nehta

Consumer Entered Health Summary

Structured Content Specification

Version 1.0 — 15 Dec 2011

Final

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Document Information

Document owner

Document Owner
The National Clinical Terminology and Information Service

Change history

Version	Date	Comments
1.0	15 Dec 2011	Initial release.

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
Medication Instruction And Action Detailed Clinical Model Specification	Version 2.1
Adverse Reaction Detailed Clinical Model Specification	Version 3.1

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1 Introduction

This document is a Structured Content Specification (SCS) for Consumer Entered Health Summary. It specifies the information structure of NEHTA-compliant Consumer Entered Health Summary in order to record allergies and medications about a subject of care within the PCEHR system.

Appendix B: *Specification Guide for Use* provides definitional details on data type constraints applied to data elements defined in the SCS. It also provides important information on how to read and use the SCS best. Therefore, it is an essential compendium for better understanding of the SCS.

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

1.1 Document Purpose

This document describes the Structured Content Specification for Consumer Entered Health Summary.

The content within this document provides reviewers (software development teams, architects, designers, clinicians and informatics researchers) with the necessary information (or references to information held outside this document) to evaluate and assess the clinical suitability of NEHTA-endorsed specifications for the electronic transfer of Consumer Entered Health Summary.

It is also a key input to the NEHTA Consumer Entered Health Summary CDA Implementation Guide [NEHT2011as], which describes how to implement NEHTA-compliant Consumer Entered Health Summary using the HL7 Clinical Document Architecture [HL7CDAR2].

1.2 Intended Audience

This document is aimed at software development teams, architects, designers, clinicians and informatics researchers who are responsible for the delivery of clinical applications, infrastructure components and messaging interfaces and also for those who wish to evaluate the clinical suitability of NEHTA-endorsed specifications.

1.3 Document Scope

This document specifies the essential clinical data groups and elements to be captured in an Consumer Entered Health Summary exchange and the constraints that should be applied. Its scope is aligned to the document Concept of Operations: Relating to the introduction of a Personally Controlled Electronic Health Record System [DHA2011b].

This is not a guide to implementing any specific messaging standard.

1.4 Known Issues

This is a preliminary draft for trial implementation.

Known issues with this document are described in A: *Known Issues*.

2 Consumer Entered Health Summary Structured Document

2.1 Purpose

The purpose is to help the subject of care and their authorised representative to keep track of the subject of care's allergies and medications. It is a convenient summary which can be provided to a clinician, thus improving communication between subject of care and clinician.

2.2 Misuse

Using to record allergies and medications as structured data.

2.3 CONSUMER ENTERED HEALTH SUMMARY

Identification

Label	CONSUMER ENTERED HEALTH SUMMARY
Metadata Type	Structured Document
Identifier	SD-16685
OID	1.2.36.1.2001.1001.101.100.16685

Definition

Definition	It is a healthcare summary about the subject of care's allergies and medications which is recorded by the subject of care or their authorised representative within the PCEHR system (as described in PCEHR Concept of Operations document).
Definition Source	NEHTA
Synonymous Names	

Data Hierarchy

	CONSUMER ENTERED HEALTH SUMMARY				
CONTEXT					
		SUBJECT OF CARE			1..1
		DOCUMENT AUTHOR			1..1
		DateTime Authored			1..1
		~~DateTime Health Event Started~~			~~0..0~~
		~~DateTime Health Event Ended~~			~~0..0~~
		~~HEALTHCARE FACILITY~~			~~0..0~~
CONTENT					
		Allergies and Adverse Reactions (ADVERSE REACTIONS)			0..1
			~~EXCLUSION STATEMENT - ADVERSE REACTIONS~~		~~0..0~~
			ADVERSE REACTION		1..*
				Substance/Agent	1..1

				~~Absolute Contraindication~~		~~0..0~~
				~~Comment (Adverse Reaction Comment)~~		~~0..0~~
				REACTION EVENT		0..1
				~~Specific Substance/Agent~~		~~0..0~~
				Manifestation		1..*
				~~Reaction Type~~		~~0..0~~
				~~Certainty (Adverse Reaction Certainty)~~		~~0..0~~
				~~Reaction Description~~		~~0..0~~
				~~Onset of Reaction (Reaction Onset Date)~~		~~0..0~~
				~~Duration of Reaction~~		~~0..0~~
				~~Additional Reaction Detail (ANATOMICAL LOCATION)~~		~~0..0~~
				~~Exposure Description~~		~~0..0~~
				~~Earliest Exposure~~		~~0..0~~
				~~Duration of Exposure~~		~~0..0~~
				~~ADDITIONAL EXPOSURE DETAIL~~		~~0..0~~
				~~Clinical Management Description~~		~~0..0~~
				~~Multimedia~~		~~0..0~~
				~~Reporting Details~~		~~0..0~~
				~~Comment (Adverse Reaction Event Comment)~~		~~0..0~~
				~~Reaction Reported~~		~~0..0~~
				~~Adverse Reaction Report~~		~~0..0~~
				~~Supporting Clinical Record Information~~		~~0..0~~
				~~INFORMATION PROVIDER~~		~~0..0~~
				~~SUBJECT~~		~~0..0~~

