



Adverse Reaction

Detailed Clinical Model Specification

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Document Information

Document owner

Document Owner

The National Clinical Terminology and Information Service

Change history

Version	Date	Comments
1.0	29 Jun 2007	Initial public release
1.1	29 Feb 2008	Minor typographical corrections and wording changes in Introduction
2.0	7 Sep 2009	Updated to incorporate changes made in the version 2.0 of the Discharge Summary Specification.
3.0	24 Aug 2011	New version created in accordance with the archetype from NEHTA Clinical Knowledge Manager ¹ .

Related documents

Name	Version/Release Date
NEHTA Acronyms, Abbreviations & Glossary of Terms	Version 1.2, Issued 25 May 2005
Participation Data Specification	Version 3.2, Issued 20 July 2011

¹ <http://dcm.nehta.org.au/ckm>

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- Standards Australia;
- Members of the Australian DataTypes Project;
- Australian Institute of Health & Welfare; and
- Ocean Informatics.

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1 Introduction

1.1 Purpose and Scope

This data group specification forms part of a suite of data specifications that NEHTA is developing for the Australian Health Informatics Community. The suite comprises specifications for a range of health topics (represented as “data groups”), which are generally agreed to be of high priority to standardise in order to achieve the benefits brought about by Level 4 (semantic) interoperability in the Australian health care setting.

NEHTA values your questions and comments about this document. Please direct your questions or feedback to clinicalinformation@nehta.gov.au.

1.2 Intended Audience

This document is intended to be read by jurisdictional ICT managers, clinicians involved in Clinical Information System specifications, software architects and developers, and implementers of Clinical Information Systems in various health care settings.

It is reasonably technical in nature and expects the audience to be familiar with the language of health data specification and have some familiarity with health information standards and specifications. Definitions and examples are provided to clarify relevant terminology usage and intent.

1.3 Background

There are several e-health priority areas to be addressed by NEHTA specifications. One area of priority is identification of the data to be communicated and its structure. NEHTA is addressing this through Data Specifications which detail the Data Elements (logically grouped), and their associated value domains.

Data Specifications need to be independent of messaging formats. They are concerned with providing an information framework in which to achieve semantic interoperability.

Data specifications have been developed:

- Based on jurisdiction and clinician identified priorities;
- Specifically to suit the Australian model for a shared EHR;
- To define collections of related information, e.g. event summaries, data groups, data elements;
- To allow for expansion and extension as electronic systems mature;
- So they are “human readable”, (with information enhanced by the hierarchical structure);
- Incorporating clinical examples of use to enhance utility and adoption; and
- To provide a set of clinical terminologies, specific to the requirements of the Australian healthcare system.

Whilst Personally Controlled Electronic Health Record (PCEHR) is referred to in these documents the implementation of the PCEHR is not dealt with here.

1.4 Terminology

NEHTA, through the National Clinical Terminology and Information Service (NCTIS), is defining a national approach to clinical terminology. Consistent and accurate articulation and interpretation of clinical terms is critical to the process of safe exchange.

The Systematised Nomenclature of Medicine - Clinical Terms[®] (SNOMED CT[®]¹) has been recommended by NEHTA and endorsed by the Australian, State and Territory governments as the preferred clinical terminology for Australia, and is now freely available for e-health software developers to use in their Australian products under IHTSDO (International Health Terminology Standards Development Organisation) licensing arrangements.

While NEHTA's achievement of a national standard clinical terminology is based on SNOMED CT as the foundational resource, local variations and customisation of terms relevant to the Australian healthcare sector will be incorporated. SNOMED CT Australian Release (SNOMED CT-AU) is the Australian extension to SNOMED CT; the integrated national release of SNOMED CT for implementation in Australian deployed clinical IT systems. NEHTA is also developing the Australian Medicines Terminology (AMT) as the designated clinical terminology for medicines available in Australia. The AMT will provide a consistent approach to the identification and naming of medicines, to support medicines management and activity across the Australian healthcare domain. The AMT will be integrated with SNOMED CT-AU in the near future.

Reference sets listed as value domains within this document have been developed taking into account data element and data group definitions and how they align and complement the SNOMED CT concept model. For further information regarding terminology and the development of reference sets please visit <http://www.nehta.gov.au/connecting-australia/terminology-and-information> and direct your questions or feedback to terminologies@nehta.gov.au.

¹SNOMED CT[®] is a registered trademark of the International Health Terminology Standards Development Organisation.

2 Adverse Reaction Data Group

2.1 Purpose

To record health information that will inform a clinical assessment of the propensity of an individual for a future reaction to a substance, class of substance or agent.

To record information about exposure events to a substance, building up a persisting and evolving summary over time.

To record information about any adverse reaction, including:

- immune mediated reactions Types I-IV (including allergic reactions and hypersensitivities), and
- non-immune mediated reactions (including pseudoallergic reactions, side effects, intolerances, drug toxicities (eg Gentamycin), drug-drug interactions, food-drug interactions, drug-disease interactions and idiosyncratic reactions).

2.2 Use

Use to record all information about adverse reactions (including allergic reactions) that are required to support direct clinical care of an individual, safe exchange of information about adverse reactions and to enable computerised knowledge-based activities such as clinical decision support and alerts.

Use to provide a single place within the health record to record a range of clinical statements about adverse reactions, including:

- record cumulative information about each exposure to a known substance, class of substance or agent; and
- record a clinician's opinion that administration of, or exposure to, a substance or agent is absolutely contraindicated.

Use to record the information about an adverse reaction that might be exchanged with other systems, including as part of an adverse reaction report sent to statutory authorities. It is likely that a formal Adverse Reaction report will require additional information that will be captured in the health record using other data groups, for example medication and problem/diagnosis etc.

This data group has been designed to allow recording of information about a more generic substance, class of substance or agent, and then allow more specific details to be recorded including identification of the specific substance on a per exposure basis, including links to other parts of the health record where further details may be located. Note: it is possible on second or subsequent exposures to a previously identified substance for a reaction not to occur and this data group allows for these events to be closely linked in a way that will assist in determining if the adverse reaction has been incorrectly identified.

In addition, it is anticipated that in some very specific clinical situations, such as immunologist assessment or for use in clinical trials, more information about the adverse reaction may be required. Additional details can be added as cluster data groups using the 'Further Exposure Details' and 'Further Reaction Details' slots. Similarly, additional details that are required only for reporting can be added using the 'Reporting Details' slot.

The act of recording an adverse reaction in the health record implies there is a potential hazard for the individual if they are exposed to the same substance/agent in the future - a relative contraindication. If a clinician considers that it is not safe for the individual to be deliberately re-exposed to the substance/agent again, for example, following a manifestation of anaphylaxis, the 'Absolute contraindication'

data flag should be recorded as 'True'. Note: Conversely, a statement about 'Severity' of propensity (with possible values such as Mild, Moderate and Severe) has deliberately not been modelled explicitly. Predicting or estimating the grade of possible severity of a future reaction is not safe to record and persist in data, except where it is absolutely clear that the risk of deliberate re-exposure is unacceptable and highly likely to cause significant harm, such as a previous manifestation of anaphylaxis, and in this case the 'Absolute contraindication' data flag should be used.

Valuable first-level information that could be presented to the clinician when they need to assess propensity for future reactions are:

- statements about previous clinical manifestations following exposure,
- source of the information/reporter, and
- a flag for absolute contra-indication.

Second-level information can be drawn from each exposure event and links to additional detailed information such as history, examination and diagnoses stored elsewhere in the record, if it is available.

2.3 Misuse

1. Not to be used for recording the absence (or negative presence) of a reaction to 'any substances' or to identified substances – use the EVALUATION.exclusion family of data groups to express a positive statement of exclusion.
2. Not to be used for recording that no information was able to be obtained about the Adverse Reaction status of a patient. Use the EVALUATION.absent_information family of data group to record a positive statement of absent information about Adverse Reactions was able to be obtained, for example, if a non-cooperative patient refuses to answer questions.
3. Not to be used to record adverse events, including failures of clinical process, interventions or products. For example: abnormal use or mistakes/errors made in administration of an agent or substance; mislabelling; harm or injury caused by an intervention or procedure; overdose etc.
4. Not to be used for recording alerts.

2.4 ADVERSE REACTION






Identification

























Label	ADVERSE REACTION
Metadata Type	Data Group
Identifier	DG-16473
OID	1.2.36.1.2001.1001.101.102.16473




Definition




Definition	A harmful or undesirable effect associated with exposure to any substance or agent, including food, plants, animals, venom from animal stings or a medication at therapeutic or sub-therapeutic doses.
Definition Source	NEHTA
Synonymous Names	<ul style="list-style-type: none"> reaction allergy allergic adverse event effect sensitivity intolerance hypersensitivity side effect toxicity interaction drug food medication agent substance immune non-immune chemical

Data Hierarchy

	ADVERSE REACTION	
	Substance/Agent	1..1
	Absolute Contraindication	0..1
	Comment (Adverse Reaction Comment)	0..1
	REACTION EVENT	0..*

		Specific Substance/Agent	0..1
		Manifestation	0..*
		Reaction Type	0..1
		Certainty (Adverse Reaction Certainty)	0..1
		Reaction Description	0..1
		Onset of Reaction (Reaction Onset Date)	0..1
		Duration of Reaction	0..1
		Additional Reaction Detail (ADDITIONAL REACTION DETAIL)	0..*
		SPECIFIC LOCATION	0..1
		Name of Location (Anatomical Location Name)	0..1
		Side	0..1
		Numerical Identifier	0..1
		Anatomical Plane	0..1
		RELATIVE LOCATION	0..*
		Identified Landmark	0..1
		Aspect (Anatomical Location Aspect)	0..1
		Distance From Landmark	0..1
		Description (Anatomical Location Description)	0..*
		Visual Markings/Orientation	0..*
		Image (Anatomical Location Image)	0..*
		Exposure Description	0..1
		Earliest Exposure	0..1
		Duration of Exposure	0..1
		ADDITIONAL EXPOSURE DETAIL	0..*

				AMOUNT OF MEDICATION	1..1
				 Quantity	0..1
				 Dose Unit	0..1
				 Quantity Description	0..1
				TIMING	1..1
				 Frequency Range (Intervention Frequency Range)	0..1
				 Interval Range (Intervention Interval Range)	0..1
				 Time (Intervention Time)	0..*
				 Day of Week (Intervention Day of Week)	0..*
				 Day of Month (Intervention Day of Month)	0..*
				 Date (Intervention Date)	0..*
				Exposure Mechanism (MEDICATION ADMINISTRATION)	1..1
				 Route	0..1
				 Site (Anatomical Site)	0..1
				 Delivery Method (Medication Delivery Method)	0..1
				 Dose Duration	0..1
				Intravenous Details (INTRAVENOUS ADMINISTRATION DETAILS)	0..*
				Clinical Management Description	0..1
				Multimedia	0..*
				Reporting Details	0..*
				Comment (Adverse Reaction Event Comment)	0..1
				Reaction Reported	0..1
				Adverse Reaction Report	0..*

		Supporting Clinical Record Information	0..1
		INFORMATION PROVIDER	0..1
		SUBJECT	0..1

2.5 Substance/Agent

Identification

Label	Substance/Agent
Metadata Type	Data Element
Identifier	DE-15521
OID	1.2.36.1.2001.1001.101.103.15521

Definition


Definition	Identification of a substance, agent, or a class of substance, that is considered to be responsible for the adverse reaction.
Definition Source	NEHTA
Synonymous Names	Agent Substance
Notes	An agent can be a substance such as food, drug or an environmental allergen.
Data Type	CodeableText
Value Domain	Substance/Agent Values

Usage

Examples	<ol style="list-style-type: none"> 1. Animal protein 2. Latex 3. Peanut 4. Penicillin 5. Bee venom
-----------------	---

Relationships

Parents

Data Type	Name	Occurrences	Condition
	ADVERSE REACTION	1..1	

2.6 Substance/Agent Values

Identification

Label	Substance/Agent Values
Metadata Type	Value Domain
Identifier	VD-15521
OID	1.2.36.1.2001.1001.101.104.15521

Definition


Definition	The set of values for the agent/substance causing the adverse reaction experienced by the patient.
Definition Source	NEHTA

