NATIONAL BLOOD AUTHORITY
AUSTRALIA

AUSTRALIAN HAEMOVIGILANCE MINIMUM DATA SET

August 2015

Version 1

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

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Contents

Document 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 Australian Haemovigilance Minimum Data Set (AHMDS) [previously called the National Haemovigilance data Dictionary] 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 'Governance for safety and quality in health service organisations' (NSQHS Standard 1)
- National Safety and Quality Health Service Standard 7 'Blood and blood products' (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'.

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.

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. 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 International Haemovigilance Network models
- adverse event data is accompanied by imputability (causality) scores
- each reportable adverse event includes additional (descriptive) data.

The first edition of AHMDS was published in 2010. This second edition supersedes the first edition, which has been reviewed and revised by the HAC. The second edition aligns more closely with the IHN/ISBT standard haemovigilance definitions with the intention to improve the quality and comparability of data from different sources.

Governance for the dataset

Authorities and accountabilities

Data provided by health service organisations will be de-identified and aggregated and analysed for national trends and other indicators.

Local health service organisations are the data custodians for local datasets, and have the accountability for release and transmission of local data to state and territory health departments. Transfusion related adverse events are investigated and reported according to local arrangements. A root cause analysis (RCA) or in depth review methodology may be performed for the investigation of serious adverse events. Adverse events are validated at the local level to ensure that they are transfusion related and imputability scores are assigned at the health service level or when submitted to each state and territory health department. Validation standards are developed by local institutions in conjunction with their department of health.

States and territories are the data custodians for jurisdictional datasets, and have the authority and accountability for release and transmission of jurisdictional data to the NBA. States and territories are responsible for validating, aggregating and de-identifying the data before the submission to the NBA.

The validation process includes the review and validation of the adverse event. This may include the review, classification and assessment of severity and imputability scores. The reported adverse event may undergo several levels of review (such as initial review and specialist review) until the data issues

are resolved. The process may also enable recommendations and tools to be developed to help health services understand and better manage serious transfusion reactions.

The **Jurisdictional Blood Committee (JBC)** represents the states and territories, and members will be conduits for communications between the NBA and their respective jurisdictional departments of health. The JBC advises on stakeholder and sector consultation, and on dissemination of any conclusions and recommendations. The final version of each national haemovigilance report may be presented to the JBC prior to publication. The NBA may require the approval of the appropriate JBC representative for the collection and publication of jurisdiction-specific data, conclusions or recommendations.

The **Haemovigilance Advisory Committee (HAC)** oversees the national haemovigilance activities. The HAC supports the ongoing national haemovigilance program. The HAC is responsible for providing guidance on data standards and definitions, advising on further data analysis and reporting and reviewing draft national haemovigilance reports.

The **NBA** will have oversight of the data governance (detailed below) of submitted jurisdictional data and of the publication process for national haemovigilance reports. The publication processes will be managed in accordance with NBA key business processes and management instructions, which guide the construction of internal and external publications. They are developed to ensure that all publications are of a similar high standard and follow a consistent format, and outline the procedures for developing, drafting, approving, printing and releasing NBA publications. The NBA will not provide any reports, presentations, case studies, commentaries or research articles in relevant academic or professional body forums, using data not already published in the national report without the consent of the HAC and reporting jurisdiction.

The NBA is bound by Commonwealth Privacy Legislation. Australian government agencies must comply with the 11 Information Privacy Principles set out at section 14 of the *Privacy Act (1988)*. The *Privacy Act (1988)* applies to the collection, storage, use and disclosure of personal information by government agencies, as well as providing individuals with certain rights to access their personal information and correct errors. The privacy and security arrangements are prescribed. National data is secured under Section 11 of the *National Blood Authority Act (2003)* which relates to protecting confidentiality of information. The NBA security policy and management instructions are consistent with *Public Service Act (1999), Privacy Act (1988), Privacy Amendment (Enhancing Privacy Protection) Act (2012), Archives Act (1983), Freedom of Information Act (1982), Criminal Code Act (1995)* and *Crimes Act (1914)*. They also adhere to the *Australian Government Protective Security Manual (2007),* the *Australian Government Information Technology Security Manual (ACSI 33)* and the *Security Equipment Catalogue (SEC)*.

