WA Haemovigilance Reporting

Guideline

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## Acknowledgements

The Department of Health WA 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 Haemovigilance materials.
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 WA Haemovigilance 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 blood transfusion safety. Surveillance of blood related adverse 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 one or both of the following:

- Clinical incidents
- Transfusion reaction adverse events

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 2015.⁴

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 focus on fresh blood components:

- Red cells
- Platelets
- Fresh frozen plasma
- Cryoprecipitate
- Cryodepleted plasma
- Whole blood* (rarely provided in WA-check pack label)

This includes:

- Australian Red Cross Blood Service (Blood Service) donated blood products
- Reinfusion of blood from intraoperative and postoperative reinfusion devices (e.g. cell salvage)
- Autologous blood (the patient’s predonated blood)

WA haemovigilance 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 miss events refer to incidents that may have, but did not cause harm, either by chance or through timely intervention. Near miss events are currently not required to be reported to the Department of Health WA for the purpose of WA haemovigilance reporting. Blood related 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 included in WA haemovigilance reporting, even if the event did not result in injury or damage. ICBT events are not considered ‘near miss’ events.

3.3. Alignment to Australian Haemovigilance Minimum Data Set

WA haemovigilance reporting activities will collect data consistent with the Australian Haemovigilance Minimum Data Set (AHMDS)\(^6\). The AHMDS (previously the National Haemovigilance Data Dictionary) provides a description of the reportable data elements and transfusion related adverse events that are required for national reporting. The AHMDS is available on the NBA website (www.nba.gov.au).
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 not a mandatory activity. However, all WA hospitals are encouraged to take part in WA haemovigilance reporting activities in order to 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 blood related adverse event data into WA 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 intervals.

4.1.3. Department of Health WA

The Department of Health WA will:

- Facilitate the availability of haemovigilance reporting tools. In WA public hospitals these will be distributed through nominated area health service Safety and Quality contacts.
- Maintain this WA haemovigilance guideline
- Review received data to ensure data quality
- Work with the WA Haemovigilance Committee to develop state-wide haemovigilance reports
- Coordinate provision of WA haemovigilance data to the NBA for inclusion in national reporting.

4.2. Australian Red Cross Blood Service Notification

All significant transfusion reactions should be reported to the Blood Service. If a reaction is suspected at any time during the transfusion, the blood bags should be returned to the hospital transfusion laboratory.

The hospital transfusion laboratory 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**

Prior to submission to the Department of Health WA, blood related adverse events are to be validated at the local (hospital or area health service) level.

The validation process includes the review and validation of the adverse event to ensure the event meets the criteria specified in the AHMDS. This may include classification of the event, assessment of severity and assigning imputability scores and, if required may involve several levels of review (such as internal review and specialist review).

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

Office of the Chief Medical Officer (Department of Health WA) sends haemovigilance tool kit (including template reporting spreadsheet) to nominated Area Health Service Safety & Quality contact at public hospitals and other contacts at licensed private health facilities.

**Public Hospitals**

- Area Health Service S&Q contact forwards haemovigilance tool kit to S&Q contact at each hospital.
- Hospital S&Q contact sends haemovigilance tool kit (including template reporting spreadsheet) to nominated hospital transfusion contact.
- Hospital transfusion contact coordinates entry of clinically validated data into template reporting spreadsheet for each blood-related adverse event. Blood related adverse events can include:
  - Clinical incidents (also entered into Datix CIMS as per CIM policy)
  - Transfusion reactions (may be captured in transfusion reaction form)
  - Other adverse events consistent with the AHMDS.
- Hospital transfusion contact sends spreadsheet (with completed data for reporting period) to hospital S&Q contact.
- Hospital S&Q contact removes patient and clinician identifying information and sends validated data (for reporting period) to Area Health Service S&Q contact.
- Area Health Service S&Q contact collates data for relevant hospitals (for reporting period) and sends to Department of Health WA.

**Licensed Private Health Facilities**

- Nominated contact at each licensed private health facility coordinates entry of validated data into the template reporting spreadsheet for each blood related adverse event. Blood related adverse events can include:
  - Clinical incidents (also entered into Datix CIMS as per CIM policy)
  - Transfusion reactions (may be captured in transfusion reaction form)
  - Other adverse events consistent with the AHMDS.
- Nominated contact at each licensed private health facility removes patient and clinician identifying information and sends validated data for relevant reporting period to Department of Health WA.

