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National E-Health Transition Authority
Clinical Data Standards

National E-Health Transition Authority
Project #2

NEHTA Specifications - Guide For Use

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Associated Documents	
Title	**Description**
Priority Event Summaries and Code Sets, and Jurisdictional Gap Analysis	Final report for NEHTA Projects #1 to #4, and summary of jurisdictional analysis of clinical information requirements.
Index of NEHTA Specifications	Structured hierarchy of the priority data groups for use as an index.
Priority Event Summaries – Descriptions	For each of the event summaries identified as priorities for national standardisation, a description of the context, together with an indication of the clinical data groups that might be expected, and some indication of implementation considerations.
NEHTA Technical Specifications	Technical specification of the completed data groups using the NEHTA specification template (ISO 11179 compliant and expanded).
NEHTA Specification Template Reference Guide	User guide for the interpretation of NEHTA specifications. Defines and further clarifies the concepts in the NEHTA specification template.
NEHTA Specifications – Guide for Use	User guide to assist with the interpretation and use of NEHTA specifications by those involved in development, implementation or operation of systems.
NEHTA Specifications – Summarised Format	Extract of key elements from the NEHTA technical specifications that provide a high level view of content without the technical detail.
Draft NEHTA Specifications – Summarised Format	Provides a high level view of content for the draft data groups that are near completion.
Adverse Reaction and Alert Archetype Representations	Archetype representations of the Adverse Reaction and Alert data groups. Archetypes allow for direct use by software systems.

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1 INTRODUCTION

1.1 Document Purpose

This document is designed to assist with the interpretation and use of NEHTA data specifications by those involved in the development, implementation or operation of systems that generate or interpret event summary data pertaining to the health care of individuals. It also describes some of the theoretical foundations underpinning NEHTA specifications and some associated issues currently under debate. Where relevant, the document is also intended to give guidance on the status of other relevant NEHTA products and their place in the current health data standards landscape.

The following 12 priority events are considered:

- Initial Health Profile;
- Medical Consultation – General Practitioner;
- Medical Consultation – Specialist;
- Diagnostic Investigation – Imaging;
- Diagnostic Investigation – Pathology;
- Hospital Discharge – Inpatient;
- Hospital Discharge – Emergency;
- Pharmacy Provision;
- Community Based Health Consultation;
- Allied Health Consultation;
- Referral; and
- Event Notification (for example, admission to hospital).

1.2 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 Australian Standards for Health Messaging, and/or repositories of data specifications such as the Australian Institute of Health and Welfare's Knowledgebase, which houses the National Health Data Dictionary (NHDD).

1.3 Background to Specification Development

The term 'Event Summary' was coined by the National Electronic Health Records Taskforce to describe a contribution to a shared Electronic Health Record that records key information pertaining to a health care activity, such as a pathology test, a hospital stay, a GP visit, etc.

NEHTA, in consultation with a broad range of stakeholders has developed clinical data specifications to support 12 priority event summary types, identified in 2004. The project to undertake the specification development is described elsewhere, and a brief overview of the project is shown in Table 1 - Overview of Project # (below).

Project Title:	Develop the Prioritised Event Summaries
Required Outcome(s):	By 30 June 2005: National endorsement of data set specifications for the 12 priority EHR/clinical event summaries.

Project Title:	Develop the Prioritised Event Summaries
Deliverable(s):	A set of technical specifications providing for each of the prioritised event summaries.
Scope Issues:	Scope of Community-based Health and Allied Health event summaries to be determined.
Methods:	Targeted consultation with clinicians and other health professionals, clinical informaticians and other health data experts, and projects and organisations currently engaged in clinical data set specification and implementation.

Table 1 - Overview of Project #2

1.4 Data Group Development

1.4.1 Generic Event Summaries and Data Groups

The NEHTA consultations have identified a high degree of commonality between the data groups required for the 12 priority events. During the prioritisation of the priority events, several indicators suggested that identifying the data groups required for each event summary might be too constraining and limit the clinical utility of the event summary construct (given the number of clinical exceptions that could be identified). An alternative proposition would be to allow the data groups used within any event summary to be dynamically allocated/selected by the clinician in line with clinical preferences at the point of care. This would mean that an event summary could include any of the identified data groups. It was envisaged that such an approach would ensure clinical utility irrespective of the clinical scenario, and remove the need to gain consensus on the data groups required for each of the priority event summaries. It also prevents the proliferation of different event summary constructs over time. Such an approach was supported by the NEHTA Clinical Reference Group (CRG) meeting on 9 September 2004.

Table 2 (below) represents the multi-disciplinary CRG consensus view of which data groups are recommended for each of the priority event summaries (based upon the initial findings of NEHTA consultations with domain experts). The table demonstrates similarities between the data groups required for each of the priority event summaries.

Data Group \ Event	Initial Health Profile	Medical Consult -GP	Medical Consult -Spec	Hosp D/c -Inpatient	Hosp D/c -ED	Pharmacy	Comm Health	Allied Health	DI -Path	DI -Imaging
Alert	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Adverse Reaction	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Legal	✓	✓	✓	✓	✓		✓	✓	✓	
Problem/Diagnosis	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Complication (now part of Problem Diagnosis)		✓	✓	✓	✓	✓	✓	✓	✓	✓
Reason for Presentation		✓	✓	✓	✓		✓	✓		
Procedure/Treatment	✓	✓	✓	✓	✓		✓	✓	✓	✓
Medication	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Clinical Synopsis/Comment	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Diagnostic Investigation Imaging		✓	✓	✓	✓		✓	✓	✓	✓
Diagnostic Investigation - Pathology		✓	✓	✓	✓		✓	✓	✓	
Immunisation	✓	✓	✓?	✓	✓		✓			
Observation	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Other Investigation (new Data Group)	✓	✓	✓	✓	✓		✓	✓	✓	✓
Comprehensive Assessment	✓	✓	✓	✓		✓	✓	✓		
Functional Status	✓	✓	✓	✓	✓		✓	✓		
Management Plan	✓	✓	✓	✓	✓	✓	✓	✓		
Requested Service		✓	✓	✓	✓	✓	✓	✓		

Data Group \ Event	Initial Health Profile	Medical Consult -GP	Medical Consult -Spec	Hosp D/c -Inpatient	Hosp D/c -ED	Pharmacy	Comm Health	Allied Health	DI -Path	DI -Imaging
Current Service	✓	✓	✓	✓			✓	✓		
Care Team	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Lifestyle	✓	✓	✓	✓	✓	✓	✓	✓		
Social Circumstance	✓	✓	✓	✓	✓	✓	✓	✓		
Social Demographics	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Family Clinical History	✓	✓	✓	✓	✓		✓	✓	✓	
Discharge				✓	✓		✓	✓		

Table 2 - Data groups recommended for the priority event summaries

As a result of these findings, NEHTA's data development has focused on further refining priority data group specifications rather than priority event summaries.

The resulting data group/element/value domain specifications have been chosen primarily on the basis of **inclusion** to provide good clinical context, rather than on the basis of **exclusion** to meet short term implementation constraints. In this sense they can be considered more a maximum data set than a minimum data set. After extensive consultation and refinement, they have been chosen for their requirement for national specification, rather than as a prescriptive set for any given implementation.

For care planning and for decision support in particular, NEHTA considers these specifications as a valuable starting point, upon which jurisdictions can agree, and for which further selection, specification and refinement of appropriate terminologies and value constraints can continue.

2 UNDERSTANDING THE METAMODEL

The NEHTA Clinical Data Standards metamodel is used to specify the overall structure of an event summary. In general, clinical information is organised hierarchically according to *event summary*, *data group*, *data element* and *value domain*. Figure 1 (below) illustrates the relationships between the various metamodel components used in the NEHTA specifications and examples.

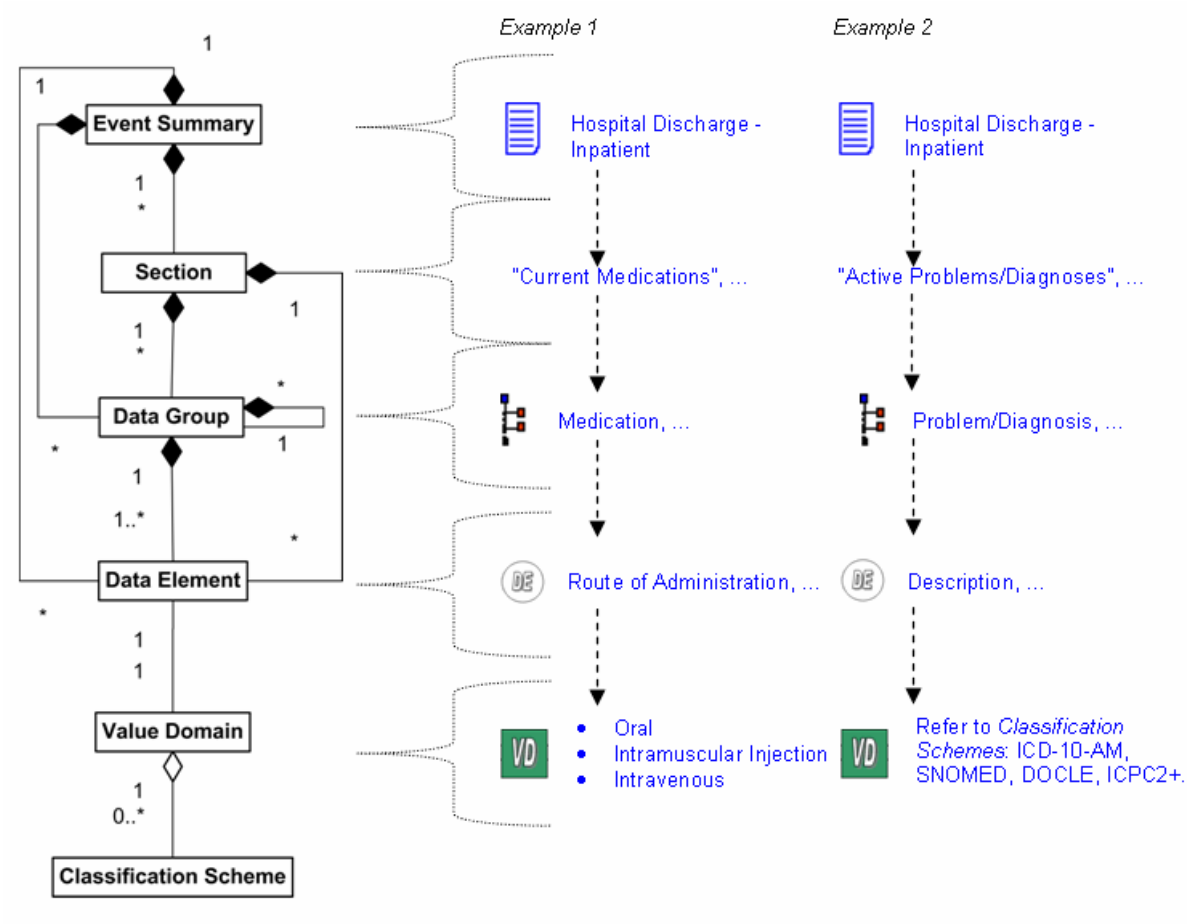


Figure 1 - High-level metamodel and examples.

2.1 Event Summary

An 'event summary' is a collection of consumer/patient health information derived from a healthcare event that is relevant to the ongoing care of that individual. These event summaries are composed of one or more data groups and/or possibly data elements, which are organised into section(s) (see Section 2.2 below). Examples of event summaries are *Hospital Discharge - Inpatient* and *Pathology Results*.

'Templates'[1] will need to be specified and standardised to build instances of event summaries at run-time. For event summaries, templates[2] will be used to generate the forms or user interface screens from which event summaries are viewed. An event summary is also validated against the template before it is received by an information system (e.g. a GP's system or a shared EHR repository) or before it is formed into a message and sent. This enables various systems to be able to generate event summaries in a consistent manner and also be able to interpret and view them as intended upon receipt. It also ensures the quality and validity of the clinical information being communicated.

[1] Full event summary specifications have not been developed by NEHTA CDS. See **Priority Event Summaries - Descriptions** for descriptive information of the priority event summaries.

[2] See *open*EHR resources: http://www.*open*EHR.org/ & http://www.openehr.org/downloads/archetypes/templates_and_archetypes.pdf

A template places constraints on the following:

- The event summary purpose;
- Allowable sections, data groups and/or data elements should be used to form an event summary for a specific purpose;
- The layout and any ordering of information items;
- Removes the optional information items that are not needed in the context of use (see Chapter 8 for discussion on the 'obligation' attribute in a given data structure);
- Selects the language and terminologies to be used from among those value domains that may refer to more than one classification scheme;
- Additional constraints such as the valid range of a value, units used, and modifying any existing constraints on information items such as minimum and maximum occurrence of data items, etc to suit specific contexts.

