

# GUIDELINE

## Haemovigilance data collection, validation and reporting

This guideline provides information to support Hospital and Health Services (HHSs) and licensed private health facilities with haemovigilance data collection, validation and analysis to assist with meeting haemovigilance requirements of National Safety and Quality Health Service (NSQHS) Standard 7.

### Introduction

Until 2013, a centralised haemovigilance system was operational across Queensland Health. In this system, data validation and analysis was undertaken by clinicians employed within a corporate Division of Queensland Health.

After the 2012 restructure of the Queensland public health system, HHSs were established and are responsible for the quality and safety of clinical services. The continuation of the centralised haemovigilance system was not consistent with the Department of Health's new system manager role and this system ceased in 2013.

This guideline was developed to assist HHSs and private licensed health facilities in their haemovigilance responsibilities.

### Queensland haemovigilance roles and responsibilities

#### *HHSs and licensed private health facilities*

Blood and blood products are the subject of NSQHS Standard 7, which applies to HHSs and licensed private health facilities. This Standard has the following criteria:

7.3 Ensuring blood and blood product adverse events are included in the incidents management and investigation system

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

#### *Department of Health*

The Department of Health will:

- facilitate the availability of tools for transfusion incident reporting being electronic forms to minimise errors in data entry and an Excel spreadsheet that can import the data from the electronic forms for local analysis
- develop and maintain this guideline on haemovigilance data collection, analysis and reporting
- work with an expert group to develop annual/biennial statewide haemovigilance reports
- coordinate data provision from HHSs and licensed private health facilities to the National Blood Authority (NBA) for national haemovigilance reporting.

## Definition of haemovigilance

Haemovigilance is defined by the International Haemovigilance Network as “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”. See also the *Australian Haemovigilance Report 2010*<sup>1</sup>.

## Scope of haemovigilance activities

### Haemovigilance focuses on fresh blood components:

- Red cells
- Platelets
- Fresh frozen plasma
- Cryoprecipitate
- Cryo-depleted plasma
- Whole blood

This includes:

- Australian Red Cross Blood Service donated blood products
- Pre-donated autologous blood (the patient’s pre-donated blood)
- Re-infusion of blood from intra-operative and post-operative re-infusion devices.

***Haemovigilance does not include manufactured plasma products (e.g. intravenous immunoglobulin, albumin, clotting factor concentrates). Incidents relating to these products should be captured in normal hospital incident procedures and reported to the manufacturer.***

### Near misses are not a part of haemovigilance activity

A near miss refers to an unplanned event that did not result in injury, illness, or damage - but had the potential to do so. Near miss information is not collected as part of the Queensland haemovigilance program. These incidents should still be reported through the normal hospital procedure of incident reporting for local analysis.

Please note that all events related to Incorrect Blood Component Transfused (IBCT) must be recorded, even if the event did not result in injury or damage. These events are not considered ‘near miss’ events. Other near miss events, such as when a wrong bag is issued or taken to a bedside, but due to vigilance of the staff it is not transfused, are not required to be reported.

## Guide to Queensland Haemovigilance reporting

Figure 1 presents the guide to Queensland haemovigilance reporting.