Office of the Chief Medical Officer (Department of Health WA) receives validated data for relevant reporting period from participating health facilities, for state-wide analysis and reporting. Reports of this analysis will be disseminated to participating hospitals.

Office of the Chief Medical Officer (Department of Health WA) coordinates provision of data to the National Blood Authority for national analysis and reporting.

National Blood Authority collates jurisdictional data and produces national report (available online).
5. Western Australian Haemovigilance data collection

5.1. Reportable blood related adverse event types

Definitions of blood related adverse events to be reported for WA Haemovigilance reporting are provided in Appendix 1. Event types to be reported are as follows:

Note: to assist in determining whether a blood related 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>
<thead>
<tr>
<th>Adverse event type</th>
<th>Acronym</th>
<th>Clinical Incident?</th>
</tr>
</thead>
<tbody>
<tr>
<td>Febrile non-haemolytic transfusion reaction</td>
<td>FNHTR</td>
<td>Not a clinical incident</td>
</tr>
<tr>
<td>Allergic reaction</td>
<td>-</td>
<td>Not a clinical incident unless allergy was already known</td>
</tr>
<tr>
<td>Incorrect blood component transfused</td>
<td>IBCT</td>
<td>Clinical incident</td>
</tr>
<tr>
<td>Anaphylactoid or anaphylactic reaction</td>
<td>-</td>
<td>Not a clinical incident unless allergy was already known</td>
</tr>
<tr>
<td>Transfusion-associated circulatory overload</td>
<td>TACO</td>
<td>May be a clinical incident but is circumstance dependent</td>
</tr>
<tr>
<td>Delayed haemolytic transfusion reaction</td>
<td>DHTR</td>
<td>Not a clinical incident</td>
</tr>
<tr>
<td>Delayed serologic reaction</td>
<td>DSTR</td>
<td>Not a clinical incident</td>
</tr>
<tr>
<td>Transfusion transmitted infection</td>
<td>TTI</td>
<td>Clinical incident</td>
</tr>
<tr>
<td>Acute haemolytic transfusion reaction (other than ABO incompatibility)</td>
<td>AHTR</td>
<td>May be a clinical incident but is circumstance dependent</td>
</tr>
<tr>
<td>Transfusion-related acute lung injury</td>
<td>TRALI</td>
<td>Not a clinical incident</td>
</tr>
<tr>
<td>Post-transfusion purpura</td>
<td>PTP</td>
<td>First occurrence is not a clinical incident; Subsequent occurrences are clinical incidents</td>
</tr>
<tr>
<td>Transfusion associated graft-versus-host disease</td>
<td>TA-GVHD</td>
<td>Not a clinical incident</td>
</tr>
<tr>
<td>ABO incompatibility</td>
<td></td>
<td>Clinical incident</td>
</tr>
<tr>
<td>Transfusion Associated Dyspnoea</td>
<td>TAD</td>
<td>May be a clinical incident but is circumstance dependent</td>
</tr>
<tr>
<td>Hypotensive transfusion reaction</td>
<td>HTR</td>
<td>Not a clinical incident</td>
</tr>
<tr>
<td>Other types of adverse events</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

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

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

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

### 5.3. Outcome severity scoring system

Reported adverse events should be accompanied by an outcome severity score as per below:

<table>
<thead>
<tr>
<th>Value</th>
<th>Meaning</th>
</tr>
</thead>
<tbody>
<tr>
<td>No morbidity</td>
<td>No ill effects, no clinical effects</td>
</tr>
<tr>
<td>Minor morbidity</td>
<td>The recipient may have required medical intervention (such as symptomatic treatment) but lack of such would not have resulted in permanent damage or impairment of body function</td>
</tr>
<tr>
<td>Severe morbidity</td>
<td>The recipient required in-patient hospitalisation or prolongation of hospitalisation directly attributable to the event; and/or</td>
</tr>
<tr>
<td></td>
<td>- the adverse event resulted in persistent or significant disability or incapacity; or</td>
</tr>
<tr>
<td></td>
<td>- the adverse event necessitated medical or surgical intervention to preclude permanent damage or impairment of a body function</td>
</tr>
<tr>
<td>Life-threatening</td>
<td>The recipient required major intervention following the transfusion (vasopressors, intubation, transfer to intensive care) to prevent death</td>
</tr>
<tr>
<td>Death</td>
<td>The recipient died following an adverse transfusion reaction</td>
</tr>
<tr>
<td>Outcome not available</td>
<td>Null response. The clinical outcome classification may be pending (extended time taken to assign clinical outcome)</td>
</tr>
</tbody>
</table>
5.4. Other reportable data

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

1) The patient
   a) Age group
   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) Date transfusion commenced
   c) Time transfusion commenced
   d) Contributory factors

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 imputability, outcome severity scoring system and 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
The WA Haemovigilance Committee will provide advice on state-wide haemovigilance reports and other haemovigilance related matters 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 JBC and the HPC/AHMAC/CHC 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 (not mandatory).

