Government of **Western Australia**
Department of **Health**

# WA Haemovigilance Reporting

# Guideline

**Version 1.0**

**30 July 2015**

**health.wa.gov.au**

# Acknowledgements

The Department of Health Western Australia would like to acknowledge and thank the Queensland Department of Health for allowing adaption of the Queensland *Guideline: Haemovigilance data collection, validation and reporting* for this document. The Department of Health WA also acknowledges the use of reference material obtained from the National Blood Authority's *Australian Haemovigilance Report: Data for 2011-12 and 2012-13* and *Australian National Haemovigilance Data Dictionary (Version 4)*.

# Contents

# 1. Introduction

Blood and blood products are the subject of National Safety and Quality Health Service (NSQHS) Standard 7 Blood and Blood Products[1], which applies to public hospitals and health services 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.

These criteria highlight the importance of conducting haemovigilance and the reporting and review of recorded blood and blood product adverse events. While Western Australian (WA) hospitals and health services conduct haemovigilance at a local level, a mechanism to enable these data to be shared between hospitals and nationally provides opportunity to improve upon clinical practice and blood product safety.

This guideline was developed to support WA hospitals with haemovigilance data collection and reporting to assist with meeting haemovigilance requirements of NSQHS Standard 7. The guideline provides information on reporting of haemovigilance data consistent with the national minimum data set to the Department of Health WA for (i) collation and reporting at a state level and (ii) provision to the National Blood Authority (NBA) for inclusion in national haemovigilance reports.

# 2. Definitions

## 2.1. Haemovigilance

Haemovigilance is defined by the International Haemovigilance Network (IHN) 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*'. [2]

Haemovigilance is widely recognised as an integral part of safety in blood transfusion. Further information on haemovigilance and the important role of haemovigilance in improving effective and appropriate management of blood products and patient safety can be found in the Australian Haemovigilance Report, Data for 2011-12 and 2012-13[3] and the annual Serious Hazards of Transfusion (SHOT) reports produced by SHOT in the United Kingdom[4].

Surveillance of adverse transfusion events is the cornerstone of haemovigilance systems.[3] Transfusion-related adverse events can include reactions to administered blood products as well as clinical incidents related to the delivery of health care.

## 2.2. Blood Related Adverse Event

For the purpose of this guideline, a blood-related adverse event is an incident and/or reaction in which harm resulted, or potentially could have resulted, from the administration of a blood product.

Blood-related adverse events can be categorised as:

- clinical incident
- transfusion reaction adverse event

### 2.2.1. Clinical incidents

For the purpose of this guideline, a clinical incident refers to an event or circumstance resulting from health care which could have, or did lead to unintended and/or unnecessary harm to a patient/consumer. The full requirements for the management of clinical incidents are outlined in the WA Health Clinical Incident Management Policy 2015.[5]

WA haemovigilance reporting is an **additional reporting activity** to the reporting of clinical incidents in accordance with the WA Health Clinical Incident Management Policy. Recording of eligible clinical incidents in the WA haemovigilance template reporting spreadsheets does **not** preclude the requirement for reporting of these incidents into Datix CIMS or reporting and follow-up of these incidents in line with relevant hospital policy.

### 2.2.2. Transfusion reaction

For the purpose of this guideline, a transfusion reaction refers to an undesirable response to a transfusion which may or may not be a result of a clinical incident depending on the nature of the event.

# 3. Scope of WA Haemovigilance reporting

WA haemovigilance reporting activities (at the state level) focus on fresh blood components:

- red cells
- platelets
- fresh frozen plasma
- cryoprecipitate
- cryodepleted plasma
- whole blood*****

This includes:

- Australian Red Cross Blood Service (Blood Service) donated blood products
- reinfusion of blood from intraoperative and postoperative reinfusion devices
- predonated autologous blood (the patient's predonated blood)

WA haemovigilance data reporting does not include manufactured plasma products (e.g. intravenous immunoglobulin, albumin, RhD immunoglobulin (Anti-D) or clotting factor concentrates). Adverse events relating to these products should be captured in normal hospital adverse reaction and/or clinical incident procedures and reported to the manufacturer as required.

