National Haemovigilance Data Dictionary

4 January 2010

Version 3
A Guide for formatting Haemovigilance Data for the Australian National Haemovigilance Data Set

National Blood Authority
Australia

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Introduction

The National Haemovigilance Program has been established on the basis of the following principles;

- That national haemovigilance be guided by a Haemovigilance Advisory Committee (HAC) established by the NBA,
- That participation be voluntary,
- That reporting be confined to fresh (labile) blood products, including autologous transfusions,
- That participating institutions define their haemovigilance reporting processes and the data collected, which should align with or exceed the national minimum data set,
- That adverse events are investigated, validated and reported at the local level. A further validation process will occur at State and Territory level to ensure data integrity,
- That the reporting model utilises existing healthcare systems to minimise the reporting burden,
- That adverse event data are coded and de-identified to maintain privacy and confidentiality,
- That reports are based on a national minimum list of serious reportable adverse events, whose definitions will continue to align with European Haemovigilance Network (EHN)[1] models,
- That reports are accompanied by imputability (causality) scores,
- That each reportable adverse event includes additional (descriptive) data.

To support a national approach to haemovigilance, States and Territories have agreed to progressively align their reporting systems with the agreed data set requirements to contribute to a comprehensive national dataset.

It is recognised that this will require all users of labile blood products to;

- Participate in the provision and analysis of data,
- Investigate and report adverse events in accordance with the national dataset.

The Haemovigilance Advisory Committee has established data definitions for the National Haemovigilance Data Set, and the purpose of this document is to define the format of the data elements in the Data Set.

[1] European Haemovigilance Network – www.ehn-org.net

Data Collection

To improve the quality, comparability and imputability of data, all information provided by States and Territories for national reporting is to be validated and de-identified by the jurisdiction before submission.

Transfusion related adverse events are investigated and reported according to local arrangements, e.g. established transfusion committees, haematologists, transfusion nurse or safety officers, hospital/pathology quality and safety units/managers.

Serious procedural and systems errors and incidents are thoroughly investigated at the local level using detailed analytical techniques such as Root-Cause-Analysis (RCA) to ensure that clinicians and hospital directors fully understand the sequence of events leading up to these events. These procedures can form part of hospital quality management.

Events are validated at the local level to ensure that they are transfusion related and imputability scores are allocated. Standards for validation are developed by local institutions in conjunction with their Departments of Health. Agreed additional data about the patient, facility, event and implicated blood product will accompany each report, as will an imputability (causality) score.

Validated reports are provided to State and Territory Departments of Health. Reports of serious adverse events will go through a secondary validation process within Departments of Health Quality Units to ensure data accuracy and completeness.

State and Territory Haemovigilance Representatives, on behalf of Departments of Health, will aggregate and de-identify data and send periodic reports to the National Blood Authority (NBA).

About this data dictionary

The data definitions in this dictionary come from two principle sources; the Haemovigilance Advisory Committee of the National Blood Authority (NBA), and the National Health Data Dictionary (NHDD) of the Australian Institute of Health and Welfare (AIHW).

Definitions have also been taken from the Australian Bureau of Statistics (ABS) and from the International Society Blood Transfusion (ISBT).

Table 1 on the following page provides a summary of the data elements in the National Haemovigilance Data Dictionary, the information they are intended to collect and the definition source.

Table 1 - Summary of Data Elements

Data Element	Summary of Information provided	Source of Definition
Age	• 0-4 • 5-14 • 15-24 • 25-34 • 35-44 • 45-54 • 55-64 • 65-74 • 75 years or older *NB There is a permissible field entry for 'Not stated'. This can be used as a trigger for a free text note which could include foetal or intra-uterine transfusions.*	AIHW National Health Data Dictionary
Sex	• Male • Female • Intersex or indeterminate	AIHW National Health Data Dictionary
Reporting Jurisdiction	• QLD • NSW • ACT • VIC • TAS • NT • SA • WA	AIHW National Health Data Dictionary
Facility of Transfusion	• Hospital – public • Hospital – private • Hospital – private free-standing day hospital facility *NB There are many more codes/options available, but it is anticipated that these three options should suffice for national haemovigilance data*	AIHW National Health Data Dictionary

Data Element	Summary of Information provided	Source of Definition
Classification of facility location	• RA 1 Major City • RA 2 Inner Regional • RA 3 Outer Regional • RA 4 Remote • RA 5 Very Remote	ABS Australian Standard Geographical Classification, Remoteness Area (ASGC-RA)
Adverse event	• Haemolytic transfusion reaction resulting from ABO incompatibility • Immediate haemolytic transfusion reactions (other than ABO) • Delayed haemolytic transfusion reactions (DHTR) • Severe febrile non-haemolytic transfusion reactions (FNHTR) • Incorrect blood component transfused (IBCT) • Infection - Bacterial • Infection - Viral • Infection - Parasitic • Infection - Other (specify) • Transfusion-related acute lung injury (TRALI) • Allergic reactions (severe) • Anaphylactoid reactions • Transfusion-associated graft versus host disease (TA-GVHD) • Post-transfusion purpura (PTP) • Transfusion-associated circulatory overload (TACO)	European Haemovigilance Network (EHN), now known as International Haemovigilance Network (IHN)
Outcome severity	• Outcome not available • No morbidity • Minor morbidity • Severe morbidity • Life-threatening • Death	HAC
Date of Transfusion	• DDMMYYYY *NB Using the date of transfusion, the data can be matched to days of the week, and to public holidays.*	HAC based on 'Date of Procedure" from AIHW National Health Data Dictionary