2.2 Section

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 health care providers. It should also ensure that it can safely be re-used for secondary purposes. A section also provides a way to navigate through the data items within an event summary, thereby enabling more efficient querying to be made.

A section may contain:

- The further set of allowable section classes or 'sub-sections'; or
- The set of allowable data groups and/or data elements that may be populated at run-time.

Further section constraints include the occurrence and obligation of these sub-sections, data groups and data elements. The default ordering of section components is as they appear in the specification.

A section does not alter the semantics or meaning of any of the data groups and/or data elements it contains. Examples of sections are *Care Team, Active Problems/Diagnoses* and *Current Medications*.

A section is defined by a *Section Heading* and constrains the valid set of sub-sections, data groups and/or data elements that can be contained within it. A section will contain pointers/logical referencing rather than actual values to its components and a section, data group and data element may be used in any number of sections. (See Section 7.2 for examples using sections).

2.3 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, ORGANISATION, and MEDICATION ITEM.

2.3.1 Hierarchical Data Group

Whilst a data group may simply consist of data elements, it may also be hierarchical such that it can contain nested data groups as well as data elements. (See Chapter 7 and the **NEHTA Specification Template Reference Guide** for further explanation). A hierarchical data group carries information such as:

- The relationships within the data group: children, parent(s), and potentially siblings, ancestors and descendants;
- The obligation and occurrence of its data components with respect to their corresponding parent;
- The hierarchical depth of the data components within their highest level data group structure; and

- Any ordering of its components. As a default, all NEHTA data specifications are presented in logical order, which is attained from the 'node order' metadata attribute value for each data item, e.g. *adverse reaction.provider identification.*

2.3.2 'Choice' Data Groups

A 'choice data group' is 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 indicated using a particular icon (see **NEHTA Specification Template Reference Guide**) in the hierarchical structure section of the NEHTA data specifications. A special type of metadata component could have been added to model a choice data group (possibly as an abstract class), however, for consistency NEHTA CDS have opted to specify this within the 'obligation' metadata attribute as a 'choice data group'. In this way, all data groups only refer to groupings of clinical content rather than abstract data groups to represent choice sets.

Choice data groups may require the system to prompt the user to manually select the appropriate data group to use via the application screen, e.g. by selecting from a combo list box. Alternatively, the data group chosen may be conditional on other data items being collected.

2.4 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 either simple or component. A data element that occurs as a member of a composite data structure is identified as a component data element. 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 [3].

The permissible values for a data element are constrained by a value domain (see Section 2.5). The same data element can be reused in any number of data groups. As such, a data element may *refer* to different value domains depending on the context it is used.

2.5 Value Domain

A 'value domain' constrains a data element's permissible values to a subset of those of its generic **datatype** (see Chapter 10). Value domains are reusable components, and therefore, the same value domain can be referred to by different data elements in different situations.

Value domains typically constrain by either specifying a lower and/or an upper bound on the range of permissible values or else specifying 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 (see Section 8.4). Table 3 (below) shows examples of value domains.

Data element	Datatype	Example of Value Domain
Severity	Coded text	"mild", "disabling", "life threatening"
Diagnosis	Coded text	Refer to terminology: SNOMED - CT

Table 3 - Value domain examples.

2.6 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

[3] Adapted from the Texas Department of State Health Services, *THCIC Hospital Discharge Data Collection, THCIC 837 Technical Specifications* (version 13), November 19, 2004.

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. [4]

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 the NEHTA CDS data specifications where they exist externally and are required in value domains.

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.

2.7 Alternative Metamodels

The **Specification Template Reference Guide** discusses the rationale for adopting the NEHTA metamodel described above. It contains a comparison with other metamodels with which the reader may be familiar, including ISO 11179, the Australian Institute of Health and Welfare's METeOR, and the *open*EHR Archetype model.

[4] As defined by ISO/IEC 11179.

3 ASSUMPTIONS

Demographics, administrative and financial data.

There are many point to point messages in healthcare that carry information related to patient and provider demographics and contact details, patient management, service delivery logistics and billing and other financial matters. NEHTA's role in developing specifications for clinical data representation and handling does not extend to these other domains of data. However, there may be circumstances where both clinical information and administrative/financial information is best sent in the same message. The current and emerging Australian Standards based on HL7 version 2 messages, described in Chapter 5, provide examples where this is often the case.

System Identifiers not included in the specifications.

Any individual item of data requires additional data to provide context and meaning. It is often both the naming of, and the relationship between data items that provides context. In addition, many clinical systems and information exchange mechanisms involve the use of unique identifiers to support the referencing of entities. These identifiers provide a shorthand label for a concept which is often more complex to explicitly name or describe. Examples include a prescription reference number to identify a medication prescription, a provider type identifier to refer to a category of healthcare provider, a LOINC code to describe a pathology test result component. The requirement for, and the scope of use of these identifiers can vary from implementation to implementation. NEHTA has taken the view that often such identifiers will be needed for system interoperability, but not necessarily for use by clinicians. Where there is likely to be a requirement for clinicians to directly use the identifier, i.e. enter into or read from a system, then NEHTA data specifications include them. Conversely, where there is unlikely to be any requirement for direct clinical involvement with an identifier, they have generally been excluded from the specifications. Readers of the NEHTA specifications should be aware that implementations may require additional identifiers for system use.

In the case of data elements that are supported by terminologies, such as *diagnosis*, *adverse reaction description,* etc, NEHTA data specifications usually expect valid clinical terms to be provided as data. In addition, where terminology codes exist, it is expected that they will be provided in event summaries. The datatypes provide support for this. However, NEHTA generally avoids naming such data elements as *diagnosis code*, or *adverse reaction description code*.

Data Group and Data Element Instances.

It is expected that data group and data element *instances* will require 'specialisation' to meet the additional requirements of some specific clinical settings or contexts. The methodology to be employed will be based on *open*EHR archetype specialisation, where the constraints of 'generic' data groups and data elements are conformed to, but additional constraints may be placed on them to create specialisations or 'sub-types' to have more contextualised use or meaning. Data items to support the recording of various pathology test results, as well as the IDENTIFICATION data groups and Date/time data elements are candidates for such specialisation.

4 MAPPING TO EXISTING REFERENCE INFORMATION MODELS

The specifications being developed by NEHTA are to support the clinical content of event summaries. As such, they are independent of any particular implementation technology. To be useful in a particular context, such as sending event summaries as messages to an EHR system, or storing clinical data in an EHR repository, specifications need to be mapped to a corresponding model used for that purpose. NEHTA has identified three prominent information models that can readily express the NEHTA information data groups. It should be noted that these are all considered potential candidates for storing and exchanging clinical information, but that none of the three have had extensive implementation validation to date. All three are based on emerging object oriented modelling architectures.

	Model			
Model Component	**NEHTA**	**CEN 13606**	***open*EHR**	**HL7 CDA**
	Event Summary	Composition	Templates, Composition	Clinical Document and Document Body
	Section	Section	Section	Document Section
	Data Group	Entry, Cluster	Entry, Cluster	Organiser Act, Entry Act
	Data Element	Element	Element	Entry Act attributes
	Value Domain, Classification Scheme		Ontology, Terminology	External Act

*Table 4 - NEHTA mapping to CEN 13606 and open*EHR *information models.*

In the short (1 to 3 year) timeframe, there will likely be a requirement for mapping NEHTA specifications to and from existing HL7 v2 based Australian Standards for healthcare messaging, such as AS4700.2 through AS4700.7. Mapping to these messaging standards is addressed in Chapter 5 of this document.

4.1 CEN 13606 EHR Extract Model

Since 1996, the European Standardisation of Health Informatics has been developing a specification to represent and exchange extracts from Electronic Health Records based on a standardised generic model. The pre-standard describes such extracts in terms of a hierarchical structure as outlined in Figure 2 - CEN 13606 EHR Extract (below). This model organises the EHR extract into a standardised structure that can be used to exchange an individual's EHR information between providers, such that clinical context and provider attestation is ensured.

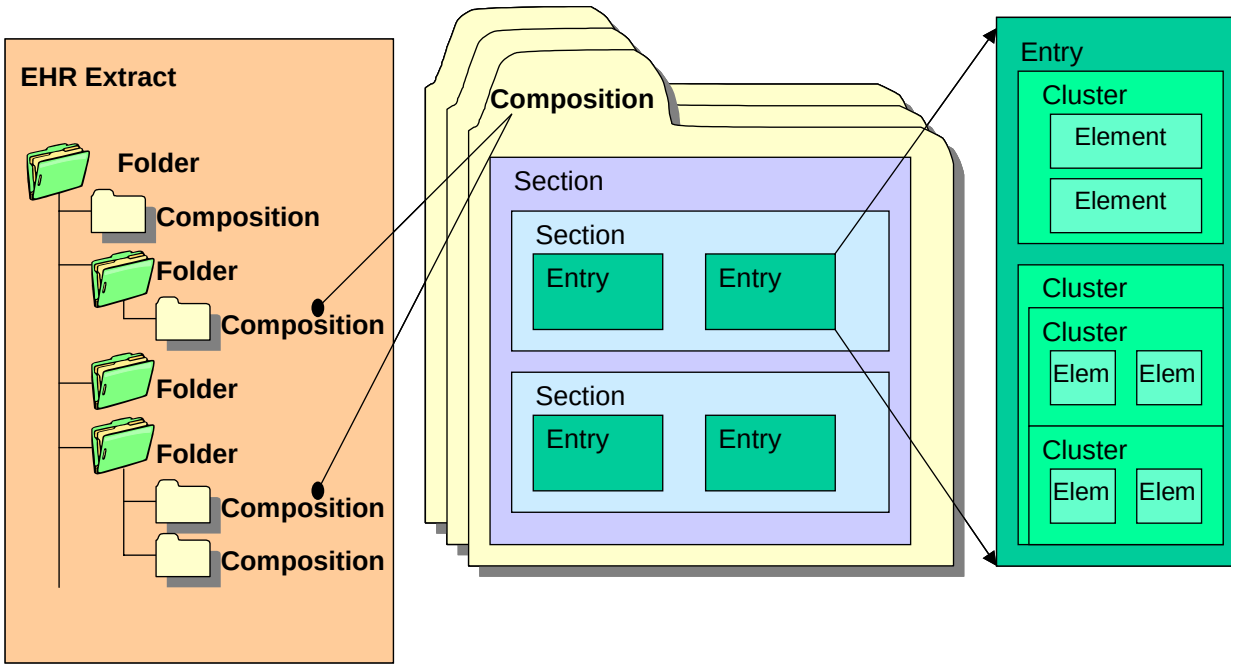


Figure 2 - CEN 13606 EHR Extract Structure

The mapping of Event Summary specifications to the CEN 13606 structure is described in Chapter 7.

4.2 *open*EHR ARCHETYPE Model

The *open*EHR Foundation has adopted a 2 tier model for expressing clinical information according to agreed archetypical representations. These archetypes use basic building blocks, such as generic clinical structures, datatypes and terminologies to construct templates for representing more complex concepts, similar to the NEHTA clinical data groups. Moreover, *open*EHR archetypes provide support for constraining the values, required data elements and certain relationships, to agreed sets or ranges. Although aimed primarily for EHR systems, archetypes provide a mechanism for capturing, representing, validating and storing related clinical information. When used in conjunction with CEN 13606 EHR extract model, archetypes can be used to provide a standardised representation of clinical information.

The mapping of NEHTA data group specifications into archetypes is seen as a logical step in reducing the amount of, and variability in human interpretation of specifications by software developers, leading to better interoperability of heterogeneous systems. Since archetypes have a formal representation that constrains a software reference model (the *open*EHR Reference Model[5]) they can be interpreted directly by software systems, and data conforming to agreed archetypes can be serialised into messages based on several technologies, including XML.

4.3 HL7 CDA Model

Health Level Seven's (HL7) Clinical Document Architecture[6] (CDA) is a developing standard used for representing a clinical document's content for both human viewing as well as for computer processing. It is included here because it is being touted as a methodology for clinical systems to readily construct human readable electronic documents with minimal requirements for structured data in the short term, whilst providing a migration path for fully structured data representation in the future. Clinical documents formatted according to CDA Release 2 can be represented at three levels of semantic 'standardisation'.

[5] Available free from The *open*EHR Foundation at http://www.openehr.org

[6] Available to HL7 members at http://www.hl7.org

Section: Each section can contain a single narrative block, and any number of CDA entries and external references. A narrative block contains the human readable content to be rendered, whereas CDA **Act** entries represent structured content provided for further computer processing, e.g. decision support applications. CDA **Act** entries typically encode content present in the narrative block of the same section.

Organizer: A derivative of the HL7 v3 RIM **Act** class, which can be used to create arbitrary groupings of other CDA entries that share a common context. An organiser can contain other organizers and/or other CDA entries, by traversing the component relationship. An organiser cannot be the source of an **entryRelationship** relationship.