Value Domain

Source	NEHTA
Permissible Values	<p>The permissible values are the members of the following 8 reference sets.</p> <p>From SNOMED CT-AU:</p> <ul style="list-style-type: none"> • [32570211000036100 <i>Substance foundation reference set</i>] <p>From AMT:</p> <ul style="list-style-type: none"> • [929360061000036106 <i>Medicinal product reference set</i>] • [929360081000036101 <i>Medicinal product pack reference set</i>] • [929360071000036103 <i>Medicinal product unit of use reference set</i>] • [929360021000036102 <i>Trade product reference set</i>] • [929360041000036105 <i>Trade product pack reference set</i>] • [929360031000036100 <i>Trade product unit of use reference set</i>] • [929360051000036108 <i>Containerized trade product pack reference set</i>]

Relationships

Parents

Data Type	Name	Occurrences	Condition
	Substance/Agent	1..1	

2.7 Absolute Contraindication

Identification

Label	Absolute Contraindication
Metadata Type	Data Element
Identifier	DE-16073
OID	1.2.36.1.2001.1001.101.103.16073

Definition


Definition	A flag indicating that a clinician has identified a propensity for a serious reaction upon further exposure to the substance/agent.
Definition Source	NEHTA
Synonymous Names	
Data Type	Boolean

Usage

Conditions of Use	Record as True if the clinician assesses that exposure to, or administration of, the agent should be avoided in future. False is not a valid value for this data element.
Conditions of Use Source	NEHTA
Examples	

Relationships

Parents

Data Type	Name	Occurrences	Condition
	ADVERSE REACTION	0..1	

2.8 Adverse Reaction Comment

Identification

Label	Comment
Metadata Type	Data Element
Identifier	DE-15590
OID	1.2.36.1.2001.1001.101.103.15590

Definition


Definition	Additional narrative about the adverse reaction not captured in other fields, including reason for flagging an absolute contraindication, instructions related to future exposure or administration of the substance/agent.
Definition Source	NEHTA
Synonymous Names	Reaction Note
Notes	Used to provide additional narrative information in relation to the adverse reaction such as finding site or route of administration.
Data Type	Text

Usage

Examples	
-----------------	--

Relationships

Parents

Data Type	Name	Occurrences	Condition
	ADVERSE REACTION	0..1	

2.9 REACTION EVENT

Identification


Label	REACTION EVENT
Metadata Type	Data Group
Identifier	DG-16474
OID	1.2.36.1.2001.1001.101.102.16474

Definition









Definition	Details about each adverse reaction event.
Definition Source	NEHTA
Synonymous Names	









Relationships

Parents

Data Type	Name	Occurrences	Condition
	ADVERSE REACTION	0..*	

Children

Data Type	Name	Occurrences	Condition
	Specific Substance/Agent	0..1	
	Manifestation	0..*	
	Reaction Type	0..1	
	Certainty (Adverse Reaction Certainty)	0..1	
	Reaction Description	0..1	
	Onset of Reaction (Reaction Onset Date)	0..1	
	Duration of Reaction	0..1	
	Additional Reaction Detail (ADDITIONAL REACTION DETAIL)	0..*	

Data Type	Name	Occurrences	Condition
	Exposure Description	0..1	
	Earliest Exposure	0..1	
	Duration of Exposure	0..1	
	ADDITIONAL EXPOSURE DETAIL	0..*	
	Clinical Management Description	0..1	
	Multimedia	0..*	
	Reporting Details	0..*	
	Comment (Adverse Reaction Event Comment)	0..1	

2.10 Specific Substance/Agent

Identification

Label	Specific Substance/Agent
Metadata Type	Data Element
Identifier	DE-16349
OID	1.2.36.1.2001.1001.101.103.16349

Definition


Definition	Specific identification of the substance/agent considered to be responsible for the adverse reaction event.
Definition Source	NEHTA
Synonymous Names	
Notes	This may include a medication trade name.
Data Type	CodeableText
Value Domain	Substance/Agent Values

Usage

Examples	
Misuse	To record broad classes of substance such as "food" or "antibiotic".

Relationships

Parents

Data Type	Name	Occurrences	Condition
	REACTION EVENT	0..1	

2.11 Manifestation

Identification

Label	Manifestation
Metadata Type	Data Element
Identifier	DE-15564
OID	1.2.36.1.2001.1001.101.103.15564

Definition


Definition	Clinical manifestation of the adverse reaction expressed as a single word, phrase or brief description.
Definition Source	NEHTA
Synonymous Names	Reaction
Notes	<p>The signs, symptoms, severity and/or certainty of the adverse reaction are relevant as it contributes towards the decision as to the immediacy and extent of treatment to be provided, as determined by a healthcare provider.</p> <p>Given that an adverse reaction has occurred, it is important to determine the manifestations of that reaction.</p>
Data Type	CodeableText
Value Domain	Clinical Manifestation Values Reference Set

Usage

Examples	<ol style="list-style-type: none"> 1. Itchy eyes. 2. Dysphagia. 3. Tinnitus. 4. Nausea. 5. Rash.
-----------------	---

Relationships

Parents

Data Type	Name	Occurrences	Condition
	REACTION EVENT	0..*	

2.12 Clinical Manifestation Values Reference Set

Identification

Label	Clinical Manifestation Values Reference Set
Metadata Type	Value Domain
Identifier	VD-15564
OID	1.2.36.1.2001.1001.101.104.15564
External Identifier	SNOMED CT-AU Concept ID: 32570071000036102

Definition


Definition	The Clinical Manifestation values reference set provides the broadest possible terminology to support the recording of Clinical manifestation of the adverse reaction in Australian eHealth implementations.
Definition Source	NEHTA

Value Domain

Source	SNOMED CT-AU
---------------	--------------

Relationships

Parents

Data Type	Name	Occurrences	Condition
	Manifestation	1..1	

2.13 Reaction Type

Identification

Label	Reaction Type
Metadata Type	Data Element
Identifier	DE-15554
OID	1.2.36.1.2001.1001.101.103.15554

Definition

Definition	The type of reaction, as determined by the clinician.
Definition Source	NEHTA
Synonymous Names	
Context	<p>This field is used to identify the type of adverse reaction as determined by:</p> <ul style="list-style-type: none"> • the signs and/or symptoms experienced by the subject of care; • information provided by a relevant individual; • previously documented history; and/or • a clinical assessment by a healthcare provider.
Context Source	NEHTA
Notes	<p>Examples include Immune mediated - Types I-IV (including allergy and hypersensitivity); Non-immune mediated - including pseudoallergic reaction, side effect, intolerance, drug toxicity, drug-drug interaction, food-drug interaction, drug-disease interaction and idiosyncratic reaction.</p>
Data Type	CodeableText
Value Domain	<p><i>Not specified.</i></p> <p>In the absence of national standard code sets, the code sets used SHALL be registered code sets, i.e. registered through the HL7 code set registration procedure¹ with an appropriate object identifier (OID), and SHALL be publicly available.</p> <p>When national standard code sets become available, they SHALL be used and the non-standard code sets SHALL be deprecated.</p>

Usage


Examples	<ol style="list-style-type: none"> 1. Allergy. 2. Idiosyncrasy. 3. Interactions.
-----------------	---

¹ <http://www.hl7.org/oid/index.cfm>

4. Intolerance / sensitivity.
5. Pseudoallergy / anaphylactoid reaction.
6. Side effects.

Relationships

Parents

Data Type	Name	Occurrences	Condition
	REACTION EVENT	0..1	

2.14 Adverse Reaction Certainty

Identification

Label	Certainty
Metadata Type	Data Element
Identifier	DE-15568
OID	1.2.36.1.2001.1001.101.103.15568

Definition


Definition	Degree of certainty, as assessed by clinician, that the specific substance/agent was the cause of the reaction.
Definition Source	NEHTA
Synonymous Names	
Notes	It is important to know the degree of certainty of an adverse reaction to an agent/substance as there may be instances where it is not clear whether it is the active agent or a secondary component causing the problem. For example, it may be the filler in a tablet that may be the allergen rather than the active drug. Another example is where there is suspicion of a reaction which warrants recording but it has not been confirmed objectively, or where a reaction has been recorded but is subsequently discounted following further observation and/or investigation.
Data Type	CodedText
Value Domain	Adverse Reaction Certainty Values

Usage

Examples	<ol style="list-style-type: none"> 1. Certain. 2. Probable. 3. Unlikely.
-----------------	---

Relationships

Parents

Data Type	Name	Occurrences	Condition
	REACTION EVENT	0..1	

2.15 Adverse Reaction Certainty Values

Identification

Label	Adverse Reaction Certainty Values
Metadata Type	Value Domain
Identifier	VD-15568
OID	1.2.36.1.2001.1001.101.104.15568

Definition

Definition	The set of values for the degree of confidence that the agent/substance has caused the adverse reaction.
Definition Source	NEHTA

Value Domain


Source	WHO-UMC causality assessment system.
Permissible Values	<p>A clinical event, including laboratory test abnormality, occurring in a plausible time relationship to agent exposure or administration, and which cannot be explained by concurrent disease or other agents or chemicals. The response to withdrawal of the agent (dechallenge) should be clinically plausible. The event must be definitive pharmacologically or phenomenologically, using a satisfactory rechallenge procedure if necessary.</p> <p>A clinical event, including laboratory test abnormality, with a reasonable time relationship to agent exposure or administration, unlikely to be attributed to concurrent disease or other agents or chemicals, and which follows a clinically reasonable response on withdrawal (dechallenge) Rechallenge information is not required to fulfil this definition.</p> <p>A clinical event, including laboratory test abnormality, with a reasonable time time relationship to agent exposure or administration, but which could also be explained by concurrent disease or other agents or chemicals. Information on agent withdrawal may be lacking or unclear.</p> <p>A clinical event, including laboratory test abnormality, with a temporal relationship to agent exposure or administration which makes a causal relationship improbable, and in which other agents, chemicals or underlying disease provide plausible explanations.</p> <p>A clinical event, including laboratory test abnormality, reported as an adverse reaction, about which more data are required for a proper assessment or the additional data are under examination.</p> <p>A reported adverse reaction which cannot be judged because information is insufficient or contradictory, and which cannot be supplemented or verified.</p>

Usage

Conditions of Use	The value domain options are mutually exclusive and cannot be used in conjunction with each other.
Conditions of Use Source	Amended from Edwards, IR and C Biriell. 'Harmonisation in Pharmacovigilance'. Drug Safety 10.2 (1994): 93-102; The Uppsala Monitoring Centre; "The use of the WHO-UMC system for standardised and causality assessment". Note: These sources specifically relate to drug adverse events or pharmacovigilance. The modifications here are done to broaden the assessment to all agents which might cause or be suspected of causing an adverse event.

