



INITIAL AUSTRALIAN

# HAEMOVIGILANCE REPORT 2008

A Report by the National Blood Authority  
Haemovigilance Project Working Group

JANUARY 2008



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## Abbreviations and acronyms

AIHW	Australian Institute of Health and Welfare
AIMS	Advanced Incident Management System
ANZSBT	Australian and New Zealand Society of Blood Transfusion
ARCBS	Australian Red Cross Blood Service
BeST	Better Safer Transfusion Program
EHN	European Haemovigilance Network
EQulP 4	Evaluation and Quality Improvement Program
FDA	US Food and Drug Administration
FFP	fresh frozen plasma
HIT	healthcare incident type
HIV	human immunodeficiency virus
HPWG	Haemovigilance Project Working Group
IIMS	Incident Information Management System
NBA	National Blood Authority
NHMD	National Hospital Morbidity Database (AIHW)
NZBS	New Zealand Blood Service
OECD	Organisation for Economic Co-operation and Development
PRIME	Queensland Health incident reporting system
QBMP	Queensland Blood Management Program
QiiT	Queensland Incidents in Transfusion
RBC	red blood cell
SHOT	Serious Hazards of Transfusion (UK)
STIR	Serious Transfusion Incident Reporting
TGA	Therapeutic Goods Administration
TTISS	Transfusion Transmitted Injuries Surveillance System
WHO	World Health Organization



## Acknowledgement

The National Blood Authority recognises and acknowledges the individuals and organisations who contributed to this report.

A number of stakeholders kindly provided transfusion safety and quality data to the National Blood Authority. They include (alphabetically) the Australian Institute of Health and Welfare, New South Wales Clinical Excellence Commission, Queensland Blood Management Program, South Australian Department of Health BloodSafe program, and the Victorian Department of Health and Human Services BeST program.

The National Blood Authority also acknowledges the contributions of the Haemovigilance Project Working Group (Table 4). Members of this group have contributed significantly to this project, which aims to develop a framework for an enduring Australian haemovigilance program.



**Dr Alison Turner**

General Manager  
National Blood Authority  
Canberra

## Message from the Chair of the National Blood Authority Clinical Advisory Council

This is the first Australian report on transfusion safety that brings together some of the disparate information that currently exists in repositories across a number of states and territories. It provides information on the types of transfusion-related adverse events that have been reported in Australia over the past few years.

Information has been sourced from where it could be found – from organisations with a national focus such as the Australian Red Cross Blood Service and the Australian Institute of Health and Welfare, from coroners' reports, and from generic healthcare reporting systems such as the Advanced Incident Management System, Incident Information Management System, and PRIME. It also contains data from the Victorian transfusion-focused reporting system, Serious Transfusion Incident Reporting.

Increasingly, healthcare professionals, governments and the public look for improved appropriateness and safety of transfusions, and better patient outcomes. However, there is a growing body of literature from Australia and overseas pointing to transfusion as a risk factor for sub-optimal and at times, adverse health outcomes.

### **Avoidable and inappropriate transfusions expose patients to unnecessary risk of harm.**

There is also an increasing body of evidence indicating that in some circumstances transfused patients do less well than non-transfused patients. We need to encourage further work in this area to quantify the risks, and identify patients who may benefit from more restrictive transfusion protocols.

I am delighted to have witnessed the enthusiasm and commitment demonstrated by all states and territories and key stakeholders to participate with the National Blood Authority in developing a framework to capture and utilise data on serious transfusion errors and reactions occurring in Australian hospitals to improve patient outcomes.

I strongly support the recommendations of the Haemovigilance Project Working Group to establish a National Haemovigilance Advisory Committee to manage an ongoing voluntary haemovigilance program and work with all stakeholders to improve transfusion safety and deliver better patient outcomes.



**Professor Richard Smallwood**

Chair  
National Blood Authority Clinical Advisory Council



## Introduction and keynote message

The robust supply and treatment with safe labile blood products is a well-established part of quality healthcare. Australia has a world-class blood supply, but despite significant advances in donor screening, product testing and sophisticated medical procedures, transfusions still pose some risk. Much of the transfusion risk today is from human error rather than from blood products. Humans are prone to errors, and even heavy investment in technology cannot fully eliminate these risks.

The primary aim of all haemovigilance systems established to date internationally is to collect, analyse, evaluate and disseminate information on a common set of adverse events surrounding the transfusion of blood and blood products. This information is used to build better and safer systems, conserve valuable resources and ultimately deliver better patient outcomes.

Australian states and territories report certain serious hospital errors (sentinel events) to the Australian Institute of Health and Welfare (AIHW). The most recent report covered the period 2004–05 and identified 130 sentinel events (AIHW & Australian Commission on Safety and Quality in Healthcare 2007). The report noted one haemolytic reaction resulting from the transfusion of ABO-incompatible blood, which is likely an underestimate of the real scope of the problem.

Healthcare professionals, government agencies and the general public expect safe products and robust processes. Governments and healthcare administrators also are charged with ensuring that resources aimed at enhancing safety and quality reach their targets.

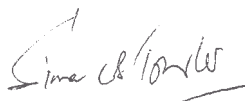
*This report provides for the first time for Australia an overview of the types of adverse transfusion events that have been reported over the past three to five years. It identifies and gives some sense of the scale of the most common problems. The challenge is to use these findings to create a sustainable framework that provides regular analysis, targets resources to change practice, and reports on the success of these changes. This report, although based on limited Australian data, makes a series of recommendations for establishing such a sustainable framework.*

Yours sincerely



**Dr Chris Hogan**

Co-Chair  
Haemovigilance Project Working Group



**Dr Simon Towler**

Co-Chair  
Haemovigilance Project Working Group

## Executive summary

**Blood products and transfusion are not risk free. Despite significant improvements in product safety through careful donor selection and product screening, transfusion errors and reactions still occur in all hospitals in all countries. Often they result from human error and can lead to patient morbidity, longer bed-stays, remedial interventions, diversion of scarce resources, and in some cases death.**

Following discussions with the National Blood Authority (NBA) in 2006, jurisdictional stakeholders identified the collection and reporting of haemovigilance data as a clear priority.

During 2007, a minimum dataset of transfusion-related adverse events was developed, defined and recommended by the NBA Haemovigilance Project Working Group (HPWG) and endorsed by the Jurisdictional Blood Committee.

Australian states and territories are at different points of development in their capacity to report against the agreed minimum dataset, and investment will be required to enable all to report to the same level. The HPWG noted the requirement for a quality analysis of the costs associated with transfusion-related adverse events to assist with formulating an understanding of the benefit of public investment in haemovigilance at the local, state and national levels.

The Australian data about fresh (labile) blood products in this report were sourced from a range of existing state-based healthcare reporting systems such as the Advanced Incident Management System, Incident Information Management System and PRIME and one transfusion-specific data incident reporting system – Serious Transfusion Incident Reporting. Data on ABO incompatibilities were sourced from the Australian Institute of Health and Welfare.

Although there were variations in reporting periods and definitions, the data demonstrate that the broad types of transfusion risks in Australia are similar to those of other countries that report transfusion adverse events, such as the United Kingdom, New Zealand, Sweden and Canada. The majority of the reported transfusion errors and adverse events resulted from preventable human error.

A key observation relating to the more than 600 transfusion-related incidents reported over the past 3-5 years in Australia was that approximately 65% of reports involved procedural errors. These included patient misidentification, labelling errors, wrong blood in tube, prescription and dispensing errors, incorrect blood component transfused, and ABO incompatibilities.

A smaller, yet still concerning number of reports related to transfusion reactions, including 106 reports of febrile non-haemolytic transfusion reactions, 59 reports of allergic reactions, 8 reports of anaphylaxis and 26 reports of haemolytic transfusion reactions. There were five reports of transfusion-related acute lung injury (TRALI), which is under-recognised and under-reported internationally (Despotis et al. 2007). All fresh products containing plasma have been implicated in TRALI. The use of clinical fresh frozen plasma is increasing in Australia. This product is still being used for warfarin reversal, for which a safer product is recommended and available.

One reporting system examined the timing of incidents relating to transfusion of labile products. While only a small proportion of transfusions were conducted overnight, 27% of reported transfusion incidents occurred between the hours of 22:00 and 07:00.

There were eight reports of transfusion-transmitted bacterial infections. There were no reports of transmission of HIV, hepatitis B or hepatitis C.

Two transfusion-related deaths were reported.

The recommendations flowing from these observations focus on four key areas:

**National haemovigilance program:** It is recommended that an enduring national haemovigilance program be established under the governance of a Haemovigilance Advisory Committee constituted under the National Blood Authority Act that builds on the successful outcomes of the National Haemovigilance Project. The program should have as its overarching rationale improvement in transfusion safety and quality to bring about better patient outcomes. This should be driven by:

- jurisdictional collaboration to standardise capture of common data
- encouraging sharing of learnings about the establishment and effective operation of state and institutionally based haemovigilance programs

- encouraging comprehensive analysis of adverse events data at the local, state and national levels and communicating the results
- encouraging the development of nationally recognised training modules for all staff involved in transfusions
- encouraging clinical learning in, and adoption of, patient blood management techniques to reduce unnecessary patient exposure to risks of allogeneic transfusions
- periodic publication of haemovigilance reports.

**Data collection and quality:** Improvements in quality of data will be achieved by states and territories continuing to work towards reporting of data that align with the agreed minimum dataset. It is recognised that this will require all users of labile blood products to participate in the provision of data, the conduct of analyses, and investigation and coordination of reporting against the national dataset. Additionally, it is recommended that:

- all information provided by states and territories be validated at both the institutional and jurisdictional levels
- measures be taken by the data custodians to ensure that privacy and other legislative requirements are met
- the Haemovigilance Advisory Committee work with clinical colleges and the Australian Red Cross Blood Service to improve recognition, treatment and reporting of TRALI
- the Haemovigilance Advisory Committee identify and work with holders of clinical, quality and safety datasets to further improve understanding of transfusion-related adverse events in Australia, including transfusion-related mortality.

**Procedural training and process improvement:**

States and territories should consider:

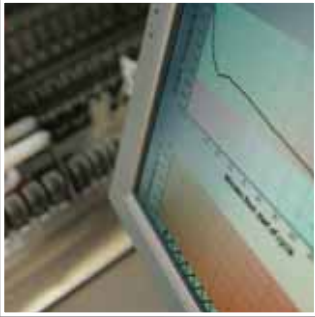
- actively encouraging minimisation of overnight transfusions of labile blood products for haemodynamically stable patients
- standardised training and development and proficiency testing, especially with respect to near-patient activities
- procedural audits of near-patient activities to identify and plug performance gaps.

- actively encouraging compliance with universal specimen labelling standards and patient identification protocols as prescribed by the National Pathology Accreditation Advisory Council and the Australian and New Zealand Society of Blood Transfusion, and accreditation standards required under the Australian Council on Healthcare Standards' Evaluation and Quality Improvement Program (EQulP 4).

**Patient blood management:** It is recommended that governments work collaboratively with clinical colleges and the ARCBS to scope, assess and, where appropriate, promote a stronger awareness and wider adoption of comprehensive patient blood management strategies. Reducing exposure to allogeneic blood and blood products will reduce exposure to transfusion risks.

Consideration should be given to strategies used internationally, such as active management of pre-operative anaemia, intra-operative cell salvage, reduction of unnecessary blood tests, further understanding of anaemia tolerance to assist the adoption of conservative transfusion triggers, and use of alternative pharmacological therapies where appropriate.

## SECTION ONE: INTRODUCTION



- 1.1 Scope of haemovigilance
- 1.2 Risk in international transfusion practice

## 1. Introduction

Haemovigilance is a quality improvement process that in addition to assisting decision making directed primarily to improving clinical outcomes and patient safety, also levers savings of both product and financial resources to the healthcare sector to deliver better patient outcomes. According to Debeir and colleagues (1999), haemovigilance is the ultimate quality indicator of a transfusion service.

### 1.1 Scope of haemovigilance

Haemovigilance is part of total healthcare vigilance – together with pharmacovigilance, vigilance on medical devices and clinical governance. The scope of haemovigilance varies according to the needs of the country or region, and can be arranged into three broad categories: donor vigilance, process control and recipient haemovigilance.

Haemovigilance programs in Canada and New Zealand cover not only labile blood products but also plasma and batch products. In some European countries the scope is limited to the collection of data on events surrounding the transfusion of labile blood products only.

Surveillance of adverse transfusion events is the cornerstone of the majority of haemovigilance systems. It encompasses many aspects such as identification of transfusion-transmitted infections via lookback processes, and surveillance of reactions (Robillard 2006). The latter may include only serious events (United Kingdom), or both serious and minor reactions (New Zealand and Singapore).

The European Union Blood Directive 2005/61/EC implementing Directive 2002/98/EC, and European Haemovigilance Network describe haemovigilance as:

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

The information gathered goes beyond just data collection, and may contribute to transfusion safety and quality via a number of ways. These include:

- providing the clinical community with reliable information on the types and frequencies of transfusion-related adverse events
- providing direction for corrective activities to prevent recurrence.

### 1.2 Risk in international transfusion practice

**Transfusions save millions of lives globally each year, and labile products become increasingly safe as a result of careful donor screening and selection procedures and more sensitive and selective product testing.**

The dominant risk in today's Organisation for Economic Co-operation and Development transfusion environment is not associated with product integrity, but with peri-transfusion processes and practices in hospitals (AuBuchon 2004; Boyce & Brook 2005; Despotis et al. 2007; Kaplan 2005; Linden 1999; Murphy & Kay 2004; Sharma et al. 2001; Spiess 2004; Stainsby et al. 2004, 2006; Stainsby, Cohen et al. 2005; Stainsby, Russell et al. 2005). Clerical errors occurring during collection, issue and transfusion of blood are the most common cause of ABO-incompatible transfusions. Between 40% and 50% of transfusion fatalities result from errors in identifying the patient or the blood component (Sharma et al. 2001). However, substantially more resources worldwide are directed at preventing HIV and hepatitis transmission than at preventing ABO mismatches.