				~~Adverse Reaction Identifier~~	~~0..0~~
				~~LINK~~	~~0..0~~
				~~Detailed Clinical Model Identifier~~	~~0..0~~
		Medications (MEDICATION ORDERS)			0..1
				~~EXCLUSION STATEMENT - MEDICATIONS~~	~~0..0~~
				Medication (MEDICATION INSTRUCTION)	1..*
				Medicine (Therapeutic Good Identification)	1..1
				Directions	1..1
				~~Ingredients and Form (CHEMICAL DESCRIPTION OF MEDICATION)~~	~~0..0~~
				~~Dose Description~~	~~0..0~~
				~~Structured Dose (AMOUNT OF MEDICATION)~~	~~0..0~~
				~~TIMING~~	~~0..0~~
				~~Additional Instruction~~	~~0..0~~
				Clinical Indication	0..1
				~~Administration Details (MEDICATION ADMINISTRATION)~~	~~0..0~~
				Comment (Medication Instruction Comment)	0..1
				~~DISPENSING~~	~~0..0~~
				~~Change Type~~	~~0..0~~
				~~Change or Recommendation? (Change Status)~~	~~0..0~~
				~~Change Description~~	~~0..0~~
				~~Change Reason (Change or Recommendation Reason)~~	~~0..0~~
				~~Indication for Authorised Use~~	~~0..0~~
				~~Medication Instruction ID~~	~~0..0~~
				~~Concession Benefit~~	~~0..0~~

				~~INFORMATION PROVIDER~~	~~0..0~~
				~~SUBJECT~~	~~0..0~~
				~~Medication Instruction Narrative~~	~~0..0~~
				~~DateTime Medication Instruction Expires~~	~~0..0~~
				~~Medication Instruction Identifier~~	~~0..0~~
				~~LINK~~	~~0..0~~
				~~Detailed Clinical Model Identifier~~	~~0..0~~

2.4 SUBJECT OF CARE

Identification

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

Definition

Definition	Identifies the person about whom the healthcare information has been captured. In other words, the subject of the information.
Definition Source	NEHTA
Synonymous Names	Patient

Usage

Conditions of Use	This is a reuse of the PARTICIPATION data group, which is described in Participation Data Specification [NEHT2011v]. The following constraints are additional to those specified in Participation Data Specification [NEHT2011v]. Constraints are explained in Appendix B: *Specification Guide for Use*. Additional obligation and occurrence constraints: • Participation Period is **PROHIBITED**. • LOCATION OF PARTICIPATION is **PROHIBITED**. • Entity Identifier is **ESSENTIAL**. • ADDRESS is **ESSENTIAL**. • Relationship to Subject of Care is **PROHIBITED**. • EMPLOYMENT DETAIL is **PROHIBITED**. • DEMOGRAPHIC DATA is **ESSENTIAL**. • Sex is **ESSENTIAL**. • DATE OF BIRTH DETAIL is **ESSENTIAL**. • Indigenous Status is **ESSENTIAL**. • Qualifications is **PROHIBITED**. Other additional constraints:

	• Participation Type **SHALL** have an implementation-specific value equivalent to “Subject of Care”. • Role **SHALL** have an implementation-specific value equivalent to “Patient”. • The value of one Entity Identifier **SHALL** be an Australian IHI. • PERSON OR ORGANISATION OR DEVICE **SHALL** be instantiated as a PERSON.
Conditions of Use Source	NEHTA
Misuse	The Authorised Representative **SHALL NOT** be recorded here.

Relationships

Parents

Data Type	Name	Occur-rences	Condi-tion
	CONSUMER ENTERED HEALTH SUMMARY	1..1	

2.5 DOCUMENT AUTHOR

Identification

Label	DOCUMENT AUTHOR
Metadata Type	Data Group
Identifier	DG-10296
OID	1.2.36.1.2001.1001.101.102.10296

Definition

Definition	The subject of care or an authorised representative who is authorised to act on behalf of the subject of care for healthcare purposes.
Definition Source	NEHTA
Synonymous Names	

Usage

Conditions of Use	When Authorised Representative is not available, the subject of care **SHALL** be the person who authored the document. This is a reuse of the PARTICIPATION data group, which is described in Participation Data Specification [NEHT2011v]. The following constraints are additional to those specified in Participation Data Specification [NEHT2011v]. Constraints are explained in Appendix B: *Specification Guide for Use*. Additional obligation and occurrence constraints: • LOCATION OF PARTICIPATION is **PROHIBITED**. • Entity Identifier is **ESSENTIAL**. • DEMOGRAPHIC DATA is **PROHIBITED**. • EMPLOYMENT DETAIL is **PROHIBITED**. • ENTITLEMENT is **PROHIBITED**. • Qualifications is **PROHIBITED**. Other additional constraints when the Authorised Representative is the Document Author: • Participation Type **SHALL** have an implementation-specific value equivalent to “Authorised Representative”. • Relationship to Subject of Care is **ESSENTIAL**.

