



To Whom it may Concern

AUSTRALIAN HAEMOVIGILANCE REPORT 2010

Please find enclosed the Australian Haemovigilance Report 2010. This report was produced under the guidance of the Haemovigilance Advisory Committee established by the National Blood Authority to improve transfusion safety in Australia through better monitoring, reporting and increasing awareness of serious transfusion related adverse events.

This report delivers 12 key recommendations in the areas of data quality, jurisdictional capacity to report haemovigilance data, prescribing practice, procedural errors, and national blood quality and safety initiatives.

The data included in this report are derived from state and territory incident management systems and should not be considered complete. Haemovigilance reporting in Australia is voluntary and national reporting is still in its infancy in many jurisdictions. Consequently, the data are not indicative of true national performance and therefore, should not be used for benchmarking or any comparative purposes. The NBA's aim is to increase the number of reported serious adverse events through improvements to haemovigilance systems in the states and territories. An increase in the number of reported serious adverse events will be indicative of more vigilant monitoring and reporting rather than a worsening of performance. Better reporting has been shown by the UK's Serious Hazards of Transfusion (SHOT) haemovigilance system to be associated with fewer transfusion related deaths and as such an improvement in patient safety.

Thank you for your interest in transfusion safety and I trust you find the Australian Haemovigilance Report 2010 informative.

Yours sincerely

Jennifer Roberts
Director, Blood Sector Clinical Development

28 July, 2010.

Saving & improving Australian lives through a world-class blood supply

1 What is the purpose for the Australian Haemovigilance Report 2010?

The transfusion of fresh blood products is not without risk and it can lead to complications. The 2010 Report conveys details on the nature and extent of transfusion errors and reactions that occurred in Australian hospitals from July 2008 – June 2009.

The report includes validated data from jurisdictional haemovigilance programs including BloodSafe in South Australia, the Queensland incidents in Transfusion program and the Victorian Blood Matters - Better Safer Transfusion Program and the Serious Transfusion Incident Reporting (STIR) program. STIR also supports haemovigilance in Tasmania, the ACT and Northern Territory. Limited data has been included from the NSW Blood Watch program.

2 Are Australian blood products safe?

Australian blood products are very safe by world standards. There are comprehensive national regulations and governance covering all aspects of blood donation and processing. Regulation occurs through the Therapeutic Goods Administration (TGA).

Potential blood donors are carefully screened, and blood is tested for a number of infectious agents including Human Immunodeficiency Virus (HIV), Human T-lymphotropic Virus' I & II (HTLV I & II), Hepatitis B and C, and Syphilis using the most sensitive and selective methodology available. The Australian Red Cross Blood Service (ARCBS) has a rapid recalls process to remove suspect products from circulation.

Blood products are stored and delivered to hospitals under carefully controlled conditions. Within hospitals and laboratories, blood is also stored and managed under carefully monitored conditions.

3 What standards cover blood transfusions in Australia?

Australia has a number of national, state and territory standards governing the entire transfusion chain. All blood components for transfusion in Australia are licenced by the TGA. The TGA also regulates donor selection, blood donation, testing, processing, storage and distribution of blood products in Australia.

In public and private laboratories, the National Association of Testing Authorities (NATA) accredits laboratory practices such as compatibility testing and blood handling to the standards prescribed by the National Pathology Accreditation Advisory Council (NPAAC).

The Royal College of Pathologists of Australasia (RCPA) certifies the currency of transfusion laboratory procedures through its quality assurance initiatives. The Australian Council on Health Care Standards (ACHS) accredits acute care hospitals against the Evaluation and Quality Improvement Program (EQulP) standard, which incorporates transfusion and blood-handling outcome measures. The majority of public and private hospitals use EQulP as their accreditation standard.

Clinical specialty colleges accredit medical training within teaching hospitals. In addition, individual hospitals within States and Territories have policies and procedures that govern how transfusions are handled within their facilities.

4 How does Australia conduct haemovigilance?

All states and territories in Australia have been monitoring blood safety through their state-based incident management systems for many years. These systems cover a wide range of incidents that occur in the hospital setting, not just transfusion related incidents and errors.

The National Blood Authority (NBA) has established a national haemovigilance program and Haemovigilance Advisory Committee (HAC) to support the continued development and alignment of jurisdictional haemovigilance reporting systems with the recommended national haemovigilance dataset, where this is not already achieved.

While the information that they collect about transfusion related incidents differs, all states and territories have agreed to align the information they collect about transfusion to allow very specific transfusion related information to be collected and provided for the purpose of national reporting.

5 What are the major transfusion risks identified in the report?

Hospitals in all countries encounter unintended consequences of transfusion. The majority of internationally reported mishaps are minor, but serious mishaps still occur and are generally the result of human error.

The Australian Haemovigilance Report 2010 notes that transfusion risks generally fall into two main categories:

- o Procedural errors such as patient mis-identification and blood sampling errors, and transfusing the wrong blood component, and*
- o Reactions such as acute transfusion reactions (for example, fever and chills) and bacterial infections.*

The available data within the report indicate that these errors and reactions are not significantly different from those occurring in other countries.

6 How frequently do transfusion errors occur?

In Australia, haemovigilance reporting is voluntary (with the exception of sentinel events). Consequently, we do not know the complete number of transfusion mishaps occurring annually. With this in mind, it is not possible to accurately produce information on the frequency of Australian errors and reactions.

Currently the Blood Service provides estimates of risk of transfusion-transmitted infection in Australia in its publication MediLink – A newsletter for clinical and scientific professionals, which can be accessed at www.transfusion.com.au

7 Does Australia have more or fewer transfusion errors than other countries?

A number of OECD countries have national haemovigilance programs, and some publish annual reports about the number and types of adverse events occurring in their hospitals..

There is no evidence at this stage to suggest that the rate of transfusion errors in Australia is outside the range experienced in OECD countries.

8 Given the types of errors and reactions identified in the report, should I reconsider my planned transfusion?

If you have any concerns regarding your planned transfusion, you should first discuss your transfusion with your doctor who can provide you with further information about the risks and benefits of transfusions, and alternatives to transfusion where appropriate.

9 What is the role of the Australian Haemovigilance Program?

The primary aim of the Australian National Haemovigilance Program is to improve transfusion safety and quality by collecting, analysing, and disseminating information on a common set of serious adverse events surrounding the transfusion of fresh blood and blood products. Recommendations to improve transfusion outcomes based on the data are developed.

Information obtained is used to build better and safer systems, conserve valuable resources and ultimately deliver better patient outcomes. The program has voluntary enrolment from both the public and private healthcare sectors, and has oversight by the Haemovigilance Advisory Committee so that it achieves its goals and objectives.

10 What is currently being done by the National Blood Authority to make transfusions safer?

The National Blood Authority (NBA), under the National Blood Agreement (2003) plays a key role in promoting transfusion appropriateness, safety and blood management through a system-wide approach. To assist its operations and improve the safety of transfusions in Australia, the NBA maintains close working relationships with Departments of Health in all States and Territories, the clinical community and a number of nationally focused organisations such as the Blood Service, the Australia and New Zealand Society of Blood Transfusion (ANZSBT), the Therapeutic Goods Administration (TGA), the National Health and Medical Research Council (NHMRC) and the Australian Commission on Safety and Quality in Health Care (ACSQHC). These important partnerships are geared to making transfusions safer and ultimately deliver better outcomes.

In conjunction with key stakeholders, the NBA is currently facilitating national projects designed to improve transfusion safety across Australia. Haemovigilance is part of a portfolio of NBA programs for blood sector clinical development. To ensure that patients are not unnecessarily exposed to the risks associated with transfusion the NBA has embarked on an ambitious program to revise the National Health and Medical Research Council's guidelines for fresh blood that will see the publication of six modules in the areas of peri-operative, critical bleeding, paediatric and neonatal, medical, obstetric and intensive care. To enhance uptake of such patient blood management principles, the NBA has also supported national educational initiatives and, more recently, established a National Patient Blood Management Program.

11 What is currently being done by States and Territories to make transfusions safer?

All State and Territory Departments of Health are focused on transfusion quality and safety, and delivering better outcomes to their patients. They report their sentinel

events to the Australian Institute of Health and Welfare (AIHW), and are also committed to providing resources for ongoing quality improvement initiatives within their hospitals.

All States and Territories have employed dedicated Transfusion Nurses or transfusion Safety Officers to educate healthcare professionals and manage transfusion appropriateness and any adverse events within hospitals.

Whilst States and Territories are currently at different stages in their abilities to report adverse events at a national level, their Quality Units and local transfusion committees capture and analyse adverse events, and provide feedback to hospitals with the aim of making tangible improvements in processes and procedures. Their quality systems also ensure that staff acquire the requisite skills, and that only appropriately skilled staff perform transfusions.

12 Where can I find more information on transfusion risks?

Further information can be obtained from State and Territory Department of Health and their Quality Units. (See Table 1).

Table 1: State and Territory Quality Units

State or Territory	Quality Unit	Website and Contact
New South Wales	Clinical Excellence Commission	<p>www.cec.health.nsw.gov.au</p> <p>Ms Bernie Harrison, Director, CEC Bernie.Harrison@cec.health.nsw.gov.au</p> <p>Ms Carolyn Der Vartanian, Program Leader, Blood Watch Carolyn.DerVartanian@cec.health.nsw.gov.au Ph: 02 9382 7818 Fx: 02 9382 7615</p>
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Queensland	Queensland Blood Management Program	<p>http://www.health.qld.gov.au/qhcss/qbmp/default.asp</p> <p>QIIT@health.qld.gov.au Ph: 07 3636 2075 – QLD incidents in Transfusion (QiiT)</p>
Western Australia		<p>Joan Bedford, Senior Policy Officer Blood, Office of the Chief Medical Officer Joan.Bedford@health.wa.gov.au</p>
South Australia	Blood Safe program	<p>www.health.sa.gov.au/bloodsafe</p> <p>Susan Ireland, Manager, Blood, Organ and Tissue Programs susan.ireland@health.sa.gov.au Ph: 08 8226 6114</p> <p>Rachel Allden, Principal Consultant - Blood, Organ and Tissue Programs rachel.alden@health.sa.gov.au Ph: 08 8463 3816 Fx: 08 8463 5540</p>
Tasmania		<p>www.health.vic.gov.au/best</p> <p>Dr James Daly james.daly@dhhs.tas.gov.au</p>
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Northern Territory	NT Health	<p>www.nt.gov.au then go to Health</p> <p>Julie Domanski, NT Transfusion Nurse Julie.Domanski@nt.gov.au Ph: 08 8922 6954 Fx: 08 8922 8843</p>

NATIONAL BLOOD AUTHORITY AUSTRALIA

AUSTRALIAN HAEMOVIGILANCE REPORT 2010

A Report by the National Blood Authority
Haemovigilance Advisory Committee

ABO and RhD Group

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This report does not identify or attempt to identify individual patients, clinicians or healthcare institutions, and every reasonable effort has been made to prevent their identification. Comments and questions should be referred to the National Blood Authority on (02) 6211 8300 or at nba@nba.gov.au

Disclaimer

This document is a general report only. The data, analysis and conclusions contained herein are intended to provide healthcare professionals and the public with general information only on transfusion-related adverse events in Australian hospitals. This report is a snapshot of currently available data, which have been obtained from limited resources. Data are not guaranteed to be comprehensive, complete, or (in some instances) fully validated. Accordingly, each of the parties involved in providing data and developing this report and their employees expressly disclaims, and accepts no responsibility for, any consequences arising from relying upon the information or recommendations contained in this document.

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Web address of this report: www.nba.gov.au/haemovigilance/index.html

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AUSTRALIAN HAEMOVIGILANCE REPORT 2010

A Report by the National Blood Authority
Haemovigilance Advisory Committee June 2010

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ABBREVIATIONS AND ACRONYMS

ABO	THE HUMAN RED CELL ABO BLOOD GROUP SYSTEM
ACHS	THE AUSTRALIAN COUNCIL ON HEALTHCARE STANDARDS
ACSQHC	AUSTRALIAN COMMISSION ON SAFETY AND QUALITY IN HEALTH CARE
AHMAC	AUSTRALIAN HEALTH MINISTERS' ADVISORY COUNCIL
AHTR	ACUTE HAEMOLYTIC TRANSFUSION REACTION
AIHW	AUSTRALIAN INSTITUTE OF HEALTH AND WELFARE
AIMS	ADVANCED INCIDENT MANAGEMENT SYSTEM
ANHDD	AUSTRALIAN NATIONAL HAEMOVIGILANCE DATA DICTIONARY
ANZSBT	AUSTRALIAN AND NEW ZEALAND SOCIETY OF BLOOD TRANSFUSION
ARCBS	AUSTRALIAN RED CROSS BLOOD SERVICE; BLOOD SERVICE
ABURG	APPROPRIATE BLOOD USE REFERENCE GROUP
BEST	BETTER SAFER TRANSFUSION PROGRAM, VICTORIA
CEC	CLINICAL EXCELLENCE COMMISSION, NEW SOUTH WALES
DHTR	DELAYED HAEMOLYTIC TRANSFUSION REACTION
EHN	EUROPEAN HAEMOVIGILANCE NETWORK (NOW IHN)
EquiP 4	EVALUATION AND QUALITY IMPROVEMENT PROGRAM
FDA	US FOOD AND DRUG ADMINISTRATION
FFP	FRESH FROZEN PLASMA
FNHTR	FEBRILE NON-HAEMOLYTIC TRANSFUSION REACTION
HAC	HAEMOVIGILANCE ADVISORY COMMITTEE
Hb	HAEMOGLOBIN
HIT	HEALTHCARE INCIDENT TYPE
HIV	HUMAN IMMUNODEFICIENCY VIRUS
HPWG	HAEMOVIGILANCE PROJECT WORKING GROUP
HTR	HAEMOLYTIC TRANSFUSION REACTION
IBCT	INCORRECT BLOOD COMPONENT TRANSFUSED
ICD-10-AM	INTERNATIONAL STATISTICAL CLASSIFICATION OF DISEASES AND RELATED HEALTH PROBLEMS, 10TH REVISION AUSTRALIAN MODIFICATION
IHN	INTERNATIONAL HAEMOVIGILANCE NETWORK (PREVIOUSLY EHN)
IIMS	INCIDENT INFORMATION MANAGEMENT SYSTEM
ISBT	INTERNATIONAL SOCIETY BLOOD TRANSFUSION
JBC	JURISDICTIONAL BLOOD COMMITTEE
NBA	NATIONAL BLOOD AUTHORITY

NHDD	NATIONAL HEALTH DATA DICTIONARY
NHMD	NATIONAL HOSPITAL MORBIDITY DATABASE (AIHW)
NHMRC	NATIONAL HEALTH AND MEDICAL RESEARCH COUNCIL
OECD	ORGANISATION FOR ECONOMIC CO-OPERATION AND DEVELOPMENT
PTP	POST TRANSFUSION PURPURA
PRIME	QUEENSLAND HEALTH INCIDENT REPORTING SYSTEM
QBMP	QUEENSLAND BLOOD MANAGEMENT PROGRAM
QiiT	QUEENSLAND INCIDENTS IN TRANSFUSION
RCA	ROOT CAUSE ANALYSIS
RBC	RED BLOOD CELL
SHOT	SERIOUS HAZARDS OF TRANSFUSION (UK)
STIR	SERIOUS TRANSFUSION INCIDENT REPORTING
TGA	THERAPEUTIC GOODS ADMINISTRATION
TACO	TRANSFUSION ASSOCIATED CIRCULATORY OVERLOAD
TA-GVHD	TRANSFUSION ASSOCIATED GRAFT VERSUS HOST DISEASE
TRALI	TRANSFUSION RELATED ACUTE LUNG INJURY
TTI	TRANSFUSION TRANSMITTED INFECTION
TTISS	TRANSFUSION TRANSMITTED INJURIES SURVEILLANCE SYSTEM
WBIT	WRONG BLOOD IN TUBE

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The National Blood Authority and the Haemovigilance Advisory Committee would like to formally acknowledge the major contribution made by Dr Simon Towler, as previous co-chair, to the Committee and the developmental phase of the National Haemovigilance Program.

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- Queensland Blood Management Program
- Queensland Health Patient Safety Centre and Queensland Incidents in Transfusion (QiiT) program
- South Australian Department of Health BloodSafe program
- Therapeutic Goods Administration
- Victorian Blood Matters, Better Safer Transfusion program and Blood Matters Advisory Committee

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MESSAGE FROM THE GENERAL MANAGER OF THE NATIONAL BLOOD AUTHORITY



I am delighted to be able to present you with the second Australian Haemovigilance Report. The report provides information on the types of transfusion-related adverse events that have been reported in Australia between July 2008 and June 2009 and is an invaluable resource for the clinical community and governments.

The second report represents significant advances over the Initial Australian Haemovigilance Report in 2008; more jurisdictions are able to contribute data, events to be reported are clearly defined and a methodology for assessing the capability of jurisdictions to provide the required data has been developed. To facilitate work in this area, the Jurisdictional Blood Committee (JBC) endorsed the establishment of the Australian National Haemovigilance Program which has the overarching goal of improving patient outcomes through improving transfusion safety and quality. Within this program, the Haemovigilance Advisory Committee (HAC) works to enable and promote the capture, analysis and reporting of serious transfusion-related adverse events. The HAC reviews and refines the ongoing haemovigilance data collection and management processes, contributing expert opinion to national reports that identify trends in national haemovigilance data, and making recommendations on prioritisation of actions to improve transfusion safety.

The states and territories have continued to develop their haemovigilance capacity through their clinicians, nurses and transfusion committees. We applaud the efforts to create this report. However, it is clear that improvements are required in the capacity to gather and validate complete reports of adverse events. Consistent and complete data is crucial to providing vital feedback to clinical staff so that patient outcomes are improved.

Haemovigilance is part of a portfolio of NBA programs for blood sector clinical development. To ensure that patients are not unnecessarily exposed to the risks associated with transfusion the NBA has embarked on an ambitious program to revise the National Health and Medical Research Council's guidelines for fresh blood that will see the publication of six modules in the areas of perioperative, critical bleeding, paediatric and neonatal, medical, obstetric and intensive care. To enhance uptake of such patient blood management principles, the NBA has also supported national educational initiatives and, more recently, established a National Patient Blood Management Program.

The second Australian Haemovigilance Report is a valuable resource for assisting in understanding the risks associated with transfusion. The importance of a greater knowledge of the frequency and types of these risks cannot be understated. I would like to sincerely thank all contributing parties for their commitment and hard work in a demanding and increasingly complex blood sector. I look forward to further improvements in the capacity to collect and provide these data and produce these reports.

Dr Alison Turner



**General Manager and CEO
National Blood Authority**

MESSAGE FROM THE CHAIR OF THE HAEMOVIGILANCE ADVISORY COMMITTEE



I am pleased on behalf of the Australian Haemovigilance Advisory Committee (HAC) and the National Blood Authority to present the 2010 Australian Haemovigilance Report.

I wish to formally acknowledge the essential contribution made by all the members of the Committee to the building of the national haemovigilance structure, the preparation and detailed review of the data here presented and the overall design, drafting and quality substance of this report. I would like to acknowledge in particular the staff that support the jurisdictional haemovigilance programs for the significant work involved in preparing data for the national dataset. I would also like to thank Dr Paul Hyland and Jennifer Roberts, from the NBA Blood Sector Clinical Development team for their ongoing guidance and hard work to achieve this outcome.

Australia has a blood supply meeting international benchmarks in safety and security. Over the last two decades, new blood donor screening and testing measures have been introduced to further reduce the risks associated with transfusions. More sensitive infectious disease screening tests for blood donors, including molecular testing for HIV and hepatitis C, are now used routinely on each donation. Red cell and platelet concentrates are now universally leucodepleted.

Today, considerations of blood product safety share focus with enhanced safeguards around product distribution, storage, patient identification and transfusion administration. Importantly these measures also sit beside a better awareness of the appropriateness of blood and blood product usage, and of clinical outcome data on transfused patient cohorts.

The journey in Australia to an active national haemovigilance program has been a long and challenging one. Recommendations for a comprehensive adverse events reporting system were made in the Stephen review in 2001, and reiterated in the Boyce-Boyd Report in 2005. The Australian Council on Healthcare Standards introduced a transfusion practice standard into its mandatory hospital clinical accreditation criteria in 2006. Jurisdictions have developed their own haemovigilance structures and reporting capacities. These now report de-identified haemovigilance data, standardised using the specifications developed by HAC in the Australian National Haemovigilance Data Dictionary, to the national haemovigilance database. This report presents this national data, along with recommendations.

Haemovigilance is now on the international arena. Indeed, haemovigilance is being seen in the wider context of 'biovigilance'. In 2009 the then European Haemovigilance Network was transformed to become the International Haemovigilance Network. Australia and many other non-European nations, including New Zealand and the U.S.A., are now full members. There is the opportunity for data sharing and further benchmarking and collaboration.

Internationally, haemovigilance data has demonstrated the need for improvements in transfusion procedures, including patient identification steps and consideration of product modifications. This Australian report reiterates much of that international experience and data. It identifies adverse transfusion events that relate to product and patient characteristics. Importantly, it also identifies events related to the ongoing risks of clerical and procedural errors and non-conformances, especially connected to patient identification, that contribute to the residual risk associated with transfusion in Australia. Thus, the data presented in this report justify an enhanced continual focus and improvement on procedural and patient identification steps in the transfusion chain.

Appropriate transfusion practice aims to improve patient outcomes, both short term and longitudinal. Avoidance of inappropriate transfusion should always be a key strategy in reducing our transfusion related morbidity here in Australia. To this end the NBA is sponsoring the review of the NHMRC Transfusion Guidelines. A suite of clinical scenario based (i.e. not product based) patient blood management guidelines is now being generated. These include: perioperative, critical bleeding, medical, intensive care, obstetric, paediatric and neonatal sections. These guidelines will inform transfusion medicine practice, including the avoidance of inappropriate prescription of blood and blood products. In parallel, the Australian Commission on Safety and Quality in Health Care are now developing a National Safety and Quality Healthcare Standard on Blood and Blood Product Safety.