Note: CDA entries such as **Observation** can also contain other CDA entries by traversing the **entryRelationship** class. There is no requirement that the organiser entry be used in order to group CDA entries.

5 HL7 VERSION 2 MESSAGES

This chapter describes the process and some of the issues associated with the use of HL7 v2 messages to transmit data conforming to NEHTA specifications between two or more systems. A number of areas of health care in Australia have adopted HL7 v2 messages for the exchange of clinical information, most notably for pathology results and e-referrals. In many cases these messages are based on current Australian Standards, specifically those shown in Table 5 (below).

AUSTRALIAN STANDARD	DESCRIPTION	FIRST ISSUED	CURRENT ISSUE	HL7 VERSION
AS4700.1	Implementation of Health Level Seven (HL7) Version 2.3.1 Part 1: Patient administration	1997	2001	2.3.1
AS4700.2	Implementation of Health Level Seven (HL7) Version 2.3.1 Part 2: Pathology orders results	1998	2004	2.3.1
AS4700.3	Implementation of Health Level Seven (HL7) Version 2.3 Part 3: Electronic messages for exchange of information on drug prescription	1999	1999 2004 (draft, based on HL7 v2.4)	2.3
AS4700.5	Implementation of Health Level Seven (HL7) Version 2.3.1 Part 5: Immunisation Messages	2002	2004 (draft, based on HL7 v2.4)	2.3.1
AS4700.6	Implementation of Health Level Seven (HL7) Version 2.3.1 Part 6: Referral and discharge summary	2004	2005 (draft, based on HL7 v2.4)	2.3.1
AS4700.7	Implementation of Health Level Seven (HL7) Version 2.3.1 Part 7: Diagnostic imaging, orders and results		2005 (draft, based on HL7 v2.3.1)	

Table 5 – Australian Standard HL7 v2 messages

Standards Australia augments the above standards with handbooks, which explain how to implement the standards, and in some cases, constrain aspects of the corresponding standard. The accompanying handbook effectively becomes a proxy standard for some detailed application requirements. A Message Usage Model (handbook HB172), recommended for development in 2000 by the National Electronic Health Records Taskforce, is nearing completion. Although broader in scope than HL7 version 2 messages, it complements the above standards and handbooks with a high level view of the health care messaging landscape both as it is now, and into the foreseeable future.

Rather than repeating the information contained in the above standards and handbooks, this chapter focuses on specific areas of the NEHTA clinical data standards that are impacted by the use of the current messaging standards.

5.1 Shortcomings of HL7v2 for clinical data transfer

HL7 version 2 is a messaging standard that was developed many years ago and suffers from the fact that the model of the clinical information that the message is designed to carry (the payload), is inextricably tied up in the structure of the message. It is in fact, defined by the message. There is no information

model that lives beyond or external to the message. Each individual message specification defines its own information model. There is no separation of concerns between the clinical information and the message structure, as there is in more modern and advanced messaging paradigms. A message to describe medication orders may make reference to a *problem* or a *diagnosis*, but there is no standardised way to describe problems or diagnoses across different message types, such as for an immunisation or a hospital discharge message. NEHTA has taken the approach of specifying the information model, independent of the messaging model. In order to use a particular HL7v2 message format to send NEHTA-specified clinical information, it becomes necessary to map each NEHTA data element to a corresponding HL7 field in a specific HL7 segment. This process has to be done for each data element on a message by message basis.

The situation is further complicated by the fact that there are many ways in which data can be mapped to HL7 message segments. Specific Australian Standards constrain these mappings to a certain extent, but there is still flexibility in the way clinical data, in particular, can be represented. This flexibility leads to implementations that are only partially interoperable at the semantic level.

5.2 Standards Overlap and Conflict

Each Australian standard for eHealth messaging has been developed by a separate group of volunteers focused on a specific requirement. The development of each standard has evolved over time, with each message specification changing in some aspect with each release. The result of this development process is that each message specification overlaps or conflicts in some respect with data elements or data element representation expressed in other message specifications. It is perfectly reasonable and expected that the way we wish to record clinical events and findings might vary over time, but problems arise when we have similar information being captured and represented differently because of differences in message specifications, particularly when those message specifications take considerable time to change. The greater the number of such dedicated message specifications developed, the greater the potential for overlap and conflict.

The specification of clinical content by NEHTA, irrespective of message specifications, is an attempt to overcome this problem. Retrofitting agreed clinical data specifications to highly specific message specifications should be seen as a short term expediency to support interoperability with existing systems, whilst the world moves to a newer, more flexible messaging paradigm.

5.3 Levels of specification and constraint

NEHTA clinical data specifications are organised in a hierarchical fashion, from high level data groups dealing with specific related data items, through individual data elements, down to specific value domains and low level constraints. The mechanism by which these different levels of specificity are addressed in event summary specifications is discussed in Chapter 7.

5.4 When a specification cannot support certain data

Several circumstances can arise where specifications are inadequate to accurately and completely convey desired clinical meaning. One circumstance is where the NEHTA clinical data specifications have no corresponding data element name. A second is where the data element exists, but the specified value domain, e.g. terminology, does not contain an appropriate value. The third arises where the clinical data specification cannot be mapped into an appropriate messaging standard because the latter is unable to represent the required data item or value. NEHTA is overseeing the establishment of new clinical specifications governance processes that will expedite the resolution of such issues, with fast turn around of data specifications and terminologies to meet evolving Australian requirements.

5.5 Compliance to Standards

The Australian Health Messaging Laboratory (AHML), housed in the Centre for Collaborative Health at the University of Ballarat, provides a service to test some HL7 version 2 messages for compliance to relevant Australian Standards. AHML is accredited by the National Association of Testing Authorities (NATA), and can furnish compliance certificates to providers of standards-compliant messages.

5.6 Specific Data Groups

The following discussion relates to the mapping of specific NEHTA clinical data groups to corresponding Australian Messaging standards. The more general issue of the use of clinical data specifications within Event Summaries and EHRs is discussed in Chapter 8.

5.6.1 Medications

The Pharmacy Provision summary can be represented using the soon to be published revised *AS4700.3 Electronic messages for exchange of information on drug prescriptions* standard based on the HL7 v2.4 RDS Pharmacy Dispense segment. However, current Medi*Connect* trial implementations implement this event summary using the HL7 RDE Pharmacy Encoded Order segment.

5.6.2 Pathology

The Diagnostic Investigation – Pathology summary can be represented using the AS4700.2 Pathology result standard based on the HL7 v2.3.1 ORU message type. Additionally, a Handbook for Pathology electronic messaging (HB262-2002), published by Standards Australia, provides implementation guidelines for pathology messaging between pathology providers and health service providers.

A status flag in the HL7 message indicates the state of both the Order Result (OBR-25) and the Observation Result (OBX-11). Some of the common values for these status flags include Provisional, Final and Corrected. These values can be used along with the Results Report/Status Change Date/Time (OBR-22) to assist in determining in new versions of the event summary. A Provisional result can be updated with a Final result and subsequently updated with a Corrected result. However, a Final result should not be updated by a Provisional result, as is the case with a Corrected result updated by a Final result. The Results Report/Status Change Date/Time (OBR-22) should be used to distinguish between two Provisional or Corrected results while there should only be one final result. As can be determined by this complex discussion, the versioning of Diagnostic Investigation summaries using the ORU message is not ideal and improved solutions should be sought.

The AS4700.2 standard uses 'Austpath' codes to standardise the names of tests, and the names of result components. The latter is based on the laboratory section of the LOINC (Logical Observation Identifiers Names and Codes) standard developed at the Regenstrief Institute in the USA, which provides a six axis coordinated naming structure, represented by unique codes. This is discussed in Section 8.4.

5.6.3 Diagnostic Imaging

The Diagnostic Investigation – Imaging summary can be represented using the soon to be published AS4700.7 Diagnostic imaging results standard based on the HL7 v2.3.1 ORU message type.

A status flag indicates the state of both the Order Result (OBR-25) and the Observation Result (OBX-11). Some of the common values for these status flags include Provisional, Final and Corrected. These values can be used along with the Results Report/Status Change Date/Time (OBR-22) to assist in determining in new versions of the event summary. A Provisional result can be updated with a Final result and subsequently updated with a Corrected result. However, a Final result should not be updated by a Provisional result, as is the case with a Corrected result updated by a Final result. The Results Report/Status Change Date/Time (OBR-22) should be used to distinguish between two Provisional or Corrected results while there should only be one final result. As can be determined by this complex discussion, the versioning of Diagnostic Investigation summaries using the ORU message is not ideal and improved solutions should be sought.

5.6.4 Discharge Referral

The majority of the Referral can be represented using the AS4700.6 Referral and Discharge Summary standard based on the HL7 v2.3.1 REF message type.

The REF I12 trigger event is used to indicate a new referral while the I13 trigger event is used for modifications of the original referral. This I13, modify referral trigger, can also be used by the referred to

provider to update the status of the original referral, such as, indicating that the Referral has been accepted and an appointment scheduled. The I14 trigger event is used when the referring party cancels the referral, perhaps because the scheduled appointment was not appropriately prompt.

The Referral is different to event summaries where it needs to support the ability of the referred to provider to respond to the request for providing care service for a consumer. An acceptance or rejection of the referral can be indicated using the HL7 V2 Modify Referral message as described above or specific message designed for the purpose, as is the case in HL7 V3.

A HL7 V2.4 edition of the AS4700.6 standard will be released for public comment during 2005 and is expected to be published by the end of that year. This new edition will provide additional support for the Referral data groups, but will not be provide complete support.

A HL7 V3 message is being balloted as a Draft Specification for Trial Use (DSTU) within the HL7 organisation. It is expected that this Care Transfer message will provide sufficient support for the entire data group requirements of Referral.

6 INTEGRATING THE HEALTH ENTERPRISE (IHE)

Integrating the Health Enterprise (IHE) is an international initiative to enunciate a set of standards to support end-to-end sharing of information for particular health settings or purposes. It does this by producing Technical Frameworks for those particular health settings/purposes. The Frameworks developed to date have included Radiology, Laboratory, Cardiology and Cross-Enterprise Document Sharing. Each Framework comprises a set of **Integration Profiles** and a set of corresponding **Transactions**.

IHE **Integration Profiles** offer a common language that healthcare professionals and vendors may use in communicating requirements for the integration of products.

IHE **Transactions** are interactions between actors (information systems or components) that transfer the required information through standards based messages.

IHE has been embraced by vendor and other groups in both the USA and in Europe. It has been canvassed as an integration approach in Australia, by Standards Australia and by HL7 Australia, but no commitment has been undertaken by either body to adopt the methodology.

The primary feature of IHE is also its primary shortcoming. The approach employed by IHE is not to define new integration standards, but rather to support the use of existing standards – initially DICOM and HL7, but potentially others. By committing to any one existing standard, there is an assumption that such a standard (defined for one purpose) is appropriate for the broader range of integration functions envisaged by the integration profiles. Further analysis of each underpinning standards needs to be carried out to avoid excessive integration costs, and to determine if there are significantly better building blocks on which to base messaging components.

It is preferable for Integration or Interoperability frameworks to be built on components which are compatible, i.e. designed to cooperate, or at least be able to cooperate, rather than from a set of standards which have to be manipulated into cooperation through burdensome mappings and complex interfaces.

NEHTA is undertaking an analysis of potential technical integration issues and expects to release an Interoperability Framework in 2005/2006.

7 ORGANISING CLINICAL CONTENT

When recording or exchanging clinical information it is important to preserve the clinical context and the relationship between data as accurately as possible. This chapter looks at mechanisms that are used to logically structure data and how that might translate into an example which a clinician might view on a screen.

7.1 Logical Data Structures

The purpose of logical data structures is to facilitate more efficient querying of data and display or presentation on screen, of the data in its intended form. Ideally, these data structures should be standardised to achieve interoperability between systems as they are sent and received. The *open*EHR Data Structures Reference Model specifies various data structures which could be used as a standard. Examples of these data structures are discussed below.

A simple data structure has a flat structure. For instance, a data group that consists only of data element(s) is a simple data structure. Simple data structures are typically implemented as a *list* of named or numbered data elements, see Figure 3 (below) for example list structure of the Alert data group, or as a named *single valued* data structure.