Table 1 shows the observed international risk of a number of adverse events following transfusion of red blood cells (RBCs) as reported by Spiess (2004). The risk of an ABO-incompatible transfusion lies between 1 per 6,000 and 1 per 20,000 units transfused, and a fatal mismatch lies between 1 per 100,000 and 1 per 500,000 units transfused (Spiess 2004).

TABLE 1: INTERNATIONAL RISKS OF TRANSFUSION

Adverse event	Incidence
Hepatitis B	1:5,800 – 150,000 units
Hepatitis C	1:872,000 units
HIV	1:1.4 million – 2.4 million units
Human T-cell lymphotropic virus	1:1.5 million units
Cytomegalovirus conversion	7%
Epstein-Barr virus	0.5%
Transfusion-related acute lung injury	1:5,000 – 1:10,000 units
ABO mismatch	
occurrence	1:6,000 – 1:20,000 units
fatality	1:100,000 – 1:500,000 units
Delayed haemolytic transfusion reaction	1:2,500 units
Alloimmunisation	
platelets	1:10 units
leucocytes	1:10 units
Red blood cells	1%
Allergic reactions	1% – 4%
Febrile non-haemolytic transfusion reaction	0.1% – 1.0%
Graft-versus-host disease	1:400 – 1:10,000
Volume overload	10% – 40%
Marrow depression	Universal

Source: Spiess (2004).

In most cases the absolute event rates are likely to be approximations. They are useful principally as indicators of relative frequency of the different adverse occurrences. The true absolute rates can only be determined by rigorous prospective observation. Such data remain relatively sparse in most areas of clinical practice.

From 1996 to 2003, 23 million components were transfused in the UK (Stainsby et al. 2005). Data from the UK haemovigilance reporting program, Serious Hazards of Transfusion (SHOT), indicate that viruses such as HIV and hepatitis C have a much lower residual risk than principal risks such as blood being transfused to the wrong patient, transfusion-related acute lung injury (TRALI), bacterially contaminated platelets and errors during phlebotomy (Table 2).

TABLE 2: RISKS OF TRANSFUSION IN THE UNITED KINGDOM, 1996–2003

Adverse event	Risk per unit supplied
Hepatitis B	1:568,000
Hepatitis C	1:4,166,666
HIV	1:7,142,857
Fatality	1:500,000
Major morbidity	1:90,909
TRALI	1:166,666
infection (mostly bacterial)	1:500,000

Source: McClelland, cited in Dax et al. (2007).

Greater than 14 million units of RBCs and 1.6 million platelets (>80% collected by apheresis) are transfused annually in the United States (Despotis et al. 2007). The leading causes of transfusion related deaths in the United States in 2001–03, based on reports to the US Food and Drug Administration (FDA), were attributable to TRALI (16%–22%),<sup>i</sup> ABO haemolytic transfusion reactions (12%–15%) and bacterial contamination of platelets (11%–18%).

Reports indicate that overnight transfusions pose greater risk of errors than daytime transfusions. In 2005, the SHOT report noted that 37% of incorrect blood component transfused errors occurred between the hours of 20:00 and 08:00. (Stainsby et al. 2006). Data on transfusion errors extracted from South Australia’s Advanced Incident Management System (AIMS) in 2006 also indicate that overnight transfusions are less safe (South Australian Department of Health 2006 (see 4.4.1)).

There is a growing international awareness and interest in the role of alternatives to transfusion in limiting exposure to blood products, and subsequently reducing the rate of errors and reactions. In particular, a range of clinician-based blood management techniques are available to reduce patient exposure to banked blood. They include:

- holistic patient blood management techniques to manage anaemia, and greater involvement of the patient in transfusion decision making where practicable and appropriate
- pharmacological agents such as erythropoietin, and iron and folate
- pre-operative autologous blood deposition
- acute normovolemic haemodilution
- intra-operative cell salvage techniques
- wound sealants
- innovative anaesthetic and surgical techniques to reduce blood loss to an extent that precludes transfusion.

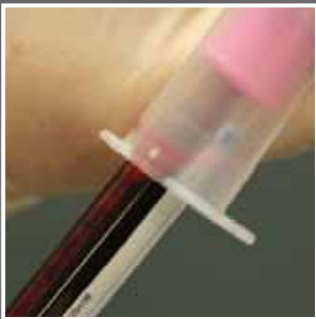
It is important that the risks of adverse events and reactions are better understood by all healthcare professionals involved with transfusions, and that positive sustained activities are developed to implement a patient-centric approach to comprehensive patient blood management. Greater knowledge of patient tolerance of anaemia and reduced exposure to allogeneic blood are the keys to reducing transfusion-related adverse events.

<sup>i</sup> TRALI is under-recognised and under-reported globally (Despotis et al. 2007). In 2003 only 21 TRALI deaths were reported to the FDA. The real fatality rate based on an incidence rate of 1:5,000 transfusions and 6% mortality indicates at least 300 deaths annually in the United States.



## SECTION TWO:

# BACKGROUND TO AUSTRALIAN TRANSFUSION SAFETY AND QUALITY



- 2.1 Previous reports into transfusion safety and quality in Australia
- 2.2 Relationships, roles and responsibilities in the Australian blood sector
- 2.3 Governance and regulatory environment
- 2.4 Transfusion risks in Australia
- 2.5 Financial impact of blood-related adverse events



## 2. Background to Australian transfusion safety and quality

In 2001, the *Review of the Australian blood banking and plasma product sector* made a number of recommendations to improve transfusion safety in Australia (Stephen 2001). The recommendations included stronger governance procedures in Australian hospitals and a national haemovigilance scheme to:

- identify contributory factors
- provide feedback to enable clinical practice and product improvements
- provide data to place Australian transfusion risks into perspective.

The report also recommended that, in association with relevant bodies, a haemovigilance project be developed as part of the national approach to improving patient safety, and that a voluntary and confidential approach, with appropriate legislative protections, be adopted for reporting adverse transfusion events in hospitals.

Reports from the UK identified bedside errors as the major risk for significant adverse transfusion outcomes. Cumulative data from the UK haemovigilance reporting program, SHOT, reported between 1996 and 2004 indicate that almost 70% of reported events were incorrect blood component transfused events. These stemmed mostly from errors at the bedside (Stainsby, Cohen et al. 2005). In Australia in 2003, the report *Development of options and costings for a national haemovigilance scheme for reporting adverse transfusion events* also identified bedside errors as the major risk for significant adverse transfusion outcomes, and found that these risks far outweigh the residual risk of infection from blood products (Corrs, Chambers & Westgarth 2003).

Also in 2003, the Australian Government established the National Blood Agreement, which defined governments' administrative, financial and operational roles and responsibilities in Australia's blood arrangements. The agreement also established the National Blood Authority (NBA) to provide sector-wide management on behalf of all Australian governments. The NBA performs a number of safety and quality roles including facilitating the development of national information systems for safety and quality issues in relation to the Australian blood sector.

In 2004, the Australian Senate Community Affairs References Committee released its report titled *Hepatitis C and the blood supply in Australia*. The report recommended that 'in order to ensure the safety of patients and continued confidence in the blood supply, the Australian Council for Safety and Quality in Health Care and the National Blood Authority implement, as a matter of priority, a national haemovigilance system' (Australian Senate Community Affairs References Committee 2004).

In 2005, *Towards better, safer blood transfusion* (Boyce & Brook 2005), a report commissioned by the Australian Council for Quality and Safety in Health Care (now the Australian Commission on Safety and Quality in Health Care) and the NBA on transfusion safety in Australia, identified systemic deficiencies in the transfusion chain from beginning to end. The report made a number of recommendations, including 'that future investment in enhancing the safety of transfusion must address clinical transfusion practice improvement, not just blood product quality'. The report noted: 'In 2005 the major risks from transfusion are associated with unsafe clinical transfusion practices and inappropriate blood product transfusion'.

A number of regional and state and territory initiatives have also contributed to the knowledge base of transfusion safety and quality in Australia. For example, the report *Red cell transfusion practices in New South Wales* (Rubin 2000) noted that 'of 1117 patients included in the study... 35% of blood transfusions were potentially inappropriate'. Inappropriate transfusions are inherently unsafe because they unnecessarily expose patients to risk. There are no reliable data available on adverse events specifically associated with putatively inappropriate transfusions.

### 2.1 Previous reports into transfusion safety and quality in Australia

**States and territories have recently implemented a number of initiatives to improve the quality and safety of transfusions. Brief descriptions of the major initiatives follow.**

**South Australia (BloodSafe):** In 2002, the South Australian Department of Human Services (now SA Health), in partnership with the Australian Red Cross Blood Service (ARCBS), launched its BloodSafe

program, a multicentre program to address key healthcare needs. These centred on transfusion appropriateness, haemovigilance and inventory management. In 2006, the NBA contracted the SA Health BloodSafe program to extract and report on transfusion safety data from its general healthcare adverse events reporting system, AIMS. Further information can be found later in this report, and at <[www.health.sa.gov.au/bloodsafe](http://www.health.sa.gov.au/bloodsafe)>.

**Victoria (Blood Matters):** In 2001, the Victorian Department of Human Services, in partnership with the ARCBS, funded the Blood Matters project to focus on bridging the gap between best practice and current practice in transfusion medicine. Tasmania also participated in and provided data to the project. The project's goal was to improve all aspects of transfusion practice. The Blood Matters project evolved into the Better Safer Transfusion (BeST) program. In 2006, the BeST program piloted Serious Transfusion Incident Reporting (STIR). The report on the pilot program was published in 2006. The findings of the pilot report will be incorporated into an ongoing STIR haemovigilance program. Further information can be found at <[www.health.vic.gov.au/best/news/stir\\_pilot.htm](http://www.health.vic.gov.au/best/news/stir_pilot.htm)>.

**New South Wales:** In 2000, Dr George Rubin reported on transfusion appropriateness in New South Wales hospitals (Rubin 2000). The report identified the gap between current practice and best practice. The New South Wales Department of Health established a user group, the Blood Use Improvement Group, to develop and promote better blood practices.

In response to this report, and a number of other issues such as a diminishing donor pool and the development of national guidelines on the use of labile blood components, NSW established the Blood Transfusion Improvement Collaborative in 2003. This group sought to reduce inappropriate transfusions in haemodynamically stable patients – the biggest single transfusion group (see Harrison et al. 2005). More recently, in 2006, the NBA commissioned the New South Wales Clinical Excellence Commission (CEC) to report on what transfusion data the state could extract from its healthcare adverse events reporting system, the Incident Information Management System (IIMS) (Clinical Excellence Commission 2006).

In 2007, the CEC launched its Blood Watch program. The program partners with all NSW area

health services and the ARCBS, with the aim of improving the safety and quality of labile blood product transfusion in all public hospitals in the state. Further information can be found at <[www.cec.health.nsw.gov.au](http://www.cec.health.nsw.gov.au)>.

**Queensland:** In 2005, Queensland Health established the Queensland Blood Management Program, which manages the state's blood and blood products. Its activities are overseen by the Queensland Blood Board.

Queensland Health developed a haemovigilance program, Queensland Incidents in Transfusion (QiiT), which is currently being piloted in two public and two private hospitals. In December 2006, prior to the commencement of the pilot project, the haemovigilance dataset was incorporated into PRIME, the incident reporting system developed by Queensland Health (data developed from PRIME are included in this report). QiiT now captures data from both the private and public health systems, with an electronic data feed from PRIME for the public pilot sites.

In 2007, Queensland Health released its first comprehensive report on adverse events across a number of modalities that occurred in its 20 public health districts. The report, *Patient safety: from learning to action* (Wakefield 2007) is a comprehensive analysis of state-wide adverse healthcare events.

**Other states/territories:** Although their reports are not in the public domain, the Northern Territory, the Australian Capital Territory, Tasmania and Western Australia also collect and report their healthcare adverse events using a number of proprietary systems such as AIMS and RiskMan, and/or employ localised quality and safety initiatives such as blood user groups, transfusion nurses and committees to investigate and report on transfusion incidents. Tasmania participates in, and contributes data to, the BeST program.

**Organisations:** Importantly, transfusion reactions are commonly reported to the ARCBS and the Therapeutic Goods Administration (TGA), especially when reactions are potentially product-related. Currently this is the primary way that transfusion safety data (especially data on infectious risk) are collected and reported on labile blood components. The ARCBS has considerable experience in providing specialist advice and dedicated products to manage adverse events.

The ARCBS investigates many reactions annually, and holds some historical data on transfusion reactions occurring in Australian hospitals.

Data on adverse outcomes in healthcare are collected in a number of Australian jurisdictions, but in the main, data gathering tends to be institution specific or part of a wider healthcare reporting picture that is not transfusion specific. For example, SA Health through its BloodSafe program and NSW Health capture data on adverse events using AIMS and IIMS, respectively. The systems are distributed by the Australian Patient Safety Foundation. They capture some haemovigilance data among a number of other healthcare incidents according to healthcare incident type, including medication errors, workplace bullying, equipment failures and occupational health and safety issues.

## 2.2 Relationships, roles and responsibilities in the Australian blood sector

**The responsibilities of governments and the National Blood Authority are set out in the National Blood Agreement 2003, which aims to ensure that Australia's blood and blood products are safe, sufficient, affordable and appropriate.<sup>ii</sup> The NBA, in conjunction with stakeholders, facilitates projects designed to ensure the appropriateness of the use of blood products and improve transfusion outcomes.**

There is a strong public perception that blood is a donated 'gift' and that its use is always safe, effective and appropriate.

In Australia, blood is voluntarily donated free from financial incentive, and distributed by the ARCBS to public and private hospitals and pathology laboratories in accordance with government policies in the National Blood Agreement. The NBA coordinates the purchase and supply of blood and blood products on behalf of all Australian governments.

The ARCBS collects, processes and supplies labile and fractionated blood components and plasma-derived products to Australian approved health providers, and provides education and specialist transfusion

advice across Australia. The operations of ARCBS are funded by all Australian governments under a Deed of Agreement managed by the NBA. The TGA regulates the manufacture of blood products, and has a keen interest in blood and plasma manufacturing activities and any adverse transfusion events that may be product related.