Consideration of the inclusion of transfusion 'near-miss' events into the national haemovigilance dataset is now being considered by the Australian Haemovigilance Advisory Committee, as we go forward with the national haemovigilance program. Eventually local donor vigilance data may also be considered for incorporation, as is the trend internationally. All Australian jurisdictions continue to build and improve their own haemovigilance reporting and analysis capacities, juxtaposed with the development of national and local patient blood management programs, together with evolving clinical data linkage capacities. We commend this report and its recommendations to the health sector generally.

Dr Chris Hogan



Chair
Australian Haemovigilance Advisory Committee

EXECUTIVE SUMMARY

The Initial Australian Haemovigilance Report 2008 presented a selection of the available information on transfusion-related adverse events reported in Australia over a period of three to five years before the report. The current report improves upon the standards of the Initial Australian Haemovigilance Report 2008 in a number of significant ways.

The National Blood Authority (NBA) has established a national haemovigilance program and Haemovigilance Advisory Committee (HAC) to support the continued development and alignment of jurisdictional haemovigilance reporting systems with the recommended national haemovigilance dataset, where this is not already achieved. To enable this, with reference to international haemovigilance and Australian national data dictionaries, the HAC has produced the Australian National Haemovigilance Data Dictionary.

This report includes validated data from jurisdictional haemovigilance programs including BloodSafe in South Australia, the Queensland Incidents in Transfusion program and the Victorian Blood Matters - Better Safer Transfusion Program and the Serious Transfusion Incident Reporting (STIR) program. STIR also supports haemovigilance in Tasmania, the ACT and Northern Territory. Limited data has been included from the NSW Blood Watch program.

The amount of labile blood products issued continues to rise in Australia (see table below). Labile blood products are used for a broad range of clinical indications; however, the majority of red cell transfusion procedures occur in patients aged over 50 years and are used for haematological and oncological conditions and perioperatively. Australia has made increasing progress towards improving the efficiency of blood utilisation and clinical transfusion practice, in line with many developed countries.

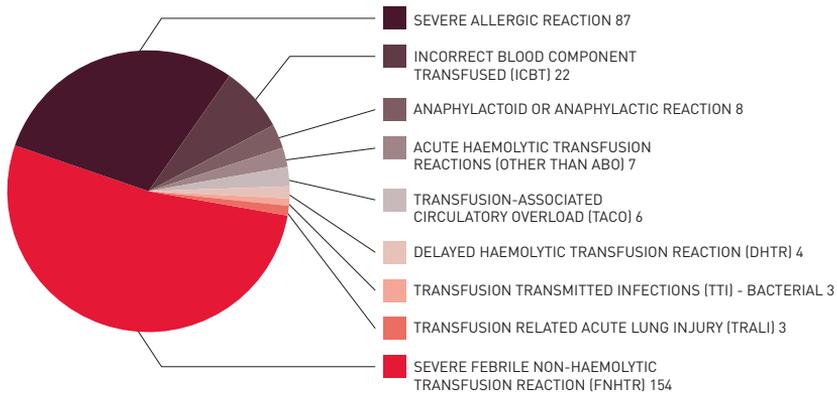
LABILE BLOOD COMPONENT	2003/04	2004/05	2005/06	2006/07	2007/08	2008/09
RBC units	736,808	744,250	757,034	777,972	768,919	793,480
Platelets (adult equivalent doses)	97,398	102,742	109,132	113,579	116,665	118,248
Fresh frozen plasma units	138,315	138,878	143,112	145,874	161,877	174,309
Cryoprecipitate units	33,053	38,056	42,847	49,333	51,957	56,420
Cryo-depleted plasma units	12,114	14,039	18,874	12,321	14,487	14,937

Blood-related clinical practice and improvement programs in a number of jurisdictions have continued to make improvements in areas such as appropriate use of blood, clinical governance, haemovigilance and ongoing education of health care professionals and ancillary staff. All jurisdictions have appointed Transfusion Nurses whose roles include the promotion of transfusion appropriateness.

The following chart indicates the relative proportions of serious adverse events reported (n=294) to the Australian National Haemovigilance Program for the 2008/09 period. The relative incidence of the adverse events appears comparable to the data of many other developed countries, with a majority of febrile reactions (n=154) and allergic reactions (n=87), with some serious anaphylactic / anaphylactoid reactions (n=8). Haemolytic transfusion reactions (Acute HTR n=7; Delayed HTR n=4), transfusion associated circulatory overload (TACO n=6), transfusion related acute lung injury (TRALI n=3) and transfusion transmitted infections (TTI n=3) all represent very low to minimal risks to patients. However, there were 22 incorrect blood component transfused (IBCT) events reported.

Incorrect blood component transfused (IBCT) occurs when a patient receives either a blood product intended for another patient or a blood product where special requirements are not ordered or met (e.g. CMV-negative or irradiated product).

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



Haemovigilance data and clinical studies cite three major areas of error that jeopardise safe transfusion: (i) accurate patient identification and proper labelling of pre-transfusion specimens; (ii) appropriate decision making regarding the clinical use of blood components; and (iii) accurate bedside verification that the correct blood is to be given to the intended recipient. The addition of near miss data to the national dataset could provide insight into the ways in which these errors occur.

This report delivers 12 key recommendations in the areas of data quality, jurisdictional capacity to report haemovigilance data, prescribing practice, procedural errors, and national blood quality and safety initiatives.

Key Recommendations – Data

1. Jurisdictions to continue to develop their haemovigilance data capture and validation systems to enhance the quality and completeness of data reported to the national dataset.
2. Programs should be implemented at the national, state and local hospital levels to improve recognition and reporting of under reported serious adverse events such as TACO and TRALI.
3. Blood sector stakeholders should consider initiatives to develop the systems and capability to enable the total number of products and patients transfused to be known.
4. Haemovigilance Advisory Committee to discuss the definition and inclusion of near misses into the dataset.

Key Recommendations – Capacity

5. Jurisdictions to investigate strategies to improve the timeliness and completeness of reporting.
6. All transfusing hospitals should have transfusion governance arrangements in place.

Key Recommendations – Prescribing

7. National Blood Authority, National Health and Medical Research Council and relevant professional bodies, colleges and societies should continue to develop, publish and promulgate Patient Blood Management Guidelines.
8. National Blood Authority and relevant professional colleges and societies should promote research on the specific elements that should be included on a blood order/prescription form to encourage alignment of prescribing with clinical guidelines.

Key Recommendations – Procedural Errors

9. Transfusing facilities should reduce the potential for procedural errors through training, stringent application of standards, proficiency testing and accreditation.
10. Jurisdictions and the National Blood Authority to encourage research into possible application of technological adjuncts such as portable barcode readers and/or radio frequency identification scanners to reduce the scope for error.

Key Recommendations – National Blood Quality and Safety Initiatives

11. Accrediting authorities should include haemovigilance in accreditation requirements.
12. National Blood Authority, Jurisdictional Blood Committee and Haemovigilance Advisory Committee to continue to engage with Australian Commission on Safety and Quality in Health Care in the judicious development of indicators and standards relevant to the blood sector.



PART ONE. INTRODUCTION

- 1.1 HAEMOVIGILANCE
- 1.2 HAEMOVIGILANCE IN AUSTRALIA
- 1.3 STATE AND TERRITORY HAEMOVIGILANCE
- 1.4 HAEMOVIGILANCE ADVISORY COMMITTEE
- 1.5 PRIVACY AND SECURITY OF DATA

1 INTRODUCTION

1.1 Haemovigilance

The transfusion of blood and blood components is a core component for healthcare service delivery to patients. However, it is also understood that the transfusion of blood products is not without risk and it can lead to complications. The manufacture of high quality labile blood products by the Australian Red Cross Blood Service (Blood Service) has largely mitigated the product related risks of transfusion. However, in common with other developed countries, the process related risks of transfusion still remain.

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

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

Surveillance of adverse transfusion events is the cornerstone of the majority of haemovigilance systems. However, there are many ways in which haemovigilance is defined. A founding definition of haemovigilance is set out in Directive 2002/98/EC of the European Parliament¹, setting standards of quality and safety for the collection, testing, processing, storage and distribution of human blood and blood components:

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

The European Haemovigilance Network (now the International Haemovigilance Network²) definition is the one most widely used and it states:

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

Haemovigilance has become a crucial part of the safety concept in blood transfusion, and increasing attention is being paid to haemovigilance in many countries.

The World Health Organization (WHO) Global Database on Blood Safety Report 2004-2005⁴, indicates that a national haemovigilance system was present in 42 (40%) of the 105 reporting countries, with 24 countries (23%) being in the process of development of such a system.

1 European Union Directive 2002/98/EC setting standards of quality and safety for the collection, testing, processing, storage and distribution of human blood and blood components and amending Directive 2001/83/EC. European Union, 2003. <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2003:033:0030:0040:EN:PDF>

2 <http://www.ihn-org.net>

3 Faber JC. Worldwide overview of existing haemovigilance systems. *Transfusion and Apheresis Science* 2004; 31: 99-110.

4 World Health Organization: Global Database on Blood Safety Report 2004-2005. http://www.who.int/bloodsafety/global_database/en/

1.2 Haemovigilance in Australia

Haemovigilance is a vital and integral part of modern transfusion medicine. In Australia, haemovigilance reporting is voluntary (with the exception of sentinel events, see Appendix II: Definitions in haemovigilance) but is seen as part of the professional duty of care for patient safety. Haemovigilance provides a very important source for identifying emerging trends in hazards related to blood transfusion. The quality of blood and blood products in Australia reduces the risks associated with transfusion that are captured in many other haemovigilance systems around the world. The core hazards of transfusion, as reported in the Initial Australian Haemovigilance Report 2008⁵ (within the limits of the then available data), can be broadly divided into procedural errors and clinical reactions.

In common with other OECD countries, such as the United Kingdom, New Zealand, Sweden and Canada, the risks to the safety of transfused patients in Australia were predominantly in the hospital environment, arising from procedural errors. The majority of the reported transfusion errors and adverse events resulted from preventable human error.

The 2008 report noted that of more than 600 transfusion related incidents reported in various jurisdictions in Australia, approximately 65% involved procedural errors. These included patient misidentification, specimen labelling errors, wrong blood in tube, prescription and dispensing errors, incorrect blood component transfused, and ABO incompatibilities. These results were broadly compatible with those of other OECD countries. For example, the UK SHOT Annual Report 2008⁶ (UK) indicates that procedural errors (incorrect blood component transfused, inappropriate and unnecessary transfusion, handling and storage errors) represented 59% of cumulative numbers of cases reviewed 1996-2008, n=5374.

The 2008 report also indicated a smaller, yet still concerning number of reports of clinical 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.

The International Society for Blood Transfusion (ISBT) has developed standard definitions for non-infectious adverse transfusion reactions in order to help national haemovigilance programs to collect comparable international data⁷.

The objectives of national haemovigilance systems are to provide an evidence base for improvement of transfusion practice, to know what the real risks and hazards of transfusion are in a given community/country, to disseminate these findings and to take appropriate actions, including the instigation of appropriate education processes to prevent reoccurrence⁸. In the same way haemovigilance data provide a basis for the consideration of product, system and procedural changes that further advance transfusion safety and appropriateness.

5 Initial Australian Haemovigilance Report 2008. National Blood Authority. Commonwealth of Australia 2008. <http://www.nba.gov.au/haemovigilance/index.html>

6 Serious Hazards of Transfusion (SHOT) Annual Report 2008. SHOT, National Blood Service, National Health Service, UK. www.shotuk.org

7 Working Party on Haemovigilance. Proposed standard definitions for surveillance of non infectious adverse transfusion reactions December 2006. ISBT.

8 Faber JC. Worldwide overview of existing haemovigilance systems. *Transfusion and Apheresis Science* 2004; 31: 99-110.

The NBA is realising these objectives through the following initiatives:

- establishing the national haemovigilance program
- establishing the Australian Haemovigilance Advisory Committee
- establishing a national haemovigilance database and Australian National Haemovigilance Data Dictionary (ANHDD)
- publishing Australian haemovigilance reports
- participating in the International Haemovigilance Network
- promoting and reporting Australian haemovigilance at local, national and international forums
- assisting Australian state and territory haemovigilance systems development
- integrating the activities and output from the national haemovigilance program with relevant linked NBA activities including the development of patient blood management clinical practice guidelines, national educational initiatives, and developing the national patient blood management program.

Haemovigilance is also supported at a national level by bodies involved in education and practice improvement, production of guidelines, product and service standards and accreditation:

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

1.3 State and territory haemovigilance

Transfusion related adverse events are investigated and reported according to local arrangements in each jurisdiction. There are a range of staff for gathering and validating haemovigilance data, including Transfusion Nurses and other clinical staff, haematologists, hospital transfusion committees, hospital quality and safety units/managers and pathology quality and safety units/managers.

Serious procedural and systems errors and incidents are thoroughly investigated at the local level using detailed analytical techniques such as root cause analysis (RCA) to ensure that clinicians and hospital directors fully understand the sequence of events surrounding these events. These procedures already form part of ordinary hospital quality management structures, but are also applicable to transfusion practice and adverse events. Transfusion adverse events are validated at the local level, to properly determine that they are transfusion related or not and then imputability scores are allocated. Standards for validation are developed by local institutions in conjunction with Departments of Health. Validated reports can be provided to state and territory haemovigilance systems such as the BloodSafe program⁹ (South Australia), Serious Transfusion Incident Reporting (STIR) program¹⁰ (Victoria, and also Tasmania, Australian Capital Territory, Northern Territory), the Blood Watch program¹¹ (New South Wales) and the Queensland Incidents in Transfusion (QiiT) program¹². At the time of this report Western Australia does not have a fully developed haemovigilance structure.

Reports of serious adverse events may go through a secondary validation process within these haemovigilance programs and Department of Health Quality Units to ensure data accuracy and completeness. State and territory haemovigilance representatives, on behalf of Departments of Health, will aggregate and de-identify data and send periodic reports to the NBA. Agreed additional de-identified data about the patient, facility, event and implicated blood product will accompany each report, as will an imputability (causality) score, assigned by the reporting jurisdiction.

9 <http://www.health.sa.gov.au/bloodsafe/>

10 <http://www.health.vic.gov.au/best/tools/stir.htm>

11 <http://www.cec.health.nsw.gov.au/programs/blood-watch.html>

12 <http://www.health.qld.gov.au/qhcss/qbmp/qiit.asp>

1.4 Haemovigilance Advisory Committee

The NBA Haemovigilance Advisory Committee (HAC) is an advisory committee, drawn from blood sector stakeholders with significant jurisdiction-based experience and responsibilities and from key Commonwealth agencies. The HAC membership includes haematologists, transfusion medicine specialists and a broad range of other relevant expertise. The HAC is established as an enduring body to enable and promote the capture, analysis and reporting of serious transfusion-related adverse events occurring in Australian public and private hospital systems. The program of work for the HAC draws on and has a number of elements in common with international models such as the International Haemovigilance Network, UK Serious Hazards of Transfusion (SHOT), New Zealand National Haemovigilance Programme¹³ and the Canadian Transfusion Transmitted Injuries Surveillance System¹⁴ (TTISS).

Participation in national haemovigilance and activities relevant to the work of the HAC is voluntary. Serious adverse event information, plus some agreed additional descriptive data, is captured and validated by local institutions and reported to state and territory Departments of Health who provide aggregated, coded and de-identified information via periodic reports to the NBA. The NBA collates the national data for analysis and subsequent consideration by the HAC for national reporting.

The work of the HAC focuses on reviewing and refining the ongoing haemovigilance data collection and management processes, contributing expert opinion to national reports that identify trends in national haemovigilance data, and making recommendations on prioritisation of actions to improve transfusion safety. The program of work has the overarching goal of improving patient outcomes through improving transfusion safety and quality.

13 <http://www.nzblood.co.nz/?t=122>

14 <http://www.phac-aspc.gc.ca/hcai-iamss/tti-it/index-eng.php>

1.5 Privacy and security of data

It is the intention of the NBA that Australian haemovigilance reports will contain no identifiable or re-identifiable data; that no patient, clinician, staff member or healthcare facility is identifiable from materials contained within the report.

The HAC and NBA are bound by Commonwealth privacy legislation. Australian government agencies must comply with the 11 Information Privacy Principles set out at section 14 of the Privacy Act (1988). The Privacy Act (1988)¹⁵ applies to the collection, storage, use and disclosure of personal information by government agencies, as well as providing individuals with certain rights to access their personal information and correct errors.

The data strategy defined by the HAC and endorsed by the Jurisdictional Blood Committee (JBC; a subcommittee of the Clinical, Technical and Ethical Principal Committee, CTEPC, and Australian Health Ministers' Advisory Council, AHMAC) precludes personal information (as defined in the Privacy Act 1988) which can reasonably be connected to any individual patient or clinician. The defined data strategy aims to protect individuals in this way.

Some transfusion incident reports may relate to rare or very infrequent events, or very serious events or mortality, which may bring about an increased risk of patient, clinician or facility identification, and the possible associated public increased scrutiny of circumstances around such reported events may also increase the likelihood of possible identification. The HAC will assess such cases to establish the risk of re-identification. Where there is a risk of re-identification, the HAC will deliberate on the risk of re-identification versus the benefits of publication (public interest). The intention is that reports will contain no identifiable or re-identifiable data, and the HAC may omit information from a national haemovigilance report to protect an individual's, clinician's or a facility's identity, but will make every endeavour to include important information to inform improvements to transfusion practice and safety, in keeping with the underlying goal and purpose of haemovigilance.

15 <http://www.privacy.gov.au/law/act>



A microscopic view of red blood cells, showing their characteristic biconcave disc shape. The cells are densely packed and appear in various orientations, some showing their concave surface. The background is a light, slightly hazy blue, making the red cells stand out.

PART TWO.
INITIAL AUSTRALIAN
HAEMOVIGILANCE
REPORT 2008

2 INITIAL AUSTRALIAN HAEMOVIGILANCE REPORT 2008

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

Data sources at that time included state and territory healthcare reporting systems, such as AIMS (Advanced Incident Management System used in the public health care sector of South Australia and Western Australia), IIMS (Incident Information Management System used by all eight NSW AHS), STIR (Serious Transfusion Incident Reporting Program 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 (Acclaim Safety Systems Ltd.), which was the healthcare reporting facility for Queensland Health. The 2008 report also made use of data from the Australian Institute of Health and Welfare (AIHW) National Hospital Morbidity Database (NHMD).

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

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

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

The Initial Australian Haemovigilance Report 2008 made four broad recommendations:

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

Table 1 summarises the progress made against the recommendations of the 2008 report. The first three recommendations have been pursued through the establishment of an ongoing National Haemovigilance Program and the HAC to provide governance to haemovigilance at a national level in Australia. The work of the HAC focuses on reviewing and refining the ongoing haemovigilance data collection and management processes, contributing expert opinion to national reports that identify trends in national haemovigilance data, and making recommendations on prioritisation of actions to improve transfusion safety. The NBA and HAC have produced the Australian National Haemovigilance Data Dictionary (ANHDD). The ANHDD standardises the data elements and their format for the Australian National Haemovigilance Dataset. The ANHDD is in its third iteration and is under continuous review.

In order to pursue the second and third recommendations a process to review State and Territory capability to provide data on transfusion-related serious adverse events was initiated and all but one of the jurisdictions have completed this process. As an aid to procedural training and process improvements the BloodSafe Transfusion e-learning program was approved for funding by the JBC as a suitable vehicle to deliver broad based education on appropriate and safe blood transfusion practices to a wide range of ancillary and professional health provider audiences over a three year period beginning December 2009. To ensure that patients are not unnecessarily exposed to the risks associated with transfusion the NBA has also embarked on a program to revise the National Health and Medical Research Council (NHMRC) guidelines for fresh blood that will see the publication of six modules in the areas of perioperative, critical bleeding, paediatric and neonatal, medical, obstetric and intensive care.

The fourth recommendation has been addressed through the development of a National Patient Blood Management Program. A National Steering Committee has been established and has begun identifying key priorities and development of national performance measures and outcomes.