Data Element	Summary of Information provided	Source of Definition
Time transfusion commenced	• HH:MM (24 hour clock)	HAC
Contributory Factors	• None identified • Product characteristic • Transfusion in emergency setting • Deliberate clinical decision • Prescribing/ordering • Specimen collection/labelling • Laboratory - pre-transfusion testing and dispensing • Transport, storage, handling • Administration of product • Indications did not meet hospital transfusion guidelines • Did not adhere to hospital transfusion procedures • Other (specify)	HAC
Imputability score	• N/A Not Assessable • 0 Excluded / Unlikely • 1 Possible • 2 Likely / Probable • 3 Confirmed / Certain	ISBT EHN SHOT UK
Product type	• Whole Blood • Red Cells • Platelets • Fresh Frozen Plasma • Cryoprecipitate • Cryo-depleted	HAC based on ARCBS product names
Concomitant blood components	• Whole Blood • Red Cells • Platelets • Fresh Frozen Plasma • Cryoprecipitate • Cryo-depleted	HAC based on ARCBS product names
Modifications	• Unmodified • CMV-negative • Irradiated • Other	HAC based on ARCBS product names

Data Transfer

Australian jurisdictions have many different systems for managing their haemovigilance data, and these systems have varying output capabilities and formats. Aggregated and de-identified data can be transferred to the NBA for inclusion in the National Haemovigilance Data Set in many electronic formats which can be discussed with the Program manager.

A suggested simple format for data transfer is a spreadsheet with one record (event) per row and the following columns;

- Age
- Sex
- Reporting Jurisdiction
- Facility of Transfusion
- Classification of facility location
- Adverse event
- Outcome severity
- Date of Transfusion
- Time transfusion commenced
- Contributory Factors - None identified
- Contributory Factors - Product characteristic
- Contributory Factors - Transfusion in emergency setting
- Contributory Factors - Deliberate clinical decision
- Contributory Factors - Prescribing/ordering
- Contributory Factors - Specimen collection/labelling
- Contributory Factors - Laboratory - pre-transfusion testing and dispensing
- Contributory Factors - Transport, storage, handling
- Contributory Factors - Administration of product
- Contributory Factors - Indications did not meet hospital transfusion guidelines
- Contributory Factors - Did not adhere to hospital transfusion procedures
- Contributory Factors - Other (specify)
- Imputability score
- Product type
- Concomitant blood components - Whole Blood
- Concomitant blood components - Red Cells
- Concomitant blood components - Platelets
- Concomitant blood components - Fresh Frozen Plasma
- Concomitant blood components - Cryoprecipitate
- Concomitant blood components - Cryo-depleted
- Modifications

Further details of the data elements are found in subsequent sections.

Age range

Identifying and definitional attributes

Metadata item type: Data Element
Technical name: Person—age range, code NN
Code: NN – see format below
Definition: The age range that best accommodates a person's completed
Data Element Concept: Person—age range

Value domain attributes

Representational attributes

Representation class: Code
Data type: Number
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 years or older
99	Not stated

Data element attributes

Collection and usage attributes

Guide for use: Used in computer assisted telephone interview (CATI) surveys in cases where the specific age is not available. Depending on the collection a different starting age may be used, but should map back to the standard output. Information at a finer level can be collected as long as it maps back to the proposed data domain, e.g. 75+ age group can be split into 75-84 and 85 years or older.

Collection methods: Collection of date of birth allows more precise calculation of age, as does the collection of a single age, this may not always be feasible. Age range should be derived from a question on date of birth or age at last birthday.

Age range

Comments: AIHW METeOR identifier: 290540
Registration status: Health, Standard 04/05/2005

In cases where an exact age is not known or not stated, age may be reported as an age range. The age ranges are consistent with the standard 10 year ranges recommended by the ABS.

Source and reference attributes

Submitting organisation: National Public Health Information Working Group

Origin: ABS, Statistical Concepts Library, Standards for Social, Labour and Demographic Variables. Age.

AIHW NHDD

Reference documents: Reference through: http://www.abs.gov.au/Ausstats/abs@.nsf/StatsLibrary and choose, Other ABS Statistical Standards, Standards for Social, Labour and Demographic Variables, Demographic Variables, Age.

Relational attributes

Implementation in Data Set Specifications:

Sex

Identifying and definitional attributes

Metadata item type:	Data Element
Technical name:	Person—sex, code N
Code:	N – see format below
Definition:	The biological distinction between male and female, as represented by a code.
Data Element Concept:	Person—sex

Value domain attributes

Representational attributes

Representation class:	Code
Data type:	Number
Format:	N
Maximum character length:	1

Permissible values:

Value	Meaning
1	Male
2	Female
3	Intersex or indeterminate
9	Not stated / inadequately described

Data element attributes

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.