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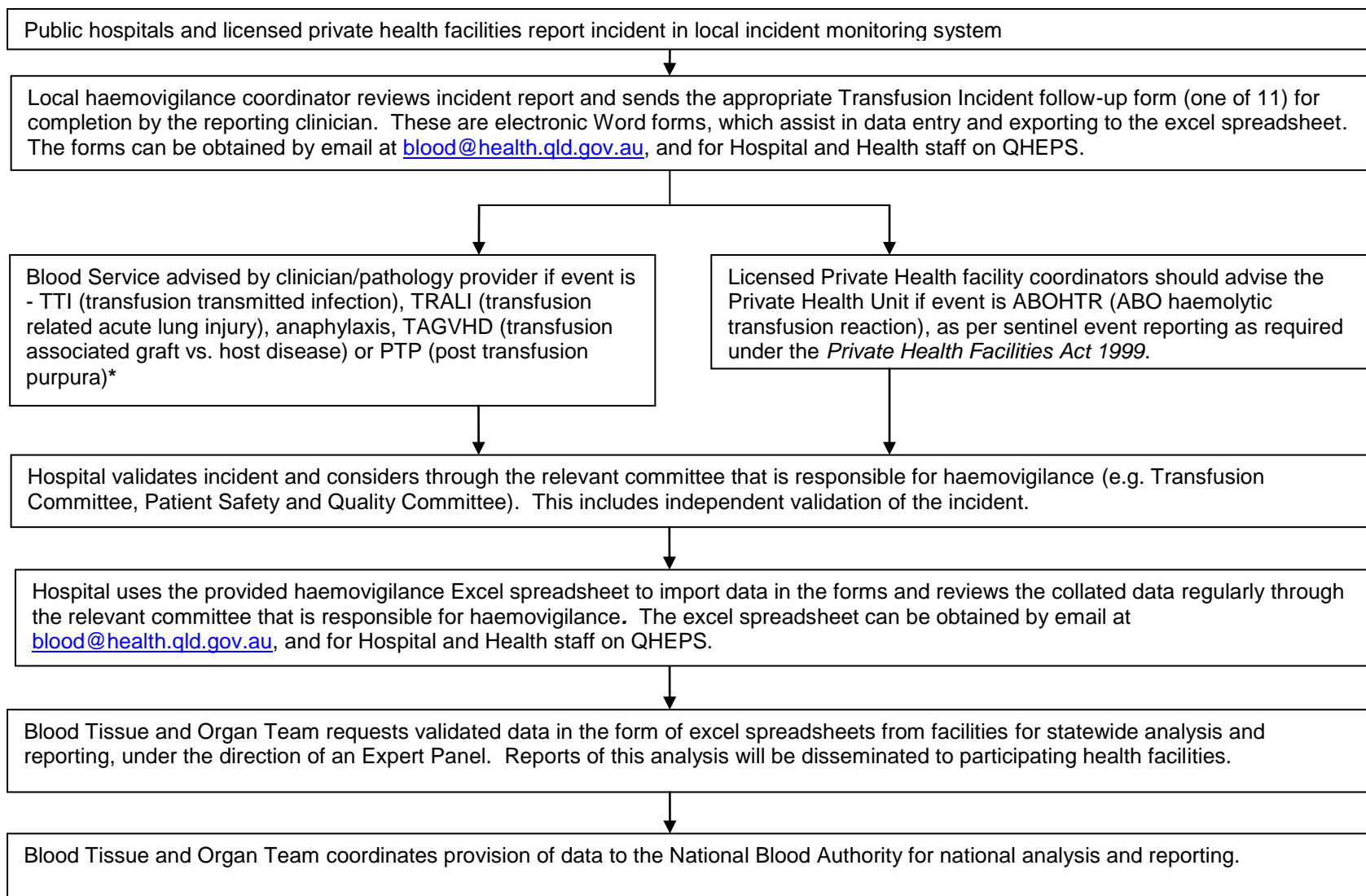
<sup>1</sup> National Blood Authority Haemovigilance Advisory Committee. *The Australian Haemovigilance Report*. National Blood Authority, 2010.

## Australian Red Cross Blood Service Notification

All significant transfusion reactions should be reported. All blood bags should be held in the clinical area for the duration of the transfusion and if a reaction is suspected at any time during the duration of the transfusion, the blood bags should be returned to blood bank. (The storage of blood bags in clinical areas depends upon hospital policy and may vary at different sites).

The blood bank will contact the Australian Red Cross Blood Service (Blood Service) if the bag is implicated in some way. For example, if a viral or bacterial infection from the transfusion bag is suspected or if TRALI is suspected.

## Figure 1: Guide to Queensland haemovigilance reporting



\*Refer to Blood Service guide: Steps for managing suspected transfusion reactions  
[http://www.transfusion.com.au/adverse\\_events/management\\_steps](http://www.transfusion.com.au/adverse_events/management_steps)

## Queensland Haemovigilance data collection

### Reportable adverse event data

The dataset of reportable adverse events for the Queensland haemovigilance system is as follows, based on the national definitions. Appendix 1 describes examples of each of the following data elements.