Relationships

Parents

Data Type	Name	Occurrences	Condition
	Certainty (Adverse Reaction Certainty)	1..1	

2.16 Reaction Description

Identification

Label	Reaction Description
Metadata Type	Data Element
Identifier	DE-15563
OID	1.2.36.1.2001.1001.101.103.15563

Definition


Definition	Narrative description of the reaction.
Definition Source	NEHTA
Synonymous Names	Reaction
Data Type	Text

Usage

Examples	<ol style="list-style-type: none"> 1. Itchy eyes. 2. Dysphagia. 3. Tinnitus.
-----------------	---

Relationships

Parents

Data Type	Name	Occurrences	Condition
	REACTION EVENT	0..1	

2.17 Reaction Onset Date

Identification

Label	Onset of Reaction
Metadata Type	Data Element
Identifier	DE-15507
OID	1.2.36.1.2001.1001.101.103.15507

Definition


Definition	Record of the date and/or time of the onset of the reaction.
Definition Source	NEHTA
Synonymous Names	DateTime Started
Notes	<p>The date or date and time that the specific Reaction commenced.</p> <p>Sometimes, the date or age at which a person reacts to an agent is a relevant to understanding a condition, or to determining appropriate treatment. Often, this will be an approximate, self-reported age, date or datetime.</p>
Data Type	DateTime

Usage

Examples	Please see Appendix B, Specification Guide for Use
-----------------	--

Relationships

Parents

Data Type	Name	Occurrences	Condition
	REACTION EVENT	0..1	

2.18 Duration of Reaction

Identification

Label	Duration of Reaction
Metadata Type	Data Element
Identifier	DE-16352
OID	1.2.36.1.2001.1001.101.103.16352

Definition


Definition	Length of duration of the reaction.
Definition Source	NEHTA
Synonymous Names	
Data Type	Duration

Usage

Examples	
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Relationships

Parents

Data Type	Name	Occurrences	Condition
	REACTION EVENT	0..1	

2.19 ADDITIONAL REACTION DETAIL

Identification


Label	Additional Reaction Detail
Metadata Type	Data Group
Identifier	DG-16150
OID	1.2.36.1.2001.1001.101.102.16150

Definition






Definition	Additional detail about the reaction, including anatomical location.
Definition Source	NEHTA
Synonymous Names	

Relationships

Parents

Data Type	Name	Occurrences	Condition
	REACTION EVENT	0..*	

Children

Data Type	Name	Occurrences	Condition
	SPECIFIC LOCATION	0..1	
	RELATIVE LOCATION	0..*	
	Description (Anatomical Location Description)	0..*	
	Visual Markings/Orientation	0..*	
	Image (Anatomical Location Image)	0..*	

2.20 SPECIFIC LOCATION

Identification


Label	SPECIFIC LOCATION
Metadata Type	Data Group
Identifier	DG-16151
OID	1.2.36.1.2001.1001.101.102.16151

Definition





Definition	Specific and identified anatomical location.
Definition Source	NEHTA
Synonymous Names	

Relationships

Parents

Data Type	Name	Occurrences	Condition
	Additional Reaction Detail (ADDITIONAL REACTION DETAIL)	0..1	

Children

Data Type	Name	Occurrences	Condition
	Name of Location (Anatomical Location Name)	0..1	
	Side	0..1	
	Numerical Identifier	0..1	
	Anatomical Plane	0..1	

2.21 Anatomical Location Name

Identification

Label	Name of Location
Metadata Type	Data Element
Identifier	DE-16153
OID	1.2.36.1.2001.1001.101.103.16153

Definition


Definition	The name of an anatomical location.
Definition Source	NEHTA
Synonymous Names	
Data Type	CodeableText
Value Domain	Body Structure Foundation Reference Set

Usage

Examples	
-----------------	--

Relationships

Parents

Data Type	Name	Occurrences	Condition
	SPECIFIC LOCATION	0..1	

2.22 Body Structure Foundation Reference Set

Identification

Label	Body Structure Foundation Reference Set
Metadata Type	Value Domain
Identifier	VD-16152
OID	1.2.36.1.2001.1001.101.104.16152
External Identifier	SNOMED CT-AU Concept Id: 32570061000036105

Definition


Definition	The set of values for named anatomical locations.
Definition Source	NEHTA

Value Domain

Source	SNOMED CT-AU
---------------	--------------

Relationships

Parents

Data Type	Name	Occurrences	Condition
	Name of Location (Anatomical Location Name)	1..1	

2.23 Side

Identification

Label	Side
Metadata Type	Data Element
Identifier	DE-16336
OID	1.2.36.1.2001.1001.101.103.16336

Definition


Definition	The laterality of an anatomical location.
Definition Source	NEHTA
Synonymous Names	Laterality
Data Type	CodedText
Value Domain	Laterality Reference Set

Usage

Examples	<ol style="list-style-type: none"> 1. Right. 2. Left. 3. Bilateral.
-----------------	--

Relationships

Parents

Data Type	Name	Occurrences	Condition
	SPECIFIC LOCATION	0..1	

2.24 Laterality Reference Set

Identification

Label	Laterality Reference Set
Metadata Type	Value Domain
Identifier	VD-16312
OID	1.2.36.1.2001.1001.101.104.16312
External Identifier	SNOMED CT-AU Concept Id: 32570611000036103

Definition


Definition	The set of values for identifying laterality of an anatomical location.
Definition Source	NEHTA

Value Domain

Source	SNOMED CT-AU
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Relationships

Parents

Data Type	Name	Occurrences	Condition
	Side	1..1	

2.25 Numerical Identifier

Identification

Label	Numerical Identifier
Metadata Type	Data Element
Identifier	DE-16338
OID	1.2.36.1.2001.1001.101.103.16338

Definition

Definition	Identify the specific anatomical site out of multiple sites.
Definition Source	NEHTA
Synonymous Names	
Data Type	CodedText
Value Domain	<i>Not specified.</i>
	In the absence of national standard code sets, the code sets used SHALL be registered code sets, i.e. registered through the HL7 code set registration procedure ² with an appropriate object identifier (OID), and SHALL be publicly available.
	When national standard code sets become available, they SHALL be used and the non-standard code sets SHALL be deprecated.


Usage

Conditions of Use	This SHALL be an ordinal number between first and eighteenth.
Conditions of Use Source	NEHTA
Examples	<ol style="list-style-type: none"> 1. First, as in 'first rib' 2. Second, as in 'second toe' 3. Third, as in 'third lumbar vertebra'

² <http://www.hl7.org/oid/index.cfm>

Relationships

Parents

Data Type	Name	Occurrences	Condition
	SPECIFIC LOCATION	0..1	

2.26 Anatomical Plane

Identification

Label	Anatomical Plane
Metadata Type	Data Element
Identifier	DE-16340
OID	1.2.36.1.2001.1001.101.103.16340

Definition


Definition	Line describing the position of a vertical anatomical plane in the body.
Definition Source	NEHTA
Synonymous Names	
Data Type	CodedText
Value Domain	<i>Not specified.</i>
	In the absence of national standard code sets, the code sets used SHALL be registered code sets, i.e. registered through the HL7 code set registration procedure ³ with an appropriate object identifier (OID), and SHALL be publicly available.
	When national standard code sets become available, they SHALL be used and the non-standard code sets SHALL be deprecated.

Usage

Examples	<ol style="list-style-type: none"> 1. Midline. 2. Midclavicular. 3. Midaxillary. 4. Midscapular.
-----------------	--

Relationships

Parents

Data Type	Name	Occurrences	Condition
	SPECIFIC LOCATION	0..1	

³ <http://www.hl7.org/oid/index.cfm>

2.27 RELATIVE LOCATION

Identification


Label	RELATIVE LOCATION
Metadata Type	Data Group
Identifier	DG-16341
OID	1.2.36.1.2001.1001.101.102.16341

Definition




Definition	Qualifiers to identify non-specific location.
Definition Source	NEHTA
Synonymous Names	
Notes	<p>An example is: 5cm (distance) inferior (aspect) to the tibial tuberosity (landmark).</p> <p>There may be more than one relative location required to provide a cross reference.</p>

Relationships

Parents

Data Type	Name	Occurrences	Condition
	Additional Reaction Detail (ADDITIONAL REACTION DETAIL)	0..*	

Children

Data Type	Name	Occurrences	Condition
	Identified Landmark	0..1	
	Aspect (Anatomical Location Aspect)	0..1	
	Distance From Landmark	0..1	

2.28 Identified Landmark

Identification

Label	Identified Landmark
Metadata Type	Data Element
Identifier	DE-16343
OID	1.2.36.1.2001.1001.101.103.16343

Definition


Definition	Identified anatomical landmark from which to specify relative anatomical location.
Definition Source	NEHTA
Synonymous Names	
Data Type	CodeableText
Value Domain	<i>Not specified.</i>
	In the absence of national standard code sets, the code sets used SHALL be registered code sets, i.e. registered through the HL7 code set registration procedure ⁴ with an appropriate object identifier (OID), and SHALL be publicly available.
	When national standard code sets become available, they SHALL be used and the non-standard code sets SHALL be deprecated.

Usage

Examples	
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Relationships

Parents

Data Type	Name	Occurrences	Condition
	RELATIVE LOCATION	0..1	

⁴ <http://www.hl7.org/oid/index.cfm>

2.29 Anatomical Location Aspect

Identification

Label	Aspect
Metadata Type	Data Element
Identifier	DE-16345
OID	1.2.36.1.2001.1001.101.103.16345

Definition

Definition	Qualifier to identify which direction the anatomical location is in relation to the identified landmark.
Definition Source	NEHTA
Synonymous Names	
Data Type	CodedText
Value Domain	<i>Not specified.</i>
	In the absence of national standard code sets, the code sets used SHALL be registered code sets, i.e. registered through the HL7 code set registration procedure ⁵ with an appropriate object identifier (OID), and SHALL be publicly available.
	When national standard code sets become available, they SHALL be used and the non-standard code sets SHALL be deprecated.

Usage


Examples	<ol style="list-style-type: none"> 1. Medial to: Relative location medial to the landmark. 2. Lateral to: Relative location lateral to the landmark. 3. Superior to: Relative location superior to the landmark. 4. Inferior to: Relative location inferior to the landmark. 5. Anterior to: Relative location anterior to the landmark. 6. Posterior to: Relative location posterior to the landmark. 7. Below: Relative location below the landmark. 8. Above: Relative location above the landmark. 9. Inferolateral to: Relative location inferior and medial to the landmark. 10. Superolateral to: Relative location superior and lateral to the landmark. 11. Inferomedial to: Relative location inferior and medial to the landmark.
-----------------	---

⁵ <http://www.hl7.org/oid/index.cfm>

12 Superomedial to: Relative location superior and medial to the landmark.

Relationships

Parents

Data Type	Name	Occurrences	Condition
	RELATIVE LOCATION	0..1	

2.30 Distance From Landmark

Identification

Label	Distance From Landmark
Metadata Type	Data Element
Identifier	DE-16346
OID	1.2.36.1.2001.1001.101.103.16346

Definition


Definition	Distance of location from the identified landmark.
Definition Source	NEHTA
Synonymous Names	
Data Type	Quantity

Usage

Examples

Relationships

Parents

Data Type	Name	Occurrences	Condition
	RELATIVE LOCATION	0..1	

2.31 Anatomical Location Description

Identification

Label	Description
Metadata Type	Data Element
Identifier	DE-16319
OID	1.2.36.1.2001.1001.101.103.16319

Definition


Definition	Description of anatomical location.
Definition Source	NEHTA
Synonymous Names	
Data Type	Text

Usage

Examples	
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Relationships

Parents

Data Type	Name	Occurrences	Condition
	Additional Reaction Detail (ADDITIONAL REACTION DETAIL)	0..*	

2.32 Visual Markings/Orientation

Identification

Label	Visual Markings/Orientation
Metadata Type	Data Element
Identifier	DE-16407
OID	1.2.36.1.2001.1001.101.103.16407

Definition


Definition	Description of any visual markings used to orientate the viewer.
Definition Source	NEHTA
Synonymous Names	
Data Type	Text

Usage

Examples	<ol style="list-style-type: none"> 1. External reference points. 2. Special sutures. 3. Ink markings.
-----------------	--

Relationships

Parents

Data Type	Name	Occurrences	Condition
	Additional Reaction Detail (ADDITIONAL REACTION DETAIL)	0..*	

2.33 Anatomical Location Image

Identification

Label	Image
Metadata Type	Data Element
Identifier	DE-16199
OID	1.2.36.1.2001.1001.101.103.16199

Definition


Definition	Image or images used to identify a location.
Definition Source	NEHTA
Synonymous Names	
Context	This element is intended to be an image, e.g. photo of the anatomical site such as a wound on the leg.
Context Source	NEHTA
Data Type	EncapsulatedData

Usage

Examples	
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Relationships

Parents

Data Type	Name	Occurrences	Condition
	Additional Reaction Detail (ADDITIONAL REACTION DETAIL)	0..*	

2.34 Exposure Description

Identification

Label	Exposure Description
Metadata Type	Data Element
Identifier	DE-16477
OID	1.2.36.1.2001.1001.101.103.16477

Definition


Definition	Description about exposure to the substance/agent.
Definition Source	NEHTA
Synonymous Names	
Data Type	Text

Usage

Examples

Relationships

Parents

Data Type	Name	Occurrences	Condition
	REACTION EVENT	0..1	

2.35 Earliest Exposure

Identification

Label	Earliest Exposure
Metadata Type	Data Element
Identifier	DE-16372
OID	1.2.36.1.2001.1001.101.103.16372

Definition


Definition	Record of the date and/or time of the earliest or initial exposure to the substance/agent.
Definition Source	NEHTA
Synonymous Names	
Data Type	DateTime

Usage

Examples	
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Relationships

Parents

Data Type	Name	Occurrences	Condition
	REACTION EVENT	0..1	

2.36 Duration of Exposure

Identification

Label	Duration of Exposure
Metadata Type	Data Element
Identifier	DE-16373
OID	1.2.36.1.2001.1001.101.103.16373

