and underwent further investigation to locate the source of his GI bleed.

Practice Notes

The patient experienced TACO. This patient was at high risk of circulatory overload due to his low weight, later discovered to be 51kg, his CCF and impaired renal function. This case highlights the complexities of decision making in the transfusion process. Appropriate prescription of blood products is important; the patient must meet the clinical indication for the product. Blood products should be ordered one unit at time, and the patient should be reassessed before further units are ordered.

In this case, the warfarin reversal clinical guidelines of the time (published by the Australasian Society of Thrombosis and Haemostasis ASTH 2004, updated 2013) were not followed. The patient's weight, CCF, renal function and the volume to be transfused should be considered when prescribing transfusion.

Transfusion-related acute lung injury (TRALI)

2009-10 Data Summary (n=8)					
Age		**Sex**		**Day of Transfusion**	
0-4 years	-	Male	2	Week day	5
5-14 years	-	Female	3	Weekend	-
15-24 years	1	Uncategorised	-	Unknown	-
25-34 years	1				
35-44 years	-	**Facility Location**		**Time of Transfusion**	
45--54 years	-	Major City	5	Between 7am and 7pm	3
55-64 years	1	Inner Regional	-	Between 7pm and 7am	2
65-74 years	-	Outer Regional	-	Unknown	-
75+ years	2	Remote	-		
Not specified	-	Very Remote	-		
Clinical Outcome Severity		**Imputability**		**Blood Component**	
Death	-	Excluded	-	Whole blood	-
Life threatening	1	Unlikely / Possible	1	Red cells	2
Severe morbidity	2	Likely / Probable	1	Platelets	1
Minor morbidity	1	Confirmed / Certain	2	Fresh Frozen Plasma	2
No morbidity	1	N/A / Not assessable	1	Cryoprecipitate	-
Outcome not available	-			Cryodepleted plasma	-
NSW					
Number of reports	3				

2010-11 Data Summary (n=8)					
Age		**Sex**		**Day of Transfusion**	
0-4 years	-	Male	2	Week day	3
5-14 years	-	Female	2	Weekend	2
15-24 years	-	Uncategorised	1	Unknown	-
25-34 years	-				
35-44 years	1	**Facility Location**		**Time of Transfusion**	
45--54 years	1	Major City	3	Between 7am and 7pm	-
55-64 years	-	Inner Regional	2	Between 7pm and 7am	-
65-74 years	-	Outer Regional	-	Unknown	-
75+ years	2	Remote	-		
Not specified	1	Very Remote	-		
Clinical Outcome Severity		**Imputability**		**Blood Component**	
Death	-	Excluded	-	Whole blood	-
Life threatening	-	Unlikely / Possible	-	Red cells	5
Severe morbidity	3	Likely / Probable	2	Platelets	-
Minor morbidity	2	Confirmed / Certain	3	Fresh Frozen Plasma	-
No morbidity	-	N/A / Not assessable	-	Cryoprecipitate	-
Outcome not available	-			Cryodepleted plasma	-
NSW					
Number of reports	3				

Source: NBA

Notes

1. Table presents aggregate data from VIC, QLD, SA, TAS, ACT and NT.
2. Age, sex and time of transfusion data is unavailable for SA.
3. Data element values (such as age, sex) missing for NSW.
4. Data unavailable for WA.

TRALI presents with respiratory distress, hypoxemia, rales on listening to the lungs (abnormal rattle or crackling sound heard with a stethoscope during breathing, caused by fluid in the lungs), and diffuse bilateral infiltrates on chest radiograph. The respiratory distress can be severe enough to require mechanical ventilation and other features may include hypotension, fever, and transient leukopenia.

In the three financial years to 2010-11, there were 19 reports to the National Haemovigilance Program of suspected TRALI, accounting for 1.6% of total reports (1207). The number of cases reporting life threatening severity dropped from two in 2008-09 to one with an imputability score of unlikely/possible in 2009-10 and zero in 2010-11.

The true incidence of TRALI is unknown, because a standard definition[46] was not developed until 2005 by the National Heart, Lung, and Blood Institute. Early reports quoted an incidence of 1 per 5000 transfused blood components[47], with subsequent reports ranging from 1 per 432 pooled whole-blood-derived platelets to 1 per 557 000 RBCs.[48] The 17th edition of the AABB Technical Manual cites an incidence range from 1:12,000 to 1:190,000 transfusions.[49]

TRALI is a significant cause of mortality and morbidity in patients who receive blood components, particularly plasma-containing components. With the decrease in the risk of transfusion transmitted HIV, Hepatitis C virus (HCV) and bacterial contamination, TRALI has become the leading cause of transfusion-related mortality reported to the US Food and Drug Administration (FDA). In combined fiscal years 2007- 08 to 2011-12, TRALI accounted for 43% of transfusion-related deaths[50] in the US.

TRALI is difficult to diagnose because there is no specific test for it and it is easily confused with alternative causes of acute lung injury (ALI) and TACO. Distinguishing TRALI and TACO at presentation can be particularly difficult. The clinical features are similar, and there are no diagnostic tests that reliably discriminate. Furthermore, a patient may simultaneously suffer both TRALI and TACO and this adds to the complexity. However, the therapy and management of the patient, and the implications for the donor, in the two reactions are very different.

As dyspnoea after a transfusion is often believed to be due to another cause (such as TACO, allergic reaction) or because there are other risk factors present for acute lung injury, TRALI is often overlooked. Typical clinical features are hypoxaemia, hypotension, fever and severe bilateral pulmonary infiltrates within 6 hours of completing a transfusion.

Early recognition allows the transfusion to be stopped immediately and oxygen and supportive therapy to be commenced. As the underlying pathology involves microvascular injury, use of diuretics may be detrimental and some patients benefit from fluid administration.

In Australia, recognising TRALI allows notification of the Blood Service and testing of the blood component and/or donor for anti-HLA and anti-granulocyte antibodies. Donors of blood components implicated in cases of TRALI often contain anti-leukocyte allo-antibodies (anti-HLA and anti-granulocyte) that are thought to be important in the pathogenesis of TRALI in a significant number of cases. Recognition of these donors by the Blood Service allows appropriate recall of implicated blood components and exclusion of the donor.

From July 2007, Australia commenced the production of male predominant FFP, cryoprecipitate and cryodepleted plasma as a risk reduction strategy for TRALI. With current levels of TRALI reporting it is not possible to comment on any potential impact of this policy on the incidence of TRALI in Australia.

