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# **Clinical Synopsis**

## **Data Specifications**

Version 1.0 - 29/06/2007

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# Document information

## Change history

Version	Date	Comments
1.0	29.06.2007	Initial public release

# Acknowledgements

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- Standards Australia;
- Royal Australian College of General Practitioners;
- Society of Hospital Pharmacists of Australia;
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- Ocean Informatics.

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# 1 Introduction

## 1.1 Purpose and Scope

The Adverse Reaction 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 healthcare setting.

## 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 healthcare 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, i.e. 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 shared EHR is referred to in these documents the implementation of the shared EHR is not dealt with here.

## 1.4 NEHTA Clinical Standards Metamodel

The NEHTA Event Summary and Clinical Data Standards metamodel is used to provide a high level overview of a family of structured documents which includes Adverse Reaction. Within this metamodel, clinical information is organised hierarchically into five levels:

- Event Summary;
- Section;
- Data Group;
- Data Element; and
- Value Domain.

Event summary collection in a shared EHR system shows the role and structure of an event summary in a shared EHR environment.

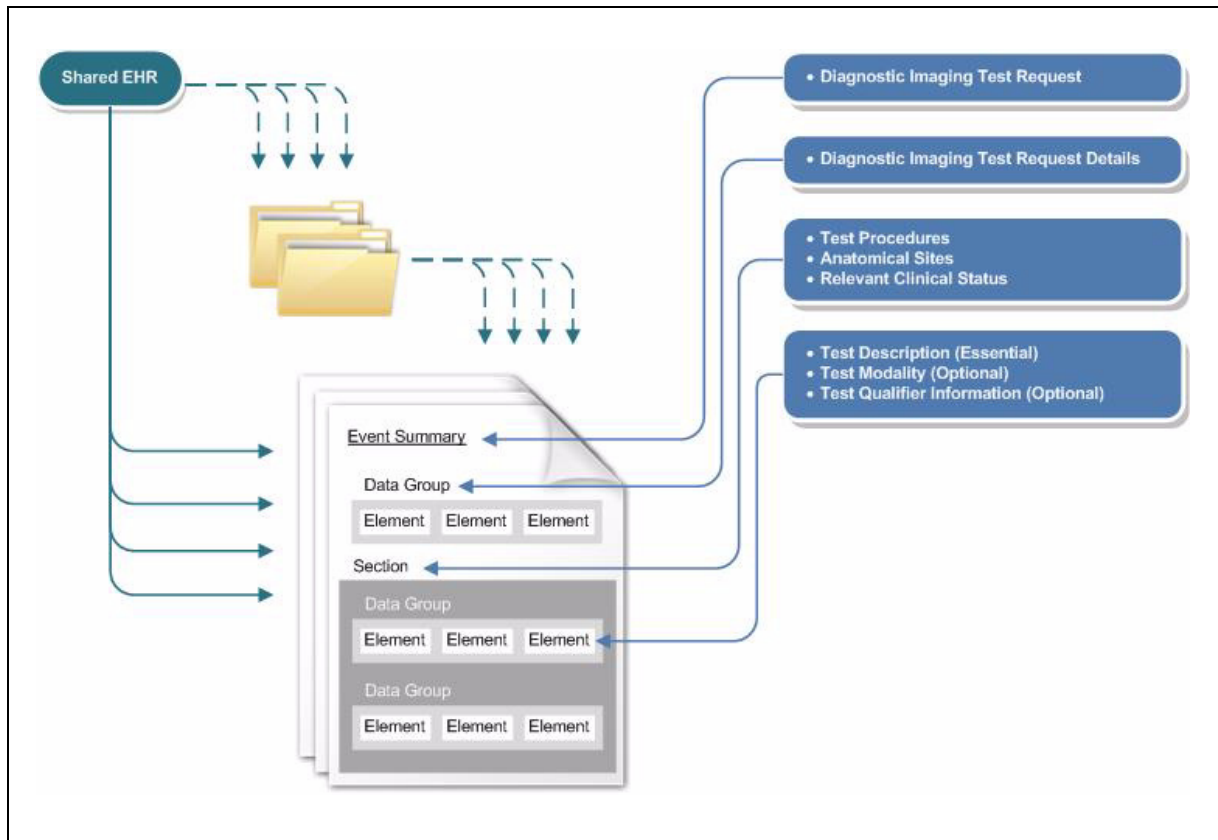


Table 1 Event summary collection in a shared EHR system

### 1.4.1 Event Summary

An event summary is a collection of health information pertinent to a subject of care and is derived from a healthcare event that is relevant to the ongoing care of that individual. The event summary (which is one of a family of care record summaries) is composed of one or more data groups and/or possibly data elements, which are organised into section(s) (see Section below).