Definition


Definition	Length of duration of exposure.
Definition Source	NEHTA
Synonymous Names	
Notes	Used to describe the length of exposure to substance/agent triggering a specific reaction event.
Data Type	Duration

Usage

Examples

Relationships

Parents

Data Type	Name	Occurrences	Condition
	REACTION EVENT	0..1	

2.37 ADDITIONAL EXPOSURE DETAIL

Identification


Label	ADDITIONAL EXPOSURE DETAIL
Metadata Type	Choice
Identifier	C-16478
OID	1.2.36.1.2001.1001.101.105.16478

Definition




Definition	Additional detail about exposure/s for this reaction event, including structured medication amount information.
Definition Source	NEHTA
Synonymous Names	

Relationships

Parents

Data Type	Name	Occurrences	Condition
	REACTION EVENT	0..*	

Children

Data Type	Name	Occurrences	Condition
	AMOUNT OF MEDICATION	1..1	
	TIMING	1..1	
	Exposure Mechanism (MEDICATION ADMINISTRATION)	1..1	

2.38 AMOUNT OF MEDICATION

Identification


Label	AMOUNT OF MEDICATION
Metadata Type	Data Group
Identifier	DG-16423
OID	1.2.36.1.2001.1001.101.102.16423

Definition





Definition	Additional detail about exposure/s for this reaction event, including structured medication amount information.
Definition Source	NEHTA
Synonymous Names	
Scope	Used to record additional exposure details to substance/agent that triggers the adverse reaction event.
Scope Source	NEHTA

Relationships

Parents

Data Type	Name	Occurrences	Condition
	ADDITIONAL EXPOSURE DETAIL	1..1	

Children

Data Type	Name	Occurrences	Condition
 	Quantity	0..1	
	Dose Unit	0..1	
	Quantity Description	0..1	

2.39 Quantity

Identification

Label	Quantity
Metadata Type	Data Element
Identifier	DE-10145
OID	1.2.36.1.2001.1001.101.103.10145

Definition


Definition	The quantity, number or proportion.
Definition Source	NEHTA
Synonymous Names	
Notes	The number of doses and/or physical amount of the therapeutic good.
Data Type	Real QuantityRatio

Usage

Examples	
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Relationships

Parents

Data Type	Name	Occurrences	Condition
	AMOUNT OF MEDICATION	0..1	

2.40 Dose Unit

Identification

Label	Dose Unit
Metadata Type	Data Element
Identifier	DE-16524
OID	1.2.36.1.2001.1001.101.103.16524

Definition


Definition	The dose unit of this amount.
Definition Source	NEHTA
Synonymous Names	
Data Type	CodedText
Value Domain	Dose Unit Reference Set

Usage

Examples	<ol style="list-style-type: none"> 1. Tablets. 2. Capsules. 3. Sachets. 4. Mg. 5. mL.
-----------------	--

Relationships

Parents

Data Type	Name	Occurrences	Condition
	AMOUNT OF MEDICATION	0..1	

2.41 Dose Unit Reference Set

Identification

Label	Dose Unit Reference Set
Metadata Type	Value Domain
Identifier	VD-16523
OID	1.2.36.1.2001.1001.101.104.16523
External Identifier	SNOMED CT-AU Concept Id: 32570641000036102

Definition


Definition	The set of values for dose unit.
Definition Source	NEHTA
Notes	Values might include: Tablets, Capsules, Sachets, mg, mL.

Value Domain

Source	SNOMED CT-AU
---------------	--------------

Relationships

Parents

Data Type	Name	Occurrences	Condition
 001011001	Dose Unit	1..1	

2.42 Quantity Description

Identification

Label	Quantity Description
Metadata Type	Data Element
Identifier	DE-16525
OID	1.2.36.1.2001.1001.101.103.16525

Definition


Definition	Free text description of the amount which may consist of the quantity and dose unit.
Definition Source	NEHTA
Synonymous Names	
Data Type	Text

Usage

Examples

Relationships

Parents

Data Type	Name	Occurrences	Condition
	AMOUNT OF MEDICATION	0..1	

2.43 TIMING

Identification


Label	TIMING
Metadata Type	Data Group
Identifier	DG-16431
OID	1.2.36.1.2001.1001.101.102.16431

Definition







Definition	Details of the timing of the use or administration of the medicine, vaccine or other therapeutic good.
Definition Source	NEHTA
Synonymous Names	
Notes	It is for recording timing of exposure to substance or agent, including medication or vaccine.

Relationships

Parents

Data Type	Name	Occurrences	Condition
	ADDITIONAL EXPOSURE DETAIL	1..1	

Children

Data Type	Name	Occurrences	Condition
	Frequency Range (Intervention Frequency Range)	0..1	
	Interval Range (Intervention Interval Range)	0..1	
	Time (Intervention Time)	0..*	
	Day of Week (Intervention Day of Week)	0..*	
	Day of Month (Intervention Day of Month)	0..*	
	Date (Intervention Date)	0..*	

2.44 Intervention Frequency Range

Identification

Label	Frequency Range
Metadata Type	Data Element
Identifier	DE-16547
OID	1.2.36.1.2001.1001.101.103.16547

Definition


Definition	The frequency as number of times per time period that the intervention is to take place.
Definition Source	NEHTA
Synonymous Names	
Notes	Includes details of variable upper and lower frequency e.g. 3-4 times a day.
Data Type	QuantityRange

Usage

Examples

Relationships

Parents

Data Type	Name	Occurrences	Condition
	TIMING	0..1	

2.45 Intervention Interval Range

Identification

Label	Interval Range
Metadata Type	Data Element
Identifier	DE-16548
OID	1.2.36.1.2001.1001.101.103.16548

Definition


Definition	The length of time between doses or interventions.
Definition Source	NEHTA
Synonymous Names	
Notes	8 Hourly is PT8H, monthly is P1M, every hour and a half is PT1H30M. Includes details of variable upper and lower intervals e.g. every 2-3 hours.
Data Type	QuantityRange

Usage

Examples	
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Relationships

Parents

Data Type	Name	Occurrences	Condition
	TIMING	0..1	

2.46 Intervention Time

Identification

Label	Time
Metadata Type	Data Element
Identifier	DE-16549
OID	1.2.36.1.2001.1001.101.103.16549

Definition


Definition	Specific time(s) during the day when the intervention should be applied.
Definition Source	NEHTA
Synonymous Names	
Data Type	DateTime

Usage

Examples

Relationships

Parents

Data Type	Name	Occurrences	Condition
	TIMING	0..*	

2.47 Intervention Day of Week

Identification

Label	Day of Week
Metadata Type	Data Element
Identifier	DE-16551
OID	1.2.36.1.2001.1001.101.103.16551

Definition


Definition	The specific and repeating day(s) of the week.
Definition Source	NEHTA
Synonymous Names	
Data Type	CodedText
Value Domain	<i>Not specified.</i>
	In the absence of national standard code sets, the code sets used SHALL be registered code sets, i.e. registered through the HL7 code set registration procedure ⁶ with an appropriate object identifier (OID), and SHALL be publicly available.
	When national standard code sets become available, they SHALL be used and the non-standard code sets SHALL be deprecated.

Usage

Examples	<ol style="list-style-type: none"> 1. Monday 2. Wednesday 3. Friday 4. Sunday
-----------------	---

Relationships

Parents

Data Type	Name	Occurrences	Condition
	TIMING	0..*	

⁶ <http://www.hl7.org/oid/index.cfm>

2.48 Intervention Day of Month

Identification

Label	Day of Month
Metadata Type	Data Element
Identifier	DE-16552
OID	1.2.36.1.2001.1001.101.103.16552

Definition


Definition	The specific and repeating day(s) of the month.
Definition Source	NEHTA
Synonymous Names	
Notes	For instance, if it is required to give a dose on the 2nd day of each month then the value is 2.
Data Type	Integer

Usage

Examples

Relationships

Parents

Data Type	Name	Occurrences	Condition
	TIMING	0..*	

2.49 Intervention Date

Identification

Label	Date
Metadata Type	Data Element
Identifier	DE-16553
OID	1.2.36.1.2001.1001.101.103.16553

Definition


Definition	Actual dates.
Definition Source	NEHTA
Synonymous Names	
Data Type	DateTime

Usage

Examples	
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Relationships

Parents

Data Type	Name	Occurrences	Condition
	TIMING	0..*	

2.50 MEDICATION ADMINISTRATION

Identification

Label	Exposure Mechanism
Metadata Type	Data Group
Identifier	DG-10108
OID	1.2.36.1.2001.1001.101.102.10108

Definition


Definition	Details about the administration of the medicine, vaccine or other therapeutic good.
Definition Source	NEHTA
Synonymous Names	
Scope	Used to describe the exposure mechanism to the substance or agent. This includes the route, anatomical site, delivery methods of medications.
Scope Source	NEHTA

Usage




Conditions of Use	This data group is repeated for every instance of medication administration being recorded.
Conditions of Use Source	NEHTA



Relationships

Parents

Data Type	Name	Occurrences	Condition
	ADDITIONAL EXPOSURE DETAIL	1..1	

Children

Data Type	Name	Occurrences	Condition
	Route	0..1	
	Site (Anatomical Site)	0..1	
	Delivery Method (Medication Delivery Method)	0..1	

Data Type	Name	Occurrences	Condition
	Dose Duration	0..1	
	Intravenous Details (INTRAVENOUS ADMINISTRATION DETAILS)	0..*	

2.51 Route

Identification

Label	Route
Metadata Type	Data Element
Identifier	DE-10147
OID	1.2.36.1.2001.1001.101.103.10147

Definition


Definition	The route by which the medication is administered.
Definition Source	NEHTA
Synonymous Names	Route of administration.
Notes	It is used to describe the route by which the substance/agent is entered into the patient's body. This includes the route of medication administration.
Data Type	CodeableText
Value Domain	Route of Administration Reference Set

Usage

Conditions of Use	Use "Unknown" only for retrospective data collection.
Conditions of Use Source	NEHTA
Examples	<ol style="list-style-type: none"> 1. Oral. 2. Subcutaneous injection. 3. Epidural. 4. Rectal. 5. Otic.

Relationships

Parents

Data Type	Name	Occurrences	Condition
	Exposure Mechanism (MEDICATION ADMINISTRATION)	0..1	

2.52 Route of Administration Reference Set

Identification

Label	Route of Administration Reference Set
Metadata Type	Value Domain
Identifier	VD-10147
OID	1.2.36.1.2001.1001.101.104.10147
External Identifier	SNOMED CT-AU Concept Id: 32570601000036100

Definition


Definition	A list of all possible routes of administration of medication.
Definition Source	NEHTA
Notes	Set of allowable values to describe the way through which a medication is administered to/by the subject of care.