Data element	Definition – Australian National Haemovigilance Data Dictionary 2010
1. ABO haemolytic transfusion reaction (sentinel event)	<p><b>ABO incompatibility:</b></p> <p>The transfusion of ABO incompatible product/s resulting in an immediate 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.</p> <p>Haemolytic transfusion reactions (HTR) are clinically suspected if one or more of the following is present in a temporal association with transfusion:</p> <ul style="list-style-type: none"> <li>• Fever and a variety of other symptoms (including dyspnoea, hypotension, tachycardia, flank or back pain etc)</li> <li>• Inadequate rise in post-transfusion Hb level</li> <li>• Drop in Hb level (<math>\geq 2</math> g/dl within 24hrs)</li> <li>• Rise in LDH (<math>\geq 50\%</math> within 24hrs)</li> <li>• Rise in bilirubin, haemoglobinuria or decrease in haptoglobin levels</li> </ul>
2. Acute non-ABO haemolytic transfusion reaction	<p><b>Immediate haemolytic transfusion reactions (other than ABO):</b></p> <p>Immediate transfusion reactions occur within 24hrs of transfusion. They may have immune or non-immune aetiology.</p>
3. Delayed haemolytic transfusion reaction	<p><b>Delayed haemolytic transfusion reaction (DHTR):</b></p> <p>Occurs between 1 and 28 days post-transfusion, and is the result of other atypical red blood cell allo-antibodies.</p>
4. Transfusion related acute lung injury (TRALI)	<p><b>Transfusion related acute lung injury (TRALI):</b></p> <p>TRALI may be immune or non-immune. Serological confirmation is not required for diagnosis. Clinical TRALI features;</p> <ul style="list-style-type: none"> <li>• Acute respiratory distress and</li> <li>• Diffuse bilateral lung infiltrations in the lung radiograph and</li> <li>• Occurrence during or within 6hrs of completion of the transfusion and</li> <li>• No evidence of transfusion associated circulatory overload (TaCO).</li> </ul>
5. Transfusion transmitted infection	<p><b>Transfusion transmitted infections (TTI):</b></p> <p><b>Bacterial infection -</b></p> <p>Transfusion transmitted bacterial infection should be clinically suspected if:</p> <ul style="list-style-type: none"> <li>• Fever <math>&gt;39^{\circ}\text{C}</math> or a change of <math>&gt;2^{\circ}\text{C}</math> from pre-transfusion value and</li> <li>• Rigors and</li> <li>• Tachycardia <math>&gt;120</math> beats/min or a change of <math>&gt;40</math> 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.</li> </ul> <p>Possible transfusion transmitted bacterial infection:</p> <ul style="list-style-type: none"> <li>• Detection of bacteria by approved techniques in the transfused blood</li> </ul>

Data element	Definition – Australian National Haemovigilance Data Dictionary 2010
	<p>component but not in the recipient's blood or</p> <ul style="list-style-type: none"> <li>• 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.</li> </ul> <p>Confirmed transfusion transmitted bacterial infection:</p> <ul style="list-style-type: none"> <li>• Detection of the same bacterial strain in the recipient's blood and in the transfused blood product by approved techniques.</li> </ul> <p><b><i>Viral infection -</i></b></p> <p>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.</p> <p><b><i>Parasitic infection -</i></b></p> <p>Detection of the same parasite in the recipient's blood and parasite or specific antibodies in the donor blood.</p>
6. Severe allergic reaction	<p><b>Severe allergic reaction:</b></p> <p>One or more of the following without hypotension, and within 24hrs of transfusion:</p> <ul style="list-style-type: none"> <li>• Rash</li> <li>• Allergic dyspnea (stridor, cyanosis, wheezing)</li> <li>• Angioedema</li> <li>• Generalised pruritis</li> <li>• Urticaria</li> </ul>
7. Anaphylaxis / anaphylactoid reaction	<p><b>Anaphylactoid or anaphylactic reaction:</b></p> <p>Allergic reaction with hypotension (Drop in systolic BP <math>\geq</math>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</p>
8. Transfusion associated graft versus host disease	<p><b>Transfusion induced graft versus host disease (TGVHD):</b></p> <p>TGVHD clinically features the following 1–6 weeks post transfusion, with no other apparent cause:</p> <ul style="list-style-type: none"> <li>• Fever</li> <li>• Rash</li> <li>• Liver dysfunction</li> <li>• Diarrhoea and</li> <li>• Cytopenia</li> </ul> <p>TGVHD is confirmed by GVHD-typical biopsy and genetic analysis to show chimerism of donor and recipient lymphocytes.</p>
9. Post-transfusion purpura	<p><b>Post-transfusion purpura (PTP):</b></p> <p>Clinically features purpura and thrombocytopenia within 12 days of transfusion. PTP is confirmed by the detection of platelet specific antibodies (usually anti-HPA-1a) in the recipient's blood, and detection of the antithetical antigen on the donor platelets, or by a positive platelet X-match.</p>