Storage

Data will be submitted and stored in a secure server space in accordance with the National Blood Authority Data and Information Governance Framework.

Access

The dataset will be held by the NBA in a secure server space and managed to prevent disaggregation and identification of patients, clinicians or health service organisations, and 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 the input from clinical experts for use in the national reports, presentations, case studies, commentaries or research articles.

No other use of this data is permitted without the permission of each JBC member in accordance with the National Blood Authority Data and Information Governance Framework.

Publication

The final version of each report will be presented to the HAC 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.

Key issue – privacy and data de-identification

Data is submitted to the national program de-identified at patient and health organisation level. Where aggregated data could potential identify a patient or health organisation 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

Person—age range

Identifying and definitional attributes	
Metadata item type:	Data Element
Short name:	Age Range
METeOR identifier:	290540 (modified)
Definition:	The age range that best accommodates a person's completed age in years, at the time of transfusion, as represented by a code.
Data Element Concept:	Person—age range
Representational attributes	
Representation class:	Code
Data type:	String
Format:	NN
Maximum character length:	2
Permissible values:	Value — Meaning 01 — 0-4 02 — 5-14 03 — 15-24 04 — 25-34 05 — 35-44 06 — 45-54 07 — 55-64 08 — 65-74 09 — 75 and older 99 — Not stated
Collection and usage attributes	
Guide for use:	Age range should be derived from a question on date of birth or age at last birthday.

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.

The age ranges here are consistent with the standard 10 year range recommended by the ABS; however, 5 year or less than 2 year range is recommended to be used for the young and elderly patients as they are at a higher risk of adverse events when compared with the other patients.

Person—sex

Identifying and definitional attributes	
Metadata item type:	Data Element
Short name:	Sex
METeOR identifier:	287316
Definition:	The biological distinction between male and female, as represented by a code.
Data Element Concept:	Person—sex
Representational attributes	
Representation class:	Code
Data type:	String
Format:	N
Maximum character length:	1
Permissible values:	Value — Meaning 1 — Male 2 — Female 3 — Intersex or indeterminate 9 — Not stated/inadequately described
Collection and usage attributes	
Guide for use:	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. CODE 3 Intersex or indeterminate. Intersex or indeterminate, refers to a person, who because of a genetic condition, was born with reproductive organs or sex chromosomes that are not exclusively male or female or whose sex has not yet been determined for whatever reason. Intersex or indeterminate, should be confirmed if reported for people aged 90 days or greater.
Collection methods:	
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.	

Jurisdiction—Australian state/territory identifier

Identifying and definitional attributes	
Metadata item type:	Data Element
Short name:	Australian state/territory identifier(Jurisdiction)
METeOR identifier:	352480
Definition:	An identifier of an Australian state or territory, as represented by a code.
Data Element Concept:	Jurisdiction—Australian state/territory identifier
Representational attributes	
Representation class:	Code
Data type:	String
Format:	N
Maximum character length:	1
Permissible values:	Value — Meaning 1 — New South Wales 2 — Victoria 3 — Queensland 4 — South Australia 5 — Western Australia 6 — Tasmania 7 — Northern Territory 8 — Australian Capital Territory 9 — Other territories (Cocos (Keeling) Islands, Christmas Island and Jervis Bay Territory)
Collection and usage attributes	
Guide for use:	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.

Health industry relevant organisation—main activity type

Identifying and definitional attributes	
Metadata item type:	Data Element
Short name:	Health industry relevant organisation type
METeOR identifier:	491557
Definition:	Describes a health industry relevant organisation based on its main activity, as represented by a code.
Data Element Concept:	Health industry relevant organisation—main activity type
Representational attributes	
Representation class:	Code
Data type:	Number
Format:	NNN
Maximum character length:	3
Permissible values:	

