



NATIONAL BLOOD AUTHORITY
AUSTRALIA

AUSTRALIAN HAEMOVIGILANCE MINIMUM DATA SET

Version 2
October 2024



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Australian Haemovigilance Minimum Data Set (Version 2) published by the National Blood Authority.

This report is available online at <http://www.blood.gov.au>



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Purpose

The purpose of this document is to detail the required data elements for the National Blood Authority's (NBA) Australian Haemovigilance Minimum Data Set (AHMDS).

The data definitions and elements for the AHMDS [previously called the National Haemovigilance Data Dictionary (NHDD)] are primarily sourced from the NBA Haemovigilance Advisory Committee (HAC) and the Australian Institute of Health and Welfare (AIHW) Metadata Online Registry (METEOR). Definitions have also been taken from national and international standards for example:

- National Safety and Quality Health Service Standard 1 'Clinical Governance' (NSQHS Standard 1)
- National Safety and Quality Health Service Standard 7 'Blood Management' (NSQHS Standard 7)
- International Haemovigilance Network (IHN) and International Society of Blood Transfusion (ISBT) 'Proposed standard definitions for surveillance of non-infectious adverse transfusion reactions' July 2011 Incorporating correction to TRALI definition (as adopted June 2013)
- International Haemovigilance Network (IHN) and International Society of Blood Transfusion (ISBT) 'Proposed standard definitions for surveillance of sentinel types of errors and incidents' (adopted 2015)
- Serious Hazards of Transfusion (SHOT) 'Definitions of current SHOT reporting categories and what to report' (January 2022)
- Centers for Disease Control and Prevention (CDC) National Healthcare Safety Network (NHSN) 'Hemovigilance Module' (2021)

The AHMDS enables consistent data collection and analysis of transfusion related adverse events occurring in Australian health service organisations to improve the quality of national haemovigilance reporting.

Version control

Date	Description	Version	Implementation
January 2010	National Haemovigilance Data Dictionary	Original	July 2011 – June 2016
August 2015	Australian Haemovigilance Minimum Data Set	Version 1	July 2017 – June 2022
October 2024	Australian Haemovigilance Minimum Data Set	Version 2	July 2025 – June 2026

Introduction

The document will provide the data elements, their definitions and formats that make up the AHMDS to enable the consistent collection, validation and reporting of national haemovigilance data. National donor adverse event definitions are not included. Donor vigilance data is reported to the NBA by the Australian Red Cross Lifeblood (Lifeblood). The National Haemovigilance Program has been established on the basis of the following principles:

- national haemovigilance is guided by the HAC established by the NBA
- participation is voluntary
- reporting is confined to fresh (labile) blood products, including autologous transfusions (such as cell salvage)
- participating institutions can define their haemovigilance reporting processes and the data collected, which should align with or exceed the AHMDS
- adverse events are investigated, validated and reported at the local level
- adverse events are reported and managed in accordance with NSQHS Standard 7, the health policies of the individual states and territories and the Health Ministers Statement on National Stewardship Expectations for the Supply of Blood and Blood Products
- the reporting model for adverse events utilises existing healthcare systems to minimise the reporting burden
- adverse event data is coded and de-identified to maintain privacy and confidentiality
- reporting is based on a national minimum list of serious reportable adverse events, whose definitions will continue to align with IHN models
- adverse event data is accompanied by imputability (causality) scores.

The NHDD was published in 2010. It was restructured and renamed to the AHMDS and published in 2015 to align more closely with the IHN/ISBT standard haemovigilance definitions with the intention to improve the quality and comparability of data from different sources. This second version of the AHMDS (2024) supersedes the first version, which has been reviewed and revised by the HAC to incorporate updated definitions from ISBT/IHN, SHOT, the NSQHS Standard – Blood Management, and changes in METEOR.

The AHMDS is to be used as a reporting tool only. The AHMDS sets the minimum requirement for adverse event reporting nationally and is not designed to provide a care pathway for clinical decisions. The definitions included in Appendix A are not intended to be clinical guidance defining an adverse event, they are to assist the jurisdictions in reporting data for the National Haemovigilance Program to the NBA. Always refer to local hospital or jurisdictional definitions for the management of acute transfusion reactions and reporting requirements.

Where possible, definitions are the ISBT definitions, or a modification of those definitions as agreed by the HAC. Additional definitions may originate from the 2010 NHDD and the 2022 *'Definitions of current SHOT reporting categories and what to report'*.

The AHMDS will be reviewed every five years by the NBA and the HAC. Changes outside of the review timeframe may be considered by the HAC for inclusion in the AHMDS (e.g. updated international definitions) and will involve consultation with jurisdictions.

How to use this document

The *Strategic Framework for the National Haemovigilance Program* (Strategic Framework) defines the scope of national haemovigilance arrangements, to emphasise activities that contribute to national standardisation. The Strategic Framework outlines incident management and haemovigilance processes, roles, and responsibilities in Australia.

As part of the National Safety Quality Health Service (NSQHS) Standards, health service organisations (HSOs) should contribute to the National Haemovigilance Program in accordance with the Strategic Framework as per Standard 7 – Blood Management, which requires compliance with the following:

- 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

The AHMDS enables consistent data collection and analysis of transfusion related adverse events occurring in Australian HSOs. The HSOs use this data to identify trends and opportunities for practice improvements to achieve better patient outcomes.

Storage

Data files are submitted to and stored by the NBA in a secure server space in accordance with the *National Blood Authority Data and Information Governance Framework* available at www.blood.gov.au.

Access

The dataset will be held by the NBA in a secure server space and managed by authorised personnel to meet relevant privacy requirements. The data will be accessible only by persons holding positions in, or managing, the Data and Information Team of the NBA for analysis purposes, and the Chief Information Officer (or as delegated) as systems administrator to ensure data is stored and managed within the agreed governance framework.

Use

Data will be accessed and analysed by the Data and Information Team with input from clinical experts for use in the national reports, presentations, commentaries or research articles. As only de-identified data is provided to the NBA, case study requests from the NBA on specific adverse events are subject to each relevant jurisdiction's approval. No other use of this data is permitted without the permission of each Jurisdictional Blood Committee (JBC) member in accordance with the *National Blood Authority Data and Information Governance Framework*.

Publication

Each report will be presented to the HAC for endorsement after finalisation by the HAC working group and may be presented to JBC prior to publication. The NBA may require the approval of the appropriate JBC representative for publication of jurisdiction-specific data, conclusions or recommendations.

Privacy and data de-identification

Data from the states and territories is received by the NBA de-identified at patient and HSO level. Where aggregated data could potentially identify a patient or HSO, the NBA will remove rare or small numbers as required, in accordance with the *National Blood Authority Data and Information Governance Framework*.

Data definitions and standards

The data element definitions adhere to national and international standards, where these standards exist (such as METEOR). The majority of jurisdictional data can conform to these standards, enabling a smoother flow of data to the national dataset with minimal transformation.

METEOR Home - <http://meteor.aihw.gov.au/content/index.phtml/itemId/181162>

The table below shows the source of the definitions for data elements.