	• Role **SHOULD** have a value chosen from 1220.0 – ANZSCO – Australia and New Zealand Standard Classification of Occupations, First Edition, 2006 – METeOR 350899. However, if a suitable value in this set cannot be found, then any code set that is both registered with HL7 and is publicly available **MAY** be used. • The value of one Entity Identifier **SHALL** be an Australian IHI. • PERSON OR ORGANISATION OR DEVICE **SHALL** be instantiated as a PERSON. Other additional constraints when the Subject of Care is the Document Author: • Participation Type **SHALL** have an implementation-specific value equivalent to “Document Author”. • Relationship to Subject of Care is **PROHIBITED**. • Role **SHOULD** have a value chosen from 1220.0 – ANZSCO – Australia and New Zealand Standard Classification of Occupations, First Edition, 2006 – METeOR 350899. However, if a suitable value in this set cannot be found, then any code set that is both registered with HL7 and is publicly available **MAY** be used. • The value of one Entity Identifier **SHALL** be an Australian IHI. • PERSON OR ORGANISATION OR DEVICE **SHALL** be instantiated as a PERSON.
Conditions of Use Source	NEHTA
Misuse	Recording the “Subject of Care” as a Document Author **SHALL NOT** be permitted when “Authorised Representative” is the author of the document.

Relationships

Parents

Data Type	Name	Occur-rences	Condi-tion
	CONSUMER ENTERED HEALTH SUMMARY	1..1	

2.6 DateTime Authored

Identification

Label	DateTime Authored
Metadata Type	Data Element
Identifier	DE-20405
OID	1.2.36.1.2001.1001.101.103.20405

Definition

Definition	The date or date and time that authoring of the Consumer Entered Health Summary by the subject of care or their authorised representative is started or done.
Definition Source	NEHTA
Synonymous Names	DateTime Consumer Entered Health Summary Created DateTime Created DateTime Issued
Data Type	DateTime

Relationships

Parents

Data Type	Name	Occur-rences	Condi-tion
	CONSUMER ENTERED HEALTH SUMMARY	1..1	

2.7 ADVERSE REACTIONS

Identification

Label	Allergies and Adverse Reactions
Metadata Type	Section
Identifier	S-20113
OID	1.2.36.1.2001.1001.101.101.20113

Definition

Definition	Information about adverse reactions and/or propensity to adverse reaction of the subject of care(including allergies and intolerances), and any relevant reaction details.
Definition Source	NEHTA
Synonymous Names	
Scope	Includes allergies and adverse reaction to all substances not just medications / medicines. This might include food allergies, bee sting allergies as well as prescription and nonprescription medicines.
Scope Source	NEHTA

Relationships

Parents

Data Type	Name	Occur-rences	Condi-tion
	CONSUMER ENTERED HEALTH SUMMARY	0..1	

Children

Data Type	Name	Occur-rences	Condi-tion
	~~EXCLUSION STATEMENT - ADVERSE REACTIONS~~	~~0..0~~	-
	ADVERSE REACTION	1..*	

2.8 MEDICATION ORDERS

Identification

Label	Medications
Metadata Type	Section
Identifier	S-16146
OID	1.2.36.1.2001.1001.101.101.16146

Definition

Definition	Medicines which the subject of care is using, this includes self-prescribed, clinician prescribed and nonprescription medicines.
Definition Source	NEHTA
Synonymous Names	
Scope	The medicines included here ensure high quality healthcare. It is important to have a record of all medicines taken by the subject of care.
Scope Source	NEHTA

Usage

Conditions of Use	The medicines listed shall include details that fully describe it, including the name of the medication, strength and dose form where appropriate. The Therapeutic Good Identification data element **SHALL NOT** be recorded as coded text.
Conditions of Use Source	NEHTA

Relationships

Parents

Data Type	Name	Occur-rences	Condi-tion
	CONSUMER ENTERED HEALTH SUMMARY	0..1	

Children

Data Type	Name	Occur-rences	Condi-tion
	~~EXCLUSION STATEMENT - MEDICATIONS~~	~~0..0~~	-
	Medication (MEDICATION INSTRUCTION)	1..*	

3 Adverse Reaction Data Group

3.1 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 (e.g. Gentamycin), drug-drug interactions, food-drug interactions, drug-disease interactions and idiosyncratic reactions).

3.2 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.

Can also be used to record an individual's reflections on their adverse reactions.

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.

3.3 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.

3.4 ADVERSE REACTION

Identification

Label	ADVERSE REACTION
Metadata Type	Data Group
Identifier	DG-15517
OID	1.2.36.1.2001.1001.101.102.15517

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	

Usage

Conditions of Use	This is a reuse of the ADVERSE REACTION data group, which is described in Adverse Reaction Detailed Clinical Model Specification [NEHT2011bb].
Conditions of Use Source	NEHTA

Relationships

Parents

Data Type	Name	Occur-rences	Condi-tion
	Allergies and Adverse Reactions (ADVERSE REACTIONS)	1..*	

Children

Data Type	Name	Occur-rences	Condi-tion
	Substance/Agent	1..1	
	~~Absolute Contraindication~~	~~0..0~~	-
	~~Comment (Adverse Reaction Comment)~~	~~0..0~~	-
	REACTION EVENT	0..1	

Data Type	Name	Occur-rences	Condi-tion
	~~Reaction Reported~~	~~0..0~~	-
	~~Adverse Reaction Report~~	~~0..0~~	-
	~~Supporting Clinical Record Information~~	~~0..0~~	-
	~~INFORMATION PROVIDER~~	~~0..0~~	-
	~~SUBJECT~~	~~0..0~~	-
	~~Adverse Reaction Identifier~~	~~0..0~~	-
	~~LINK~~	~~0..0~~	-
	~~Detailed Clinical Model Identifier~~	~~0..0~~	-

3.5 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

Usage

Conditions of Use	Substance/Agent **SHALL NOT** be recorded as coded text.
Conditions of Use Source	NEHTA
Examples	1. Animal protein. 2. Latex. 3. Peanut. 4. Penicillin. 5. Bee venom.