Data element	Definition – Australian National Haemovigilance Data Dictionary 2010
10. Incorrect blood component transfused	<p><b>Incorrect blood component transfused (ICBT):</b></p> <p>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.</p>
11. Transfusion associated cardiac overload	<p><b>Transfusion-associated circulatory overload (TaCO):</b></p> <p>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</p>
12. Febrile non-haemolytic transfusion reaction	<p><b>Severe febrile non-haemolytic transfusion reaction (FNHTR):</b></p> <p>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;</p> <ul style="list-style-type: none"> <li>• Fever (<math>\geq 38^{\circ}\text{C}</math> or change of <math>\geq 1^{\circ}\text{C}</math> from pre-transfusion level)</li> <li>• Chills</li> <li>• Cold</li> <li>• Rigor</li> <li>• Other symptoms of discomfort</li> </ul>

For an event to be deemed as valid it must reflect the prescribed definition. The Blood Tissue and Organ Team is responsible for amending and updating the agreed dataset and associated definitions to align with changes at the national level.

## Imputability scoring system for reporting adverse events

Reported adverse events should be accompanied by an imputability score as described below:

Imputability Score	Assessment	Criteria
N/A	Not assessable	Insufficient data for assessment
Level 0	Excluded	Conclusive evidence beyond reasonable doubt for attributing the reaction to causes other than blood or blood components
Level 1	Unlikely	Evidence is clearly in favour of attributing the adverse events to causes other than blood or blood components.
Level 2	Possible	Evidence is indeterminate for attributing the adverse reaction either to blood components or alternative causes.
Level 3	Likely/probable	Evidence is clearly in favour of attributing the adverse reaction either to blood components
Level 4	Confirmed/certain	Conclusive evidence beyond reasonable doubt for attributing the adverse reaction to the blood or blood component.

The Blood Tissue and Organ Team is responsible for amending and updating the above 'Imputability scoring system' to align with changes at the national level.

## Other reportable data

The following additional data is collected to support the analysis of adverse events:

### The Patient

1. Age
2. Sex

### The Facility

3. Reporting Jurisdiction
4. Public or private facility
5. Classification of facility location (RRMA)
6. On-site or off-site issuing pathology service

Note that the facility information above is supplied to the NBA by the Queensland Department of Health

### The Adverse Event

7. Type of adverse event
8. Outcome severity
9. Date event occurred
10. Time transfusion commenced
11. Contributory factors
12. Imputability score