TABLE 1 – Progress against Recommendations of Initial Australian Haemovigilance Report 2008

	RECOMMENDATION	WHO WAS RESPONSIBLE	STRATEGY	OUTCOME
1	Development of an enduring national haemovigilance program	NBA	HAC established under the National Blood Authority Act to guide and focus the program	<p>National consistency of reporting; refinement of haemovigilance data management processes</p> <p>Publication of national reports and recommendations to improve transfusion safety</p> <p>Coordinated and cooperative engagement with the health, education and quality and safety sectors to share learnings widely, effectively and efficiently haemovigilance data management processes</p>
2a	States and Territories continue to align their reporting systems with the agreed dataset to create a comprehensive national minimum dataset	NBA HAC	HAC established under the National Blood Authority Act to guide and focus the program	Standardised national dataset of serious transfusion-related adverse events; ANHDD
2b	All information provided by states and territories for national reporting be validated and de-identified	State and Territory Departments of Health	Mechanisms established to ensure information is securely held and managed according to relevant privacy principles, policies and legal requirements	Six States and Territories can currently report validated de-identified data to the national haemovigilance program

	RECOMMENDATION	WHO WAS RESPONSIBLE	STRATEGY	OUTCOME
3a	HAC work with clinical specialty colleges and the Blood Service to enhance awareness and understanding of the aetiology, diagnosis and treatment of TRALI	NBA HAC State and Territory Departments of Health Relevant professional Colleges and Societies	BloodSafe Transfusion e-learning program Revision of NHMRC Clinical Practice Guidelines on the Use of Blood Components Educational initiatives from State and Territory safety and quality programs	TRALI has a higher international profile due to increased scrutiny in the literature TRALI still has a low reporting frequency and efforts to enhance awareness in Australia will be maintained
3b	HAC should identify and work with holders of clinical, quality and safety national datasets to further improve understanding of transfusion-related adverse events in Australia	NBA HAC Relevant organisations	HAC members have identified potential sources of relevant data, and the committee is working towards collaboration	HAC has forged links with the RCPA Quality Assurance Program Key Incident Monitoring & Management Systems (KIMMS) which holds data from pathology practices on key incident indicators
3c	States and Territories actively encourage minimisation of overnight transfusions in haemodynamically stable patients	State and Territory Departments of Health	BloodSafe Transfusion e-learning program Revision of NHMRC Clinical Practice Guidelines on the Use of Blood Components Educational initiatives from State and Territory safety and quality programs	Education on transfusion practice is decreasing the practice In the 2008/09 data n=165 events reported time of transfusion, of which n=43 (26%) were overnight transfusions (between 7pm and 7am)

	RECOMMENDATION	WHO WAS RESPONSIBLE	STRATEGY	OUTCOME
3d	HAC work collaboratively with quality and safety units, research bodies and other relevant organisations to explore possible application of technological solutions	NBA HAC State and Territory Departments of Health	Data from trials of barcode readers and radio frequency identification technologies are analysed	This recommendation is repeated in the current report
4	Governments work collaboratively with clinical colleges, health providers and the Blood Service to scope, assess and promote patient blood management strategies	NBA HAC State and Territory Departments of Health	The development of a National PBM Program was endorsed by JBC in February 2009	A National Steering Committee has been established and has begun identifying key priorities and development of national performance measures and outcomes



PART THREE. AUSTRALIA'S CAPACITY TO REPORT HAEMOVIGILANCE DATA

- 3.1 NEW SOUTH WALES
- 3.2 VICTORIA
- 3.3 QUEENSLAND
- 3.4 WESTERN AUSTRALIA
- 3.5 SOUTH AUSTRALIA
- 3.6 TASMANIA
- 3.7 AUSTRALIAN CAPITAL TERRITORY
- 3.8 NORTHERN TERRITORY

3 AUSTRALIA'S CAPACITY TO REPORT HAEMOVIGILANCE DATA

3.1 New South Wales

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

The Blood Watch program is supported by all NSW area health services (AHS) and coordinated centrally by the CEC. The program is in turn supported by the NSW Health/CEC Blood Clinical and Scientific Advisory Committee. The Blood Watch improvement teams ensure that there is appropriate local review of and response to any serious transfusion related incidents. All NSW public hospitals use a centralised incident reporting system, the Incident Information Management System (IIMS; based on Adverse Incidents Monitoring System (AIMS), iSOFT Group Ltd) as their only incident reporting tool. IIMS is used to collect data and allows for the provision of reports on jurisdiction level haemovigilance incidents as one part of its broader incident information management function. IIMS was implemented in all NSW public health facilities in May 2005. The system is designed to allow healthcare professionals (of all professions and support levels) to report incidents, including near misses and risks to patient and staff safety. Reporting of incidents and near misses is mandated in the Incident Management Policy Directive PD2007-061¹⁶. There is a specific category for incidents involving Blood and Blood products which allows the notifier to select what type of blood product was involved and the nature of the problem. The remaining fields are designed to capture a wide range of fairly general incident reporting information, and include a free text description of the risk/incident. Additional analysis of IIMS reported incidents with a Blood/Blood product Principal Incident Type (PIT) is performed by experts at the CEC.

Blood/Blood product category incidents are included in routine IIMS reports of patterns and trends in reported incidents. In order to derive additional information regarding adverse transfusion events, the CEC performs a targeted analysis of the free text description of adverse events provided within the Blood/Blood Product category of incident reports within IIMS. The key lessons derived from this analysis are presented to the NSW Health Blood Clinical and Scientific Advisory Committee on an annual basis.

The reliability of data on reported incidents in the Blood/Blood product category is dependent on the staff member recognising that a significant adverse event has occurred and initiating the incident report. Most fields relating to the Blood/Blood product IIMS notification form are not mandatory for completion. In some AHS all Blood/Blood Product PIT are flagged to the transfusion nurse/project officer for review. In many cases the information necessary to accurately classify and analyse these incidents is absent from initial IIMS reports, and is only subsequently obtained by seeking required data from hospital and laboratory staff, records and databases. Beyond the review of the incident by the incident manager assigned within IIMS for this category of event, there is currently no jurisdictional review of incident data to validate recorded data. However it is intended to review the process for assigning scores within the AHS in the near future. Other issues that the CEC has highlighted include the need for education in relation to the recognition of transfusion-related adverse events, a problem that is common to the majority of jurisdictions, and the variability in quality of reports entered into IIMS.

16 http://www.health.nsw.gov.au/policies/pd/2007/pdf/PD2007_061.pdf

The level of validation of haemovigilance data at most AHS suggests that the Blood/Blood product incident data in IIMS, at present, is likely to have a somewhat limited reliability in terms of meeting the data reporting requirements of a national haemovigilance reporting system.

The reliability of data across the jurisdiction would be greatly improved by:

- all Area Health Services routinely reviewing the Blood/Blood product incidents in IIMS through an appropriately trained AHS incident manager resource (a Transfusion Nurse or Transfusion Safety Officer)
- collection of additional information on all serious transfusion events, to support meaningful haemovigilance data reporting, and
- addition of an Area Health Service review of data on serious transfusion events by an appropriately constituted subgroup of the Blood Clinical and Scientific Advisory Committee. This could include the allocation of an agreed imputability rating for adverse transfusion events.

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

3.2 Victoria

The Serious Transfusion Incident Reporting (STIR) system is part of the 'Blood Matters – Better Safer Transfusion' program¹⁷. Blood Matters is a collaboration between the Department of Health and the Blood Service and its working groups operate under the auspices of a multidisciplinary Advisory Committee.

STIR collects haemovigilance data on events from participating public and private hospitals. Victorian hospitals participated in a pilot in 2005/06, which was then extended into routine operation in Victorian hospitals and now includes participation from Tasmania, ACT and NT. Victorian hospitals each have a general incident reporting system, such as RiskMan (RiskMan International Pty Ltd), which typically include blood-related incidents.

Hospitals submit an initial notification to the STIR office, which then provides a detailed follow up form tailored to the likely type of event. Categories of events reportable to STIR are:

- incorrect blood component transfused (IBCT)
- acute transfusion reaction (including anaphylaxis)
- delayed transfusion reaction
- transfusion associated graft versus host disease
- transfusion-related acute lung injury (TRALI)
- transfusion associated circulatory overload (TACO)
- post-transfusion purpura
- post-transfusion viral infection
- bacterial/other infection
- wrong blood in tube (WBIT)
- other near miss events.

17 http://www.health.nsw.gov.au/policies/pd/2007/pdf/PD2007_061.pdf

The electronic system used to manage incident reporting data as part of STIR has been developed within the Blood Matters program. Initial incident reporting occurs through hospital submission of a web form which, after verification, can be automatically imported into the STIR database. Second level reporting by hospitals collects additional relevant detailed information specific to the event type. This level of reporting is submitted on paper, and is currently manually entered by personnel who also carry out the data analysis functions. No information identifying the reporting institution or patient is maintained in the database. The Department of Health is introducing a state wide incident reporting system for all publicly funded health services in Victoria. Under such a system, blood incident reporting would be aligned with the STIR criteria, and so remove the need for separate first level reporting to STIR. Work is underway to automate the provision of data from the second level forms, to reduce the burden on hospital and program staff.

Reporting to STIR is voluntary in Victoria. To May 2010, the majority of the more than 640 events reported to STIR have come from 54 Victorian institutions (38 public and 16 private hospitals). It is estimated for Victoria this represents approximately 68% of the total blood transfusion activity, based on information from the Victorian Admitted Episode Dataset. Of the total events reported, approximately 38% of events to date have been procedural, such as incorrect blood component transfused (including transfusion of a unit intended for another patient, or which did not meet a patient's individual requirements, such as failure to provide irradiated components), 'wrong blood in tube' events and other 'near miss' events.

Hospitals are expected to review and validate data prior to submission to STIR. In most institutions this occurs through review by the hospital transfusion committee. In addition to hospital level validation, the STIR program validates incident data. This includes review and re-assessment of imputability rating by an expert panel comprised of medical and nursing clinicians and laboratory scientists. If the STIR expert panel rating differs from the hospital's assessment, both are recorded but the STIR rating is treated as the primary record. A substantial number of events are reclassified for type or imputability after review by the expert panel, and this review is considered a key strength of the STIR program. ABO incompatible blood transfusions are also reportable to the Victorian sentinel event program, and RCA for these events are reviewed by the STIR expert group, with comments and recommendations provided back to reporting hospitals.

Aggregate information from STIR is presented to the Blood Matters Advisory Committee and used to develop policies, recommendations and educational resources for Victorian hospitals. The first STIR report for 2006/07 is available at the BeST website and the second report for 2008/09 is due to be available soon. Experience from STIR was presented at the 12th International Haemovigilance Seminar in Dubrovnik in February 2010.

Working within established clinical governance structures such as transfusion committees, availability of Transfusion Nurses and rural transfusion trainers in an increasing number of Victorian hospitals has been recognised as an important element in supporting developments in transfusion practice improvement, including adverse event reporting, investigation and participation in haemovigilance activities at an institutional, state and national level.

3.3 Queensland

Queensland Health established the Queensland Blood Management Program (QBMP) to meet the Queensland Governments requirements under the National Blood Agreement, which include the quality and safety of transfusion practice in Queensland's hospitals. In 2006 QBMP commenced work on the development of a jurisdictional haemovigilance system to incorporate reporting from public and private hospitals, and public and private pathology providers. Implementation of the haemovigilance system, Queensland Incidents in Transfusion (QiiT), commenced in 2008/09 and there are now 107 hospitals participating (75 public and 32 private).

The development of QiiT represents one aspect of the ongoing work related to the quality and safety of transfusion practice. QiiT will form an integral part of the transfusion governance initiatives underway that include state wide audits, staff training and credentialing, appropriate use and promoting local clinical governance of transfusion practice. The analysis of the data from QiiT will be used to monitor and augment all these governance initiatives, and provide recommendations to all levels of the health service to drive practice improvement.

The Queensland Incidents in Transfusion (QiiT) Haemovigilance System is a stand alone system, which is built upon local incident reporting systems within both private and public health care facilities. The events reported in the local incident reporting systems are either fed automatically by electronic notification (public facilities) or by completion and faxing of an adverse event form (private facilities) to the QBMP team. This initial notification is entered into the QiiT database, which generates an electronic receipt of notification that is returned to the facility's Haemovigilance Coordinator. Local analysis of events, including RCAs, is undertaken as part of the incident reporting cycle. Further data on the event is collected on a category specific follow up form, the data from which is imported into the QiiT database prior to further analysis of the event. The validation and review of the completed events is performed by expert medical, laboratory, nursing and patient safety officers, who are members of the QBMP team and the QiiT Working Group. The Working Group formulates recommendations and the annual haemovigilance report, which are then submitted to the Haemovigilance Committee, a sub-committee of the Queensland Blood Board. The Haemovigilance Committee oversees the functions and governance of the QiiT haemovigilance system.

The most important aspect of the QiiT system is communication of the findings back to staff in health care facilities. Regular communication is maintained through the Haemovigilance Coordinators at participating hospitals, e-forums, quarterly newsletters and the annual report. In addition the performance of the system is monitored and feedback is provided to Hospital Executives biannually and key performance indicators are reported regularly to the Haemovigilance Committee and Queensland Blood Board.

3.4 Western Australia

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

Given the concurrent development of new ACHS accreditation standards to include transfusion practice, informed transfusion consent and a commitment to improving the appropriateness of transfusion practice the WA PBM program is an effective strategy to address WA's multiple responsibilities with regards to blood transfusion. The WA PBM program comprises:

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

The WA PBM program is continuing to develop with the PBM health network now being established. WA has finalised its incident monitoring IT system tender and will institute AIMS 4. This will allow comparisons between WA and other jurisdictions also using AIMS 4 (SA public hospitals use AIMS; NSW IIMS is based on the AIMS reporting system). The Chief Medical Officer, Dr Simon Towler, will issue an Operational Circular to all area health providers advising of the compulsory reporting requirements when the system is on line. The case review and imputability elements of haemovigilance will be built into the individual AHS PBM programs. WA expects to provide detailed haemovigilance data in 2011.

The larger metropolitan and regional public and private hospitals have established transfusion committees with meeting schedules varying from two monthly to half yearly. The Transfusion Nurses/Coordinators in the public teaching hospitals monitor activities, and investigate transfusion-related incidents in their institutions. In addition they undertake some general auditing and staff education. Reports covering incidents, management of severe haemorrhage, audit findings, and policy reviews are provided to the Transfusion Committees by the Coordinators or Laboratory Scientists.

3.5 South Australia

BloodSafe is an ongoing collaboration between the South Australian Department of Health, the Blood Service and South Australian public and private hospitals and their transfusion service providers. The BloodSafe mission is to coordinate a safety and quality framework for all steps of blood transfusion practice to improve patient outcomes and ensure sufficiency of the blood supply.

Seven Transfusion Nurses cover the major public metropolitan hospitals, country regions and private hospitals. They contribute to the reporting, investigation and follow-up of adverse and near miss events through existing hospital systems such as transfusion reaction reports and Advanced Incident Management System (AIMS, iSOFT Group Ltd); clinical auditing programs; education, including the BloodSafe e-learning package¹⁸ and educational materials; and guidelines, policies and best practice protocols aimed at embedding improved practices.

The capture and analysis of haemovigilance data in SA is currently undertaken on an individual hospital / health service basis and in the public sector is reported through AIMS. The private sector utilise varying incident management systems which are reviewed internally via Safety and Quality and/or Transfusion Committees. There is no combined registry of public and private transfusion related incidents. The Blood Service encourages adverse reaction reporting but primarily receives notification of suspected major reactions such as TRALI and suspected bacterial contamination. The Department of Health mandates reporting of sentinel events related to ABO incompatibility causing major haemolysis by all health services (public and private).

The current version of the AIMS software program was acquired by the SA Department of Health in 2003. The system allows incidents to be reported electronically and data to be available centrally for analysis. The function of the software is to:

- provide easy and accessible incident reporting to all health system employees and contractors
- store information relating to voluntarily reported adverse incidents and near misses for management action, analysis and risk reduction activity, and
- provide a management framework for follow up of incidents by appropriate personnel to enable management of risks associated with clinical care.

The AIMS system allows for reporting of incidents by any health care professional using the 'notifier' component of the database. This component of the database captures the descriptive account of the incident, the nature of event, incident type and any management/third party comments. The 'classifier' component of the database contains more detailed information on the incident based on a hierarchical classification structure that captures contributing factors, prevention factors, minimising factors, actions taken and outcomes.

18 <https://www.bloodsafelearning.org.au>

The Haemovigilance system within AIMS was developed with the Australian Patient Safety Foundation (APSF) after a review into the reporting of incidents related to blood and blood components in 2004. The report identified that there were no stand alone categories for blood & blood component reporting, event description, causation and data analysis possibilities. The APSF and BloodSafe Program developed and piloted a Blood & Blood Component reporting element in 2004. An assessment of the AIMS system in the Initial Australian Haemovigilance Report 2008 identified gaps in AIMS reported data from SA and the level at which data could be drilled down to. The BloodSafe program has been instrumental in supporting haemovigilance reporting and review as well as designing and implementing interventions aimed at harm minimisation.

It must be acknowledged that the current haemovigilance system relies on voluntary reporting and classification of incidents by either the AIMS call centre, AIMS data manager or where available BloodSafe Transfusion Nurses. Due to limited operating hours (06.30-22.30) of the AIMS call centre there is the potential to miss incidents due to closure. Anecdotal reports of staff not reporting incidents in both the clinical and laboratory areas highlight the need for 24/7 incident reporting access. The experience of the individual classifying the incident can make the difference between useful reportable incident data and incident reports with inadequate causation, detail and morbidity outcomes.

Pathology services are the frontline to identifying many incidents and are often the first port of call for reaction investigation information. Several strict controls implemented over the past decade have assisted in minimising specimen related errors and identifying wrong blood in tube (WBIT) incidents. These include electronic transfusion history and blood group checks on the electronic pathology reporting system, minimum patient identifier acceptance, patient identification declaration, and zero tolerance for labelling errors. The BloodSafe Transfusion Nurses work closely with the Transfusion Service scientists to ensure reactions are investigated, medically reviewed and where appropriate the BloodSafe nurses will further investigate / liaise with clinicians.

Major events such as WBIT, incorrect blood component transfused and TRALI are reported to the hospital Patient Safety Manager / Quality and Safety unit for review and if appropriate RCA investigation. Transfusion incident rates, types and outcomes are a standing agenda item at Hospital Transfusion Committee meetings. All BloodSafe transfusion nurse consultants have undertaken RCA and Clinical Practice Improvement (CPI) training to assist in the review and investigation of clinical incidents and provide consistency in incident reporting classifications. All SA hospitals have access to free BloodSafe resources to assist in safe transfusion practice through the BloodSafe program and to meet EQUIP 4 standards 1.5.5 Blood and Blood Components including:

- pre transfusion specimen collection posters, blood fridge product registers and maintenance records, consent guidelines, pre transfusion checklists, reaction management guidelines, 'Flippin Blood' resource books, consumer information and all staff are encouraged to complete the BloodSafe e-learning transfusion practice certificate course.

Any alignment of current AIMS reporting with NBA Haemovigilance categories requires manual review of entered data and either reclassification into fields dependant on reported data. The final dataset is not compatible with the requirements and significant modification or redevelopment of the system is required to fulfil the data index requirements. The laboratory investigation and classification of adverse reactions reported in electronic results does not include the suspected type of reaction. Laboratories commonly record 'No serological evidence of transfusion reaction' which is of little use for investigating reaction types.

Transferring current datasets from AIMS into index categories requires manual manipulation, interpretation of imputability scores and many data fields cannot be completed due to wide variances or omissions in current reporting system / reporter data entry. There remains a considerable amount of development for AIMS to incorporate the national haemovigilance index. The current weaknesses in the systems have been identified as:

- the voluntary nature of reporting
- call centre operating hours
- Identification of a blood related incidents, particularly in the categories of TRALI, TACO, delayed haemolytic reactions and bacterial infections in the clinical setting.

Despite the reporting gaps for the national haemovigilance dataset, there remains a robust system for the investigation, review and management of reported blood and blood component incidents / adverse events in SA due to the collaborative efforts of the SA Department of Health, Blood Service, BloodSafe Program and the Pathology Services.

The incident management system in South Australia is currently under review with a new system planned for acquisition and implementation in the second half of 2010. The Department of Health Blood Organ and Tissue Programs aims to incorporate the Haemovigilance reporting data index into an updated system to allow ease of reporting of Blood and Blood component adverse events in a format that meets NBA requirements.

The current process of standardising transfusion services across the state public sector also has the potential to improve the level of incident reporting and data availability. Recent improvements / future developments include:

- a single reaction investigation and reporting form across all public hospital sites (February 2010)
- the development of a universal Transfusion Request form incorporating specimen bar code stickers (July 2010)
- initiation of a single transfusion laboratory IT system across all of health (in progress).

3.6 Tasmania

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

A state wide incident reporting system operates across all public sector hospitals and health facilities. The Electronic Incident Management System (EIMS, 'Risk MonitorPro' rL Solutions) is used at local and state wide levels to report and manage health care incidents as a key component of quality improvement. Blood related incidents represent approximately 1% of the total number of incidents reported.

EIMS provides all public hospitals in Tasmania with a consistent, standard approach to incident reporting. All incidents are followed up and SAC1 and SCA2 incidents are referred to a Serious Incident Panel.

Reporting to STIR is a separate process to EIMS as the two systems are not aligned. A key issue for Tasmania is reporting to a national database. Given that STIR and EIMS are not a good match it appears that that provision of information via STIR would be the most practical option.

Reporting to EIMS is voluntary. However, as indicated, all public hospitals are effectively operated by the Department of Health and Human Services (DHHS) and all use EIMS for incident reporting. It is estimated that the private hospitals in Tasmania represent approximately 10% of the total transfusion activity in the state. All private hospitals record incidents, including blood related incidents, to their own risk management systems however they do not contribute data to EIMS or STIR. Private hospitals have indicated an interest in contributing towards a state wide and national database.

Transfusion related incidents in the public sector are entered into EIMS with follow up incidents according to type and severity. Many haemovigilance activities are coordinated by Blood Transfusion Nurses with positions now in place at each of the four major Tasmanian public hospitals. The role of these positions include education of clinical staff, development of policies and guidelines, conduct audits of blood product utilisation and incident reporting and monitoring. Nursing staff undertake the required training in transfusion practice in order to meet the mandatory competency requirements.

There is considerable clinical commitment to haemovigilance in Tasmania which is reflected in local governance and activities, participation in STIR and involvement in national clinical committees. There are good links with the Blood Service regarding haemovigilance activities. Blood Transfusion nurses were funded following commencement of the national blood arrangements in order to contribute to jurisdictional requirements of the National Blood Agreement.

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

Future haemovigilance strategies include:

- investigating the capacity to streamline the data provision to STIR taking account of a business analysis recent conducted by Australian Healthcare Associates Ltd
- having a consistent suite of incidents reported to EIMS and STIR by all public facilities, and
- further engagement of the private sector in haemovigilance activities.

3.7 Australian Capital Territory

ACT Health has a broad haemovigilance program which includes employment of a transfusion nurse, education and awareness activities such as BloodSafe e-learning for all clinical staff, and auditing programs. ACT Health also participates in the STIR system and is part of the Victorian Blood Matters collaborative administered by the Victorian Department of Health. The two ACT public hospitals each use a general incident reporting system that alerts a Transfusion Nurse, who then reports haemovigilance data through STIR. It is also anticipated that the three private hospitals will shortly participate. In addition to ACT Health validation, STIR also validates incident data. This includes review and re-assessment of imputability rating by an expert STIR panel comprised of medical and nursing clinicians and laboratory scientists. Although the data are held by STIR, ACT may report the outcomes depending on its own assessment.