Symbol	Data element definition description/source
*	METEOR definition
**	Modified from a METEOR definition
^	2010 NHDD
^^	Modified from 2010 NHDD
~	National Safety and Quality Health Care Standards 2017 (Second Edition)
¹	Definition created by the NBA in order to receive de-identifiable health service organisation data from the states and territories

The definitions included in **Appendix A** have been either sourced or adapted from the ISBT Working Party on Haemovigilance proposed standard definitions available at: <http://www.isbtweb.org/working-parties/haemovigilance/> unless otherwise stated within the definition.

Person—age range

Identifying and definitional attributes																																	
<i>Metadata item type:</i> ⁱ	Data Element																																
<i>Short name:</i> ⁱ	Age Range																																
<i>METEOR identifier:</i> ⁱ	290540 (modified)																																
<i>Definition:</i> ⁱ	The age range that best accommodates a person's completed age in years, at the time of transfusion, as represented by a code.**																																
<i>Data Element Concept:</i>	Person—age range																																
Representational attributes																																	
<i>Representation class:</i> ⁱ	Code																																
<i>Data type:</i> ⁱ	String																																
<i>Format:</i> ⁱ	XX																																
<i>Maximum character length:</i> ⁱ	2																																
<i>Permissible values:</i> ⁱ	<table border="1"> <thead> <tr> <th>Value</th> <th>Meaning</th> </tr> </thead> <tbody> <tr><td>1</td><td>0-28 days (neonate)</td></tr> <tr><td>2</td><td>29 days - <1 year (infant)</td></tr> <tr><td>3</td><td>1-4 years</td></tr> <tr><td>4</td><td>5-9 years</td></tr> <tr><td>5</td><td>10-14 years</td></tr> <tr><td>6</td><td>15-17 years</td></tr> <tr><td>7</td><td>18-24 years</td></tr> <tr><td>8</td><td>25-34 years</td></tr> <tr><td>9</td><td>35-44 years</td></tr> <tr><td>10</td><td>45-54 years</td></tr> <tr><td>11</td><td>55-64 years</td></tr> <tr><td>12</td><td>65-74 years</td></tr> <tr><td>13</td><td>75-84 years</td></tr> <tr><td>14</td><td>85 years and older</td></tr> <tr><td>99</td><td>Not stated</td></tr> </tbody> </table>	Value	Meaning	1	0-28 days (neonate)	2	29 days - <1 year (infant)	3	1-4 years	4	5-9 years	5	10-14 years	6	15-17 years	7	18-24 years	8	25-34 years	9	35-44 years	10	45-54 years	11	55-64 years	12	65-74 years	13	75-84 years	14	85 years and older	99	Not stated
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12	65-74 years																																
13	75-84 years																																
14	85 years and older																																
99	Not stated																																
Collection and usage attributes																																	
<i>Guide for use:</i> ⁱ	<p>Age range should be derived from a question on date of birth or age at last birthday.</p> <p>The following are changes to the age range in the current AHMDS when compared to the superseded 2010 NHDD and 2015 AHMDS:</p>																																

** Modified from METEOR definition

	<ul style="list-style-type: none"> • The 0-4 age group is split into three age groups for neonates, infants and 1-4 years. • The 5-14 age group is split into two age groups for 5-9 years and 10-14 years. • The 15-24 age group is split into two age groups for 15-17 years and 18-24 years. • The 75 and older age group is split into two age groups for 75-84 years and 85 years and older.
<i>Comments:</i>	The METEOR data type for age range is listed as a number not string.
<p>Rationale for inclusion: Age range is a core data element in demographic statistics. It is used when an exact age is not known or not stated for privacy concerns. Analysis of this data element will contribute to the understanding of differences in the occurrence and outcome of adverse events between different age groups.</p>	

Person—sex

Identifying and definitional attributes											
<i>Metadata item type:</i> ⁱ	Data Element										
<i>Short name:</i> ⁱ	Sex										
<i>METEOR identifier:</i> ⁱ	635126										
<i>Definition:</i> ⁱ	The distinction between male, female, and others who do not have biological characteristics typically associated with either the male or female sex, as represented by a code.*										
<i>Data Element Concept:</i>	Person—sex										
Representational attributes											
<i>Representation class:</i> ⁱ	Code										
<i>Data type:</i> ⁱ	Number										
<i>Format:</i> ⁱ	N										
<i>Maximum character length:</i> ⁱ	1										
<i>Permissible values:</i> ⁱ	<table border="1"> <thead> <tr> <th>Value</th> <th>Meaning</th> </tr> </thead> <tbody> <tr> <td>1</td> <td>Male</td> </tr> <tr> <td>2</td> <td>Female</td> </tr> <tr> <td>3</td> <td>Other</td> </tr> <tr> <td>9</td> <td>Not stated/inadequately described</td> </tr> </tbody> </table>	Value	Meaning	1	Male	2	Female	3	Other	9	Not stated/inadequately described
Value	Meaning										
1	Male										
2	Female										
3	Other										
9	Not stated/inadequately described										
Collection and usage attributes											
<i>Guide for use:</i> ⁱ	<p>Diagnosis and procedure codes should be checked against the national ICD-10-AM sex edits, unless the person is undergoing, or has undergone a sex change or has a genetic condition resulting in a conflict between sex and ICD-10-AM code.</p> <p>CODE 3 Other - replaces 'Intersex or indeterminate' The label 'Other' is used because a more descriptive term has not been widely agreed within the general community.</p>										
Rationale for inclusion:											
Sex is a core data element in demographic statistics. Analysis of this data element will contribute to the understanding of differences in the occurrence and outcome of adverse events between the sexes											

* METEOR definition

Jurisdiction—Australian state/territory identifier

Identifying and definitional attributes																					
<i>Metadata item type:</i> ⁱ	Data Element																				
<i>Short name:</i> ⁱ	Australian state/territory identifier (Jurisdiction)																				
<i>METEOR identifier:</i> ⁱ	352480																				
<i>Definition:</i> ⁱ	An identifier of the Australian state or territory of a jurisdiction, as represented by a code.*																				
<i>Data Element Concept:</i>	Jurisdiction—Australian state/territory identifier																				
Representational attributes																					
<i>Representation class:</i> ⁱ	Code																				
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Collection and usage attributes																					
<i>Guide for use:</i> ⁱ	The order presented here is the standard for the Australian Bureau of Statistics (ABS).																				
Rationale for inclusion:																					
To explain the location for where the incident happened, to enable data to be analysed and compared at a jurisdictional level as well as a national level.																					

* METEOR definition

Health industry relevant organisation—main activity type

Identifying and definitional attributes																																							
<i>Metadata item type:</i> ⁱ	Data Element																																						
<i>Short name:</i> ⁱ	Health industry relevant organisation type																																						
<i>METEOR identifier:</i> ⁱ	372264																																						
<i>Definition:</i> ⁱ	Describes a health industry relevant organisation based on its main activity, as represented by a code. *																																						
<i>Data Element Concept:</i>	Health industry relevant organisation—main activity type																																						
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* METEOR Definition

	<p>118 Retail sale/supplier of medical goods – hearing aids</p> <p>119 Retail sale/supplier of medical goods – dispensing community pharmacist</p> <p>120 Retail sale/supplier of medical goods – other</p> <p>121 Public health program service provider</p> <p>122 General health administration service provider</p> <p>123 Private health insurance</p> <p>188 Other Main Health Care Service providers</p> <p>198 Regional health service not further defined</p> <p>199 State/territory health authority not further defined</p> <p>200 Secondary/non-Health Care Services organisation</p> <p>201 Pharmaceutical industry</p> <p>202 University</p> <p>203 Non-health related insurance</p> <p>204 Residential aged care facility</p> <p>288 Other Secondary/non-Health Care Services organisation</p>
Collection and usage attributes	
<i>Guide for use:</i> ⁱ	<p>It is anticipated that only codes 101, 102, or 103 will be reported to the National Haemovigilance Program. Details and guidance on other codes can be found in the AIHW National Health Data Dictionary.</p> <p>With the increase in the reporting of transfusions at residential facilities, 105 and 204 may also be anticipated to be reported in the future.</p>
Rationale for inclusion:	
To provide the ability to compare data between public and private sectors and determine whether there are differences in transfusion practice and adverse event occurrences.	