> Note: reporting requirements of the WA Health Clinical Incident Management Policy 2015 covers a broader definition of blood products than is included in the scope of WA haemovigilance data reporting. Reporting of clinical incidents into Datix CIMS does include reporting of incidents involving manufactured plasma products.

## 3.1. Near miss events

Near misses refer to events/incidents that may have, but did not cause harm, either by chance or through timely intervention. Near misses are currently not a part of required national haemovigilance reporting activity. Information on near miss events is **not** required to be supplied by health services and private health facilities to the Department of Health WA for the purpose of WA haemovigilance reporting. Near miss clinical incidents should be reported into Datix CIMS or other hospital clinical incident management systems (for private hospitals) in line with relevant policy.

## 3.2. Incorrect blood component transfused

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 for the purpose of WA (state) haemovigilance reporting activities. However, these events may be captured in normal hospital incident procedures.

***Note: Whole blood rarely provided in WA - check pack label**

### 3.3. Alignment to Australian National Haemovigilance Data Set

WA haemovigilance reporting activities will collect data consistent with the Australian National Haemovigilance Data Set (ANHDS). The data elements that make up the ANHDS are defined in the Australian National Haemovigilance Data Dictionary (ANHDD) (Version 4).[6] The data dictionary provides a description of the reportable data elements including a description of the transfusion-related adverse events that are required. The data dictionary is available on the NBA website (www.nba.gov.au).

Reportable adverse events to be captured in WA haemovigilance reporting are also detailed in Section 5 of this guideline and examples are provided in Appendix 1. Section 5 of the guideline includes mapping of the reportable adverse event types to the WA Health Clinical Incident Management Policy 2015. This is to assist with identifying whether the adverse event type is considered a clinical incident in accordance with the WA Health Clinical Incident Management Policy.

# 4. Process for WA Haemovigilance reporting

Figure 1 presents the process for WA haemovigilance reporting.

## 4.1. Western Australian Haemovigilance roles and responsibilities

Provision of haemovigilance data to the Department of Health WA is a voluntary activity for hospitals, it is not mandatory. While voluntary, hospitals are encouraged to take part in WA haemovigilance reporting activities as these will contribute to national haemovigilance efforts and assist hospitals and health services achieving compliance with Standard 7.

### 4.1.1. Hospitals and licensed private health facilities

Participating hospitals and licensed private health facilities will:

- identify and investigate blood-related adverse events
- report blood-related adverse events according to local and state required arrangements
- collect, enter and validate required data in the WA haemovigilance template reporting spreadsheet
- provide validated haemovigilance data to Department of Health WA as outlined in Figure 1 within requested timeframes.

### 4.1.2. Health Services Safety and Quality Staff (WA Health)

- Coordinate the distribution of haemovigilance reporting tools for blood-related adverse event reporting to nominated public hospital contacts
- Coordinate submission of validated data from public hospitals to the Department of Health WA at requested (6 monthly) intervals.

### 4.1.3. Department of Health WA

The Department of Health WA will:

- facilitate the availability of tools for blood-related adverse event reporting; including the WA haemovigilance template reporting spreadsheet and supporting documentation. In WA public hospitals these will be distributed through nominated area health service Safety and Quality contacts.

- develop and maintain this guideline for WA haemovigilance data collection and reporting
- work with the WA Haemovigilance Committee to develop state-wide haemovigilance reports (provided to participating hospitals)
- review received data to ensure data quality
- coordinate data provision from participating WA public hospitals and health services and licenced private health facilities to the NBA for inclusion in national haemovigilance reporting.

## 4.2. Australian Red Cross Blood Service Notification

All significant transfusion reactions should be reported to the Blood Service. 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 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.

## 4.3. Data Validation

Validation of information submitted for haemovigilance reporting activities is vital to ensuring that the information is complete and correct, so that resultant analyses are based on accurate data. For WA haemovigilance reporting blood-related adverse events are validated at the local (hospital or area health service) level to ensure that they are transfusion related prior to submission to the Department of Health WA.

The validation process includes the review and validation of the adverse event by expert reviewers. This may include classification of the event, assessment of severity and assigning imputability scores. The reported adverse event may undergo several levels of review (such as internal review and specialist review) until any data issues are resolved.