Relationships

Parents

Data Type	Name	Occur-rences	Condi-tion
	ADVERSE REACTION	1..1	

3.6 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	Occur-rences	Condi-tion
	ADVERSE REACTION	0..1	

Children

Data Type	Name	Occur-rences	Condi-tion
	~~Specific Substance/Agent~~	~~0..0~~	-
	Manifestation	1..*	
	~~Reaction Type~~	~~0..0~~	-
	~~Certainty (Adverse Reaction Certainty)~~	~~0..0~~	-
	~~Reaction Description~~	~~0..0~~	-
	~~Onset of Reaction (Reaction Onset Date)~~	~~0..0~~	-
	~~Duration of Reaction~~	~~0..0~~	-
	~~Additional Reaction Detail (ANATOMICAL LOCATION)~~	~~0..0~~	-

Data Type	Name	Occur-rences	Condi-tion
	~~Exposure Description~~	~~0..0~~	-
	~~Earliest Exposure~~	~~0..0~~	-
	~~Duration of Exposure~~	~~0..0~~	-
	~~ADDITIONAL EXPOSURE DETAIL~~	~~0..0~~	-
	~~Clinical Management Description~~	~~0..0~~	-
	~~Multimedia~~	~~0..0~~	-
	~~Reporting Details~~	~~0..0~~	-
	~~Comment (Adverse Reaction Event Comment)~~	~~0..0~~	-

3.7 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	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.
Data Type	CodeableText

Usage

Conditions of Use	The Manifestation data element **SHALL NOT** be recorded as coded text.
Conditions of Use Source	NEHTA
Examples	1. Itchy eyes. 2. Dysphagia. 3. Tinnitus. 4. Nausea. 5. Rash.

Relationships

Parents

Data Type	Name	Occur-rences	Condi-tion
	REACTION EVENT	1..*	

4 Medication Instruction Data Group

4.1 Purpose

Recording intent to use or to continue to use a medicine, vaccine or other therapeutic good including instructions on use, dispensing and administration, where necessary.

4.2 Use

For recording instructions to dispense, administer or use a medicine, vaccine or other therapeutic good. This medication instruction can be used in many circumstances including: a record in a progress note; an item in a medication list, prescription or drug chart (to be dispensed and/or administered); or in a summary document such as discharge summary or a referral for care. The instruction may be complex and involve more than one activity, such as in the case of a reducing dose of Predisolone, or multiple medications as components of the same order. This would include a written order by a physician, dentist, nurse practitioner, or other designated health professional for a medication to be dispensed and administered to a patient.

This instruction will generally apply to things that can be prescribed or are available 'over the counter'.

Use for orders for vaccinations or other therapeutic goods. These may be presented differently in different applications but require the same structure.

Use for the consistent representation of an item in a medication list comprising the medicines that a clinicians collectively expect the individual to be taking.

The information recorded may separate dose, route and timing to achieve a computable and sharable specification but also allows for narrative instructions for orders like 'Frusemide 40mg two tablets in the morning and one at lunch' to ensure compatibility with existing systems. To achieve a structure statement for such compound orders, two items are required: 'Frusemide 40mg two tablets in the morning' and 'Frusemide 40mg one tablet at lunch'. The instruction will usually include information about the timing and dose (which may be structured) and in some settings will include the route of administration. The amount of the medicines will usually be given in terms of a number and a dose unit but may be a textural statement to ensure compatibility with existing systems and also coverage of all scenarios.

Use to represent a prescription item for a medicine, vaccine or other therapeutic good within a document such as an electronic prescription or a medication chart.

The content is potentially complex. Where the content is re-usable in other contexts, especially the paired Medication Action DCM (for recording dispensing, administration etc) the content has been specified in re-useable data groups. For example: Amount and Amount range data groups contain the detail about Medication dose; Timing data group contains detail about structured dose timing; Medication administration data group contains structure around administration for both the order and the action; and Chemical description data group described the specific ingredients within a medicine. All of these data groups together are required to make up the total maximal dataset for a re-useable medication instruction.

4.3 Misuse

Not to be used to record administration, use or dispensing. (For those use Medication Action DCM)

Not to be used to record ordering of blood products, implants or major devices such as pacemakers and defibrillators, etc.

4.4 MEDICATION INSTRUCTION

Identification

Label	Medication
Metadata Type	Data Group
Identifier	DG-16211
OID	1.2.36.1.2001.1001.101.102.16211

Definition

Definition	Information pertaining to one or more therapeutic goods that is represented to achieve, or is likely to achieve, its principal intended action by pharmacological, chemical, immunological or metabolic means in or on the body of a human.
Definition Source	NEHTA
Synonymous Names	Drug Medicine Potion Therapeutic
Scope	For use in the healthcare setting. Captures detailed information on the medication being used by or prescribed for the subject of care for their personal healthcare. This includes recording of legal substances such as over-the-counter medications, complementary and alternative medications, prescribed medications and nonprescription medications.
Scope Source	NEHTA