## 2.3 Governance and regulatory environment

**The regulation of blood collection and processing is shared among a number of agencies.**

The TGA regulates the manufacture of blood and plasma components by the ARCBS through the *Australian Code of Good Manufacturing Practice – Human Blood and Tissues* (TGA 2000) and Council of Europe *Guide to the preparation, use and quality assurance of blood components* (Council of Europe 2006). It regulates the plasma-derived products fractionated by CSL Limited through the *British Pharmacopoeia* 'Minimum standard for products, evaluation for safety, quality and efficacy for Proprietary Medicinal Products guidelines' and the *Australian code of good manufacturing practice for medicinal products* (TGA 2002). These standards prescribe processes for donor selection and care, blood collection and processing, laboratory testing for infectious markers, manufacture, and inventory transport and management to the point of delivery to laboratories and hospitals. The TGA does not regulate processes surrounding patient care or transfusions within hospitals unless they involve some form of product after-processing. There is pharmacovigilance of batch plasma and fractionated products, and rapid recall of implicated fresh blood products in association with the ARCBS through separate processes.

The National Association of Testing Authorities accredits laboratory practice to the Australian Standard AS-4633 (2005), which is the standard prescribed by the National Pathology Accreditation Advisory Council. The Royal College of Pathologists of Australasia accredits the currency of laboratory processes and procedures through its quality assurance initiatives.

<sup>ii</sup> See <[www.nba.gov.au/PDF/national\\_blood\\_agreement.pdf](http://www.nba.gov.au/PDF/national_blood_agreement.pdf)>.

The Australian Council on Healthcare Standards assesses acute care hospitals against the Evaluation and Quality Improvement Program (EQulP 4) 1.5.5 standard for accreditation. In addition to quality care and systems standards, this standard has some transfusion and blood-handling outcome measures. The majority of public and private hospitals use EQulP 4 as their accreditation standard.

Clinical specialty colleges have a role in licensing and accreditation of training within teaching hospitals, and a specific role in reporting adverse events. For example, the Royal Australasian College of Surgeons initiated the Australasian Survey of Surgical Mortality in 2005.

## 2.4 Transfusion risks in Australia

The ARCBS captures and reports information on a number of adverse events related to transfusion reactions in Australia.

The data indicate that the rates of reported adverse events in Australia reflect the international experience in some cases, but diverge in others. For instance, there seems to be less reported risk of hepatitis B in Australia than in some other countries, but greater reported risk of receiving bacterially contaminated platelets. At present, the ARCBS is funded to test only a proportion of platelets for bacterial contamination prior to release, but this is due to change.<sup>iii</sup>

**TABLE 3:** RESIDUAL RISK ESTIMATES FOR TRANSFUSION-TRANSMITTED DISEASE IN AUSTRALIA, 2007

Adverse event	Risk per unit issued
Hepatitis B <sup>a</sup>	Approximately 1:660,000
Hepatitis C (Ab + NAT) <sup>a</sup>	Less than 1:10 million
HIV (Ab + NAT) <sup>a</sup>	Less than 1:10 million
Human T-cell lymphotropic virus I and II (Ab) <sup>a</sup>	Less than 1:10 million
Bacterial sepsis due to contaminated platelets <sup>b</sup>	1:100,000
Malaria <sup>a</sup>	1:4.9 million – 10.2 million

Key: Ab – antibody; NAT – nucleic acid test.

Sources: <sup>a</sup>ARCBS (2007), <sup>b</sup>ARCBS (2006).

In 2000 a cluster of three transfusion deaths occurred in Sydney hospitals due to preventable ABO-incompatible transfusions. Following the coronial enquiry in 2001, the ABC program *The World Today* reported that ‘all three patients (sic) died after being transfused with incompatible blood. The state’s Chief Magistrate, Patricia Staunton, says human error and a culture of complacency were to blame’. The Chief Magistrate recommended that hospitals:

- investigate and trial known developments including computerised barcoding of blood products
- introduce the mandatory reporting of adverse outcomes relating to the administration of incorrect blood
- emphasise the need for staff to be educated and updated about hospital protocols.

<sup>iii</sup> In March 2007, Australian Government Health Ministers agreed to fund bacterial testing of 100% of Australia’s platelet supply commencing in 2008–09.



## 2.5 Financial impact of blood-related adverse events

**Australia's financial arrangements for the supply of labile and fractionated blood products are unique. Costs are shared between the Commonwealth (63%) and states and territories (37%). Blood and blood products in Australia are provided free of charge to patients under these arrangements.**

In 2006–07, Australian governments provided approximately AU\$617 million for the collection, manufacture and distribution of all blood and blood products in Australia, which included approximately AU\$320 million for fresh (labile) products. The aggregate cost represents approximately 3% of the overall budget for acute hospitals, and less than 1% of the recurrent national health budget (Flood et al. 2006).

Currently there is no comprehensive costing model to determine the true cost of an individual transfusion in Australia. The ARCBS is in the process of developing such a model that includes calculations of costs associated with adverse events. This model will provide, for the first time, an insight into the costs to the health sector of the investigation and treatment of transfusion-related adverse events in areas such as additional bed-stays, additional diagnostic tests, additional consumption of therapeutic and human resources, re-admissions, increased absences from work, and other costs. This analysis will be useful in further formulating an understanding of the benefit of public investment in haemovigilance at the local, state and national levels.

# SECTION THREE: DEVELOPMENT OF THE AUSTRALIAN HAEMOVIGILANCE PROJECT



3.1 Haemovigilance Project Working Group progress and achievements to date

### 3. Development of the Australian Haemovigilance Project

In 2006, the National Blood Authority held discussions with a number of jurisdictional stakeholders seeking comment on where Australian transfusion safety and quality priorities lay.

The systematic reporting of haemovigilance data as part of a wider transfusion safety and quality agenda was identified as a clear priority. States and territories also expressed a preference to explore the use of existing incident reporting systems to report nationally agreed and defined adverse events rather than creating an additional reporting burden. There was a strong desire for the data to be used primarily to promote patient safety and deliver better transfusion outcomes.

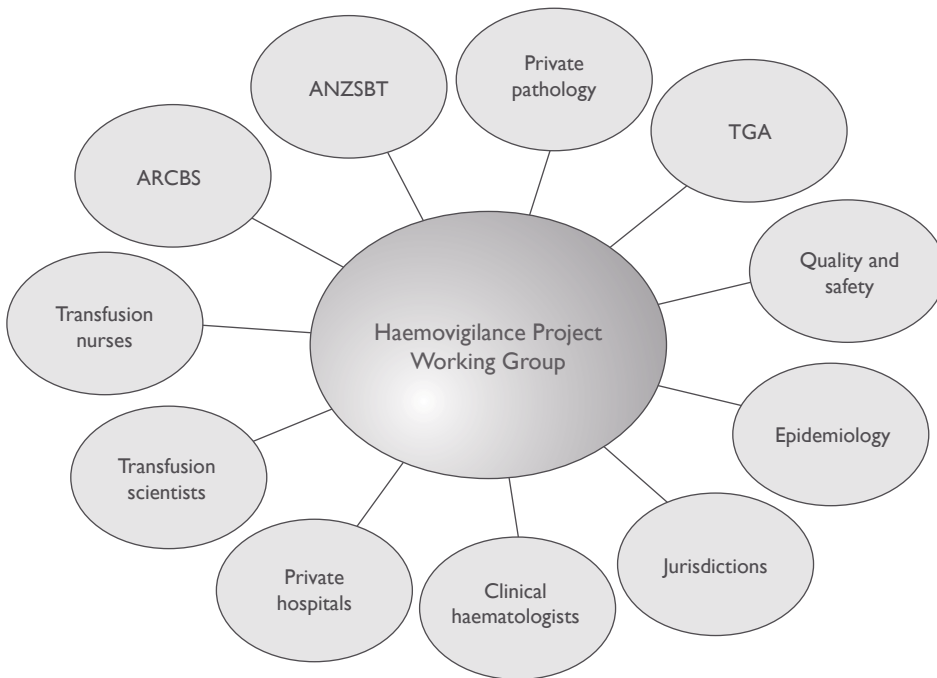
In response, the National Blood Authority established and provides secretariat support to the Haemovigilance Project Working Group (HPWG) (Figure 1 and Table 4). The role of the HPWG is to guide the development of a systematic Australian

haemovigilance program, drawing on the best aspects of existing international models and state and territory incident management data collection systems as much as practicable to:

- capture deidentified data in a national database about serious adverse events resulting from transfusion of labile blood products within Australian public and private hospitals
- disseminate the information through periodic reports for the purposes of providing feedback to build enduring quality and safety improvements into the transfusion chain.

Working group members are experts in transfusion medicine, science, nursing and epidemiology. The HPWG also has representation from both public and private healthcare sectors and governments. It includes membership from the Australian and New Zealand Society of Blood Transfusion (ANZSBT), the ARCBS, the TGA and a number of other transfusion-focused entities (Figure 1).

FIGURE 1: CONSTITUTION OF THE HAEMOVIGILANCE PROJECT WORKING GROUP



**TABLE 4:** MEMBERSHIP OF THE HAEMOVIGILANCE PROJECT WORKING GROUP

Member	Role
Dr Chris Hogan (Co-Chair)	Consultant Haematologist, Haematology Department, Royal Melbourne Hospital, Victoria
Dr Simon Towler (Co-Chair)	Executive Director, Health Policy and Clinical Reform Division, Department of Health, Western Australia
Dr Simon Brown	Consultant Haematologist, Queensland Blood Management Program, Royal Brisbane and Women's Hospital, Queensland
Dr Graeme Bryant	Consultant Haematologist, Sullivan Nicolaides Pathology, Queensland (representing the Australian Association of Pathology Providers)
Ms Annette Dahler	Transfusion Nurse, ACT Health
Mr Ken Davis	Supervising Scientist, Diagnostic Services and Transfusion Medicine, Institute of Medical and Veterinary Science, South Australia, and immediate past President, Australian and New Zealand Society of Blood Transfusion
Associate Professor Robert Flower	Supervising Scientist, Pacific Laboratory Medicine Services (PALMS) Transfusion Service, New South Wales
Ms Bernie Harrison	Director, Quality Systems Assessment, Clinical Excellence Commission, New South Wales
Dr Bevan Hokin	Pathology Laboratory Director, Sydney Adventist Hospital, New South Wales (representing the Australian Private Hospitals Association)
Ms Sue Ireland	Program Manager, Blood, Organ and Tissue Programs, Department of Health, South Australia
Ms Susan McGregor	Transfusion Nurse, Sunshine Hospital, Victoria
Professor John McNeil	Head, Department of Epidemiology and Preventative Medicine, Monash Medical School, Victoria
Dr Richard Pembrey	Clinical Advisor, Blood and Tissues Unit, Therapeutic Goods Administration, ACT
Dr Erica Wood	Transfusion Medicine Specialist, Australian Red Cross Blood Service, Victoria

### 3.1 Haemovigilance Project Working Group progress and achievements to date

In 2006–07, the HPWG assessed the strengths and weaknesses of international programs and identified which components could be mapped over to and utilised in an Australian program. The best aspects were integrated into a framework tailored to Australia.

The HPWG researched state and territory healthcare reporting systems, and recommended the adoption of a voluntary model that makes best use of existing systems and scarce healthcare resources.

To date the working group has defined and recommended a list of national reportable serious adverse events relating to transfusion of allogeneic and autologous labile blood products (Table 5). These events and definitions are based on the European Haemovigilance Network/International Society of Blood Transfusion definitions. The



HPWG has also developed a set of reportable additional descriptive data to assist analysis and identification of early trends, and the development of recommendations.

The HPWG has also recommended a reporting framework to govern the safe management of validated, deidentified information from both the public and private sectors. These arrangements have been endorsed by the Jurisdictional Blood Committee.

**TABLE 5: PROPOSED ADVERSE EVENTS FOR NATIONAL HAEMOVIGILANCE IN AUSTRALIA**

Adverse event
<b>Sentinel event</b>
<ul style="list-style-type: none"> <li>• haemolytic transfusion reaction resulting from ABO incompatibility</li> </ul>
<b>Other serious transfusion reactions</b>
<ul style="list-style-type: none"> <li>• immediate haemolytic transfusion reaction (other than ABO)</li> <li>• delayed haemolytic transfusion reaction</li> <li>• severe febrile non-haemolytic transfusion reaction</li> </ul>
<b>Incorrect blood component transfused</b>
<b>Transfusion infections</b>
<ul style="list-style-type: none"> <li>• bacterial</li> <li>• viral</li> <li>• protozoal</li> <li>• other serious infections such as variant Creutzfeldt-Jakob disease</li> </ul>
<b>Transfusion-associated acute lung injury</b>
<b>Allergic reactions (severe)</b>
<b>Anaphylaxis/anaphylactic reactions</b>
<b>Transfusion-associated graft-versus-host disease</b>
<b>Post-transfusion purpura</b>
<b>Transfusion-associated circulatory overload</b>

The adoption of a standardised list of national reportable serious adverse events means that Australian states and territories can report against the same list of errors and reactions when they contribute data to a national haemovigilance program. A standardised reporting framework also means that reports will be investigated and validated at their source, where the extent of causality can be known and reported. This ultimately will allow for more robust analysis and evidence-based conclusions.

All participants are cognisant of the importance of privacy and confidentiality. Safe custodianship and appropriate policies and procedures are being developed under legal guidance to ensure compliance with all privacy principles and legislative requirements.

## SECTION FOUR:

# AUSTRALIAN DATA ON BLOOD ISSUAGE AND ADVERSE TRANSFUSION EVENTS



- 4.1 Data sources and caveats
- 4.2 Issuance and transfusions of blood in Australia
- 4.3 Australian adverse events data capture and reporting systems
- 4.4 Contributing reports
  - 4.4.1 Advanced Incident Management System data: South Australia
  - 4.4.2 Incident Information Management System data: NSW
  - 4.4.3 Serious Transfusion Incident Reporting data: Victoria
  - 4.4.4 PRIME data: Queensland
  - 4.4.5 Australian Institute of Health and Welfare data
  - 4.4.6 Other states and territories

## 4. Australian data on blood issuance and adverse transfusion events

### 4.1 Data sources and caveats

This report presents a selection of the available information on transfusion-related adverse events reported in Australia over the past three to five years. It does not include haemovigilance data from individual hospitals or hospital networks, only information reported to and held at the state or territory level.