Sex

Collection methods:

Operationally, sex is the distinction between male and female, as reported by a person or as determined by an interviewer. When collecting data on sex by personal interview, asking the sex of the respondent is usually unnecessary and may be inappropriate, or even offensive. It is usually a simple matter to infer the sex of the respondent through observation, or from other cues such as the relationship of the person(s) accompanying the respondent, or first name. The interviewer may ask whether persons not present at the interview are male or female.

A person's sex may change during their lifetime as a result of procedures known alternatively as sex change, gender reassignment, transsexual surgery, transgender reassignment or sexual reassignment. Throughout this process, which may be over a considerable period of time, the person's sex could be recorded as either Male or Female.

In data collections that use the ICD-10-AM classification, where sex change is the reason for admission, diagnoses should include the appropriate ICD-10-AM code(s) that clearly identify that the person is undergoing such a process. This code(s) would also be applicable after the person has completed such a process, if they have a procedure involving an organ(s) specific to their previous sex (e.g. where the patient has prostate or ovarian cancer).

CODE 3 Intersex or indeterminate
Is normally used for babies for whom sex has not been determined for whatever reason. Should not generally be used on data collection forms completed by the respondent. Should only be used if the person or respondent volunteers that the person is intersex or where it otherwise becomes clear during the collection process that the individual is neither male nor female.

CODE 9 Not stated/inadequately described
Is not to be used on primary collection forms. It is primarily for use in administrative collections when transferring data from data sets where the item has not been collected.

Sex

Comments:	The definition for Intersex in Guide for use is sourced from the ACT Legislation (Gay, Lesbian and Transgender) Amendment Act 2003. AIHW METeOR identifier: 287316 Registration status: Health, Standard 04/05/2005 Community services, Standard 25/08/2005 Housing assistance, Standard 10/02/2006

Source and reference attributes

Submitting organisation:

Origin:	AIHW NHDD Australian Institute of Health and Welfare (AIHW) National Mortality Database 1997/98 AIHW 2001 National Diabetes Register, Statistical Profile, December 2000 (Diabetes Series No. 2.) Australian Capital Territory 2003. Legislation (Gay, Lesbian and Transgender) Amendment Act 2003
Reference documents:	Legislation (Gay, Lesbian and Transgender) Amendment Act 2003. See http://www.legislation.act.gov.au/a/2003-14/20030328-4969/pdf/2003-14.pdf Australian Bureau of Statistics AS4846 Health Care Provider Identification, 2004, Sydney: Standards Australia AS5017 Health Care Client Identification, 2002, Sydney: Standards Australia In AS4846 and AS5017 alternative codes are presented. Refer to the current standard for more details.

Relational attributes

Implementation in Data Set Specifications:	Supersedes Person—sex, code N Health, Superseded 04/05/2005, Community services, Superseded 31/08/2005 Is used in the formation of Episode of admitted patient care— major diagnostic category, code (AR-DRG v5.1) NN Health, Standard 01/03/2005 Is used in the formation of Episode of admitted patient care— diagnosis related group, code (AR-DRG v5.1) ANNA Health, Standard 01/03/2005

Australian State/Territory identifier (Jurisdiction)

Identifying and definitional attributes

Metadata item type:	Data Element
Technical name:	Jurisdiction—Australian state/territory identifier, code N
Code:	N
Definition:	An identifier of the Australian state or territory of a jurisdiction, as represented by a code.
Data Element Concept:	Jurisdiction—Australian state/territory identifier

Value domain attributes

Representational attributes

Representation class:	Code
Data type:	Number
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)

Data element attributes

Collection and usage attributes

Guide for use:	The order presented here is the standard for the Australian Bureau of Statistics (ABS). Other organisations (including the Australian Institute of Health and Welfare) publish data in state order based on population (that is, Western Australia before South Australia and Australian Capital Territory before Northern Territory).
Collection methods:	
Comments:	AIHW METeOR identifier: 352480 Registration status: Health, Standard 05/12/2007

Australian State/Territory identifier (Jurisdiction)

Source and reference attributes

Submitting organisation:	Health expenditure advisory committee
Origin:	AIHW NHDD
Reference documents:	Australian Bureau of Statistics 2005. Australian Standard Geographical Classification (ASGC). Cat No. 1216.0. Canberra: ABS. Viewed on 30/09/2005

Relational attributes

Implementation in Data Set Specifications:	Government health expenditure NMDS 2008-2009 Health, Standard 05/12/2007 Implementation start date: 01/07/2008

Health industry relevant Organisation Type

Identifying and definitional attributes

Metadata item type:	Data Element
Technical name:	Health industry relevant organisation—main activity type, code NNN
Code:	NNN – see format below
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

Value domain attributes

Representational attributes

Representation class:	Code
Data type:	Number
Format:	NNN
Maximum character length:	3

Permissible values:

Value	Meaning
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 practice – medical – general
109	Clinical practice – medical – specialist
110	Clinical practice – medical – other
111	Clinical practice – dental
112	Clinical practice – other

Health industry relevant Organisation Type

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	Provision and administration of public health program
122	General health administration
123	Private health insurance provider
188	Main Health Care Services provider – other
198	Regional health service (not further defined)
199	State/territory health authority (not further defined) Secondary/non-Health Care Service organisation
201	Pharmaceutical industry provider
202	University
203	Non-health related insurance provider
288	Secondary/non-Health Care Service organisation – other

Health industry relevant Organisation Type

Data element attributes

Collection and usage attributes

Guide for use:

It is anticipated that only codes 101, 102, or 103 will be reported in the National Haemovigilance Database. Details and guidance on other codes can be found in the AIHW National Health Data Dictionary.

CODE 101 Hospital – public
An organisation comprised of a health care facility or group of health care facilities established under Commonwealth, state or territory legislation as a hospital or a free-standing day procedure unit, and authorised to provide treatment and/or care to patients. Comprises all health care facilities that are reported as public hospitals to the Public Hospital Establishments National Minimum Data Set (PHE NMDS). This includes organisations such as rehabilitation hospitals; psychiatric hospitals; mothercraft hospitals; and hospices and multi-purpose services defined as hospitals. The list of public hospitals reported to the PHE NMDS is available at www.aihw.gov.au/publications/index.cfm in the Australian Hospital Statistics annual report.
NOTE 1: Excludes providers of services where those providers are not captured in the hospital financial statements. For example, the provider of a pathology or pharmacy service may be co-located within the hospital, but as a private service, and will pay the hospital for use of the site. The provider of this service should be recorded under codes 106 to 112.

CODE 102 Hospital – private (excluding private free-standing day hospital facilities)
An organisation comprised of a health care facility or a group of health care facilities established under Commonwealth, state or territory legislation as a hospital or a free-standing day procedure unit, and authorised to provide treatment and/or care to patients. Is derived from the Object class 'Hospital' and 'Hospital–public' Code 101 above.
Comprises hospitals that are NOT reporting to the PHE NMDS. NOTE: State and territory data providers are to refer to the GHE NMDS Collection Guidelines for instructions on how to report expenditure for this category. Excludes private free-standing day hospital facilities reported under code 103.

Health industry relevant Organisation Type

CODE 103 Hospital - private free-standing day facility (excluding private non free-standing day hospital facilities)
An organisation comprised of one or more private free-standing day hospital facilities which provide investigation and treatment for acute conditions on a day-only basis and is approved by the Commonwealth as a hospital for the purposes of private health insurance benefits. The four main types of private free-standing day hospitals are specialist endoscopy, opthalmic, plastic/cosmetic and general. Excludes private non free-standing day hospital facilities reported under code 102.

Collection methods:

Comments: It is anticipated that only codes 101, 102, or 103 will be reported in the National Haemovigilance Database.

Source and reference attributes

Submitting organisation: Health Expenditure Advisory Committee

Origin: AIHW NHDD

Reference documents: Organisation for Economic Cooperation and Development 2000.
A System of Health Accounts. Version 1.0. Paris: OECD. Australian Bureau of Statistics 2006. Australian and New Zealand Standard Industry Classification. Cat. no. 1292.0.
Canberra: ABS. RACGP 6 September 2005 <www.racgp.org.au/whatisgeneralpractice>

Relational attributes

Implementation in Data Set Specifications: Government health expenditure organisation expenditure data cluster Health, Standard 05/11/2007
Government health expenditure organisation revenue data element cluster Health, Standard 05/12/2007

Classification of Facility Location

Identifying and definitional attributes

Metadata item type:	Data Element
Technical name:	Classification of facility location
Code:	"RA "[N] – see format below
Definition:	This classification allocates areas of land to one of five arbitrary categories, as an indication of geographical remoteness.
Data Element Concept:	Geographical – location relevant to population centres

Value domain attributes

Representational attributes

Representation class:	Code
Data type:	Number
Format:	"RA "[N]
Maximum character length:	4

Permissible values:

Value	Meaning
RA 1	Major City
RA 2	Inner Regional
RA 3	Outer Regional
RA 4	Remote
RA 5	Very Remote

Data element attributes

Collection and usage attributes

Guide for use:	The ASGC-RA has been developed by the Australian Bureau of Statistics, It is possible to find the RA classification of a location by using either the Doctor Connect website; http://www.doctorconnect.gov.au/internet/otd/Publishing.nsf/Content/RA-locator or accessing the Health Workforce Queensland RRMA/ASGC-RA search engine; http://www.healthworkforce.com.au/main_rrma.asp
Collection methods:	The ASGC-RA code can be calculated automatically from postcode data using datacubes from the Australian Bureau of Statistics. A quicker method for small data sets is outlined above in "*Guide for use*"
Comments:	

Classification of Facility Location

Source and reference attributes

Submitting organisation:

Origin: ABS

Reference documents: Details are available from the Australian Bureau of Statistics

Relational attributes

Implementation in Data Set Specifications: From 1 July 2009, the outdated and flawed Rural, Remote and Metropolitan Areas (RRMA) system will be replaced by the Australian Standard Geographical Classification – Remoteness Areas (ASGC-RA) system.