All UK Blood Services use male donors to provide 100% FFP and plasma for platelet pooling. The SHOT UK Steering Group reports that the risk of highly likely/probable TRALI due to FFP has fallen from 15.5 per million units issued (1999-2004) to 3.2 per million (2005-06).[51] The New Zealand Blood Service[52] has also reduced the risk of TRALI through the production of FFP from males with no history of blood transfusion and introduction of HLA antibodies screening for female plateletpheresis donors.

Transfusion transmitted infections (TTI)

2009-10 Data Summary (n=18)					
Age		**Sex**		**Day of Transfusion**	
0-4 years	1	Male	6	Week day	7
5-14 years	-	Female	1	Weekend	-
15-24 years	-	Uncategorised	-	Unknown	-
25-34 years	-				
35-44 years	-	**Facility Location**		**Time of Transfusion**	
45--54 years	1	Major City	4	Between 7am and 7pm	7
55-64 years	-	Inner Regional	2	Between 7pm and 7am	-
65-74 years	1	Outer Regional	1	Unknown	-
75+ years	4	Remote	-		
Not specified	-	Very Remote	-		
Clinical Outcome Severity		**Imputability**		**Blood Component**	
Death	-	Excluded	1	Whole blood	-
Life threatening	-	Unlikely / Possible	1	Red cells	2
Severe morbidity	1	Likely / Probable	-	Platelets	5
Minor morbidity	2	Confirmed / Certain	5	Fresh Frozen Plasma	-
No morbidity	4	N/A / Not assessable	-	Cryoprecipitate	-
Outcome not available	-			Cryodepleted plasma	-
NSW					
Number of reports	11				

2010-11 Data Summary (n=11)					
Age		**Sex**		**Day of Transfusion**	
0-4 years	-	Male	3	Week day	7
5-14 years	1	Female	5	Weekend	2
15-24 years	-	Uncategorised	1	Unknown	-
25-34 years	-				
35-44 years	-	**Facility Location**		**Time of Transfusion**	
45--54 years	1	Major City	4	Between 7am and 7pm	8
55-64 years	4	Inner Regional	4	Between 7pm and 7am	-
65-74 years	3	Outer Regional	1	Unknown	1
75+ years	-	Remote	-		
Not specified	-	Very Remote	-		
Clinical Outcome Severity		**Imputability**		**Blood Component**	
Death		Excluded		Whole blood	
Life threatening	1	Unlikely / Possible	5	Red cells	4
Severe morbidity	2	Likely / Probable	1	Platelets	5
Minor morbidity	3	Confirmed / Certain	3	Fresh Frozen Plasma	-
No morbidity	3	N/A / Not assessable	-	Cryoprecipitate	-
Outcome not available	-			Cryodepleted plasma	-
NSW					
Number of reports	2				

Source: NBA

Notes

1. Table presents aggregate data from VIC, QLD, SA, TAS, ACT and NT.
2. Age, sex and time of transfusion data is unavailable for SA.
3. Data element values (such as age, sex) missing for NSW.
4. Data unavailable for WA.

The National Haemovigilance Program allows the reporting of four distinct TTI categories:

- Transfusion transmitted infections - Bacterial
- Transfusion transmitted infections - Viral
- Transfusion transmitted infections - Parasitic
- Transfusion transmitted infections - Other (such as Creutzfeldt-Jakob disease).

From 2008-09 to 2010-11:

- there were 32 reports of TTI to the National Haemovigilance Program, all of which were related to bacterial infections but not necessarily confirmed
- there were no reports of any TTI resulting from viral or parasitically contaminated components
- there was an increase in the reports of TTIs from 3 in 2008-09 to 18 in 2009-10 and a decrease to 11 in 2010-11
- there were 2 cases (one in 2008-09 and one in 2010-11) with life threatening severity reported.

All cases of life threatening severity and severe morbidity which occurred in 2009-10 and 2010-11 were assigned an imputability score of unlikely/possible.

Table 27: TTI clinical outcome severity by imputability, 2009-10 and 2010-11

Clinical Outcome Severity	Imputability					Total
	Excluded	Unlikely / Possible	Likely / Probable	Confirmed / Certain	N/A / Not assessable	
Death						
2009-10	-	-	-	-	-	-
2010-11	-	-	-	-	-	-
Life threatening						
2009-10	-	-	-	-	-	-
2010-11	-	1	-	-	-	1
Severe morbidity						
2009-10	-	1	-	-	-	1
2010-11	-	2	-	-	-	2
Minor morbidity						
2009-10	1	0	-	1	-	2
2010-11	-	-	1	2	-	3
No morbidity						
2009-10	-	-		4	-	4
2010-11	-	2	-	1	-	3
Outcome not available						
2009-10	-	-	-	-	-	-
2010-11	-	-	-	-	-	-
Total	**1**	**6**	**1**	**8**	**-**	**16**

Source: NBA

Notes

1. Table presents aggregate data from VIC, QLD, SA, TAS, ACT and NT.
2. Outcome severity and imputability data unavailable for WA and NSW.

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-cell lymphotrophic virus (HTLV) I and II, and syphilis. 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 viral risk estimates presented in Table 28 have recently been revised based on Blood Service data from 1 January 2010 to 31 December 2011. These estimates are updated annually. The risk of viral TTI in Australia is exceedingly low.

Table 28: Blood Service residual risk estimates for transfusion-transmitted infections

Agent and testing standard	Window Period (Days)	Estimate of residual risk 'per unit'
HIV (antibody + NAT)	5.6	Less than 1 in 1 million
HCV (antibody + NAT)	3.1	Less than 1 in 1 million
HBV (HBsAg)	23.9	Approximately 1 in 764,000
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

Note: The risk estimates for HIV, HCV, HBV and HTLV are based on Blood Service data from 1 January 2010 to 31 December 2011.

Currently, the risks of bacterial TTI[53] are significantly greater than those of viral TTI from screened agents. Bacterial contamination of blood components may result from the introduction of low concentrations of skin bacteria at the time of phlebotomy, or less commonly, from undiagnosed donor bacteraemia, or very rarely, during blood processing. Transfusion-associated bacterial sepsis is caused more frequently by contaminated platelets than by red cell components because many species of bacteria can proliferate to critical levels under the room temperature conditions used for platelet storage.

Bacterial contamination of platelet components is recognised as the most significant residual infectious risk of blood transfusion in developed countries. There were no severe cases (such as death, life threatening or severe morbidity) related to platelet transfusion in Australia in 2009-10 or 2010-11.

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 blood donation, 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.

In the UK in 2011, bacteria screening for platelet donations was rolled out in National Health Service Blood and Transplant (NHSBT). The UK Blood Service also maintained high standards of collection, processing and program vigilance. Strategies to reduce the bacterial contamination of blood components are under continual review in the UK.[42] There were no proven reports of TTI to the UK SHOT Program in 2010 or 2011, indicating that bacterial and viral screening is effective in improving the safety of the UK blood supply.