### The Implicated Blood Product

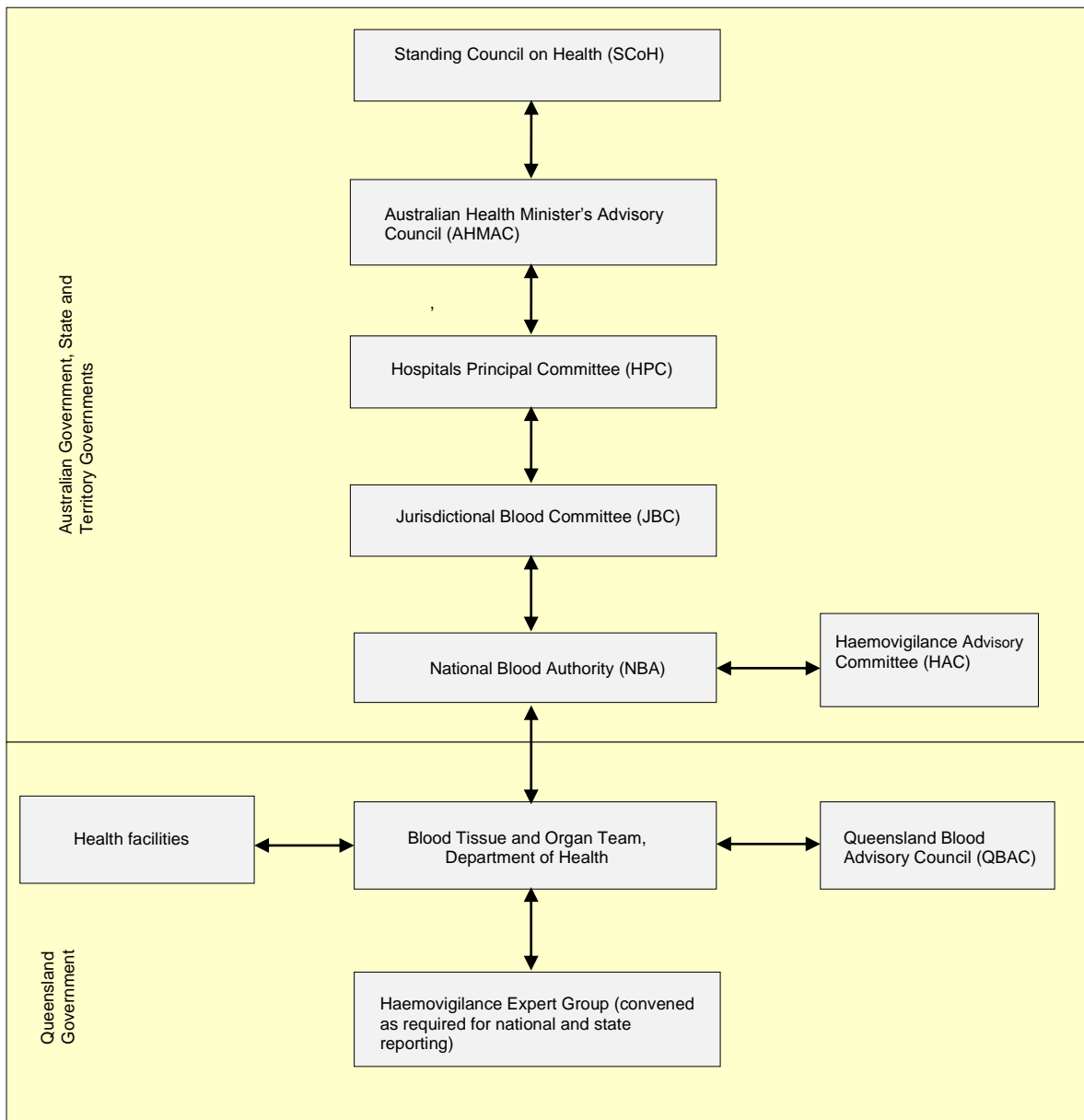
13. Product type
14. Modifications
15. Concomitant blood components

The Blood Tissue and Organ Team is responsible for amending and updating the above list of 'reportable additional data' to align with changes at the national level.



## Haemovigilance governance arrangements

The following diagram shows the national and state level governance arrangements for haemovigilance.



### Haemovigilance expert group

This group will provide advice on annual/biennial statewide haemovigilance reports. It will be convened as required.

### Blood Tissue and Organ Team

The Blood Tissue and Organ Team provides advice to the Chief Health Officer on the Department of Health's obligations under the National Blood Agreement (2003). Broadly these obligations, which extend across both public and private sectors, encompass:

- participation in national strategic policy development through the Jurisdictional Blood Committee (JBC) and the HPC/AHMAC/AHMC processes;
- funding and blood budget management;
- supply planning and supply chain management;
- ensuring efficient supply and use of blood and blood products so as to minimise wastage.

The Blood Tissue and Organ Team is responsible for the Department of Health's responsibilities for haemovigilance detailed on page 1 of this guideline.