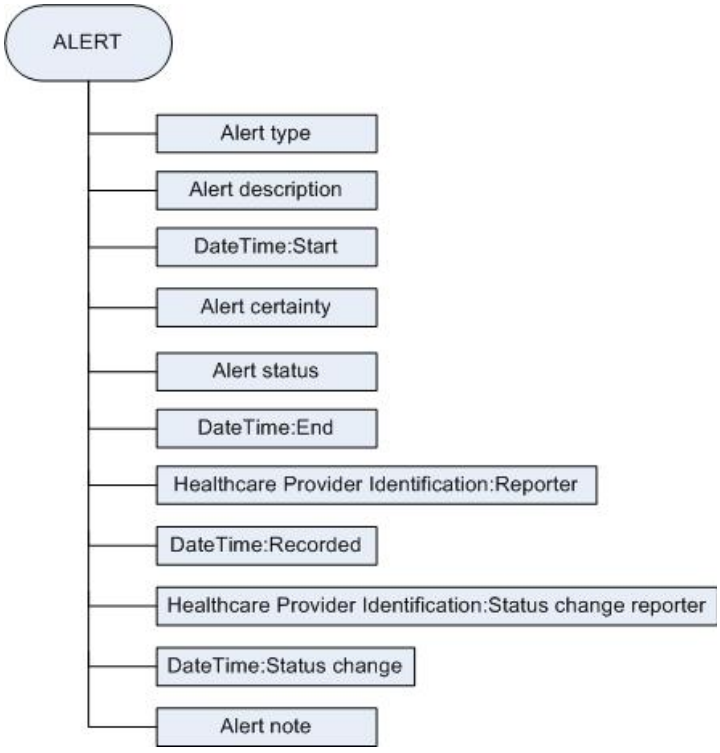


Figure 3- List representation of the Alert data group

Clinical information often requires the use of hierarchical data groups rather than data groups consisting simply of data elements. Hierarchical data groups contain nested data groups as well as data elements. An event summary is typically viewed as a complex data structure such that it can contain one or more data groups, which themselves may be hierarchical. For example an ADVERSE REACTION data group may contain a PROVIDER IDENTIFICATION data group (that has data elements such as ID, name, contact details, etc) for recording information about the provider who reported the adverse reaction.

Complex data structures may be implemented in a number of ways:

- *Tree* of values. Figure 4 (below) shows the tree structure for the MEDICATION data group. It shows only the sub-data groups that occur in the hierarchy, but it can be expanded to show the various data elements within the sub-data groups.

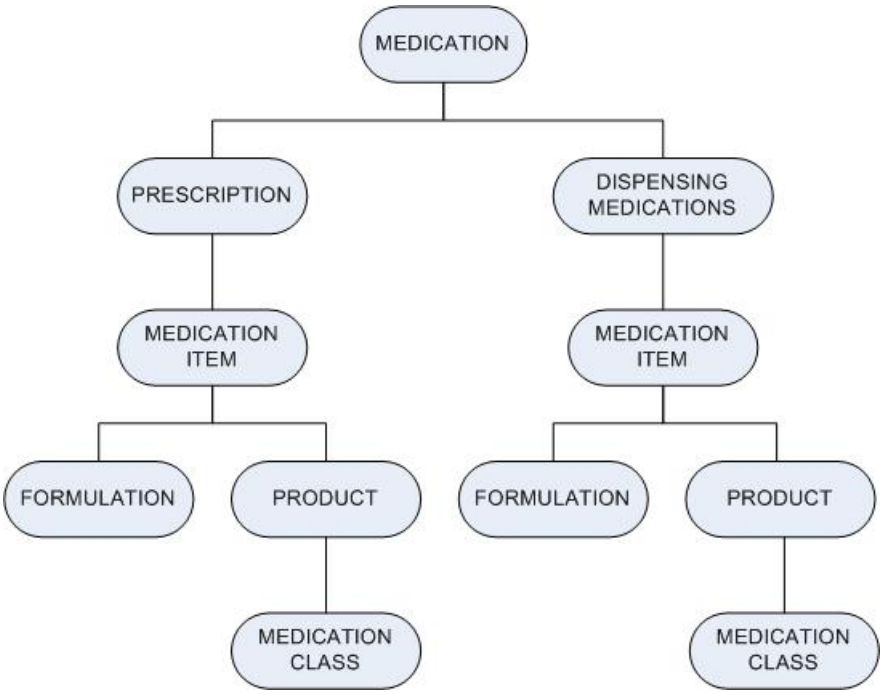


Figure 4 - Tree representation of the Medication data group

- *Table* of values with named columns and/or named rows. (See example of using the PATHOLOGY data group to represent a *Full Blood Examination* as a table structure in Table 6).

7.2 Context-specific organisation of clinical content

The way that information items are organised can vary depending upon the context in which it is used, and how it will be used. Event summaries may present/communicate information in various ways using templates (discussed in Section 2.1), which place constraints on sections and data structures to be used to organise data groups and data elements. Figure 5 (below) and Figure 6 (below) illustrate examples of how the MEDICATION data group may be used and presented in various use cases – the first one being a prescription followed by a representation of a current medications list. Medication/Prescribing history would have a similar list structure with the additional column indicating the cease date.

Presentation/display of clinical content may include data *values* that are viewed. This may vary to be more context-specific and/or appear more 'user-friendly'. For example, the event summary specification may have additional constraints to specify which date and time format to use. Another example might be the display of a generic or 'virtual' medicine name value – one might have the option to display only the common, shorter name rather than the full name, which is attainable from terminology servers.

The ordering of information items can be specified for event summaries. In Figure 5 (below) for example, the MEDICATION ITEM list within PRESCRIPTION is ordered according to ascending Prescribing line item reference. There may also be cases where the ordering of items is constrained to be *fixed* at all times such that it cannot be sorted in any other order other than the one specified.

While the names of data groups and data elements provided in the NEHTA data specifications may be used as event summary section headings and field entry 'labels' consecutively, they are relatively generic to support reusability. Therefore, different names may be used to be more context-specific and user-friendly. (See Section 11.1 for discussion on design-time and run-time names).

PRESCRIPTION <SECTION>								
Prescription reference		740522						
PRESCRIBER <SUB-SECTION>								
<LIST>	Name	Dr. P. SCRIBER						
	Organisation	Basketville Central Clinic						
	Address	7 Marks St, Adelaide, SA 5000						
	PBS approval number	12345						
	Provider number	7654321X						
PATIENT Details <SUB-SECTION>								
<LIST>	Name	Jean Kim CITIZEN						
	Address	777 Camomile Boulevard, Basketville						
Date prescribed		01/02/2005						
Prescription expiry		05/2005						
Type of prescription		PBS						
MEDICATION ITEMS <SUB-SECTION>								
	Prescribing line item reference	**Generic Name**	**Brand Name**	**Strength**	**Form**	**Dose**	**Frequency**	**Route**
<LIST>	Item 1	Amoxicillin	Amoxil	500 mg	Tablet	1	Three times daily	Oral
	Item 2	Captopril	Capoten	25 mg	Tablet	1	Twice daily	Oral
Prescription note:								

Figure 5- Medication prescription.

CURRENT MEDICATIONS LIST <SECTION>										
		Generic Name	**Brand Name**	**Strength**	**Form**	**Dose**	**Frequency**	**Route**	**Instructions**	**Date ordered**
<LIST>	1	Amoxicillin	Amoxil	500 mg	Tablet	1	Three times daily	Oral	Before meals	05/2005 see Script>>
	2	Captopril	Capoten	25 mg	Tablet	1	Twice daily	Oral	-	04/2005 see Script>>

Figure 6 - Current medications list.

8 HOW TO USE DATA ITEMS IN AN EVENT SUMMARY

For any given event summary, the actual data that might be supplied can vary significantly. It is almost impossible to determine which particular information items might be relevant to a given healthcare event. The data groups provide a method to organise data elements that relate to the same broad topic. Within these data groups there are data elements that are considered likely candidates for inclusion in an event summary, should information pertaining to the group as a whole be deemed to be relevant. The data groups can be considered as a checklist of priority areas for inclusion in a given summary. Within any data group, the specification data elements can be considered as a checklist for inclusion. Ultimately it will be up to the clinician, in combination with his/her clinical information system and local practice/policy rules to determine which data should be provided in a given clinical context.

However, the specifications identify four classes of data elements:

- **Essential** - Indicates that the data item is considered to be a core component of information and required in order for the entry to make sense. For example, Alert without an Alert description does not make sense.
- **Desirable** - Indicates 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** - The data item may be supplied if required within a context, and if the data is available. However, it is not necessary to provide the data in order for the data entry to make sense to a broad audience. It is recognised that for more complex or specialised healthcare provider settings, some items deemed optional may be viewed essential to them. The design of such more complex specifications via archetype specialisation will be included in the next phase of NEHTA specification development.
- **Conditional** - 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).

This chapter canvasses a range of issues likely to be encountered by developers and implementers when trying to match data specifications with specific contextual use in event summaries. It covers general areas such as default values, data/time specifications, terminologies, as well as specific areas related to medications, pathology, diagnostic imaging, alerts and adverse reactions.

8.1 Default Values

In any particular implementation, user interfaces are often improved by the use of default values to pre-populate fields in input forms. The business rules determining what such default values should be are likely to be context specific. Future versions of these specifications, based upon archetypes, may include default values for some data elements, where agreement can be reached on defaults which are clinically safe in a broad range of cases.

8.2 Date and Time

Dates and times are critical for providing clinical context for findings and events. Date and time form a continuum. Sometimes, health care providers need to capture a complete date and time combination, or timestamp. Other times they only require a date, or sometimes, only a time, independent of the date is required. Sometimes, a partial or an estimated date is required, the former to explicitly indicate approximation, e.g. some future test, the latter because of lack of information (an event which occurred in the past). All of these possible date representations are supported through the generic datatype described in the specifications as DateTime. The ability to constrain DateTime values to, say just date, is an important feature required of implementations, and for which an archetype methodology will provide. Further discussion on datatypes can be found in Chapter 10.

8.3 A Note on "notes"

During the development of these specifications, there has been considerable debate as to the wisdom or meaning of specifying free text data elements, especially those labelled "notes". Some have argued that it runs counter to the very notion of standardisation. The developers of the specifications have considered these arguments, and decided there is merit in articulating specific instances where free text is likely to be required either because there is no alternative method for clinicians to express their concepts, or where additional information might be required to qualify other "standardised" representations being reported. If nothing else, it provides a specification for names of fields in event summaries (and therefore EHRs) that can provide paths to the information for later retrieval and presentation.

8.4 Value Domains and Terminologies

Apart from numerical values such as quantities, dates, times and durations, the values of many data elements in any event summary or EHR are often expected to come from a predefined set. By ensuring specified names, spellings, etc, this facilitates electronic decision support, the expression of queries for searching EHRs and the filtering of results based on certain values. Sets of such predefined values are variously referred to as nomenclatures, vocabularies, terminologies, classifications, code sets or term sets. The distinctions between these related, but overlapping concepts vary from the subtle to the profound. In this document, we differentiate between value sets, which are "internal" or local to the data element, e.g. for severity of an adverse reaction, and values which come from large "external" reference terminologies such as SNOMED-CT, ICPC2+, AMDT, etc.

8.4.1 Terminologies and Electronic Decision Support

In some cases, such as the reporting of pathology results and other observations, the **name** of the finding being reported, as distinct from its **value**, will likely need to come from a reference terminology, such as SNOMED-CT or LOINC. This is because there are far too many types of findings to specify a dedicated data element for each one. Decisions about choosing dedicated data elements to represent findings, versus choosing names from terminologies to fill generic observation data elements, will need to be considered further in the light of requirements for electronic decision support. Another issue is the matching of names in terminologies to those used in Clinical Guidelines. For example, there is no observation name in the LOINC laboratory codeset for "HbA1c", a label which appears frequently in Australian guidelines for diabetes management. "Australianisation" of US-centric terminologies, if only to support Australian spelling, will need considerable resources before the benefits of electronic decision support can be realised. Changes to existing Australian messaging standards, changes to the codesets recommended therein, or the adoption of alternative messaging standards, will be required.

8.4.2 Coded Values

Most clinical terminologies use an alpha, numeric, or alphanumeric code to uniquely identify each concept. This allows for alternative spelling, alternative language or alternative meaning(s) of a given term or rubric. It also allows for complex phrases or combinations of concepts to be represented by a single, short identifier, sometimes called a "code phrase". The latter of these, a combination of several concepts into a compound concept is referred to as "pre-coordination", and is a principal reason for some terminologies having huge numbers of terms. A discussion of this in the context of LOINC appears below in Section 8.4.3.

In order to manage the use of coded values in eHealth communication, it is desirable to capture the textual name or meaning used by the clinician, together with the code and an identifier of the terminology system, including the version. This is particularly important for longitudinal health records where terminology systems might vary considerably over the life-span of an individual's EHR.

As a general approach throughout the NEHTA data element and value domain specifications, the **identification of actual codes has been avoided**. This has been done to reduce the proliferation of yet more codes, until such time as both a unified national approach to terminology and a unified national approach to eHealth messaging have been developed and endorsed. The existing Australian Standards for HL7v2 messages already provide codes for many of the data element's value domains, and where they do not, there is significant NEHTA standardisation activity occurring during 2005-2006. Across existing

Australian Standards, there are coding conflicts. Sometimes the values of the same data element are represented by different codes across different standards. New codes should not be allocated and propagated without careful analysis and justification.