Australian data sources include state and territory healthcare reporting systems, such as AIMS (used in the public healthcare sector of South Australia and Western Australia), IIMS (used by all eight NSW area health services), STIR (used by the Victorian Department of Human Services Quality Improvement Unit), RiskMan (used by ACT Health and a number of private healthcare organisations), and PRIME, which is the healthcare reporting facility for Queensland Health. This report also makes use of data from the AIHW National Hospital Morbidity Database (NHMD).

While every effort has been made to report quality information, readers should use caution when interpreting the information about transfusion adverse events contained in this report.

The following caveats apply to the adverse events data presented in this section:

- Not all adverse events occurring have been reported and therefore calculation of rates or frequencies of events is not possible.
- Information may be defined and collected differently in each state/territory, making an inter-jurisdictional comparison not possible and inappropriate.
- Much of the currently available data used for this report have not been validated and lack imputability criteria. This reduces the certainty of a causal link between transfusions and the reported adverse events.
- Voluntary adverse event reporting will always give rise to a difference between *reported* adverse events and *actual* adverse events due to differing propensities to report. An increase in the number of

events reported may be due to increased vigilance and reporting or to an actual increase in events.

- Data have been collected over different reporting periods, which hinders comparability.

### 4.2 Issuance and transfusions of blood in Australia

All developed countries are managing increased demand for their scarce blood resources. Chronic diseases associated with ageing populations and greater longevity in OECD countries, earlier and more aggressive medical interventions, emerging disease threats associated with population movements and natural population increases strain blood resources.

Notwithstanding efforts to ensure blood products are used wisely and appropriately, donor recruitment and retention require constant inputs. The World Health Organization (WHO) estimates that 81 million units of blood were collected globally in 2005, and that global need approximates 10 to 30 units of blood per 1,000 head of population (Dax et al. 2007).

WHO also estimates that developed nations, which hold approximately 20% of the world's population, consume about 80% of global blood resources (Dax et al. 2007).

In 2006, the NBA commissioned a benchmarking report on fresh blood products (NBA 2007). The report compared and contrasted aspects of Australia's performance on fresh blood products against those of a number of other countries.<sup>iv</sup> The report considered indicators such as donor numbers and donor trends, production costs and product mix, usage and demand for healthcare services, and demographic variables such as population increases, ageing and rates of disease. The report indicated that in Australia in 2004–05, 36.5 units of RBCs were issued per 1,000 head of population. This compares to Finland (48.6) and New Zealand (30.8).

<sup>iv</sup> The authors of this report note that the data presented in the report should be treated with caution. While every effort was made to validate data, the authors were not able to guarantee that consistent robust data definitions were applied by agencies, and that data were therefore comparable.

**TABLE 6:** LABILE BLOOD AND BLOOD PRODUCTS ISSUED IN AUSTRALIA, 2003–07

Labile blood component	2003–04 <sup>a</sup>	2004–05 <sup>a</sup>	2005–06 <sup>a</sup>	2006–07 <sup>b</sup>
RBC units	736,804	744,250	757,034	779,120
Platelets (adult equivalent doses)	102,265	107,802	109,132	119,630
Fresh frozen plasma units	138,285	138,842	142,450	149,110
Cryoprecipitate units	33,053	38,056	42,847	48,732
Cryo-depleted plasma units	12,114	14,039	18,874	16,780

Sources: <sup>a</sup>NBA (2007), <sup>b</sup>NBA unpublished data (2007).

Although the NBA collects data on the number and type of blood products issued annually in Australia (Table 6), there are no direct or accurate data on the number of units of labile products transfused annually. Also not known is the exact amount of labile blood products lost through expiry, recalls, misplacement and inappropriate storage and transportation, although an increasing number of institutions are contributing to the ARCBS Electronic Returns Information Capture web-based wastage reporting system. However, the NBA’s benchmark report used data from the AIHW NHMD to develop a measure of the number of transfusions occurring in public and private hospitals for the period 2000–01 to 2003–04 (Table 7).

**TABLE 7:** NUMBER OF SEPARATIONS INVOLVING TRANSFUSIONS OF BLOOD PRODUCTS, 2000–01 TO 2003–04

Year	Number of transfusions of blood and gamma globulins	Annual growth (%)	As a proportion of all separations
2000–01	185,781		3.0
2001–02	200,772	8.1	3.1
2002–03	217,400	8.3	3.3
2003–04	238,347	9.6	3.5
		<b>Average: 8.7</b>	

Source: NBA (2007).

A second measure of the volume of blood transfused in Australian hospitals is the number of RBC and platelet transfusion procedures performed in Australian hospitals (Table 8). The AIHW NHMD data indicate that in 2003–04, transfusion of RBCs represented 66% (173,103/263,011) of all transfusion procedures reported. For the same period, platelet transfusions represented 8.7% (23,028/263,011) of all transfusions reported (NBA 2007).

**TABLE 8:** TRANSFUSION PROCEDURES PERFORMED IN AUSTRALIAN HOSPITALS, 2000–01 TO 2003–04

Year	RBCs		Platelets	
	Number of transfusions	Growth rate (%)	Number of transfusions	Growth rate (%)
2000–01	146,335		17,654	
2001–02	156,127	6.7	19,236	9.0
2002–03	165,431	6.0	21,048	9.4
2003–04	173,103	4.6	23,028	9.4
		<b>Average: 5.8</b>		<b>Average: 9.3</b>

Source: NBA (2007).

NHMD data indicate that the number of RBC transfusion procedures grew by an average of 5.8% annually between 2000–01 and 2003–04, and platelet transfusions grew by an average of 9.3% over the same period. The rate of all transfusions grew by an average of 8.7% over the period.

Noteworthy is the forecast effect of population increase and ageing on the future demand for blood and blood products.

Between 1999 and 2005, Australia’s population grew by 1.2% annually, which means that population increase alone contributed approximately 6% to demand for labile blood products over the period (NBA 2007).

Australia’s ageing population is expected to have a significant impact on the future demand for labile blood components, and indeed all blood products and transfusion services. Based on Australian Bureau of Statistics data, in 1999 the number of people aged 65 years and over was 2,328,000 (12.3% of population) (NBA 2007). This group is expected to grow to 3,796,000 (16.9% of population) by 2016.

Older people use more healthcare services and labile blood products than younger people. Age-related diseases (in particular, tumours and haematological malignancies) and joint replacements will increase in absolute and relative numbers as the Australian population ages. At the same time, technological advances will mean earlier diagnosis, and earlier,

often more aggressive interventions. Overall, this relationship will mean greater demand for labile blood products, more transfusions and a likely increase in the number of reports of adverse events.

At the same time, however, this anticipated increased demand for labile blood products will be tempered by a better understanding of patient blood management techniques, improved peri-operative assessment and anaemia management strategies, improved surgical and anaesthetic techniques that minimise blood loss, and increased surgical blood salvaging.

### 4.3 Australian adverse event data capture and reporting systems

**Currently there are several different incident reporting systems in use within jurisdictions, which capture a variety of adverse healthcare events (Table 9).**

These systems capture a wide range of healthcare incidents and, with the exception of STIR and the pilot QiiT project, are not specifically transfusion focused. However, the South Australian and New South Wales experiences show that they can be modified to capture some transfusion-specific data. AIMS requires less modification to capture specific transfusion-related events than does IIMS. The private sector generally uses RiskMan to capture and analyse its healthcare adverse events.

**TABLE 9:** CURRENT STATE AND TERRITORY HEALTHCARE INCIDENT REPORTING SYSTEMS

Jurisdiction	Reporting system
New South Wales	Incident Information Management System (IIMS)
Queensland	PRIME; Queensland Incidents in Transfusion (QiiT) currently being piloted
Victoria	Serious Transfusion Incident Reporting (STIR)
Western Australia	Advanced Incident Management System (AIMS)
South Australia	Advanced Incident Management System (AIMS)
Northern Territory	Advanced Incident Management System (AIMS)
Tasmania	Serious Transfusion Incident Reporting (STIR)
Australian Capital Territory	RiskMan

#### 4.4 Contributing reports

Data extracted from the major state and territory healthcare incident reporting systems have informed this report. Table 10 identifies these systems and their respective reporting periods. The differences in reporting periods add to the difficulties encountered in attempting to analyse and compare transfusion-related adverse events across Australia.

**TABLE 10:** REPORTING PERIODS FOR STATE/TERRITORY REPORTING SYSTEMS

Reporting system	Data collection period							
	2000	2001	2002	2003	2004	2005	2006	2007
AIHW NHMD								
AIMS (South Australia)								
IIMS (New South Wales)								
PRIME (Queensland)								
STIR (Victoria)								

For this report, data were also obtained from the AIHW NHMD and coroners' reports, but not sought from specific clinical registries or the ARCBS.

#### 4.4.1 Advanced Incident Management System data: South Australia

In mid 2006, the NBA contracted the South Australian Department of Health to extract and report on AIMS healthcare incident types (HITs) and map them against the European Haemovigilance Network (EHN) events and their definitions. The department engaged the Australian Patient Safety Foundation to map and report AIMS HITs against the EHN list.

#### Methodology

A BloodSafe Program nurse was appointed to the project to review the AIMS database for blood-related HITs reported over a two-year period from 1 June 2004 to 31 May 2006. The review was limited to public hospitals in South Australia that used AIMS.

In some cases HITs were reviewed and analysed individually to determine the validity of incident classification and reclassify incidents where necessary.

#### Findings

Preliminary results identified a total of 886 blood-related adverse events. Of these, 5% (40/886) were excluded due to misclassification, and 4% (36/886) involved fractionated products. These were excluded from analysis.

In total, 810 transfusion-related incidents were analysed. Metropolitan hospitals accounted for 95% (770/810) of reports. Twenty-seven percent (219/810) of incidents involving fresh blood components occurred in overnight transfusions between the hours of 22:00 and 07:00.

The three most commonly reported incident types are shown in Table 11.

TABLE 11: AIMS: TOP THREE REPORTED INCIDENTS, 1 JUNE 2004 TO 31 MAY 2006

Incident type	Number
Transfusion reaction	206
Pre-transfusion specimen labelling	159
Product quality/storage/wastage	111

Source: South Australian Department of Health (2006).

Transfusion reactions accounted for 25% (206/810) of reports. The three most commonly reported reactions are shown in Table 12.

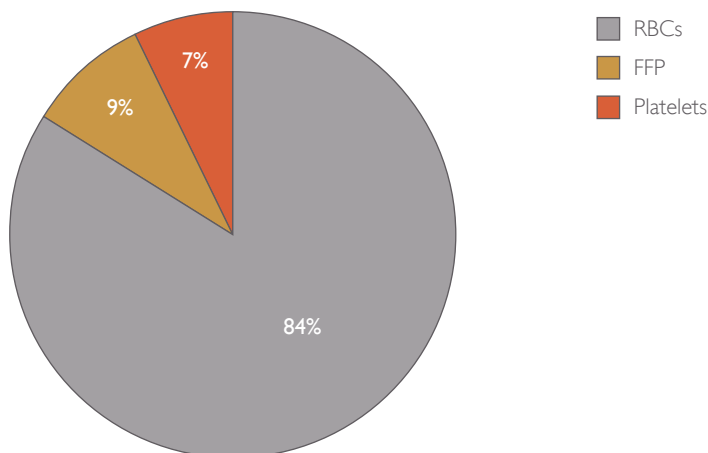
TABLE 12: AIMS: TOP THREE TRANSFUSION REACTIONS, 1 JUNE 2004 TO 31 MAY 2006

Reaction	Number
Febrile non-haemolytic transfusion reaction	86
Allergy	59
Transfusion-associated circulatory overload	5

Source: South Australian Department of Health (2006).

Sixty-nine percent (69%) of reported incidents involved labile blood components, and RBCs were implicated in 84% of reactions (Figure 2). Platelets were implicated in 7% of reported incidents, and fresh frozen plasma (FFP) was implicated in 9%. There were no reports involving cryoprecipitate.

FIGURE 2: AIMS: REACTIONS – IMPLICATED BLOOD COMPONENTS, 1 JUNE 2004 TO 31 MAY 2006



### Case studies

Following is deidentified composite material drawn from South Australian case studies.

#### CASE ONE

A patient in their 80s with a haematological disorder was incorrectly administered a unit of fresh frozen plasma. The medical prescription on the infusion chart was for ‘platelets, but the medical record and the order form for the transfusion laboratory stated ‘fresh frozen plasma’. A senior registered nurse on the next shift identified the error, when a further unit of fresh frozen plasma was delivered to the ward and it was noted that the infusion chart order stated ‘platelets’. The order was questioned/clarified and the patient subsequently received a dose of platelets.

#### CASE TWO

An incorrect unit of red cells (intended for another patient) was transfused to a 50-year-old patient in recovery. The blood group of the unit administered was fortunately the same ABO and Rh(D) group as the patient’s; however, the pack was intended for another patient (labelled with another patient’s name and registration number). The patient was not wearing an identification band. There was no adverse outcome as the unit was ABO identical.



## Conclusion

South Australia is advanced in its work in using AIMS across the entire state public health sector. AIMS is a generalised health incident reporting system and not specific for transfusion-related adverse events. This is evident in the narrow focus of the EHN definitions generally reflecting their origins. The AIMS HIT classification, in contrast, is designed to be used across the spectrum of healthcare. Nationally standardised definitions for serious adverse events would need to be incorporated into AIMS.

Classification and coding definitions need to be made more consistent so that there is less variation in how incident details are captured. This would enable easier and more consistent data analysis.

The strengths of AIMS include its capture of contributing factors, minimising factors and preventable actions and coverage of the whole transfusion process. It allows easy, accessible incident reporting, storing of information relating to adverse incidents and near misses for management action, and analysis and risk reduction activity. Its alert systems are useful for notifying staff that a new incident has been logged to allow follow-up in real time ('closing the loop').

### 4.4.2 Incident Information Management System data: New South Wales

In July 2006, the NBA contracted the Clinical Excellence Commission to review incidents reported in the New South Wales healthcare reporting system (IIMS) relating to blood and blood products. IIMS is the primary healthcare incident repository for NSW Health's eight Area Health Services, the Children's Hospital at Westmead, Justice Health and Ambulance NSW.