### **Queensland Blood Advisory Council (QBAC)**

QBAC, chaired by the Chief Health Officer, provides advice to the Department of Health on the provision and maintenance of a safe, sufficient and cost effective supply of blood and blood products for Queensland.

### **Health facilities**

Health facilities are responsible for:

- meeting the requirements of the National Safety and Quality Health Service Standard 7 for Blood and Blood Products;
- reporting and management of transfusion incidents;
- independent validation of incident reports;
- local analysis of incidents, and implementation of actions to decrease risks associated with transfusions;
- participation in state and national reporting.

### **Haemovigilance reporting**

The Department of Health has a Memorandum of Understanding with the NBA in relation to the development and maintenance of the Transfusion Incident Follow-Up Forms and the Haemovigilance Excel Spreadsheet which can import data from these forms. These forms and spreadsheet allow the collection of haemovigilance data at a local level (note that Microsoft Office 2007 or later is required to import all the relevant data from the forms into the spreadsheet).

When data is required for annual/biennial statewide and national reporting, the Department of Health will contact HHSs and licensed private health facilities seeking agreement to provide de-identified data for these reports. HHSs and licensed private health facilities wishing to participate in statewide and national haemovigilance reporting may provide their data to the Department of Health via the excel spreadsheet.

### **National haemovigilance program**

The NBA requests state and territory data to inform national haemovigilance reports. There is no mandated requirement for data provision; this is voluntary. There is no blood related data included in Health Service Directive for data collection and provision of data to the Chief Executive. While voluntary, HHS and private licensed health facility participation in haemovigilance activities will contribute to achieving compliance with NSQHS Standard 7.

If a HHS or licensed private health facility provides the Department of Health with haemovigilance data, this will be forwarded for national reporting. The NBA designed the Haemovigilance Excel Spreadsheet to be suitable for data to be included in the national analysis.

The national haemovigilance system is overseen by the Haemovigilance Advisory Committee (HAC). The objective of the Haemovigilance Advisory Committee is to provide advice to governments on ways to:

- support the ongoing national haemovigilance program;
- improve the quality, comparability and imputability of Australian haemovigilance data.

This will include advice and guidance on:

- required data sets for haemovigilance;
- data standards and definitions;
- data management and usage;
- clinical implications of analysed data;
- the reporting framework.

The HAC will identify and consider national trends in haemovigilance data and strategies which could be implemented to improve transfusion procedural training and process improvements.

The Blood Tissue and Organ Team is responsible for updating this guideline if the national minimum dataset changes.

No patient identifying information is provided.

### Intellectual Property

Any intellectual property developed as a result of the work or activities of the Haemovigilance Expert Group and Haemovigilance Committee will belong to the State of Queensland acting through Queensland Health.

In relation to haemovigilance data submitted to the National Haemovigilance System, the NBA publishes resulting reports. As an Australian Government agency, the NBA asserts Creative Commons copyright to data which they publish.

## Appendix 1: Examples of reportable adverse event data to be captured in haemovigilance data collections

### ABO haemolytic transfusion reaction (sentinel event) example:

Two patients side by side in an oncology ward require non-urgent blood transfusions. It was the practice to give these non-urgent transfusions at night because the staff were less busy then. Patient 1 was O pos and Patient 2 was B neg. The two units of blood were collected from the blood fridge and taken to the ward where it was checked by two nursing staff in the treatment area. The units of blood were mixed up and as no bedside check of patient ID was made, the bloods were transfused to the wrong patients. The patients' name bands were not checked. Patient 1 suffered a severe acute haemolytic reaction after the first 50mls of blood and required admission to ICU. Patient 2 had the transfusion stopped and suffered no ill effects.

### Acute non-ABO haemolytic transfusion reaction example:

A 24 year old female was transfused with two units RBC because of a post-partum haemorrhage and required two further units 2 days later. During the second transfusion she became febrile, dyspnoeic and passed dark urine. She was subsequently found to have a positive \*DAT, haemoglobinuria and deteriorating renal function. Further screening of the patient's pre transfusion blood sample showed anti-K and it was confirmed that the second transfusion was K positive.