The ACT is a small jurisdiction with a population of 347,000 people, although the complete catchment covers an extensive area of south-eastern New South Wales with a total catchment population of about 500,000. The ACT is serviced by two public and three private hospitals, all of which provide transfusion services to their consumers through three pathology providers. ACT Health established and funded a Haemovigilance Project that operated for two years and concluded in February 2005. As a consequence of this project a permanent ACT Health Transfusion Nurse position was created and recruited under ACT Health Population Health Division in 2007.

The advantage of the ACT being a small jurisdiction has allowed the Transfusion Nurse to promote and sustain a jurisdictional approach to haemovigilance in the ACT with the key purpose of working with medical, nursing and laboratory staff to promote safe and appropriate use of blood and blood products in accordance with both the National and International Guidelines. The service provided by the Transfusion Nurse covers all of the ACT, both public and private practice. In addition, the ACT maintains an Appropriate Use of Blood Reference Group (AUBRG) with membership from hospitals and laboratories in both the public and private sectors.

The ACT Health transfusion nurse provides clinical leadership in the area of haemovigilance in the ACT. This is achieved by maintaining and refining transfusion related adverse event monitoring and providing education for staff and patients together with clinical policy development and implementation across the ACT. The two ACT public hospitals each use RiskMan as their general incident reporting system. The RiskMan classifications were modified to not only capture data on adverse events reportable to STIR but also to isolate possible risks at a local level.

The BloodSafe e-learning program was made mandatory training for all staff involved in the transfusion chain at hospitals across the ACT. To date (mid May 2010) the ACT has recorded 1715 registrations to the program. Competency assessment tools were developed and made available to clinical areas to support this education framework. It is anticipated that all staff administering blood and blood products will complete these assessments.

ACT Transfusion Champions Forum, supported by ACT Population Health Division, was held in June 2009. The forum brought together nurses and other health professionals from the NBA, Blood Matters Victoria, ACT Health, Calvary Health Care, National Capital Hospital, Calvary John James Hospital and ACT Pathology to: improve knowledge in relation to blood transfusion safety and quality nationally and across the ACT, enhance clinical care in accordance with best practice, and to support the development of strategies to mitigate significant increases in the cost of blood and blood products through blood management and waste reduction and resulting improved patient outcomes. This forum was the platform to formally launch the ACT Transfusion Champions Networks operating within Calvary Health Care and The Canberra Hospital. The private hospitals across the ACT have representatives within these networks. It is anticipated that the Transfusion Champions Networks will:

- enhance clinical care in accordance with best practice with a focus on transfusion of blood and blood products and its documentation within their clinical area
- ensure relevant accreditation criterion are met as outlined in EQUIP4 1.5.5 in their clinical area
- identify risks associated with transfusion practice in their clinical area and report these to the transfusion nurse and their managers
- promulgate information and quality improvement activities associated with transfusion
- assist clinical development nurses with competency assessments associated with transfusion.

The Canberra Hospital and Calvary Health Care participated in the Australian and New Zealand Society of Blood Transfusion (ANZSBT) Transfusion Consent Survey 2009. This survey provided ACT Health with the opportunity to review current practice and benchmarking against similar hospitals in Australia and New Zealand. The formal results are pending.

Areas of high risk in relation to patient identification and transfusion specimen labelling were identified in the ACT. Collaboration between relevant stakeholders has resulted in an extensive education & competency assessment campaign within these areas to improve patient safety outcomes. This significant intervention could circumvent possible sentinel events such as ABO incompatible transfusions. This will continue to be monitored and reported through the transfusion committees.

3.8 Northern Territory

There is currently no routine reporting format for haemovigilance data and no structured review of serious transfusion incidents at a jurisdictional level in the Northern Territory. However, since 2008 the NT Government Department of Health and Families (DHF) has operated a territory wide transfusion safety program and a transfusion nurse was appointed to support this safety initiative for the Northern Territory Hospital Network.

In August 2008, the transfusion nurse wrote a report recommending that the NT Network Hospitals join the Victorian Blood Matters' STIR program. A NT Transfusion Committee (NTTC) has been established to oversee transfusion safety in NT public hospitals. Members include clinicians, scientists, nurses and quality staff. The NTTC held its first meeting in March 2009 and meets quarterly. A summary of key learnings from the haemovigilance surveillance process is presented at NTTC meetings.

During the period December 2008 to February 2010, with the support of the NT Transfusion Nurse, all NT public hospitals that transfuse blood and blood products joined the STIR system. It is likely that the NT's sole private hospital will also agree to contribute relevant data in the near future. Reporting haemovigilance data via the NT Transfusion Safety program and STIR is voluntary. In July 2009, RiskMan software was introduced and covers all NT Network Hospitals. There are four transfusion-related incident categories: administration, transfusion reaction, blood product and documentation. Transfusion-related incidents are flagged for the attention of the transfusion nurse who coordinates a central repository for all NT jurisdictional reports to STIR.

Further to the haemovigilance duties of the transfusion nurse, the DHF has provided funding from the 2009/10 Quality and Safety Budget for two haemovigilance projects:

- Blood Transport System Project—the aim of this project is to purchase containers suitable for transporting blood products within and between the NT hospitals, and for medical retrievals
- Transfusion Information for Indigenous Patients Project—the aim of this project is to produce transfusion information that is culturally appropriate for Indigenous patients receiving blood products as part of their treatment in NT Network Hospitals.

The transfusion nurse also coordinates transfusion safety program activities such as clinical audit, education and raising awareness for hospital nursing staff with a focus on the identification and reporting of transfusion incidents. The NT transfusion nurse negotiates with staff at each of the five hospitals to encourage and promote transfusion education for medical, nursing, midwifery, laboratory and phlebotomy staff. A transfusion learning package is mandatory for nurses and midwives at the Royal Darwin Hospital. It is currently being implemented. It is not mandatory at the remaining four public hospitals; however the transfusion nurse is continuing to promote the learning package to senior nursing staff. Learning packages for patient care assistants and phlebotomists have also been developed but are yet to be implemented. The BloodSafe e-learning tool is also promoted as an appropriate educational tool for medical staff.

A NT Blood Transfusion Manual was approved by the NTTC in March 2009. This is available on the DHF intranet and all clinical staff have access to these Clinical Guidelines and Policies information. A Blood Transfusion Request Form was re-designed in 2008/09 to incorporate the NHMRC and ANZSBT Clinical Practice Guidelines on the Use of Blood Components. When clinicians order blood they must choose a clinical indication from a list on the reverse side of the form. This encourages compliance with the guidelines and prompts the clinicians to consider their decision to transfuse.

Future plans to improve haemovigilance in the NT include:

- encourage reporting of transfusion-related incidents into RiskMan; any incidents that meet the NBA definitions to be reported further into STIR
- the NTTC will review all transfusion-related incidents and give recommendations for improvement. The NT will give permission to STIR to pass aggregated haemovigilance data on to the NBA, when asked to do so
- continue to promote transfusion education across the NT Network Hospitals
- implement written informed consent for transfusion in 2010
- a jurisdictional level Safety and Quality Clinical Governance Framework is in early stages of development for the NT Network Hospitals and will incorporate full governance and incident review requirements including review of serious transfusion incidents.



PART FOUR.

TRENDS IN BLOOD PRODUCT ISSUE AND USAGE IN AUSTRALIA

- 4.1 BLOOD PRODUCTS COLLECTED AND ISSUED
- 4.2 DEMOGRAPHICS OF BLOOD USE
- 4.3 CLINICAL BLOOD USAGE

4 TRENDS IN BLOOD PRODUCT ISSUE AND USAGE IN AUSTRALIA

All developed countries are facing increased demand for their blood resources. Important factors that contribute to competing supply and demand pressures for blood resources are; chronic diseases associated with ageing populations and longer life spans in developed countries; earlier medical interventions often involving blood products; emerging disease threats associated with population movements; and natural population increases.

4.1 Blood products collected and issued

In Australia, blood is voluntarily donated free from financial incentive, and distributed by the Blood Service to public and private hospitals and pathology laboratories in accordance with government policies in the National Blood Agreement and National Blood Authority Act 2003.

The NBA coordinates the purchase and supply of blood and blood products on behalf of all Australian governments. The Blood Service collects, processes and supplies labile blood products to Australian approved health providers. The operations of the Blood Service are funded by all Australian governments under a Deed of Agreement managed by the NBA. The Therapeutic Goods Administration (TGA) regulates blood and plasma manufacturing activities and monitors any adverse transfusion events that may be product related.

Table 2 summarises the numbers of labile blood products issued throughout Australia during 2008/09. Table 3 and Table 4 summarise the numbers of labile blood products issued throughout Australia during 2003/09. Red blood cells represent the major product issued. The level of red cell issues fell in 2007/08, possibly due to various jurisdictional efficiencies that were implemented. The red cell issues rose again in 2008/09. Demand for platelets, fresh frozen plasma and cryoprecipitate units has steadily increased since 2003/04.

The NBA holds data on the number and type of blood products issued annually in Australia (Table 2 to Table 4). However, there are no direct or accurate data on the number of units of labile blood products transfused annually. Also not known is the exact amount of labile blood products lost through expiry, recalls, misplacement and inappropriate storage and transportation. An increasing number of jurisdictions and institutions are collecting data and implementing audits to track the fate of blood products.

TABLE 2 – Labile blood products issued in Australia 2008/09

2008/09	RED BLOOD CELLS	PLATELETS	CLINICAL FFP	CRYOPRECIPITATE	CRYODEPLETED
	UNITS	ADULT DOSES	ADULT DOSES	UNITS	UNITS
NSW	243,811	32,489	55,691	20,460	5,084
VIC	205,580	30,269	31,399	19,102	2,095
QLD	165,915	32,809	34,930	7,197	5,250
WA	70,143	8,507	12,540	4,661	887
SA	74,247	8,925	13,434	1,720	1,002
TAS	15,351	2,185	1,636	1,674	90
ACT	12,316	2,154	2,282	1,278	473
NT	6,118	911	778	328	56
NATIONAL	793,480	118,248	174,309	56,420	14,937

TABLE 3 – Labile blood products issued in Australia 2003/09

LABILE BLOOD COMPONENT	2003/04	2004/05	2005/06	2006/07	2007/08	2008/09
RBC units	736,808	744,250	757,034	777,972	768,919	793,480
Platelets (adult equivalent doses)	97,398	102,742	109,132	113,579	116,665	118,248
Fresh frozen plasma units	138,315	138,878	143,112	145,874	161,877	174,309
Cryoprecipitate units	33,053	38,056	42,847	49,333	51,957	56,420
Cryo-depleted plasma units	12,114	14,039	18,874	12,321	14,487	14,937

TABLE 4 – Labile blood products issued in Australia 2003/09 per 1000 population (2008 Census data)

LABILE BLOOD COMPONENT	2003/04	2004/05	2005/06	2006/07	2007/08	2008/09
RBC units	36.83	36.79	37.02	37.31	36.31	36.83
Platelets (adult equivalent doses)	4.87	5.08	5.34	5.45	5.51	5.49
Fresh frozen plasma units	6.91	6.87	7.00	7.00	7.64	8.09
Cryoprecipitate units	1.65	1.88	2.10	2.37	2.45	2.62
Cryo-depleted plasma units	0.61	0.69	0.92	0.59	0.68	0.69

Figure 1 shows the trend in total red blood cell product issues over the last six years. There is a total increase of 3.1% in red blood cell issues in 2008/09 over the previous year.

FIGURE 1 - Total Red Blood Cell issues in Australia 2003/09

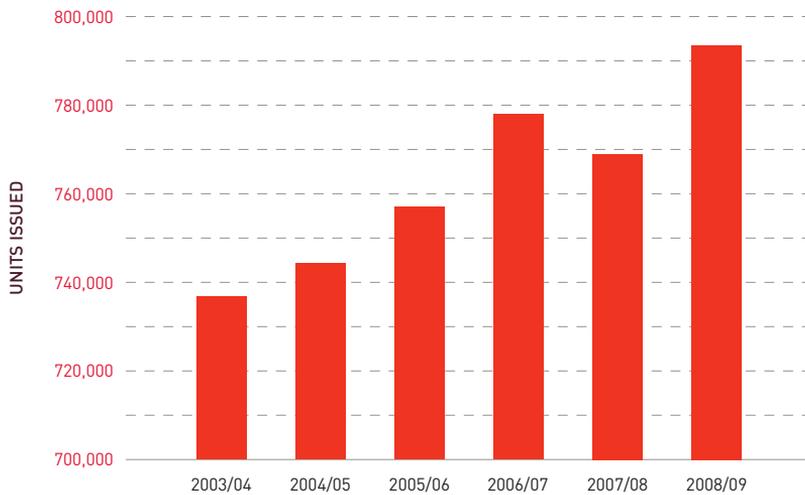
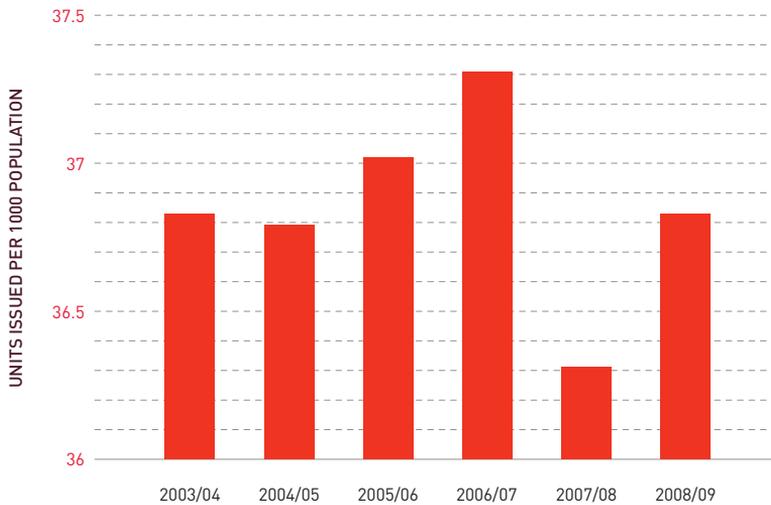


Figure 2 shows the trend in red blood cell product issued per 1,000 capita over the last six years.

FIGURE 2 - Total Red Blood Cells per 1,000 head population issues in Australia 2003/09



In 2008/09 red cell issues increased 3.2% nationally compared with 2007/08, with increased issues across all jurisdictions. However, Australia has made increasing progress towards improving the efficiency of blood utilisation and clinical transfusion practice, in line with many developed countries. Blood-related clinical practice and improvement programs in a number of jurisdictions have continued to make improvements in areas such as appropriate use of blood, clinical governance, haemovigilance and ongoing education of clinical and health care professionals. All jurisdictions have appointed Transfusion Nurses whose roles include the promotion of transfusion appropriateness.

4.2 Demographics of blood use

Australia's population continues to increase annually¹⁹, both through natural increases (i.e. the excess of births over deaths) as well as net overseas migration (i.e. net gain of population through immigration to, and emigration from, Australia). For the calendar year ending December 2008, Australia's population increased by 1.9%. This increase is the largest recorded for a 12 month period for fifty years. Increases in population will inevitably result in increased future demand for health care services, and blood and blood products.

Australia has an ageing population profile, similar to that of most developed countries. This is a result of sustained low birth rates and increasing life expectancy. This is resulting in proportionally fewer children (less than 15 years of age) in the population. The median age (the age at which half the population is older and half is younger) of the Australian population has increased by 5.1 years over the last two decades, from 31.8 years at 30 June 1989 to 36.9 years at 30 June 2009. Between 30 June 2008 and 2009 the median age remained steady at 36.9. Over the next several decades, population ageing is expected to have significant implications for Australia including increased demands on the health system²⁰.

Australians have one of the highest life expectancies in the world, second only to Japan²¹. This results in proportionally greater numbers of elderly people in the population, many of whom have or may develop both acute and chronic medical conditions, which may require blood and/or blood product support.

In the 12 months to 30 June 2009, the number of people aged 65 years and over in Australia increased by 85,800 people representing a 3.0% increase. The proportion of the population aged 65 years and over increased from 11.0% to 13.3% between 30 June 1989 and 30 June 2009.

In the 12 months to 30 June 2009, the number of people aged 85 years and over increased by 21,000 people (5.8%) to reach 383,400. Over the past two decades the number of elderly people increased by 167.8%, compared with a total population growth of 30.1% over the same period.

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

19 ABS-3101.0 Australian Demographic Statistics, Canberra www.abs.gov.au

20 Economic Implications of an Ageing Australia. Productivity Commission 2005 Canberra. <http://www.pc.gov.au/projects/study/ageing/docs/finalreport>

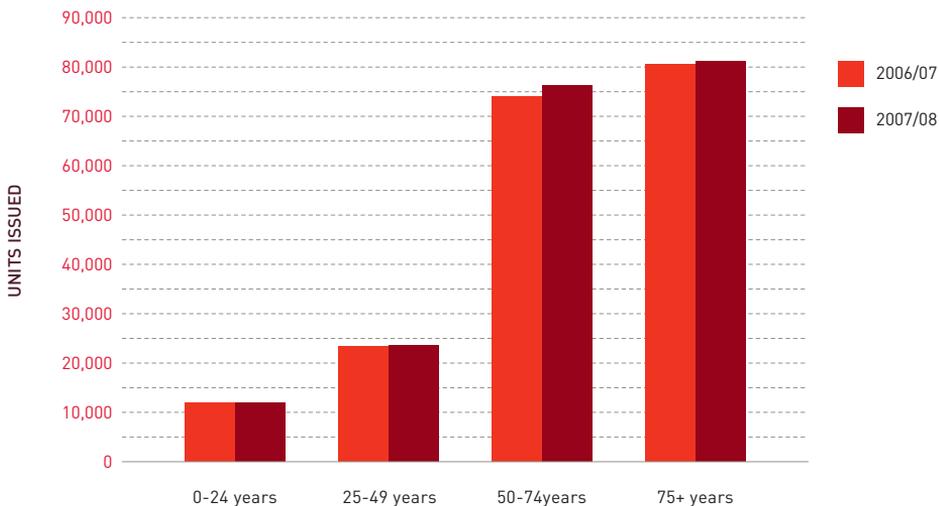
21 Australia's Health 2008. Australian Institute of Health and Welfare 2008 Canberra. www.aihw.gov.au

The AIHW publishes data relating to transfusion of blood and immunoglobulin on an annual basis. There are, however, a number of limitations²² with respect to the analysis and the potential use of these data for blood supply demand planning, including the following:

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

Nevertheless, these data do provide some insight into Australian transfusion trends. Figure 3 below charts the number of Red Cell transfusion procedures in 2006/07 and 2007/08 by patient age²³.

FIGURE 3 - Red Cell Transfusions by Patient Age



22 Limitations of NHMD data. Australian Institute of Health and Welfare
<http://www.aihw.gov.au/hospitals/datacubes/datasource.cfm>

23 National Hospital Morbidity Database. Australian Institute of Health and Welfare
http://www.aihw.gov.au/hospitals/nhm_database.cfm

The majority of red cell transfusion procedures occur in patients aged over 50 years. The AIHW National Hospital Morbidity Database reports similar trends across all blood products. Table 5 details transfusion procedures (defined by ICD-10-AM procedure codes) by patient age in Australia for the 2006/07 period. Table 6 details transfusion procedures (defined by ICD-10-AM procedure codes) by patient age in Australia for the 2007/08 period.

TABLE 5 – ICD-10-AM / ACHI Transfusion Procedures by Patient Age 2006/07

2006/07	NUMBER OF PROCEDURES BY PATIENT AGE				PERCENTAGE OF PROCEDURES BY PATIENT AGE			
	0-24yrs	25-49yrs	50-74yrs	75+yrs	0-24yrs	25-49yrs	50-74yrs	75+yrs
Transfusion of								
Whole blood	537	2095	536	431	15%	58%	15%	12%
Packed red cells	11865	23380	73945	80556	6%	12%	39%	42%
Platelets	4030	4014	12879	5059	16%	15%	50%	19%
Leukocytes	5	30	130	18	3%	16%	71%	10%
Autologous blood	322	692	5075	1638	4%	9%	66%	21%
Other serum	3145	5064	13924	9019	10%	16%	45%	29%
Blood expander	183	949	2270	1187	4%	21%	49%	26%
Other substance	60	162	203	160	10%	28%	35%	27%

TABLE 6 – ICD-10-AM / ACHI Transfusion Procedures by Patient Age 2007/08

2006/07	NUMBER OF PROCEDURES BY PATIENT AGE				PERCENTAGE OF PROCEDURES BY PATIENT AGE			
	0-24yrs	25-49yrs	50-74yrs	75+yrs	0-24yrs	25-49yrs	50-74yrs	75+yrs
Transfusion of								
Whole blood	490	2126	572	384	14%	60%	16%	11%
Packed red cells	11860	23615	76187	81160	6%	12%	40%	42%
Platelets	4012	4161	14217	5653	14%	15%	51%	20%
Leukocytes	8	20	48	14	9%	22%	53%	16%
Autologous blood	315	613	5250	1813	4%	8%	66%	23%
Other serum	3308	5366	16431	10101	9%	15%	47%	29%
Blood expander	187	798	2629	1443	4%	16%	52%	29%
Other substance	54	136	208	131	10%	26%	39%	25%

This phenomenon is not unique to Australia. Recent epidemiological information was obtained from the United States, England, and Denmark that highlighted similar age and sex distributions of transfused patients²⁴. Most of the red cell products were transfused to older recipients, and the distribution between men and women was approximately equal. The distribution for platelets was over a wider age range. The distribution for plasma was also directed to the elderly.

It has been noted that there is a marked increase in blood product consumption with increasing age. This has stimulated research into demographic modelling for blood products. Some researchers have forecast a large increase in clinical use of RBC units per 1000 population in Australia over the next decade²⁵.