Health-care incident—geographic remoteness, remoteness classification (ASGS-RA) Code N

Identifying and definitional attributes																	
<i>Metadata item type:</i> ⁱ	Data Element																
<i>Short name:</i> ⁱ	Geographic remoteness																
<i>METEOR identifier:</i> ⁱ	702573																
<i>Definition:</i> ⁱ	The remoteness of the location at which a health-care incident took place, based on the physical road distance to the nearest urban centre and its population size, as represented by a code. *																
<i>Data Element Concept:</i>	Health-care incident—geographic remoteness																
Representational attributes																	
<i>Representation class:</i> ⁱ	Code																
<i>Data type:</i> ⁱ	Number																
<i>Format:</i> ⁱ	N																
<i>Maximum character length:</i> ⁱ	1																
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9	Not stated/inadequately described																
Collection and usage attributes																	
<i>Guide for use:</i> ⁱ	<p>CODE 1 Major cities of Australia 'Major cities of Australia' includes Statistical Area Level 1s (SA1s) with an average Accessibility/Remoteness Index of Australia (ARIA+) index value of 0 to 0.2.</p> <p>CODE 2 Inner regional Australia 'Inner regional Australia' includes SA1s with an average ARIA+ index value greater than 0.2 and less than or equal to 2.4.</p>																

* METEOR definition

CODE 3 Outer regional Australia
 'Outer regional Australia' includes SA1s with an average ARIA+ index value greater than 2.4 and less than or equal to 5.92.

CODE 4 Remote Australia
 'Remote Australia' includes SA1s with an average ARIA+ index value greater than 5.92 and less than or equal to 10.53.

CODE 5 Very remote Australia
 'Very remote Australia' includes SA1s with an average ARIA+ index value greater than 10.53.

CODE 6 Migratory
 'Migratory' is composed of off-shore, shipping and migratory SA1s.

CODE 9 Not stated/inadequately described

Comments: ¹

Mapping of the remoteness codes between the current AHMDS and the superseded 2010 NHDD, 2015 AHMDS:

Current	2015	2010
1	1	RA 1
2	2	RA 2
3	3	RA 3
4	4	RA 4
5	5	RA 5
6	6	Not Included
9	Not included	Not included

Rationale for inclusion:

This data element will be used to analyse the difference in the occurrence and outcome of adverse events in different geographic areas.

Health-care incident—transfusion-related adverse event

Identifying and definitional attributes																			
Metadata item type: ⁱ	Data Element																		
Short name: ⁱ	Transfusion-related adverse event																		
METEOR identifier: ⁱ	Not applicable																		
Definition: ⁱ	<p>Adverse event is an incident that results, or could have resulted, in harm to a patient or consumer. A near miss is a type of adverse event ~</p> <p>Incident (clinical) is an event or circumstance that resulted, or could have resulted, in unintended or unnecessary harm to a patient or consumer; or a complaint, loss or damage. An incident may also be a near miss. ~</p> <p><i>Notes: The term 'clinical' refers to any laboratory or clinical treatment area.</i></p> <p><i>Near misses are not included as adverse events in national haemovigilance reporting at this time. Complaints, loss or damage are also not included.</i></p>																		
Data Element Concept:	Health-care incident—transfusion-related adverse event																		
Representational attributes																			
Representation class: ⁱ	Code																		
Data type: ⁱ	String																		
Format: ⁱ	[X(250)]																		
Maximum character length: ⁱ	250																		
Permissible values: ⁱ	<table border="1"> <thead> <tr> <th>Value</th> <th>Meaning</th> </tr> </thead> <tbody> <tr> <td>ADU</td> <td>Avoidable, delayed, under or over transfusion</td> </tr> <tr> <td>AHTR</td> <td>Acute haemolytic transfusion reaction (other than ABO incompatibility)</td> </tr> <tr> <td>Allergic</td> <td>Allergic reaction</td> </tr> <tr> <td>Anaphylactic</td> <td>Anaphylactic reaction</td> </tr> <tr> <td>DHTR</td> <td>Delayed haemolytic transfusion reaction</td> </tr> <tr> <td>DSTR</td> <td>Delayed serologic transfusion reaction</td> </tr> <tr> <td>FNHTR</td> <td>Febrile non-haemolytic transfusion reaction</td> </tr> <tr> <td>Hypotensive</td> <td>Hypotensive transfusion reaction</td> </tr> </tbody> </table> <p>Refer to Appendix A for definitions of Transfusion-related adverse event permissible values.</p>	Value	Meaning	ADU	Avoidable, delayed, under or over transfusion	AHTR	Acute haemolytic transfusion reaction (other than ABO incompatibility)	Allergic	Allergic reaction	Anaphylactic	Anaphylactic reaction	DHTR	Delayed haemolytic transfusion reaction	DSTR	Delayed serologic transfusion reaction	FNHTR	Febrile non-haemolytic transfusion reaction	Hypotensive	Hypotensive transfusion reaction
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DSTR	Delayed serologic transfusion reaction																		
FNHTR	Febrile non-haemolytic transfusion reaction																		
Hypotensive	Hypotensive transfusion reaction																		

ⁱ National Safety and Quality Health Service (NSQHS) Standards Definition

	<p>IBCT – ABOi Incorrect blood component transfused - ABO incompatibility</p> <p>IBCT - SRNM Incorrect blood component transfused - Specific requirements not met</p> <p>IBCT - WCT Incorrect blood component transfused - Wrong component transfused</p> <p>Other Other types of adverse events (specify)</p> <p>PTP Post-transfusion purpura</p> <p>TACO Transfusion-associated circulatory overload</p> <p>TAD Transfusion associated dyspnoea</p> <p>TA-GVHD Transfusion associated graft-versus-host disease</p> <p>TRALI Transfusion-related acute lung injury</p> <p>TTI - B Transfusion transmitted infection-bacterial</p> <p>TTI - O Transfusion transmitted infection-other</p> <p>TTI - P Transfusion transmitted infection-parasitic</p> <p>TTI - V Transfusion transmitted infection - viral</p>
Collection and usage attributes	
<i>Guide for use:</i> ⁱ	This data element is used to categorise adverse transfusion reactions. ABO incompatibility is for sentinel event reporting.
<i>Collection methods:</i> ⁱ	This information should be captured by the local incident/quality management system. Collection and validation methods may vary across jurisdictions.
<i>Comments:</i>	The definitions provided for the Adverse Events at Appendix A are either modified from, or align with, those used by the IHN, ISBT and SHOT, and are referenced appropriately. However, the national minimum data set accepts the categorisation assigned by the contributing jurisdiction and the reviewing clinicians, regardless of minor differences to definitions.
Rationale for inclusion:	
NSQHS Standard 7 requires that HSOs capture and report incidents including adverse events. Standard definitions are essential for the surveillance and national or international comparisons of adverse events and where they are inconsistent then they should be mapped to the most appropriate value.	