Case Study 7

Importance of communication between the Blood Service, clinical staff and patients on the risk of TTI

A teenage girl was under treatment for lymphoma when she developed thrombocytopenia (platelet count: 25). She was transfused with 300ml platelets in the daystay ward and was discharged on the same day. The hospital blood bank notified the clinical staff of positive results of the initial microbiologic screening ('initial machine positive – IMP' status) six days after transfusion. Clinical staff did not notify the patient and/or her parents until she was seen in the outpatient department 13 days after her transfusion. However, she had a blood culture taken 3 days after transfusion during her short stay in the emergency department for some unrelated febrile illness. Blood culture result was negative after 5 days, excluding an ongoing systemic infection. IMP status of the platelet unit was confirmed and propioni bacterium was cultured.

Considerations

- Should the Blood Service/blood bank have notified the clinical staff earlier?
- Should the clinical staff have notified the patient and/or her parents earlier of the potential risk of platelet contamination and possibility of patient suffering infection?
- How can clinical staff be more vigilant and proactive in managing immunosuppressed patients to prevent a possible overwhelming infection?

Post-transfusion purpura (PTP)

2009-10 Data Summary (n=2)					
Age		**Sex**		**Day of Transfusion**	
0-4 years	-	Male	-	Week day	2
5-14 years	-	Female	2	Weekend	-
15-24 years	-	Uncategorised	-	Unknown	-
25-34 years	-				
35-44 years	-	**Facility Location**		**Time of Transfusion**	
45--54 years	-	Major City	1	Between 7am and 7pm	2
55-64 years	-	Inner Regional	1	Between 7pm and 7am	-
65-74 years	-	Outer Regional	-	Unknown	-
75+ years	1	Remote	-		
Not specified	1	Very Remote	-		
Clinical Outcome Severity		**Imputability**		**Blood Component**	
Death	-	Excluded	-	Whole blood	-
Life threatening	-	Unlikely / Possible	1	Red cells	2
Severe morbidity	1	Likely / Probable	-	Platelets	-
Minor morbidity	1	Confirmed / Certain	1	Fresh Frozen Plasma	-
No morbidity	-	N/A / Not assessable	-	Cryoprecipitate	-
Outcome not available	-			Cryodepleted plasma	-
NSW					
Number of reports	-				

2010-11 Data Summary (n=1)	
NSW	
Number of reports	1

Source: NBA

Notes

1. Table presents aggregate data from VIC, QLD, SA, TAS, ACT and NT.
2. Age, sex and time of transfusion data is unavailable for SA.
3. Data element values (such as age, sex) missing for NSW.
4. Data unavailable for WA.

Purpura occurs when small blood vessels leak blood under the skin, most commonly when the platelet count in the blood is low (thrombocytopenia). Purpura presents as purple-coloured spots and patches that occur on the skin, organs, and in mucus membranes, including the lining of the mouth.

Purpura can have many causes, but PTP is an immune-mediated complication of transfusion. Onset is typically within 12 days of transfusion. PTP is confirmed by the detection of platelet specific-antibodies in the recipient's blood, and detection of the antithetical antigen on the donor platelets, or by a positive platelet cross-match. Antibodies against HPA-1a are the most common cause of PTP.

It is the first time that 3 confirmed cases of this rare transfusion-related adverse reaction were reported to the National Haemovigilance Program. One case was classified as severe morbidity and one as minor morbidity. Both cases were related to red blood cell transfusion. Classification information was not provided for the third case.

Incorrect blood component transfused (IBCT)

2009-10 Data Summary (n=23)					
Age		**Sex**		**Day of Transfusion**	
0-4 years	5	Male	14	Week day	18
5-14 years	-	Female	8	Weekend	5
15-24 years	1	Uncategorised	1	Unknown	-
25-34 years	2				
35-44 years	1	**Facility Location**		**Time of Transfusion**	
45--54 years	2	Major City	17	Between 7am and 7pm	17
55-64 years	1	Inner Regional	6	Between 7pm and 7am	5
65-74 years	7	Outer Regional	-	Unknown	1
75+ years	3	Remote	-		
Not specified	1	Very Remote	-		
Clinical Outcome Severity		**Imputability**		**Blood Component**	
Death	-	Excluded	-	Whole blood	1
Life threatening	-	Unlikely / Possible	-	Red cells	16
Severe morbidity	2	Likely / Probable	-	Platelets	5
Minor morbidity	13	Confirmed / Certain	19	Fresh Frozen Plasma	-
No morbidity	8	N/A / Not assessable	4	Cryoprecipitate	-
Outcome not available	-			Cryodepleted plasma	-
NSW					
Number of reports	-				

2010-11 Data Summary (n=30)					
Age		**Sex**		**Day of Transfusion**	
0-4 years	2	Male	13	Week day	17
5-14 years	-	Female	13	Weekend	9
15-24 years	4	Uncategorised	-	Unknown	-
25-34 years	2				
35-44 years	2	**Facility Location**		**Time of Transfusion**	
45--54 years	4	Major City	18	Between 7am and 7pm	20
55-64 years	2	Inner Regional	6	Between 7pm and 7am	6
65-74 years	5	Outer Regional	1	Unknown	-
75+ years	5	Remote	1		
Not specified	-	Very Remote	-		
Clinical Outcome Severity		**Imputability**		**Blood Component**	
Death	-	Excluded	-	Whole blood	-
Life threatening	1	Unlikely / Possible	1	Red cells	18
Severe morbidity	2	Likely / Probable	2	Platelets	4
Minor morbidity	8	Confirmed / Certain	18	Fresh Frozen Plasma	3
No morbidity	14	N/A / Not assessable	4	Cryoprecipitate	-
Outcome not available	1			Cryodepleted plasma	-
NSW					
Number of reports	4				

Source: NBA

Notes

1. Table presents aggregate data from VIC, QLD, SA, TAS, ACT and NT.
2. Age, sex and time of transfusion data is unavailable for SA.
3. Data element values (such as age, sex) missing for NSW.
4. Data unavailable for WA.

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

In the three financial years to 2010-11:

- there were 75 reports of IBCT to the National Haemovigilance Program, accounting for 6.2% of all reports (1207)
- there were two cases reporting life threatening severity, with one in 2008-09 and another in 2010-11
- the majority of cases were related to red cell transfusion.