4.3 Clinical blood usage

The ageing population is likely to also result in an increase in certain types of surgical procedures which currently require blood support, such as hip and knee replacements. As an example, between 2001/02 and 2007/08, there has been a 15.7% increase in the number of hip replacements and hip replacement revisions performed within Australian hospitals^{26 27}.

A number of international studies have been undertaken examining changes in red cell usage over time, with particular focus on the impact of an ageing population. In 2006, Wallis et al.²⁸ reported on a study examining the changing indications for red cell transfusion from 2000 to 2004 in the North of England. The authors noted that the mean age of the recipient of a red cell unit was 63.6 years (compared with 62.6 years in 1999/2000), and that red cell transfusion for medical indications rose from 52% to 62%, with the most common indications being primary haematological disorders (18.2% of all transfused red cells), gastrointestinal haemorrhage (13.8%) and non-haematological malignancies (8.8%).

These results are consistent with similar studies undertaken by groups in other developed countries with ageing population profiles. The Blood Service 'Bloodhound' study²⁹ showed a similar age profile for Australian patients receiving red cell transfusions, with 58% of patients being 65 years or older and the median age of recipients being 69 years. The Bloodhound study following the fate of 5052 RBC units, indicated that for 53.4% of units the urgency of the surgical procedure and the urgency of transfusion was less than 24 hours. Only a small proportion was required to support elective surgery.

24 Cobain TJ, Vamvakis EC, Wells A, Titlestad K. A Survey of the Demographics of Blood Use. *Transfusion Medicine* 2007; 17: pp1-15.

25 Ali A, Auvinen M-K, Rautonen J. The aging population poses a global challenge for blood services. *Transfusion* 2010; 50(3) pp584-588.

26 Australian Hospital Statistics 2005-06. Australian Institute of Health and Welfare 2006 Canberra. <http://www.aihw.gov.au/publications/index.cfm/title/10455>

27 Australian Hospital Statistics 2007-08. Australian Institute of Health and Welfare 2006 Canberra. <http://www.aihw.gov.au/publications/index.cfm/title/10776>

28 Wallis JP, Wells AW, Chapman CE. Changing indications for red cell transfusion from 2000 to 2004 in the North of England. *Transfusion Medicine* 2006; 16(6): 411-417.

29 Shortt J, Polizzotto MN, Waters N, Borosak M, Moran M, Comande M, et al. Assessment of the urgency and deferability of transfusion to inform emergency blood planning and triage: the Bloodhound prospective audit of red blood cell use. *Transfusion* 2009; 49(11) pp2296-2303.

Approximately 1/3 of tagged red cells were used to support surgery, 1/3 for haematology/oncology and 1/3 for other medical and miscellaneous indications. The breakdown of the clinical indications for transfusion was as follows:

- 33.6% for haematological and oncological conditions
- 27.8% for surgical specialities (including cardiothoracic 5.6%, orthopaedic 9.8%, vascular 2.3%, solid organ transplantation 2.3% and other 9.5%)
- 13.5% for other medical conditions (including gastroenterology 8.7%, nephrology 2.8%, paediatric specific indications 0.1% and other 1.9%)
- 12.7% for unspecified anaemia
- 3.8% for obstetrics and gynaecology
- 2.1% for trauma
- 6.5% where the indication was unknown.

Just under 10% of transfused red cells were used to support elective surgery or non-urgent medical conditions.

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



PART FIVE.

AVAILABLE AUSTRALIAN HAEMOVIGILANCE DATA FOR JULY 2008 - JUNE 2009

5.1 DATA SOURCES AND CAVEATS FOR 2010 REPORT

5 AVAILABLE AUSTRALIAN HAEMOVIGILANCE DATA FOR JULY 2008–JUNE 2009

5.1 Data sources and caveats for 2010 report

The current report improves upon the standards of the Initial Australian Haemovigilance Report 2008 in a number of significant ways.

The NBA and HAC support the continued development and alignment of jurisdictional haemovigilance reporting systems with the recommended National Haemovigilance Dataset, where this is not already achieved. To enable this, with reference to international haemovigilance and Australian national data dictionaries, the HAC have produced the ANHDD. The ANHDD standardises the data elements and their format for the Australian National Haemovigilance Dataset. The ANHDD is in its third iteration and is under continuous review.

The data sources for this report include validated jurisdictional level haemovigilance data through a number of programs. These programs include BloodSafe in South Australia and the Blood Matters- Better Safer Transfusion Program and STIR program in Victoria and Tasmania (the STIR program has also been implemented in the ACT and NT). The data supplied by the jurisdictions through these programs were compliant with the standards specified in the ANHDD.

The Queensland Blood Management Program (QBMP) also supplied validated jurisdictional level haemovigilance data (Queensland Incidents in Transfusion (QiiT) haemovigilance system), although there were a number of definitional and conceptual differences in the data.

There was discrepancy between the age categories used for QiiT and the national dataset. Table 7 shows the transformation used to map the QiiT age categories to those of the national haemovigilance dataset. The decision was taken to align the ranges with a bias towards increasing the age category e.g. the 20-29yrs QiiT range has been coded as 25-34yrs in the national dataset. This allowed re-coding of the 28 day-1 year QiiT category and aligned with the concept that transfusion is more likely with increased age. De-identification of patient data at the QiiT level made it impractical to recode every incident from the original patient records according to national haemovigilance dataset standards.

TABLE 7 – Transformation of age categories between QiiT and ANHDD standards

QiiT PATIENT AGE		NATIONAL HAEMOVIGILANCE DATASET PATIENT AGE
28 days-1 year	was re-coded as	0-4 years
1-9 years	was re-coded as	5-14 years
10-19 years	was re-coded as	15-24 years
20-29 years	was re-coded as	25-34 years
30-39 years	was re-coded as	35-44 years
40-49 years	was re-coded as	45-54 years
50-59 years	was re-coded as	55-64 years
60-69 years	was re-coded as	65-74 years
70-79 years	was re-coded as	> 75 years
> 80 years	was re-coded as	> 75 years

All NSW public hospitals use a centralised incident reporting system, the Incident Information Management System (IIMS) as their only incident reporting tool. IIMS is used to collect data and allows for the provision of reports on jurisdiction level haemovigilance incidents as one part of its broader incident information management function. There is a specific category for incidents involving Blood and Blood products which allows the notifier to select what type of blood product was involved and the nature of the problem. The remaining fields are designed to capture a wide range of fairly general incident reporting information, and include a free text description of the risk/incident.

The IIMS data within the 'Blood/Blood Products' category are included in overall reporting on IIMS data by the CEC as an integral component of patient safety clinical incident management in NSW public hospitals. In addition, a detailed review of the data reported within the 'Blood/Blood Products' category within IIMS is performed annually by staff at the CEC and the relevant information obtained from this review is presented for consideration by the Blood Clinical & Scientific Advisory Committee.

In order to derive additional information regarding adverse transfusion events, the CEC performs a targeted analysis of the free text description of adverse events provided within the Blood/Blood Product category of incident reports within IIMS. There is as yet no process that would support the jurisdictional allocation of imputability ratings for adverse transfusion events for, and as formally required by the national haemovigilance system agreed dataset rules. It is recognised that many of the reports captured by IIMS within the Blood/Blood product incident category are not serious transfusion events as defined by the International Haemovigilance Network (IHN), and a major limitation for detailed analysis is the presence of much potentially relevant data in non-mandated, free-text fields.

The data from NSW was not generally compatible with the standards of the national haemovigilance dataset. A very limited number of incidents could be formally included for this reason, and these lacked specific associated data fields (that are also agreed national dataset requirements) such as patient age range and gender, clinical outcome severity, imputability, and blood product type.

In WA, the larger metropolitan and regional public and private hospitals have established transfusion committees with meeting schedules varying from two monthly to half yearly. The Transfusion Nurses/Coordinators in the public teaching hospitals monitor activities, and investigate transfusion-related incidents in their institutions. However, WA cannot provide any detailed haemovigilance data until 2011.

Figure 4 shows a representation of the jurisdictions contributing haemovigilance data to the current report. Validated jurisdictional level data was submitted by Victoria, Queensland, South Australia, Tasmania, the Australian Capital Territory and the Northern Territory. A small amount of relevant, but incompatible, data was submitted by New South Wales. WA is the only jurisdiction not contributing to the national dataset for the reporting period of this report (July 2008 – June 2009).

FIGURE 4 - Jurisdictions contributing haemovigilance data to the 2010 Report

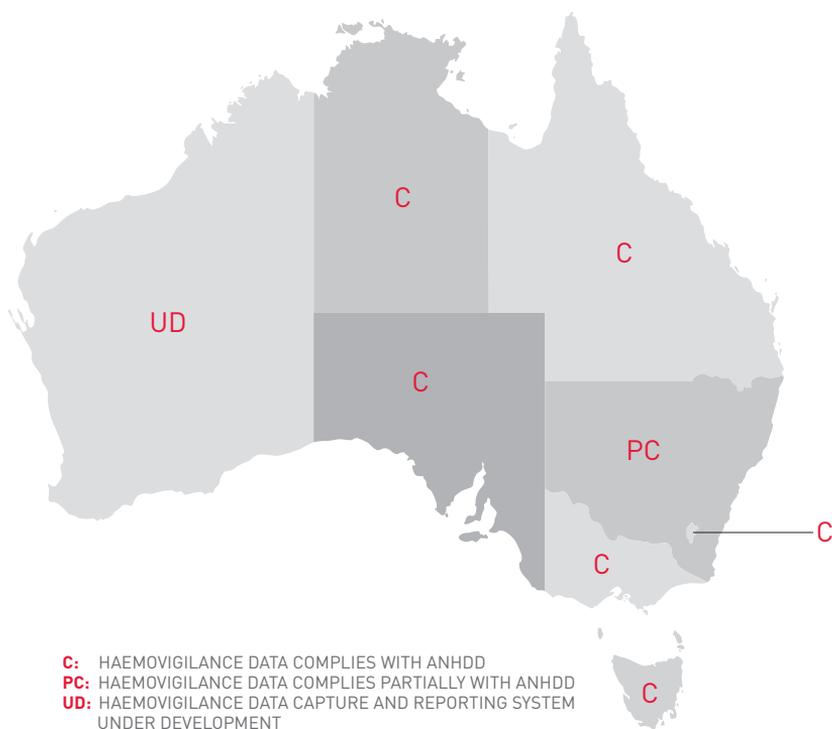


Image adapted from Outline map of Australia (with state borders)
 © Copyright Commonwealth of Australia (Geoscience Australia) 2010

It should be noted that the data is not complete for every reported adverse event in the national dataset, and data elements may be missing (e.g. Time of Transfusion, Blood Product, Imputability, etc.). Where data elements are missing the figures presented in the data summaries for each adverse event may be less than the total expected.



PART SIX.

OVERVIEW OF NOTIFICATIONS OF SERIOUS TRANSFUSION-RELATED ADVERSE EVENTS

6.1 TRANSFUSION RISKS

6 OVERVIEW OF NOTIFICATIONS OF SERIOUS TRANSFUSION-RELATED ADVERSE EVENTS

Transfusions save millions of lives globally each year, and labile blood products have become increasingly safe as a result of fastidious donor screening and selection policies and increasingly sensitive and selective product testing.

6.1 Transfusion risks

The direct product related risks associated with transfusion in Australia are now very small. When considering the significance of specific risks, it is often useful to compare them to the risks associated with everyday living. The risk estimates listed in Table 8 are very small when compared to everyday risks (refer to the Calman scale in Table 9 below): e.g. the chance of being killed in a road accident is about 1 in 10,000. The most common types of reactions to transfusion are not serious and include, for example, headache, mild fever, itching and urticarial reactions.

The morbidity associated with major ABO incompatibility remains one of the most common fatal complications of blood transfusion. Most of these events are due to avoidable procedural errors (such as patient/sample identification errors). Other serious risks associated with transfusion, based on overseas estimates, are outlined in Table 8 below (degree of recognition/reporting of events results in variable incidences. Many are underestimated due to likely under-reporting).

TABLE 8 – *Transfusion Risks*³⁰

ADVERSE REACTION	RISK PER UNIT TRANSFUSED (UNLESS SPECIFIED)
Bacterial sepsis	1: 75,000 for platelets 1: 500,000 for red cells
Haemolytic reactions:	
Acute	1: 12,000 to 77,000
Delayed	1: 4,000 to 9,000
Anaphylaxis–IgA deficiency	1: 20,000 to 50,000
TACO; Fluid overload/cardiac failure	Up to 1% of patients receiving transfusions
TRALI	1: 5,000 to 190,000
Transfusion-associated graft vs. host disease	Rare

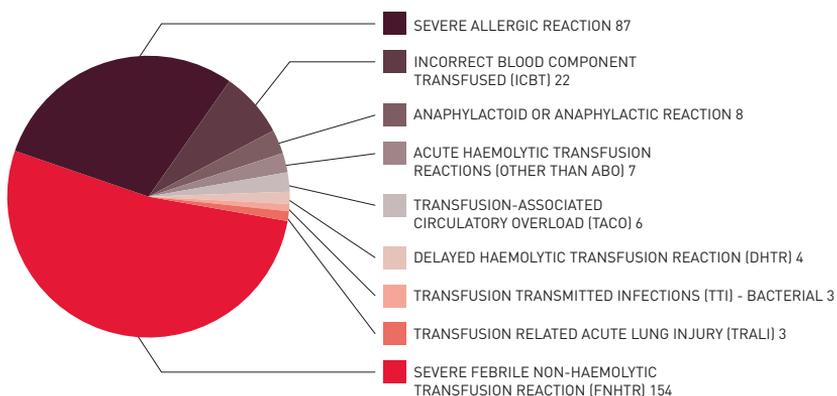
30 Blood Component Information Circular of Information An extension of blood component labels 2009. Australian Red Cross Blood Service 2009 <http://www.manual.transfusion.com.au/admin/file/content13/c6/BCI%202009.pdf>

TABLE 9 – The Calman Chart for explaining risk³¹

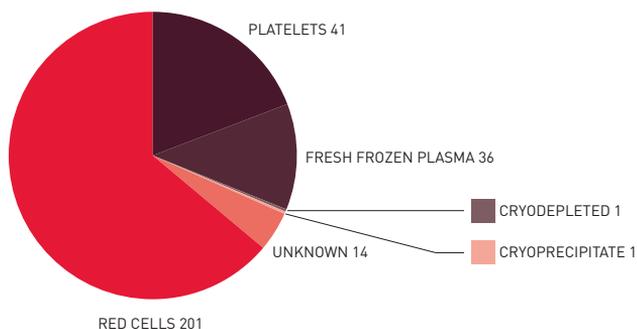
RISK LEVEL	UK RISK PER ONE YEAR
Negligible	< 1:1,000,000 e.g. death from a lightning strike
Minimal	1:100,000–1:1,000,000 e.g. death from a train accident
Very low	1:10,000–1:100,000 e.g. death from an accident at work
Low	1:1000–1:10,000 e.g. death from a road accident
High	> 1:1000 e.g. transmission of chickenpox to susceptible household contacts

Figure 5 illustrates the relative proportions of serious adverse events reported (independent of assigned imputability) to the Australian National Haemovigilance Program for the 2008/09 period. The relative incidence of the adverse events appears comparable to the data of many other developed countries, with a majority of febrile reactions and allergic reactions. Haemolytic transfusion reactions (HTR), transfusion associated circulatory overload (TACO), transfusion related acute lung injury (TRALI) and transfusion transmitted infections all represent very low to minimal risks to patients. However, there were 22 IBCT events reported. Although these events are a minimal risk to patients receiving a transfusion, they are all founded in avoidable human error.

Figure 6 illustrates the relative proportion of blood products implicated in serious adverse events. Table 10 further refines these data by detailing the numbers of adverse events reported categorised by the implicated blood product.

FIGURE 5 – Australian serious transfusion related adverse events reported 2008/09

31 Calman K. The Health of the Nation. British Journal of Hospital Medicine 1996; 56 pp125-126.

FIGURE 6 - Blood products implicated in serious adverse events 2008/09**TABLE 10** - Numbers of adverse events by blood product

	RED BLOOD CELLS	PLATELETS	FRESH FROZEN PLASMA	CRYODEPLETED	CRYOPRECIPITATE	UNKNOWN	TOTALS
FNHTR	134	15	2	0	0	3	154
Allergic	40	19	27	0	1	0	87
Anaphylactic	1	2	2	1	0	2	8
AHTR (other than ABO incompatibility)	7	0	0	0	0	0	7
DHTR	1	3	0	0	0	0	4
TACO	2	0	1	0	0	3	6
TRALI	1	0	1	0	0	1	3
Bacterial TTI	1	1	0	0	0	1	3
IBCT	14	1	3	0	0	4	22
Totals (n=294)	201	41	36	1	1	14	294



PART SEVEN - SIXTEEN.

- 7 SEVERE FEBRILE NON-HAEMOLYTIC TRANSFUSION REACTIONS (FNHTR)
- 8 ALLERGIC REACTIONS (SEVERE)
- 9 ANAPHYLACTIC AND ANAPHYLACTOID REACTIONS
- 10 ACUTE HAEMOLYTIC TRANSFUSION REACTIONS (OTHER THAN ABO INCOMPATIBILITY)
- 12 DELAYED HAEMOLYTIC TRANSFUSION REACTIONS (DHTR)
- 13 TRANSFUSION-ASSOCIATED CIRCULATORY OVERLOAD (TACO)
- 14 TRANSFUSION-RELATED ACUTE LUNG INJURY (TRALI)
- 15 TRANSFUSION TRANSMITTED INFECTIONS (TTI)
- 16 INCORRECT BLOOD COMPONENT TRANSFUSED (IBCT)

7 SEVERE FEBRILE NON-HAEMOLYTIC TRANSFUSION REACTIONS (FNHTR)

DATA SUMMARY (N=154)					
AGE	GENDER		DAY OF TRANSFUSION		
0-4 years	13	Male	81	Week day	115
5-14 years	7	Female	67	Weekend	34
15-24 years	5	Uncategorised	6	Unknown	5
25-34 years	11				
35-44 years	12	FACILITY LOCATION	TIME OF TRANSFUSION		
45-54 years	10	Major City	132	Between 7am and 7pm	60
55-64 years	19	Inner Regional	7	Between 7pm and 7am	21
65-74 years	25	Outer Regional	10	Unknown	73
75+ years	42	Remote	-		
not specified	10	Very Remote	-		
CLINICAL OUTCOME SEVERITY	IMPUTABILITY		BLOOD PRODUCT		
Outcome not available	55	Excluded	1	Whole blood	-
No morbidity	77	Unlikely / Possible	59	Red cells	134
Minor morbidity	14	Likely / Probable	77	Platelets	15
Severe morbidity	3	Confirmed / Certain	5	Fresh Frozen Plasma	2
Life threatening	5	N/A / Not assessable	12	Cryoprecipitate	-
Death	-			Cryo-depleted	-

Febrile non-haemolytic transfusion reactions (FNHTR, see Appendix II: Definitions in haemovigilance) are the most common reported complications of blood transfusion in Australia. Although the incidence rates for FNHTR have been reported at less than 1 percent with current methods that use single donor apheresis units and leukoreduced products³² FNHTRs continue to occur.

An increased understanding of the pathophysiology of FNHTR may advance our ability to prevent these reactions. The underlying pathology for initiating the reaction has multiple mechanisms proposed, and is most likely multivariate so multiple methods may be necessary to prevent these transfusion reactions.

32 Geiger TL, Howard SC. Acetaminophen and diphenhydramine pre-medication for allergic and febrile non haemolytic transfusion reactions: good prophylaxis or bad practice? *Transfusion Medicine Review* 2007; 21 pp1-12.

Currently, the literature indicates that prophylactic medication with antipyretics does not reduce the incidence of FNHTR, and that antipyretic use may prevent fevers but not other symptoms of FNHTR such as chills, cold, and discomfort³³.

In 2008/09 there were 154 reports to the national haemovigilance program. The majority of cases were linked with transfusion of red blood cells. Data for patient age and gender, facility location and day and time of transfusion all fall within expected distributions. Table 11 details the clinical outcome severity of the reported cases by their imputability.

TABLE 11 – FNHTR clinical outcome severity by imputability

CLINICAL OUTCOME SEVERITY	IMPUTABILITY				
	EXCLUDED	UNLIKELY / POSSIBLE	LIKELY / PROBABLE	CONFIRMED / CERTAIN	N/A / NOT ASSESSABLE
Outcome not available	-	5	45	-	5
No morbidity	1	48	23	1	4
Minor morbidity	-	3	7	4	-
Severe morbidity	-	-	2	-	1
Life threatening	-	3	-	-	2
Death	-	-	-	-	-

The current definition of Febrile Non-Haemolytic Transfusion Reactions (FNHTR) used by the HAC in the ANHDD aligns with the definitions used by the International Haemovigilance Network (IHN) and the International Society for Blood Transfusion (ISBT) Working Party on Haemovigilance.

However, there is still some divergence between the definitions in use. The Victorian STIR system uses a higher temperature threshold than specified by the ANHDD; STIR specifies a fever >38.5°C or a change of 1.5°C above baseline (this STIR definition matches that of the New Zealand Blood National Haemovigilance Programme). This results in FNHTR incidents that are reportable to the national haemovigilance program being screened out by STIR.

There are often clinically confounding factors that complicate diagnosis and reporting of FNHTR. Examples are developed in the case studies below. Fever may also accompany other acute transfusion reactions, including acute haemolytic transfusion reactions, infusion of a bacterially contaminated blood component or TRALI and the diagnosis of FNHTR is generally a diagnosis of exclusion requiring a flexible approach.

33 Tobian AA, King KE, Ness PM. Transfusion premedications: a growing practice not based on evidence. *Transfusion* 2007; 47 pp1089-1096.