Examples of commonly used care record summaries include Referral, Hospital Discharge and Diagnostic Imaging Results.

### 1.4.2 Section

The contents of an event summary may be organised into one or more sections. A section is an organising container. Its purpose is to organise information in the manner that is suitable for the primary purpose it is collected, and that is useful for healthcare providers. A section also provides a way to navigate through the data items within an event summary, thereby enabling more efficient querying to be made.

### 1.4.3 Data Group

A data group is a composite data structure (a collection of data elements or smaller data groups) for holding related items of information. Values of all the component data elements are often required to provide unambiguous meaning in a given context. A data group “organises” the data it holds. A data group can only be assigned values through the data elements that are contained within it. Examples of data groups are ADVERSE REACTION, ALERT, and MEDICATION.

### 1.4.4 Data Element

A data element is the smallest named unit of information in the model that can be assigned a value. Data elements are identified as being either simple or as a component.

A component data element is one that occurs as a member of a composite data structure. A data element that occurs in a segment outside the defined boundaries of a composite data structure is identified as a simple data element. The distinction between simple and component data elements is strictly a matter of context since a data element can be used in either capacity<sup>1</sup>.

The permissible values for a data element are constrained by a value domain (see Value Domain).

The same data element can be reused in any number of data groups; e.g. the "DateTime:Start" data element is used in both the ADVERSE REACTION and the ALERT data groups, however a data element may refer to different value domains depending on the context in which it is used.

### 1.4.5 Value Domain

A value domain constrains the permissible values for a data element. The value domain may specify the type of data value that is valid for a specific data element or be more specific about the coding system the values are drawn from or subset of codes. 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 situations

Value domains constrain by either specifying a lower and/or upper bound on the range of permissible values or else specify a finite set of prescribed values. Such a set of prescribed values can be specified directly with the definition of the data element, or in a separate but associated specification or else by reference to one or more external vocabulary/terminology sets. Value domain examples (below) are shown below:

Data Element	Data Type	Example of Value Set	Example of Value Domain
Severity	Coded text	Code-set that describes severity of problem, diagnosis, or allergic reaction	"mild", "disabling", "life threatening"
Diagnosis	Coded text	Code set that describe diagnosis, problems, or issues	Valid SNOMED CT codes drawn from the disorders hierarchy

Table 2 Value domain examples

### 1.4.6 Classification Scheme

A classification scheme is a terminological system used to classify objects. It is organised in some specified structure, limited in content by a scope, and designed for assigning objects to concepts defined within it. Concepts are usually assigned to an object by linking the terms representing those concepts in the terminological system to the object. This process is called classification, and the terms assigned through classification are used for retrieval. In general, any terminological system is a classification scheme if its intent is for classifying objects<sup>2</sup>.

A classification scheme is used to encompass terminologies and vocabularies used for various uses such as direct clinical use and statistical analysis. Classification schemes are referred to in NEHTA's data specifications where they exist externally and are required in value domains. Often these classifications schemes are underpinned by a set of codes, where each code maps to one or more entries in

1. Adapted from the Texas Department of State Health Services, *THCIC Hospital Discharge Data Collection*, THCIC 837\ Technical Specifications (version 13), November 19, 2004.  
2. As defined by ISO/IEC 11179.

the classification scheme. Classification schemes are sometimes referred to as codesets.

A value domain may consist of permissible values sourced from zero or more existing, external classification schemes, depending upon the completeness and sufficiency of those classification schemes. Values that are not available in one classification scheme may be obtained from other classification schemes, or depending upon the context and/or local system requirements, a preferred classification scheme may be used from a selection of valid classification schemes for that value domain.

## **1.5 Terminology**

NEHTA is defining a national approach to clinical terminology. An interim licence with the College of American Pathology (CAP) for use of SNOMED CT® within Australia was in place from 2006. The International Health Terminology Standards Development Organisation (IHTSDO) was formed in April 2007 and Australia is one of the foundation member countries. New national SNOMED CT licence arrangements are now in place, managed by NEHTA.