In the period 2009-10 to 2010-11, the majority of cases (39 out of 49) were assigned an imputability score of confirmed/certain. The only case with life threatening severity was confirmed to be related to red cell transfusion. Incidence was independent of patient age and sex, blood component, facility location, day and time of transfusion.

Table 29: IBCT clinical outcome severity by imputability, 2009-10 and 2010-11

Clinical Outcome Severity	Imputability					Total
	Excluded	Unlikely / Possible	Likely / Probable	Confirmed / Certain	N/A / Not assessable	
Death						
2009-10	-	-	-	-	-	-
2010-11	-	-	-	-	-	-
Life threatening						
2009-10	-	-	-	-	-	-
2010-11	-	-	-	1	-	1
Severe morbidity						
2009-10	-	-	-	1	1	2
2010-11	-	-	-	2	-	2
Minor morbidity						
2009-10	-	-	-	10	3	13
2010-11	1	-	-	5	2	8
No morbidity						
2009-10	-	-	-	8	-	8
2010-11	-	1	2	9	2	14
Outcome not available						
2009-10	-	-	-	-	-	-
2010-11	-	-	-	1	-	1
Total	**1**	**1**	**2**	**37**	**8**	**49**

Source: NBA

Notes

1. Table presents aggregate data from VIC, QLD, SA, TAS, ACT and NT.
2. Outcome severity and imputability data unavailable for WA and NSW.

Table 30 details the contributory factors for reported IBCT events for 2008-09 to 2010-11. 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'. This data highlights the range of problems that contribute to IBCT events, and the key observation for IBCT is that staff should conform to their local facility guidelines for transfusing.

Table 30: Contributory factors cited in IBCT, 2008-09 to 2010-11

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

Source: NBA

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

1. accurate patient identification and proper labelling of pre-transfusion specimens
2. appropriate decision-making regarding the clinical use of blood components
3. 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 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.

There are also electronic systems that can increase compliance in pre-transfusion sampling and administration, and reduce the risk of human error.[54,55] The Australian Haemovigilance Report 2010 recommended the investigation and use of technology, such as portable barcode readers and/or radio-frequency identification scanners, to reduce the scope for error.

This report delivers several recommendations on human errors (see PART 05: RECOMMENDATIONS).

The following case study illustrates:

- a failure of bedside administration check to ensure the correct component was given to the correct patient
- the feasibility of using 2D barcode and patient safety software to improve blood administration and reduce human errors.

Case Study 8

Incorrect product was given to patient due to a failure of bedside administration checks

A young woman had an elective surgical major wound debridement. In recovery the surgical site was bleeding and the patient was returned to theatre for wound exploration.

The patient was haemodynamically unstable with Hb 59g/L. Two group O RhD negative emergency uncrossmatched units were requested from the blood bank and sent to theatre via a pneumatic chute system.

The units were collected from the chute and placed in the theatre.

A unit of blood was administered to the patient around the same time as anaesthesia induction. The patient became hypotensive (systolic BP 75) and hypoxic (O_2 sat 86% on 100% O_2). This was thought to be due to the anaesthesia induction. The second unit of blood was commenced and after 100ml the patient developed a rash with swelling and urticaria over her upper chest, arms and around her eyes. An acute transfusion reaction was suspected and transfusion was ceased.

A check of the product found that the two units transfused were not group O, RhD negative emergency units, but group A positive units labelled for another patient. The patient blood group was O positive.

The patient recovered after 3 weeks in intensive care requiring treatment for disseminated intravascular coagulation and acute renal failure.

Practice Notes

ABO incompatible transfusions may occur due to laboratory or bedside administration errors. In this case, there was a failure of the bedside administration checks to ensure the correct product was given to the correct patient. As a result of this incident, the use of 2D barcode and patient safety software to assist in blood administration was implemented as a pilot in the hospital. The results of the pilot study demonstrated that this technology significantly improves the bedside check of patient and blood product identification.

The error occurred when the person collecting the blood from the chute did not check the name on the units. The units in the chute at the time had been requested by another theatre but not yet collected. Robust processes are required for collection of blood components from chutes.

A further error occurred when there was a failure in theatre of the bedside administrative check.

Staff may have had some delay in their recognition of the signs of a possible ABO incompatible transfusion reaction due to the complex surgical setting and some initial features suggesting an allergic reaction. Staff should be provided with ongoing education about transfusion reactions and the management of such reactions.

Contributory factors

Summary Data	2009-10	2010-11
Contributory Factors	Number of reports	Number of reports
None identified	15	34
*Product characteristic	136	172
*Transfusion in emergency setting	7	17
*Deliberate clinical decision	6	1
*Prescribing/ordering	27	10
*Specimen collection/labelling	13	11
*Laboratory (testing/dispensing)	10	5
*Transport, storage, handling	1	-
*Administration of product	14	9
*Indications do not meet guidelines	18	15
*Procedure did not adhere to facility transfusion guidelines	30	16
Other	11	16

Source: NBA

Notes

1. Table presents aggregate data from VIC, QLD, TAS, ACT and NT.
2. Contributory factor data are unavailable for NSW, SA and WA.
3. * refers to human errors.

The National Haemovigilance Program requests that where applicable states and territories report data on factors contributing to each adverse event. The contributory factor categories defined seek to mirror key stages of the transfusion chain. Definitions for contributory factors can be found in Table 38, page 137. 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
- the most notable difference between the Australian national data and UK data is that 'near miss' events are included in the UK national dataset. This difference will be addressed through the implementation of NSQHS Standard 7[56] which requires that 'reporting on blood and blood product incidents (including near miss) is included in regular (local, state and national) incident reports'
- VIC, QLD, TAS, NT and ACT reported validated and complete contributory factor data to the National Haemovigilance Program.

The following analysis is based on the data provided by VIC, QLD, TAS, NT and ACT.

- The most frequent contributory factor was 'product characteristic', accounting for 136 adverse events in 2009-10 and 172 in 2010-11. 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 characteristic and component characteristic, the current terminology and definition may not be appropriate and could lead to confusion for data collectors and users.

- In 2009-10, there were 37 adverse event reports (12% of reports) that cited one or more contributory factors that could have been avoided. The most important contributory factors cited were 'prescribing/ordering', 'indications do not meet guidelines' and 'procedure did not adhere to transfusion guidelines'. Together, this data suggests that inappropriate use of blood components was a contributory factor for a significant number of preventable transfusion-related adverse events.

- In 2010-11, there were 43 adverse event reports (11% of reports) that cited one or more contributory factors that could have been avoided. Contributory factors were cited across the transfusion chain, and the main factors included 'prescribing/ordering', 'specimen collection/labelling', 'laboratory testing/dispensing', 'administration of product', 'clinical indications for transfusion that did not meet facility transfusion guidelines' and 'procedures that did not adhere to facility transfusion guidelines'.

