WA Haemovigilance Reporting Guideline

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WA Haemovigilance Reporting Guideline 2021

About this Guideline

The Guideline information is accurate at the time of publication. Please check the WA health resources and links for any updated processes or templates since the time of this publication.

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Disclaimer

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1. Introduction

Blood and blood products are the subject of National Safety and Quality Health Service (NSQHS) Standard 7 Blood Management[1], which applies to public and private health service organisations. Part of this Standard ensures a quality assurance mechanism is in place surrounding the reporting of Transfusion Related Adverse Events (TRAEs). The relevant actions are:

> Action 7.7 The health service organisation uses processes for reporting transfusion-related adverse events in accordance with national guidelines and criteria.
>
> Action 7.8 The health service organisation participates in haemovigilance activities, in accordance with the national framework.

These highlight the importance of conducting haemovigilance including the reporting and review of recorded adverse events.

This guideline was developed to support WA health service providers (HSP) with haemovigilance data collection to meet the requirements of NSQHS Standard 7. It provides information on reporting of haemovigilance data consistent with the Australian Haemovigilance Minimum Data Set (AHMDS) 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.

This guideline is not intended as a substitute for local HSP guidelines relating to the detection, management and investigation of suspected or actual transfusion reactions.

WA haemovigilance events are reported through a secure web-based program using REDCap™. REDCap is hosted by the Department of Health WA. Web based access through the internet is available to HSP's and provided to staff involved in reporting haemovigilance events.

If you need to register for access or require an electronic link to the REDCap program, please request via email: bloodmanagement@health.wa.gov.au

2. Definitions

2.1. Haemovigilance

Haemovigilance is defined as a set of surveillance procedures covering the entire transfusion chain, from the donation and processing of blood and its components, to their provision and transfusion to patients, to their follow-up. It includes monitoring, reporting, investigating and analysing adverse events related to the donation, processing and transfusion of blood, as well as development and implementation of recommendations to prevent the occurrence or recurrence of adverse events.

Haemovigilance is widely recognised as an integral part of transfusion safety. Surveillance of adverse events is the cornerstone of haemovigilance systems.[3] Adverse events are reported to enable identification of previous adverse reactions or special transfusion requirements, and to drive improvement opportunities. They can include reactions to administered blood products as well as clinical incidents related to the delivery of health care.

2.2. Transfusion Related Adverse Event (TRAE)

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

Transfusion-related adverse events can be categorised as one or both of the following:

- Clinical incidents
- Transfusion reaction

2.2.1. Clinical incidents

For the purpose of this guideline, a clinical incident refers to an event or circumstance resulting from health care provision (or lack thereof) which could have or did lead to unintended or unnecessary physical or psychological harm to a patient. The full requirements for the management of clinical incidents are outlined in the WA Health Clinical Incident Management Policy 2019.[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 REDCap Program 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/Cryodepleted plasma
- Cryoprecipitate

This includes:

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

Current WA haemovigilance reporting does not include manufactured plasma products (e.g. 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 and the Therapeutic Goods Administration (TGA) as required. https://www.tga.gov.au/reporting-problems

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 for WA haemovigilance reporting. Transfusion 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).[5] Appendix 1 provides a descriptive list of the reportable data elements and transfusion related adverse events that are required for local and national reporting.

4. Process for WA Haemovigilance reporting

Figure 1 (see page 8) presents the process for WA haemovigilance reporting.

4.1. WA Haemovigilance roles and responsibilities

Provision of haemovigilance data to the Department of Health is not mandatory. However, all WA HSP's are encouraged to participate in WA haemovigilance reporting activities, to demonstrate compliance with the National Standards[1] and contribute to the national picture of haemovigilance.

4.1.1. Health Service Providers

Participating HSP's will:

- Identify and investigate TRAEs as per local policies and reporting guidelines
- Report TRAEs according to local and state required arrangements
- Collect, enter and validate TRAE data into WA Haemovigilance REDCap Program. Appendix 2 provides a detailed list of the reportable data fields required to submit an adverse event in the REDCap system.
- Provide validated haemovigilance data to Department of Health as outlined in Figure 1 within requested timeframes.