Value Domain

Source	SNOMED CT-AU
---------------	--------------

Relationships

Parents

Data Type	Name	Occurrences	Condition
 001011001	Route	1..1	

2.53 Anatomical Site

Identification

Label	Site
Metadata Type	Data Element
Identifier	DE-10156
OID	1.2.36.1.2001.1001.101.103.10156

Definition


Definition	A description of the site of administration.
Definition Source	NEHTA
Synonymous Names	
Notes	Location on or in the body of the subject of care where the substance/agent entered the body or therapeutic good was administered.
Data Type	CodeableText
Value Domain	Body Structure Foundation Reference Set

Usage

Examples	<ol style="list-style-type: none"> 1. Left thigh 2. Upper arm 3. Entire left renal artery
-----------------	--

Relationships

Parents

Data Type	Name	Occurrences	Condition
	Exposure Mechanism (MEDICATION ADMINISTRATION)	0..1	

2.54 Body Structure Foundation Reference Set

Identification

Label	Body Structure Foundation Reference Set
Metadata Type	Value Domain
Identifier	VD-16152
OID	1.2.36.1.2001.1001.101.104.16152
External Identifier	SNOMED CT-AU Concept Id: 32570061000036105

Definition


Definition	The set of values for named anatomical locations.
Definition Source	NEHTA

Value Domain

Source	SNOMED CT-AU
---------------	--------------

Relationships

Parents

Data Type	Name	Occurrences	Condition
	Site (Anatomical Site)	1..1	

2.55 Medication Delivery Method

Identification

Label	Delivery Method
Metadata Type	Data Element
Identifier	DE-16470
OID	1.2.36.1.2001.1001.101.103.16470

Definition


Definition	The method of delivery if this should be specified.
Definition Source	NEHTA
Synonymous Names	
Data Type	Text

Usage

Examples	<ol style="list-style-type: none"> 1. Delivery via nebuliser or spacer 2. Delivery via syringe pump
-----------------	---

Relationships

Parents

Data Type	Name	Occurrences	Condition
	Exposure Mechanism (MEDICATION ADMINISTRATION)	0..1	

2.56 Dose Duration

Identification

Label	Dose Duration
Metadata Type	Data Element
Identifier	DE-16471
OID	1.2.36.1.2001.1001.101.103.16471

Definition


Definition	The length of time over which to administer each dose.
Definition Source	NEHTA
Synonymous Names	
Data Type	Duration

Usage

Examples	1. An intravenous administration may have to be over a period of 5 minutes
-----------------	--

Relationships

Parents

Data Type	Name	Occurrences	Condition
	Exposure Mechanism (MEDICATION ADMINISTRATION)	0..1	

2.57 INTRAVENOUS ADMINISTRATION DETAILS

Identification


Label	Intravenous Details
Metadata Type	Data Group
Identifier	DG-16472
OID	1.2.36.1.2001.1001.101.102.16472

Definition

Definition	Details of intravenous administration.
Definition Source	NEHTA
Synonymous Names	

Relationships

Parents

Data Type	Name	Occurrences	Condition
	Exposure Mechanism (MEDICATION ADMINISTRATION)	0..*	

2.58 Clinical Management Description

Identification

Label	Clinical Management Description
Metadata Type	Data Element
Identifier	DE-16482
OID	1.2.36.1.2001.1001.101.103.16482

Definition


Definition	Description about the clinical management provided.
Definition Source	NEHTA
Synonymous Names	
Data Type	Text

Usage

Conditions of Use	Used to describe details about clinical management provided to manage or treat the adverse reaction.
Conditions of Use Source	NEHTA
Examples	

Relationships

Parents

Data Type	Name	Occurrences	Condition
	REACTION EVENT	0..1	

2.59 Multimedia

Identification

Label	Multimedia
Metadata Type	Data Element
Identifier	DE-16376
OID	1.2.36.1.2001.1001.101.103.16376

Definition


Definition	Inclusion of any multimedia file to support the recording of the reaction event.
Definition Source	NEHTA
Synonymous Names	
Notes	An example is a photo of a rash or presentation with angioneurotic oedema.
Data Type	EncapsulatedData

Usage

Examples

Relationships

Parents

Data Type	Name	Occurrences	Condition
	REACTION EVENT	0..*	

2.60 Reporting Details

Identification

Label	Reporting Details
Metadata Type	Data Element
Identifier	DE-16325
OID	1.2.36.1.2001.1001.101.102.16325

Definition


Definition	Further details required for reporting to regulatory bodies.
Definition Source	NEHTA
Synonymous Names	
Notes	This free text data element is currently a placeholder for further structured data that is as yet undefined. See Appendix A, <i>Known Issues</i> for further information.
Data Type	Text

Usage

Examples	
-----------------	--

Relationships

Parents

Data Type	Name	Occurrences	Condition
	REACTION EVENT	0..*	

2.61 Adverse Reaction Event Comment

Identification

Label	Comment
Metadata Type	Data Element
Identifier	DE-16483
OID	1.2.36.1.2001.1001.101.103.16483

Definition


Definition	Further comment about the reaction event.
Definition Source	NEHTA
Synonymous Names	
Data Type	Text

Usage

Examples

Relationships

Parents

Data Type	Name	Occurrences	Condition
	REACTION EVENT	0..1	

2.62 Reaction Reported

Identification

Label	Reaction Reported
Metadata Type	Data Element
Identifier	DE-16379
OID	1.2.36.1.2001.1001.101.103.16379

Definition


Definition	Was the adverse reaction reported to a regulatory body?
Definition Source	NEHTA
Synonymous Names	
Data Type	Boolean

Usage

Examples	
-----------------	--

Relationships

Parents

Data Type	Name	Occurrences	Condition
	ADVERSE REACTION	0..1	

2.63 Adverse Reaction Report

Identification

Label	Adverse Reaction Report
Metadata Type	Data Element
Identifier	DE-16484
OID	1.2.36.1.2001.1001.101.103.16484

Definition


Definition	Link to an Adverse Reaction Report sent to a regulatory body.
Definition Source	NEHTA
Synonymous Names	
Data Type	Link

Usage

Examples	
-----------------	--

Relationships

Parents

Data Type	Name	Occurrences	Condition
	ADVERSE REACTION	0..*	

2.64 Supporting Clinical Record Information

Identification

Label	Supporting Clinical Record Information
Metadata Type	Data Element
Identifier	DE-16485
OID	1.2.36.1.2001.1001.101.103.16485

Definition


Definition	Link to further information about about the presentation and findings that exist elsewhere in the health record.
Definition Source	NEHTA
Synonymous Names	
Notes	Examples are presenting symptoms, examination findings, diagnosis.
Data Type	Link

Usage

Examples

Relationships

Parents

Data Type	Name	Occurrences	Condition
	ADVERSE REACTION	0..1	

2.65 INFORMATION PROVIDER

Identification

Label	INFORMATION PROVIDER
Metadata Type	Data Group
Identifier	DG-10296
OID	1.2.36.1.2001.1001.101.102.10296

Definition


Definition	Details pertinent to the identification of the source of the adverse reaction information.
Definition Source	NEHTA
Synonymous Names	
Notes	<p>This does not necessarily have to be a person and, in particular, not a healthcare provider. Types of sources include:</p> <ul style="list-style-type: none"> • the subject of care; • a subject of care agent, e.g. parent, guardian; • the clinician; and • a device or software

Usage

Conditions of Use	<p>This SHALL NOT be used unless the provider of the information is not the <i>Composer/Author</i> of the enclosing Structured Document.</p> <p>This is a reuse of the PARTICIPATION data group, which is described in Participation Data Specification [NEHT2011v].</p> <p>The following constraints are additional to those specified in Participation Data Specification [NEHT2011v]. Constraints are explained in <i>Appendix B</i>.</p> <ul style="list-style-type: none"> • Participation Type SHALL have a fixed value of “Information Provider”. • PERSON OR ORGANISATION OR DEVICE SHALL be instantiated as a PERSON or as a DEVICE.
Conditions of Use Source	NEHTA

Relationships

Parents

Data Type	Name	Occurrences	Condition
	ADVERSE REACTION	0..1	

2.66 SUBJECT

Identification

Label	SUBJECT
Metadata Type	Data Group
Identifier	DG-10296
OID	1.2.36.1.2001.1001.101.102.10296

Definition


Definition	The individual about whom the adverse reaction information is being recorded.
Definition Source	NEHTA
Synonymous Names	
Scope	Generally only used when the recorder needs to make it explicit. Otherwise, subject of the enclosing Structured Document is assumed.
Scope Source	NEHTA

Usage

Conditions of Use	<p>This SHALL NOT be used unless the subject of the information is not the <i>Subject of Care</i> of the enclosing Structured Document.</p> <p>This is a reuse of the PARTICIPATION data group, which is described in Participation Data Specification [NEHT2011v].</p> <p>The following constraints are additional to those specified in Participation Data Specification [NEHT2011v]. Constraints are explained in <i>Appendix B</i>.</p> <ul style="list-style-type: none"> Participation Type SHALL have a fixed value of "Subject". PERSON OR ORGANISATION OR DEVICE SHALL be instantiated as a PERSON.
Conditions of Use Source	NEHTA

Relationships

Parents

Data Type	Name	Occurrences	Condition
	ADVERSE REACTION	0..1	

3 Exclusion Statement - Adverse Reactions Data Group

3.1 EXCLUSION STATEMENT - ADVERSE REACTIONS

Identification

Label	EXCLUSION STATEMENT - ADVERSE REACTIONS
Metadata Type	Data Group
Identifier	DG-16137
OID	1.2.36.1.2001.1001.101.102.16137




Definition






Definition	Statements about Adverse Reactions that need to be positively recorded as not prescribed for, or used by, the subject of care.
Definition Source	openEHR Foundation
Scope	To positively record the absence or exclusion of any adverse reactions within the health record.
Scope Source	openEHR Foundation

Usage

Conditions of Use	Use to record the positive exclusion or absence of adverse reactions within the health record. This data group avoids the need to use terminology to express negation about any item within the health record. It is important to note that the Exclusion Statement information is time-specific. Its validity may not extend beyond the point in time when the information is recorded. The patient should always be asked to verify previous statements on adverse reaction to a substance.
Conditions of Use Source	openEHR Foundation

Data Hierarchy

	EXCLUSION STATEMENT - ADVERSE REACTIONS	
	Global Statement	0..*
	No Known Adverse Reaction to	0..1

	No Known Allergic Reaction to	0..1
	No Known Hypersensitivity Reaction to	0..1
	No Known Intolerance to	0..1
	INFORMATION PROVIDER	0..1
	SUBJECT	0..1

3.2 Global Statement

Identification

Label	Global Statement
Metadata Type	Data Element
Identifier	DE-16302
OID	1.2.36.1.2001.1001.101.103.16302

Definition


Definition	The statement about the absence or exclusion.
Definition Source	openEHR Foundation
Synonymous Names	
Context	This can be used to capture any information that is needed to be explicitly recorded as being absent or excluded within the record.
Context Source	openEHR Foundation
Data Type	CodedText
Value Domain	Global Statement Values

Usage

Conditions of Use	Captures any information that is needed to be explicitly recorded as being absent or excluded within the record.
Conditions of Use Source	openEHR Foundation
Examples	

Relationships

Parents

Data Type	Name	Occurrences	Condition
	EXCLUSION STATEMENT - ADVERSE REACTIONS	0..*	

3.3 Global Statement Values

Identification

Label	Global Statement Values
Metadata Type	Value Domain
Identifier	VD-16299
OID	1.2.36.1.2001.1001.101.104.16299

Definition


Definition	The set of values for the global statements about the exclusion.
Definition Source	openEHR Foundation

Value Domain

Source	NEHTA	
Permissible Values	<i>Not asked</i>	No information about adverse reactions to any substance is available because the patient was not asked or not able to be asked
	<i>None known</i>	No information about adverse reactions to any substance is known
	<i>None supplied</i>	No information about adverse reactions to any substance is supplied
	<i>No known adverse reactions</i>	No known adverse reactions to any substance
	<i>No known allergic reactions</i>	No known allergic reactions to any substance
	<i>No known hypersensitivity reactions</i>	No known hypersensitivity reaction to any substance
	<i>No known intolerances</i>	No known intolerances to any substance
	Please see Appendix A, Known Issues	

Relationships

Parents

Data Type	Name	Occurrences	Condition
	Global Statement	1..1	

3.4 No Known Adverse Reaction to

Identification

Label	No Known Adverse Reaction to
Metadata Type	Data Element
Identifier	DE-16305
OID	1.2.36.1.2001.1001.101.103.16305

Definition


Definition	Positive statement about adverse reactions to substances that are explicitly known to have not been identified at the time of recording.
Definition Source	openEHR Foundation
Synonymous Names	
Data Type	CodeableText
Value Domain	<i>Not specified.</i>
	In the absence of national standard code sets, the code sets used SHALL be registered code sets, i.e. registered through the HL7 code set registration procedure ¹ with an appropriate object identifier (OID), and SHALL be publicly available.
	When national standard code sets become available, they SHALL be used and the non-standard code sets SHALL be deprecated.

Usage

Examples

Relationships

Parents

Data Type	Name	Occurrences	Condition
	EXCLUSION STATEMENT - ADVERSE REACTIONS	0..1	

¹ <http://www.hl7.org/oid/index.cfm>

3.5 No Known Allergic Reaction to

Identification

Label	No Known Allergic Reaction to
Metadata Type	Data Element
Identifier	DE-16306
OID	1.2.36.1.2001.1001.101.103.16306

Definition


Definition	Positive statement about allergic reactions to substances that are explicitly known to have not been identified at the time of recording.
Definition Source	openEHR Foundation
Synonymous Names	
Data Type	CodeableText
Value Domain	<i>Not specified.</i>
	In the absence of national standard code sets, the code sets used SHALL be registered code sets, i.e. registered through the HL7 code set registration procedure ² with an appropriate object identifier (OID), and SHALL be publicly available.
	When national standard code sets become available, they SHALL be used and the non-standard code sets SHALL be deprecated.