- Interestingly, the number of reports related to prescribing ('prescribing/ordering' and 'indications do not meet guidelines') dropped from 17 to 7 from 2009-10 to 2010-11. In the context of increased reporting, it is possible that this could indicate improved adherence to practice guidelines. Conversely, reports relating to the safety of procedures ('specimen collection/labelling' and 'procedure did not adhere to facility transfusion guidelines') remained as a significant contributory factor.

- Table 31 and Table 32 show that 'procedure did not adhere to facility transfusion guidelines' impacted:
  - 27 IBCT adverse events with 13 in 2009-10 and 14 in 2010-11
  - 6 FNHTRs with 5 in 2009-10 and 1 in 2010-11
  - 7 severe allergic reactions in 2009-10
  - 3 acute haemolytic transfusion reaction in 2009-10
  - 1 anaphylactoid or anaphylactic reaction in 2009-10
  - 1 TACO reaction in 2010-11
  - 1 DHTR in 2009-10.

- The clinical outcome severities related to 'procedure did not adhere to facility transfusion guidelines' included:
  - 2 cases reporting life threatening severity with 1 in 2009-10 and 1 in 2010-11
  - 12 cases reporting severe morbidity with 9 in 2009-10 and 3 in 2010-11

- 21 cases reporting minor morbidity with 15 in 2009-10 and 6 in 2010-11
- 10 cases reporting no morbidity with 5 in 2009-10 and 5 in 2010-11.

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

- ANZSBT Guidelines for the Administration of Blood Products
- 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[57] reported 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[42] 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 numbers of cases (9,925) reviewed from 1996-97 to 2010-11.

NSQHS Standard 7 recommended the following strategies (refer to Action 7.2.1) 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 report also delivers a recommendation to reconsider the definitions in the ANHDD, including those for contributory factors.

Table 31: Contributory factors cited by adverse event and by clinical outcome severity, 2009-10

Contributory Factors	Adverse event										Clinical outcome severity					
	FNHTR	Severe Allergic reaction	IBCT	Anaphylactic / Anaphylactoid	Acute HTR (not ABO)	TACO	DHTR	TTI Bacterial	TRALI	PTP	Outcome not available	No morbidity	Minor morbidity	Severe morbidity	Life threatening	Death
None identified	1	-	-	-	1	3	5	1	3	1	-	1	6	7	1	-
Product characteristic	69	53	-	7	1	2	1	1	1	1	1	45	72	14	4	-
Transfusion in emergency setting	1	4	1	1	-	-	-	-	-	-	-	2	2	2	1	-
Deliberate clinical decision	1	2	3	-	-	-	-	-	-	-	-	4	2	-	-	-
Prescribing/ordering	4	5	12	1	3	1	1	-	-	-	-	12	6	8	1	-
Specimen collection/labelling	-	-	12	-	1	-	-	-	-	-	-	-	10	3	-	-
Laboratory (testing/dispensing)	2	-	7	-	-	-	-	-	1	-	-	2	6	2	-	-
Transport, storage, handling	-	-	1	-	-	-	-	-	-	-	-	-	1	-	-	-
Administration of product	1	-	12	-	1	-	-	-	-	-	-	-	11	3	-	-
Indications do not meet guidelines	5	3	5	2	-	-	1	1	1	-	1	5	6	6	-	-
Procedure did not adhere to facility transfusion guidelines	5	7	13	1	3	-	1	-	-	-	-	5	15	9	1	-
Other	1	-	5	-	-	-	-	4	-	-	-	4	6	-	-	-

Source: NBA

Note: NSW, SA and WA contributory factor data is unavailable.

Table 32: Contributory factors cited by adverse event and by clinical outcome severity, 2010-11

Contributory Factors	Adverse event									Clinical outcome severity					
	FNHTR	Severe Allergic reaction	IBCT	Anaphylactic / Anaphylactoid	Acute HTR (not ABO)	TACO	DHTR	TTI Bacterial	TRALI	Outcome not available	No morbidity	Minor morbidity	Severe morbidity	Life threatening	Death
None identified	2	7	-	3	1	7	5	6	3	-	5	13	13	3	-
Product characteristic	99	54	4	9	-	1	2	3	1	-	17	132	24	-	-
Transfusion in emergency setting	4	6	4	1	-	2	-	-	-	1	2	9	4	1	-
Deliberate clinical decision	-	1	-	-	-	-	-	-	-	-	-	1	-	-	-
Prescribing/ordering	2	1	5	1	-	-	-	1	-	-	5	4	1	-	-
Specimen collection/labelling	-	-	11	-	-	-	-	-	-	1	1	6	2	1	-
Laboratory (testing/dispensing)	-	-	5	-	-	-	-	-	-	1	-	2	1	1	-
Transport, storage, handling	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Administration of product	-	-	8	-	-	1	-	-	-	-	1	5	2	1	-
Indications do not meet guidelines	3	6	2	3	-	1	-	-	-	-	1	6	8	-	-
Procedure did not adhere to facility transfusion guidelines	1	-	14	-	-	1	-	-	-	1	5	6	3	1	-
Other	3	4	8	-	-	-	-	1	-	1	2	10	2	1	-

Source: NBA

Note: NSW, SA and WA contributory factor data is unavailable.

NSW Data

Haemovigilance data supplied by NSW was collected through the public hospital IIMS which was designed to capture information relating to a range of incidents. IIMS is not a specific haemovigilance reporting system and data on adverse events and incidents cannot be associated with any demographic or other data.

The NSW incident data does offer some insight into the types of errors that occur and the relative prevalence reported. Table 33 summarises the NSW Haemovigilance incident data for 1 July 2009 to 30 June 2011. The most prevalent incidents were Mislabelled (2009-10 only, n=153/305) and Mislabelled/Documentation/Consent (2010-11 only, n=1116/1253). From the data supplied, it is not possible to link these incidents to any patient harm or adverse event, but given the absolute numbers of complications reported (see Table 41 and Table 42 in Appendix IV) it is highly likely that these incidents led to a significant number of the reported complications.

There were other incidents reported that would also have a significant chance of causing patient harm; wrong blood or component administered to wrong patient (n=0 in 2009-10, n=6 in 2010-11) and wrong patient (n=24 in 2009-10, n=5 in 2010-11).