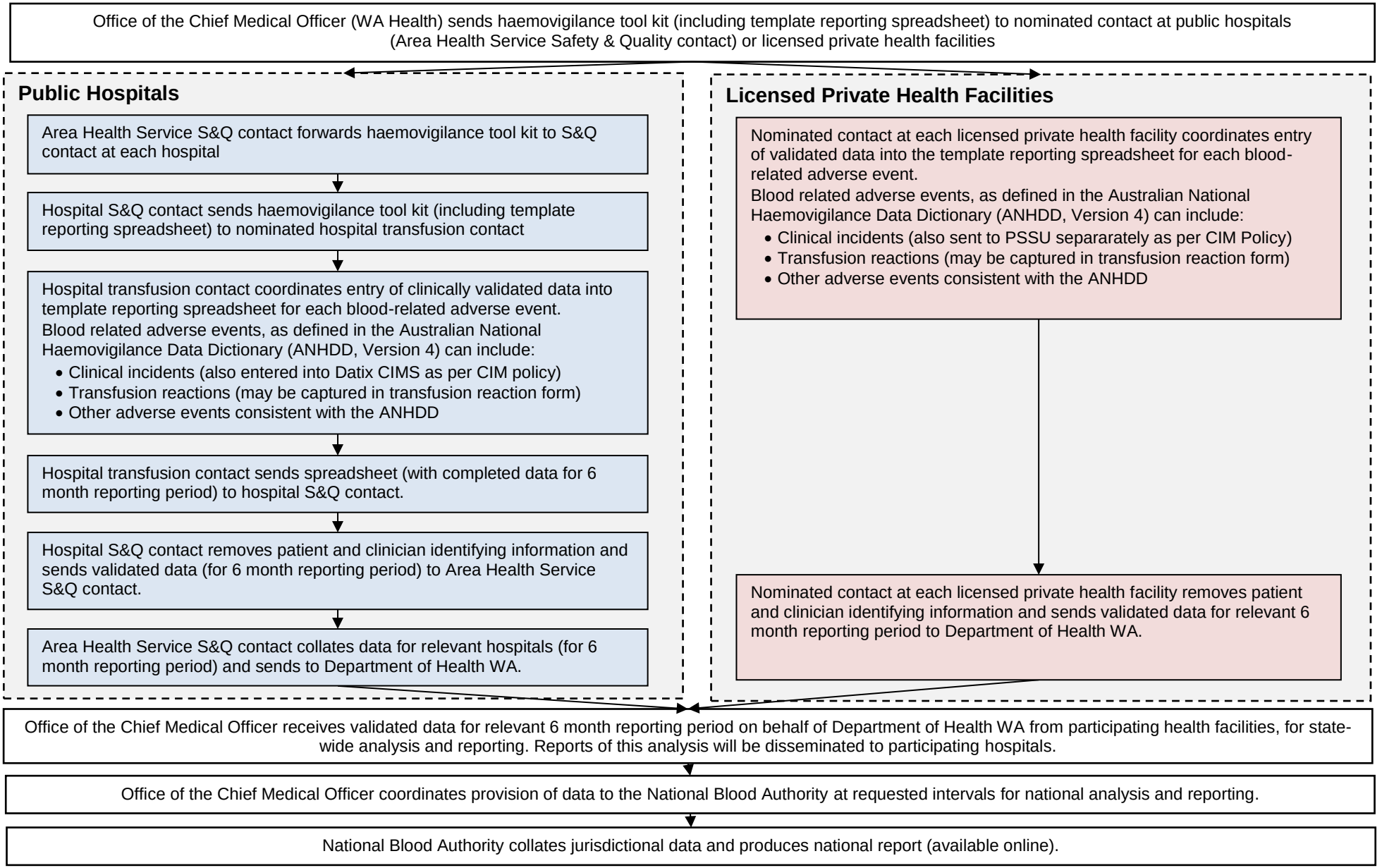
It is recommended that each hospital determines a process of data validation to ensure that all qualifying blood-related adverse events (clinical incidents and/or transfusion reactions) are accurately captured in the WA haemovigilance template reporting spreadsheet. This may require coordination between hospital transfusion, Safety and Quality and other staff as required.