Difficulties with diagnoses and the burden of reporting for this common event may justify higher reporting thresholds. The ISBT suggests that for the purpose of international comparisons, only the most severe cases of FNHTR should be reported (fever [$>39^{\circ}\text{C}$ oral or equivalent and a change of $>2^{\circ}\text{C}$ from pre-transfusion value; chills/rigors). The following case studies illustrate the difficulties diagnosing FNHTR. The HAC will continue to consider the appropriate definition in order to provide guidance and greater consistency throughout Australia.

> CASE STUDY 1

Severe Febrile Non Haemolytic Transfusion Reactions (FNHTR) are defined as fever $>38^{\circ}\text{C}$ or change or $>1^{\circ}\text{C}$ from pre-transfusion level; chills; cold; rigor and other symptoms of discomfort. A female patient presented with a diagnosis of breast cancer with lung metastases; cystitis and cellulitis of the breast. Wound swabs of the breast wound confirming MRSA. This patient was for palliative care.

Pretesting: Hb 93, plat 526, WCC15.1, CRP155.4, at 1710hrs.

Vital signs recorded: Temp 37.7°C ; HR 101; BP 98/64

Patient transfused 1 unit RBC at 1910.

Vital signs at 2300hrs Temp 38.7°C ; HR 106; BP 100/65

A 1 degree temperature spike was identified with no other significant changes in the patient's clinical picture. This was not identified as a possible transfusion reaction by ward staff and was noted in the clinical record No Reaction Observed or Reported by Patient. The transfusion nurse identified this as a possible FNHTR as part of the haemovigilance review.

The patient was known to have an ongoing sepsis and was receiving multiple Intravenous (IV) antibiotics. Patient blood cultures were attended to monitor ongoing sepsis but not as a result of possible transfusion work up and the culture recorded No Growth at 48hrs. The RBC unit was not returned for culture. However, the patient was changed to another broad spectrum IV antibiotic.

This raises a number of questions for practitioners to consider:

- Was the temperature spike related to the transfusion or the patients known sepsis?
- Why wasn't the patient reviewed in light of a possible transfusion reaction at the time of transfusion?
- Should this be reported as a Severe FNHTR?

> CASE STUDY 2

An elderly female presented with one month of worsening exertional dyspnoea on a background of CCF and iron deficiency anaemia (which was noted to need further investigation).

Co morbidities included: Type II Diabetes Mellitus, Hypertension, obesity and gastro-oesophageal reflux disease. Investigations showed microcytic anaemia with Hb 59, Plat 319, WCC 17.9, CRP 32.8, Ferritin 8, Transferrin 3.5, and Serum Iron 4. She was transfused 4 units of RBC and Ferrin H 1gm in 500mls Normal Saline. During the 4th unit of RBC (only 20ml of the RBC unit was transfused) the transfusion was ceased due to a 0.2°C spike in temperature.

Pre-transfusion vital signs at 2010hrs: Temp 37.8°C; HR 105; BP 126/70.

Observations at 2020hrs when Transfusion stopped: Temp 38.0°C; HR 94; BP 140/80.

The patient denied sweating, rigors, and chest pain. The patient continued to register a temperature of 38.1°C until 0600hrs the next day. Patient blood cultures were attended which recorded No Growth at 48hrs, however no additional post transfusion testing was requested. The medical officer reviewing the patient documented that the transfusion could continue, to administer paracetamol, to monitor patient for chills and rigors and if they presented to stop the transfusion and have the patient reviewed. As the 4th unit had already been breached and discarded, no further transfusions were administered.

This raises a number of questions for practitioners to consider:

- Should this be reported as a Severe FNHTR?
- Was this appropriate management of this patient?
- Would nursing staff identify this as a possible transfusion reaction in most circumstances?

8 ALLERGIC REACTIONS (SEVERE)

DATA SUMMARY (N=87)					
AGE	GENDER		DAY OF TRANSFUSION		
0-4 years	4	Male	45	Week day	65
5-14 years	13	Female	38	Weekend	21
15-24 years	10	Uncategorised	4	Unknown	1
25-34 years	3				
35-44 years	3	FACILITY LOCATION		TIME OF TRANSFUSION	
45-54 years	12	Major City		79	Between 7am and 7pm
55-64 years	7	Inner Regional		2	Between 7pm and 7am
65-74 years	14	Outer Regional		5	Unknown
75+ years	19	Remote		-	
Not specified	2	Very Remote		-	
CLINICAL OUTCOME SEVERITY	IMPUTABILITY		BLOOD PRODUCT		
Outcome not available	17	Excluded		1	Whole blood
No morbidity	29	Unlikely / Possible		26	Red cells
Minor morbidity	16	Likely / Probable		53	Platelets
Severe morbidity	8	Confirmed / Certain		5	Fresh Frozen Plasma
Life threatening	16	N/A / Not assessable		2	Cryoprecipitate
Death	1				Cryo-depleted

Allergic reactions (see Appendix II: Definitions in haemovigilance) are the second most common transfusion related adverse event in the national dataset. There were 87 allergic reactions reported. Of these, 24 were associated with severe morbidity or life threatening severity, and 1 incident was likely/probably linked to the death of a patient. Table 12 details the clinical outcome severity of the reported cases by their imputability.

TABLE 12 – Severe allergic reaction clinical outcome severity by imputability

CLINICAL OUTCOME SEVERITY	IMPUTABILITY				
	EXCLUDED	UNLIKELY / POSSIBLE	LIKELY / PROBABLE	CONFIRMED / CERTAIN	N/A / NOT ASSESSABLE
Outcome not available	-	1	16	-	-
No morbidity	-	13	16	-	-
Minor morbidity	-	2	9	5	-
Severe morbidity	-	2	6	-	-
Life threatening	1	8	5	-	2
Death	-	-	1	-	-

Allergic reactions may include urticaria (hives), oedema, pruritis, and angioedema. Urticarial reactions are presumably due to soluble antigens in the donor unit to which the recipient has been previously sensitised, and are typically dose dependent. These reactions have historically been estimated to occur in 1%–3% of transfusions. Leukoreduction has no effect on decreasing these rates³⁴, suggesting that cytokines released from white blood cells during storage are likely not responsible. Unless the patient has a history of transfusion related severe allergic reactions, these incidents cannot be foreseen.

Allergic reactions are a common complication of blood transfusion. The management depends on the severity of the reaction, and sometimes consideration of other causes, e.g. anti-IgA antibodies, latex or drug allergy, may be required. An important step in minimising a patient's exposure to these allergic complications is by ensuring that patients only receive appropriate blood transfusions. There are many studies that have documented a high rate of inappropriate transfusions both nationally and internationally. The following case studies illustrate the clinical presentation of transfusion related severe allergic reactions.

34 Uhlmann EJ, Isgriggs E, Wallhermfechtel M, Goodnough LT. Prestorage universal WBC reduction of RBC units does not affect the incidence of transfusion reactions. *Transfusion* 2001; 41 pp997–1000.

> CASE STUDY 1

A female patient received two units of red cells post-operatively. During the second unit she complained of itchiness over both arms, which then spread over her back and finally to the rest of her body.

A red rash, with a few hives, then developed and she complained of a 'burning tongue'. Examination of the tongue revealed no swelling. There was no alteration in her blood pressure, pulse and oxygen saturations during or after the reaction. She was given an oral antihistamine, and the symptoms resolved within 2 hours. No investigations were performed.

> CASE STUDY 2

A male patient received a pool of platelets for chemotherapy induced thrombocytopenia. During the transfusion he developed an urticarial rash, pruritus and shortness of breath.

His blood pressure fell from 120/70 to 96/45 and his pulse increased from 86 to 138. He remained afebrile and his oxygen saturations did not drop. Both an antihistamine and intravenous hydrocortisone were administered. Investigations revealed negative blood cultures and a normal chest X-ray. His symptoms resolved within 3 hours.

9 ANAPHYLACTIC AND ANAPHYLACTOID REACTIONS

DATA SUMMARY (N=8)					
AGE	GENDER		DAY OF TRANSFUSION		
0–4 years	-	Male	3	Week day	6
5–14 years	-	Female	4	Weekend	1
15–24 years	1	Uncategorised	1	Unknown	1
25–34 years	-				
35–44 years	2	FACILITY LOCATION	TIME OF TRANSFUSION		
45–54 years	1	Major City	7	Between 7am and 7pm	6
55–64 years	2	Inner Regional	-	Between 7pm and 7am	-
65–74 years	1	Outer Regional	-	Unknown	2
75+ years	-	Remote	-		
Not specified	1	Very Remote	-		
CLINICAL OUTCOME SEVERITY	IMPUTABILITY		BLOOD PRODUCT		
Outcome not available	1	Excluded	-	Whole blood	-
No morbidity	3	Unlikely / Possible	-	Red cells	1
Minor morbidity	1	Likely / Probable	2	Platelets	2
Severe morbidity	-	Confirmed / Certain	1	Fresh Frozen Plasma	2
Life threatening	3	N/A / Not assessable	5	Cryoprecipitate	-
Death	-			Cryo-depleted	1

Anaphylaxis is an acute hypersensitivity reaction that can present as, or rapidly progress to, a severe life threatening reaction³⁵. Anaphylactoid reactions are clinically indistinguishable, but differ from anaphylaxis by their immune mechanism. A distinction between anaphylaxis and anaphylactoid reaction is impossible on the basis of clinical signs and symptoms alone; a clinical definition cannot differentiate between the two.

35 Rüggeberg JU, Gold MS, Bayas J-M, Blum MD, Bonhoeffer J, Friedlander S, et al. Anaphylaxis: Case definition and guidelines for data collection, analysis, and presentation of immunization safety data. *Vaccine* 2007; 25(31): pp5675-5684.

This position is consistent with recent suggestions for a revised nomenclature for allergy, issued by the European Association for Allergy and Clinical Immunology (EAACI) and the World Allergy Organisation, referring to anaphylactoid reactions simply as 'non-allergic anaphylaxis'³⁶.³⁷ Diagnosis of anaphylactic and anaphylactoid reactions can be difficult, and an international symposium recently acknowledged that a widely accepted definition of anaphylaxis is lacking, and this contributes to the wide variation in standards of diagnosis and management³⁸.

There were 8 reports to the national haemovigilance program, with 3 reporting life threatening severity. The cases were linked with transfusion of red blood cells, platelets, fresh frozen plasma and with cryo-depleted plasma.

36 Johansson SG, Hourihane JO, Bousquet J, Brujnzeel-Koomen C, Dreborg S, Haahtela T, et al. A revised nomenclature for allergy. An EAACI position statement from the EAACI nomenclature task force. *Allergy* 2001; 56(9) pp813-824.

37 Johansson SG, Bieber T, Dahl R, Friedmann PS, Lanier BQ, Lockey RF, et al. Revised nomenclature for allergy for global use: Report of the Nomenclature Review Committee of the World Allergy Organization, October 2003. *Journal of Allergy and Clinical Immunology* 2004; 113(5) pp832-836.

38 Sampson HA, Munoz-Furlong A, Bock SA, Schmitt C, Buss R, Chowdhury BA, et al. Symposium on the definition and management of anaphylaxis: summary report. *Journal of Allergy and Clinical Immunology* 2005; 115(3) pp584-591.

10 ACUTE HAEMOLYTIC TRANSFUSION REACTIONS (OTHER THAN ABO INCOMPATIBILITY)

DATA SUMMARY (N=7)					
AGE	GENDER		DAY OF TRANSFUSION		
0-4 years	-	Male	4	Week day	7
5-14 years	-	Female	3	Weekend	-
15-24 years	1	Uncategorised	-	Unknown	-
25-34 years	1				
35-44 years	-	FACILITY LOCATION	TIME OF TRANSFUSION		
45-54 years	1	Major City	7	Between 7am and 7pm	4
55-64 years	2	Inner Regional	-	Between 7pm and 7am	3
65-74 years	1	Outer Regional	-	Unknown	-
75+ years	1	Remote	-		
Not specified	-	Very Remote	-		
CLINICAL OUTCOME SEVERITY	IMPUTABILITY		BLOOD PRODUCT		
Outcome not available	1	Excluded	-	Whole blood	-
No morbidity	4	Unlikely / Possible	2	Red cells	7
Minor morbidity	-	Likely / Probable	2	Platelets	-
Severe morbidity	-	Confirmed / Certain	1	Fresh Frozen Plasma	-
Life threatening	2	N/A / Not assessable	2	Cryoprecipitate	-
Death	-			Cryo-depleted	-

Acute transfusion reactions occur within 24hrs of transfusion, excluding reactions related to other causes e.g. incorrect component transfused, haemolytic reactions, transfusion-related acute lung injury (TRALI), transfusion associated circulatory overload (TACO), etc. A diagnosis of acute haemolytic transfusion reaction can be difficult, as reactions are often seen in patients with concurrent illnesses that may have other causes for their symptoms.

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

There were 7 reports to the national haemovigilance program, with 2 cases reporting life threatening severity imputed to be likely/probable and confirmed/certain. All cases were linked with transfusion of red blood cells. The national haemovigilance program does not yet gather data on antibodies associated with haemolytic transfusion reactions. Data from more mature haemovigilance systems suggest that this category of transfusion related reactions is currently under reported.

11 DELAYED HAEMOLYTIC TRANSFUSION REACTIONS (DHTR)

DATA SUMMARY (N=4)					
AGE		GENDER		DAY OF TRANSFUSION	
0–4 years	-	Male	-	Week day	3
5–14 years	-	Female	4	Weekend	1
15–24 years	-	Uncategorised	-	Unknown	-
25–34 years	-				
35–44 years	-	FACILITY LOCATION		TIME OF TRANSFUSION	
45–54 years	-	Major City	4	Between 7am and 7pm	2
55–64 years	2	Inner Regional	-	Between 7pm and 7am	2
65–74 years	2	Outer Regional	-	Unknown	-
75+ years	-	Remote	-		
Not specified	-	Very Remote	-		
CLINICAL OUTCOME SEVERITY		IMPUTABILITY		BLOOD PRODUCT	
Outcome not available	-	Excluded	-	Whole blood	-
No morbidity	4	Unlikely / Possible	-	Red cells	1
Minor morbidity	-	Likely / Probable	-	Platelets	3
Severe morbidity	-	Confirmed / Certain	2	Fresh Frozen Plasma	-
Life threatening	-	N/A / Not assessable	2	Cryoprecipitate	-
Death	-			Cryo-depleted	-

In contrast to the acute haemolytic transfusion reactions, delayed haemolytic transfusion reactions (DHTR) are triggered by the production of antibodies (beyond the ABO system) post transfusion and therefore is not detectable at the time of pre-transfusion compatibility testing.

DHTR are relatively common following blood transfusions, but may be difficult to diagnose and easily missed as presentation may be remote (in time and place) from the causal transfusion. UK data reported the interval in days between the implicated transfusion and clinical signs or symptoms of a DHTR to have a median of 8 days with a range of 2 to 18 days.

There were 4 DHTR reported to the national haemovigilance program. No cases were associated with patient morbidity. The national haemovigilance program does not yet gather data on antibodies associated with haemolytic transfusion reactions.

UK data has suggested that DHTR were responsible for 10.2% of all serious transfusion-related hazards between 1996 and 2003³⁹. Researchers have observed that DHTR are probably under-reported and under-recognised in the UK⁴⁰. The current figures for Australia imply that DHTR may be severely under-recognised and/or under-reported.

39 Stainsby D, Knowles SM, Milkins C, Jones H, Cohen H. Can haemolytic transfusion reactions be avoided by better transfusion practice? *Vox Sanguinis* 2005; 89 (Suppl. 1) pp14.

40 Milkins C, Knowles S, DeSilva M, Contreras M, Stainsby D. INTERNATIONAL FORUM Prevention and diagnosis of delayed haemolytic transfusion reactions. *Vox Sanguinis* 2006; 91 pp365–367.

12 TRANSFUSION-ASSOCIATED CIRCULATORY OVERLOAD (TACO)

DATA SUMMARY (N=6)					
AGE		GENDER		DAY OF TRANSFUSION	
0–4 years	-	Male	2	Week day	2
5–14 years	-	Female	1	Weekend	1
15–24 years	-	Uncategorised	3	Unknown	3
25–34 years	-				
35–44 years	-	FACILITY LOCATION		TIME OF TRANSFUSION	
45–54 years	-	Major City	1	Between 7am and 7pm	2
55–64 years	-	Inner Regional	1	Between 7pm and 7am	-
65–74 years	1	Outer Regional	1	Unknown	4
75+ years	2	Remote	-		
Not specified	3	Very Remote	-		
CLINICAL OUTCOME SEVERITY		IMPUTABILITY		BLOOD PRODUCT	
Outcome not available	4	Excluded	-	Whole blood	-
No morbidity	1	Unlikely / Possible	1	Red cells	2
Minor morbidity	-	Likely / Probable	2	Platelets	-
Severe morbidity	-	Confirmed / Certain	-	Fresh Frozen Plasma	1
Life threatening	-	N/A / Not assessable	3	Cryoprecipitate	-
Death	1			Cryo-depleted	-

Transfusion of significant volumes of blood products to patients with reduced cardiopulmonary regulation capacity (children and adults with cardiopulmonary disease) can lead to overload of the circulatory system, termed transfusion associated circulatory overload (TACO). Patients at the highest risk for TACO include those younger than 3 and those older than 60 years of age, particularly those with underlying cardiac dysfunction⁴¹. To avoid this complication, transfusion speed and volume must be monitored very carefully in these patients.

In 2008/09 there were 6 reports of TACO to the national haemovigilance program. There was 1 report associated with a patient's death, and this was assigned an imputability score of unlikely / possible. Patients were aged over 65 in the 3 reports that specified patient age.

TACO incidence estimates have ranged from one per approximately 3000 transfusions to 8% of transfusions depending upon patient population and reporting method⁴². These rates suggest that although TACO is a serious complication of transfusion, it remains largely under-recognised and under-reported. The reasons for the low numbers reported to date in Australia may relate to a combination of limited awareness by hospital staff of this problem, a lack of clinical recognition that this is a potentially serious problem, and issues relating to reporting within hospitals and subsequent reporting to jurisdictional and national haemovigilance programs. Increased recognition of TACO by clinical staff is needed to raise awareness and increase focus on this important and, in many cases, avoidable complication of blood transfusion.

41 Zhou L, Giacherio D, Cooling L, et al. Use of B-natriuretic peptide as a diagnostic marker in the differential diagnosis of transfusion associated circulatory overload. *Transfusion* 2005; 45 pp1056–1063.

42 Popovsky MA. Transfusion-associated circulatory overload. *ISBT Science Series* 2008; 3(1) pp166–169.

13 TRANSFUSION-RELATED ACUTE LUNG INJURY (TRALI)

DATA SUMMARY (N=3)					
AGE	GENDER		DAY OF TRANSFUSION		
0-4 years	-	Male	2	Week day	1
5-14 years	-	Female	-	Weekend	-
15-24 years	-	Uncategorised	1	Unknown	2
25-34 years	1				
35-44 years	-	FACILITY LOCATION	TIME OF TRANSFUSION		
45-54 years	-	Major City	1	Between 7am and 7pm	1
55-64 years	-	Inner Regional	-	Between 7pm and 7am	-
65-74 years	-	Outer Regional	1	Unknown	2
75+ years	-	Remote	-		
Not specified	2	Very Remote	-		
CLINICAL OUTCOME SEVERITY	IMPUTABILITY		BLOOD PRODUCT		
Outcome not available	1	Excluded	-	Whole blood	-
No morbidity	-	Unlikely / Possible	-	Red cells	1
Minor morbidity	-	Likely / Probable	2	Platelets	-
Severe morbidity	-	Confirmed / Certain	-	Fresh Frozen Plasma	1
Life threatening	2	N/A / Not assessable	1	Cryoprecipitate	-
Death	-			Cryo-depleted	-

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

The incidence of TRALI is unknown, because a standard definition⁴³ has not been available until recently. Early reports quoted an incidence of 1 per 5000 transfused blood components⁴⁴, with subsequent reports ranging from 1 per 432 pooled whole-blood-derived platelets to 1 per 557 000 RBCs⁴⁵.

43 Webert MA, Blajchman MA. Transfusion-related acute lung injury. *Current Opinion in Hematology* 2005; 12 pp480-487.

44 Popovsky MA, Moore SB. Diagnostic and pathogenetic considerations in transfusion-related acute lung injury. *Transfusion* 1985; 25 pp573-577.

45 Kleinman S, Caulfield T, Chan P, et al. Toward an understanding of transfusion-related acute lung injury: statement of a consensus panel. *Transfusion* 2004; 44 pp1774-1789.

TRALI is a significant cause of mortality and morbidity in patients who receive blood products, particularly plasma containing products. With the decrease in the risk of transfusion transmitted HIV, HCV and bacterial contamination, TRALI has become the leading cause of transfusion-related mortality reported to the US Food and Drug Administration (FDA). Data from the FDA for 2005 and 2006 TRALI accounted for 56% of transfusion related deaths.

The 2008/09 data contains 3 reports for TRALI, with 2 reports associated with life threatening severity both of which were assigned imputability scores of likely / probable.

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

The following case study illustrates the difficulties associated with diagnosing TRALI. It has been suggested that TRALI is an under reported disorder, and this is likely due to difficulty with diagnosis and the complex co-morbidities usually associated with acute lung injuries.

> CASE STUDY 1

A 55 year old male on the high dependency unit was prescribed FFP. The patient was fully conscious and receiving 30% inspired oxygen to maintain his oxygen saturations at 95%. Within 15 minutes of starting the FFP the oxygen saturations fell to 48%.

This was associated with an increase in body temperature by 1°C and rigors. The patient was reviewed promptly and received hydrocortisone. It took 10 hours for the oxygen saturations and inspired oxygen requirements to return to the pre-FFP levels. Blood cultures were taken and subsequently found to be negative. No chest X-ray (CXR) was performed at the time of the reaction. However, 'routine' CXRs performed on the morning before and after the reaction revealed no abnormalities pre-reaction, but diffuse patchy infiltrates 10 hours after the reaction. No other investigations were performed.