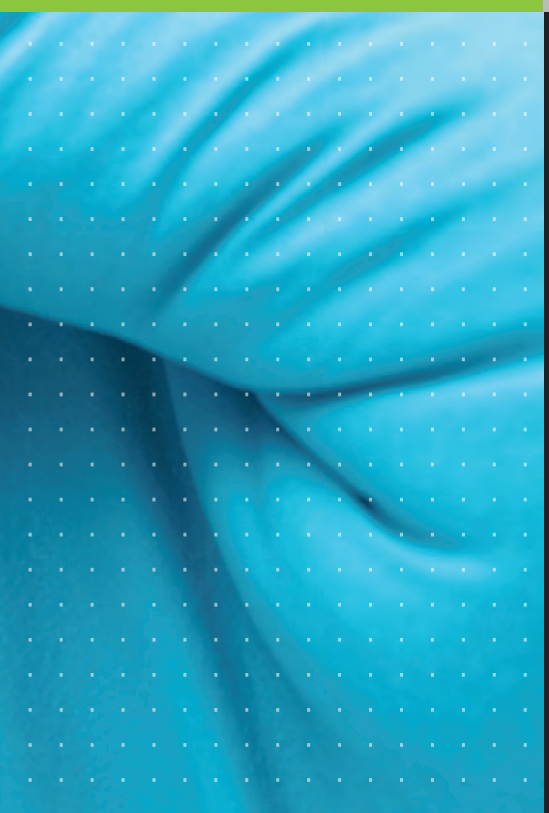
The NSW data also supports the conclusion that procedural or human errors, including IBCT, inappropriate and unnecessary transfusion, and dispensing errors, are strong contributory factors to transfusion-related adverse events.

Table 33: NSW Haemovigilance incident data for 1 July 2009 to 30 June 2011

Incidents	Number of reports	
	2009-10	2010-11
Dispensing of expired or unsuitable component	16	19
Dispensing of expired or unsuitable component & Fever > 39°C	0	1
Incorrect administration of blood or component dosage	17	8
Incorrect administration procedure	40	46
Incorrect equipment	22	19
Incorrect infusion rate	26	15
Mislabelled (2009-10 only)	153	-
Mislabelled/Documentation/Consent (2010-11 only)	-	1,116
Taking blood sample from incorrect patient	1	13
Wrong blood dispensed	5	5
Wrong blood or component administered to wrong patient	0	6
Wrong component ordered (2009-10 only)	1	-
Wrong patient	24	5
Total	**305**	**1,253**

RECOMMENDATIONS

PART 05

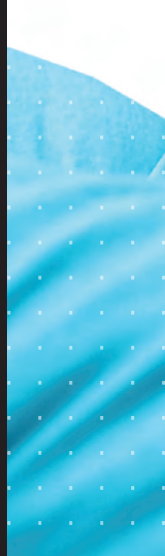


National blood quality and safety initiatives

Reducing human errors

Data standards

Reporting capacity



PART 05
RECOMMENDATIONS

The NBA, in conjunction with the HAC, makes 10 recommendations in this report 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. Conduct a scoping exercise for a national haemovigilance system
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 (FNHTR and severe allergic reactions) and that cause the greatest numbers of severe patient outcomes (FNHTR, severe allergic reactions, TACO, anaphylactoid reactions).

In relative terms, the data suggests that TACO and TRALI, adverse events which account for disproportionate numbers of life threatening and severe morbidity events, are greatly under-reported. However, in overall terms it could be said that most reactions are probably under-reported, with the possible exception of ABO incompatible transfusion events which are sentinel events.

National quality and safety initiatives should aim to support clinical staff to recognise and manage these events, in order to minimise outcome severity for patients, and also to encourage full reporting of these events to increase visibility within transfusion practice. Haemovigilance activities should also clearly prioritise reporting of those adverse events where reporting may alter outcomes for future patient cohorts.

Table 34: Recommendations on national blood quality and safety initiatives

	Recommendation	Who is Responsible	Strategy	How that will be measured
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'	Publication and distribution of 'Guidance on Recognition and Management of Acute Transfusion-Related Adverse Events' Conduct an evaluation on the implementation of the guidance document
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 outcomes for Recommendations 6, 9 and 10 will also contribute to improving reporting of serious adverse events	Publication and distribution of 'Guidance on Recognition and Management of Acute Transfusion-Related Adverse Events' Increased rates of reporting

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 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 35: 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	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
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 will recommend strategies, and/or develop case studies and/or promote the use of: 2D barcode technology and electronic devices to assist with patient bedside safety checks Electronic prescription technologies
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	Publication and distribution of tools Conduct evaluations of the implementation of tools

Data standards

The data standards should be revised and updated as haemovigilance matures in Australia. Donor vigilance has been conducted by the Blood Service for many years; however, the HAC is pleased to include the data in the national report for the first time. The ANHDD will be revised and redeveloped, and details of this data dictionary and its use will be communicated directly to hospitals to help them with their haemovigilance activities.

Table 36: 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	HAC to endorse a revised data dictionary and definitions	Publication and distribution of revised ANHDD
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 number of public and private facilities submitting data to the National Haemovigilance Program will increase
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 will continue to be included in future national haemovigilance reports The Blood Service will continue to 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 haemovigilance systems and the JBC, is conducting a scoping exercise to determine the feasibility of a national haemovigilance system to which all transfusing facilities would report their data directly. The results of this exercise will be considered by the JBC in 2013-14. While this feasibility study is underway, states and territories should continue to maintain existing systems and improve capacities for haemovigilance data reporting.

Table 37: Recommendations on reporting capacity

	Recommendation	Who is Responsible	Proposed Strategy	How that will be measured
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	NBA's scoping exercise for the National Haemovigilance System will be considered by the JBC in 2013-14
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	The number of public and private facilities submitting data to the National Haemovigilance Program will increase

APPENDIX I: INTERNATIONAL CONTEXT

The first haemovigilance system in Europe was initiated in France in 1994[58], 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.

Communication between haemovigilance systems is organised through the IHN[59], previously the European Haemovigilance Network founded in 1997. The network started with five member countries from Europe and grew to 28, including seven from outside Europe.[60] It now has 32 international members and six more countries are in the application stage. The NBA participates in and reports on Australian haemovigilance data to the IHN.

The IHN holds annual haemovigilance seminars for member countries and researchers. The 15th International Haemovigilance Seminar was held in Brussels in February 2013.[61] The seminar highlighted the achievements of mature haemovigilance systems and provided an opportunity for developing countries to actively participate in the haemovigilance program and present the specific aspects and challenges in those countries.