## Methodology

As with AIMS, the primary goal was to identify the extent to which IIMS reports could be mapped to the current EHN definitions of adverse events. Secondly, the project sought to gauge the extent to which IIMS could serve as a haemovigilance reporting tool.

Data for the period July 2005 to June 2006 were reviewed by a nurse experienced in transfusion. Free text descriptions were read and classified in one of the following ways:

- mapping to EHN definitions
- other transfusion-related events
- incidents not related to blood type or transfusion.

A registered nurse who was an experienced clinical reviewer exported the free-text data entries to a spreadsheet. The text descriptions were then analysed against the EHN definitions.

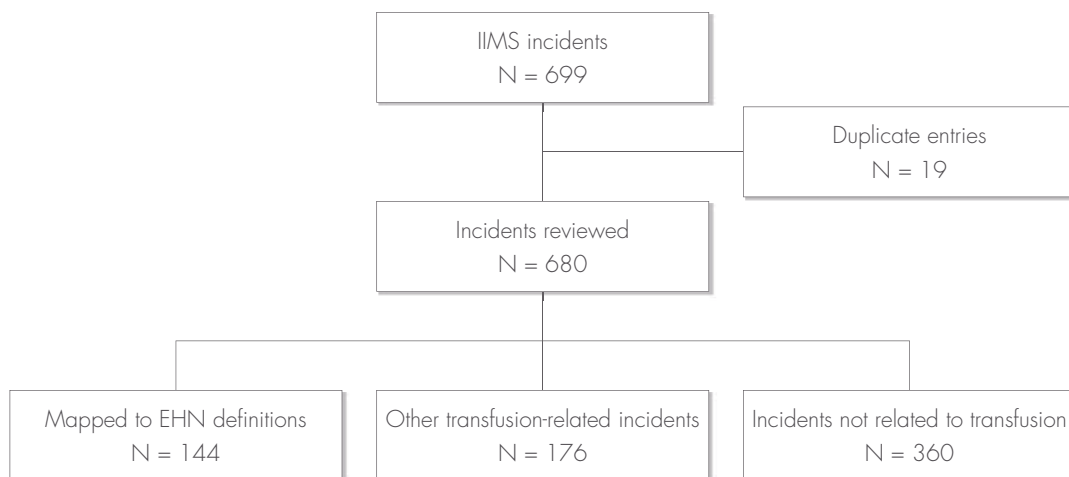
## Findings

Six hundred and ninety-nine entries were found with the text descriptors *blood* and/or *blood product*. Nineteen duplicate entries were identified and removed from analysis.

Of the 680 remaining entries, 21% (144/680) mapped to EHN definitions, 26% (176/680) related to transfusion but did not map across, and 53% (360/680) were not related to adverse events, blood or blood transfusion (see Figure 3).

Incidents that failed to map to EHN descriptors included storage, wastage and transport issues. Incidents that ultimately were not transfusion-related included medication errors, needle stick injuries and failure to administer anti-Rh(D) when required.

**FIGURE 3:** IIMS: INCIDENT DISTRIBUTION UNDER CLASSIFICATION FOR BLOOD AND/OR BLOOD PRODUCTS, JULY 2005 TO JUNE 2006



Incidents that mapped to EHN definitions are shown in Table 13.

**TABLE 13:** IIMS: INCIDENTS REPORTED, JULY 2005 TO JUNE 2006

Incident type	Number	%
Mislabelled specimen	52	36
Immune complications of transfusion	29	20
Incorrect equipment used for transfusion	27	19
Wrong component ordered for patient	10	7
Component mistakenly administered to wrong patient	8	6
Laboratory error	6	4
Transfusion-transmitted infection	4	3
Dispensing expired or unsuitable component	4	3
Cardiovascular and metabolic complication of transfusion	2	1
Blood component mistakenly ordered for wrong patient	2	1
<b>Total</b>	<b>144</b>	<b>100</b>

Source: Clinical Excellence Commission (2006).

The three most commonly reported incident types are shown in Table 14.

**TABLE 14:** IIMS: TOP THREE REPORTED INCIDENTS, JULY 2005 TO JUNE 2006

Incident	Number
Mislabelled specimens	52
Immune complications of transfusion	29
Incorrect equipment used for transfusion	27

Source: Clinical Excellence Commission (2006).

The most frequently reported incident was specimen mislabelling, which included wrong blood in tube, discrepancies between the blood request form information and the blood sample, and labelling errors.

Transfusion reactions such as immune complications, infections and cardio-metabolic complications accounted for 5% (35/680) of reports. The three most commonly reported transfusion reactions and their implicated products are shown in Table 15. There were no reports of transfusion-related acute lung injury recorded.

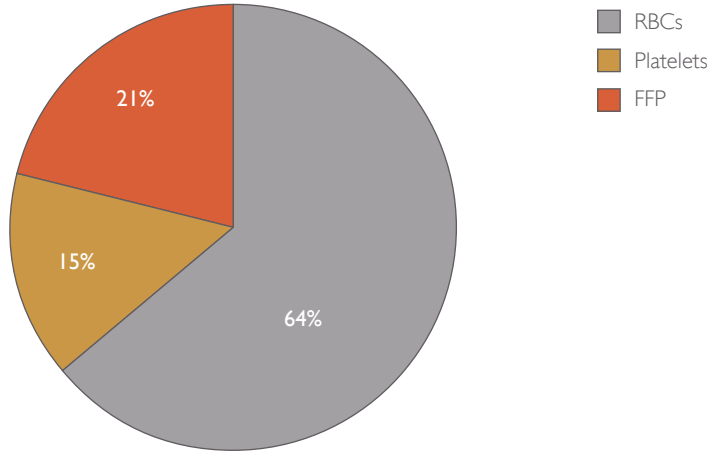
**TABLE 15:** IIMS: TOP THREE TRANSFUSION REACTIONS, JULY 2005 TO JUNE 2006

Transfusion reaction	Product	Number
Reaction – febrile/rash/rigors/shortness of breath	RBCs	15
	FFP	6
	Platelets	3
Reaction – positive bacterial growth on culture	RBCs	2
	Platelets	2
Cardiovascular and metabolic complication of transfusion	RBCs	2

Source: Clinical Excellence Commission (2006).

Fresh blood components were involved in 33 of the 35 reported transfusion reactions (Figure 4). Two reactions involved a plasma-derived batch product. RBC transfusions accounted for 64% (21/35) of reactions, fresh frozen plasma (FFP) 21% (7/35), and platelets 15% (5/35).

FIGURE 4: IIMS: REACTIONS – IMPLICATED BLOOD COMPONENTS, JULY 2005 TO JUNE 2006



On four occasions patients developed a bacteremia from transfusion of labile products. RBCs and platelets were implicated on two occasions each. On three of four occasions the causative organism was a bacillus species. There was one death recorded.

**Conclusion**

IIMS was not designed specifically for haemovigilance but as a state-wide voluntary incident reporting system. Consequently, many of the data fields that would be expected in a haemovigilance reporting system are not included in the IIMS incident classification. The creation of mandatory fields in the blood/blood product incident type categories would be necessary if IIMS were to be used as a haemovigilance system. Further training of staff, comprehensive education around the transfusion process, and inclusion of the EHN definitions would all contribute to improving the quality of the data entered into the system.

#### 4.4.3 Serious Transfusion Incident Reporting data: Victoria

The Victorian Department of Human Services piloted the Better Safer Transfusion STIR project during July–October 2006. Its aim was to capture serious transfusion incidents and near misses involving labile blood products in selected Victorian hospitals. Six health services (12 hospitals) contributed data. The report is a public document, available at <[www.health.vic.gov.au/best](http://www.health.vic.gov.au/best)>.

#### Methodology

Paper-based reports from contributing hospitals were transcribed into electronic spreadsheets and reviewed by an expert group consisting of a clinical haematologist, a transfusion scientist and a transfusion nurse. Each report and diagnosis was appraised before its inclusion. Diagnoses were adjusted in 11 reports (28%) following review.

#### Findings

The STIR report identified 17 acute transfusion reactions and 18 pre-transfusion procedural errors consisting of five wrong blood in tube incidents and 13 near misses (see Table 16).

TABLE 16: STIR: INCIDENTS REPORTED, JULY–OCTOBER 2006

Incident type	Number	%
Incorrect blood component transfused	2	5
Acute transfusion reaction	17	40
Delayed transfusion reaction	1	2
Transfusion-associated graft-versus-host disease	0	0
Transfusion-related acute lung injury	2	5
Posttransfusion purpura	0	0
Bacterial infection	2	5
Viral infection	0	0
Wrong blood in tube	5	12
Near miss	13	31
<b>Total</b>	<b>42</b>	<b>100</b>

Source: Victorian Department of Human Services (2007).

The most frequently reported events were acute transfusion reactions, which accounted for 40% (17/42) of incidents. Pre-transfusion procedural errors, wrong blood in tube and near misses as a group, accounted for 43% (18/42) of reports. The three most common incidents are shown in Table 17.

**TABLE 17:** STIR: TOP THREE REPORTED INCIDENTS, JULY–OCTOBER 2006

Incident	Number of incidents
Acute transfusion reaction	17
Near miss	13
Wrong blood in tube	5

Source: Victorian Department of Human Services (2007).

The three most commonly reported acute transfusion reactions were febrile non-haemolytic transfusion reactions 33% (6/18), other transfusion reactions 28% (5/18) and allergic transfusion reactions 22% (4/18). The three most common reactions are shown in Table 18.

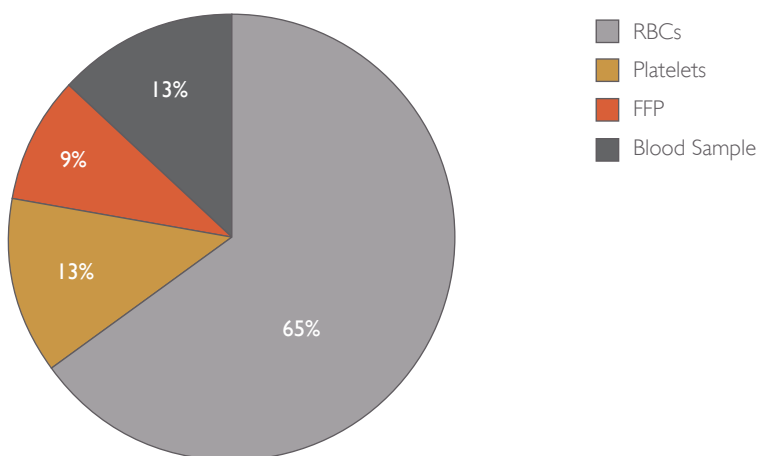
**TABLE 18:** STIR: TOP THREE ACUTE TRANSFUSION REACTIONS, JULY–OCTOBER 2006

Acute transfusion reaction	Number
Febrile non-haemolytic transfusion reaction	6
Other transfusion reactions	5
Allergic transfusion reactions	4

Source: Victorian Department of Human Services (2007).

The report noted that labile blood components were involved in 39 out of 45 reported incidents. RBC transfusions accounted for 65% (29/45) of reports, fresh frozen plasma 9% (4/45), and platelets 13% (6/45) (Figure 5). Blood sample errors accounted for 13% (6/45) of reports.

**FIGURE 5:** STIR: REACTIONS–IMPLICATED BLOOD COMPONENTS, JULY–OCTOBER 2006



## CASE STUDY

A patient was undergoing major emergency abdominal surgery for a bowel obstruction. The patient had abnormal coagulation tests including an International Normalised Ratio (INR) of 2.5.

Fresh frozen plasma and Prothrombinex-VF® were administered to correct the coagulation abnormalities. Thirty minutes into the transfusion, the patient developed dyspnoea, itching/rash, profound hypotension, markedly elevated pulse rate, hypoxia, and airway obstruction due to facial and neck swelling. The patient required anti-histamines, intravenous steroids and adrenaline to control the reaction and required transfer to the intensive care unit for ventilatory support.

The event was assessed as being a serious allergic/anaphylactic reaction, probably to the fresh frozen plasma. Fortunately, the patient made a full recovery.

## Conclusion

STIR was modelled closely on the United Kingdom's Serious Hazards of Transfusion (SHOT) system and more recently the New Zealand Blood Service haemovigilance system. It includes the intention to only collect serious incidents and also the incorporation of data validation steps to provide some assurance about the quality of the aggregated data. These design decisions reflect the importance of finding a balance between the time taken for hospitals to report versus the need for adequate factual information including imputability, for both clinical and process incidents.

An initial desk-top workshop and the pilot project were valuable for identifying problems and solutions prior to wider involvement. In 2007, STIR has been rolled out as a state-wide program as part of the Better Safer Transfusion Program, with participation from both public and private sectors.

Victoria is currently developing a state-wide Incident Information System to capture incidents across hospitals, including transfusion incidents through STIR. Reporting into STIR will be strengthened by this integration with the state-wide reporting system.

### 4.4.4 PRIME data: Queensland

## Methodology

Queensland's public hospitals and laboratories use a common information technology platform. Queensland Health employs a generic adverse events reporting system, PRIME, to capture and report raw data about a range of healthcare-related adverse events in the public system. Non-validated haemovigilance data

are electronically downloaded to the Queensland Blood Management Program (QBMP), where the information is validated and reported as part of the current pilot project.

Queensland Incidents in Transfusion (QiiT) is currently being piloted in two public and two private hospitals. QiiT is designed to capture specific transfusion-related data from both private and public systems. It has a paper-based validation process. Data originating in the private sector are captured and reported on local incident reporting systems (e.g. RiskMan) and then reported to QBMP using a paper-based system.

Table 19 shows a snapshot of incidents reported through PRIME from all Queensland public hospitals except one. The data were captured and reported to the QBMP as part of the ongoing development of QiiT, between 13 December 2006 and 30 June 2007. The data are not validated.

## Findings

Over the period December 2006 to June 2007, the project identified 66 primary transfusion-related incidents that mapped to the EHN and HPWG data definitions (Table 19). All reported errors and events were captured electronically through the PRIME system.