Value	Meaning
	Main health care services organisation
101	Hospital – public
102	Hospital – private (excluding private free-standing day hospital facility)
103	Hospital – private free-standing day hospital facility (excluding private non free-standing day hospital facility)
104	Residential facility – mental health care
105	Residential facility – other
106	Provider of ambulance service
107	Medical and diagnostic laboratory
108	Clinical practices – medical – general
109	Clinical practices – medical – specialist
110	Clinical practices – medical – other
111	Clinical practices – dental
112	Clinical practices – other
113	Community health facility – substance abuse
114	Community health facility – mental
115	Community health facility – other
116	Blood and organ bank
117	Retail sale/supplier of medical goods – optical glasses and other vision products
118	Retail sale/supplier of medical goods – hearing

		aids
	119	Retail sale/supplier of medical goods – dispensing community pharmacist
	120	Retail sale/supplier of medical goods – other
	121	Public health program service provider
	122	General health administration service provider
	123	Private health insurance
	188	Other Main Health Care Service providers
	198	Regional health service not further defined
	199	State/territory health authority not further defined
	200	Secondary/non-Health Care Services organisation
	201	Pharmaceutical industry
	202	University
	203	Non-health related insurance
	204	Residential aged care facility
	288	Other Secondary/non-Health Care Services organisation
Collection and usage attributes		
Guide for use: ℹ	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. With the increase in the reporting of transfusions at residential facilities, 105 and 204 may also be anticipated to be reported in the future.	
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 Service Organisation ID Number

Identifying and definitional attributes	
Metadata item type: ℹ	Data Element
Short name: ℹ	ID Number
METeOR identifier: ℹ	Not available
Definition: ℹ	The health service organisation number (a de-identified number) as represented by a number.
Data Element Concept:	Number assigned to the health service organisation
Representational attributes	
Representation class: ℹ	Code
Data type: ℹ	Number
Format: ℹ	NNN
Maximum character length: ℹ	3
Permissible values: ℹ	001 to 999 assigned by each state and territory to the health service organisation that transaction is from
Rationale for inclusion: To collect and analyse data on how many organisations are providing data on adverse event reporting.	

Health-care incident—geographic remoteness, remoteness classification (ASGC-RA)

Identifying and definitional attributes	
Metadata item type:	Data Element
Short name:	Geographic remoteness
METeOR identifier:	466881
Definition:	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
Data Element Concept:	Health-care incident—geographic remoteness
Representational attributes	
Representation class:	Code
Data type:	String
Format:	N
Maximum character length:	1
Permissible values:	Value — Meaning 1 — Major cities of Australia 2 — Inner regional Australia 3 — Outer regional Australia 4 — Remote Australia 5 — Very remote Australia 6 — Migratory
Collection and usage attributes	
Guide for use:	CODE 1 Major cities of Australia 'Major cities of Australia' includes Census Collection Districts (CDs) with an average Accessibility/Remoteness Index of Australia (ARIA+) index value of 0 to 0.2. CODE 2 Inner regional Australia 'Inner regional Australia' includes CDs with an average ARIA+ index value greater than 0.2 and less than or equal to 2.4. CODE 3 Outer regional Australia 'Outer regional Australia' includes CDs 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 CDs 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 CDs with an average ARIA+ index value greater than 10.53. CODE 6 Migratory 'Migratory' is composed of off-shore, shipping and migratory CDs.
Comments:	Mapping of the remoteness codes between the current AHMDS and the superseded AHMDS 2010: **Current version** **2010 version** 1 RA 1 2 RA 2 3 RA 3 4 RA 4 5 RA 5 6 RA 6
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	Adverse event is an unwanted and usually harmful outcome as a result of error or an incident. Incident is a deviation from standard operating procedure (may lead to an adverse reaction).Adverse reaction is an undesirable response to a transfusion which may or may not be a result of an incident (ISBT).
Data Element Concept:	Health-care incident—transfusion-related adverse event
Representational attributes	
Representation class: ℹ	Code
Data type: ℹ	String
Format: ℹ	[X(21)]
Maximum character length: ℹ	21
Permissible values: ℹ ***Refer to Appendix A for definitions of permissible values.***	Value — Meaning FNHTR — Febrile non-haemolytic transfusion reaction Allergic — Allergic reaction IBCT — Incorrect blood component transfused Anaphylactic — Anaphylactoid or anaphylactic reaction TACO — Transfusion-associated circulatory overload DHTR — Delayed haemolytic transfusion reaction DSTR — Delayed serologic reaction TTI — Transfusion transmitted infection Transfusion transmitted bacterial infection Transfusion transmitted viral infection Transfusion transmitted parasitic infection AHTR — Acute haemolytic transfusion reaction (other than ABO incompatibility) TRALI — Transfusion-related acute lung injury PTP — Post-transfusion purpura