8.4.3 Logical Observation Identifiers Names and Codes (LOINC)

LOINC was initially established by the Regenstrief Institute to standardise and codify the names of laboratory test results. It has been extended to cover other clinical observations and to support the naming of sections in clinical notes generally. LOINC has been adopted extensively for reporting findings in HL7 v2 messages. It has also been incorporated into SNOMED, with each LOINC code being mapped to a corresponding, dedicated SNOMED code.

For laboratory results, a unique code is assigned to a result name based on 6 components, as follows:

<analyte/component>:<kind of property of observation or measurement>:<time aspect>:<system(sample)>:<scale>:<method>

Moreover, some of the six components can be further divided into subcomponents. Thus, each LOINC code represents a complex, pre-coordinated concept. For systems, and therefore humans, to make sense of a given code, they need to understand the composite structure. There are two main advantages for encoding laboratory result names in this fashion. Firstly, the codes are language independent, and therefore capable of being mapped into representations in other languages. Secondly, they could reduce the amount of information that needs to be transmitted "across the wire" in messages.

One disadvantage with pre-coordinated coding, is that all receiving systems need to interpret the code, and understand the component axes which LOINC uses.

The Australian Standard *AS4700.2: Pathology orders and results* encourages the use of local descriptions to be sent. Thus,

```
789-8^Red Cell Count^LN^RCC^Red Cell Count^NATA1234.
```

would be sent in lieu of the default HL7 standard of:

789-8, representing the concept LOINC pre-coordinated concept

```
ERYTHROCYTES:NCNC:PT:BLD:QN:AUTOMATED COUNT.
```

It might be practical for pathology laboratory systems to handle the generation of encoded data based on LOINC, but the situation is more problematic for potential receiving systems such as GP clinical information systems and EHR systems such as Health*Connect*, which need to be able to interpret many coding systems to support interpretation of medications, allergies, problems/diagnoses, procedures/treatments, etc. The greater the variability, and the greater the complexity of these coding systems, the more complex the software needs to be in order to handle these diverse coding systems.

The process of representing NEHTA clinical data specifications as archetypes is viewed as a potential mechanism for shifting the clinical complexity embodied in coding systems such as LOINC, out of the terminology and into the information structures designed to carry the data. These data structures are more closely allied to the software systems processing the data. The right balance between terminology complexity (particularly pre-coordination), versus information model complexity (as expressed in data elements or archetypes), is something that will evolve over time, and as we gain more experience with sharing information between heterogeneous systems. Other significant factors that will influence where this balance should occur, are the technical requirements to enable electronic decision support, where data pertaining to an individual needs to be matched against clinical knowledge in evidence-based guidelines.

8.4.4 Linking to terminologies during data entry and EHR queries

In order to input data or perform data queries in a clinical setting, the provider's clinical information system will need access to the specification terminologies at the time of interaction. Health care providers should see the process of data entry as independent of any particular terminology architecture, but they may need a mechanism for navigating to appropriate terms in as an efficient manner as possible. The strong coupling between the data element for which a value is being sought and the underlying

terminology necessitates a uniform approach to terminology representation, governance and promulgation. NEHTA is currently developing a strategy to ensure this.

8.5 Linkages between items of information

The relationship between information items should be made explicit such that a clinician can reconstruct the complete context that was captured at a particular point in time and subsequently make informed decisions. Moreover participants can understand previous events in the care process, the possible next steps to be done and the context behind them, therefore enable efficient service coordination. In general, the *real-world* healthcare process implies the way information should be linked as shown in Figure 7.

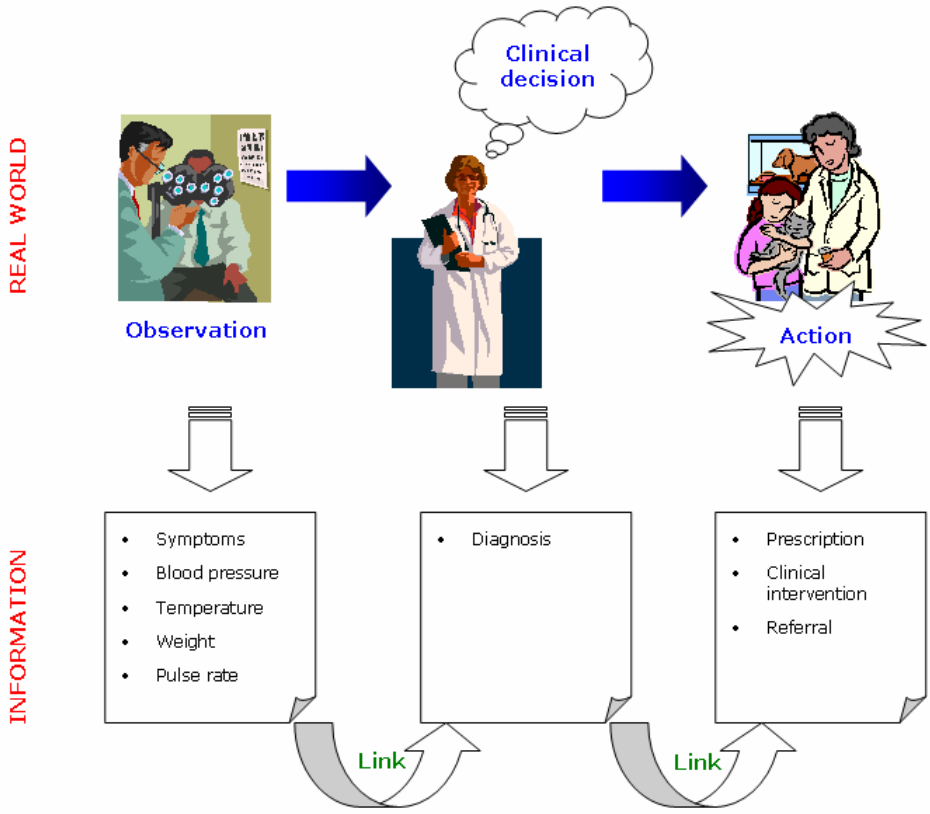


Figure 7 - Information linking

Types of relationships can be defined according to a number of facets. Relatively simple relationships in clinical content include:

- Timing or sequencing of activities such as observation history and prescribing history;
- Grouping by service type such as tests, procedures, GP consultations, hospital admissions and referrals;
- Grouping by patient's medical profile such as allergies, alerts, current medications, immunisations, active problems/diagnoses, family history; and
- Grouping by role such as GP, pathology, specialist, allied healthcare provider, carer.

Complex relationships in clinical content include:

- Relating a medication to a diagnosis;
- Relating a diagnosis with observations; and
- Relating an adverse reaction to a medication.

Over time, a series of event summaries and messages are created for a subject of care, and in order for these to be retrieved in a manner that is useful for end-users, they must be stored in a persistent manner

within a shared EHR repository with linkages to organise the data in a structured way as shown in Figure 8 (below). From a system perspective, the ability to link related items of information allows:

- Support for efficient and handling of complex querying;
- Change and version management; and
- Electronic decision support.

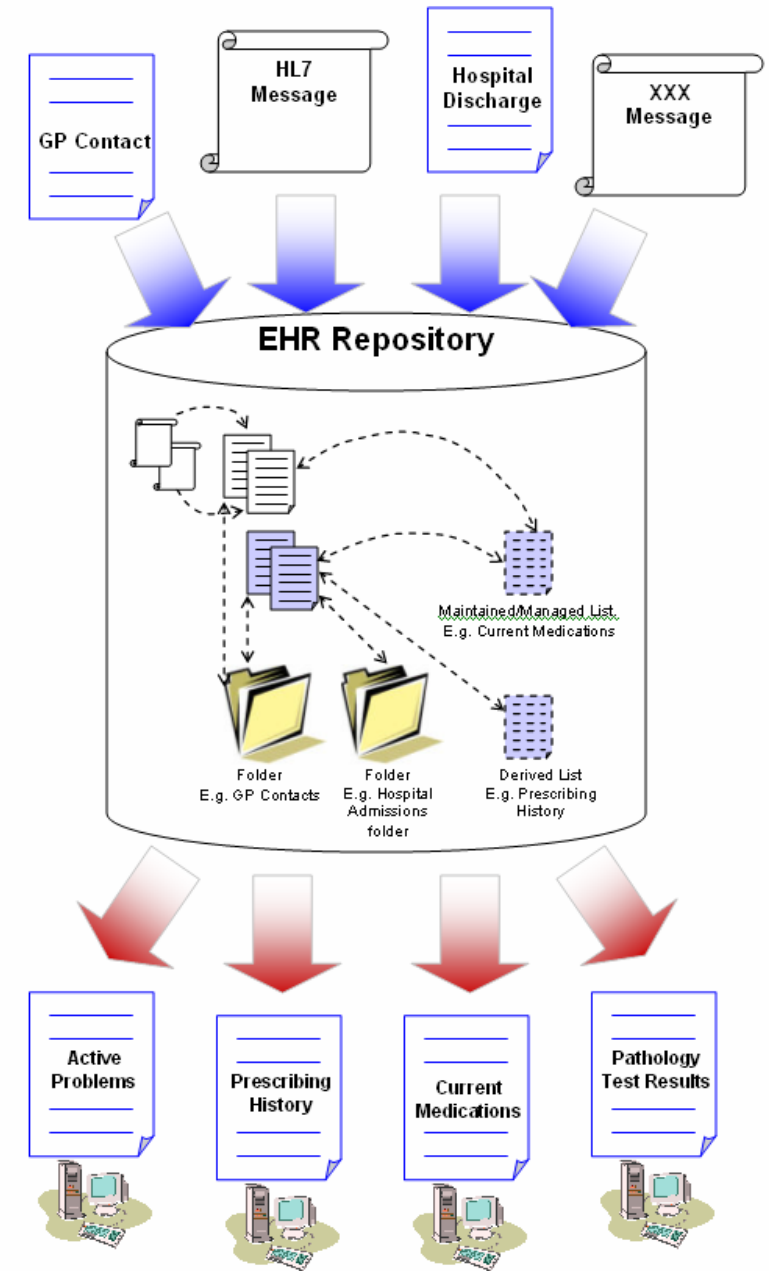


Figure 8. Implicit linkage of information based on the real-world healthcare process.

The left of Figure 9 shows an example of linking a prescribed medication to a problem/diagnosis within a GP Consultation note.

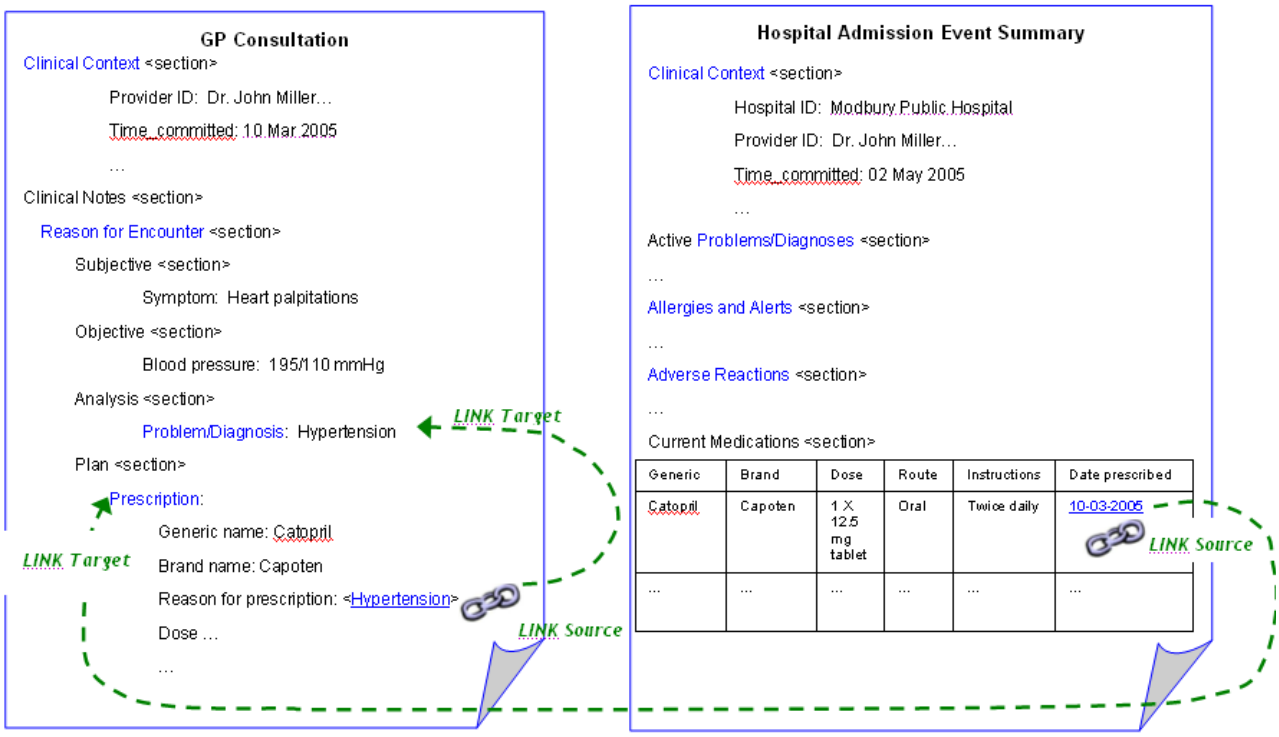


Figure 9 - Examples of linking related items of information.