4.1.2. Department of Health

The Department of Health will:

- Facilitate timely and regularly updated haemovigilance reporting using the WA Haemovigilance REDCap Program. In WA public HSP's these will be distributed through nominated area HSP contacts
- Maintain, review and update WA haemovigilance guidance and support materials
- Maintain, review and update the register of HSP's with access to WA Haemovigilance REDCap Program
- Review data to ensure data quality and undertake robust analysis with the WA Haemovigilance Committee
- Lead and facilitate the WA Haemovigilance Committee

- Produce and distribute annual state-wide haemovigilance reports
- Coordinate provision of WA haemovigilance data to the NBA for inclusion in national reporting.

4.2. Australian Red Cross Blood Lifeblood Notification

The following suspected transfusion reactions should be reported to Lifeblood.

- Suspected Transfusion Related Acute Lung Injury (TRALI)
- Suspected Transfusion Transmitted Infections (TTI)
- Reactions or incidents suspected to be related to blood components quality or Lifeblood manufacturing or labelling errors

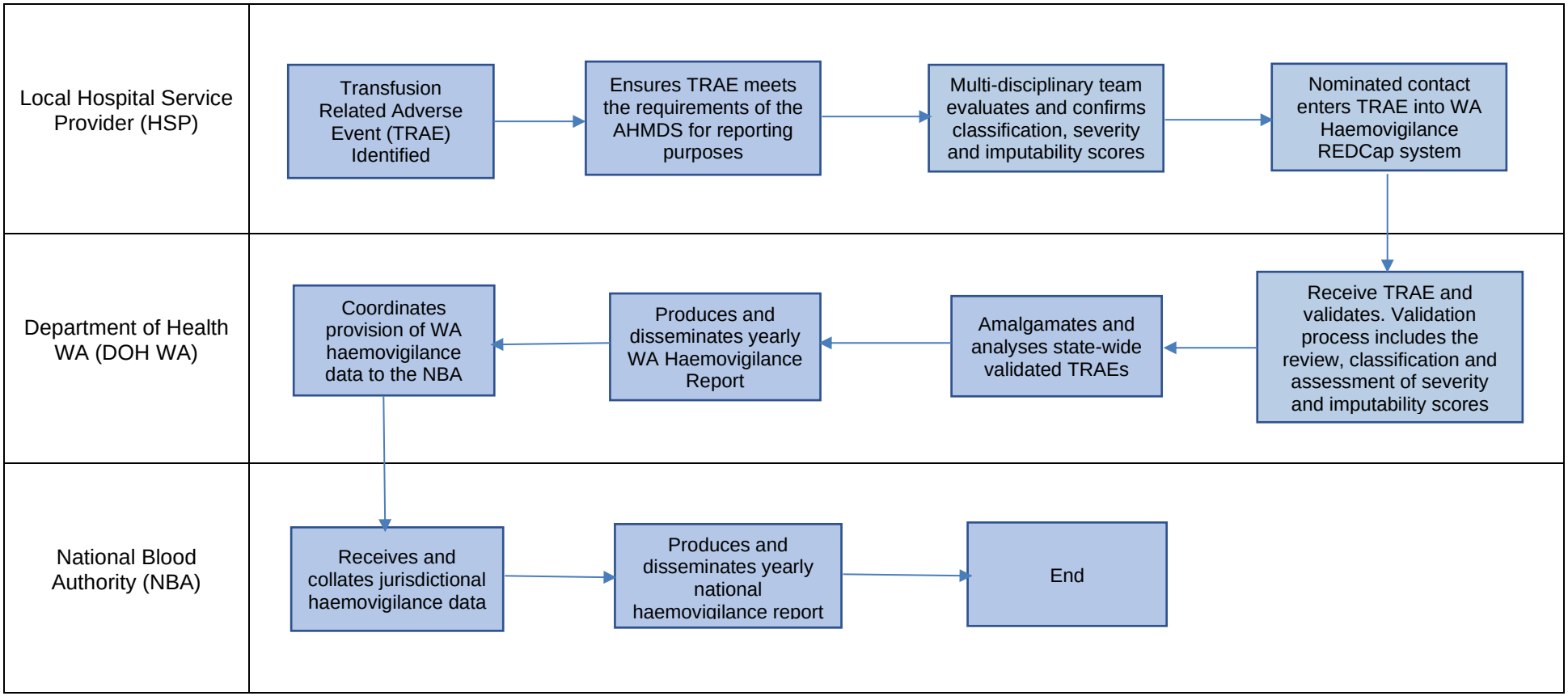
4.3. Data Validation

Prior to submission to the Department of Health TRAEs are to be validated at the local (HSP) level.

The validation process includes the review and confirmation 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 Department of Health WA will review data received from participating HSP's 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 WA Haemovigilance reporting



5. WA Haemovigilance data collection

5.1. Reportable transfusion related adverse event types

Definitions of TRAEs to be reported for WA Haemovigilance reporting are provided in Appendix 1.

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

5.2. Outcome severity scoring system

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

Value	Meaning
No morbidity	No ill effects, no clinical effects
Minor morbidity	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
Severe morbidity	The recipient required in-patient hospitalisation or prolongation of hospitalisation directly attributable to the event; and/or • the adverse event resulted in persistent or significant disability or incapacity; or • the adverse event necessitated medical or surgical intervention to preclude permanent damage or impairment of a body function
Life-threatening	The recipient required major intervention following the transfusion (vasopressors, intubation, transfer to intensive care) to prevent death
Death	The recipient died following an adverse transfusion reaction
Outcome not available	Null response. The clinical outcome classification may be pending (extended time taken to assign clinical outcome)