National haemovigilance program
The Office of the Chief Medical Officer will obtain formal agreement from hospitals and health services, including licensed private health facilities and related pathology providers, prior to providing data contributed by those sites to the NBA for use in national reporting.

The national haemovigilance system is overseen by the Haemovigilance Advisory Committee (HAC). The HAC has been established to:
- analysis of the available haemovigilance data
- provide recommendations for further analysis, research and best practice initiatives based on evidence where possible
- improve the quality, comparability and imputability of Australian haemovigilance data.
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: Reportable blood related adverse events for WA haemovigilance reporting

The dataset of reportable adverse events for WA haemovigilance reporting is as follows. Refer to the Australian Haemovigilance Minimum Data Set (August 2015) for further information.

Note: to assist in determining whether a blood related 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>
<thead>
<tr>
<th>Adverse event type</th>
<th>Definition (where possible this is the ISBT Definition)</th>
<th>Clinical Incident?</th>
</tr>
</thead>
<tbody>
<tr>
<td>Febrile non-haemolytic transfusion reaction (FNHTR)</td>
<td>For the purpose of national and international comparison, only the most serious cases of FNHTR defined below should be reported to WA Haemovigilance reporting and the National Haemovigilance Program: Presents with the following during or within 4 hours of transfusion without any other cause such as haemolytic transfusion reaction, bacterial contamination or underlying condition: - fever (&gt;39°C oral or equivalent) and - a change of ≥2°C from pre-transfusion value and - chills/rigors.</td>
<td>Not a clinical incident</td>
</tr>
<tr>
<td>Allergic reaction</td>
<td>An allergic reaction may present only with mucocutaneous signs and symptoms during or within 4 hours of transfusion: - morbilliform rash with pruritus - urticarial - localised angioedema - oedema of lips, tongue and uvula - periorbital pruritus, erythema and oedema - conjunctival oedema. This type of allergic reaction is called ‘minor allergic reaction’ in some haemovigilance systems.</td>
<td>Not a clinical incident unless allergy was already known</td>
</tr>
<tr>
<td>Incorrect blood component transfused (IBCT)</td>
<td>All reported episodes where a patient was transfused with a blood component that did not meet the appropriate requirements or that was intended for another patient. Include even if any of the following apply: - the component was ABO compatible (e.g. an immune compromised patient requires irradiated cellular products but receives non irradiated blood instead) - only a small quantity of blood was transfused and/or - there was no adverse reaction</td>
<td>Clinical incident</td>
</tr>
<tr>
<td>Anaphylactoid or anaphylactic reaction</td>
<td>An allergic reaction can also involve respiratory and/or cardiovascular systems and present like an anaphylactic reaction. There is an 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.</td>
<td>Not a clinical incident unless allergy was already known</td>
</tr>
<tr>
<td>Adverse event type</td>
<td>Definition (where possible this is the ISBT Definition)</td>
<td>Clinical Incident?</td>
</tr>
<tr>
<td>--------------------</td>
<td>------------------------------------------------------</td>
<td>--------------------</td>
</tr>
</tbody>
</table>
| Transfusion-associated circulatory overload (TACO) | TACO is characterised by any 4 of the following:  
  - acute respiratory distress  
  - tachycardia  
  - increased blood pressure  
  - acute or worsening pulmonary oedema on frontal chest radiograph  
  - evidence of positive fluid balance.  
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 |
| Delayed serologic reaction (DSTR) | There is DSTR when, after a transfusion, there is demonstration of clinically significant antibodies against red blood cells which were previously absent (as far as is known) and when there are no clinical or laboratory features of haemolysis. This term is synonymous with alloimmunisation. | 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.  
**Transfusion transmitted bacterial infection**  
Transfusion transmitted bacterial infection should be clinically suspected if:  
  - fever >39°C or a change of >2°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 30mmHg 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.  
**Transfusion transmitted 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, Hepatitis B, Hepatitis C and CMV. | Clinical incident |
<table>
<thead>
<tr>
<th>Adverse event type</th>
<th>Definition (where possible this is the ISBT Definition)</th>
<th>Clinical Incident?</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Transfusion transmitted parasitic infection</strong></td>