Patient—outcome severity

Identifying and definitional attributes													
Metadata item type: ⁱ	Data Element												
Short name: ⁱ	Outcome severity												
METEOR identifier: ⁱ	Not applicable												
Definition: ⁱ	Hierarchical categories to define harm done to the patient as a result of an adverse event. [^]												
Data Element Concept:	Patient—outcome severity												
Representational attributes													
Representation class: ⁱ	Code												
Data type: ⁱ	String												
Format: ⁱ	[X(21)]												
Maximum character length: ⁱ	21												
Permissible values: ⁱ	<table border="1"> <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 a 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 <ul style="list-style-type: none"> - 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 </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 as a result of an adverse transfusion reaction <i>'Death' should be used only if death is possibly, probably or definitely related to transfusion. If the</i> </td> </tr> </tbody> </table>	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 a body function	Severe morbidity	The recipient required in-patient hospitalisation or prolongation of hospitalisation directly attributable to the event; and/or <ul style="list-style-type: none"> - 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 as a result of an adverse transfusion reaction <i>'Death' should be used only if death is possibly, probably or definitely related to transfusion. If the</i>
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Life-threatening	The recipient required major intervention following the transfusion (vasopressors, intubation, transfer to intensive care) to prevent death												
Death	The recipient died as a result of an adverse transfusion reaction <i>'Death' should be used only if death is possibly, probably or definitely related to transfusion. If the</i>												

[^] 2010 National Haemovigilance Data Dictionary definition

	<p><i>patient died of another cause, the severity of the reaction should be graded as 'minor morbidity' 'severe morbidity' or 'life-threatening'.</i></p> <p>Outcome not available Null response. The clinical outcome classification may be pending (extended time taken to assign clinical outcome) or permanently unavailable</p>
Collection and usage attributes	
<i>Guide for use:</i>	The delineation between 'Minor morbidity' and 'Severe morbidity' may present difficulty in the classification in some adverse reaction cases.
<i>Collection methods:</i> ¹	The coding and validation of events are the sole responsibility of the HSOs.
<i>Comments:</i>	<p>The reporting of this data element should reflect that clinical outcome severity is separate to the severity/risk inherent to some contributory factors, and is separate (but related) to the imputability of the transfusion episode. Reporting should also make it clear that there are no reliable denominators in the Australian haemovigilance sector and estimations of rates of incidence and their severities are not reliable.</p> <p>Note: Use minor morbidity for a DSTR event due to increased monitoring for potential future harm to those who make red blood cell antibodies as a result of the transfusion. The impact is unknown at the time of the DSTR event.</p>
Rationale for inclusion:	
Patient outcome severity information is used to assess and compare the severity of adverse events and to develop actions and recommendations on quality and safety improvement.	

Health-care incident—imputability score

Identifying and definitional attributes															
<i>Metadata item type:</i> ⁱ	Data element														
<i>Short name:</i> ⁱ	Imputability score														
<i>METEOR identifier:</i> ⁱ	Not applicable														
<i>Definition:</i> ⁱ	A hierarchical representation of the extent to which the adverse event is capable of being assigned or credited to the transfusion. [^]														
<i>Data Element Concept:</i>	Health-care incident—imputability score														
Representational attributes															
<i>Representation class:</i> ⁱ	Code														
<i>Data type:</i> ⁱ	String														
<i>Format:</i> ⁱ	XX														
<i>Maximum character length:</i> ⁱ	2														
<i>Permissible values:</i> ⁱ	<table border="1"> <thead> <tr> <th>Value</th> <th>Meaning</th> </tr> </thead> <tbody> <tr> <td>01</td> <td>Excluded</td> </tr> <tr> <td>02</td> <td>Unlikely</td> </tr> <tr> <td>03</td> <td>Possible</td> </tr> <tr> <td>04</td> <td>Probable (likely)</td> </tr> <tr> <td>05</td> <td>Definite (certain)</td> </tr> <tr> <td>99</td> <td>Not assessable</td> </tr> </tbody> </table>	Value	Meaning	01	Excluded	02	Unlikely	03	Possible	04	Probable (likely)	05	Definite (certain)	99	Not assessable
Value	Meaning														
01	Excluded														
02	Unlikely														
03	Possible														
04	Probable (likely)														
05	Definite (certain)														
99	Not assessable														
Collection and usage attributes															
<i>Guide for use:</i> ⁱ	<p>Align the health service organisation assigned imputability with the meanings provided below to generate the indicated code.</p> <p>CODE 01 Excluded</p> <p>When there is conclusive evidence beyond reasonable doubt for attributing the adverse reaction to causes other than the transfusion</p> <p>CODE 02 Unlikely</p> <p>When the evidence is clearly in favour of attributing the adverse reaction to causes other than the transfusion</p> <p>CODE 03 Possible</p> <p>When the evidence is indeterminate for attributing the adverse reaction to the transfusion</p>														

[^] 2010 National Haemovigilance Data Dictionary definition

	<p>CODE 04 Probable (likely) When the evidence is clearly in favour of attributing the adverse reaction to the transfusion</p> <p>CODE 05 Definite (certain) When there is conclusive evidence beyond reasonable doubt for attributing the adverse reaction to the transfusion</p> <p>CODE 99 Not assessable There are insufficient data for assessment.</p>																					
<i>Collection methods:</i> ⁱ	Imputability is assigned and validated at the local or state level.																					
<i>Comments:</i> ⁱ	<p>All haemovigilance data is accepted, but imputability may be used to filter out low imputability events (Codes 01 and 02 and 03) from national reporting.</p> <p>Mapping of the imputability codes between the current AHMDS and the superseded 2010 NHDD, 2015 AHMDS :</p> <table border="1" data-bbox="667 943 1158 1267"> <thead> <tr> <th>Current</th> <th>2015</th> <th>2010</th> </tr> </thead> <tbody> <tr> <td>01 – Excluded</td> <td>0 – Excluded</td> <td>0 – Excluded or Unlikely</td> </tr> <tr> <td>02 – Unlikely</td> <td>1 – Unlikely</td> <td>1 – Possible</td> </tr> <tr> <td>03 – Possible</td> <td>2 – Possible</td> <td>2 – Likely/Probable</td> </tr> <tr> <td>04 – Probable (likely)</td> <td>3 – Probable (likely)</td> <td>3 – Confirmed/Certain</td> </tr> <tr> <td>05 – Definite (certain)</td> <td>4 – Definite (certain)</td> <td>Not included</td> </tr> <tr> <td>99 – Not assessable</td> <td>9 – Not assessable</td> <td>9 – N/A - Not Assessable</td> </tr> </tbody> </table>	Current	2015	2010	01 – Excluded	0 – Excluded	0 – Excluded or Unlikely	02 – Unlikely	1 – Unlikely	1 – Possible	03 – Possible	2 – Possible	2 – Likely/Probable	04 – Probable (likely)	3 – Probable (likely)	3 – Confirmed/Certain	05 – Definite (certain)	4 – Definite (certain)	Not included	99 – Not assessable	9 – Not assessable	9 – N/A - Not Assessable
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05 – Definite (certain)	4 – Definite (certain)	Not included																				
99 – Not assessable	9 – Not assessable	9 – N/A - Not Assessable																				
<p>Rationale for inclusion: This element provides data about whether the transfusion is related to the adverse event.</p>																						