5.3. Imputability scoring system

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	Indeterminate (possible)	Evidence is indeterminate for attributing the adverse reaction to the transfusion
3	Likely (probable)	Evidence is clearly in favour of attributing the adverse reaction to the transfusion
4	Certain (definite)	Conclusive evidence beyond reasonable doubt for attributing the adverse reaction to the transfusion
9	Not assessable	Insufficient data for assessment

5.4. Other reportable data

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

1) **The patient**
    a) Medical Record Number (not mandatory)
    b) Age group
    c) Sex
2) **The facility**
    a) Reporting jurisdiction
    b) Public or private patient (required only if event submitted from privately operated public hospital ie Joondalup Health Campus, Midland Hospital)
    c) Classification of facility location
3) **The transfusion information**
    a) Date transfusion commenced
    b) Time transfusion commenced
4) **The adverse event data**
    a) Date reaction observed
    b) Time reaction observed
    c) Adverse event type
    d) Outcome severity (refer section 5.2)
5) **Contributory factors**
    a) Any significant event or factor that may have played a role in the occurrence of the adverse event
6) **Imputability score** (refer to section 5.3)
7) **Product Type**
    a) Product type
    b) Additional product type characteristics ie washed product, apheresis, pooled, paediatric

8) **Clinically relevant information to provide a broader understanding of the adverse event (not mandatory)**

   a) Signs and symptoms of the adverse event

   b) Management of the adverse event

   c) Investigations carried out as a result of the adverse event

The Department of Health WA is responsible for amending and updating the imputability, outcome severity scoring system and list of reportable additional data to align with national level changes.

5.5. Haemovigilance governance arrangements

5.5.1. WA Haemovigilance Committee

The WA Haemovigilance Committee will provide advice on state-wide haemovigilance reports and other haemovigilance related matters in WA. The Committee meets biannually.

5.5.2. Office of the Chief Medical Officer

OCMO 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) which reports to the Health Chiefs Executive Forum (HCEF)
- funding and blood budget management
- supply planning and supply chain management
- ensuring efficient supply and use of blood and blood products to minimise wastage.

The OCMO is responsible for the Department of Health WA responsibilities for haemovigilance detailed within this guideline.