The IHN has established an international haemovigilance database. A recent pilot study on 12 haemovigilance systems showed that the establishment of such a database is possible and already yields relatively valid and comparable information.[60]

The 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 having a national haemovigilance system increased from 42 in 2004-2005 to 57 in 2011.[62]

A WHO Global Consultation on Haemovigilance was held in Dubai, United Arab Emirates, in November 2012. This consultation involved around 150 participants from over 50 countries.[63] The consultation:

- highlighted the importance of national haemovigilance systems
- assessed the nature and magnitude of current challenges and barriers to the implementation of haemovigilance systems, particularly in developing countries
- provided a platform for countries to share experience in developing national haemovigilance systems
- defined strategies for developing haemovigilance systems.

The International Society of Blood Transfusion (ISBT) also contributes to haemovigilance at a global level, through its Working Party on Haemovigilance, consisting of individual members of ISBT. ISBT and IHN collaborate on development of definitions, surveys and other educational activities.

In most of the countries conducting haemovigilance, reporting is obligatory, and in all European countries the reporting of serious transfusion reactions and events became mandatory after the EU Blood Directive implementation in November 2005. There is a minority of countries in which reporting is restricted to adverse reactions that occur after the transfusion of blood products. In most countries, additional reporting is required, or desired, ranging from reporting the misuse of blood products (such as not based on the proper indications), to reporting data on virtually the whole blood transfusion chain.

The majority of the serious adverse reactions and events that are reported internationally happen in the hospital part of the blood transfusion chain. Data from the UK SHOT program have drawn attention to the fact that about 50% of these are due to administrative errors. Mature haemovigilance systems have documented the success of various measures to further improve the safety of blood products. Two key examples are:

- a blood diversion pouch is used in many countries during blood donation in order to minimise the risk of contaminating skin bacteria
- the decision to transfuse only plasma from male donors.

These examples have been demonstrated to result in significant decreases of serious adverse reactions due to bacterial contamination of blood components (particularly platelets) and TRALI reactions respectively.

With reliable mature data streams and proven clinical benefits, many countries are seeking to install and improve haemovigilance systems. One notable recent addition is the USA.

The situation in the USA is complex. It is obligatory to report all fatal transfusion reactions to the 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 first component of the network, the Haemovigilance Module or Haemovigilance System to monitor adverse events associated with transfusions, was launched in February 2010. Another network component, the Donor Haemovigilance System, was launched in October 2010 to track and reduce the occurrence of adverse events associated with blood donation.[65] Due to advances in donor screening, improved testing, automated data systems, and changes in transfusion medicine practices, the risks associated with blood transfusion have decreased in the USA. The latest FDA annual report of transfusion fatalities indicates that the blood supply is safer today than any previous time in history and transfusion-related deaths appear to be declining.[50]

APPENDIX II: DEFINITIONS IN HAEMOVIGILANCE

The following definitions and descriptions are used in the Australian National Haemovigilance Data Dictionary.

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, 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 of the National Haemovigilance Program.

Other serious transfusion reactions and events

Severe 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.

Severe 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
- urticarial.

Anaphylactoid or anaphylactic 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)

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 (TGVHD)

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

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

TGVHD 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 38: 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 39: Definitions for 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.

Event Type	Definition
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.
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.

Table 40: 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

APPENDIX IV: NSW HAEMOVIGILANCE DATA FOR 2009-10 AND 2010-11

NSW is committed to contributing to a National Haemovigilance Program and the CEC has been collecting and analysing information on transfusion-related adverse events in public hospitals since 2004-05. Information is reported voluntarily via the electronic IIMS which was designed to capture information relating to a range of incidents. IIMS is not a specific haemovigilance reporting system and as a result many of the expected haemovigilance-specific data fields are not included within the IIMS incident classifications.

Those incidents reported into the blood/blood product category Principal Incident Type are included in IIMS reports regularly released by the CEC. In order to derive additional information regarding adverse transfusion events, the CEC performs a targeted analysis of the free text description of adverse events provided within the blood/blood product category. The criteria for this analysis are the incidents and complications identified in the ANHDD. The results of the analysis are reported annually to the NSW Blood Clinical and Scientific Advisory Committee and biennially to the NBA.

The number of incidents reported in IIMS under the blood/blood product category for 2009-11 that meet the haemovigilance data dictionary criteria are provided in Table 41 and Table 42.

In 2009-10 the total number of incidents entered under the IIMS Blood Category was 1826:

- 16.7% (n=305) of entries were labelled as Incidents
- 10.9% (n=200) of entries were labelled as Complications
- 72.3% (n=1321) of incidents recorded entered under the IIMS Blood Category did not meet the European Haemovigilance Network definitions. These included documentation issues (n=642), occupational health and safety (n=86), needle stick injury (n=9), postpartum haemorrhage (n=27) and wastage (n=183).

In 2010-11 the total number of incidents entered under the IIMS Blood Category was 1865:

- 67.1% (n=1253) of all entries were labelled as Incidents
- 14.8% (n=186) of the 1253 incidents were labelled as Complications.

It should be noted that currently NSW does not assign imputability scores into the IIMS reporting system. IIMS in its current state cannot provide the level of detail required for true haemovigilance to be recorded due to the limitations in IIMS functionality, categories and sub categories. Furthermore, the reliability of data on reported incidents in the blood/blood product category is dependent on the staff member recognising that a significant adverse event has occurred and initiating the incident report. Continuous education in relation to the recognition of transfusion-related adverse events is required.

A key focus in NSW in relation to reducing adverse events associated with transfusion has been to reduce inappropriate transfusion. The Blood Watch program commenced in 2006 and over the last six years there has been at least a 10% reduction in red blood cell transfusions for inpatients in NSW public hospitals. A primary focus for the program continues to be improving all aspects of identification, treatment and reporting of transfusion-related adverse events.

Note: In 2009-10 NSW was divided into Area Health Services, and then in 2010-11 NSW was divided into Local Health Districts.