	TA-GVHD	Transfusion associated graft-versus-host disease
	TAD	Transfusion Associated Dyspnoea
	Hypertensive	Hypotensive Transfusion Reaction
	ABO	ABO incompatibility
	Other	Specify other types of adverse events

Collection and usage attributes	
Guide for use:	This data element is used to categorise clinical conditions relating to adverse transfusion reactions. ABO incompatibility is for sentinel event reporting.
Collection methods:	This information should be captured by the local incident/quality management system. Collection and validation methods may vary across jurisdictions.
Comments:	The definitions provided for the Adverse Events at Appendix A align with those used by the International Haemovigilance Network (IHN) and International Society of Blood Transfusion (ISBT), 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 health service organisations 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; 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	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 - 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)

	or permanently unavailable
Collection and usage attributes	
Guide for use:	The delineation between 'Minor morbidity' and 'Severe morbidity' may present difficulty in the classification in some adverse reaction cases.
Collection methods:	The coding and validation of events are the sole responsibility of the health service organisations.
Comments:	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.
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	
Metadata item type:	Data element
Short name:	Imputability score
METeOR identifier:	Not available
Definition:	A hierarchical representation of the extent to which the adverse event is capable of being assigned or credited to the transfusion.
Data Element Concept:	Health-care incident—imputability score
Representational attributes	
Representation class:	Code
Data type:	String
Format:	N
Maximum character length:	1
Permissible values:	Value — Meaning 0 — Excluded 1 — Unlikely 2 — Possible 3 — Probable (likely) 4 — Definite (certain) 9 — Not assessable
Collection and usage attributes	
Guide for use:	Align the health service organisation assigned imputability with the meanings provided below to generate the indicated code. CODE 0 Excluded When there is conclusive evidence beyond reasonable doubt for attributing the adverse reaction to causes other than transfusion CODE 1 Unlikely When the evidence is clearly in favour of attributing the adverse reaction to causes other than the transfusion CODE 2 Possible When the evidence is indeterminate for attributing the adverse reaction to the transfusion CODE 3 Probable (likely) When the evidence is clearly in favour of attributing the adverse reaction the transfusion

	CODE 4 Definite (certain) When there is conclusive evidence beyond reasonable doubt for attributing the adverse reaction to the transfusion CODE 9 Not assessable There are insufficient data for assessment.
Collection methods: ℹ	Imputability is assigned and validated at the local or state level.
Comments: ℹ	All haemovigilance data is accepted, but imputability may be used to filter out low imputability events (Codes 0 and 1 and 2) from national reporting. Mapping of the imputability codes between the current AHMDS and the superseded AHMDS 2010: **Current version** **2010 version** 0 0 1 0 2 1 3 2 4 3 9 9

Rationale for inclusion:

This element provides data about whether the transfusion is related to the adverse event.

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

Identifying and definitional attributes	
Metadata item type: ℹ	Data Element
Short name: ℹ	Date of transfusion
METeOR identifier: ℹ	Modified from 270298
Definition: ℹ	The date on which a transfusion commenced during an inpatient episode of care.
Data Element Concept:	Episode of admitted patient care (procedure)—procedure commencement date
Representational attributes	
Representation class: ℹ	Date
Data type: ℹ	Date/Time
Format: ℹ	DDMMYYYY
Maximum character length: ℹ	8
Collection and usage attributes	
Guide for use: ℹ	For admitted patients, record date of procedure for all transfusions undertaken during an episode of care in accordance with the current edition of ICD-10-AM.
Collection methods: ℹ	Date of transfusion >= admission date Date of transfusion <= separation date
Comments: ℹ	DDMMYYYY format should be used such as 01072014 for 1 July 2014.
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.	

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	Modified from 269972
Definition: ℹ	Time at which a transfusion commenced during an inpatient episode of care.
Data Element Concept:	Episode of admitted patient care (procedure)—transfusion commencement time
Representational attributes	
Representation class: ℹ	Time
Data type: ℹ	Date/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	The 24 hour format should be used (e.g. 2130 for 'nine thirty' at night)
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.	