Person—discovery/recognition date of adverse event

Identifying and definitional attributes	
<i>Metadata item type:</i> ⁱ	Data Element
<i>Short name:</i> ⁱ	Discovery/recognition date of adverse event
<i>METEOR identifier:</i> ⁱ	Not applicable
<i>Definition:</i> ⁱ	The earliest date that an adverse event was discovered/recognised. ^{**}
<i>Data Element Concept:</i>	Person – discovery/recognition date of adverse event
Representational attributes	
<i>Representation class:</i> ⁱ	Date
<i>Data type:</i> ⁱ	Date
<i>Format:</i> ⁱ	DDMMYYYY
<i>Maximum character length:</i> ⁱ	8
Collection and usage attributes	
<i>Guide for use:</i> ⁱ	Record the date of any transfusion-related adverse event that has been experienced by a patient. This could be the same as the transfusion date or sometime after. This includes an adverse event taking place days, weeks, months, or even years after a transfusion. The date recorded should be the earliest date that the specific transfusion-related adverse event was discovered/recognised.
<i>Comments:</i>	DDMMYYYY format should be used such as 01072014 for 1 July 2014. Note this is not the date of the transfusion, it is the date that the adverse event was discovered/recognised.
Rationale for inclusion:	
Analysis of this data element will identify adverse events where there was a delayed reaction and/or when the transfusion date is unknown.	

^{**} Modified from METEOR definition

Episode of admitted patient care (procedure)—transfusion commencement date

Identifying and definitional attributes	
<i>Metadata item type:</i> ⁱ	Data Element
<i>Short name:</i> ⁱ	Date of transfusion
<i>METEOR identifier:</i> ⁱ	270298 (modified)
<i>Definition:</i> ⁱ	The date on which the implicated transfusion commenced. ^{**}
<i>Data Element Concept:</i>	Episode of admitted patient care (procedure)—transfusion commencement date
Representational attributes	
<i>Representation class:</i> ⁱ	Date
<i>Data type:</i> ⁱ	Date
<i>Format:</i> ⁱ	DDMMYYYY
<i>Maximum character length:</i> ⁱ	8
Collection and usage attributes	
<i>Guide for use:</i> ⁱ	Record the date the implicated transfusion commenced.
<i>Collection methods:</i> ⁱ	Date of transfusion ≥ admission date Date of transfusion ≤ separation date
<i>Comments:</i> ⁱ	DDMMYYYY format should be used such as 01072014 for 1 July 2014. Note: If transfusion date is not known, enter 00011900
Rationale for inclusion:	
Analysis of this data element will contribute to understanding any differences in the occurrence and outcomes of adverse events between week days and weekends and improving transfusion practice.	

^{**} Modified from METEOR definition

Episode of admitted patient care (procedure)—transfusion commencement time

Identifying and definitional attributes	
Metadata item type: ⁱ	Data Element
Short name: ⁱ	Time of transfusion
METEOR identifier: ⁱ	682942 (modified)
Definition: ⁱ	The time at which the implicated transfusion commenced**
Data Element Concept:	Episode of admitted patient care (procedure)—transfusion commencement time
Representational attributes	
Representation class: ⁱ	Time
Data type: ⁱ	Time
Format: ⁱ	hhmm
Maximum character length: ⁱ	4
Collection and usage attributes	
Guide for use: ⁱ	Required to identify the time of commencement of the transfusion.
Comments: ⁱ	<p>The 24 hour format should be used (e.g. 2130 for 'nine thirty' at night)</p> <p>Note: National reporting may use the transfusion commencement time to denote day/night. The basis for this is that shift times differ across health service organisations. For the purposes of national haemovigilance reporting and data analysis, 'night' is between 7pm and 7am (which is a generalised maximum spread of hours that ordinary hours can be worked).</p>
Rationale for inclusion:	
Analysis of this data element will contribute to understanding the differences in the occurrence and outcomes of adverse events between day and night and improving transfusion practice.	

** Modified from METEOR definition

Health-care incident—contributory factor

Identifying and definitional attributes				
<i>Metadata item type:</i> ⁱ		Data array		
<i>Short name:</i> ⁱ		Contributory factor		
<i>METEOR identifier:</i> ⁱ		Not applicable		
<i>Definition:</i> ⁱ		Any significant event or factor that may have played a role in the occurrence of the adverse event. ^		
<i>Data Element Concept:</i>		Health-care incident—contributory factor		
<i>Format:</i>		XXXXX except other [X(512)]		
Collection and usage attributes - Contributory factor data elements				
<i>Short name:</i> ⁱ	<i>Definition:</i> ⁱ	<i>Data type:</i> ⁱ	<i>Maximum character length:</i> ⁱ	<i>Permissible values:</i> ⁱ
None identified	No contributory factors have been attributed to the adverse event.	String	5	True or False
Product characteristic	The product contributed to the reaction due to an inherent but not necessarily faulty characteristic (such as an allergic or anaphylactic reaction to a product; unknown significance of anti-HLA antibodies).	String	5	True or False
Product defect	A product defect is blood or a blood component which does not meet the quality, safety and efficacy requirements set in the <i>Therapeutic Goods Order No.102¹ and 88²</i> approved under the <i>Therapeutic Goods Act 1989</i> or which contains (remaining) contaminating agents despite screening, testing and processing having been undertaken properly (e.g. product discarded after positive infection test result following a window period). Other examples may include bacterial contaminated product, haemolysed product or product labelled with incorrect phenotype stated.	String	5	True or False
Transfusion in emergency setting	The transfusion was administered under emergency conditions.	String	5	True or False

ⁱ 2010 National Haemovigilance Data Dictionary definition

Deliberate clinical decision	The decision to transfuse was made with clinical forethought, and with due consideration of the increased possibility of a transfusion reaction (e.g. where no other more suitable product is available).	String	5	True or False
Prescribing or ordering	Event(s) during prescribing or ordering the product contributed to the transfusion reaction.	String	5	True or False
Specimen collection or labelling	Event(s) during specimen collection or labelling contributed to the transfusion reaction.	String	5	True or False
Laboratory pre-transfusion testing and dispensing	Event(s) during laboratory pre-transfusion testing or dispensing of the product contributed to the transfusion reaction.	String	5	True or False
Transport, storage, handling	Event(s) during the transport, storage or handling of the product contributed to the transfusion reaction.	String	5	True or False
Administration of product	Event(s) during the administration of the product contributed to the transfusion reaction.	String	5	True or False
Indications did not meet hospital transfusion guidelines	The clinical indications for transfusion did not meet hospital transfusion guidelines.	String	5	True or False
Did not adhere to hospital transfusion procedures	The transfusion procedures did not adhere to hospital transfusion procedures.	String	5	True or False
Other	A description of the event(s) that contributed to the adverse transfusion reaction, other than other defined events, as represented by text.	String	512	Free text
<i>Guide for use:</i> i	Each element (Product characteristic, Transfusion in emergency setting, Deliberate clinical decision, etc.) should be viewed as separate. They are grouped here as an 'array' as they are part of the same concept, "Health-care incident—contributory factor". A True/False value should be returned for each element except for "other" which allows for descriptive free text.			