Table 41: NSW haemovigilance data for 1 July 2009 to 30 June 2010

Incidents	Number of reports
Dispensing of expired or unsuitable component	16
Dispensing of expired or unsuitable component and Fever > 39°C	0
Incorrect administration of blood or component dosage	17
Incorrect administration procedure	40
Incorrect equipment	22
Incorrect infusion rate	26
Mislabelled	153
Taking blood sample from incorrect patient	1
Wrong blood dispensed	5
Wrong blood or component administered to wrong patient	0
Wrong component ordered	1
Wrong patient	24
Total	**305**

Complications	Number of reports
Transfusion-transmitted infections	
2.1.2- Bacteria/Infection	
Transfusion reaction - positive bacteria growth on culture	1
Transfusion reaction >39°C - RBC	10
Immune Complications of Transfusion	
2.2.3 TRALI	
TRALI - transfusion-related acute lung injury	3
2.2.7 Anaphylactic reaction	
Anaphylactic reaction	5
2.2.9 Alloimmunisation	
Transfusion reaction - antibodies formed	0
Cardiovascular and Metabolic Complications of Transfusion	
Transfusion reaction - fluid overload	4
Unspecified Transfusion reaction	
Unspecified Transfusion reaction	150
Transfusion reaction - rash	27
Total	**200**

Table 42: NSW haemovigilance data for 1 July 2010 to 30 June 2011

Incidents	Number of reports
Dispensing of expired/unsuitable component	19
Dispensing of expired/unsuitable component plus fever >39°C	1
Incorrect administration of blood or component dosage	8
Incorrect administration procedure	46
Incorrect equipment	19
Incorrect infusion rate	15
Mislabelled/Documentation/Consent	1,116
Taking blood sample from incorrect patient	13
Wrong blood dispensed	5
Wrong blood or component administered to wrong patient	6
Wrong patient	5
Sub-total	1,253
n/a - does not meet ANHDD criteria	612
Total	**1,865**

Complications	Number of reports
ABO incompatibility	4
Anaphylactic or anaphylactoid reaction	8
DHTR	3
Immediate haemolytic transfusion reactions (other than ABO)	1
PTP	1
Severe allergic reaction	39
FNHTR	115
TRALI	3
TTI	2
TACO	10
Total	**186**

APPENDIX V: ODDS RATIO DATA FOR DONOR VIGILANCE

Table 43: Data used for the calculation of odds ratio, 2011-12

All phlebotomy types	Collections	Events	Total-group	TOTAL- AE	Total event-event	Age gp -event	CI-	OR	CI+
Male 16-17yrs	23,271	1,502	1,430,836	1,403,132	27,704	21,769	3.331	3.395	3.688
Male 18-20yrs	31,317	1,214	1,422,790	1,394,798	27,992	30,103	1.894	2.009	2.132
Male 21-30yrs	115,414	3,065	1,338,693	1,312,552	26,141	112,349	1.319	1.37	1.423
Male 31-40yrs	109,520	1,681	1,344,587	1,317,062	27,525	107,839	0.71	0.746	0.784
Male 41-50yrs	158,422	1,274	1,295,685	1,267,753	27,932	157,148	0.348	0.368	0.389
Male 51-60yrs	202,380	1,130	1,251,727	1,223,651	28,076	201,250	0.23	0.245	0.26
Male 61-70yrs	131,050	505	1,323,057	1,294,356	28,701	130,545	0.16	0.174	0.191
Male 71+yrs	13,608	34	1,440,499	1,411,327	29,172	13,574	0.087	0.124	0.175
Total	**784,982**	**10,405**							
Female 16-17yrs	28,166	2,968	1,425,941	1,399,703	26,238	25,198	6.036	6.284	6.541
Female 18-20yrs	37,364	2,431	1,416,743	1,389,968	26,775	34,933	3.46	3.613	3.772
Female 21-30yrs	124,345	5,329	1,329,762	1,305,885	23,877	119,016	2.376	2.449	2.524
Female 31-40yrs	90,304	2,192	1,363,803	1,336,789	27,014	88,112	1.178	1.231	1.287
Female 41-50yrs	128,993	2,116	1,325,114	1,298,024	27,090	126,877	0.774	0.809	0.845
Female 51-60yrs	159,478	2,416	1,294,629	1,267,839	26,790	157,062	0.713	0.743	0.775
Female 61-70yrs	93,454	1,278	1,360,653	1,332,725	27,928	92,176	0.625	0.662	0.7
Female 71+yrs	7,021	71	1,447,086	1,417,951	29,135	6,950	0.399	0.507	0.645
Total	**669,125**	**18,801**							
Grand total	**1,454,107**	**29,206**							

Notes:

CI - = confidence interval (lower limit)
OR = odds ratio
CI+ = confidence interval (upper limit)

ABBREVIATIONS AND ACRONYMS

AAPP	Australian Association of Pathology Practices
ABO	The human red cell ABO blood group system
ABS	Australian Bureau of Statistics
ABDR	Australian Bleeding Disorders Registry
ABURG	Appropriate Blood Use Reference Group
AHCDO	Australian Haemophilia Centre Directors' Organisation
ACHI	Australian Classification of Health Interventions
ACHS	Australian Council on Health Care
ACSQHC	Australian Commission on Safety and Quality in Health Care
ACT	Australian Capital Territory
AHMAC	Australian Health Ministers' Advisory Council
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
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
AUBRG	Appropriate Use of Blood Reference Group
BCSH	British Committee for Standards in Haematology
BeST	Better Safer Transfusion Program
BP	Blood pressure
CCF	Congestive cardiac failure
CEC	Clinical Excellence Commission, New South Wales
CIMS	Clinical Incident Monitoring System
CMV	Cytomegalovirus
CXR	Chest x-ray
DAT	Direct Antiglobulin Test
DHTR	Delayed haemolytic transfusion reaction
EAACI	European Academy of Allergy and Clinical Immunology

EIMS	Electronic Incident Management System
EHN	European Haemovigilance Network (now IHN)
EQuIP	Evaluation and Quality Improvement Program
FDA	US Food and Drug Administration
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
HIT	Healthcare Incident Type
HIV	Human immunodeficiency virus
HPWG	Haemovigilance Project Working Group
HR	Heart rate
HTC	Hospital Transfusion Committee
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
ISBT	International Society for Blood Transfusion
JBC	Jurisdictional Blood Committee
JMO	Junior Medical Officer
MB-FFP	Methylene blue treated fresh frozen plasma
MET	Medical Emergency Team
NBA	National Blood Authority
NCOPP	National Coalition of Public Pathology
NHDD	National Health Data Dictionary
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
NTTC	Northern Territory Transfusion Committee
OECD	Organisation for Economic Co-operation and Development

PBM	Patient Blood Management
PTP	Post transfusion purpura
PR	Pulse rate
PRIME	Queensland Health incident reporting system
QBMP	Queensland Blood Management Program
QiiT	Queensland Incidents in Transfusion
QLD	Queensland
RCA	Root cause analysis
RBC	Red blood cell
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
TGA	Therapeutic Goods Administration
TACO	Transfusion-associated circulatory overload
TA-GVHD	Transfusion-associated graft versus host disease
TIRG	Transfusion Incident Review Group
TNC	Transfusion Nurse Consultant
TPE	Therapeutic plasma exchange
TRALI	Transfusion-related acute lung injury
TTI	Transfusion transmitted infection
TTP	Thrombotic thrombocytopenic purpura
TTISS	Transfusion Transmitted Injuries Surveillance System
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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