The Office of the Chief Medical Officer (OCMO) will review data received from participating hospitals to ensure data quality prior to preparation of state-level reports and provision of haemovigilance data to the NBA.

## 4.4. Outcome Severity and Imputability

The final assessment of the clinical outcome severity, the severity assessment code and the imputability should be made by the local Transfusion Committee or equivalent. This may include seeking agreement of an external reviewer.

## Figure 1: Overview of reporting process for Western Australian Haemovigilance reporting



# 5. Western Australian Haemovigilance data collection

## 5.1. Reportable adverse event data

The dataset of reportable adverse events for WA haemovigilance reporting is as follows in Table 1, based on the national data definitions. Please remember WA haemovigilance reporting is an **additional reporting activity** to the reporting of clinical incidents in accordance with the WA Health Clinical Incident Management Policy and other relevant hospital policy (for private hospitals). Those adverse events that are not a clinical incident must still be reported and followed up in line with relevant hospital policy, such as reporting on the hospital transfusion reaction form.

> Note: to assist with determining whether a reportable adverse event is considered a clinical incident, mapping of the adverse event type to the WA Health Clinical Incident Management Policy 2015 is included in the right hand column.

### Table 1. Reportable adverse events for WA haemovigilance reporting

| Adverse event type | **Definition** (where possible this is the ISBT Definition) | Clinical Incident? |
|---|---|---|
| Febrile non-haemolytic transfusion reaction (FNHTR) | Presents with one or more of the following during or within 4 hours of transfusion without any other cause such as haemolytic transfusion reaction, bacterial contamination or underlying condition:<br>• fever (≥38°C oral or equivalent and a change of ≥1°C from pre-transfusion value)<br>• chills<br>• rigors<br>This may be accompanied by headache and nausea.<br>FNHTR could be present in absence of fever (if chills or rigors without fever).<br>For the purpose of national and international comparison, only the most serious cases of FNHTR defined below should be reported to the National Haemovigilance Program:<br>• fever (≥39°C oral or equivalent and a change of ≥2°C from pre-transfusion value and chills/rigors. | Not a clinical incident |
| Allergic reaction | An allergic reaction may present only with mucocutaneous signs and symptoms during or within 4 hours of transfusion:<br>• morbilliform rash with pruritus<br>• urticarial<br>• localised angioedema<br>• oedema of lips, tongue and uvula<br>• periorbital pruritus, erythema and oedema<br>• conjunctival oedema.<br>This type of allergic reaction is called ‘minor allergic reaction’ in some haemovigilance systems. | Not a clinical incident unless allergy was already known |

| Adverse event type | **Definition** (where possible this is the ISBT Definition) | Clinical Incident? |
|---|---|---|
| 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. | Clinical incident |
| Anaphylactoid or anaphylactic reaction | An allergic reaction can also involve respiratory and/or cardiovascular systems and present like an anaphylactic reaction. There is anaphylactic reaction when, in addition to mucocutaneous symptoms, there is airway compromise or severe hypotension requiring vasopressor treatment (or associated symptoms like hypotonia, syncope). The respiratory signs and symptoms may be laryngeal (tightness in the throat, dysphagia, dysphonia, hoarseness, stridor) or pulmonary (dyspnoea, cough, wheezing/bronchospasm, hypoxemia). Such a reaction usually occurs occurring during or very shortly after transfusion. | Not a clinical incident unless allergy was already known |
| Transfusion-associated circulatory overload (TACO) | TACO is characterised by any 4 of the following:<br>• acute respiratory distress<br>• tachycardia<br>• increased blood pressure<br>• acute or worsening pulmonary oedema on frontal chest radiograph<br>• evidence of positive fluid balance.<br>Occurring within 6 hours of completion of transfusion. An elevated BNP is supportive of TACO. | May be a clinical incident but is circumstance dependent |
| Delayed haemolytic transfusion reaction (DHTR) | A DHTR usually manifests between 24 hours and 28 days after a transfusion and clinical or laboratory features of haemolysis are present. Signs and symptoms are similar to AHTR but are usually less severe. DHTR may sometimes manifests as an inadequate rise of post-transfusion haemoglobin level or unexplained fall in haemoglobin after a transfusion. Blood group serology usually shows abnormal results. | Not a clinical incident |
| Transfusion transmitted infection (TTI) | The recipient had evidence of infection following transfusion of blood components and there was no evidence of infection prior to transfusion and no evidence of an alternative source of infection.<br>***Transfusion transmitted bacterial infection***<br>Transfusion transmitted bacterial infection should be clinically suspected if:<br>• fever >39°C or a change of >2°C from pre transfusion value and<br>• rigors and<br>• tachycardia >120 beats/min or a change of >40 beats/min from pre transfusion value or a rise or drop of 30mmHg in systolic blood pressure within 4 hours of transfusion are present.<br><u>Possible transfusion transmitted bacterial infection:</u><br>• detection of bacteria by approved techniques in the transfused blood component but not in the recipient's blood or<br>• 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. | Clinical incident |