\*DAT – Direct antiglobulin test

### Delayed haemolytic transfusion reaction (DHTR) example:

A 38 year old female patient with myelodysplastic syndrome required two units of RBCs. The patient had known anti- E antibodies. Two days later the patient had chills, fever, jaundice and a falling Hb. The DAT was positive and anti-E+ was identified in her plasma. The pre-transfusion testing did not include antibody identification, despite known existing antibodies.

### Febrile non-haemolytic transfusion reaction (FNHTR) example:

A 72 year old female underwent a total hip replacement. The following day she required 2 units of allogenic red cells. She developed hypertension, rigors, chills and a fever. Blood cultures were not taken. The patient received antipyretics, the symptoms resolved and the transfusion was given without further incidents.

### Transfusion related acute lung injury (TRALI) example:

A 65 year old man was admitted to ICU post-operatively following an aortic aneurysm repair. Because of post-operative bleeding and prolonged prothrombin time, he was given 3 units of FFP. During the 3rd unit his oxygen saturation dropped with severe bilateral pulmonary shadowing on a chest X-ray. He also became febrile and hypotensive. CVP was low and echo did not indicate LVF, MI or fluid overload. Serological investigations for TRALI revealed that the donor had HLA antibodies and the patient was positive for the antigen and it was concluded that this case was highly likely to be TRALI.

### Transfusion transmitted infection example:

A 49 year old male developed rigors and hypotension following transfusion of a two-day old unit of apheresis platelets for treatment of leukaemia. The patient was given IV fluids and antibiotics but went on to develop a fever and symptoms of cardiac failure. He died 15 hours post transfusion. E.coli was cultured from the patient's blood and the platelet pack and it was concluded that the E.coli infection was transmitted via the transfusion.

### Severe allergic reaction example:

A 73 year old man required two units of RBC's following debridement of an infected foot. After approximately 100mls of the first bag, he developed dyspnoea with tachycardia and a rash over his stomach, chest and neck. The transfusion was stopped and phenergan and hydrocortisone were administered. The patient was tested and found to have IgA antibodies and subsequent infusions of washed red cells have been tolerated.

### Anaphylaxis/anaphylactoid reaction example:

A 55 year old man on warfarin was scheduled for a colonoscopy and biopsy. He discontinued his warfarin 3 days prior to admission and his INR was 1.65 on the day prior to the procedure. He was ordered FFP. Within 10 minutes of starting the transfusion, the patient developed an urticarial rash. Within a few minutes he had become hypotensive BP58/33, dyspnoeic, developed rigors and lost consciousness. He was treated with adrenalin (epinephrine) and hydrocortisone and took over 30 minutes to become haemodynamically stable.

### Transfusion associated graft versus host disease (TA-GVHD) example:

A 25 year old patient with acute B lymphoblastic leukaemia who developed diarrhoea, fever rash, liver dysfunction and pancytopenia 2 weeks following a red cell transfusion. The diagnosis was established following a skin biopsy.

### Post-transfusion purpura (PTP) example:

58 year old female was admitted to ICU following a motor vehicle accident. She had a compound fractured femur, fractured 4th and 5th ribs causing pneumothorax. She also had a history of COPD and required ventilation. The patient developed septicaemia and disseminated intravascular coagulation with a Hb 80 g/L and platelet count of  $16 \times 10^9$  g/L following which she was transfused with 2 units of apheresis platelets and 2 units red cells. She developed further thrombocytopenia 7 days after her transfusions with purpura and minor haemorrhage. Investigation revealed anti-HPA1a antibodies. Her platelet genotype was HPA1a negative. She had also been transfused previously, less than one year before the implicated transfusion and there was no complication from that transfusion.

### Incorrect blood component transfused (IBCT) example:

A telephone request for blood was incompletely documented in the laboratory, resulting in the wrong patient's sample being selected for pre-transfusion testing. There were 2 patients on the same ward with similar names, and both the laboratory and the ward failed to check the full details. Fortunately the blood given was ABO compatible and the patient was not harmed.

### Transfusion-associated cardiac overload example:

A 78 year old male developed dyspnoea, tachycardia and hypertension following 3 units of red cells. He was in positive fluid balance and required IV diuretics to treat the cardiac overload.