There may also be a potential need for generating and viewing a set of EHR lists (see Section 8.6.1) that are related. Examples include:

- The ability for a current medications list to be viewed in conjunction with the adverse reactions/therapeutic precautions list; and
- The ability to view a problem/diagnosis list, the list of medications associated with each problem, and the list of providers responsible for treating each problem. A problem entry may be sourced from a number of event summaries, possibly posted by different providers, and moreover, a single medication may be given to treat more than one problem. Supporting such a requirement is non-trivial, and may therefore influence the way data is structured and linked in order for this to be feasible either in the near or longer term. A complex and comprehensive formulary with therapeutic classes, indications, etc would be needed to acquire the level of detail to be recorded. A few approaches to support this might be via:
  - The provision of complex request criteria. This would entail specifying additional attributes that capture additional information/context as data is inputted so that related data can be more easily constructed as they are required on demand; or
  - Specification of a set of predefined complex templates for related EHR lists and/or EHR views; or
  - A knowledge base and using decision-support system to help identify, collate and output the relevant related data when requested.

Explicit linkages in clinical content are required to support this and for users to 'drill-down' into a particular list item and view its details. The right of Figure 9 illustrates how the same information item, i.e. prescribed medication is used to generate the current medications list within a hospital admission event summary. The current medication list item links back to the GP Consultation note from which it was sourced.

Requirements for establishing these relationships include knowledge bases, an intelligent user interface that guides and prompts the user to enter data in a logical fashion to better allow the system to generate the relevant linkages at time of data entering or 'on-the-fly'. For example, the data entry screens may be presented according to the sequence of real-world actions as in Figure 9 above.

8.5.1 Methods of linking and use of links

The concept of 'linking' information items may be viewed as:

- Hyperlinks for users; and/or
- Logical 'pointers' within the information system.

The result of establishing a link may involve the reference to the related information item being recorded, or the reference plus the actual value of the information item either being retrieved and/or recorded.

The *Link* datatype:

The clinical data specifications use a Link datatype, which is defined as (see also Appendix A):
A general link, reference or pointer to an object, data, or application that exists logically or stored electronically in a computer system. For example, URI (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". It can also be an absolute or relative path within a file/directory structure, e.g. in a 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".

Data elements that are clearly specified as links include:

- PARTICIPANT Email Address, URL; and
- PATHOLOGY episode related problem/diagnosis.

The clinical data specifications do not place constraints on how the data might be linked when they are implemented. The datatypes specified for each of the data elements correspond to their *values* irrespective of where or how these values might be collected or presented to the user when accessed. The MEDICATION data group for instance, has a few data elements that are relevant only for systems rather than end-users, either for unique identification and/or to support linkages. The *values* MEDICATION Prescription reference, Prescribing line item, Dispensing reference, Dispensing reference line item, in particular, are specified as TEXT. However, they may be implemented as *links* to enable individual MEDICATION ITEMs, e.g. if they are listed under a 'Current Medications' list, to be referenced from their PRESCRIPTION and/or DISPENSING MEDICATIONS, and vice versa.

8.6 Management of information currency, e.g. current medications

The management of information currency is particularly relevant and critical to enable informed clinical decision-making. In general, the types of clinical information that need to be kept 'current' or up to date are those that are regarded as 'persistent,' i.e. information that remains clinically significant over a relatively long period of time. Examples include family history, medication list, problem list, and allergies. This is opposed to information that is collected at a particular instant in time, e.g. GP encounter, biochemistry test, medication prescription, and hospital discharge transactions. This section will introduce the concept of EHR lists and discuss how such information *may* be kept current using a complex example 'Current Medications'.

8.6.1 EHR Lists

An 'EHR List' is a collection of similar EHR items describing a key aspect of a subject of care's health formed to serve a specific purpose. There are subsets of lists that are of particular interest within health, e.g. Problem List, for which there is a benefit in maintaining and viewing. By summarising the information in an EHR list, providers can efficiently make decisions at the point of care.

Provider Managed Lists

Provider managed lists imply authorised/responsible/ownership of lists, submission of complete lists always, and any changes resulting in complete replacements of lists. Managed lists may be managed by a single owner, e.g. a GP or service coordinator, an organisation, or multiple owners such as a care team.

Examples of provider managed lists include:

- Current Medications;
- Problems/Diagnoses;

- Allergies/Adverse Reactions;
- Alerts; and
- Care Team.

Ideally, a 'currency' indicator needs to be recorded for the whole managed list with a date that the list was deemed 'current,' i.e. last reviewed or updated.

EHR Maintained Lists

'EHR maintained lists' are maintained by the system, and implies confirm/create/update/delete/alter entries in event summaries. A maintained list has separate logical structures that can be referenced explicitly by event summaries, i.e. services will be provided to support creating, and updating/inserting/deleting entries to such lists. For example, pharmacies dispensing a drug could trigger an insert into to the 'current medications' list. Or a Home Medicines Review (HMR) could trigger an update to the 'current medications' list to change a dose, or perhaps, a complete creation/recreation or the 'current medications' list.

EHR Maintained List Entry is a single data item within an EHR maintained list defined by its descriptive name, its actual value, and a reference to its source event summary.

Both types of lists require the provider's clinical judgements about the validity, relevance and importance of data items that should or should not form its content.

8.6.2 Rationale for Acquiring, Sharing and Managing Current Medications List

Unlike other types of lists such as 'Prescribing History' list where it can be automatically generated and maintained by the system based on a query across all historical prescription records, or event summaries added to the EHR (known as 'Derived Lists'), current medications lists require more complex acquisition and management. Furthermore, it needs to be shared by the multiple providers and organisations that use it to manage the care of a patient that is particularly crucial with respect to chronic disease management. Current medications lists require clinical judgement by clinicians and patient involvement as to:

- The 'true' currency of the medicine, e.g. the medicine has been administered for the required period, but is still in the patient's blood stream, so is 'recent' as opposed to 'current'[7].
- Whether or not the medicine should be removed from the list due to a range of reasons such as patient concordance/compliance:
  - Failure to commence drug administration;
  - To administer according to instructions, e.g. frequency, dose, etc;
  - Abandoning the drug altogether before the recommended date, which will affect the accuracy of the expected medication cease date; and
  - Administering a drug that was not prescribed by the General Practitioner (GP).

  Patients may not concord/comply because:

  - Patients find medication schedules confusing;
  - Patients often forget what they have taken;
  - Patients start feeling better and stop taking the medication; and/or
  - Patients do not feel they can afford medications.
- Whether or not the drug may have adverse effects; and
- Whether or not there may be drug-drug interactions.

[7] Miller, G. 'Draft Medicine Currency and Shared EHRs', Health*Connect* (Draft Report), 12 Mar 2004.

To understand the requirements for the current medications list and how it will be managed, the steps involved in the medication management process must be considered[8] These are:

1. Order Formulation;
2. Order Communication;
3. Order Verification;
4. Order Translation;
5. Dispensing;
6. Administration;
7. Patient Monitoring; and
8. Outcomes.

Steps 1 and 3 in particular require 'current medications' for use in drug interaction checking, and to avoid therapeutic duplication. At present, the 'current' medications of a patient can be obtained from either of these probable authoritative data sources:

a) Inpatient medications – hospital pharmacy system, which consequently only records *dispensed* drugs, inpatient medication chart, clinical data repository; and
b) Outpatient medications – ambulatory documentation system, clinical data repository and community pharmacy system.

With the view to an implementation of a national shared EHR, the current medications list should ideally reside and be sourced/originate from the national shared EHR for the patient.

8.6.3 Models for sharing current medication information

Are 'current' medications lists managed, maintained, or derived from, or a hybrid of these types of lists? There are technological, provider-workflow, medico-legal and patient-privacy aspects to consider.

We can identify that in general, there are four main models for medication currency:

1. Single Owner Medication Currency Model (uses a managed list);
2. Multiple Owner Medication Currency Model (uses a managed list);
3. Maintained Medication Currency Model (uses a maintained list); and
4. Hybrid Medication Currency Model (uses both managed and maintained types of list).

Note that it is recommended that all of these models should implement *version management* of lists and *audit trails*. It is also recommended that the original source or 'master' copy of the current medications list for a patient reside in the shared EHR repository. Local systems should always refer first to this central repository for the most up-to-date list, and make changes to it.

Single Owner Medication Currency Model

The GP or service coordinator manages this type of list as he/she receives notifications about new event summaries containing new medication information being recorded into the shared EHR system.

[8] Integrating the Healthcare Enterprise (IHE) from the IHE Strategic Development Medication Management Subcommittee, 2003.

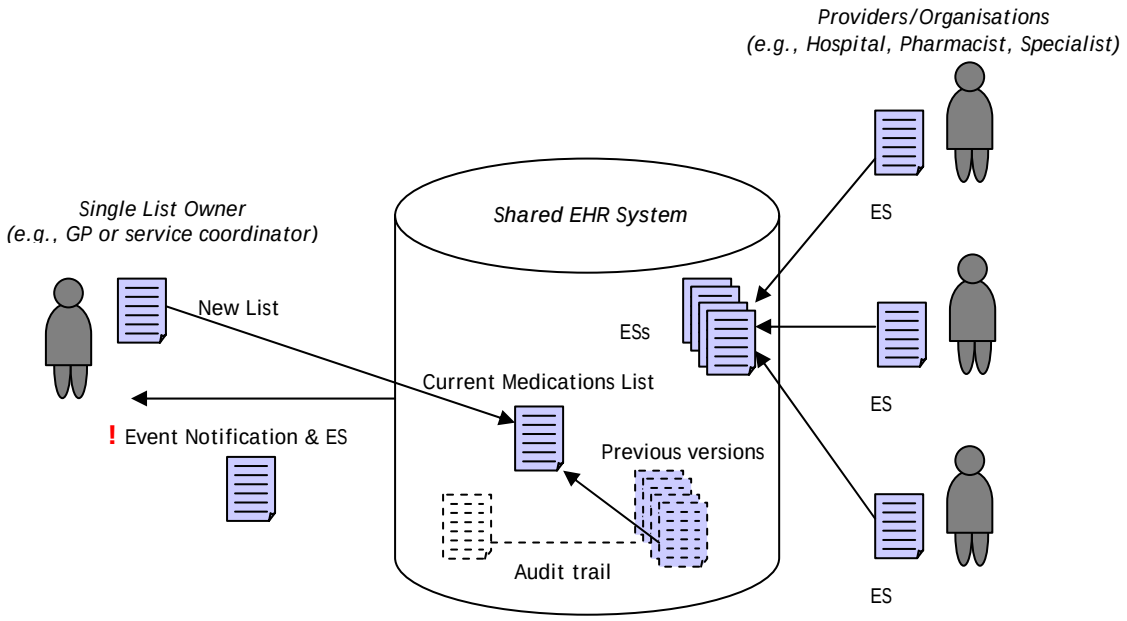


Figure 10 - Single Owner Medication Currency Model

Multiple Owner Medication Currency Model

This model requires submission by multiple contributors of complete list always, and any changes resulting in complete replacements of lists. For example, if access control is based on the patient's 'Care Team', when a new list is submitted by any one of the owners, e.g. the GP, pharmacist or patient, a notification is sent to the other contributors. This may occur via email, advising that the current medications list has been updated. At this point they can download the latest medications list from the shared EHR system. Figure 11 (below) illustrates an example of how the model works if the multiple owners consisted of the GP, pharmacist and patient.