| Adverse event type | **Definition** (where possible this is the ISBT Definition) | Clinical Incident? |
|---|---|---|
| TTI (cont.) | <u>Confirmed transfusion transmitted bacterial infection:</u><br>• detection of the same bacterial strain in the recipient's blood and in the transfused blood product by approved techniques.<br>***Transfusion transmitted viral infection***<br>Following investigation, the recipient has evidence of infection post transfusion and no clinical or laboratory evidence of infection prior to transfusion and either, at least one component received by the infected recipient was donated by a donor who had evidence of the same infection, or, at least one component received by the infected recipient was shown to have been contaminated with the virus. Reports should at least consider HIV, Hepatitis B, Hepatitis C and CMV.<br>***Transfusion transmitted parasitic infection***<br>Detection of the same parasite in the recipient's blood and parasite or specific antibodies in the donor blood. | |
| Acute haemolytic transfusion reaction (other than ABO incompatibility) (AHTR) | An AHTR has its onset within 24 hours of a transfusion. Clinical or laboratory features of haemolysis are present.<br>Common signs of AHTR are fever, chills/rigors, facial flushing, chest pain, abdominal pain, back/flank pain, nausea/vomiting, diarrhoea, hypertension, pallor, jaundice, oligoanuria, diffuse bleeding and dark urine.<br>Common laboratory features are haemoglobinaemia, haemoglobinuria, decreased serum haptoglobin, unconjugated hyperbilirubinaemia, increased LDH and AST levels and decreased haemoglobin levels.<br>Not all clinical or laboratory features are present in case of AHTR. | May be a clinical incident but is circumstance dependent |
| Transfusion-related acute lung injury (TRALI) | In patients with no evidence of acute lung injury (ALI) prior to transfusion, TRALI is diagnosed if a new ALI is present (all five criteria should be met) during or within 6 hours of completion of transfusion:<br>• Acute onset<br>• Hypoxemia<br>  ○ PaO2 / FiO2 < 300 mm Hg or<br>  ○ Oxygen saturation is < 90% on room air or<br>  ○ Other clinical evidence<br>• Bilateral infiltrates on frontal chest radiograph<br>• No evidence of left atrial hypertension (i.e. circulatory overload)<br>• No temporal relationship to an alternative risk factor for ALI, during or within 6 hours of completion of transfusion.<br>Alternate risk factors for ALI are:<br>• Direct Lung Injury<br>  ○ Aspiration<br>  ○ Pneumonia<br>  ○ Toxic inhalation<br>  ○ Lung contusion<br>  ○ Near drowning<br>• Indirect lung injury<br>  ○ Severe sepsis | Not a clinical incident |