Although SNOMED CT is a comprehensive clinical reference terminology it is recognised that this does not provide a total solution and will need to be supplemented by local extensions. NEHTA is therefore establishing a National Terminology Service to manage Australian extensions to SNOMED CT. The Australian Medicines Terminology will supply terms to populate the Vaccine Brand Name and Route.

## 2 Specifications




The objective of this specification is to provide detailed information regarding the data elements (and their associative hierarchies and value domains) relevant to the transfer of information within the Clinical Synopsis domain.

The specification references other data group information, the details of which may be found in other NEHTA Specifications.

A Section can be thought of as an organisational heading. A data group is a collection of related data elements and/or data groups that can be treated as a single block, which might be subject to cardinality and obligation constraints.

### 2.1 Obligation Legend

In the following specifications, data obligation may be categorised as:

- Essential:**  Indicating that the data item is considered to be a core component of information and required in order for the entry to make sense, e.g. Alert without an Alert description does not make sense;
- Desirable:**  Indicating that the data item is considered worthy of being supplied where the data is known. The data item is deemed important in terms of providing additional or supplementary information in conjunction with essential data items. The data item should be supplied to provide as much context as possible for users to make informed decisions and/or to support various implementation requirements such as efficient indexing, querying and electronic decision support;
- Optional:**  Indicating that the data item may be supplied if required within a context and if the data is available, but it is not necessary for the data entry to make sense. It is recognised that for more complex or specialised healthcare provider settings, some items deemed optional may be viewed essential to them; or
- Conditional:** *a→b* Indicating that the data item is required on the condition of some other data item(s) being supplied, or based on the value(s) of another data item(s).

### 2.2 NEHTA Data Specifications ICON Legend







Icon	Metadata Types
	Event Summary
	Sections
	Packages
	Data Groups
	Data Elements
	Value Domains

Table 3 Metadata types





Icon	Explanation
	"Choice data group" - a single data group to be chosen from a set of data groups. Data groups of the same hierarchical depth within a hierarchical data group that make up a "choice set" are indicted using this icon.
	Multiple occurrences.*
	Externally sourced specifications.
	Externally sourced Data Group Specifications.

Table 4 Other Icons







Icon	Datatype	Explanation
	Text	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).
	CodedText	Coded text <i>without</i> exceptions; text with code mappings.
	CodeableText	Coded text with exceptions; flexible datatype to support various ways of holding text, both free text, coded text and combinations of free + coded.
	DateTime	Used for specifying a single date and/or time. Has the ability to indicate a level of precision, as well as an indication that the date/time is estimated. String representations of known dates should conform to ISO 8601.
	Duration	The period of time during which something continues.  <b>Usage/Examples</b> Example (1) 3 hours. Example (2) 6 months. Example (3) 1 year.
	Number	A whole number or positive integer, and where (according to ISO 11404) - <i>integer</i> is the mathematical datatype comprising the exact integral values  <b>Usage/Examples</b> Example (1) 1. Example (2) 50. Example (3) 125.

Table 5 Datatypes






Icon	Datatype	Explanation
	Boolean	A value of true or false.  <b>Usage/Example</b> Example (1) An actual value entered by the user might be "yes" or could be chosen by a mouse click on an icon such as <input checked="" type="checkbox"/>
<b>ID</b>	UniqueIdentifier	A general unique identifier to identify a physical or virtual object or concept.
	TimeInterval	Two Date/Time values that define the initial and later points in time.  <b>Usage/Examples</b> Example (1) 12:00 – 18:00. Example (2) 1:30 a.m. – 6:00 p.m.
	Quantity	Used for recording many real world measurements and observations. Consists of the property being recorded, the magnitude value, and the units. It may also include precision and number of decimal places.  <b>Usage/Examples</b> Example (1) Property = width. Example (2) Units = centimetres. Example (3) Value = 100.
	QuantityRange	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.  <b>Usage/Examples</b> Example (1) Temperature range of -20 to 100 °C Example (2) 30-50 mg of a prescribed drug.
	EncapsulatedData	Used to specify how to supply metadata such as the type of data encapsulated (such as JPEG images, HTML, etc. using RFC 1521 MIME types), whether the data is inline or passed by reference, what character set is used to encode the data, any low resolution "thumbnail" representation included, any compression algorithm or integrity check information included.