Was this a case of transfusion associated lung injury (TRALI)? Unfortunately, this diagnosis was not considered and appropriate laboratory investigations were not undertaken. However, the clinical picture is highly suggestive of TRALI.

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

Early recognition allows the transfusion to be stopped immediately and commencement of oxygen and supportive therapy. As the underlying pathology involves microvascular injury, use of diuretics may be detrimental and some patients benefit from fluid administration. Recognising TRALI allows notification of the Blood Service and testing of the blood component and/or donor for anti-HLA and anti-granulocyte antibodies.

Donors of blood products implicated in cases of TRALI often contain anti-leukocyte allo-antibodies (anti-HLA and anti-granulocyte) that are thought to be important in the pathogenesis of TRALI in a significant number of cases. Recognition of these donors by the Blood Service allows appropriate exclusion of implicated blood products.

14 TRANSFUSION TRANSMITTED INFECTIONS (TTI)

DATA SUMMARY (N=3)					
AGE		GENDER		DAY OF TRANSFUSION	
0-4 years	-	Male	1	Week day	2
5-14 years	-	Female	1	Weekend	-
15-24 years	-	Uncategorised	1	Unknown	1
25-34 years	1				
35-44 years	-	FACILITY LOCATION		TIME OF TRANSFUSION	
45-54 years	-	Major City	2	Between 7am and 7pm	2
55-64 years	-	Inner Regional	-	Between 7pm and 7am	-
65-74 years	-	Outer Regional	-	Unknown	1
75+ years	1	Remote	-		
Not specified	1	Very Remote	-		
CLINICAL OUTCOME SEVERITY		IMPUTABILITY		BLOOD PRODUCT	
Outcome not available	1	Excluded	1	Whole blood	-
No morbidity	1	Unlikely / Possible	1	Red cells	1
Minor morbidity	-	Likely / Probable	-	Platelets	1
Severe morbidity	-	Confirmed / Certain	-	Fresh Frozen Plasma	-
Life threatening	1	N/A / Not assessable	1	Cryoprecipitate	-
Death	-			Cryo-depleted	-

The national haemovigilance program allows the reporting of four distinct transfusion transmitted infection categories:

- Transfusion transmitted infections - Bacterial
- Transfusion transmitted infections - Viral
- Transfusion transmitted infections - Parasitic
- Transfusion transmitted infections - Other (e.g. vCJD).

The 2008/09 data contains 3 reports for transfusion transmitted infections (TTI), all of which related to bacterial infections. There was 1 report associated with life threatening severity and this was assigned an imputability score of unlikely / possible.

In Australia, the mandatory tests for all blood donations are for ABO and Rh(D) blood groups, red cell antibodies, and the following infections: human immunodeficiency virus (HIV) 1 and 2, hepatitis B and C, human T-cell lymphotropic virus (HTLV) I and II, and syphilis. Test results are checked before blood components are released for clinical use or further manufacture. Only donations that have satisfactory blood group results, are non-reactive for infectious disease screening and meet other defined specifications are released. If an infectious disease screening test is confirmed reactive, the donation is destroyed.

The viral risk estimates presented in Table 13 have recently been revised based on Blood Service data from 1 January 2007 to 31 December 2008. These estimates are updated annually. The risk of viral TTI in Australia is exceedingly low (for comparisons see Table 9 - The Calman Chart for explaining risk).

TABLE 13 – ARCBS Residual risk estimates for transfusion-transmitted infections

AGENT AND TESTING STANDARD	WINDOW PERIOD (DAYS)	ESTIMATE OF RESIDUAL RISK 'PER UNIT'
HIV (antibody + NAT)	9	Approximately 1 in 5.4 million
HCV (antibody + NAT)	5.4	Approximately 1 in 2.7 million
HBV (HBsAg)	38	Approximately 1 in 739,000
HTLV I & II (antibody)	51	Approximately 1 in 17.5 million
Variant Creutzfeldt-Jakob Disease (vCJD) [No testing]		Possible. Not yet reported in Australia.
Malaria (antibody)	N/A	1 in 4.9 million to 1 in 10.2 million

HIV, HCV, HBV risk estimates are based on ARCBS data from 1 January 2007 to 31 December 2008
HTLV risk estimate based on data from 1 January 2004 to 31 December 2008.

Currently, the risks of bacterial TTI⁴⁶ are significantly greater those of viral TTI from screened agents. This trend is also apparent in recent data from the Serious Hazards of Transmission (SHOT UK) reports, the French Haemovigilance system and US FDA fatality reports⁴⁷.

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

In Australia, the major components of the management strategies for TTI include the pre-donation questionnaire, to identify factors associated with TTI risk, and screening for antibody, antigen and viral nucleic acids.

In April 2008, the Blood Service commenced pre-release screening of 100% of platelet components. Worldwide, bacterial contamination of platelet components is recognised as the most significant residual infectious risk of blood transfusion in developed countries. As a cause of death from transfusion, bacterial sepsis is second only to ABO incompatibility. The addition of bacterial contamination screening is a significant step in further improving the safety of the blood supply.

In the event that a unit of platelets to be transfused is potentially contaminated with bacteria (initial machine positive (IMP) notification), clinicians are contacted so that the clinical condition of the patient can be urgently appraised. Around 50% IMP notifications will be found to be false positive (i.e. no bacteria confirmed). Difficulties in reporting TTI are noted when transfused patients are asymptomatic, or display possible symptoms that are clinically managed with rapid initiation of broad spectrum intravenous antibiotics. Such clinical interventions may pre-emptively destroy proof that a patient is infected, confounding reporting of the incident.

When the Blood Service recalls suspect blood products the TGA are notified regarding the recalled items, their fate and any clinical follow-up done with the patient.

46 Wagner SJ. Transfusion-Transmitted Bacterial Infection: Risks, Sources and Interventions. *Vox Sanguinis* 2004; 86 pp157-63.

47 Fatalities Reported to FDA Following Blood Collection and Transfusion, Annual Summary for Fiscal Year 2009. Food and Drug Administration, US. <http://www.fda.gov/BiologicsBloodVaccines/SafetyAvailability/ReportaProblem/TransfusionDonationFatalities/ucm113649.htm>

15 INCORRECT BLOOD COMPONENT TRANSFUSED (IBCT)

DATA SUMMARY (N=22)					
AGE	GENDER		DAY OF TRANSFUSION		
0–4 years	2	Male	12	Week day	15
5–14 years	-	Female	10	Weekend	2
15–24 years	-	Uncategorised	-	Unknown	5
25–34 years	4				
35–44 years	-	FACILITY LOCATION	TIME OF TRANSFUSION		
45–54 years	1	Major City	12	Between 7am and 7pm	12
55–64 years	3	Inner Regional	2	Between 7pm and 7am	2
65–74 years	5	Outer Regional	8	Unknown	8
75+ years	7	Remote	-		
not specified	-	Very Remote	-		
CLINICAL OUTCOME SEVERITY	IMPUTABILITY		BLOOD PRODUCT		
Outcome not available	2	Excluded	-	Whole blood	-
No morbidity	17	Unlikely / Possible	-	Red cells	14
Minor morbidity	2	Likely / Probable	-	Platelets	1
Severe morbidity	-	Confirmed / Certain	21	Fresh Frozen Plasma	3
Life threatening	1	N/A / Not assessable	1	Cryoprecipitate	-
Death	-			Cryo-depleted	-

Incorrect blood component transfused (IBCT) occurs when a patient receives a blood product intended for another patient or a blood product where special requirements (e.g. CMV-negative or irradiated product) are not met.

In common with other types of event, IBCT represents failure of the system, which needs to be identified and subsequently corrected to prevent similar events happening in the future. Reporting of these events may occur through a hospital's quality or incident management system and therefore not come to the attention of the blood bank. It is important that all such incidents or events are reported through local processes, which are likely to include reporting to the blood bank.

In 2008/09 there were 22 reports of IBCT to the national haemovigilance program, with 1 report associated with life threatening severity. Incidence was independent of patient age and gender, blood product, facility location, and day and time of transfusion; all data fell within expected distributions. Almost all, 21 of the 22 reported cases, had an imputability score of confirmed/certain.

Historically, errors at the time of administration of blood or blood components are the most frequent documented site of error that result in incorrect blood component transfused^{48,49}. However, other errors that precede the administration of a blood product such as errors in patient blood sampling, laboratory procedures and withdrawal of blood components from storage refrigerators have also been reported as important contributory factors in many IBCT incidents⁵⁰. It is unfortunate that these trends have not yet been reversed and are still common, even in countries with mature haemovigilance systems⁵¹.

Collecting near miss data is an effective means of highlighting human and system failures associated with transfusion that may otherwise go unnoticed. These data can be used to identify areas where resources need to be targeted in order to prevent future harm to patients, improving the overall safety of transfusion.

Table 14 summarises the contributory factors (see Definitions for contributory factors in Appendix II: Definitions in haemovigilance) cited for IBCT cases reported to the national haemovigilance program in 2008/09.

TABLE 14 – Contributory factors cited in IBCT

CONTRIBUTORY FACTOR	NUMBER OF REPORTS
None identified	-
Product characteristic	3
Transfusion in emergency setting	-
Deliberate clinical decision	5
Prescribing/ordering	13
Specimen collection/labelling	7
Laboratory (testing/dispensing)	8
Transport, storage,	3
Administration of product	5
Indications do not meet guidelines	6
Procedure did not adhere to facility transfusion guidelines	2
Other	4

48 McClelland DBL, Phillips P. Errors in blood transfusion in Britain: survey of hospital haematology departments. *British Medical Journal* 1994; 308 pp1205-1206.

49 Sazama, K. Reports of 355 transfusion associated deaths: 1976 through 1985. *Transfusion* 1990; 30 pp583-590.

50 Serious Hazards of Transfusion (SHOT) Annual Report 1996-1997. SHOT, National Blood Service, National Health Service, UK. www.shotuk.org

51 Annual Haemovigilance Report 2008. Agence Francaise de Securite Sanitaire des Produits de Sante (AFSSAPS), France. <http://www.afssaps.fr/Afssaps-media/Publications/Information-in-english>

Table 14 indicates a broad range of factors in the 2008/09 data that contributed to IBCT, however, it cannot be overemphasised that the final barrier to the administration of an incorrect blood component to a patient is at the bedside during the processes of prescribing as well as the intravenous administration of blood and blood products. Although there are a number of guidelines produced that recommend, in detail, the procedures for pre-transfusion bedside checks (e.g. ANZSBT Guidelines for administration of blood components⁵²) the problem still remains.

Haemovigilance data and clinical studies cite three major areas of error that jeopardise safe transfusion: (i) accurate patient identification and proper labelling of pre-transfusion specimens; (ii) appropriate decision making regarding the clinical use of blood components; and (iii) accurate bedside verification that the correct blood is to be given to the intended recipient. The SHOT scheme showed that approximately 70% of IBCT event errors take place in clinical areas, the most frequent error being failure of the final patient ID check at bedside.

There are electronic systems that can increase compliance in pre-transfusion sampling and administration, and reduce the risk of human error^{53 54}. It was a recommendation of the Initial Australian Haemovigilance Report 2008 that the HAC 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.

The use of such systems should be encouraged; however, where this is currently not feasible, strict adherence to correct procedure for patient identification will mitigate errors both at pre-transfusion sampling and at the final bedside check prior to administration of the blood product.

52 Guidelines for the administration of blood components 2004. Australian & New Zealand Society of Blood Transfusion, Sydney. <http://www.anzsb.org.au/>

53 New technology for transfusion safety. Dzik WH. *British Journal of Haematology* 2007; 136(2) pp181-190.

54 A computer-assisted transfusion management system and changed transfusion practices contribute to appropriate management of blood components. Ohsaka A, Abe K, Ohsawa T, Miyake N, Sugita S, Tojima I. *Transfusion* 2008; 48(8) pp1730-1738.

The following case studies illustrate the errors typically found in IBCT cases.

> CASE STUDY 1

An elderly male receiving Fludaribine for non-Hodgkin's lymphoma should have been receiving irradiated blood products to prevent possible transfusion associated graft versus host disease (TA-GVHD). However, the request forms sent to the blood bank failed to contain the information that the patient required irradiated blood products and the patient received 10 units of non-irradiated red blood cells.

The need for irradiated blood had been placed on the patient's laboratory file as a 'flag' to remind laboratory staff to select irradiated blood. However, the patient's care was transferred to another hospital and the flag indicating the need for irradiated blood did not automatically transfer between the laboratory information systems.

The request form and prescription should indicate the need for irradiated blood each time blood products are requested. This is the responsibility of the staff requesting the blood components. Patient groups who require irradiated blood products are given in the national ANZSBT guidelines. The IT laboratory system flag serves as an additional check to remind laboratory staff to issue irradiated blood. However, such 'flags' may not be transferred between blood bank laboratories at different hospitals, so it is important that medical staff ensure their local blood bank staff are aware of these special requirements. TA-GVHD has been associated with use of red cells, platelets and whole blood, but not fresh frozen plasma or cryoprecipitate. If TA-GVHD develops the mortality is high (90%).

Good communications between laboratories in different transfusion facilities are vital for safe and efficient patient care. Ideally laboratory information systems shared by transfusion facilities should be electronically linked. The introduction and proper implementation of an Individual Healthcare Identifier in Australia may contribute to better communication and interoperability between healthcare organisations and providers. It is ultimately the responsibility of the clinical care team to ensure full and proper handover of a patient and their clinical records.

> CASE STUDY 2

An elderly male presented with 3 days of bright rectal bleeding, increasing lethargy and dyspnoea on exertion. Blood samples were drawn for FBE, Urea and Electrolytes, LFTs, and a Blood Group, screen and 2 unit crossmatch. Test results from these blood samples showed Hb 92 g/L and Blood Group O Rh(D) Positive. 2 Units of O Rh(D) Positive RBCs were crossmatched for the patient and placed in the blood fridge in the laboratory. The attending physician decided that transfusion was not indicated at this stage, and the patient was admitted for further investigation and management.

12 hours following admission the patient had a further large rectal bleed estimated by nursing staff to be 1000ml, and became hypotensive and tachycardic. Following urgent review the patient was transfused with the 2 units of the already crossmatched O Rh(D) Positive RBCs and taken to theatre for urgent colonoscopy.

On arrival in theatre, blood was drawn for an urgent repeat FBE and an urgent further 4 unit crossmatch. The blood group of this new sample provided was A Rh(D) Positive. Previous testing had shown blood group O Rh(D) Positive. An urgent re-bleed of the patient was requested. The results of testing of this sample confirmed that the blood group of the patient was Group A Rh(D) Positive. 4 units of A Rh(D) Positive RBCs were crossmatched and transfused over a 12 hour period.

On investigation of this incident it was revealed that the nurse drawing the initial blood samples was unable to obtain enough blood for all the tests requested, and asked the doctor to draw the sample for the Group and crossmatch. The patient's identity was not confirmed by the doctor at the time the sample was taken, and the sample was labelled at the main work station from the patient details on the request form, not by the patient at the bedside. When received in the hospital laboratory both the sample and request form conformed to the laboratory's pre-transfusion labelling requirements. The patient had not attended the Health Service previously, so there was no historical Blood Group recorded. The laboratory tested that first new sample and entered the results, including the patient's blood group (O Rh(D) Positive) in the Laboratory Information System. When the second crossmatch was requested and a new sample provided and tested, the potentially fatal error was discovered. The initial group and crossmatch sample was labelled with the intended recipient's details, but had been inadvertently drawn from another patient. As a result, the 2 units of Group O Rh(D) Positive RBCs were correctly crossmatched and issued by the laboratory, according to the information provided, but were transfused to the incorrect patient. By chance, the ABO and Rh(D) group of the transfused RBCs were compatible with the recipient and the patient suffered no adverse effects.

This case history reinforces the need for adherence to policy and procedural requirements; positive patient identification is a vital prerequisite for all pre-transfusion sampling, and sample labelling should occur at the bedside immediately after taking the sample. Education on the potential consequences of ABO incompatible transfusion should reinforce the need to adhere to these protocols.

However, other aspects of clinical practice highlighted by this case are the human factors involved. A recent detailed study of pre-transfusion sample collection errors showed that the majority involved doctors whereas phlebotomists were only involved in a small number⁵⁵. Provision of training and competence assessment of phlebotomy techniques for medical and all other staff involved in sample collection is routinely provided. However, extension of dedicated phlebotomy services could alleviate errors by doctors with a heavy clinical workload, particularly out of hours.

> CASE STUDY 3

A 65 year old female 48 hours post Total Hip Replacement (THR) was prescribed 2 units of RBCs on a background of ongoing blood loss, ischaemic heart disease, and a now decreased Hb 87g/L (previous day 92g/L.)

The orthopaedic Resident Medical Officer completed the crossmatch request form at 1330 hours and at 1430 hours the nurse caring for the patient drew and labelled the sample for crossmatch. The sample was taken to the laboratory by the ward assistant and the requested units crossmatched and placed in the blood fridge at 1630 hours.

At 2030 hours the patient complained of central chest pain and a medical review of the patient was requested by the nurse in charge. The reviewing doctor noted the morning order for the 2 unit transfusion in the patient's medical record and asked the nurse caring for the patient what time the transfusion had been given. The prescribed transfusion had not been given. The attending doctor then requested that the transfusion commence immediately.

The first unit was obtained from the laboratory and transported to the ward by an orderly at 2100 hours. At 2110 hours the night nurse (who has now taken over the care for this patient) administered the RBCs crossmatched and labelled for THR this patient to another THR patient in the adjacent bed. The error was discovered 15 minutes into the transfusion and then ceased, when the intended recipient again complained of chest pain. Fortunately both patients were Group O, Rh(D) positive, as was the unit issued and labelled for the first patient.

On reviewing the circumstances around this significant transfusion incident it was revealed that the nurse who drew and labelled the crossmatch sample did not hand over the first patient's transfusion requirement plan to the evening nurse taking over. There was no information in the clinical notes on the transfusion request form to indicate urgency, so the laboratory, following local protocol, did not advise the ward when the crossmatched blood for the patient was first available to collect. The night staff had just commenced their shift and there were only 2 Registered Nurses rostered on the shift. They were busy with night medications and did not want to disturb other patients in the intended recipient's room, so checked the blood and paperwork at the nurses' station. Therefore, no identity of product against patient was undertaken at the bedside. The patient in the adjacent bed was of comparable age and had also undergone a THR.

55 Lundy D, Laspina S, Kaplan H, Rabin Fastman B, Lawlor E. Seven Hundred and Fifty-Nine (759) Chances to Learn a 3-year pilot project to analyse transfusion-related near-miss events in the Republic of Ireland. *Vox Sanguinis* 2007; 92(3) pp233-241.

Case Study 3 emphasises the importance of policy and procedural requirements for patient and product identification at the bedside. Human factors highlighted in this study emphasise communication for continuity of care between teams through complete and accurate clinical notes and records. This study also reinforces data⁵⁶ that transfusions overnight should be limited (due to poor lighting, lower staff-to-patient ratio, patients sleeping, reluctance to wake the patient in order to perform observations, or limited availability of medical staff). The SHOT (UK) system recommends that transfusions out of core hours should be avoided unless clinically essential. The UK National Comparative Audit of Overnight Red Blood Cell Transfusion⁵⁷, though, recognises that some transfusions overnight are essential and some transfusions occur for reasons that may not be deemed clinically essential, but are nonetheless acceptable always provided that patient safety is paramount.

Key strategies to avoid IBCT revolve around education:

- all facilities which transfuse patients should have a Transfusion Nurse / Haemovigilance Officer and a provision for access to a Transfusion Committee
- the Transfusion Committee should be supportive of a RCA approach in investigating IBCT and develop action plans to address adverse events
- the Transfusion Nurse / Committee should present regular feedback and updates on the analyses of IBCT and procedural errors to staff involved in the error or working in the area where the error occurred. It is vital to present real clinical scenarios to clinical staff, medical and nursing, so that
 - they can identify with the circumstances of the event; and they can develop an appreciation for the potential consequences including the possibility of a fatal outcome for the patient.

56 The Safe administration of blood transfusions at night. Stevenson T. Nursing Times 2007; 103(5) pp33.

57 National Comparative Audit of Overnight Red Blood Cell Transfusion. NHS (UK) 2008.

16 CONTRIBUTORY FACTORS

CONTRIBUTORY FACTORS	NUMBER OF REPORTS
None identified	162
Product characteristic	27
Transfusion in emergency setting	-
Deliberate clinical decision	8
Prescribing/ordering	69
Specimen collection/labelling	8
Laboratory (testing/dispensing)	13
Transport, storage, handling	3
Administration of product	7
Indications do not meet guidelines	11
Procedure did not adhere to facility transfusion guidelines	16
Other	8

The national haemovigilance program asks for data on factors contributing to each adverse event, where applicable (see Definitions for contributory factors in Appendix II: Definitions in haemovigilance). The categories defined seek to mirror key stages of the transfusion chain. It should be noted that these categories are not mutually exclusive and more than one contributory factor may be associated with an adverse event.

There were 162 reported transfusion associated adverse events in which there were no identified contributory factors. There were 92 adverse event reports (31% of reports) that cited one or more contributory factors that could have been avoided. These included prescribing/ordering, specimen collection/labelling, laboratory (testing/dispensing), transport, storage, handling, administration of product, or adverse events where the clinical indications for transfusion did not meet the facilities' transfusion guidelines or where the transfusion procedures did not adhere to the facilities' transfusion procedures.

The most cited contributory factor in the data was the prescribing/ordering process, occurring in 23% of adverse event reports (n=69). These avoidable errors can be mitigated through training, stringent application of standards and proficiency testing. This contributory factor was cited in; a TACO reaction (1 of 6), anaphylactoid or anaphylactic reactions (2 of 8), (4 of 7), incorrect blood component transfused (13 of 22), severe allergic reactions (20 of 87), and in severe febrile non-haemolytic transfusion reactions (29 of 154). Clinical outcome severities that had the prescribing/ordering process as a contributory factor included 1 case of patient death, 9 cases with life threatening severity, 2 cases with severe morbidity, 53 cases with no morbidity, and 4 cases where the outcome was not available.