Comments: ⁱ

1. Current TGO: TGO No. 102 – Standard for Blood and Blood Components (note this order includes the requirements of the CoE document ‘Guide to the preparation, use and quality assurance of blood components’ 14th edition) <https://www.tga.gov.au/therapeutic-goods-orders> (as amended from time to time)
2. Current TGO: TGO No. 88 – Standards for donor selection, testing and minimising infectious disease transmission via therapeutic goods that are human blood and blood components, human tissues and human cellular therapy products <https://www.tga.gov.au/therapeutic-goods-orders> (as amended from time to time)

Rationale for inclusion:

The purpose for this data element is to capture the data on adherence to hospital transfusion guidelines and transfusion procedures, on process errors, or on any relevant lapses throughout the transfusion chain (if any; e.g. cold chain, faulty product etc.)

Transfusion—product type

Identifying and definitional attributes	
<i>Metadata item type:</i> ⁱ	Data Element
<i>Short name:</i> ⁱ	Product type
<i>METEOR identifier:</i> ⁱ	Not applicable
<i>Definition:</i> ⁱ	The blood product/s which may cause the adverse event during or after the transfusion. ^^
<i>Data Element Concept:</i>	Transfusion—product type
Representational attributes	
<i>Representation class:</i> ⁱ	Code
<i>Data type:</i> ⁱ	String
<i>Format:</i> ⁱ	[X(50)]
<i>Maximum character length:</i> ⁱ	50
<i>Permissible values:</i>	
Value	Meaning
Red blood cells	WB Red Blood Cells WB Paediatric Red Blood Cells
Platelets	WB Platelet Pool Apheresis Platelet Paediatric Apheresis Platelet
Fresh frozen plasma	WB Clinical FFP Paediatric WB Clinical FFP Apheresis Clinical FFP
Cryoprecipitate	WB Cryoprecipitate Apheresis Cryoprecipitate
Cryo-depleted Plasma	WB Cryo-depleted Plasma Apheresis Cryo-depleted Plasma
Multiple product types	More than one type of product that may cause the adverse event
Cell salvage	Autologous cell salvage
Pre-deposit	Autologous pre-deposit
Other products	Directed donation complying with Guidelines Granulocytes
Collection and usage attributes	
<i>Guide for use:</i> ⁱ	The administered labile blood product or fresh blood component can be coded as one of the categories presented.

^^ Modified from 2010 National Haemovigilance Data Dictionary definition

Comments: ⁱ

Product groupings are used rather than components and there is no requirement to collect ABO or Rh(D) data for all products.

Rationale for inclusion:

To collect and analyse the fresh blood product data which may contribute to the adverse event during or after the transfusion.

Transfusion — product type modification

Identifying and definitional attributes	
<i>Metadata item type:</i> ⁱ	Data Element
<i>Short name:</i> ⁱ	Product type modification
<i>METEOR identifier:</i> ⁱ	Not applicable
<i>Definition:</i> ⁱ	Blood product modification data on labile products coded according to Lifeblood product nomenclature. ^^
<i>Data Element Concept:</i>	Transfusion—product type modification
Representational attributes	
<i>Representation class:</i> ⁱ	Code
<i>Data type:</i> ⁱ	String
<i>Format:</i> ⁱ	[X(12)]
<i>Maximum character length:</i> ⁱ	12
<i>Permissible values:</i>	
Value	Meaning
Irrad	Irradiated
CMV	Cytomegalovirus Seronegative
Wash	Washed
Null	Unmodified product
Other	Any modification not mentioned above
Collection and usage attributes	
<i>Guide for use:</i> ⁱ	Modified products are available from Lifeblood, but the inclusion of every modification in the national dataset is not justified. Products will be coded as one of five values.
<i>Comments:</i> ⁱ	This is an optional field. Data without coding for this field will be assigned the “Null” value.
Rationale for inclusion:	
To collect and analyse the fresh blood product modification data which may contribute to the adverse event during or after the transfusion.	

^{^^} Modified from 2010 National Haemovigilance Data Dictionary definition

Appendix A – Definitions of Reported* Transfusion-related Adverse Events

* **Disclaimer:** This list is not intended to be clinical guidance defining an adverse event, this is a list of transfusion-related adverse events reported as part of the national data set.

Where possible, definitions are the [ISBT](#) definitions or a modification of those definitions as agreed by the HAC. Additional definitions may originate from the 2010 NHDD and/or SHOT (refer to page 4 of this document for references).

Adverse Event	Definition – Where possible this is the ISBT Definition
ABO incompatibility (ABO)	These are a subgroup of the IBCT category.
Avoidable, delayed, under or over transfusion (ADU)	<p>Avoidable transfusion: Where the intended transfusion is carried out, and the blood component itself is suitable for transfusion and compatible with the patient, but where the decision leading to the transfusion is flawed. (SHOT definition)</p> <p>Delayed transfusion: Where a transfusion of a blood component was clinically indicated but was not undertaken or non-availability of blood components led to a significant delay. (SHOT definition modified)</p> <p>Under (or over) transfusion: A dose/rate inappropriate for the patient’s needs, excluding those cases which result in TACO. (SHOT definition)</p> <p><i>For further guidance on what to report under this category, see Appendix C.</i></p>
Acute haemolytic transfusion reaction (other than ABO incompatibility) (AHTR)	<p>An AHTR has its onset within 24 hours of a transfusion. Clinical or laboratory features of haemolysis are present.</p> <p>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.</p> <p>Common laboratory features are haemoglobinaemia, haemoglobinuria, decreased serum haptoglobin, unconjugated hyperbilirubinaemia, increased LDH and AST levels and decreased haemoglobin levels.</p> <p>Not all clinical or laboratory features are present in cases of AHTR. (ISBT definition)</p>

Allergic reaction (Allergic)	<p>An allergic reaction may present only with mucocutaneous signs and symptoms during or within 4 hours of transfusion:</p> <ul style="list-style-type: none"> • morbilliform rash with itching • urticaria • localised angioedema • oedema of lips, tongue and uvula • periorbital pruritus, erythema and oedema • conjunctival oedema <p>(ISBT definition) This type of reaction is usually associated with an outcome severity of minor morbidity. An allergic reaction that involves respiratory and/or cardiovascular systems should be reported as an anaphylactic reaction.</p>
Anaphylactic reaction (Anaphylactic)	<p>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 during or very shortly after transfusion. (ISBT definition) This type of reaction is usually associated with an outcome severity of severe morbidity, life threatening or death.</p>
Delayed haemolytic transfusion reaction (DHTR)	<p>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 manifest as an inadequate rise of post-transfusion haemoglobin level or unexplained fall in haemoglobin after a transfusion. Blood group serology usually shows abnormal results. (ISBT definition)</p>
Delayed serologic transfusion reaction (DSTR)	<p>DSTR is defined by the demonstration of post transfusion clinically significant red blood cell antibodies against red blood cells which were previously undetected and when there are no clinical or laboratory features of haemolysis. This term is synonymous with alloimmunisation. (ISBT definition modified)</p>