Usage

Conditions of Use	This is a reuse of the MEDICATIONS data group, which is described in Medication Instruction And Action Detailed Clinical Specification [NEHT2011ay].
Conditions of Use Source	NEHTA

Relationships

Parents

Data Type	Name	Occur-rences	Condi-tion
	Medications (MEDICATION ORDERS)	1..*	

Children

Data Type	Name	Occur-rences	Condi-tion
	Medicine (Therapeutic Good Identification)	1..1	
	Directions	1..1	
	~~Ingredients and Form (CHEMICAL DESCRIPTION OF MEDICATION)~~	~~0..0~~	-
	~~Dose Description~~	~~0..0~~	-
	~~Structured Dose (AMOUNT OF MEDICATION)~~	~~0..0~~	-
	~~TIMING~~	~~0..0~~	-
	~~Additional Instruction~~	~~0..0~~	-
	Clinical Indication	0..1	
	~~Administration Details (MEDICATION ADMINISTRATION)~~	~~0..0~~	-
	Comment (Medication Instruction Comment)	0..1	
	~~DISPENSING~~	~~0..0~~	-
	~~Change Type~~	~~0..0~~	-
	~~Change or Recommendation? (Change Status)~~	~~0..0~~	-
	~~Change Description~~	~~0..0~~	-
	~~Change Reason (Change or Recommendation Reason)~~	~~0..0~~	-
	~~Indication for Authorised Use~~	~~0..0~~	-
	~~Medication Instruction ID~~	~~0..0~~	-
	~~Concession Benefit~~	~~0..0~~	-
	~~INFORMATION PROVIDER~~	~~0..0~~	-
	~~SUBJECT~~	~~0..0~~	-
	~~Medication Instruction Narrative~~	~~0..0~~	-
	~~DateTime Medication Instruction Expires~~	~~0..0~~	-

Data Type	Name	Occur-rences	Condi-tion
	~~Medication Instruction Identifier~~	~~0..0~~	-
	~~LINK~~	~~0..0~~	-
	~~Detailed Clinical Model Identifier~~	~~0..0~~	-

4.5 Therapeutic Good Identification

Identification

Label	Medicine
Metadata Type	Data Element
Identifier	DE-10194
OID	1.2.36.1.2001.1001.101.103.10194

Definition

Definition	The medicine, vaccine or other therapeutic good being ordered, administered to or used by the subject of care.
Definition Source	Therapeutic Goods Administration
Synonymous Names	Item Name
Context	This includes medications and medical devices. It includes drugs, appliances, dressings and reagents.
Context Source	NEHTA
Notes	Identifies a therapeutic good, which is broadly defined as a good which is represented in any way to be, or is likely to be taken to be, for therapeutic use (unless specifically excluded or included under Section 7 of the Therapeutic Goods Act 1989). Therapeutic use means use in or in connection with: • preventing, diagnosing, curing or alleviating a disease, ailment, defect or injury; • influencing, inhibiting or modifying a physiological process; • testing the susceptibility of persons to a disease or ailment; • influencing, controlling or preventing conception; • testing for pregnancy; or • replacement or modification of parts of the anatomy. From [TGA1989a]. The formal definition of a therapeutic good (from the Therapeutic Goods Act 1989) can be found at: [TGA1989a].
Data Type	CodeableText

Usage

Conditions of Use	The Medicine data element **SHALL NOT** be recorded as coded text.
Conditions of Use Source	NEHTA

Examples	Some examples are: 1. Panadeine Forte tablet: uncoated, 20 tablets. 2. Panadeine Forte (paracetamol 500 mg + codeine phosphate 30 mg) tablet: uncoated, 1 tablet. 3. Je-Vax (Japanese encephalitis virus inactivated vaccine) injection: powder for, vial.

Relationships

Parents

Data Type	Name	Occur-rences	Condi-tion
	Medication (MEDICATION INSTRUCTION)	1..1	

4.6 Directions

Identification

Label	Directions
Metadata Type	Data Element
Identifier	DE-16429
OID	1.2.36.1.2001.1001.101.103.16429

Definition

Definition	A complete narrative description of how much, when and how to use the medicine, vaccine or other therapeutic good.
Definition Source	NEHTA
Synonymous Names	
Data Type	Text

Usage

Examples	1. 1 tablet daily. 2. As directed on bottle.

Relationships

Parents

Data Type	Name	Occur-rences	Condi-tion
	Medication (MEDICATION INSTRUCTION)	1..1	

4.7 Clinical Indication

Identification

Label	Clinical Indication
Metadata Type	Data Element
Identifier	DE-10141
OID	1.2.36.1.2001.1001.101.103.10141

Definition

Definition	A reason for ordering the medicine, vaccine or other therapeutic good.
Definition Source	NEHTA
Synonymous Names	Reason for Medicine
Notes	The reason why the individual is taking the medicine.
Data Type	Text

Usage

Conditions of Use	To ensure high quality healthcare it is important to record reasons for medicines taken by the individual, this includes reason for prescription and non-prescription medicines.
Conditions of Use Source	NEHTA
Examples	1. Asthma. 2. Depression.