| Adverse event type | **Definition** (where possible this is the ISBT Definition) | Clinical Incident? |
|---|---|---|
| TRALI (cont.) | ○ Shock<br>○ Multiple trauma<br>○ Burn injury<br>○ Acute pancreatitis<br>○ Cardiopulmonary bypass<br>○ Drug overdose<br><br>TRALI should be indicated with a possible imputability to transfusion if it presents a temporal relationship to an alternative risk factor for ALI as described above.<br><br>TRALI is therefore a clinical syndrome and neither presence of anti-HLA or anti-HNA antibodies in donor(s) nor confirmation of cognate antigens in recipient is required for diagnosis. | |
| Post-transfusion purpura (PTP) | PTP is characterized by thrombocytopenia arising 5-12 days following transfusion of cellular blood components with findings of antibodies in the patient directed against the Human Platelet Antigen (HPA) system. | First occurrence is not a clinical incident;<br>Subsequent occurrences are clinical incidents |
| Transfusion associated graft-versus-host disease (TA-GVHD) | TA-GVHD clinically features the following 1–6 weeks post transfusion, with no other apparent cause:<br>• fever<br>• rash<br>• liver dysfunction<br>• diarrhoea<br>• cytopaenia<br><br>TA-GVHD is confirmed by GVHD-typical biopsy and genetic analysis to show chimerism of donor and recipient lymphocytes. | Not a clinical incident |
| 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.<br><br>Haemolytic transfusion reactions (HTR) are clinically suspected if one or more of the following is present in a temporal association with transfusion:<br>• fever and a variety of other symptoms (including dyspnoea, hypotension, tachycardia, flank or back pain)<br>• inadequate rise in post-transfusion Hb level<br>• drop in Hb level (≥20 g/L within 24 hours)<br>• rise in LDH (≥50% within 24 hours)<br>• rise in bilirubin, haemoglobinuria or decrease in haptoglobin levels | Clinical incident |

| Adverse event type | **Definition** (where possible this is the ISBT Definition) | Clinical Incident? |
|---|---|---|
| ABO incompatibility (cont.) | It should be noted that adverse events attributed to transfusion of ABO incompatible products are included in the Incorrect Blood Component Transfused (IBCT) category. Such events could equally be described as acute haemolytic transfusion reactions, but the key failure is IBCT. Transfusion of ABO incompatible products to a patient is considered a 'sentinel event' and is also subject to other reporting channels outside of the National Haemovigilance Program. | |
| Transfusion Associated Dyspnoea (TAD) | TAD is characterized by respiratory distress within 24 hours of transfusion that does not meet the criteria of TRALI, TACO, or allergic reaction. Respiratory distress should be the most prominent clinical feature and should not be explained by the patient's underlying condition or any other known cause. | May be a clinical incident but is circumstance dependent |
| Hypotensive transfusion reaction (HTR) | This reaction is characterized by hypotension defined as a drop in systolic blood pressure of ≥30mm Hg occurring during or within one hour of completing transfusion and a systolic blood pressure ≤80mm Hg. | Not a clinical incident |
| Other types of adverse events | Other types of adverse events not defined in this data dictionary but defined and published by the ISBT at<br>http://www.isbtweb.org/working-parties/haemovigilance/<br>Other transfusion reactions:<br>a. Haemosiderosis<br>Transfusion-associated haemosiderosis is being defined as a blood ferritin level of ≥ 1000 micrograms/L, with or without organ dysfunction in the setting of repeated RBC transfusions.<br>b. Hyperkalaemia<br>Any abnormally high potassium level (> 5 mml/L, or ≥ 1.5 mml/L net increase) within an hour of transfusion can be classified as a transfusion-associated hyperkalaemia.<br>c. Unclassifiable Complication of Transfusion (UCT)<br>Occurrence of an adverse effect or reaction temporally related to transfusion, which cannot be classified according to an already defined adverse transfusion event (ATE) and with no risk factor other than transfusion and no other explaining cause. | |

Refer to the Australian National Haemovigilance Data Dictionary (Version 4) for further information.

For an event to be deemed as valid it must reflect the prescribed definition. The Office of the Chief Medical Officer is responsible for amending and updating the agreed dataset and associated definitions to align with changes at the national level.

## 5.2. Imputability scoring system for reporting adverse events

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

| Value | Assessment | Criteria |
|---|---|---|
| 0 | Excluded | Conclusive evidence beyond reasonable doubt for attributing the adverse reaction to causes other than transfusion |
| 1 | Unlikely | Evidence is clearly in favour of attributing the adverse reaction to causes other than the transfusion |
| 2 | Possible | Evidence is indeterminate for attributing the adverse reaction to the transfusion |
| 3 | Probable (likely) | Evidence is clearly in favour of attributing the adverse reaction to the transfusion |
| 4 | Definite (certain) | Conclusive evidence beyond reasonable doubt for attributing the adverse reaction to the transfusion |
| 9 | Not assessable | Insufficient data for assessment |

Office of the Chief Medical Officer is responsible for amending and updating the above imputability scoring system to align with changes at the national level.