Health-care incident—contributory factor

Identifying and definitional attributes	
Metadata item type: ⓘ	Data array
Short name: ⓘ	Contributory factor
METeOR identifier: ⓘ	Not applicable
Definition: ⓘ	Any significant event or factor that may have played a role in the occurrence of the adverse event.
Data Element Concept:	Health-care incident—contributory factor

Collection and usage attributes - *Contributory factor data elements*

Short name: ⓘ	***Definition:*** ⓘ	***Data type:*** ⓘ	***Maximum character length:*** ⓘ	***Permissible values:*** ⓘ
None identified	No contributory factors have been attributed to the adverse event.	String	4	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	4	True or False
Transfusion in emergency setting	The transfusion was administered under emergency conditions.	String	4	True or False
Deliberate clinical decision	The decision to transfuse was made with clinical forethought, and with due consideration of the possibility of a transfusion reaction.	String	4	True or False
Prescribing or ordering	Event(s) during prescribing or ordering the product contributed to the transfusion reaction.	String	4	True or False
Specimen collection or labelling	Event(s) during specimen collection or labelling contributed to the transfusion reaction.	String	4	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	4	True or False
Transport, storage, handling	Event(s) during the transport, storage or handling of the product contributed to the transfusion reaction.	String	4	True or False
Administration of product	Event(s) during the administration of the product contributed to the transfusion	String	4	True or False

	reaction.			
Indications did not meet hospital transfusion guidelines	The clinical indications for transfusion did not meet hospital transfusion guidelines.	String	4	True or False
Did not adhere to hospital transfusion procedures	The transfusion procedures did not adhere to hospital transfusion procedures.	String	4	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	50	
Guide for use: 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. The "Other (specify)" element can be used as a free text section if detail is necessary.			
Comments: ℹ				

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	
Metadata item type: ℹ	Data Element
Short name: ℹ	Product type
METeOR identifier: ℹ	Not available.
Definition: ℹ	The blood product/s which may cause the adverse event during or after the transfusion.
Data Element Concept:	Transfusion—product transfused
Representational attributes	
Representation class: ℹ	Code
Data type: ℹ	String
Format: ℹ	[X(19)]
Maximum character length: ℹ	19

Permissible values:

Value	Meaning
Red cells	WB Red Cell - Leucodepleted WB Paediatric Red Cell - Leucodepleted (Set of 4) WB Washed Red Cell - Leucodepleted Apheresis Red Cell - Leucodepleted
Platelets	WB Platelet Pool - Leucodepleted Apheresis Platelet - Leucodepleted Paediatric Apheresis Platelet - Leucodepleted (Set of 4)
Fresh frozen plasma	WB Clinical FFP - Buffy Coat Poor Paediatric WB Clinical FFP (Set of 4) 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 types of products that may cause the adverse event
Autologous transfusion	Including Cell salvage
Other products	Directed donation complying with AHMAC Guidelines Serum Eye Drops Granulocytes

Collection and usage attributes	
Guide for use: ℹ	The administered labile blood product or fresh blood component can be coded as one of the categories presented.
Comments: ℹ	Product grouping are used rather than components and 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.	