Table 5 Datatypes


Icon	Datatype	Explanation
	Link	<p>This is a general link, reference or pointer to an object, data, or application that exists logically or stored electronically in a computer system.</p> <p><b>Usage/Examples</b></p> <p>Example (1) 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 – "<a href="http://www.google.com">http://www.google.com</a>".</p> <p>Example (2) An absolute or relative path within a file/directory structure – e.g. in Windows operating system, the 'link' or absolute path to a particular letter (Word document) may be - "C:\Documents and Settings\guestUser\My Documents\Letter.doc".</p>
A:B	Ratio	<p>The relative magnitudes of two Quantity values (usually expressed as a quotient).</p> <p><b>Usage/Examples</b></p> <p>Example (1) 1/3. Example (2) 1:3.</p>
a,b,c...	Sequence	<p>Ordered collection of items.</p> <p><b>Usage/Example</b></p> <p>Example (1) A person's given names, e.g. "David Phillip Andrew" would be held as 3 items grouped in order to form a single entity.</p>
{b,a,c}	Set	<p>Unordered collection of items with values that must be unique within the set.</p>

Table 5 Datatypes

# CLINICAL SYNOPSIS

## Identification

<b>Name</b>	CLINICAL SYNOPSIS		
<b>Metadata Type</b>	Data Group		
<b>Identifier</b>	DG-013	<i>External Identifier</i>	
<b>Version</b>	1.0		

## Definition

<b>Definition</b>	Comments on relevant health related issues pertinent to the subject of care.
<b>Definition Source</b>	NEHTA
<b>Synonymous Names</b>	Clinical comment, Clinical note, Clinical summary.
<b>Scope</b>	Narrative information is captured or entered here by a healthcare provider from the focus of a healthcare provider, carer, subject of care and/or others unrelated to the subject of care.
<b>Scope Source</b>	NEHTA
<b>Assumptions</b>	

## Hierarchical Structure



## Usage

<b>Conditions of Use</b>	This data group is repeated for every instance of a clinical synopsis. Used to capture a contextual summary that may not otherwise be available in other individual data items.
<b>Conditions of Use Source</b>	NEHTA
<b>Misuse</b>	Used in place of other individual data items.

## Data Flow



<b>Sender Type</b>	Either system or human.
<b>Sender Role(s)/Organisation(s)/Jurisdiction(s)</b>	Sender Role(s) can include: Healthcare provider. Sender Organisation(s) can include: Healthcare institution, Medical practice.
<b>Recipient Type</b>	Either system or human.
<b>Recipient Role(s)/Organisation(s)/Jurisdiction(s)</b>	Recipient Role(s) can include: Healthcare provider. Recipient Organisation Role(s) can include: Healthcare institution, Medical practice.

## Relationships

### Children

Data Type	Name	Version	Obligation	Condition	Occurrence
T <sub>010</sub>	Information Provided By	1.0	Essential		Single
T	Clinical Synopsis Comment	1.0	Essential		Single

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	REPORTER IDENTIFICATION	1.0	Essential		Single
	DateTime Recorded	1.0	Essential		Single

# Clinical Synopsis Comment

## Identification

<b>Name</b>	Clinical Synopsis Comment		
<b>Metadata Type</b>	Data Element		
<b>Identifier</b>	DE-082	<i>External Identifier</i>	
<b>Version</b>	1.0		

## Definition

<b>Definition</b>	Comments on the subject of care's health issues from the perspective of a healthcare provider, carer, subject of care or an unrelated person as entered per the healthcare provider system.
<b>Definition Source</b>	NEHTA
<b>Synonymous Names</b>	Clinical synopsis, Clinical comment, Clinical summary.
<b>Context</b>	Used to provide narrative information in relation to the subject of care's health issues.
<b>Context Source</b>	NEHTA
<b>Assumptions</b>	
<b>Data Type</b>	Text
<b>Value Domain</b>	

## Usage


<b>Conditions of Use</b>	
<b>Conditions of Use Source</b>	
<b>Examples</b>	<p>Example 1) Admitted for elective bronchoscopy for assessment of left lingular and bibasal pneumonia. No focal endobronchial pathology identified. No evidence of malignancy and no pathogens isolated on bronchial brushings and washings.</p> <p>Example 2) 3/52 ago involved in a rear end motor vehicle accident, mid-velocity impact- complaining of neck pain, dizziness, nausea and difficulties concentrating. Disturbed sleep. No spinal cord signs.</p>
<b>Misuse</b>	

## Data Flow

<b>Sender Type</b>	Either system or human.
<b>Sender Role(s)/Organisation(s)/Jurisdiction(s)</b>	Sender Role(s) can include: Healthcare provider. Sender Organisation(s) can include: Healthcare institution, Medical practice.
<b>Recipient Type</b>	Either system or human.
<b>Recipient Role(s)/Organisation(s)/Jurisdiction(s)</b>	Recipient Role(s) can include: Healthcare provider. Recipient Organisation Role(s) can include: Healthcare institution, Medical practice.