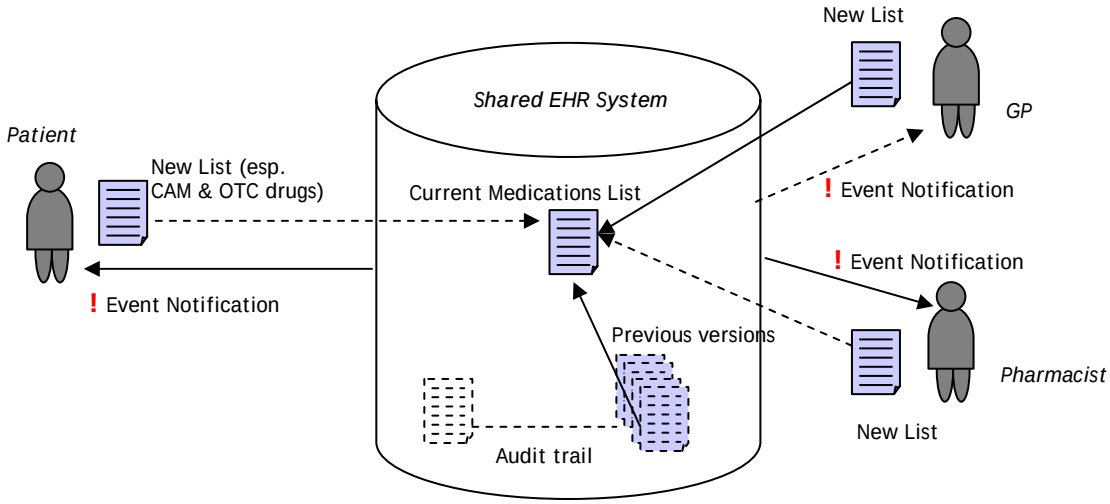


Figure 11 - Multiple Owner Medication Currency Model

Note that *provider incentives* for the management of current medication lists will need to be decided upon should either single owner and multiple owner medication currency models be adopted.

Rationale for Managed Lists, i.e. manual/provider/consumer maintenance:

- Creation of a new current medications list due where a medication record for the patient does not exist; and

- Consumers should be able to manage their own drugs, and also they are required to 'push' additional and potentially critical information about their over the counter (OTC) drugs, and complementary and alternative medicines (CAM):
  - There will always be consumers that are reluctant to state that they have abandoned taking a prescribed drug before the expected cease date due to other factors such as personal preference. This will always be out of scope for the core IT implementation considerations, although provision of patient education about the importance of complying may assist in this regard, either through the GP, or an online patient education tool.

Maintained Medication Currency Model

In the maintained medication currency model, a **maintained list** is used. This type of list is maintained by the system, and implies confirm/create/update/delete/alter entries in event summaries. A maintained list has separate logical structures which can be referenced explicitly by event summaries, i.e. services will be provided to support creating, and /updating/inserting/deleting entries to such lists. For 'current medications', pharmacies dispensing a drug could trigger an insert into the 'current medications' list. A Home Medicines Review (HMR) could trigger an update to the 'current medications' list to change a dose, or perhaps, a complete creation/recreation of the 'current medications' list.

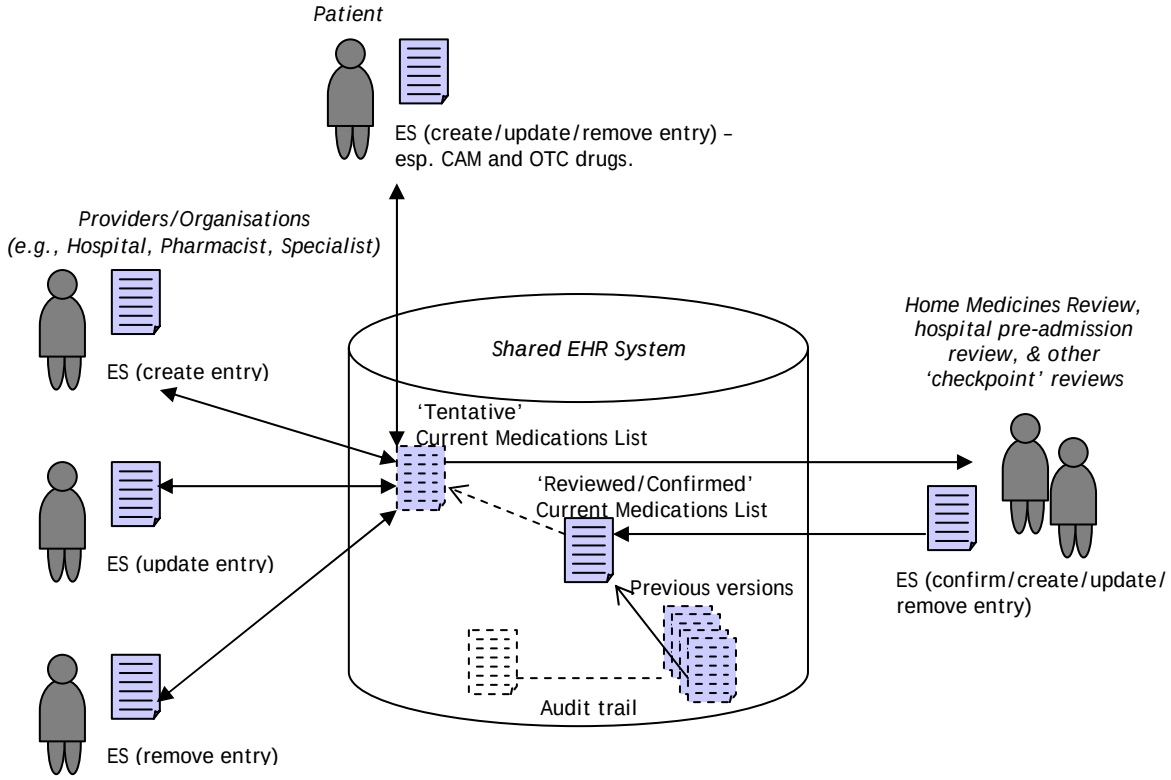


Figure 12 - Maintained Medication Currency Model

Rationale for Maintained Lists, i.e. automated maintenance:

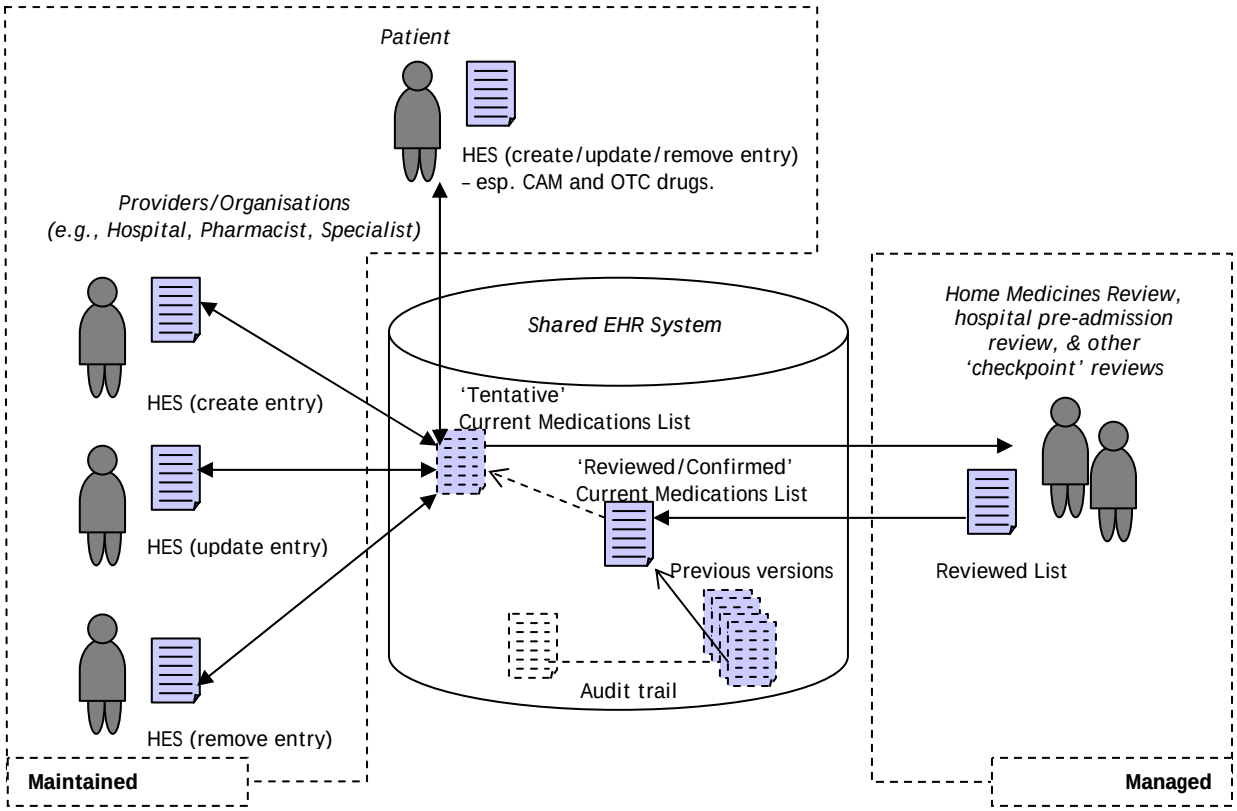
- Ability to have any authorised prescriber/dispenser to update the list by posting the appropriate event summary that contains only the added/changed entry/entries. Requires an audit trail, i.e. who made the change, change description, when it was changed, and rationale for the change to *entries* within the list;
- More efficient for managed lists as the whole list need not be uploaded again if only making one or a few changes;
- Assuming that the existing data is already accurate, the use of this model can reduce data entry errors and duplications since users are only required to make changes to the appropriate entries; and
- Reduce provider workload. Providers do not need to scan through and attest the entire list when prescribing/dispensing/altering a single medication.

Current medication lists include a 'working' or 'tentative' current medications list item, which are yet to be confirmed or reviewed in a HMR. This can reduce time lags in the currency of lists, and items

added/changed, though not yet 'confirmed' and provide as much information as clinicians need to make decisions.

Removing items from 'current medications' may be assisted by the system by calculating the duration of administration and flag the item as part of the 'tentative' current medications list for manual removal by the GP or pharmacist.

The maintained list can be implemented using the *open*EHRs approach where the current medications list is implemented as a *persistent transaction* or *composition* that gets updated when new event summary, i.e. *event transactions* get recorded.



Hybrid Medication Currency Model

Figure 13 : Hybrid Medication Currency Model

Advantages of a hybrid model:

- Allows flexibility in the way currency is managed, thus does not require as much change in existing processes or workflows; and
- Currency is better kept up to date due to the different methods.

Current medication lists require a combination of a maintained and managed list, making it difficult to implement. As a first step to addressing this difficult issue, the boundaries or the extent to which the current medications list can be maintained by the system, and managed by providers and consumers must be identified.

Management and maintenance models should ideally be based on a more comprehensive medication state model, which includes the relevant states mentioned previously in this report. A 'medication status' will need to be added as an explicit attribute or property of a medication entry in a list, and/or of a medication prescription event summary.

Figure 14 (below) shows an example of how list management and version management might occur in a shared EHR system.

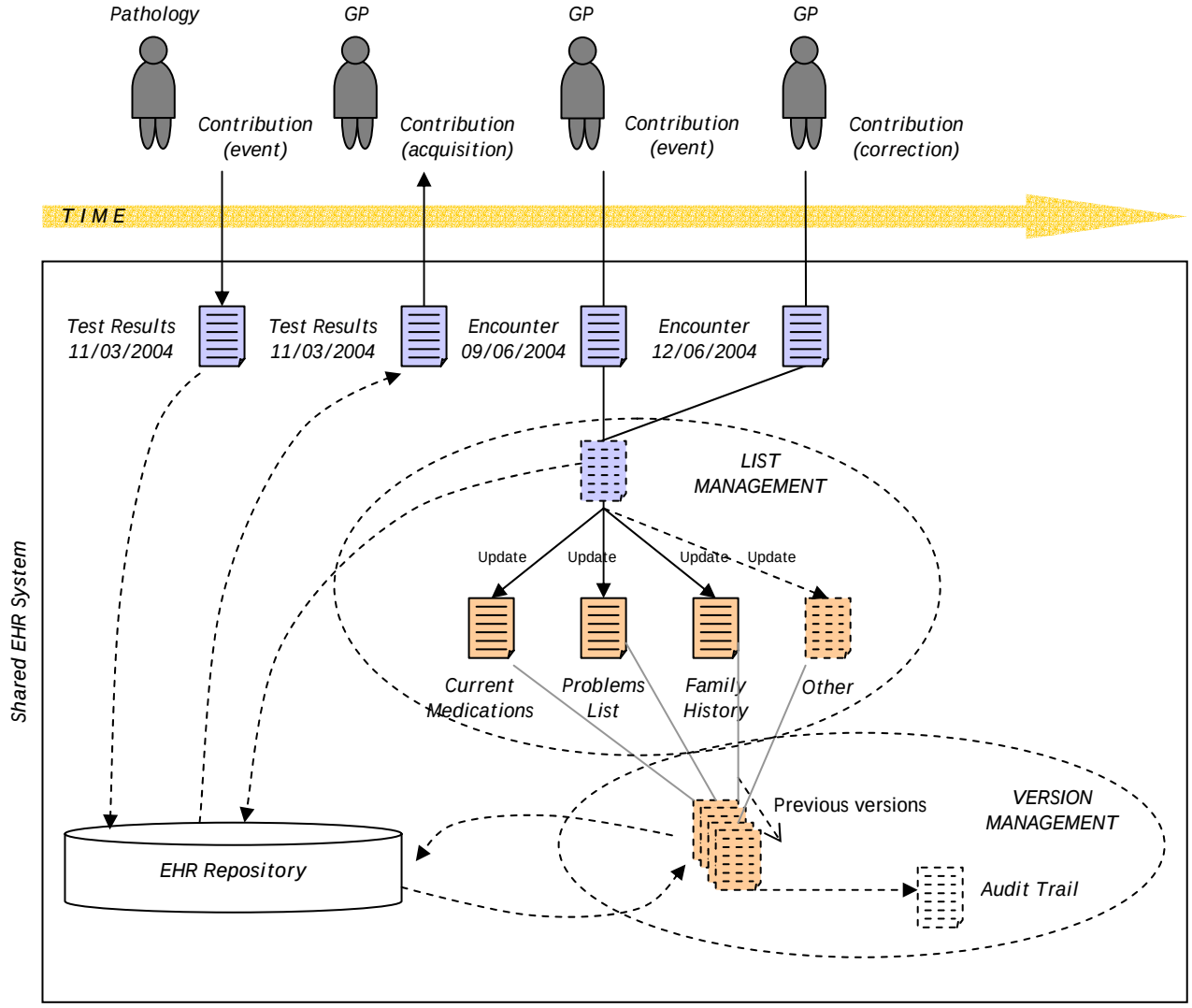


Figure 14 - List management for a single subject of care's EHR.