## 5.3. Other reportable data

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

**1) The patient**

a) Age range
b) Sex

**2) The facility**

a) Reporting jurisdiction
b) Public or private facility
c) Classification of facility location

**3) The adverse event**

a) Type of adverse event
b) Outcome severity
c) Date transfusion commenced
d) Time transfusion commenced
e) Contributory factors
f) Imputability score

**4) The implicated blood product**

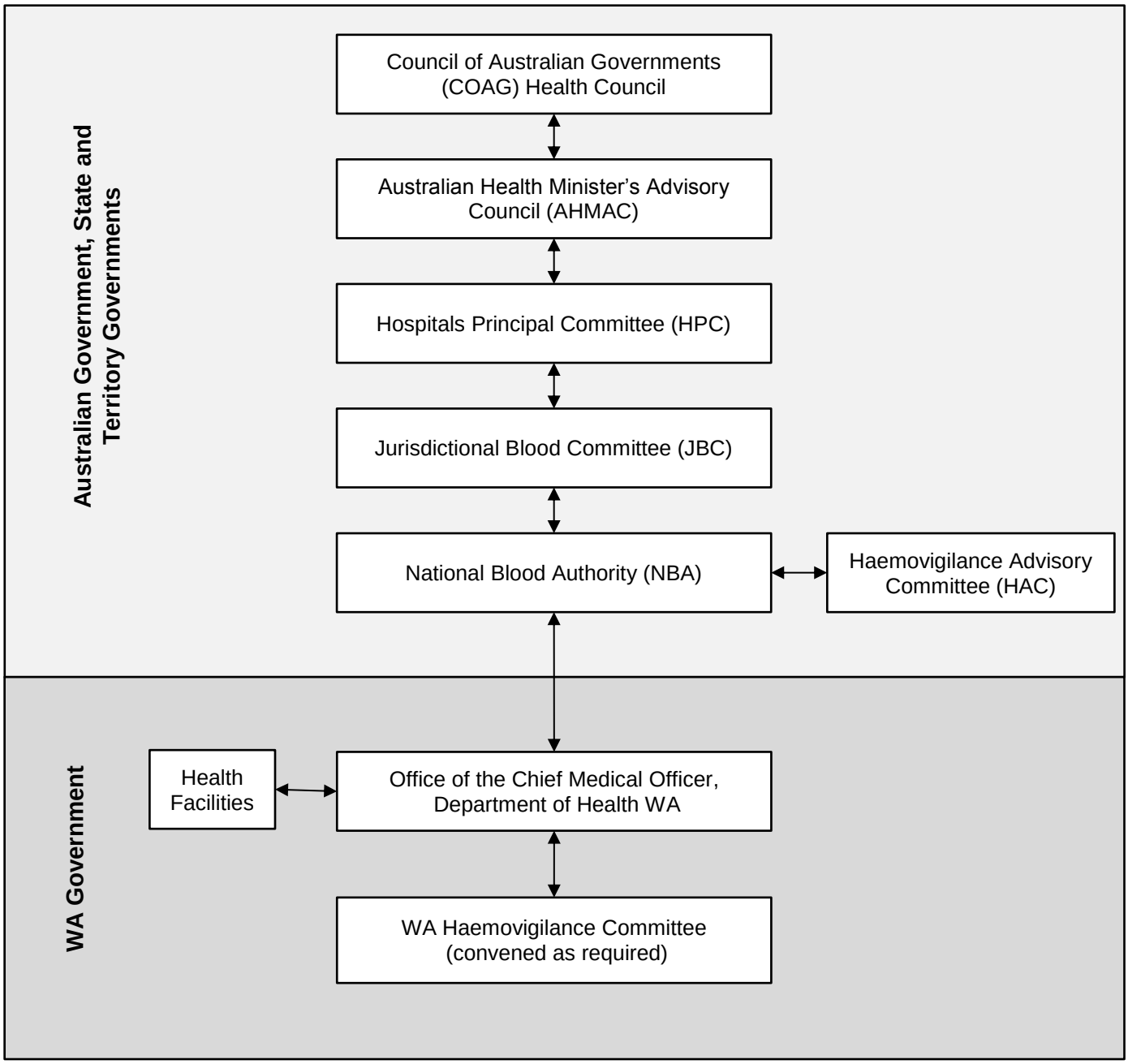
a) Product type
b) Concomitant blood components
c) Blood product modification

The Office of the Chief Medical Officer is responsible for amending and updating the above list of reportable additional data to align with changes at the national level.