## Relationships

### Parents

Data Type	Name	Version	Obligation within parent	Condition within parent	Occurrence within parent
	CLINICAL SYNOPSIS	1.0	Essential		Single

## DateTime Recorded

### Identification

<b>Name</b>	DateTime Recorded		
<b>Metadata Type</b>	Data Element		
<b>Identifier</b>	DE-15531	<i>External Identifier</i>	
<b>Version</b>	1.0		

### Definition

<b>Definition</b>	The date or date and time when the clinical synopsis recording was made.
<b>Definition Source</b>	NEHTA
<b>Synonymous Names</b>	
<b>Context</b>	
<b>Context Source</b>	
<b>Assumptions</b>	For instances of a DateTime Recorded (the date or date and time that information was recorded in this clinical record) the date and time could be the system date and time when the data is entered, but the date and/or time could be over-ridden if required.
<b>Data Type</b>	DateTime
<b>Value Domain</b>	

### Usage


<b>Conditions of Use</b>	Where possible, exact dates should be used. Incomplete dates should generally only be used for retrospective data collection.
<b>Conditions of Use Source</b>	NEHTA
<b>Examples</b>	Example 1) 31/03/2004. Example 2) 03/2004. Example 3) 2004. Example 4) 31/03/2004 13:10.
<b>Misuse</b>	Entering approximate dates when an exact date is available.

### Data Flow

<b>Sender Type</b>	Either system or human.
<b>Sender Role(s)/Organisation(s)/Jurisdiction(s)</b>	Sender Role(s) can include: Healthcare provider. Sender Organisation Role(s) can include: Healthcare institution, Medical practice. Sender Jurisdiction Role(s) can include: Government health program.
<b>Recipient Type</b>	Either system or human.
<b>Recipient Role(s)/Organisation(s)/Jurisdiction(s)</b>	Recipient Role(s) can include: Healthcare provider. Recipient Organisation Role(s) can include: Healthcare institution, Medical practice. Recipient Jurisdiction Role(s) can include: Government health program.

### Relationships

#### Parents

Data Type	Name	Version	Obligation within parent	Condition within parent	Occurrence within parent
	CLINICAL SYNOPSIS	1.0	Essential		Single

# REPORTER IDENTIFICATION

## Identification

<b>Name</b>	REPORTER IDENTIFICATION		
<b>Metadata Type</b>	Data group		
<b>Identifier</b>	DG-15530	<b>External Identifier</b>	AS4846-2006
<b>Version</b>	1.0		

## Definition

<b>Definition</b>	Details pertinent to the identification of a healthcare provider individual who is reporting the alert information.
<b>Definition Source</b>	NEHTA
<b>Synonymous Names</b>	
<b>Context</b>	
<b>Context Source</b>	NEHTA
<b>Scope</b>	
<b>Scope Source</b>	NEHTA
<b>Assumptions</b>	

## Usage


<b>Conditions of Use</b>	
<b>Conditions of Use Source</b>	
<b>Misuse</b>	

## Data Flow



<b>Sender Type</b>	Either system or human.
<b>Sender Role(s)/Organisation(s)/Jurisdiction(s)</b>	Sender Role(s) can include: Healthcare provider. Sender Organisation(s) can include: Healthcare institution, Medical practice.
<b>Recipient Type</b>	Either system or human.
<b>Recipient Role(s)/Organisation(s)/Jurisdiction(s)</b>	Recipient Role(s) can include: Healthcare provider. Recipient Organisation Role(s) can include: Healthcare institution, Medical practice.





