NATIONAL BLOOD AUTHORITY
AUSTRALIA

Australian Haemovigilance Report 2013

1 What is the purpose for the Australian Haemovigilance Report 2013?

The transfusion of fresh blood products is not without risk and can lead to complications. The 2013 Australian Haemovigilance Report provides details of the nature and extent of transfusion errors and reactions that occurred in Australian hospitals in 2009-10 and 2010-11.

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 (Blood Service) has a rapid recalls process to remove suspect products from circulation.

Blood products are stored and delivered to hospitals under strictly 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.

Accreditation to the National Safety and Quality Health Service (NSQHS) Standards commenced on 1 January 2013 in line with each individual health organisation's current accreditation cycle. The Standards are considered essential to improving the safety and quality of care for patients. Under these arrangements, health services such as hospitals, day procedure services and public dental clinics are required to be accredited to the NSQHS Standards. Other health services may choose to use the NSQHS Standards as part of their internal quality systems.

Accreditation requirements rest with the Health Departments that regulate health services in various jurisdictions. It has been agreed that all (public and private) hospitals, day procedure services and public dental clinics will need to be accredited to the NSQHS Standards.

The Australian Council on Health Care Standards (ACHS) accredits organisations against the Evaluation and Quality Improvement Program (EQuIP) standard, which incorporates transfusion and blood-handling outcome measures.

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 they collect about transfusion related incidents differs, all states and territories have agreed to align data collection 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 2013 notes that the main transfusion risk categories are:

- Adverse reactions such as allergic or immunological reactions which arise from the interaction of patient and blood component characteristics
- Human errors, which continue to contribute significantly to transfusion-related risks to patients.

The available data within the report indicates 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, however under the NSQHS Standard 7 from 1 January 2013 health service organisations are to ensure blood and blood product adverse events are included in the incidents management and investigation system.

The 2013 report shows significant increases in many types of reported incidents compared with the 2010 report, however comparisons must be undertaken with care as reporting systems have improved and support for reporting has increased dramatically since the previous report.

913 adverse events were reported to the National Haemovigilance Program between 1 July 2009 and 30 June 2011. During this period, there were no deaths associated with transfusion adverse events (compared with 2 deaths in 2008-09). Most event types also saw a decrease in life-threatening severity from the previous report.

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

The number of transfusion errors cannot be directly compared with other countries as Australia's haemovigilance system is not yet fully developed in all states, and some types of events are under-reported. However, the data does show that the factors which contribute to the errors are comparable with other developed nations which have haemovigilance programs, including the UK and NZ.

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 National 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 are developed based on the data.

Information obtained is used to build better and safer systems, conserve valuable blood resources and ultimately deliver better patient outcomes through better informed decision making about transfusion.

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

The NBA plays a key role under the National Blood Agreement 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 all state and territory health departments, 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 published four modules of patient blood management guidelines: critical bleeding/massive transfusion, perioperative, medical and critical care. Two further modules are under development: obstetrics and paediatrics/neonates.

11 What is currently being done by states and territories to make transfusions safer?

All state and territory health departments are focused on transfusion quality and safety, and delivering better outcomes to their patients. 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 health departments and Quality Units:

State/Territory	Contact
New South Wales	Sally Francis Program Leader Blood Watch Clinical Excellence Commission Level 13, 227 Elizabeth St Sydney NSW 2001 Ph: 02 9269 5510 http://www.cec.health.nsw.gov.au/
Victoria	Linley Bielby Program Manager Department of Health 100-154 Batman Street West Melbourne VIC 3003 Ph: 03 9694 0102 http://www.health.vic.gov.au/bloodmatters/
Queensland	Ellen Hawes Director, Blood Tissue and Organ Team Health Coordination Service Unit Queensland Health PO Box 2368 Fortitude Valley QLD 4006 http://www.health.qld.gov.au/qhcss/qbmp/
Western Australia	Trudi Gallagher State Patient Blood Management Clinical Coordinator DOH CMO Royal St Perth WA 6000 Ph: 08 9222 2190 www.health.wa.gov.au/bloodmanagement/professionals/index.cfm
South Australia	Susan Ireland Manager, Blood, Organ and Tissue Programs Department of Health and Ageing PO Box 287 Rundle Mall SA 5000 Ph: 08 8226 6114 Rachel Allden Principal Consultant Blood, Organ and Tissue Programs Department of Health and Ageing PO Box 287 Rundle Mall SA 5000 Ph: 08 8463 7062 http://www.sahealth.sa.gov.au/wps/wcm/connect/public+content/sa+health+internet/clinical+resources/clinical+programs/blood+products+and+programs

Tasmania	Helen Atkinson Blood Transfusion Nurse THO-South Royal Hobart Hospital GPO Box 1061 Hobart Tas 7001 03 6222 8549 Dawn Richardson Blood Transfusion Nurse THO-North Launceston General Hospital PO Box 1963 Launceston Tas 7250 03 6348 7691 Erin Wearne Blood Transfusion Nurse THO-North West Mersey Community Hospital PO Box 258 Burnie Tas 7320 03 6426 5193 http://www.dhhs.tas.gov.au/
Australian Capital Territory	Maria Burgess ACT Health C/O ACT Pathology PO Box 11 Woden ACT 2606 Ph: 02 6244 4092 Carolyn Duck Senior Policy Officer, Blood & Blood Products Health Directorate ACT Level 1, Building 10, Canberra Hospital Yamba Dr Garran ACT 2605 Ph: 02 6205 3094 http://health.act.gov.au/professionals/blood-and-blood-products/blood-and-blood-products
Northern Territory	Diann Black Transfusion Nurse Royal Darwin Hospital PO Box 41326 Casuarina NT 0811 Ph: 08 8922 8888 http://health.nt.gov.au/