The ASGC-RA has been developed by the Australian Bureau of Statistics, uses 2006 Census data, and is widely used by Commonwealth and state agencies. Most importantly, moving to the ASGC-RA will improve incentives for attracting health services to areas of genuine need.

The new classification system will be phased in from July 2009.

Adverse Event

Identifying and definitional attributes

Metadata item type:	Data Element
Technical name:	Adverse event
Code:	[X(59)] – see format below
Definition:	The clinically diagnosed transfusion-related adverse event that occurred
Data Element Concept:	Patient – adverse incident resulting from transfusion

Value domain attributes

Representational attributes

Representation class:	Text
Data type:	String
Format:	[X(59)]
Maximum character length:	59

Permissible values:

Value	Meaning
ABO incompatibility	Definition at Appendix I
Immediate haemolytic transfusion reactions (other than ABO)	Definition at Appendix I
Delayed haemolytic transfusion reaction (DHTR)	Definition at Appendix I
Severe febrile non-haemolytic transfusion reaction (FNHTR)	Definition at Appendix I
Incorrect blood component transfused (ICBT)	Definition at Appendix I
Transfusion transmitted infections (TTI)	Definition at Appendix I
Transfusion related acute lung injury (TRALI)	Definition at Appendix I
Severe allergic reaction	Definition at Appendix I
Anaphylactoid or anaphylactic reaction	Definition at Appendix I
Transfusion induced graft versus host disease (TGVHD)	Definition at Appendix I
Post-transfusion purpura (PTP)	Definition at Appendix I
Transfusion-associated circulatory overload (TaCO)	Definition at Appendix I

Adverse Event

Data element attributes

Collection and usage attributes

Guide for use: Used to categorise clinical conditions relating to adverse transfusion reactions.

Collection methods: Collection and validation methods vary across jurisdictions.

Comments: The definitions provided for the Adverse Events (Appendix I) align with those used by the International Haemovigilance Network (IHN) and International Society Blood Transfusion (ISBT). However, it is not expected that they are applied rigorously.
The national data set accepts the categorisation assigned by the contributing jurisdiction and the reviewing clinicians, regardless of minor differences to definitions.

Source and reference attributes

Submitting organisation: Haemovigilance Advisory Committee

Origin: National Blood Authority

Reference documents:

Relational attributes

Implementation in Data Set Specifications:

Clinical Outcome Severity

Identifying and definitional attributes

Metadata item type:	Data Element
Technical name:	Patient – Outcome Severity
Code:	[X(21)] – see format below
Definition:	Hierarchical categories to define harm done to the patient as a result of an adverse event
Data Element Concept:	Patient – Clinical Outcome Severity

Value domain attributes

Representational attributes

Representation class:	Text
Data type:	String
Format:	[X(21)]
Maximum character length:	21

Permissible values:

Value	Meaning
Outcome not available	Definition at Appendix II
No morbidity	Definition at Appendix II
Minor morbidity	Definition at Appendix II
Severe morbidity	Definition at Appendix II
Life-threatening	Definition at Appendix II
Death	Definition at Appendix II

Data element attributes

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 jurisdictions.
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.

Clinical Outcome Severity

Source and reference attributes

Submitting organisation: Haemovigilance Advisory Committee

Origin: National Blood Authority

Reference documents:

Relational attributes

Implementation in Data Set Specifications: The permissible field entries for Clinical Outcome Severity and their definitions are based on those of the ISBT and SHOT.
This data standard should afford the HAC sufficient granularity to discuss the data in a meaningful way, whilst ensuring alignment with Australian jurisdictional standards and also with international haemovigilance reporting standards.

Date of Transfusion

Identifying and definitional attributes

Metadata item type:	Data Element
Technical name:	Episode of admitted patient care (procedure)—transfusion commencement date,
Code:	DDMMYYYY
Definition:	The date on which the transfusion commenced during an inpatient episode of care.
Data Element Concept:	Episode of admitted patient care (procedure)—procedure commencement date

Value domain attributes

Representational attributes

Representation class:	Date
Data type:	Date / Time
Format:	DDMMYYYY
Maximum character length:	8

Data element attributes

Collection and usage attributes

Guide for use:	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:	Date of transfusion >= admission date Date of transfusion <= separation date
Comments:	AIHW METeOR identifier: 270298 Registration status: Health, Standard 01/03/2005 The National Centre for Classification in Health advises the Health Data Standards Committee of relevant changes to the ICD-10-AM. Required to provide information on the timing of the procedure in relation to the episode of care.