Appendix A – Definitions of Transfusion-related Adverse Events

Adverse Event	Definition – Where possible this is the ISBT Definition
Febrile non-haemolytic transfusion reaction (FNHTR)	Presents with one or more of the following during or within 4 hours of transfusion without any other cause such as haemolytic transfusion reaction, bacterial contamination or underlying condition: • fever ($\geq$38^{o}C oral or equivalent and a change of $\geq$ 1^{o}C from pre-transfusion value) • chills • rigors This may be accompanied by headache and nausea. FNHTR could be present in absence of fever (if chills or rigors without fever). 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: • fever ($\geq$39^{o}C oral or equivalent and a change of $\geq$ 2^{o}C from pre-transfusion value and chills/rigors
Allergic reaction	An allergic reaction may present only with mucocutaneous signs and symptoms during or within 4 hours of transfusion: • morbilliform rash with itching • 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.
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 • the component was ABO compatible and/or • even if only a small quantity of blood was transfused and/or • there was no adverse reaction
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 (dyspnea, cough, wheezing/bronchospasm, hypoxemia). Such a reaction usually occurs occurring during or very shortly after transfusion.
Transfusion-associated circulatory overload (TACO)	TACO is characterised by any 4 of the following: • acute respiratory distress • tachycardia • increased blood pressure • acute or worsening pulmonary oedema on frontal chest radiograph • evidence of positive fluid balance Occurring within 6 hours of completion of transfusion. An elevated BNP is supportive of TACO.
Delayed haemolytic transfusion reaction (DHTR)	A DHTR usually manifests between 24 hours and 28 days after a transfusion and clinical or laboratory features of hemolysis are present. Signs and symptoms are similar to AHTR but are usually less severe. DHTR may sometimes manifests as an inadequate rise of post-transfusion hemoglobin level or unexplained fall in hemoglobin after a transfusion. Blood group serology usually shows abnormal results.
Delayed serologic reaction (DSTR)	There is a 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 hemolysis. This term is synonymous with alloimmunization.
Transfusion transmitted infection (TTI)	The recipient had evidence of infection following transfusion of blood components and there was no evidence of infection prior to transfusion and no evidence of an alternative source of infection. *Transfusion transmitted bacterial infection* Transfusion transmitted bacterial infection should be clinically suspected if: • fever >39°C or a change of >2°C from pre transfusion value and • rigors and • tachycardia >120 beats/min or a change of >40 beats/min from pre transfusion value or a rise or drop of 30mmHg in systolic blood pressure within 4 hours of transfusion are present Possible transfusion transmitted bacterial infection: • detection of bacteria by approved techniques in the transfused blood component but not in the recipient's blood or

	• detection of bacteria in the recipient's blood following transfusion but not in the transfused blood component and no other reasons are ascertainable for the positive blood culture • Confirmed transfusion transmitted bacterial infection: • detection of the same bacterial strain in the recipient's blood and in the transfused blood product by approved techniques *Transfusion transmitted viral infection* Following investigation, the recipient has evidence of infection post transfusion and no clinical or laboratory evidence of infection prior to transfusion and either, at least one component received by the infected recipient was donated by a donor who had evidence of the same infection, or, at least one component received by the infected recipient was shown to have been contaminated with the virus. Reports should at least consider HIV, Hepatitis B, Hepatitis C and CMV. *Transfusion transmitted parasitic infection* 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)	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 hemoglobinemia, hemoglobinuria, decreased serum haptoglobin, unconjugated hyperbilirubinemia, increased LDH and AST levels and decreased hemoglobin levels. Not all clinical or laboratory features are present in case of AHTR.
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 o Pa02 / Fi02 < 300 mm Hg or o Oxygen saturation is < 90% on room air or o 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 o Aspiration o Pneumonia o Toxic inhalation o Lung contusion o Near drowning • Indirect lung injury o Severe sepsis o Shock o Multiple trauma o Burn injury o Acute pancreatitis o Cardiopulmonary bypass o 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
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.
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 • cytopenia TA-GVHD is confirmed by GVHD-typical biopsy and genetic analysis to show chimerism of donor and recipient lymphocytes.
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 • if no adverse reaction occurred All cases are to be included, whether the first error occurred in the blood establishment, in the blood

	transfusion laboratory or in clinical areas. Note that these are a subgroup of the IBCT category. Transfusion of ABO incompatible products to a patient is considered a 'sentinel event' and is also subject to other reporting channels outside of the National Haemovigilance Program.
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.
Hypotensive transfusion reaction	This reaction is characterized by hypotension defined as a drop in systolic blood pressure of $\geq$30 mm Hg occurring during or within one hour of completing transfusion and a systolic blood pressure $\leq$ 80 mm Hg.
Other types of adverse events	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/

Abbreviations and acronyms

ABS	Australian Bureau of Statistics
AHMRC	Australian Health Ministers' Advisory Council
AIHW	Australian Institute of Health and Welfare
AHMDS	Australian Haemovigilance Minimum Data Set
HAC	Haemovigilance Advisory Committee
IHN	International Haemovigilance Network
ISBT	International Society of Blood Transfusion
JBC	Jurisdictional Blood Committee
METeOR	Metadata Online Registry
NBA	National Blood Authority
RCA	Root Cause Analysis
STIR	Serious Transfusion Incidents Reporting System
WB	Whole blood