Usage

Examples	
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Relationships

Parents

Data Type	Name	Occurrences	Condition
	EXCLUSION STATEMENT - ADVERSE REACTIONS	0..1	

² <http://www.hl7.org/oid/index.cfm>

3.6 No Known Hypersensitivity Reaction to

Identification

Label	No Known Hypersensitivity Reaction to
Metadata Type	Data Element
Identifier	DE-16307
OID	1.2.36.1.2001.1001.101.103.16307

Definition


Definition	Positive statement about hypersensitivity reactions to substances that are explicitly known to have not been identified at the time of recording.
Definition Source	openEHR Foundation
Synonymous Names	
Data Type	CodeableText
Value Domain	<i>Not specified.</i>
	In the absence of national standard code sets, the code sets used SHALL be registered code sets, i.e. registered through the HL7 code set registration procedure ³ with an appropriate object identifier (OID), and SHALL be publicly available.
	When national standard code sets become available, they SHALL be used and the non-standard code sets SHALL be deprecated.

Usage

Examples	
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Relationships

Parents

Data Type	Name	Occurrences	Condition
	EXCLUSION STATEMENT - ADVERSE REACTIONS	0..1	

³ <http://www.hl7.org/oid/index.cfm>

3.7 No Known Intolerance to

Identification

Label	No Known Intolerance to
Metadata Type	Data Element
Identifier	DE-16308
OID	1.2.36.1.2001.1001.101.103.16308

Definition


Definition	Positive statement about intolerances to substances that are explicitly known to have not been identified at the time of recording.
Definition Source	openEHR Foundation
Synonymous Names	
Data Type	CodeableText
Value Domain	<i>Not specified.</i>
	In the absence of national standard code sets, the code sets used SHALL be registered code sets, i.e. registered through the HL7 code set registration procedure ⁴ with an appropriate object identifier (OID), and SHALL be publicly available.
	When national standard code sets become available, they SHALL be used and the non-standard code sets SHALL be deprecated.

Usage

Examples

Relationships

Parents

Data Type	Name	Occurrences	Condition
	EXCLUSION STATEMENT - ADVERSE REACTIONS	0..1	

⁴ <http://www.hl7.org/oid/index.cfm>

3.8 INFORMATION PROVIDER

Identification

Label	INFORMATION PROVIDER
Metadata Type	Data Group
Identifier	DG-10296
OID	1.2.36.1.2001.1001.101.102.10296

Definition


Definition	Details pertinent to the identification of the source of the adverse reaction information.
Definition Source	NEHTA
Synonymous Names	
Notes	<p>This does not necessarily have to be a person and, in particular, not a healthcare provider. Types of sources include:</p> <ul style="list-style-type: none"> • the subject of care; • a subject of care agent, e.g. parent, guardian; • the clinician; and • a device or software

Usage

Conditions of Use	<p>This SHALL NOT be used unless the provider of the information is not the <i>Composer/Author</i> of the enclosing Structured Document.</p> <p>This is a reuse of the PARTICIPATION data group, which is described in Participation Data Specification [NEHT2011v].</p> <p>The following constraints are additional to those specified in Participation Data Specification [NEHT2011v]. Constraints are explained in <i>Appendix B</i>.</p> <ul style="list-style-type: none"> • Participation Type SHALL have a fixed value of “Information Provider”. • PERSON OR ORGANISATION OR DEVICE SHALL be instantiated as a PERSON or as a DEVICE.
Conditions of Use Source	NEHTA

Relationships

Parents

Data Type	Name	Occurrences	Condition
	EXCLUSION STATEMENT - ADVERSE REACTIONS	0..1	

3.9 SUBJECT

Identification

Label	SUBJECT
Metadata Type	Data Group
Identifier	DG-10296
OID	1.2.36.1.2001.1001.101.102.10296

Definition


Definition	The individual about whom the adverse reaction information is being recorded.
Definition Source	NEHTA
Synonymous Names	
Scope	Generally only used when the recorder needs to make it explicit. Otherwise, subject of the enclosing Structured Document is assumed.
Scope Source	NEHTA

Usage

Conditions of Use	<p>This SHALL NOT be used unless the subject of the information is not the <i>Subject of Care</i> of the enclosing Structured Document.</p> <p>This is a reuse of the PARTICIPATION data group, which is described in Participation Data Specification [NEHT2011v].</p> <p>The following constraints are additional to those specified in Participation Data Specification [NEHT2011v]. Constraints are explained in <i>Appendix B</i>.</p> <ul style="list-style-type: none"> Participation Type SHALL have a fixed value of "Subject". PERSON OR ORGANISATION OR DEVICE SHALL be instantiated as a PERSON.
Conditions of Use Source	NEHTA

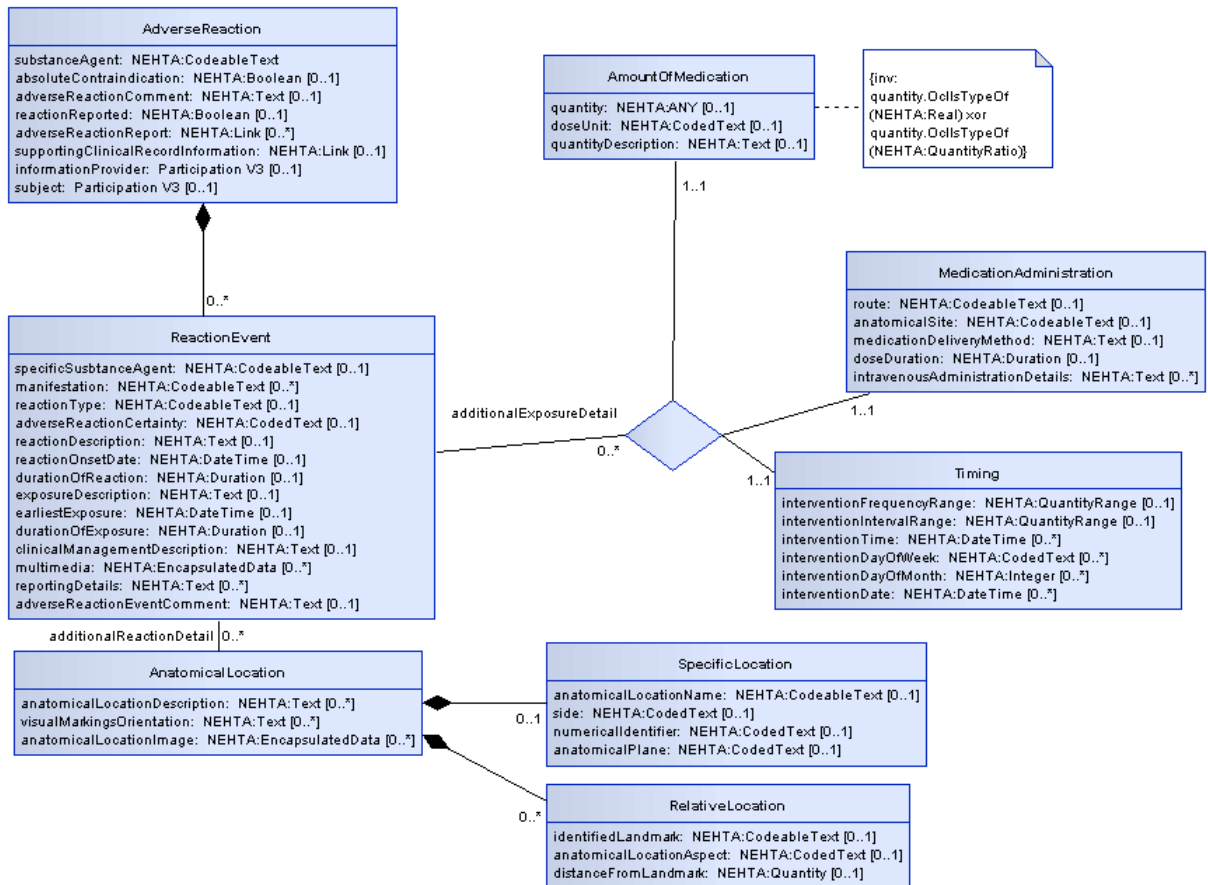
Relationships

Parents

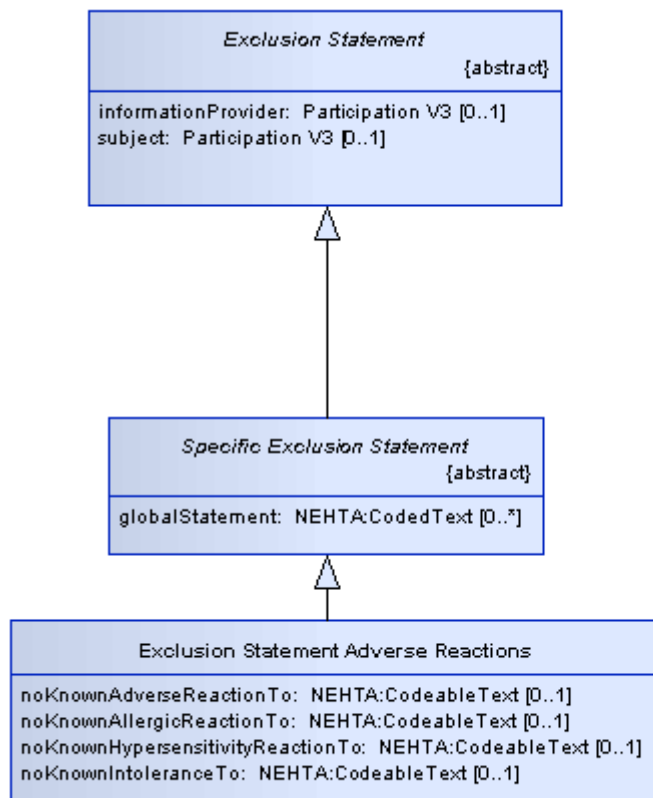
Data Type	Name	Occurrences	Condition
	EXCLUSION STATEMENT - ADVERSE REACTIONS	0..1	

4 UML Class Diagram

The following figure presents the data hierarchy using a UML 2.0 class diagram. The diagram displays data groups and data elements, together with their names, data types and multiplicities. Data elements are displayed as attributes. Data groups are displayed as classes, their names are represented as association role names. Association role names are only displayed if they differ from the associated class name. The diagram shows the data hierarchy excluding the details of participation. The default multiplicity is 1..1.



UML class diagram of the Adverse Reaction data hierarchy.



UML class diagram of the Exclusion Statement for Adverse Reaction data hierarchy.

Reference List

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- [SA2006a] Standards Australia, 2006, *AS 4846 (2006) – Healthcare Provider Identification*, accessed 12 November 2009.
<http://infostore.saiglobal.com/store/Details.aspx?ProductID=318554>
- [SA2006b] Standards Australia, 2006, *AS 5017 (2006) – Healthcare Client Identification*, accessed 12 November 2009.
<http://infostore.saiglobal.com/store/Details.aspx?ProductID=320426>

Appendix A. Known Issues

This appendix lists known issues with this specification at the time of publishing. NEHTA are working on solutions to these issues, but we encourage and invite comments to further assist the development of these solutions.

Reference	Description
Data Hierarchy	This detailed clinical model has not yet been fully mapped to HL7 CDA. Mapping to CDA may reveal inconsistencies in the data hierarchy requiring normative change.
'Intervention Day of Week' Data Element	In the future its data type needs to be changed to Integer with values from '0 to 6' or '1 to 7'.
'Quantity' Data Element	In the future this data element needs to be updated in order to cater for quantities of non-medications.
'Anatomical Site' Data Element	In the future this data element needs to be updated in order to cater for administration of non-medications.
'Global Statement Values' Data Element	The list of permissible values is a sample set to initiate discussion and collaboration to develop the correct set of values.
Exclusion Statement	The Exclusion Statement detailed clinical model is the subject of on-going development and review and may well change in the future.
Undefined Value Domains	<p>The following data elements lack a defined value domain: 'Numerical Identifier', 'Anatomical Plane', 'Anatomical Location Aspect' and 'Intervention Day of Week'</p> <p>NEHTA is in the process of developing national code sets for these items. In the meantime, you are free to use your own code set(s) providing any code set used SHALL be registered, i.e. registered through the HL7 code set registration procedure with an appropriate object identifier (OID), and SHALL be publicly available. Note that when national standard code set(s) do become available, they SHALL be used and the non-standard code sets SHALL be deprecated.</p>

Appendix B. Specification Guide for Use

B.1 Overview

Each Detailed Clinical Model (DCM) and Structured Content Specification (SCS) is designed to be a shared basis for data interpretation. It specifies rigorous business and technical definitions of data which systems may need to share. It is intended to be a logical specification of the data to be persisted within or communicated between systems. It is also the foundation for conformance, compliance and accreditation testing of implemented systems. NEHTA's CDA implementation guides are guides to the implementation of HL7 CDA R2 messages based upon these DCMs and SCSs.