Relationships

Parents

Data Type	Name	Occur-rences	Condi-tion
	Medication (MEDICATION INSTRUCTION)	0..1	

4.8 Medication Instruction Comment

Identification

Label	Comment
Metadata Type	Data Element
Identifier	DE-16044
OID	1.2.36.1.2001.1001.101.103.16044

Definition

Definition	Consumer or nominated authorised representative entered additional information about the medicine or the rationale for current dose, timing and use.
Definition Source	NEHTA
Synonymous Names	
Data Type	Text

Usage

Examples	1. Self prescribed medicine. 2. Prescribed by GP. 3. Asthma is worse in spring time.
Misuse	Use for recording medicines description.

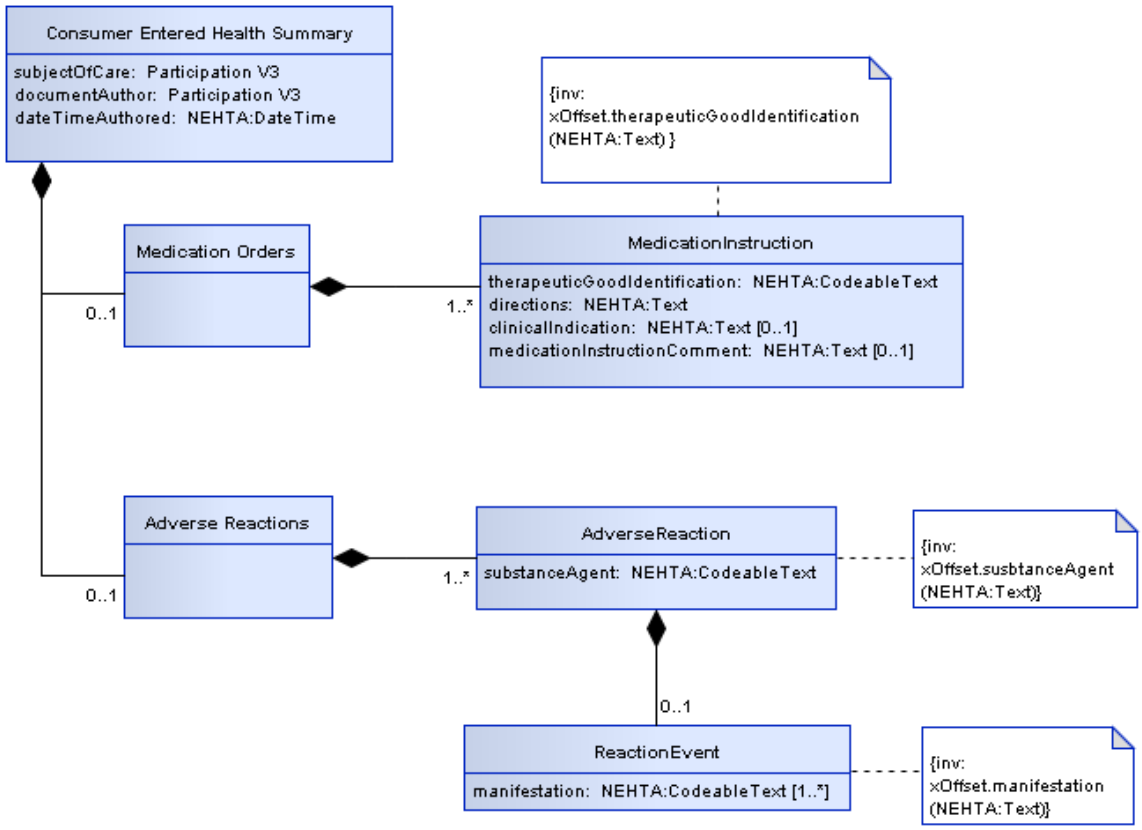
Relationships

Parents

Data Type	Name	Occur-rences	Condi-tion
	Medication (MEDICATION INSTRUCTION)	0..1	

5 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 Consumer Entered Health Summary data hierarchy.

Reference List

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[NEHT2005a] National E-Health Transition Authority, 25 May 2005, *NEHTA Acronyms, Abbreviations & Glossary of Terms*, Version 1.2, accessed 09 November 2009. http://www.nehta.gov.au/component/docman/doc_download/8-clinical-information-glossary-v12

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[NEHT2011ar] National E-Health Transition Authority, To be published, *Information Requirements - Consumer Entered Health Summary*, Version 0.6.

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[NEHT2011bb] National E-Health Transition Authority, *Adverse Reaction Detailed Clinical Model Specification*, Version 3.1.

[NEHT2011v] National E-Health Transition Authority, 20 July 2011, *Participation Data Specification*, Version 3.2, accessed 22 July 2011. http://www.nehta.gov.au/component/docman/doc_download/1341-participation-data-specification-v32

[RFC1521] Network Working Group, 1993, *RFC1521 - MIME (Multipurpose Internet Mail Extensions) Part One*, accessed 7 June 2010. http://www.faqs.org/rfcs/rfc1521.html

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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

[TGA1989a] Commonwealth of Australia, 1989, *THERAPEUTIC GOODS ACT 1989 - SECT 3*. http://www.austlii.edu.au/au/legis/cth/consol_act/tga1989191/s3.html#therapeutic_goods

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
Document Status	As a NEHTA Managed Specification, the contents of this document are the result of extensive clinical collaboration and editorial review, and the specification is considered to be “Final”. Nonetheless, as software implementations and standards review of this specification progress, normative updates may be required.
Links to external resources	If a link (usually in references section) spans across several lines, certain PDF readers have problems opening it.