TABLE 19: PRIME: INCIDENTS REPORTED, DECEMBER 2006 TO JUNE 2007

Incident type	Number	%
Febrile non-haemolytic transfusion reaction	20	30
Incorrect blood component transfused	13	20
Blood sample collected from wrong patient	13	20
Severe allergic reaction	6	9
Anaphylaxis	5	8
Acute (non-ABO) haemolytic transfusion reaction	4	6
Post-transfusion fluid overload	2	3
Delayed haemolytic transfusion reaction	2	3
Transfusion-transmitted infection (including bacterial)	1	2
<b>Total</b>	<b>66</b>	<b>100</b>

Source: Queensland Health (2007).

The most frequently reported incident was febrile non-haemolytic transfusion reaction, which accounted for 30% (20/66) of incidents. Incorrect blood component transfused and blood sample collected from wrong patient each accounted for 20% (13/66) of reports. The three most common incidents are shown in Table 20.

TABLE 20: PRIME: TOP THREE REPORTED INCIDENTS, DECEMBER 2006 TO JUNE 2007

Incident	Number
Febrile non-haemolytic transfusion reaction	20
Incorrect blood component transfused	13
Blood sample collected from wrong patient	13

Source: Queensland Health (2007).



### Conclusion

QiiT has been designed to collect, validate and analyse haemovigilance data from both the public and private healthcare systems. During the development of QiiT, careful consideration was given to minimising the impact on the staff who report and feed back data to the system. A specific dataset was agreed for the pilot project and was incorporated into PRIME in December 2006 before the initiation of the pilot project, which was designed to test the validation of primary reports.

The data presented here are unvalidated data from PRIME. Although an electronic data feed has been established from the public system, until further software development is undertaken the reports from the private system will be extracted from the local incident reporting system and submitted using a paper-based adverse event form. Preliminary analysis of the data in PRIME and the initial stages of the pilot project have confirmed the need for a validation process to ensure that only appropriate adverse events are analysed further. Validation of the reports will allow further analysis of events and correct reporting of the haemovigilance dataset.

#### 4.4.5 Australian Institute of Health and Welfare data

### Methodology

The AIHW captures national healthcare data on its National Hospital Morbidity Database. All state and territory departments of health provide healthcare data from both public and private hospitals.

In 2005, the NBA requested the AIHW to interrogate its database for records with ABO incompatibility as a diagnosis for the period July 2000 to June 2005. These events are registered under code T80.3, which is the AIHW code for ABO incompatibilities. The AIHW database makes no distinction between morbid and innocuous events, nor does it look at causality.

The database records incidents in terms of patient separations, which are episodes of care during any one admission. A patient may have more than one separation during a single hospital visit. For example, a trauma patient may be admitted through the emergency department and go to theatre, then go to a post-operative (recovery) ward, and ultimately end up in a rehabilitation ward.

### Findings

Between July 2000 and June 2005, the AIHW NHMD identified a total of 67 episodes of care (separations) Australia-wide for which an ABO incompatibility reaction was listed as a primary or secondary diagnosis. These data do not distinguish between ABO incompatibility of different aetiology, and are not reported by states and territories to the sentinel events reports. The data indicate an average of 13 ABO incompatibilities per year over the five-year period (Table 21). The extent of morbidity or mortality, if any, associated with these incidents is not known.

**TABLE 21:** AIHW: SEPARATIONS THAT INCLUDED ABO INCOMPATIBILITY AS A DIAGNOSIS, 2000-01 TO 2004-05

	2000-01	2001-02	2002-03	2003-04	2004-05
(T80.3) ABO incompatibility <sup>a</sup>	12	23	12	9	11
RBCs issued ('000)	706.0 <sup>b</sup>	694.8 <sup>c</sup>	730.0 <sup>c</sup>	736.8 <sup>c</sup>	744.3 <sup>c</sup>
Frequency of ABO incompatibility <sup>a</sup>	1:58,833	1:30,209	1:60,833	1:81,867	1:67,664

Sources: <sup>a</sup>AIHW (2006) unpublished data, <sup>b</sup>ARCBS (2002), <sup>c</sup>NBA monthly product issuance reports, 2001-02, 2002-03, 2003-04 and 2004-05.

## Conclusion

The AIHW NHMD is not specifically designed to capture transfusion-related morbidity or mortality. Other ABO incompatibilities such as feto-maternal incompatibilities are also captured. There are no data on the outcomes of these ABO incompatibilities.

National data on the actual number of units transfused are unavailable. However, an approximation can be made by assuming a 5% product loss due to expiry and wastage through recalls, and inappropriate storage and transport. (This assumes that 95% of issued units were actually transfused.) Assuming that all reported ABO incompatibilities were transfusion-related, the average ABO incompatibility rate over the period is calculated at approximately 1 per 51,213 RBC units transfused.

The data also do not account for the possibility of over-reporting due to double-counting or included instances of feto-maternal incompatibility, nor do they consider under-reporting of events that were by chance innocuous and therefore unrecognised and not reported.

### 4.4.6 Other states and territories

The ACT Department of Health established the Appropriate Blood Use Reference Group, which aims to cooperatively pursue transfusion best practice and standardise blood management across all hospitals in the ACT. In addition, ACT Health has employed a transfusion nurse to investigate adverse transfusion events and manage the ACT's haemovigilance data within public hospitals.

Western Australia has employed transfusion nurses for a number of years, operating in the major metropolitan hospitals of Perth. These positions educate hospital staff and audit transfusion practice across a number of campuses. The WA ARCBS has also recently employed two transfusion nurses who ensure that following an adverse event haemovigilance documents are completed and the right samples are collected for subsequent investigation. WA Health uses AIMS as its healthcare adverse event reporting platform.

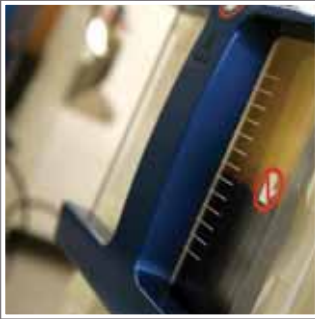
The Northern Territory has five public and one private hospital. The majority of transfusions in the territory take place in these establishments. They contribute

adverse event data through their transfusion committees to a central database located at the Royal Darwin Hospital. NT Health use AIMS for recording and reporting the territory's healthcare adverse events. At present the private sector has other arrangements for reporting and investigating transfusion adverse events.

Tasmania's three major hospitals report their haemovigilance data to the Victorian BeST STIR adverse events reporting system.

## SECTION FIVE:

# KEY OBSERVATIONS AND RECOMMENDATIONS



- 5.1 Key observations
  - 5.1.1 Data findings
  - 5.1.2 Causes
  - 5.1.3 Capacity of state systems to provide defined reports
  - 5.1.4 Cost implications
  - 5.1.5 Summary
- 5.2 Key recommendations
  - 5.2.1 Development of an enduring national haemovigilance program
  - 5.2.2 Data collection and quality
  - 5.2.3 Procedural training and process improvements
  - 5.2.4 Patient blood management

## 5. Key observations and recommendations

### 5.1 Key observations

#### 5.1.1 Data findings

For this initial Australian haemovigilance report, it must be noted that the data used were collected over different reporting periods. Direct comparison is therefore not possible or appropriate. It should also be noted that much of the currently available data used for this report have not been validated and may therefore lack imputability criteria. This reduces the certainty of a causal link between transfusions and the reported adverse events.

However, the overall intent of the project was to collate data to allow for the sharing of information about the broad patterns of incidents and areas of concern, rather than performance monitoring. On that basis, the data provide a useful insight into blood-related adverse events.

Specifically, the data show that there is minimal risk of infection from the provision of blood and blood products in Australia, as there were no reports of HIV, hepatitis B or hepatitis C in the data collected for this project. However, consistent with international experience, the data show that patient harm resulting from reactions and near misses is occurring in Australian hospitals. Across the various reporting periods from which the data were drawn more than 600 transfusion-related incidents, errors and reactions were reported, of these:

- There were 134 instances of patient misidentification, mislabelling, wrong blood in tube or near misses reported. If unrecognised prior to transfusion, these errors can lead to patients receiving the wrong blood, which may result in severe morbidity or mortality.
- There were 172 prescription and dispensing errors reported. Typically, they included ordering or providing the wrong blood component or delivering an out-of-specification component.
- There were 30 reports of incorrect blood component transfused. This human error is a major cause of patient morbidity and mortality.
- There were 67 reports over five years of ABO incompatibility. However, there are no published, consolidated data on the aetiology, morbidity or mortality associated with these events.
- There were 26 reports of haemolytic transfusion reactions, and eight reports of transfusion-transmitted infections, none of which were viral.

- There were 59 reports of allergic reactions and eight reports of anaphylaxis.
- There were 106 reports of febrile non-haemolytic transfusion reactions.
- There were five reports of transfusion-related acute lung injury, which is known to be under-recognised and under-reported, including when compared to suspected cases reported to the ARCBS for investigation.
- There were nine reports of circulatory overload as a result of over-transfusion. A number of deaths have occurred in Australia and internationally as a result of over-transfusion.
- Twenty-seven percent (219/810) of events extracted from AIMS involved labile components transfused overnight between the hours of 22:00 and 07:00.
- Two transfusion-related deaths were reported.

#### 5.1.2 Causes

Adverse events reported in the data available for this initial report can be categorised into two main causative types: procedural errors and transfusion reactions.

- Procedural and near-patient errors were the predominant adverse events reported. States reported procedural errors across the entire transfusion chain in three main areas:
  - *Pre-laboratory processes*: near-patient activities such as prescription errors, patient identification and phlebotomy errors, and sample labelling and transportation.
  - *Laboratory processes*: documentation and process errors, blood labelling, blood and product selection, and errors in releasing products.
  - *Post-laboratory point-of-care procedures*: collection, handling and storage, delivery of prepared blood products, bedside patient identification errors, and administration of blood products to the wrong patient.
- There were 212 reports of acute and delayed reactions. Febrile non-haemolytic transfusion reactions were the most common reactions reported, and the second most common event reported after procedural errors.

The report also raises a consistent concern about the difficulties in recognising and accurately diagnosing transfusion-related acute lung injury (TRALI), especially in acutely ill patients with comorbidities.

Under-recognition and misdiagnosis of TRALI is a worldwide phenomenon (Despotis et al. 2007).

All blood products containing plasma have been implicated in causing TRALI. Between 2003–04 and 2005–06, issuance of FFP increased by 3%. However, this product is still being widely used for routine warfarin reversal, despite the availability of national consensus guidelines and recommendation of a safer product (Prothrombinex-HT®) for this purpose (Baker et al. 2006).

The HPWG discussed and agreed that there is value in the regular use at the local level of detailed analytical techniques such as root-cause analysis or similar analytical techniques to investigate serious events. Their use ensures that clinicians and hospital directors fully understand the sequence of events leading up to adverse events. The HPWG also noted results of studies beyond the scope of the current report that found suboptimal clinical decision making leading to inappropriate blood use and unnecessary patient exposure to transfusion risk.

### 5.1.3 Capacity of state systems to provide defined reports

During the project, all members of the HPWG and key stakeholders expressed strong enthusiasm and support for an enduring national system that will identify and report serious transfusion errors and reactions and share learnings and information to improve transfusion safety and quality.

This support was largely reflective of the commitment to extract data from existing adverse event reporting systems, rather than increasing the burden of clinical-based reporting, and a shared focus on using the data to further promote patient safety management.

It is, however, clear that investment in modifying existing healthcare reporting systems will be required if they are to accurately capture, manage and report the agreed standardised set of adverse transfusion events. Currently these systems are at varying degrees of development and readiness to report against a proposed minimum dataset.

Further work would be required at the state and territory level to refine the dataset and the fields required to support the data, clearly focus on those events that cause or could cause harm to patients and ensure that the data can continue to be defined, identified and analysed from existing routine data-collection systems.

### 5.1.4 Cost implications

The HPWG was conscious of the lack of a comprehensive cost-benefit analysis of a dedicated focus on haemovigilance. Members noted that the application of the model currently being developed by the ARCBS that determines the total cost of transfusion – with scenario modelling of adverse events not resulting in death – will provide such insight. Notwithstanding the need for the development of such a model, the HPWG believes that a clear focus at the national level on carefully targeted resources to addressing the issues will ultimately result in significant community gain.

### 5.1.5 Summary

Despite the data gaps and the preliminary status of this haemovigilance report, there is sufficient evidence to indicate that harm is being done and that preventable errors are occurring in Australian hospitals.

## 5.2 Key recommendations

### 5.2.1 Development of an enduring national haemovigilance program

Noting the findings of previous reports (see 2.1) and the successful outcomes of the National Haemovigilance Project in identifying the types of transfusion-related adverse events reported in Australia over the last three to five years, it is recommended that:

- governments support the establishment of an enduring national haemovigilance program
- a Haemovigilance Advisory Committee be established under the National Blood Authority Act to guide and focus the program
- the program focus on further refining the ongoing data management processes, publishing national reports that identify trends, and making recommendations on prioritisation of actions to improve transfusion safety
- the program have as its overarching goal improvement in transfusion safety and quality to ensure better patient outcomes. This should be driven by:
  - collaboration with all relevant stakeholders to standardise the capture of a common national dataset of serious transfusion-related adverse events, and to improve the comprehensiveness of data captured
  - active engagement with the health, education and quality and safety sectors to share learnings widely, effectively and efficiently

- publication of reports based on a comprehensive analysis of reliable data; these reports should identify the causes of transfusion events and make recommendations for national quality and safety investments that lead to genuine improvements in patient safety outcomes
- encouraging the development of nationally recognised training modules to improve the competencies of all staff involved in transfusions
- promoting patient blood management techniques to reduce exposure to allogeneic transfusion risks
- collaborative engagement with the work of the Australian Commission on Safety and Quality in Health Care.

### 5.2.2 Data collection and quality

To support the proposed national haemovigilance program it is recommended that states and territories continue to align their reporting systems with the agreed dataset to create a comprehensive national minimum dataset.

It is recognised that this will require all users of labile blood products to:

- participate in the provision and analysis of data
- investigate and report adverse events in accordance with the national dataset.