Each DCM specifies all of the data components required for any use of a clinical concept, for instance an entry in a medical record such as a procedure or an imaging test. As such they are maximal data sets. DCMs are building blocks which are trimmed to size for use in construction SCSs.

Each SCS specifies the data for a single type of clinical document or information exchange, such as a discharge summary. It is assembled using DCMs which have been constrained to eliminate data components not relevant to the particular context. For example, procedure in a discharge summary uses only some of the data components required by procedure in a specialist report.

B.2 The Structured Content Specification Metamodel

The NEHTA Structured Content Metamodel (see Figure 1) is used to specify the overall structure of a Structured Content Specification.

A DCM can be considered as a Data Group with no parent.

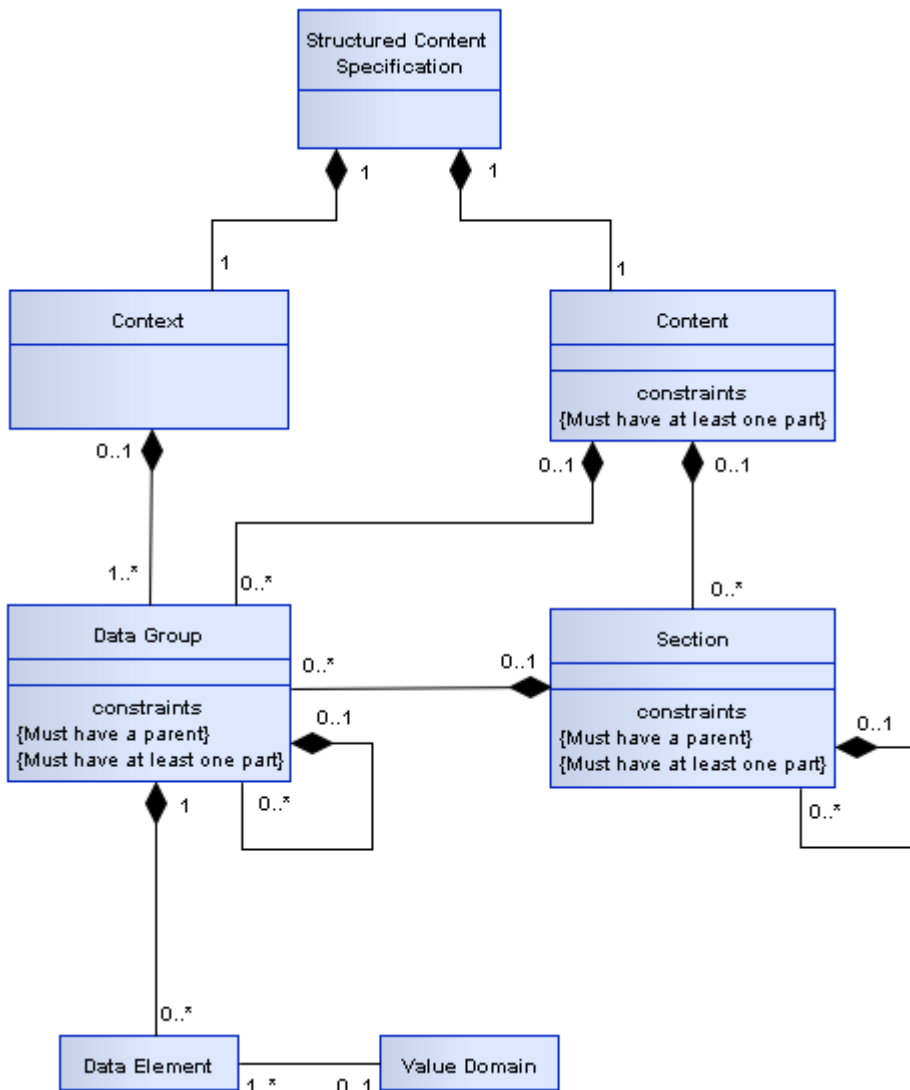


Figure 1: SCS Metamodel

There are two main components used to organise information within a Structured Content Specification (SCS) as follows:

Context: This contains information related to the overall context of the document.

Content: This contains information, which changes between different SCSs, but is always structured as shown, and consists of the following components:

- Section
- Data Group
- Data Element
- Value Domain

These components are described in more detail below.

Context

The purpose of the Context is to identify and classify the document and to provide subjects of care and involved healthcare providers with the information related to the relevant healthcare events.

Content

The Content contains a collection of health information pertinent to a subject of care which is derived from the healthcare event described in the document. The detail **MAY** be organised into one or more sections, each of which contains one or more data groups and/or possible data elements.

Section

The contents of the structured document Content **MAY** be subdivided into one or more sections. A section is an organising container that gives a reader a clue as to the expected content. The primary purpose of a section is to organise information in the manner that is suitable for the primary purpose for which it is collected, and that provides a way to navigate through the data components within the document, thereby enabling more efficient querying. It **SHOULD** also support safe re-use for secondary purposes, e.g. clinical coding or inclusion in a summarised form in an electronic health record. A section is context-specific to the document in which it resides.

Data Group

Each data group is used to represent one concept. A data group consists of other data groups and/or data elements. Some data groups are reused across detailed clinical models.

Participation

Participation is a special case of a data group that is based on a data group template, which is reused throughout the detailed clinical models (DCMs) and SCSs. Participations are an amalgam of the Actors (see below) operating within a defined healthcare domain and the Roles that they are playing within that domain.

A Participant has been defined to align with the concepts of the NEHTA interoperability framework. It equates to an *Entity* that is related to the action described in an SCS as an *Actor*. A participant can be a human, an organisation or an IT system.

[\[NEHT2011v\]](#) defines the full Participation specification.

Choice

Choice represents a decision to be made at run-time between a disjunctive mandatory set of data groups defined at design-time, i.e. one and only one member of the set **SHALL** be chosen.

For example, at design time a Healthcare Provider provides a service but it is not until run-time that a decision can be made as to whether the provider is a person or an organisation. Hence when a Healthcare Provider Participant is instantiated, it **SHALL** be done with the choice of either the *Person* data group or the *Organisation* data group.

Data Element

A data element is the smallest named unit of information in the model that can be assigned a value. For example, 'DateTime of Observation' and 'Observation Note'. Data elements are bound to data types (see [Data Types Legend](#)). Some data elements are reused in different data groups.

Whilst all data elements are constrained by their data type, some data elements are further constrained by value domains (see [Value Domain](#) below).

Value Domain

A value domain constrains the permissible values for a data element. The values **MAY** be a subset of values based on a generic data type.

Value domains are reusable components and therefore, the same value domain can be referred to by different data elements in different contexts. Value domains are often specified as a reference set. A reference set (or a subset) is a constrained list of SNOMED CT-AU, AMT or LOINC concepts that are appropriate to a particular context. It **SHOULD** be noted that many of these reference sets have been developed specifically for the context in which they appear. An assessment of fitness for purpose **SHOULD** therefore be undertaken before using any of the reference sets in another context.

Value domains constrain by either specifying a lower and/or upper bound on the range of permissible values or else by specifying a finite set of prescribed values. Such a set of prescribed values can be specified directly within the definition of the data element, or in a separate but associated specification or else by reference to one or more vocabulary/terminology reference sets. The table below provides some examples of value domains.

Data Element	Data Type	Example of Value Domain										
Sex	CodedText	[SA2006a] and [SA2006b] derive their values from METeOR 270263 which includes values such as: <table border="1" data-bbox="616 1234 1342 1462"> <thead> <tr> <th>Value</th> <th>Meaning</th> </tr> </thead> <tbody> <tr> <td><u>1</u></td> <td>Male</td> </tr> <tr> <td><u>2</u></td> <td>Female</td> </tr> <tr> <td><u>3</u></td> <td>Intersex or Indeterminate</td> </tr> <tr> <td><u>9</u></td> <td>Not Stated/Inadequately Described</td> </tr> </tbody> </table>	Value	Meaning	<u>1</u>	Male	<u>2</u>	Female	<u>3</u>	Intersex or Indeterminate	<u>9</u>	Not Stated/Inadequately Described
Value	Meaning											
<u>1</u>	Male											
<u>2</u>	Female											
<u>3</u>	Intersex or Indeterminate											
<u>9</u>	Not Stated/Inadequately Described											
Diagnosis	CodeableText	A SNOMED CT-AU reference set which references concepts such as 'Bronchitis' (Concept ID: 32398004)										
Therapeutic Good Identification	CodeableText	An AMT reference set which references concepts such as 'Ibuprofen Blue (Herron) (ibuprofen 200 mg) tablet: film-coated, 1 tablet' (Concept ID: 54363011000036107)										
<i>To Be Advised</i>	CodeableText	A LOINC subset which references concepts such as 'Cholesterol [Moles/volume] in Serum or Plasma' (ID: 14647-2)										

Table 1: Value Domain Examples

B.3 Icon Legend

These legends describe all icons that are used within the various NEHTA information specifications.

Metadata Types Legend

The following table explains each of the icons used to represent the metadata types within DCMs and SCSs.







Icon	Metadata Types
	Structured Document
	Section
	Data Group
	Participation
	Choice

Table 2: Metadata Types Legend

Data Types Legend

The following table explains each of the icons used to represent the data types bound to each data element in the SCSs. These data types are a profile of the **ISO 21090-2011** data types as specified in [\[NEHT2010c\]](#).

Icon	Data type	Explanation
	Boolean (ISO 21090: BL)	A primitive data type, sometimes called the logical data type, having one of two values: <i>true</i> and <i>false</i> . Many systems represent true as <i>non-zero</i> (often 1, or -1) and false as <i>zero</i> .
		<p>Usage/Examples</p> <ul style="list-style-type: none"> An actual value entered by a user might be 'yes' or could be chosen by a mouse click on an icon such as <input checked="" type="checkbox"/>.



CodeableText
(ISO 21090: CD)

Coded text *with* exceptions; flexible data type to support various ways of holding text, both free text and coded text. Commonly used to support compliance for early adopters of the Structured Content Specifications. Whilst it is recommended that the values in this data type come from the bound value domain, it allows other value domains to also be used (with or without translations to the bound value domain) or free text alternatives. This is a recognition that it **MAY** not be possible to define an entire value domain for a complex concept (e.g. *Diagnosis*) or that there **MAY** be competing code sets in existence. Note that within exchange specifications and/or message profiles this data type **MAY** be constrained to mandate compliance with the bound value domain.

Usage/Examples

- AIHW Separation Mode specifies the status at separation of a person from an organisation. An early adopter **MAY** have a similar concept (coded or otherwise) that maps to this data element but does not strictly comply with the AIHW values.
- A SNOMED CT-AU coded/complex expression that embodies single or multiple concepts. The SNOMED CT-AU concepts behind these CodeableText components are specified in the Structured Content Specification value domains.



CodedText
(ISO 21090: CD)

Coded text *without* exceptions; text with code mappings. Values in this data type **SHALL** come from the bound value domain, with no exceptions. Often used for reference sets with only a small number of applicable values, e.g. Gender and Document Status.

Usage/Examples

[\[SA2006b\]](#) specifies the following value domain representing a type of address:

Value	Meaning
1	Business
2	Mailing or Postal
3	Temporary Accommodation
4	Residential (permanent)
9	Not Stated/Unknown/Inadequately Described














DateTime
(ISO 21090: TS)

Used for specifying a single date and/or time. Has the ability to indicate a level of precision, but not whether the date/time is estimated. String representations of known dates **SHALL** conform to the nonextended format within the **ISO 21090-2011** standard, i.e. YYYYMMDDHHMMSS.UUUU[+]-ZZzz.