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 of 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.

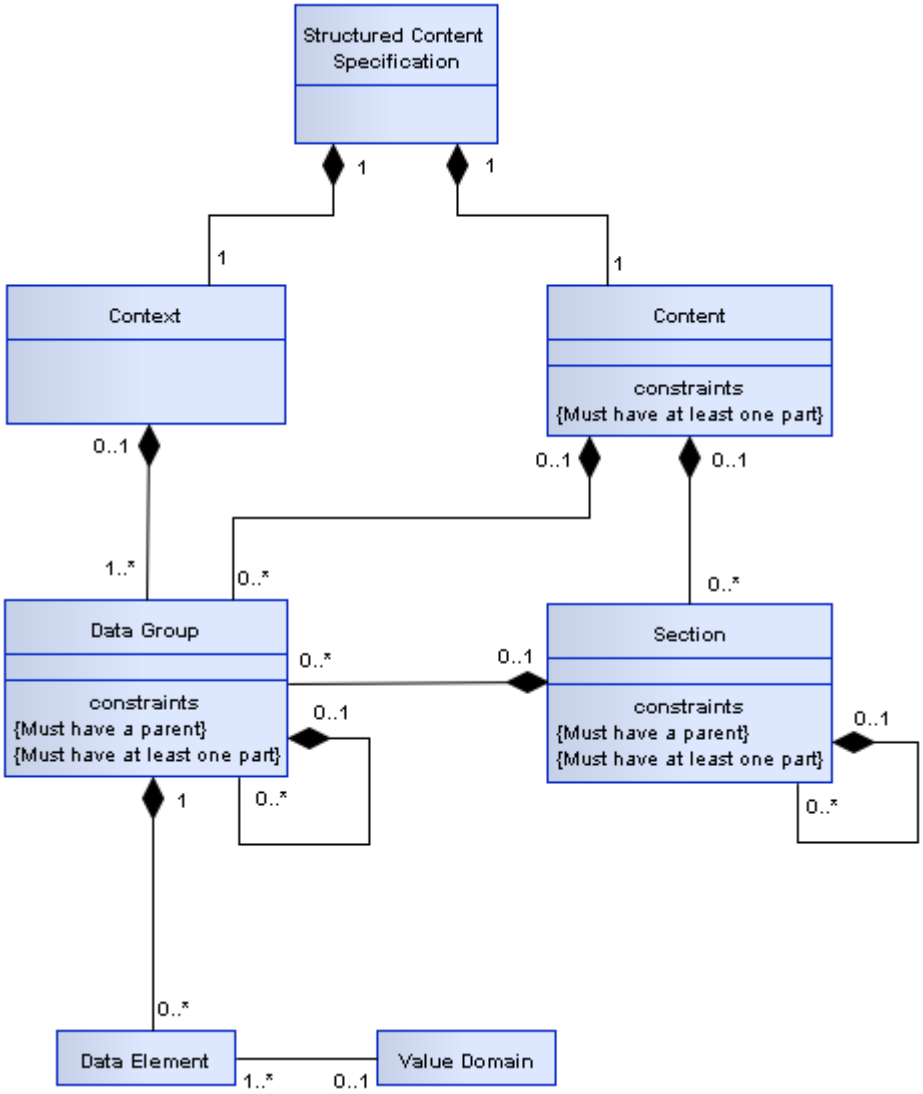

Figure 1: SCS Metamodel

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.

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

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: *true* and *false*. Many systems represent true as *non-zero* (often 1, or -1) and false as *zero*. **Usage/Examples** • An actual value entered by a user might be 'yes' or could be chosen by a mouse click on an icon such as ☑.

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** • 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** • 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** • 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** • 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 – *'http://www.google.com'*. • 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 *C:\Documents and Settings\GuestUser\MyDocuments\letter.doc*

 Quantity (ISO 21090: PQ)	Used for recording many real world measurements and observations. Includes the magnitude value and the units. **Usage/Examples** • 100 centimetres • 25.5 grams
 QuantityRatio (ISO 21090: RTO)	The relative magnitudes of two *Quantity* values (usually expressed as a quotient). **Usage/Examples** • 25 mg/500 ml • 200 mmol per litre
 QuantityRange (ISO 21090: IVL)	Two *Quantity* 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** • -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** • 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** • 01/01/2008 – 31/12/2008 • 1:30 a.m. – 6:00 p.m., duration/width = 16.5 hours

	UniqueIdentifier (ISO 21090: II)	A general unique value to identify a physical or virtual object or concept. 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

Obligation Legend

Obligation in DCMs or SCSs specifies whether or not a data component **SHALL** be populated in the logical record architecture of a message. NEHTA intends that all data components will be implemented.

Implementation guides specify the rules and formats for implementing and populating data components in specific messaging formats.

The following table defines the obligations.

Keyword	Interpretation
Essential	Indicates that the data component is considered a mandatory component of information and **SHALL** be populated. **Usage/Examples:** The Participant component for a Subject of Care **SHALL** include an Entity Identifier data component in order to hold the IHI.
Optional	Indicates that the data component is not considered a mandatory component of information and **MAY** be populated. **Usage/Examples:** This is only needed when a DCM incorrectly asserts that a data component is Essential. It will be used with a note stating that the DCM needs revision.
Prohibited	Indicates that the data component is considered a forbidden component of information and **SHALL NOT** be populated. **Usage/Examples:** Within a Participation data group depicting a Subject of Care, the Participation Healthcare Role **SHALL NOT** be completed.