To improve the quality, comparability and imputability of data, it is recommended that all information provided by states and territories for national reporting be validated and deidentified. Mechanisms will need to be established to ensure information is securely held and managed according to relevant privacy principles and policies and legal requirements.

To improve the accuracy of reporting of transfusion-related acute lung injury, it is recommended that the proposed Haemovigilance Advisory Committee work in conjunction with clinical specialty colleges and the ARCBS to enhance awareness and understanding of the aetiology, diagnosis and treatment of this condition.

It is further recommended that the proposed Haemovigilance Advisory Committee identify and work with holders of clinical, quality and safety national datasets to further improve understanding of transfusion-related adverse events in Australia.

### 5.2.3 Procedural training and process improvements

It is recommended that states and territories actively encourage minimisation of overnight transfusions in haemodynamically stable patients.

In recognition of the prevalence of procedural errors, it is recommended that state and territory governments consider:

- facilitating standardised training and development and periodic proficiency testing to address procedural errors and gaps, especially near-patient errors
- performing procedural audits of near-patient activities to identify weak points, including opportunities to support improved clinical decision making, and focus resources to improve transfusion safety
- actively encouraging compliance with universal specimen labelling standards and patient identification, as prescribed by the National Pathology Accreditation Advisory Council and the Australian and New Zealand Society of Blood Transfusion, and the Australian Council on Healthcare Standards accreditation standards required under EQulP 4.

It is recommended that the proposed Haemovigilance Advisory Committee work collaboratively with quality and safety units, research bodies and other relevant organisations to explore possible application of technological adjuncts such as portable barcode readers and/or radio-frequency identification scanners to reduce the scope for error.

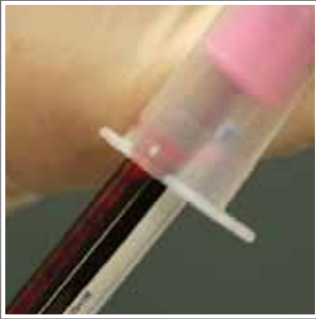
### 5.2.4 Patient blood management

It is recommended that governments work collaboratively with clinical colleges and the ARCBS to scope, assess and, where appropriate, promote a stronger awareness and adoption of comprehensive patient blood management strategies. Reducing exposure to allogeneic blood and blood products will reduce exposure to unnecessary transfusion risks.

Consideration should be given to strategies used internationally, such as active management of pre-operative anaemia, intra-operative cell salvage, reduction of unnecessary blood tests, further understanding of anaemia tolerance to assist the adoption of conservative transfusion triggers, and use of alternative pharmacological therapies where appropriate.

APPENDIX:

# THE INTERNATIONAL CONTEXT



International haemovigilance initiatives

International reports: key data and trends

## The international context

### International haemovigilance initiatives

Pioneering work on haemovigilance first began in France in 1991. Since then numerous schemes have been developed around the world. As of 2005, voluntary systems operated in Japan, South Africa, Austria, Belgium, Denmark, Finland, Greece, Ireland, Norway, New Zealand and the United Kingdom. Obligatory systems operated in France, Germany, Poland, Russia, Slovak Republic and Switzerland. Dual systems (where parts are obligatory and parts are voluntary) ran in Sweden, Czech Republic and Italy (Engelfreit et al. 2006; Faber 2004, 2006).

In Canada, the Krever report reviewed the circumstances surrounding transfusion-related HIV and hepatitis C infections during the early 1980s and recommended sweeping reforms (Commission of Inquiry on the Blood System in Canada 1997). Haemovigilance and improved transfusion practices became the responsibilities of provincial governments rather than a central agency. Canadian blood suppliers and plasma manufacturers are now obligated to report serious adverse events and fatalities to the Public Health Agency of Canada through the Transfusion Transmitted Injuries Surveillance System. However, there is currently no obligation on healthcare professionals working in hospitals to report transfusion reactions.

Following the Canadian and French HIV and hepatitis C enquiries in the 1990s, the UK National Blood Service developed a voluntary haemovigilance program, Serious Hazards of Transfusion (SHOT). The program captures data from private as well as public hospitals, but the extent of reporting by the private sector is unknown. SHOT has been operating for more than 10 years, and is an acknowledged leader in haemovigilance data capture and reporting.

The UK is currently implementing the European Union blood safety directives through its Serious Adverse Blood Reactions and Events reporting system. In addition to satisfying the requirements of the EU in reporting to the Medicines and Healthcare Products Regulatory Agency, the UK also reports adverse events to SHOT. At the time of printing, the relevant parties were still clarifying their respective roles and responsibilities under the new arrangements.

The EU entered the blood safety and quality arena in 2001 with Directive 2001/83/EC and update Directive 2002/98/EC. In 2005, the EU issued Directive 2005/61/EC mandating the implementation of traceability and notification of serious adverse reactions and events described in Directive 2002/98/EC. In this context, all EU countries have mandated haemovigilance programs, but are free to implement the program that best meets their needs. Member states are at different stages of implementation. The EU model does not regulate hospital practices, but focuses mostly on product safety. Mascaretti and colleagues (2004) reported that, among European countries:

- 13/17 (77%) have specific national transfusion laws
- 11/17 (65%) maintain haemovigilance programs
- 5/17 (29%) have national programs
- 4/17 (24%) have local hospital-based haemovigilance programs
- 5/17 (29%) have no haemovigilance scheme.

In November 2006, the UK-based National Patient Safety Agency, in conjunction with SHOT and the National Blood Transfusion Committee, published a set of competency requirements for UK hospitals, *Right patient, right blood: new advice for safer blood transfusions*.<sup>v</sup> The document provides guidance on technological investments and appropriate blood use to deliver safer transfusions.

The European Haemovigilance Network was formed in 1998. It consists of 11 members: Belgium, France, Luxembourg, Portugal, The Netherlands, Austria, Denmark, Finland, Greece, Ireland and the UK. Australia, Canada, Croatia, Norway and Switzerland are associate members. The European Haemovigilance Network works closely with the International Society of Blood Transfusion.

The New Zealand Haemovigilance program commenced in 2005 following a pilot project, and is auspiced by the New Zealand Blood Service. It builds on the models of UK's SHOT program and the Irish Blood Service. New Zealand anonymously records the type of event, severity and imputability. Like Singapore and France, the New Zealand model

<sup>v</sup> See <[www.npsa.nhs.uk/display?contentId=5354](http://www.npsa.nhs.uk/display?contentId=5354)>.



collects data on all reactions including minor ones. Reporting near misses remains the responsibility of individual district health boards.

In January 2003, the Singapore National Haemovigilance Programme was introduced following a successful five-month pilot study (Teo 2005). The voluntary program is sponsored by the Singapore Health Science Authority and covers all serious and minor adverse reactions to blood transfusions and near-miss events. The program is organised as a shared initiative, coordinated by the National Blood Service and involving hospital transfusion committees. All 12 hospitals in Singapore participate in the program, with response rates rising from an initial 1.28 per 1,000 transfusions to 5 per 1,000 transfusions in 2004.

The World Health Organization (WHO) has documented policies on blood safety and appropriateness of transfusion (WHO 2007). WHO encourages member states to include haemovigilance activities as part of their transfusion governance arrangements. The United Nations also focuses on improving the safety of blood, especially in the developing countries of the Middle East and sub-Saharan Africa, where much of the blood transfused is replacement from friends and family and testing is limited.

International haemovigilance systems, such as the European Haemovigilance Network, Serious Hazards of Transfusion, Transfusion Transmitted Injuries Surveillance System and others, have published reports over a number of years on transfusion incidents and contributed a great deal to the identification of transfusion adverse events and promotion of transfusion safety and quality.

### International reports: key data and trends

A number of studies and reports such as the BaCon Study (1998–2000) (Heuhnert et al. 2001), the CRIT Study (2000–01) (Corwin et al. 2004) and the Leucoreduction Study (2004) (King et al. 2004) have contributed significantly to the knowledge base in transfusion safety. Others (see, for example, Pape & Habler 2007; Hébert et al. 1999; Steiner & Despotis 2007; Rao et al. 2004) have provided insight into

transfusion outcomes associated with restricted versus liberal transfusion policies for selected patient groups.

These studies tend to focus on events occurring within individual hospitals or hospital networks. With the exception of annual reports, there is a general lack of *national* data that include national denominators such as the number of units issued or units transfused.

In 2006, the National Blood Authority researched the available international haemovigilance data relating to the transfusion of labile blood products (RBCs, platelets and plasma) for the period 1998–2006. Three databases (Embase, Cochrane and MedLine) were searched for national transfusion-related adverse events data that also contained denominator data.

The search found 412 abstracts, and 46 full-text articles were requested and reviewed. Of these only 24 provided useful data. A further four websites and 316 adverse event records were included. Five articles contributed 72% of reportable data. Twenty-nine types of adverse events and seven different denominators were reported nationally.

Researchers found a lack of reporting consistency, and wide country-to-country variation in rates for the same adverse event (Table 22). Some countries reported near misses but others did not. Some reported only serious events, while others reported a wide range of adverse events. Information on imputability was lacking, as were definitions of adverse events. Under-reporting of adverse events in some voluntary systems was a likely cause of the wide variation in adverse event rates. Under-recognition of adverse events across both voluntary and mandated systems may have also contributed to the wide variation in reported adverse event rates. For example, some countries reported low incidences of adverse events such as bacterial contamination and delayed haemolytic transfusion reactions, which tend to occur relatively frequently.

TABLE 22: SELECTED NATIONALLY REPORTED RATES OF ADVERSE EVENTS, 1998–2006

Adverse event	Reported frequency	
ABO incompatibility	RBCs	1:10,353 – 48,333
	Platelets	1:21,442 – 39,967
	FFP	Not available
	All components	1:19,241 – 30,000
Bacterial infection	RBCs	1:39,873 – 5,000,000
	Platelets	1:4,441 – 100,000
	FFP	1:20,672
	All components	1:20,000 – 45,907
Transfusion-related acute lung injury	RBCs	1:29,000 – 200,000
	Platelets	1:9,563 – 200,000
	FFP	1:46,471
	All components	0 – 422,953

Source: NBA (2006), unpublished data.

The European Union, through the Council of Europe, has mandated that all member countries have a haemovigilance program that meets the minimum standards as described in the earlier EU Directive 2002/98/EC. By 2005, 11/25 (44%) of EU member states had national or local haemovigilance programs in place. The EU does not mandate what data to collect and report; it only provides guidance in conjunction with the European Haemovigilance Network. In 2006, there were still differences in the depth and breadth of haemovigilance across member states (Gorham 2007).

In the UK, the SHOT program has been running for more than 10 years. Between 1996 and 2005, SHOT reported 46 fatalities in the UK that were definitely attributable to transfusions. A further 13 deaths were *probably* caused by transfusion, and 46 *possibly* caused by transfusion (Stainsby et al. 2006). The 2005 SHOT annual report (Stainsby et al. 2006) also identified 10 ABO-mismatch transfusions in 2005, an historic low since the program began in 1996.

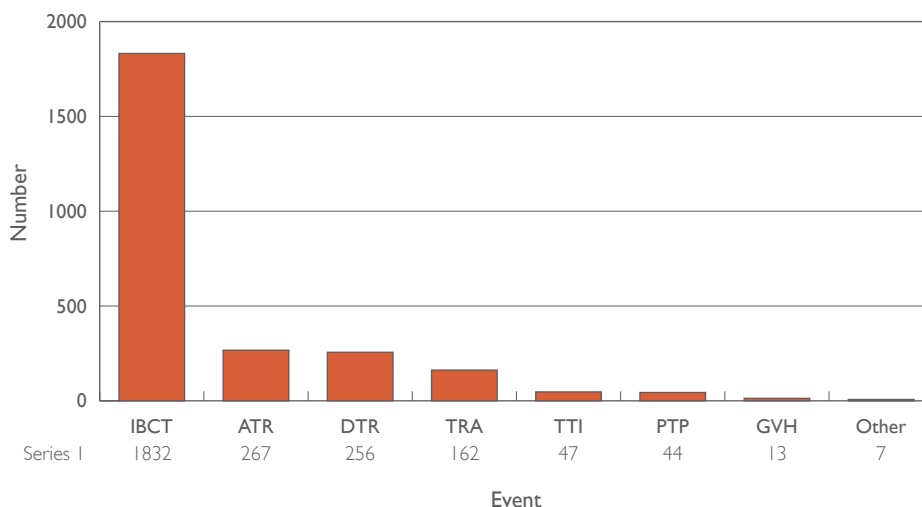
Data compiled from SHOT annual reports over a nine-year period (1996–2004) show that in the UK the overwhelming number of serious adverse transfusion events were associated with incorrect blood component transfused (Stainsby, Cohen et al. 2005; Stainsby et al. 2004) (Table 23 and Figure 6). In a separate paper on adverse events over a six-year period (1996/7 to 2001/2), Stainsby and colleagues (2004) noted 1,045 reported episodes of incorrect blood component transfused in UK hospitals. Fifty-one percent (901/1,045) of these events were attributable to near-patient errors during phlebotomy or blood administration. Forty-nine deaths were *definitely* or *probably* due to transfusion. A further 29 fatalities were *possibly* attributable to transfusion. McClelland and Phillips (as cited in Myhre & McRuer 2000) reported that one-third of 245 laboratories reported incidents in which the patient received a wrong unit of blood.

TABLE 23: CUMULATIVE SHOT (UK) DATA, 1996–2004

Adverse event	Number	% of reports
Incorrect blood component transfused	1,832	70
Acute transfusion reaction	267	10
Delayed transfusion reaction	256	10
Transfusion-related acute lung injury	162	6
Transfusion-transmitted infection	47	2
Posttransfusion purpura	44	2
Graft-versus-host disease	13	<1
Other	7	<1
<b>Total</b>	<b>2628</b>	<b>100</b>

Source: Stainsby, Cohen et al. (2005).

FIGURE 6: CUMULATIVE SHOT (UK) ADVERSE EVENTS DATA, 1996–2004



Key: IBCT – incorrect blood component transfused; ATR – acute transfusion reaction; DTR – delayed transfusion reaction; TRA – transfusion-related acute lung injury; TTI – transfusion-transmitted infection; PTP – post-transfusion purpura; GVH – graft-versus-host disease.