<p>Febrile non-haemolytic transfusion reaction (FNHTR)</p>	<p>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.</p> <p>FNHTR 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:</p> <ul style="list-style-type: none"> • rise in temperature of 2°C or more above baseline, or absolute temperature of 39°C or over; • may be accompanied by chills/rigors, headache and nausea. <p>(SHOT and ISBT definitions modified)</p> <p>Definitions with a lower temperature rise may still be considered FNHTR for the purposes of hospital transfusion committee and/or jurisdictional reporting.</p>
<p>Hypotensive transfusion reaction (Hypotensive)</p>	<p>This reaction is characterized by hypotension occurring during or within one hour of completing transfusion and defined as:</p> <p>Adults drop in systolic blood pressure of ≥ 30 mm Hg and a systolic blood pressure ≤ 80 mm Hg.</p> <p>(ISBT definition modified)</p> <p>Infants, children and adolescents (1 year to 18 years) > 25% drop in systolic blood pressure from baseline</p> <p>Neonates and small infants (<1 year) > 25% drop in baseline blood pressure value by whichever measurement is being recorded (e.g., mean blood pressure)</p> <p>(CDC definition modified)</p>

Incorrect blood component transfused (IBCT)

Do NOT report if a clinical decision has been taken to knowingly transfuse components not meeting specification in view of clinical urgency.

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

- only a small quantity of blood was transfused and/or
- there was no adverse reaction

(ISBT definition modified)

ABO incompatibility (IBCT-ABOi)

Where a blood component was transfused which was unintentionally ABO incompatible.

All cases are to be included, regardless of where the first error occurred e.g. Lifeblood, the blood transfusion laboratory or clinical areas. (ISBT definition modified)

Note: 'Haemolytic blood transfusion reaction resulting from ABO incompatibility resulting in serious harm or death' is considered a 'sentinel event' and is also subject to other reporting channels outside of the National Haemovigilance Program. (See 2020 Australian Sentinel Events List) at: <https://www.safetyandquality.gov.au/our-work/indicators-measurement-and-reporting/incident-management-and-sentinel-events>

For further guidance on what to report under this category, see Appendix D.

Specific requirements not met (IBCT-SRNM)

Where a patient was transfused with a blood component that did not meet their specific transfusion requirements. (SHOT definition modified)

For further guidance on what to report under this category, see Appendix D.

Wrong component transfused (IBCT-WCT) excluding ABOi

Where a patient was transfused with a blood component:

- a) which was incompatible with the recipient (e.g. antigen/antibody incompatibility, including Rh D).
- b) which was intended for another patient but was compatible with the recipient.
- c) other than that prescribed, e.g. platelets instead of red blood cells.

(SHOT definition modified)

For further guidance on what to report under this category, see Appendix D.

Other types of adverse events (Other)	Other types of adverse events not defined in this AHMDS but defined and published by the ISBT at http://www.isbtweb.org/working-parties/haemovigilance/ (ISBT definition modified)
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. (ISBT definition)
Transfusion-associated circulatory overload (TACO)	The presence of a total of 3 or more of criteria A-E below including at least one required criterion during or up to 12 hours after transfusion: Required criteria A. Acute or worsening respiratory compromise and/or B. Evidence of acute or worsening pulmonary oedema Additional criteria C. Evidence of cardiovascular system changes e.g., development of tachycardia, hypertension, jugular venous distension, enlarged cardiac silhouette and/or peripheral oedema D. Evidence of fluid overload e.g., a positive fluid balance; clinical improvement following diuresis E. Supportive result of a relevant biomarker, e.g., an increase of B-type natriuretic peptide levels (SHOT definition modified)
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. (ISBT definition)
Transfusion associated graft-versus-host disease (TA-GVHD)	TA-GVHD clinically features the following 1–6 weeks post transfusion, with no other apparent cause: <ul style="list-style-type: none">● fever● rash● liver dysfunction● diarrhoea● pancytopenia TA-GVHD is confirmed by GVHD-typical biopsy and genetic analysis to show chimerism of donor and recipient lymphocytes. (ISBT definition modified)

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
 - $\text{PaO}_2 / \text{FiO}_2 < 300$ 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 that may cause ALI (independent of TRALI) include:

- 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.

(ISBT definition modified)

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. (ISBT definition)

Transfusion transmitted bacterial infection (TTI-B)

Transfusion transmitted bacterial infection should be clinically suspected if:

- fever $\geq 39^{\circ}\text{C}$ or a change of $\geq 2^{\circ}\text{C}$ from pre transfusion value and
- rigors and/or
- tachycardia

In the event of a suspected TTI-B the following can be used as guidance in assigning imputability.

Potential transfusion transmitted bacterial infection:

- detection of bacteria by approved techniques in the transfused blood component but not in the recipient's blood (excluding initial pre-release blood component bacterial screening in the absence of evidence of infection or a reaction) 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 (2010 NHDD)

Other transfusion transmitted infection (TTI – O)

Transfusion transmitted parasitic infection (TTI-P)

Detection of the same parasite in the recipient's blood and parasite or specific antibodies in the donor blood. (2010 NHDD)

Transfusion transmitted viral infection (TTI-V)

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. (2010 NHDD)

Appendix B – Rationale for data collection

AHMDS data elements for transfusion related adverse events, and rationale for data collection	
Data element	Rationale
Person - Age range	To identify differences in the occurrence and outcome of adverse events between different age groups.
Person - Sex	To identify differences in the occurrence and outcome of adverse events between the sexes.
Jurisdiction - Australian state/ territory identifier	To identify differences in transfusion practice and occurrences and outcomes of adverse events in different states/territories.
Health industry relevant organisation - main activity type	To identify differences in transfusion practice and adverse event occurrences between public and private organisations.
Health-care incident - geographic remoteness, remoteness classification (ASGS-RA) Code N	To identify occurrences and outcomes of adverse events in different geographic areas.
Health-care incident – transfusion related adverse event	To identify the type of adverse event and allow for grouping analysis.
Patient - outcome severity	To compare the severity of adverse events.
Health-care incident - imputability score	To identify whether the transfusion is related to the adverse event.
Person - Discovery/ recognition date of adverse event	To identify the earliest date that an adverse event was discovered/recognised.
Episode of admitted patient care (procedure) - transfusion commencement date	To identify differences in the occurrence and outcomes of adverse events between week days and weekends.
Episode of admitted patient care (procedure) - transfusion commencement time	To identify differences in the occurrence and outcomes of adverse events between day and night.
Healthcare incident - Contributory factor	To identify factors that contributed to the adverse event.
Transfusion - product type	To identify the blood product that may have contributed to the adverse event.
Transfusion - Product type modification	To identify the modification data of a blood product which may contribute to the adverse event during or after the transfusion.