Usage/Examples

- Partial dates: 2008, 20081001.
- To indicate 1:20 pm on May the 31st, 1999 for a time zone which is 5 hours behind Coordinated Universal Time (UTC): 19990531132000-0500.

	Duration (ISO 21090: PQ.TIME)	The period of time during which something continues. Consists of a value and a unit which represents the time value, e.g. hours, months. Compound durations are not allowed, e.g. 10 days 3 weeks 5 hours.
		Usage/Examples
		<ul style="list-style-type: none"> • 3 hours • 6 months • 1 year
	Any (ISO 21090: ANY)	Represents a data element where the data type to be used is conditional upon another data component. The values that can be required will vary considerably depending on the context. Note that this is an abstract data type that is the basis for all data types and SHOULD NOT be used in an actual implementation.
	EncapsulatedData (ISO 21090: ED)	Data that is primarily intended for human interpretation or for further machine processing outside the scope of this specification. This includes unformatted or formatted written language, multimedia data, or structured information as defined by a different standard (e.g., XML signatures).
		Usage/Examples
		<ul style="list-style-type: none"> • JPEG images • HTML documents • [RFC1521] MIME types
	Integer (ISO 21090: INT)	The mathematical data type comprising the exact integral values (according to [NEHT2010c]).
		Usage/Examples
		<ul style="list-style-type: none"> • 1 • -50 • 125
	Link (ISO 21090: TEL)	This is a general link, reference or pointer to an object, data or application that exists logically or is stored electronically in a computer system.
		Usage/Examples
		<ul style="list-style-type: none"> • URL (Uniform Resource Locator) – the World Wide Web address of a site on the internet, such as the URL for the Google internet search engine – ‘<i>http://www.google.com</i>’. • An absolute or relative path within a file/directory structure – e.g. in the Windows® operating system, the “link” or absolute path to a particular letter could be <i>C:\Documents and Settings\GuestUser\MyDocuments\letter.doc</i>

	Quantity (ISO 21090: PQ)	Used for recording many real world measurements and observations. Includes the magnitude value and the units.
Usage/Examples		
<ul style="list-style-type: none"> • 100 centimetres • 25.5 grams 		
	QuantityRatio (ISO 21090: RTO)	The relative magnitudes of two <i>Quantity</i> values (usually expressed as a quotient).
Usage/Examples		
<ul style="list-style-type: none"> • 25 mg/500 ml • 200 mmol per litre 		
	QuantityRange (ISO 21090: IVL)	Two <i>Quantity</i> values that define the minimum and maximum values, i.e. lower and upper bounds. This is typically used for defining the valid range of values for a particular measurement or observation. Unbounded quantity ranges can be defined by not including a minimum and/or a maximum quantity value.
Usage/Examples		
<ul style="list-style-type: none"> • -20 to 100 Celsius • 30-50 mg • >10 kg 		
	RealNumber (ISO 21090: REAL)	A computational approximation to the standard mathematical concept of real numbers. These are often called floating point numbers.
Usage/Examples		
<ul style="list-style-type: none"> • 1.075 • -325.1 • 3.14157 		
	Text (ISO 21090: ST)	Character strings (with optional language). Unless otherwise constrained by an implementation, can be any combination of alpha, numeric or symbols from the Unicode character set. Sometimes referred to as free text.
Usage/Examples		
“The patient is a 37 year old man who was referred for cardiac evaluation after complaining of occasional palpitations, racing heart beats and occasional dizziness.”		
	TimeInterval (ISO 21090: TS)	An interval in time, with (optionally) a start date/time and (optionally) an end date/time and/or a duration/width.
Usage/Examples		
<ul style="list-style-type: none"> • 01/01/2008 – 31/12/2008 • 1:30 a.m. – 6:00 p.m., duration/width = 16.5 hours 		



UniqueIdentifier A general unique value to identify a physical or virtual object or concept.

(ISO 21090: II) In using this data type, the attributes of the UniqueIdentifier data type **SHOULD** be populated from the identifiers as defined in AS 4846 (2006) [SA2006a] and AS 5017 (2006) [SA2006b] as follows:

root: a globally unique object identifier that identifies the combination of geographic area, issuer and type. If no such globally unique object identifier exists, it **SHALL** be created.

extension: a unique identifier within the scope of the root that is directly equivalent to the identifier designation element.

identifierName: a human readable name for the namespace represented by the root that is populated with the issuer or identifier type values, or a concatenation of both as appropriate. The content of this attribute is not intended for machine processing and **SHOULD NOT** be used as such.

identifierScope: the geographic span or coverage that applies to or constrains the identifier. It is directly equivalent to the geographic area element. The content of this attribute is not intended for machine processing and **SHOULD NOT** be used as such.

Also, the following constraints apply on the UniqueIdentifier data type:

The *root* attribute **SHALL** be used.

For an entity identifier the *root* attribute **SHALL** be an OID that consists of a node in a hierarchically-assigned namespace, formally defined using the ITU-T's ASN.1 standard.

For an entity identifier the *root* attribute **SHALL NOT** be a UUID.

The *extension* attribute **SHALL** be used.

Usage/Examples

IHIs, HPI-Is, HPI-Os and patient hospital medical record numbers are examples of identifiers that **MAY** be carried by this data type.

Table 3: Data Types Legend

Keywords Legend

Where used in this document and in DCMs and SCSs, the keywords **SHALL**, **SHOULD**, **MAY**, **SHALL NOT** and **SHOULD NOT** are to be interpreted as described in [RFC2119].

The following table defines these keywords

Keyword	Interpretation
SHALL	This word, or the terms 'required' or 'must', means that the definition is an absolute requirement of the specification.
SHOULD	This word, or the adjective 'recommended', means that there MAY exist valid reasons in particular circumstances to ignore a particular component, but the full implications SHALL be understood and carefully weighed before choosing a different course.

MAY	This word, or the adjective 'optional', means that a component is truly optional. One implementer MAY choose to include the component because a particular implementation requires it, or because the implementer determines that it enhances the implementation while another implementer MAY omit the same component. An implementation which does not include a particular option SHALL be prepared to interoperate with another implementation which does include the option, perhaps with reduced functionality. In the same vein, an implementation which does include a particular option SHALL be prepared to interoperate with another implementation which does not include the option (except of course, for the feature the option provides).
SHALL NOT	This phrase, or the phrase 'must not' means that the definition is an absolute prohibition of the specification.
SHOULD NOT	This phrase, or the phrase 'not recommended' means that there MAY exist valid reasons in particular circumstances when the particular behaviour is acceptable or even useful, but the full implications SHOULD be understood and the case carefully weighed before implementing any behaviour described with this label.

Table 4: Keywords Legend

B.4 Information Model Specification Parts Legends

This section illustrates the format and parts used to define each Section, Data Group and Data Element within NEHTA's information model specifications and identifies when each part is applicable.

Data Hierarchy

The top-level component contains a data hierarchy. Each row contains information about a single data component. The entries are nested to represent inclusion of one component in another. Each entry contains three occupied cells. One contains an icon to indicate its data type. One contains the label and description of the component (if the label is different from the name, the name is displayed in brackets after the label). One contains the multiplicity range for the data component.

In a SCS a component may be prohibited, that is it occurs in the referenced DCM but it **SHALL** not be included in documents created according to the SCS. This is represented by a multiplicity range of 0..0, the text of the entry is also in a ~~strike through~~ font and it has a grey background.

Chapter Name

Each section, data group, data element, value domain or choice has its own eponymous chapter. The chapter name is used in all data hierarchies.

Identification Section Legend

The following table illustrates the layout of the Identification section and describes the various parts of the section.

Label	A suggested display name for the component. (Source NEHTA.)
--------------	---

Metadata Type	The metadata type of the component, e.g. section, data group or data element. (Source NEHTA.)
Identifier	A NEHTA assigned internal identifier of the concept represented by the component. (Source NEHTA.)
OID	An object identifier that uniquely identifies the concept represented by the data component. (Source NEHTA.)
External Identifier	An identifier of the concept represented by the data component which is assigned by an organisation other than NEHTA. (Source NEHTA.)

Table 6: Identification Section Legend

Definition Section Legend

The following table illustrates the layout of the Definition section and describes the various parts of the section.

Definition	The meaning, description and/or explanation of the data component. (Source NEHTA.)
	For data groups used in a particular context the definition MAY be a refinement of the generic data group definition.
Definition Source	The authoritative source for the Definition statement.
Synonymous Names	A list of any names the data component MAY also be known as. (Source NEHTA.)
	Implementers MAY prefer to use synonymous names to refer to the component in specific contexts.
Scope	Situations in which the data component may be used, i.e. the extent and capacity within which this data component may be used, including the circumstances under which the collection of specified data are required or recommended.
	For example, Medication Instruction (data group) has a scope which includes all prescribable therapeutic goods, both medicines and non-medicines.
	This attribute is not relevant to data elements or value domains. (Source NEHTA.)
Scope Source	The authoritative source for the Scope statement.
Context	The environment in which the data component is meaningful, i.e. the circumstance, purpose and perspective under which this data component is defined or used.
	For example, Street Name has a context of Address. (Source NEHTA.)
Assumptions	Suppositions and notions used in defining the data component. (Source NEHTA.)
Assumptions Source	The authoritative source for the Assumptions statement.
Notes	Informative text that further describes the data component, or assists in the understanding of how the data component can be used. (Source NEHTA.)
Notes Source	The authoritative source for the Notes statement.
Data Type	The data type of the data element, e.g. DateTime or Text. (Source NEHTA.)

Value Domain	The Data type is applicable only to data elements.
	The valid data types are specified in the Data Types Legend .
	The name and identifier of the terminologies, code sets and classifications to define the data element value range, or a statement describing what values to use in the absence of a defined value domain for the related data element.
	In the absence of national standard code sets, the code sets used SHALL be registered code sets, i.e. registered through the HL7 code set registration procedure with an appropriate object identifier (OID), and SHALL be publicly available.
	When national standard code sets become available, they SHALL be used and the non-standard code sets SHALL be deprecated. (Source NEHTA.)
The Value Domain is applicable only to CodedText and CodeableText data elements.	

Table 7: Definition Section Legend

Value Domain Section Legend

The following table illustrates the layout of the Value Domain section and describes the various parts of the section.

Source	The name of the terminology or vocabulary from which the value domain's permissible values are sourced, e.g. SNOMED CT-AU, LOINC.
Version Number	Version number of the value domain source.
Permissible Values	List of permissible values in the value domain.

Table 8: Value Domain Section Legend

Usage Section Legend

The following table illustrates the layout of the Usage section and describes the various parts of the section.

Examples	One or more demonstrations of the data that is catered for by the data element. (Source NEHTA.)
	Where a data element has an associated value domain examples representative of that domain are used where possible. Where the value domain is yet to be determined an indicative example is provided.
	Implementation guides MAY contain specific examples for how data elements SHALL be populated and how they relate to each other.
Conditions of Use	The Value Domain is applicable only to CodedText and CodeableText data elements.
	Prerequisites, provisos and/or restrictions for use of the component. (Source NEHTA.)

Conditions of Use Source	The authoritative source for the Conditions of Use statement.
Misuse	Incorrect, inappropriate and/or wrong uses of the component. (Source NEHTA.)
Default Value	A common denomination, or at least a usable denomination, from the Value Domain where available and/or applicable, typically assigned at the creation of an instance of the component. (Source NEHTA.)

Table 9: Usage Section Legend

Relationships Section Legend

The Relationships section specifies the cardinality and conditionality between parent and child data components.

The following table illustrates the layout of the Children relationships table.

Data Type	Name	Occurrences	Condition
Icon illustrating the Metadata type or Data type	Component Name	The maximum and minimum number of instances of this child component that SHALL occur.	The conditions that SHALL be met to include this child data element. Only applicable for elements with a Conditional obligation.

Table 10: Children Legend

The following table illustrates the layout of the Parent relationships table. Note that the relationships described by this table are from the parent to the child component.

Data Type	Name	Occurrences	Condition
Icon illustrating the Metadata or Data type	Component Name	The maximum and minimum number of instances of the component described on this page that SHALL occur.	The conditions that SHALL be met to include the data element. Only applicable for elements with a Conditional obligation.

Table 11: Parent Legend

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