5.5.3. Health Service Providers

Health facilities are responsible for:

- meeting the requirements of the National Safety and Quality Health Service Standard 7 for Blood Management
- 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).

5.5.4. National haemovigilance program

OCMO has agreement from HSP's, to provide haemovigilance data contributed by those sites to the NBA for use in national reporting.

The national haemovigilance system is overseen by the JBC through the Haemovigilance Advisory Committee (HAC). The HAC has been established to:

- analyse 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.

Appendix 1: Reportable transfusion related adverse events for WA reporting

The dataset of reportable adverse events for WA haemovigilance reporting is as follows. Refer to the Australian Haemovigilance Minimum Data Set (August 2015) [5] for further information.

Note: to assist in determining whether a transfusion related adverse event is considered a clinical incident, mapping of the adverse event type to the WA Health Clinical Incident Management Policy 2019 is included in the right-hand column.

Adverse event type	Definition (where possible this is the ISBT Definition)	Clinical Incident?
Febrile non-haemolytic transfusion reaction (FNHTR)	For 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 (≥39ºC oral or equivalent) and a change of ≥2ºC 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: • 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.	Not a clinical incident unless allergy was already known
Incorrect blood component transfused (IBCT)	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 and/or • only a small quantity of blood was transfused and/or • there was no adverse reaction	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	TACO is characterised by any 4 of the following: • acute respiratory distress	May be a clinical incident but is

Adverse event type	Definition (where possible this is the ISBT Definition)	Clinical Incident?
overload (TACO)	• 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.	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 like AHTR but are usually less severe. DHTR may sometimes manifest as an inadequate rise of post-transfusion haemoglobin (Hb) level or unexplained fall in Hb 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) * Requires additional reporting to Lifeblood	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 <u>Possible transfusion transmitted bacterial infection:</u> • 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. <u>Confirmed transfusion transmitted bacterial infection:</u> • 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. ***Transfusion transmitted parasitic infection***	Clinical incident

Adverse event type	Definition (where possible this is the ISBT Definition)	Clinical Incident?
TTI (cont.)	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. 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.	May be a clinical incident but is circumstance dependent

Transfusion-related acute lung injury (TRALI)
* Requires additional reporting to Lifeblood
	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

Adverse event type	Definition (where possible this is the ISBT Definition)	Clinical Incident?
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; 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: • 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 (unintentionally) 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 Lifeblood, the 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 local and National Haemovigilance Programs.	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:	

Adverse event type	Definition (where possible this is the ISBT Definition)	Clinical Incident?
	http://www.isbtweb.org/fileadmin/user_upload/Proposed_definitions_2011_surveillance_non_infectious_adverse_reactions_haemovigilance_incl_TRALI_correction_2013_TACO_correction_2018.pdf	

6. References

1. Australian Commission on Safety and Quality in Health Care, *National Safety and Quality Health Service Standards. 2nd ed.* Sydney. ACSQHC, 2017. Available at: https://www.safetyandquality.gov.au/standards/nsqhs-standards/blood-management-standard (accessed 3 November 2021).

2. World Health Organisation, A guide to establishing a national haemovigilance system. Geneva, 2016. Available at: https://apps.who.int/iris/bitstream/handle/10665/250233/9789241549844-eng.pdf;jsessionid=6A76E826122594FAF5279999B08C17FD?sequence=1

3. National Blood Authority, *Haemovigilance Reporting.* Canberra. Available at: https://www.blood.gov.au/haemovigilance-reporting

4. Department of Health, Western Australia. *Clinical Incident Management Policy*. (2019). Perth: Patient Safety Surveillance Unit. https://ww2.health.wa.gov.au/-/media/Files/Corporate/Policy-Frameworks/Clinical-Governance-Safety-and-Quality/Policy/Clinical-Incident-Management-Policy-2019/Clinical-Incident-Management-Policy-2019.pdf

5. National Blood Authority *Australian Haemovigilance Minimum Data Set* (August 2015). Version 1. Canberra, 2015. Available at: https://www.blood.gov.au/haemovigilance-reporting (accessed 13 January 2020).

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