Appendix C – What to report for Avoidable, Delayed, Under or over transfusion (ADU)

Definition	What to report*
<p><u><i>Avoidable, Delayed, Under or over transfusion (ADU)</i></u></p> <p>Avoidable transfusion: Where the intended transfusion is carried out, and the blood component itself is suitable for transfusion and compatible with the patient, but where the decision leading to the transfusion is flawed. (SHOT definition)</p> <p>Delayed transfusion: Where a transfusion of a blood component was clinically indicated but was not undertaken or non-availability of blood components led to a significant delay. (SHOT definition modified)</p> <p>Under (or over) transfusion: A dose/rate inappropriate for the patient’s needs, excluding those cases which result in TACO. (SHOT definition modified)</p>	<p>Failure to transfuse when indicated, under or over-transfusion, avoidable transfusion and significant delays in transfusion, whether caused by the laboratory or the clinical area. This includes:</p> <p>Prescription errors associated with:</p> <ul style="list-style-type: none"> • Components that are not required or are inappropriate as a result of erroneous laboratory results, transcription errors or faulty clinical judgement • Components that are for an inappropriate indication • Inappropriate volume transfused • Infusion pump errors leading to under or over transfusion <p>Also:</p> <ul style="list-style-type: none"> • Transfusion of asymptomatic patients with a haematinic deficiency • Avoidable use of emergency Rh D negative blood where group-specific or crossmatched blood was readily available for the patient or the laboratory could have supplied a more suitable component, including use of Rh D negative blood when time would allow a more appropriate group to be remotely allocated from a remote release refrigerator system. <p>Delays</p> <ul style="list-style-type: none"> • Delays in provision of blood components in an emergency • Cases where a delay in transfusion adversely affected the patient’s clinical outcome <p>(SHOT definition modified)</p>

* Adapted from 'Definitions of current SHOT reporting categories and what to expect – Revised January 2022'

Appendix D – What to report for incorrect blood component transfused (IBCT)

Definition	What to report*
<p><u>ABO incompatibility (IBCT-ABOi)</u></p> <p>Where a blood component was transfused which was unintentionally ABO incompatible. All cases are to be included regardless of where the first error occurred e.g. Lifeblood, the blood transfusion laboratory or clinical areas.</p> <p>(ISBT definition modified)</p>	<p>Do NOT report if a clinical decision has been taken to knowingly transfuse components not meeting specification in view of clinical urgency.</p> <p>Patients receiving a blood component of an incorrect ABO group</p> <ul style="list-style-type: none"> • intended for a different patient OR • due to clinical and/or laboratory errors in the transfusion process. <p>Examples include:</p> <ul style="list-style-type: none"> • ‘Wrong blood in tube’ associated with group & screen phlebotomy errors • Changes in grouping requirements following haemopoietic stem cell transplant or solid organ transplant. • Testing and procedural errors associated with ABO grouping • Component selection errors • Collection & administration errors • Incorrect component selected from stock. (Includes adult units to neonates) • Failure to supply low titre negative group mismatched platelets or plasma components <p>(SHOT definition modified)</p>
<p><u>Specific requirements not met (IBCT-SRNM)</u></p> <p>Where a patient was transfused with a blood component that did not meet their specific transfusion requirements.</p> <p>(SHOT definition modified)</p>	<p>Transfusion of a blood component of inappropriate specification or that did not meet the patient’s individual requirements. Examples include <i>failure</i> to transfuse:</p> <ul style="list-style-type: none"> • Cytomegalovirus (CMV)-negative components where indicated • Irradiated components where indicated • Human leucocyte antigen (HLA)-matched platelets where indicated • Red blood cells of correct phenotype for patients with a clinical requirement for phenotype matching e.g. haemoglobinopathy • Antigen-negative red blood cells for patients with known clinically significant red blood cell antibodies • appropriate components due to invalid, incomplete or errors in laboratory testing <p>(SHOT definition modified)</p>

Definition	What to report*
<p><u>Wrong component transfused (IBCT-WCT) excluding ABOi</u></p> <p>Where a patient was transfused with a blood component:</p> <ol style="list-style-type: none"> which was incompatible with the recipient (e.g. antigen/antibody incompatibility, including RhD). which was intended for another patient but was compatible with the recipient. other than that prescribed, e.g. platelets instead of red blood cells. <p>(SHOT definition modified)</p>	<p>Do NOT report if a clinical decision has been taken to knowingly transfuse components not meeting specification in view of clinical urgency.</p> <p>Patients receiving a blood component of an incorrect antigen/antibody (including Rh D)</p> <ul style="list-style-type: none"> intended for a different patient OR due to clinical and/or laboratory errors in the transfusion process. <p>Examples include:</p> <ul style="list-style-type: none"> 'Wrong blood in tube' associated with antigen/antibody (including Rh D) group & screen phlebotomy errors Changes in grouping requirements following haemopoietic stem cell transplant or solid organ transplant. Testing and procedural errors associated with antigen/antibody (including Rh D grouping) Component selection errors Collection & administration errors Incorrect component selected from stock (Includes adult units to neonates) Failure to supply low titre negative group mismatched platelets or plasma components <p>Note: IBCT-WCT does not include WBIT if identified prior to administration.</p> <p>(SHOT definition modified)</p>

* Adapted from 'Definitions of current SHOT reporting categories and what to expect – Revised January 2022'

Abbreviations and acronyms

ABO	ABO Incompatibility
ABS	Australian Bureau of Statistics
ADU	Avoidable, Delayed, Under or Over Transfusion
AHMAC	Australian Health Ministers' Advisory Council
AHMDS	Australian Haemovigilance Minimum Data Set
AHTR	Acute haemolytic transfusion reaction
AIHW	Australian Institute of Health and Welfare
Anti-HLA	Anti-Human Leukocyte Antibodies
ALI	Acute Lung Injury
ARIA	Accessibility/Remoteness Index of Australia
AST Levels	Aspartate Aminotransferase level
CDC	Centers for Disease Control
CDs	Census Collection Districts
CMV	Cytomegalovirus
DHTR	Delayed haemolytic transfusion reaction
DSTR	Delayed serologic transfusion reaction
CoE	Council of Europe
FFP	Fresh Frozen Plasma
FiO ₂	Fraction of inspired oxygen
FNHTR	Febrile Non-Haemolytic Transfusion Reaction
HAC	Haemovigilance Advisory Committee
HIV	Human Immunodeficiency Virus
HLA	Human Leucocyte Antigen
HPA	Human Platelet Antigen
IBCT- SRNM	Incorrect blood component transfused - Specific Requirements Not Met
IBCT- WCT	Incorrect blood component transfused – Wrong Component Transfused
HSO	Health Service Organisation
ICD-10 AM	The International Statistical Classification of Diseases and Related Health Problems, Tenth Revision, Australian Modification
ID	Identification
IHN	International Haemovigilance Network
ISBT	International Society of Blood Transfusion
JBC	Jurisdictional Blood Committee
LDH Levels	Lactate Dehydrogenase Level

METEOR	Metadata Online Registry
mmHg	Millimetres of mercury (measurement of pressure)
NBA	National Blood Authority
NHDD	National Haemovigilance Data Dictionary
NSQHS	National Safety and Quality Health Service (Standards)
PaO ₂	Partial pressure of oxygen
PTP	Post-Transfusion Purpura
RA	Remote Area
RCA	Root Cause Analysis
Rh D	Rhesus D Antigen
SA	Statistical Area
SHOT	Serious Hazards of Transfusion (Scheme)
STIR	Serious Transfusion Incidents Reporting (System)
TACO	Transfusion-Associated Circulatory Overload
TAD	Transfusion Associated Dyspnoea
TA-GVHD	Transfusion Associated Graft-Versus-Host Disease
TGO	Therapeutic Goods Order
TRALI	Transfusion-Related Acute Lung Injury
TTI - B	Transfusion Transmitted Infection - Bacterial
TTI - O	Transfusion Transmitted Infection - Other
TTI - P	Transfusion Transmitted Infection - Parasitic
TTI - V	Transfusion Transmitted Infection - Viral
WB	Whole blood