Conditional	Indicates that a data component is considered Essential only on satisfaction of a given condition. Individual data components specify the obligation of the data component when the condition is not met. When a condition is met, the data component is considered to be essential and **SHALL** be populated. When a condition is not met, the data component may be considered as Prohibited, or the data component may be considered Optional. **Usage/Examples:** Within a Pathology Result Report, the *Specimen Detail* data group is Essential if the requested test is to be performed on a specimen, otherwise it **SHALL NOT** be populated.

Table 5: Obligations Legend

Where Essential child data components are contained within Optional parent data components, the child data components only need to be populated when the parent is populated.

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.)

	The Data type is applicable only to data elements. The valid data types are specified in the Data Types Legend.
Value Domain	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. The Value Domain is applicable only to CodedText and CodeableText data elements.
Conditions of Use	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

Appendix C. Mappings from Requirements

This appendix lists data elements from the NEHTA Information Requirements - Consumer Entered Health Summary [NEHT2011ar] document and matches them to their associated data elements in this Structured Content Specification (SCS) augmented with NEHTA Participation Data Specification [NEHT2011v].

Some cells in the mapping table are empty. This is used to indicate that the cell has the same value as the cell immediately above it.

Requirement Section	Data Item	SCS Data Element
Individual	Component	SUBJECT OF CARE
		When Subject of Care is the Document Author DOCUMENT AUTHOR
	Person Name	SUBJECT OF CARE.PARTICIPANT.PERSON OR ORGANISATION OR DEVICE.PERSON.PERSON NAME
		When Subject of Care is the Document Author DOCUMENT AUTHOR.PARTICIPANT.PERSON OR ORGANISATION OR DEVICE.PERSON.PERSON NAME
	Person Identifier	SUBJECT OF CARE.PARTICIPANT.Entity Identifier
		When Subject of Care is the Document Author DOCUMENT AUTHOR.PARTICIPANT.Entity Identifier
	Date of Birth	SUBJECT OF CARE.PARTICIPANT.PERSON OR ORGANISATION OR DEVICE.PERSON.DEMOGRAPHIC DATA.DATE OF BIRTH DETAIL
	Date of Birth Estimated?	SUBJECT OF CARE.PARTICIPANT.PERSON OR ORGANISATION OR DEVICE.PERSON.DEMOGRAPHIC DATA.DATE OF BIRTH DETAIL.DATE OF BIRTH ACCURACY INDICATOR
	Sex	SUBJECT OF CARE.PARTICIPANT.PERSON OR ORGANISATION OR DEVICE.PERSON.DEMOGRAPHIC DATA.Sex
	Address	SUBJECT OF CARE.PARTICIPANT.Address
		When Subject of Care is the Document Author DOCUMENT AUTHOR.PARTICIPANT.Address
	Communication Details	SUBJECT OF CARE.PARTICIPANT.ELECTRONIC COMMUNICATION DETAIL
		When Subject of Care is the Document Author DOCUMENT AUTHOR.PARTICIPANT.ELECTRONIC COMMUNICATION DETAIL
	Indigenous Status	SUBJECT OF CARE.PARTICIPANT.PERSON OR ORGANISATION OR DEVICE.PERSON.DEMOGRAPHIC DATA.Indigenous Status
Authorised Representative	Component	DOCUMENT AUTHOR
	Person Name	DOCUMENT AUTHOR.PARTICIPANT.PERSON OR ORGANISATION OR DEVICE.PERSON.PERSON NAME

Requirement Section	Data Item	SCS Data Element
	Person Identifier	DOCUMENT AUTHOR.PARTICIPANT.Entity Identifier
	Address	DOCUMENT AUTHOR.PARTICIPANT.Address
	Communication Details	DOCUMENT AUTHOR.PARTICIPANT.ELECTRONIC COMMUNICATION DETAIL
Allergies and Adverse Reactions	Component	Allergies and Adverse Reactions (ADVERSE REACTIONS)
	Allergies and Adverse Reaction	Allergies and Adverse Reactions (ADVERSE REACTIONS).ADVERSE REACTION
	Agent Description	Allergies and Adverse Reactions (ADVERSE REACTIONS).ADVERSE REACTION.Substance/Agent
	Reaction Description	Allergies and Adverse Reactions (ADVERSE REACTIONS).ADVERSE REACTION.REACTION EVENT.Manifestation
Medicines	Component	Medications (MEDICATION ORDERS)
	Medicine	Medications (MEDICATION ORDERS).Medication (MEDICATION INSTRUCTION)
	Item Description	Medications (MEDICATION ORDERS).Medication (MEDICATION INSTRUCTION).Medicine (Therapeutic Good Identification)
	Dose Information	Medications (MEDICATION ORDERS).Medication (MEDICATION INSTRUCTION).Directions
	Reason for Medicine	Medications (MEDICATION ORDERS).Medication (MEDICATION INSTRUCTION).Clinical Indication
	Additional Comments	Medications (MEDICATION ORDERS).Medication (MEDICATION INSTRUCTION).Comment (Medication Instruction Comment)
Document Control	Component	*This is described in the CDA Implementation Guide*

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