Source and reference attributes

Submitting organisation:	National Blood Authority
Origin:	National Centre for Classification in Health National Health Data Committee

Date of Transfusion

Reference documents:	Australian Institute of Health and Welfare (AIHW) 2000. Australian hospital statistics 1998-1999. AIHW cat. no. HSE 11. Canberra: AIHW (Health Services Series no. 15)

Relational attributes

Implementation in Data Set Specifications:

Time of Transfusion

Identifying and definitional attributes

Metadata item type:	Data Element
Technical name:	Time of Transfusion
Code:	NN:NN – see format below
Definition:	Time at which an admitted patient commences an episode of care.
Data Element Concept:	Time of Transfusion

Value domain attributes

Representational attributes

Representation class:	Time
Data type:	Time
Format:	HHMM
Maximum character length:	4

Data element attributes

Collection and usage attributes

Guide for use:	Required to identify the time of commencement of the transfusion.
Collection methods:	
Comments:	The 24 hour format should be used (e.g. 2130 for 'nine thirty' at night)

Source and reference attributes

Submitting organisation:	Haemovigilance Advisory Committee
Origin:	National Blood Authority
Reference documents:	

Relational attributes

Implementation in Data Set Specifications:	ISO 8601:2000 : Data elements and interchange formats - Information interchange - Representation of dates and times

Contributory Factors

Identifying and definitional attributes

Metadata item type:	Data Array
Technical name:	Adverse event - Contributory Factors
Code:	Array of True/False values plus a Text String
Definition:	Any significant event or factor that may have played a role in the occurrence of the adverse event
Data Element Concept:	Event – Contributory Factors

Value domain attributes

Representational attributes

Representation class:	True/False, Text
Data type:	True/False, String
Format:	NNNNN , [X(512)]
Maximum character length:	
Permissible values:	

Element	Value	Meaning
None identified	True/False	No contributory factors have been attributed to the adverse event
Product characteristic	True/False	The product contributed to the reaction due to an inherent but not necessarily faulty characteristic (e.g. an allergic or anaphylactic reaction to a product; unknown significance of anti-HLA antibodies)
Transfusion in emergency setting	True/False	The transfusion was administered under emergency conditions
Deliberate clinical decision	True/False	The decision to transfuse was made with clinical forethought, and with due consideration of the possibility of a transfusion reaction
Prescribing/ordering	True/False	Event(s) during prescribing or ordering the product contributed to the transfusion reaction
Specimen collection/labelling	True/False	Event(s) during specimen collection or labelling contributed to the transfusion reaction

Contributory Factors

Laboratory - pre-transfusion testing and dispensing	True/False	Event(s) during laboratory pre-transfusion testing or dispensing of the product contributed to the transfusion reaction
Transport, storage, handling	True/False	Event(s) during the transport, storage or handling of the product contributed to the transfusion reaction
Administration of product	True/False	Event(s) during the administration of the product contributed to the transfusion reaction
Indications did not meet hospital transfusion guidelines	True/False	The clinical indications for transfusion did not meet hospital transfusion guidelines
Did not adhere to hospital transfusion procedures	True/False	The transfusion procedures did not adhere to hospital transfusion procedures
Other (specify)	[X(512)]	Free-text field. Please specify the event(s) that contributed to the adverse transfusion reaction

Data element attributes

Collection and usage attributes

Guide for use: 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, “Contributory Factors”

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.

Collection methods:

Comments: The impetus for this data element is the capture of data on adherence to hospital transfusion guidelines and transfusion procedures, on errors made during the processes (if any), or on any relevant lapses throughout the transfusion chain (if any; e.g. cold chain, faulty product etc.).

Contributory Factors

Source and reference attributes

Submitting organisation: Haemovigilance Advisory Committee

Origin: National Blood Authority

Reference documents:

Relational attributes

Implementation in Data Set Specifications:

Imputability Score

Identifying and definitional attributes

Metadata item type:	Data Element
Technical name:	Imputability Score
Code:	N – see format below
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:	

Value domain attributes

Representational attributes

Representation class:	Code
Data type:	Number
Format:	N
Maximum character length:	1

Permissible values:

Value	Meaning
0	*Excluded* When there is conclusive evidence beyond reasonable doubt for attributing the reaction to causes other than blood or blood components; or *Unlikely* When the evidence is clearly in favour of attributing the adverse events to causes other than blood or blood components
1	*Possible* When the evidence is indeterminate for attributing the adverse reaction either to blood components or alternative causes
2	*Likely/Probable* When the evidence is clearly in favour of attributing the adverse reaction either to blood components

Imputability Score

3	*Confirmed/Certain* When there is conclusive evidence beyond reasonable doubt for attributing the adverse reaction either to blood components
9	*N/A - Not Assessable* When there are insufficient data for assessment

Data element attributes

Collection and usage attributes

Guide for use: Align the jurisdictionally assigned imputability with the meanings provided to generate the indicated code.

Note that the value ‘0’ is used for imputability of ‘Excluded’ or ‘Unlikely’

Collection methods: Imputability is assigned and validated at the jurisdictional level

Comments: All haemovigilance data is accepted, but Imputability may be used to filter out low imputability events (Codes 0, 1) from national reporting.