Table 15 summarises the number of cited contributory factors by adverse event and by clinical outcome severity.

TABLE 15 – Contributory factors cited by adverse event, and by clinical outcome severity

	BY ADVERSE EVENT										BY CLINICAL OUTCOME SEVERITY				
	FNHTR	SEVERE ALLERGIC REACTION	IBCT	ANAPHYLACTIC / ANAPHYLACTOID	ACUTE HTR (NOT ABO)	TACO	DHTR	TTI BACTERIAL	TRALI	OUTCOME NOT AVAILABLE	NO MORBIDITY	MINOR MORBIDITY	SEVERE MORBIDITY	LIFE THREATENING	DEATH
None identified	100	51	-	1	2	2	4	2	-	64	68	7	9	13	1
Product characteristic	11	9	3	2	-	-	-	1	1	-	3	22	-	2	-
Transfusion in emergency setting	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Deliberate clinical decision	3	-	5	-	-	-	-	-	-	1	7	-	-	-	-
Prescribing/ordering	29	20	13	2	4	1	-	-	-	4	53	-	2	9	1
Specimen collection/labelling	-	1	7	-	-	-	-	-	-	-	6	1	-	1	-
Laboratory (testing/dispensing)	-	2	8	-	3	-	-	-	-	1	9	-	-	3	-
Transport, storage, handling	-	-	3	-	-	-	-	-	-	-	1	1	-	1	-
Administration of product	1	1	5	-	-	-	-	-	-	1	3	3	-	-	-
Indications do not meet guidelines	3	-	6	1	1	-	-	-	-	1	7	-	-	3	-
Procedure did not adhere to facility transfusion guidelines	10	2	2	2	-	-	-	-	-	1	10	1	-	4	-
Other	2	2	4	-	-	-	-	-	-	3	2	1	1	1	-

In 2004, a retrospective analysis⁵⁸ of data from the UK Serious Hazards of Transfusion (SHOT UK) scheme, reported a total of 1630 events of which 64% were errors in the transfusion process. In more recent data the, SHOT Annual Report 2008 reports that procedural errors (IBCT, inappropriate and unnecessary transfusion, handling and storage errors) represented 59% cumulative numbers of cases reviewed 1996-2008, n=5374. There are, of course, important differences between the Australian national data and UK data, most notably the UK inclusion of 'near miss' events in their national dataset. However, the SHOT data highlights the continuing difficulty of decreasing human error rates in the transfusion process.

Recent Australian data from the STIR program⁵⁹ were presented at the 12th International Haemovigilance Seminar. The data drew on 60 institutions in four jurisdictions (covering approximately 6.5 million people, 30% of the total Australian population) and reported that combined procedural adverse events, incorporating IBCT, wrong blood in tube and near miss events, accounted for 38% of all reports during the 2006/09 period.

Common themes relating to procedural events included:

- failure to comply with established patient identification procedures when collecting pre-transfusion samples
- over-representation of specimen labelling issues from some clinical areas, including wrong blood in tube events from emergency departments, and use of maternal labels on cord blood samples sent for blood grouping
- failure to identify patients at the bedside before transfusion administration
- transfusions administered out of hours
- problems with collection of units from satellite blood refrigerators (located outside the laboratory).

A supportive culture of adverse event reporting must be encouraged and maintained to promote candid reporting of such contributory factors. Australian data, in line with many other haemovigilance programs, shows that a significant proportion of adverse events may be avoidable by following established protocols and guidelines.

58 Stainsby D, Williamson L, Jones H, Cohen H. 6 Years of SHOT Reporting - Its Influence on UK Blood Safety. *Transfusion and Apheresis Science* 2004; 31 pp123-31.

59 Wood E, Stevenson L, Botting K, Cole-Sinclair M, Curcic S, Daly J, Glazebrook B, Magrin G, Maxwell E, Rogers R, Smith C, Waters N, Wilks D, McNicol L. Lessons about procedural adverse events in transfusion from the Serious Transfusion Incident Reporting (STIR) program, 2006-09. 12th International Haemovigilance Seminar. *Blood Transfusion* 2010; 8 [Suppl. 1] s45-s46.



PART SEVENTEEN.

KEY OBSERVATIONS AND RECOMMENDATIONS

- 17.1 KEY OBSERVATIONS - DATA
- 17.2 KEY OBSERVATIONS - CAPACITY
- 17.3 KEY OBSERVATIONS - PRESCRIBING
- 17.4 KEY OBSERVATIONS - PROCEDURAL ERRORS
- 17.5 KEY OBSERVATIONS - NATIONAL BLOOD QUALITY AND SAFETY INITIATIVES

17 KEY OBSERVATIONS AND RECOMMENDATIONS

17.1 Key Observations - Data

The quality of haemovigilance data in Australia has improved significantly since the Initial Haemovigilance Report 2008, in three key areas:

1. **Data Consistency:** The adoption by all jurisdictions of the ANHDD through the direction of the JBC has allowed amalgamation of data from multiple jurisdictions. The substantial efforts in all jurisdictions to work towards submission of data in accordance with the ANHDD have underpinned the quality of the national dataset
2. **Data Validity:** In addition to the consistency of the data, the validity of the data submitted has also improved. All jurisdictions have already developed, enhanced or have clear plans to establish a system to investigate and validate reports of transfusion reactions and events
3. **Data Completeness:** While substantial efforts have been made to improve the complete capture of serious adverse events and reactions for the national dataset, significant challenges remain to achieve this. For example, the current very low reporting rate of TACO and TRALI is of concern. Both of these events are likely under reported to the national dataset. Additionally, systems to capture haemovigilance data from the private sector require further development in most jurisdictions.

Important contextual data is also missing in the Australia blood sector.

For instance, it is not possible to ascertain the total number of units transfused as there are gaps in the data surrounding the fate of each issued product. It is not possible on a national basis to know how many units issued were not finally transfused, or the reason those units were not transfused. A proportion of issues are damaged or lost in transit. For a proportion of issues there is also 'accepted expiry' where slight surplus stocks are held because the clinical facility is a long distance from a distribution point, and there is a safety requirement to hold contingency stock. As further examples: an individual unit may be issued from a laboratory more than once; the rigorous cold chain requirements to ensure product integrity may also be increasing product loss. The business systems and resources are not in place across Australia for the complex tracking of blood products in the clinical setting.

Also, it is not possible at this time to determine nationally the total number of patients transfused in Australia over a particular timeframe. It is possible to determine how many units have been issued to a given hospital or private pathology provider, but that is where the national information trail ceases.

Until these two key pieces of information are directly accessible, blood sector analysis will be limited in its conclusions.

While the HAC made a purposeful decision to exclude near misses in the first iteration of the required dataset, to allow states and territories time to work towards establishment and embedding of their haemovigilance systems, near miss data can contribute power to the understanding of procedural causes of transfusion adverse events. These include patient or specimen misidentification with the potential for major morbidity associated with those types of events. The HAC will consider the inclusion of near miss information in future national haemovigilance activity.

TABLE 16 – Key Recommendations – Data

	RECOMMENDATION	WHO IS RESPONSIBLE	PROPOSED STRATEGY	HOW WILL IT BE MEASURED
1	Jurisdictions to continue to develop their haemovigilance data capture and validation systems (which should include donor vigilance) to enhance the quality and completeness of data reported to the national dataset	NBA/JBC State and Territory Departments of Health Blood Service Private sector hospitals and private pathology providers	JBC to consider strategies for further development of Haemovigilance systems State and Territory Departments of Health to consider establishing ongoing funding for maintenance of Haemovigilance systems if funding not already in place	All jurisdictions will provide validated data in accordance with the data dictionary by 2012 Data from each jurisdiction will include information from both the public and private sectors
2	Programs should be implemented at the national, state and local hospital levels to improve recognition and reporting of under reported serious adverse events such as TACO and TRALI	JBC NBA State and Territory Departments of Health Hospital Educators Relevant professional Colleges and Societies	Incorporate TACO and TRALI into: • SA BloodSafe-e Learning • Post Graduate Certificate in Transfusion Practice • JMO Education Include advice on risks of TACO and TRALI in Patient Blood Management Guidelines	Reports of TACO and TRALI will be significantly increased by 2012 Recognition of TACO and TRALI will be included in national educational initiatives by 2012 Recognition and reporting of TACO and TRALI will be included in state and local education initiatives by 2012
3	Develop the systems and capability to enable the total number of products and patients transfused to be known	JBC NBA State and Territory Departments of Health NBA Blood Service AIHW Clinicians Clinical coders	Jurisdictions to consider initiatives to: • Use data linkage to determine the number of patients transfused in the public hospital system • Improve the capture and utilisation of registry data	The total number of products transfused will be able to be reported by the beginning of 2012 The total number of patients transfused by product will be better reported in AIHW hospital data for both public and private sectors The total number of patients transfused in the public sector will be known for each jurisdiction through data linkage
4	HAC to discuss the definition and inclusion of near misses into the dataset	HAC NBA JBC State and Territory Departments of Health	HAC to discuss near miss definition in data dictionary Promote inclusion of near misses information in jurisdictional data systems	HAC has evaluated the implementation of near miss data in the national haemovigilance dataset Jurisdictions are starting to capture and report near miss by 2012

17.2 Key Observations - Capacity

While states and territories have made significant progress towards the establishment of their haemovigilance systems, the allocation of resources in some jurisdictions has not been adequate to allow timely reporting of information that complies fully with the agreed, JBC endorsed, national haemovigilance data requirements.

It is critical that the reported information is investigated, analysed and used to improve transfusion safety, and eventually to also inform and improve the appropriateness of clinical usage. Mature haemovigilance systems integrate and utilise the reporting of adverse events into a wider safety and quality program. These programs use data to initiate improvements such as system changes, targeted audit and/or education programs, and changes to equipment or processes, among other things. Unfortunately, not all jurisdictions have mature haemovigilance systems, where events are fully analysed, interpreted and corrective actions initiated. Investment is required to improve transfusion safety through the integration of haemovigilance data into mature quality and safety programs.

TABLE 17 – Key Recommendations – Capacity

	RECOMMENDATION	WHO IS RESPONSIBLE	PROPOSED STRATEGY	HOW WILL IT BE MEASURED IN 2012?
5	Jurisdictions to consider strategies to improve the timeliness and completeness of reporting	JBC State and Territory Departments of Health State and Territory Quality and Safety Units	JBC to investigate strategies to support further development of Haemovigilance systems State and Territory Departments of Health to consider establishing ongoing funding for maintenance of Haemovigilance systems	Reports are provided in accordance with the timeframe agreed by the Jurisdictional Blood Committee
6	All transfusing hospitals should have transfusion governance arrangements in place	State and Territory Departments of Health State and Territory Quality and Safety Units Hospital Administrators	Jurisdictions to consider providing a directive to administrators responsible for transfusion institutions to establish haemovigilance governance arrangements	All transfusing hospitals actively participate in haemovigilance reporting, investigation and quality and safety corrective activities

17.3 Key Observations - Prescribing

Prescribing/Blood ordering was reported internationally as the leading contributory factor in IBCT. Previous studies of RBC transfusion in Australian hospitals have found that 16% to 30% of transfusions did not meet indication guideline criteria^{60,61,62}. This exposes patients unnecessarily to the potential for harm in circumstances where they are unlikely to receive a health benefit. Patient Blood Management concepts, which are gaining support internationally, provide a framework to avoid unnecessary transfusions.

These are patient focussed management strategies that centre around three action pillars:

1. Optimisation of the patient's own blood volume (especially red cell mass)
2. Minimisation of the patient's blood loss
3. Increasing tolerance of anaemia.

The NBA is working with the NHMRC and the ANZSBT to engage the relevant professional colleges to publish Patient Blood Management Guidelines. The guidelines will have six clinical scenario based modules that will be published, in turn, as available:

- critical bleeding/massive transfusion
- perioperative
- medical
- intensive care
- obstetrics
- paediatrics/neonatal.

60 Tobin SN, Campbell DA, Boyce NW. Durability of response to a targeted intervention to modify clinician transfusion practices in a major teaching hospital. *Med J Aust* 2001; 174: 445-448.

61 Rubin GL, Schofield WN, Dean MG, Shakeshaft AP. Appropriateness of red blood cell transfusions in major urban hospitals and effectiveness of an intervention. *Med J Aust* 2001; 175: 354-358.

62 Metz J, McGrath KM, Copperchini ML, et al. Appropriateness of transfusions of red cells, platelets and fresh frozen plasma. An audit in a tertiary care teaching hospital. *Med J Aust* 1995; 162: 572-573.

TABLE 18 – Key Recommendations – Prescribing

	RECOMMENDATION	WHO IS RESPONSIBLE	PROPOSED STRATEGY	HOW WILL IT BE MEASURED
7	Continue to develop, publish and promulgate Patient Blood Management Guidelines	NBA ANZSBT NHMRC Relevant professional Colleges and Societies	NBA to continue to work with professional Colleges and Societies and the NHRMC to publish PBM guidelines	Guidelines will be published Clinical audits will evaluate the extent that prescribing is in accordance with the guidelines Number of patients that have suffered harm from transfusion as a result of an unnecessary transfusion
8	Research and publish the specific elements that should be included on a blood order/prescription form to encourage alignment of prescribing with clinical guidelines	Relevant professional Colleges and Societies	NBA to consider engaging relevant bodies to work with to develop a national blood order/prescription form	Specific elements of a high quality form have been published on the NBA website and provided to all hospitals that transfuse

17.4 Key Observations - Procedural Errors

Reported adverse events can be categorised into two main causative types: procedural errors and transfusion reactions. While transfusion reactions feature strongly in both the initial and this second Report, procedural errors are avoidable and remain a significant concern. Procedural errors occur across the entire hospital transfusion chain in three main areas:

1. **Pre-laboratory processes:** activities such as prescription errors, patient identification and phlebotomy errors, and sample labelling and transportation mishaps
2. **Laboratory processes:** documentation and process errors, analytical and recording errors, blood labelling, blood and product selection, and errors in releasing products
3. **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.

While many of these errors are picked up prior to product issue or to actual transfusion, they represent a significant number of 'near misses'. A recommendation has been made to evaluate the inclusion of near misses in future jurisdictional data reporting requirements and the national haemovigilance reports. These data would reinforce the need for system changes to minimise these procedural lapses and the potential for harm they represent. Information technology solutions are relevant here.

TABLE 19 – Key Recommendations – Procedural Errors

	RECOMMENDATION	WHO IS RESPONSIBLE	PROPOSED STRATEGY	HOW WILL IT BE MEASURED
9	Reduce the potential for procedural errors through training, stringent application of standards, proficiency testing and accreditation	State and Territory Departments of Health Administration staff Quality and Safety personnel Hospital educators Clinical staff	Standardised training and development Periodic proficiency testing Compliance with specimen labelling standards and patient identification, as prescribed by the NPAAC and the ANZSBT, and the ACHS accreditation standards required under EQUIP	National Haemovigilance Program
10	Research possible application of technological adjuncts such as portable barcode readers and/or radio frequency identification scanners to reduce the scope for error	HAC Quality and Safety organisations, Research Bodies	Jurisdictions and the NBA to encourage this research	Research on technological strategies to reduce misidentification errors has been undertaken and recommendations provided to the JBC

17.5 Key Observations - National Blood Quality and Safety Initiatives

Since publication of the 2008 Report the NBA and the HAC has been working with the ACSQHC to develop a national indicator for Transfusion Safety and a National Quality and Safety Standard (and measures) for blood and blood products.

TABLE 20 – Key Recommendations – National Blood Quality and Safety Initiatives

	RECOMMENDATION	WHO IS RESPONSIBLE	PROPOSED STRATEGY	HOW WILL IT BE MEASURED IN 2012?
11	Include Haemovigilance in Accreditation requirements	NBA HAC ACHS NATA RCPA ACSQHC	NBA and HAC to continue to work with ACHS to monitor and improve accreditation requirements for haemovigilance	Haemovigilance monitoring, reporting included in EQUiP Accreditation requirements
12	NBA, JBC and HAC to continue to engage with ACSQHC in the judicious development of indicators and standards relevant to the blood sector	NBA JBC HAC ACSQHC	Provision of timely input as required by ACSQHC into the development of a Standard for Blood and Blood Products	Quality and Safety Standard for Blood and Blood Products developed in consultation with stakeholders



APPENDIX AND REFERENCES

APPENDIX I: THE INTERNATIONAL CONTEXT

Haemovigilance and surveillance systems for blood transfusion were initiated in France in 1994, in large part as a reaction to the human immunodeficiency virus scandal in the 1980s/early 1990s. Other European countries followed this initiative, notably the Serious Hazards of Transfusion (SHOT) program in the UK in 1996. The French and UK systems are the most mature and continue to provide insightful data.

A recent international forum⁶³ requested information on haemovigilance systems in 24 countries. In all but a few of the participating countries, a comprehensive haemovigilance system had been implemented. Subsequent to the adoption and implementation of the European Blood Directive (2002/98/EC) and three additional implementing directives (2004/33/EC, 2005/61/EC and 2005/62/EC), the majority of European (EU) countries have established a national haemovigilance system.

Communication between these systems is organised through the International Haemovigilance Network (IHN), previously the European Haemovigilance Network (EHN, founded 1997). The IHN hold annual haemovigilance seminars for member countries and researchers. The last such meeting was the 12th International Haemovigilance Seminar⁶⁴ held in Dubrovnik, Croatia, in February 2010.

Globally, the concept of haemovigilance has steadily expanded and the number of haemovigilance systems outside Europe is increasing⁶⁵. Several of these systems have also joined the IHN. Furthermore, initiated by the World Health Organization, a Global Steering Committee for Haemovigilance has been installed to promote haemovigilance particularly in developing countries. In most of the countries conducting haemovigilance reporting is obligatory and in all European countries the reporting of serious transfusion reactions became mandatory after EU Blood Directive implementation in November 2005.

There are a minority of countries in which reporting is restricted to adverse reactions that occur after the transfusion of blood products (including TTI). In most countries, additional reporting is required, or desired, ranging from reporting the misuse of blood products (i.e. not based on the proper indications), to reporting data on virtually the whole blood transfusion chain.

The majority of the serious adverse reactions and events that are reported internationally happen in the hospital part of the blood transfusion chain. Data from the UK have drawn the attention to the fact that about 50% of these are due to administrative errors. Mature haemovigilance systems have documented the success of various measures to further improve the safety of blood products. Two key examples are the blood diversion pouch used in many countries during blood donation in order to minimise the risk of contaminating skin bacteria and the decision to use only plasma from male donors. These examples have been demonstrated to result in significant decreases of serious adverse reactions due, respectively, to bacterial contamination of blood products (particularly platelets) and TRALI reactions.

63 Englefriet CP, Reesink HW. International forum–Haemovigilance. *Vox Sanguinis* 2006; 90 pp207–241.

64 12th International Haemovigilance Seminar. *Blood Transfusion* 2010; 8 (Suppl. 1).

65 de Vries, R.R.P. Haemovigilance: recent achievements and developments in the near future. *ISBT Science Series* 2009; 4 pp60–62.

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

The situation in the USA is complex. It is obligatory to report all fatal transfusion reactions to the FDA, but until 2009 no official national haemovigilance system was used. The Biovigilance Component of the National Healthcare Safety Network (NHSN) is a public/private collaboration between the Center for Disease Control (CDC) and the transfusion and transplant communities⁶⁶. Biovigilance will include collection of adverse event data to improve outcomes in the use of blood products, organs, tissues, and cellular therapies. The Haemovigilance Module is the first part of the new Biovigilance Component to be developed in the NHSN. The result of a unique public-private partnership between CDC and subject matter experts convened by AABB, this module is designed for staff in healthcare facility transfusion services to track adverse events, including recipient adverse reactions and quality control incidents, related to blood transfusion. Participating facilities will be able to analyse their own data, and, where appropriate, independently compare their data with national aggregate rates in a confidential manner through NHSN.

66 <http://www.cdc.gov/nhsn/bio.html>

APPENDIX II: DEFINITIONS IN HAEMOVIGILANCE

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

Sentinel events

ABO incompatibility

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

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

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

Other serious transfusion reactions and events

Severe febrile non-haemolytic transfusion reaction (FNHTR)

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

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

Severe allergic reaction

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

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

Anaphylactoid or anaphylactic reaction

Allergic reaction with hypotension (Drop in systolic BP >30mm Hg) during or within 24hrs of transfusion or intractable hypotension or shock with loss of consciousness during transfusion, and without any indication of other cause.

Acute haemolytic transfusion reactions (other than ABO incompatibility)

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

Delayed haemolytic transfusion reaction (DHTR)

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

Transfusion-associated circulatory overload (TACO)

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

Transfusion related acute lung injury (TRALI)

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

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

Transfusion transmitted infections (TTI)**Bacterial infection**

Transfusion transmitted bacterial infection should be clinically suspected if:

- fever $>39^{\circ}\text{C}$ or a change of $>2^{\circ}\text{C}$ from pre-transfusion value, and
- rigors, and
- tachycardia >120 beats/min or a change of >40 beats/min from pre-transfusion value or a rise or drop of 30mm Hg in systolic blood pressure within 4 hours of transfusion are present.

Possible transfusion transmitted bacterial infection:

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

Confirmed transfusion transmitted bacterial infection:

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

Viral infection

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

Parasitic infection

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

Transfusion associated graft versus host disease (TA-GVHD)

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

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

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

Post-transfusion purpura (PTP)

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

Incorrect blood component transfused (IBCT)

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

Definitions for contributory factors

TABLE 21 – ANHDD Definitions for Contributory Factors

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

Multiple entries allowed

At least one value to be returned

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**SAVING & IMPROVING AUSTRALIAN LIVES
THROUGH A WORLD-CLASS BLOOD SUPPLY**

NATIONAL BLOOD AUTHORITY AUSTRALIA

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