<td>Detection of the same parasite in the recipient's blood and parasite or specific antibodies in the donor blood.</td>
<td></td>
</tr>
<tr>
<td><strong>Acute haemolytic transfusion reaction (other than ABO incompatibility) (AHTR)</strong></td>
<td>An AHTR has its onset within 24 hours of a transfusion. Clinical or laboratory features of haemolysis are present. 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. Common laboratory features are haemoglobinaemia, haemoglobinuria, decreased serum haptoglobin, unconjugated hyperbilirubinaemia, increased LDH and AST levels and decreased haemoglobin levels. Not all clinical or laboratory features are present in case of AHTR.</td>
<td>May be a clinical incident but is circumstance dependent</td>
</tr>
</tbody>
</table>
| **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:  
- Acute onset  
- Hypoxemia  
  - PaO2 / FiO2 < 300 mm Hg or  
  - Oxygen saturation is < 90% on room air or  
  - Other clinical evidence  
- Bilateral infiltrates on frontal chest radiograph  
- No evidence of left atrial hypertension (i.e. circulatory overload)  
- No temporal relationship to an alternative risk factor for ALI, during or within 6 hours of completion of transfusion.  
Alternate risk factors for ALI are:  
- Direct Lung Injury  
  - Aspiration  
  - Pneumonia  
  - Toxic inhalation  
  - Lung contusion  
  - Near drowning  
- Indirect lung injury  
  - Severe sepsis  
  - Shock  
  - Multiple trauma  
  - Burn injury  
  - Acute pancreatitis  
  - Cardiopulmonary bypass  
  - Drug overdose  
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.  
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. | Not a clinical incident |
<table>
<thead>
<tr>
<th>Adverse event type</th>
<th>Definition (where possible this is the ISBT Definition)</th>
<th>Clinical Incident?</th>
</tr>
</thead>
<tbody>
<tr>
<td>Post-transfusion purpura (PTP)</td>
<td>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.</td>
<td>First occurrence is not a clinical incident; Subsequent occurrences are clinical incidents</td>
</tr>
</tbody>
</table>
| 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  
- cytopaenia  
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 | All cases where a blood component was transfused which was ABO incompatible. Include all such events even if:  
- only a small quantity of blood was transfused, and/or  
- no adverse reaction occurred  
All cases are to be included, whether the first error occurred in the Blood Service, hospital transfusion laboratory or in clinical areas.  
Note that these events are a subgroup of the IBCT category.  
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. | Clinical incident |
| 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 minimum data set but defined and published by the ISBT can be found at: [http://www.isbtweb.org/working-parties/haemovigilance/](http://www.isbtweb.org/working-parties/haemovigilance/)  
Other transfusion reactions:  
a. Haemosiderosis  
Transfusion-associated haemosiderosis is being defined as a blood ferritin level of ≥ 1000 micrograms/L, with or without organ |
<table>
<thead>
<tr>
<th>Adverse event type</th>
<th>Definition (where possible this is the ISBT Definition)</th>
<th>Clinical Incident?</th>
</tr>
</thead>
<tbody>
<tr>
<td>Other (cont.)</td>
<td>Dysfunction in the setting of repeated RBC transfusions.</td>
<td></td>
</tr>
<tr>
<td></td>
<td>b. <strong>Hyperkalaemia</strong></td>
<td></td>
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<tr>
<td></td>
<td>Any abnormally high potassium level (&gt; 5 mmol/L, or ≥ 1.5 mmol/L net increase) within an hour of transfusion can be classified as a transfusion-associated hyperkalaemia.</td>
<td></td>
</tr>
<tr>
<td></td>
<td>c. <strong>Unclassifiable Complication of Transfusion (UCT)</strong></td>
<td></td>
</tr>
<tr>
<td></td>
<td>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.</td>
<td></td>
</tr>
</tbody>
</table>
Appendix 2: Examples of reportable blood related adverse events

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 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 haemolytic transfusion reaction (other than ABO incompatibility) example:
A 24 year old female was transfused with two units RBC because of a post-partum haemorrhage and required two further units two 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 2 units of allogeneic 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 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 an echocardiogram 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 with a BP 58/33 mmhg,
dyspnoaic, 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 septicemia and disseminated
intravascular coagulation with a Hb 64 g/L and platelet count of 16 x 10 g/L following which she
was transfused with 2 units of apheresis platelets and 2 units of 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.
References