Source and reference attributes

Submitting organisation: Haemovigilance Advisory Committee

Origin: International Society of Blood Transfusion Working Party on Haemovigilance

European Haemovigilance Network / International Haemovigilance Network

Serious Hazards of Transfusion (SHOT) UK

Reference documents:

Relational attributes

Implementation in Data Set Specifications:

Product Type

Identifying and definitional attributes

Metadata item type:	Data Element
Technical name:	Product Type
Code:	[X(19)] – see format below
Definition:	The blood product administered as the primary transfusion implicated in the adverse event
Data Element Concept:	Product Type

Value domain attributes

Representational attributes

Representation class:	Text
Data type:	String
Format:	[X(19)]
Maximum character length:	19

Permissible values:

Value	Meaning
Whole Blood	WHOLE BLOOD WHOLE BLOOD, Fresh Unrefrigerated Leucocyte Depleted
Red Cells	RED CELLS RED CELLS, Buffy Coat Removed RED CELLS, Leucocyte Depleted RED CELLS, Paediatric Leucocyte Depleted RED CELLS, Washed
Platelets	PLATELETS Apheresis Leucocyte Depleted PLATELETS Paediatric Apheresis Leucocyte Depleted PLATELETS Pooled Leucocyte Depleted
Fresh Frozen Plasma	FRESH FROZEN PLASMA FRESH FROZEN PLASMA Paediatric
Cryoprecipitate	CRYOPRECIPITATE CRYOPRECIPITATE Apheresis
Cryo-depleted	CRYO-DEPLETED PLASMA CRYO-DEPLETED PLASMA Apheresis

Product Type

Data element attributes

Collection and usage attributes

Guide for use: The administered labile blood product can be coded as one of six categories presented

Collection methods:

Comments: At the first HAC meeting, the discussion highlighted that there would be value in collecting data on the broad product type (i.e. Whole Blood, Red Cells, etc.) but there would be no extra utility in collecting ABO or Rh(D) data for all products. It is suggested that products will be rolled-up according to the ARCBS products names as shown above.

Source and reference attributes

Submitting organisation: Haemovigilance Advisory Committee

Origin: National Blood Authority

Reference documents: Australian Red Cross Blood Service product list

Relational attributes

Implementation in Data Set Specifications:

Concomitant Blood Components

Identifying and definitional attributes

Metadata item type:	Data Array
Technical name:	Concomitant Blood Components
Code:	Array of True/False values
Definition:	Additional blood products administered with or following the primary transfusion
Data Element Concept:	Product - Concomitant Blood Components

Value domain attributes

Representational attributes

Representation class:	True/False
Data type:	True/False
Format:	NNNNN
Maximum character length:	5
Permissible values:	

Element	Value	Meaning
Whole Blood	True/False	WHOLE BLOOD WHOLE BLOOD, Fresh Unrefrigerated Leucocyte Depleted
Red Cells	True/False	RED CELLS RED CELLS, Buffy Coat Removed RED CELLS, Leucocyte Depleted RED CELLS, Paediatric Leucocyte Depleted RED CELLS, Washed
Platelets	True/False	PLATELETS Apheresis Leucocyte Depleted PLATELETS Paediatric Apheresis Leucocyte Depleted PLATELETS Pooled Leucocyte Depleted
Fresh Frozen Plasma	True/False	FRESH FROZEN PLASMA FRESH FROZEN PLASMA Paediatric
Cryoprecipitate	True/False	CRYOPRECIPITATE CRYOPRECIPITATE Apheresis
Cryo-depleted	True/False	CRYO-DEPLETED PLASMA CRYO-DEPLETED PLASMA Apheresis

Concomitant Blood Components

Data element attributes

Collection and usage attributes

Guide for use:	Each element (Whole Blood, Red Cells, Platelets, etc.) should be viewed as separate. They are grouped here as an 'array' as they are part of the same concept, "Concomitant Blood Components" A True/False value should be returned for each element to signify the classes of concomitant blood products administered.
Collection methods:	Administered labile blood products can be rolled up into one of six categories presented. Where possible and relevant to the adverse event, administered products can be coded as above.
Comments:	At the first HAC meeting, the discussion highlighted that there would be value in collecting data on the broad product type (i.e. Whole Blood, Red Cells, etc.) but there would be no extra utility in collecting ABO or Rh(D) data for all products. It is suggested that products will be rolled-up according to the ARCBS products names as shown above.

Source and reference attributes

Submitting organisation:	Haemovigilance Advisory Committee
Origin:	National Blood Authority
Reference documents:	Australian Red Cross Blood Service product list

Relational attributes

Implementation in Data Set Specifications:	

Modification

Identifying and definitional attributes

Metadata item type:	Data Element
Technical name:	Blood Product - Modification
Code:	[X(12)] – see format below
Definition:	Blood product modification data on labile products coded according to ARCBS product nomenclature
Data Element Concept:	Product - Modification

Value domain attributes

Representational attributes

Representation class:	Text
Data type:	String
Format:	[X(12)]
Maximum character length:	12

Permissible values:

Value	Meaning
Null	Unmodified product
CMV-negative	CMV-negative
Irradiated	Irradiated; Irradiated NEONATAL; Hyper concentrated / irradiated; Irradiated for IUT
Other	Hyper concentrated; Directed; For intrauterine transfusion; Not NAT tested; Low anti-T; IgA deficient; Secretor plasma Le(b+); Not for neonatal use; Phenotype reserve; Low anti-A/B; Autol release