## Relationships

### Parents

Data Type	Name	Version	Obligation within parent	Condition within parent	Occurrence within parent
	CLINICAL SYNOPSIS	1.0	Essential		Single

### Children

Data Type	Name	Version	Obligation	Condition	Occurrence
	<b>HEALTHCARE PROVIDER IDENTIFIER-INDIVIDUAL</b> (see external reference for full specification: AS4846 - 2006)	1.0	Desirable		Single
	<b>PERSON NAME</b> (see external reference for full specification: AS4846 - 2006)	1.0	Essential		Single

	<p><b>ORGANISATION NAME</b> (see external reference for full specification: AS4846 - 2006)</p>	<p>1.0</p>	<p>Conditional</p>	<p>(required if requesting healthcare provider facility is external to the Diagnostic Imaging Service provider facility)</p>	<p>Single</p>
	<p><b>ADDRESS</b> (see external reference for full specification: AS4846 - 2006)</p>	<p>1.0</p>	<p>Conditional</p>	<p>(required if requesting healthcare provider facility is external to the Diagnostic Imaging Service provider facility)</p>	<p>Single</p>
	<p><b>ELECTRONIC COMMUNICATION DETAILS</b> (see external reference for full specification: AS4846 - 2006)</p>	<p>1.0</p>	<p>Essential</p>		<p>Single</p>
	<p><b>Provider Occupation Category</b></p>	<p>1.0</p>	<p>Optional</p>	<p>(may be required for certain test requests, e.g. MRI)</p>	<p>Single</p>

## Information Provided By

### Identification

<b>Name</b>	Information Provided By		
<b>Metadata Type</b>	Data Element		
<b>Identifier</b>	DE-503	<i>External Identifier</i>	
<b>Version</b>	1.0		

### Definition

<b>Definition</b>	A category specifying the source of the subject of care's health information in this record.		
<b>Definition Source</b>	NEHTA		
<b>Synonymous Names</b>			
<b>Context</b>			
<b>Context Source</b>			
<b>Assumptions</b>			
<b>Data Type</b>	CodedText		
<b>Value Domain</b>	Information Provided By values		

### Usage


<b>Conditions of Use</b>	To specify the source of the subject of care's health information when information is being captured by a healthcare provider.
<b>Conditions of Use Source</b>	NEHTA
<b>Examples</b>	Example 1) Subject of care. Example 2) Carer. Example 3) Other.
<b>Misuse</b>	

### Data Flow

<b>Sender Type</b>	Either system or human.
<b>Sender Role(s)/Organisation(s)/Jurisdiction(s)</b>	Sender Role(s) can include: Healthcare provider. Sender Organisation(s) can include: Healthcare institution, Medical practice.
<b>Recipient Type</b>	Either system or human.
<b>Recipient Role(s)/Organisation(s)/Jurisdiction(s)</b>	Recipient Role(s) can include: Healthcare provider. Recipient Organisation Role(s) can include: Healthcare institution, Medical practice.

### Relationships

#### Parents

Data Type	Name	Version	Obligation within parent	Condition within parent	Occurrence within parent
	CLINICAL SYNOPSIS	1.0	Essential		Single

## VD Information Provided By values

### Identification

<b>Name</b>	Information Provided By values
<b>Metadata Type</b>	Value Domain
<b>Identifier</b>	VD-050
<b>Version</b>	1.0

### Definition

<b>Definition</b>	A category which specifies the source of the information.
<b>Definition Source</b>	NEHTA

### Value Domain

<b>Source</b>	NEHTA
<b>Version Number</b>	
<b>Permissible Values</b>	Carer; Device; Healthcare provider; Other; and Subject of care.

### Usage

<b>Default Value</b>	Healthcare provider.
<b>Conditions of Use</b>	The value domain options are mutually exclusive and cannot be used in conjunction with each other. Carer: An individual who provides regular and sustained care and/or assistance to the subject of care. Other: An individual who does not provide regular and sustained care and/or assistance to the subject of care.
<b>Conditions of Use Source</b>	NEHTA
<b>Misuse</b>	

### Relationships

#### Parents

Data Type	Name	Version
T <sub>010</sub>	Information Provided By	1.0

# Acronyms

<b>AIHW</b>	Australian Institute of Health & Welfare
<b>EHR</b>	Electronic Health Record
<b>HL7</b>	Health Level Seven
<b>MBS</b>	Medical Benefits Scheme
<b>METeOR</b>	MEtadata On-line Registry ( <a href="http://meteor.aihw.gov.au">http://meteor.aihw.gov.au</a> )
<b>NEHTA</b>	National E-Health Transition Authority
<b>SEHR</b>	Shared Electronic Health Record

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