Source: Stainsby, Cohen et al. (2005).

Stainsby and colleagues estimate that based on SHOT reports, the risk in the UK of an error occurring during transfusion of a blood component is 1 per 16,500 units transfused (Stainsby, Russell et al. 2005). They also estimate the risk of an ABO-incompatible transfusion at 1 per 100,000 and the risk of death at 1 per 1,500,000 units transfused.

During 2005, 1,358 near-miss incidents were reported to SHOT (Stainsby et al. 2006), an increase of 26% on 2004 levels. Patient misidentification at the time of phlebotomy resulting in wrong blood in tube was the most frequently reported event, accounting for 574/1,358 (42.2%) of reports. At the same time, there was a 47% reduction in ABO incompatibilities from 19 in 2004 to 10 in 2005, and a 54% reduction since 2001–02.

Six hundred nine adverse events were analysed (Table 24). There were three transfusion-transmitted infections (0.5%) plus one further report of probable variant Creutzfeldt-Jakob disease.

**TABLE 24:** SHOT (UK) HAEMOVIGILANCE DATA, 2005

Adverse event	Number	% of reports
Incorrect blood component transfused	485	80
Acute transfusion reaction	68	11
Delayed transfusion reaction	28	5
Transfusion-related acute lung injury	23	4
Transfusion-transmitted infection	3	<1
Posttransfusion purpura	2	<1
<b>Total</b>	<b>609</b>	<b>100</b>

Source: Stainsby et al. (2006).

The report identified five transfusion-related deaths. One case was due to the transfusion of ABO-incompatible RBCs, another was due to anaphylaxis following transfusion of fresh frozen plasma, two were caused by transfusion-related acute lung injury (TRALI), and one was possibly from transfusion-associated circulatory overload.

In 2005, SHOT reported that 37% of incorrect blood component transfused events occurred between the hours of 20:00 and 08:00, concluding that overnight transfusions are inherently less safe. Data on transfusion errors extracted from AIMS in Australia in 2006 also indicate that overnight transfusions are less safe (South Australian Department of Health 2006). In that report, 27% (219/810) of reported incidents involving labile components occurred in overnight transfusions between the hours of 22:00 and 07:00.

After a short hiatus in 2006, SHOT reintroduced near-miss reporting in 2007 (Stainsby et al. 2006).

The French haemovigilance system captures and reports both major and minor adverse events, and by 2003 there were in excess of 68,000 reports on

the national database (Rebido et al. 2004). In 2003, there were 6,933 reports, of which 2,911 (42%) incidents had strong transfusion imputability. These included seven confirmed cases of bacterial contamination and 137 reports of incorrect blood components transfused. There were 12 cases of ABO incompatibility, 15 cases of TRALI and 12 deaths (Rebido et al. 2004). Two fatalities involved the transfusion of ABO-incompatible RBCs. Three were due to bacterially contaminated products, three to TRALI and three to volume overload, and one was caused by a febrile non-haemolytic transfusion reaction.

The report noted 1,898 (65%) acute reactions and 1,013 (35%) delayed adverse reactions. More than 50% of acute reactions were allergic and 22% were febrile non-haemolytic transfusion reactions. Almost all of the 1,013 delayed adverse reactions (98.5%) were red cell immunisation (development of new alloantibodies). There were seven viral infections (six hepatitis C and one cytomegalovirus) with strong transfusion imputability.

The death rate in France (2002–03) from transfusion-related incidents was 4.8 per 1 million blood products issued (one death per 208,333 products issued) (Rebido et al. 2004).

AuBuchon (2004) reported a global declining frequency of transmission of viral infections (HIV, hepatitis B and hepatitis C) over the past two decades compared to the three leading causes of transfusion-related mortality in the United States between 2001 and 2003 – bacterial contamination of platelets, TRALI and ABO mistransfusions (Despotis et al. 2007). The report noted that the probability of an occurrence or fatality arising due to any of the three hazards significantly exceeds the current risk of *transmission* of HIV or hepatitis C (Table 25). Indeed, Despotis and colleagues (2007) reported that these three problems alone accounted for 40% to 50% of transfusion-related mortality in the United States between 2001 and 2003. Yet transfusion safety and quality remain focused on products rather than processes.

**TABLE 25:** DECLINING FREQUENCY OF TRANSMISSION OF HIV AND HEPATITIS C OVER THE PAST TWO DECADES COMPARED TO THE OCCURRENCE OF THREE NON-VIRAL HAZARDS OF TRANSFUSION

Error/reaction	Occurrence	Fatality
HIV <sup>b</sup>	1:1.4m – 2.4m units	No data
Hepatitis C <sup>b</sup>	1:872,000 units	No data
Bacterially contaminated platelets <sup>a</sup>	1:2,000 units	1:40,000 units
Transfusion-related acute lung injury <sup>a</sup>	1:5,000 units	1:100,000 units
Mistransfusion (RBCs) <sup>a</sup>	1:12,000 units	1:600,000 units

Sources: <sup>a</sup>AuBuchon (2004). <sup>b</sup>Spieß (2004).

In light of increasing near-miss reports, in 2007 the Irish Blood Service proposed to conduct hospital audits rather than continue reporting near-miss data from enrolled hospitals. The rationale being that many years of reporting near misses had not effectively reduced the occurrence of these errors. Armed with these data, the service hopes to improve performance within the transfusion chain.

In 2005, Swissmedic reported 579 adverse events occurring in Swiss blood establishments and hospitals (Swissmedic 2005). The most commonly reported event was febrile non-haemolytic transfusion reaction at 154/579 (27%). Allergic reactions occurred in 91/579 (16%) and anaphylactic reactions formed 13/579 (2%) of reactions. There was one reported fatality, which was due to TRALI.

In the United States, transfusion-related fatalities are reported to the US Food and Drug Administration (FDA) (Myhre & McRuer 2000), and the Medical Event Reporting System for Transfusion Medicine

(MERS-TM) is used by a number of transfusion services and blood centres to collect, classify and analyse events that could potentially compromise transfusion safety (Parhan 2006). There is no requirement for blood establishments to report other transfusion-related morbidity or errors to the FDA. In 2003, bacterial contamination following transfusion was considered the second most common cause of death after clerical errors (Hillyer et al. 2003).

Linden (1999) reported that between 1976 and 1985, 100 million units of blood products were transfused in the United States. During this period there were 131 fatalities linked to ABO incompatibilities, of which 95% (124/131) involved RBCs or whole blood units. The fatality rate was 1 per 760,000 units transfused. In 49% of cases the recipient received a transfusion intended for someone else.

In a separate study that focused on New York State (Linden et al. 1992), overall error rates were estimated at 1 per 12,000 units transfused overall, with 1 per

33,000 resulting in an ABO-incompatible RBC transfusion and 1 per 600,000 resulting in a fatal haemolytic transfusion reaction.

The US Centers for Disease Control and Prevention estimates that hospital-acquired infections kill approximately 100,000 patients, afflict two million patients and cost more than US\$27 billion annually (*Washington Times* 2007). Commencing in 2008, US Medicare will not cover costs associated with eight serious preventable adverse events – including incompatible blood transfusions (*Washington Times* 2007).

The Canadian transfusion environment is serviced by two organisations, the Canadian Blood Services and HemaQuebec. Blood suppliers and plasma manufacturers are mandated to report serious adverse events and fatalities to the Public Health Agency of Canada through the Transfusion Transmitted Injuries Surveillance System (TTISS). However, there is no obligation on healthcare professionals working in hospitals to report transfusion reactions.

In its latest TTISS report (for 2002–03), the Public Health Agency reported that eight provinces containing 206 hospitals contributed haemovigilance data (Public Health Agency of Canada 2005). During this period, 296 serious adverse events were analysed. Two hundred sixty-seven related to the administration of blood components and 29 related to batch plasma products. The most commonly reported serious event was major allergic reaction/anaphylaxis (36%), followed by TRALI (13%) and circulatory overload (13% also). ABO incompatibilities formed 5% of reports of serious reactions.

RBCs were implicated in 144/267 (54%) of reports. There were 15 fatalities; however, only two were definitely attributable to transfusion (one was due to bacterial contamination and the other post-transfusion purpura). There were 137 life-threatening events, and long-term sequelae following three events. The outcome of all reported reactions is shown in Table 26.

**TABLE 26:** TRANSFUSION TRANSMITTED INJURIES SURVEILLANCE SYSTEM DATA, 2002–03

Severity of adverse event	Number	%
Fatality	15	6
Life threatening	137	51
Long-term sequelae	3	1
Minor or no sequelae	109	41
Undetermined	3	1
<b>Total</b>	<b>267</b>	<b>100</b>

Source: Public Health Agency of Canada (2005).

The New Zealand haemovigilance program commenced in 2005 as a pilot project. It is now fully established and operates through the 11 district health boards.

Data were published in the New Zealand Blood Service (NZBS) annual haemovigilance report (2005) covering eight months of reporting from 1 May 2005 to 1 December 2005. In addition to data on all transfusion-related adverse events (serious and minor), the NZBS collected comprehensive data on the number of donations, blood issuance, components transfused, wastage, product contamination, and batch and fractionated plasma products. Near misses were not part of the national dataset, but district health boards were encouraged to collect near-miss data for their own quality management.

During the eight months of reporting in 2005, 271 events involving 257 recipients were analysed (Table 27).

**TABLE 27:** NEW ZEALAND BLOOD SERVICE HAEMOVIGILANCE DATA, MAY–DECEMBER 2005

Adverse event	Number	%
Febrile non-haemolytic transfusion reaction	131	48
Allergic reaction	89	33
Other	16	6
Incorrect blood component transfused	10	4
Transfusion-related acute lung injury	10	4
Transfusion-associated circulatory overload	8	3
Delayed transfusion reaction	6	2
Transfusion-transmitted infection: bacterial	1	0
<b>Total</b>	<b>271</b>	<b>100</b>

Source: *New Zealand Blood Service (2005)*.

During the reporting period, 104,934 blood components were transfused. Seventy-eight percent of transfusions involved RBCs, 7% were platelets (apheresis and pooled), and 2% were labile plasma components.

Of the 271 events analysed in New Zealand, 246 involved a single component or product. In 25 instances, multiple products were involved.

The report noted that 184/271 (68%) of adverse events involved RBCs, 30/271 (11%) involved platelets and 29/271 (11%) involved plasma products.

There were no reported deaths resulting from ABO incompatibility during the reporting period, but three deaths were attributable to transfusion-associated circulatory overload.

Internationally, the transfusion of autologous blood is also not error free. Linden (1994, as cited in Linden 1999) reviewed 251,228 pre-operative autologous donations (of which 124,601 were transfused). There were three errors in collection and six transfusion errors involving eight units, with a calculated risk per transfused unit of 1 in 16,000. Two autologous patients received blood of another patient and one nearly received blood of another.

In a Canadian study on autologous transfusions, Goldman (1997, as cited in Linden 1999) identified one mistransfusion in 16,873 units collected at one blood centre. There were 112 other errors, nearly half of which would have resulted in the unit not being available when needed. The blood was received too late or sent to the wrong hospital. This represents an error rate of 1 per 1,298 autologous units collected.

There are no data available on the rate of errors associated with the transfusion of autologous blood in Australia.

Clearly the international trend is for safer products through more sensitive and selective testing, but it is also clear that the major risk in today's transfusion environment is avoidable human procedural error surrounding near-patient and point-of-care activities within hospitals. Wherever there is human activity, there is potential for error. The transfusion chain is particularly prone to error because it is complex and heavily laden with urgency, multi-tasking and at times fatigue. Errors can be reduced through improvements in education and training, targeted resourcing to overcome performance gaps, and focused changes to transfusion practices and procedures, particularly point-of-care procedures.

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WHO (World Health Organization) 2007, 'Blood transfusion safety: safe and appropriate use', <[www.who.int/bloodsafety/en](http://www.who.int/bloodsafety/en)>, accessed 20 September 2007.

**Further information and additional resources may be found at the following websites:**

National Blood Authority, [www.nba.gov.au](http://www.nba.gov.au)

American Association of Blood Banks, [www.aabb.org](http://www.aabb.org)

Australian Association of Pathology Practices, [www.aapp.asn.au](http://www.aapp.asn.au)

Australian Commission on Safety and Quality in Health Care, [www.safetyandquality.org](http://www.safetyandquality.org)

Australia and New Zealand Society of Blood Transfusion, [www.anzsb.org.au](http://www.anzsb.org.au)

Australian Private Hospitals Association, [www.apha.org.au](http://www.apha.org.au)

Australian Red Cross Blood Service, [www.transfusion.com.au](http://www.transfusion.com.au)

British Columbia Provincial Blood Coordinating Office, [www.pbco.ca](http://www.pbco.ca)

Clinical Excellence Commission, [www.cec.health.nsw.gov.au](http://www.cec.health.nsw.gov.au)

European Haemovigilance Network, [www.ehn-org.net](http://www.ehn-org.net)

International Society of Blood Transfusion, [www.isbt-web.org](http://www.isbt-web.org)

Medical Event Reporting System – Transfusion Medicine, [www.mers-tm.net](http://www.mers-tm.net)

National Pathology Accreditation Advisory Council, [www.health.gov.au/npaac](http://www.health.gov.au/npaac)

National Patient Safety Agency (UK), [www.npsa.nhs.uk](http://www.npsa.nhs.uk)

Network for Advancement of Transfusion Alternatives, [www.nataonline.com](http://www.nataonline.com)

Serious Hazards of Transfusion (UK), [www.shotuk.org](http://www.shotuk.org)

Society for the Advancement of Blood Management, [www.sabm.org](http://www.sabm.org)

South Australia Department of Health, BloodSafe program, [www.health.sa.gov.au/bloodsafe](http://www.health.sa.gov.au/bloodsafe)

Therapeutic Goods Administration, [www.tga.gov.au](http://www.tga.gov.au)

Victorian Government: Better Safer Transfusion, [www.health.vic.gov.au/best/news/stir\\_pilot.htm](http://www.health.vic.gov.au/best/news/stir_pilot.htm)

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