Data element attributes

Collection and usage attributes

Guide for use:	Modified products are available from the ARCBS, but the inclusion of every modification in the national dataset is not justified. Products will be coded as one of four values
Collection methods:	This is an optional field

Modification

Comments:	Data without coding for this field will be assigned the "Null" value

Source and reference attributes

Submitting organisation:	Haemovigilance Advisory Committee
Origin:	National Blood Authority
Reference documents:	

Relational attributes

Implementation in Data Set Specifications:	A high proportion of transfused patients may be immunosuppressed (e.g. oncology) suggesting the need to capture data on CMV negative transfusions and on irradiated product transfusions. Data structured in this way should be relatively easy to implement in all jurisdictions.

Appendix I - Definitions for Serious Transfusion Reactions and Events

ABO incompatibility;
The transfusion of ABO incompatible product/s resulting in an immediate haemolytic transfusion reaction. Generally major ABO red blood cell mis-matches result in significant morbidity or mortality, but minor incompatibilities may be innocuous and not result in harm. Incompatible platelet and plasma transfusions may or may not result in haemolysis and harm.

Haemolytic transfusion reactions (HTR) are clinically suspected if one or more of the following is present in a temporal association with transfusion;

- Fever and a variety of other symptoms (including dyspnoea, hypotension, tachycardia, flank or back pain etc)
- Inadequate rise in post-transfusion Hb level
- Drop in Hb level (≥2 g/dl within 24hrs)
- Rise in LDH (≥50% within 24hrs)
- Rise in bilirubin, haemoglobinuria or decrease in haptoglobin levels

Immediate haemolytic transfusion reactions (other than ABO);
Immediate transfusion reactions occur within 24hrs of transfusion. They may have immune or non-immune aetiology.

Delayed haemolytic transfusion reaction (DHTR);
Occurs between 1 and 28 days post-transfusion, and is the result of other atypical red blood cell allo-antibodies.

Severe febrile non-haemolytic transfusion reaction (FNHTR);
Presents with one or more of the following during or within 4hrs of transfusion without any other cause such as haemolytic transfusion reaction or infection;

- Fever (≥38^{o}C or change of ≥1^{o}C from pre-transfusion level)
- Chills
- Cold
- Rigor
- Other symptoms of discomfort

Incorrect blood component transfused (ICBT);
A patient receives a blood component destined for someone else, or receives a component not to specification. For instance, an immune compromised patient may require irradiated cellular products but receive ordinary banked blood instead. No distinction is made whether or not harm was done.

Transfusion transmitted infections (TTI);
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 30mm Hg 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.

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, HepB, HepC and CMV.

Parasitic infection;
Detection of the same parasite in the recipient's blood and parasite or specific antibodies in the donor blood.

Transfusion related acute lung injury (TRALI);
TRALI may be immune or non-immune. Serological confirmation is not required for diagnosis. Clinical TRALI features;

- Acute respiratory distress and
- Diffuse bilateral lung infiltrations in the lung radiograph and
- Occurrence during or within 6hrs of completion of the transfusion and
- No evidence of transfusion associated circulatory overload (TaCO).

Severe allergic reaction;
One or more of the following without hypotension, and within 24hrs of transfusion;

- Rash
- Allergic dyspnea (stridor, cyanosis, wheezing)
- Angioedema
- Generalised pruritis
- Urticaria

Anaphylactoid or anaphylactic reaction;
Allergic reaction with hypotension (Drop in systolic BP ≥30mm Hg) during or within 24hrs of transfusion or intractable hypotension or shock with loss of consciousness during transfusion, and without any indication of other cause

Transfusion induced graft versus host disease (TGVHD);
TGVHD clinically features the following 1–6 weeks post transfusion, with no other apparent cause;

- Fever
- Rash
- Liver dysfunction
- Diarrhoea and
- Cytopenia

TGVHD is confirmed by GVHD-typical biopsy and genetic analysis to show chimerism of donor and recipient lymphocytes.

Post-transfusion purpura (PTP);
Clinically features purpura and thrombocytopenia within 12 days of transfusion. PTP is confirmed by the detection of platelet specific antibodies (usually anti-HPA-1a) in the recipient's blood, and detection of the antithetical antigen on the donor platelets, or by a positive platelet X-match.

Transfusion-associated circulatory overload (TaCO);
Features respiratory distress, tachycardia, increased blood pressure, typical signs of cardiogenic lung oedema in the chest x-ray, evidence of a positive fluid balance and/or a known compromised cardiac status during or within 12 hours after transfusion

Appendix II – Definitions for Clinical Outcome Severity

Field Entry	*Definition / Explanation*
Outcome not available	Null response. The clinical outcome classification may be pending (extended time taken to assign clinical outcome) or permanently unavailable
No morbidity	No ill effects, no clinical effects
Minor morbidity	The recipient may have required medical intervention (e.g. 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