# 6. Haemovigilance governance arrangements

Figure 2 shows the national and state level governance arrangements for haemovigilance.

**Figure 2: National and state level governance arrangements for haemovigilance**




### WA Haemovigilance Committee

This group will provide advice on state-wide haemovigilance reports and other matters related to haemovigilance in WA as needed. It will be convened as required.

### Office of the Chief Medical Officer

The Office of the Chief Medical Officer has carriage of obligations of the Department of Health WA under the National Blood Agreement (2003). Broadly these obligations encompass:

- participation in national strategic policy development through the Jurisdictional Blood Committee (JBC) and the HPC/AHMAC/COAG Health Council 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 Office of the Chief Medical Officer is responsible for the Department of Health WA's responsibilities for haemovigilance detailed on page 4 of this guideline.

### 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 blood-related adverse events;
- independent validation of blood-related adverse event reports;
- local analysis of incidents, and implementation of actions to decrease risks associated with transfusions;
- participation in state and national reporting.

### Haemovigilance reporting

The Office of the Chief Medical Officer will obtain agreement from hospitals and health services, including licensed private health facilities, as well as related pathology providers, prior to providing data contributed by those sites to the NBA for use national reporting. Hospitals and health services, including licensed private health facilities, wishing to participate in state-wide and national haemovigilance reporting should provide their data to the Department of Health WA via the WA template reporting spreadsheet.

### National haemovigilance program

The NBA requests jurisdictional data to inform national haemovigilance reports. There is no mandated requirement for data provision; this is voluntary. While voluntary, hospitals and health services, including licensed private health facility, participation in haemovigilance activities will contribute to achieving compliance with NSQHS Standard 7.

If a hospitals and/or health service, including a licensed private health facility, provides the Department of Health WA with haemovigilance data, this will be forwarded to the NBA for national reporting.

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 Office of the Chief Medical Officer is responsible for updating this guideline if the national minimum dataset changes.

No patient or clinician identifying information will be provided to the NBA without prior consent from hospitals or health services.

# 7.Intellectual Property

Any intellectual property developed as a result of the work or activities of the WA Haemovigilance Committee will belong to the State of Western Australia acting through the Department of Health WA.

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 events to be captured in haemovigilance data collections

The examples below have been taken from the Queensland Guideline for Haemovigilance Data Collection and Reporting (Queensland Health).

### 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. 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 (direct antiglobulin test), 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.

### 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 two units of allogenic red cells. She developed hypertension, rigors, chills and a fever. Blood cultures were not taken. The patient received antipyretics, the symptoms resided 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 three units of FFP. During the third 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 three 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 two 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 fourth and fifth 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 x 10 g/L following which she was transfused with two units of apheresis platelets and two units red cells. She developed further thrombocytopenia seven 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 two 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 three units of red cells. He was in positive fluid balance and required IV diuretics to treat the cardiac overload.

# References


1. Australian Commission on Safety and Quality in Health Care, *National Safety and Quality Health Service Standards (September 2012)*. Sydney. ACSQHC, 2012. http://www.safetyandquality.gov.au/wp-content/uploads/2011/09/NSQHS-Standards-Sept-2012.pdf

2. http://www.ihn-org.com

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5. Department of Health, Western Australia. Clinical Incident Management Policy. (2015). Perth: Patient Safety Surveillance Unit. http://ww2.health.wa.gov.au/Corporate/Articles/A_E/Clinical-incident-management-system

6. Australian National Haemovigilance Data Dictionary (Version 4) published by the National Blood Authority http://www.blood.gov.au

**This document can be made available in alternative formats on request for a person with a disability.**