8.7 Ability to retain sufficient context of data for shared care

The data elements within any given data group have been chosen carefully to provide sufficient context for unambiguous interpretation without overburdening the clinicians with redundant information. Software developers should be aware of the structures used to represent related information (as described in Section 8.5 above, and elsewhere in this document). This is of particular importance for complex hierarchical structures such as those required to represent medications and pathology tests/results. The use of links and references to implicit information defined in other data groups needs careful consideration. For instance, the healthcare provider role may be required in certain contexts, but not in others.

8.8 Support for different perspectives by different providers

One of the reasons for not being prescriptive about obligation of data elements in a data group is that different contexts will require different data. For example, in most situations the batch number of an immunisation vaccine would not be wanted. Implementations will, in most instances, decide which data elements are relevant for which contexts. NEHTA has provided definitions and specifications for data elements that might be needed in certain contexts, and for which it is deemed highly desirable for the naming and representation of these to be standardised.

8.9 Client Identification and Demographics

Storing detailed demographics of the subject of care, clinicians or healthcare provider may not be required within an EHR. A unique identifier for these parties may be sufficient in circumstances where national Client and Provider registries/indexes are available to provide this detail. This approach provides a degree of information security as the health record data is separated from the identities of the parties recorded within the health record.

In the case of point-point messaging between two health care providers, there is a requirement to assiduously ensure that the client(s) to whom the message refers is/are unambiguously identified. Both providers must agree that they are communicating about the same subject of care. NEHTA has adopted the Australian Standards for Client Identification (draft AS5017:2005) as the basis for the set of demographics information pertaining to a given client. Data elements within this data group are assumed to be available in systems to populate required fields on a context by context basis. The client identification data elements are not repeated explicitly in any other data groups. For example, the pathology data group does not include a data element 'Patient Age' or 'Patient Date of Birth', even though that might be important information for interpreting pathology result reference ranges. There is an assumption that such information would be available and linked to by systems, e.g. via a demographics server on an implementation basis if necessary.

8.10 Provider Identification, Demographics and Roles

As for client identification, the repeated storage of provider details within each event summary contributing to an EHR may not be efficient or desirable. A provider ID might be the preferred implementation paradigm for most event summary implementations.

In the case of point-point messaging between two health care providers, however, there is a requirement to ensure that the provider(s) to whom the message refers are unambiguously identified. NEHTA has adopted the Australian Standards for Provider Identification (AS4846:2004) as the basis for the set of demographics information pertaining to a given provider. Data elements within this data group are assumed to be available in systems to populate required fields on a context by context basis.

8.11 Medications

Medication data groups are structured around the concept of a **Medication Item**, which is notionally 'prescribed', 'dispensed' and 'administered'. It is important to appreciate that data describing a medication item can vary through this lifecycle from prescribing through to administration. For instance, the name of the drug dispensed might differ from the brand name prescribed. The dosage could change. The frequency of administration might vary. The NEHTA specifications represent this by 'repeating' the medication item in three contexts. A way to interpret the specifications is illustrated in Figure 15 (below).

The capture of accurate medication information is seen as an important aspect of electronic health records that can reduce medication errors and help with decision support. In order for these goals to be realised, the terms used to describe each medication, the language used to describe dose, frequency and duration all need to be consistent across systems. Medication names, in particular need to come from a standard reference database. The Australian Medicines and Devices Terminology (AMDT) is the database currently being developed to provide this. The AMDT will provide information about every medicinal product sold in Australia. For each product, the *Actual Medicine Name* (often referred to as 'brand name'); the corresponding *Virtual Medicine Name* (often referred to as "generic name"), the form, packaging, ingredients and other relevant data will be stored. The medication data items that are used to record an individual's medication history will use the AMDT database to populate relevant fields wherever possible. The AMDT will link each product to appropriate medication class information, so that clinical information systems can perform class-based queries.

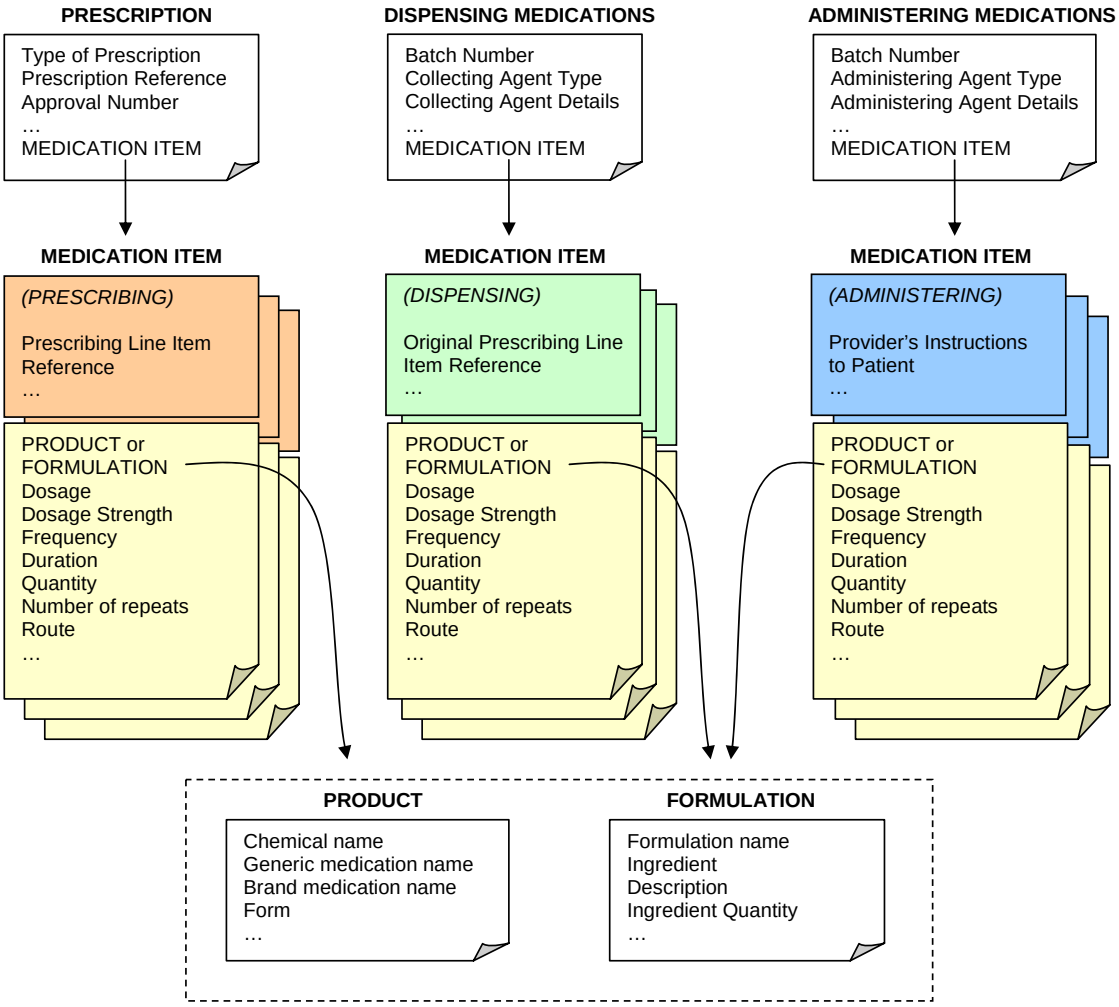


Figure 15 - Medication data groups

8.12 Pathology

Pathology data groups are structured around the concept of a **pathology episode**, i.e. a collection of data concerning an order for one or more tests, on one or more specimens.

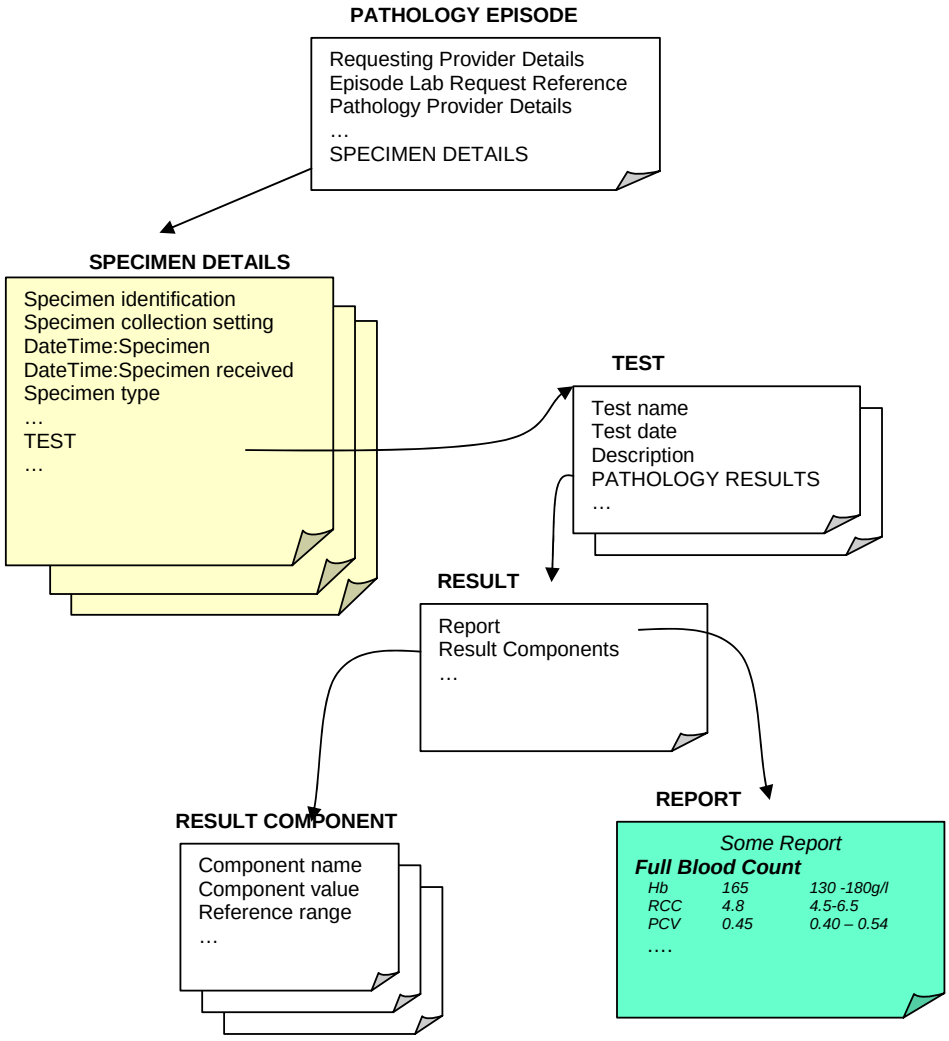


Figure 16 - Pathology data groups

From Figure 16 (above) it can be seen that there are relationships between any given test result, and a specific specimen, that may need to be tracked. However, for many circumstances the specimen details are not required. For many shared care settings, only some specific findings are wanted.

8.12.1 Complex structures encountered in Pathology Test Results

Both Pathology and Imaging tests can result in complex report structures that contain mixtures of qualitative and quantitative results. For instance, a Full Blood Examination might yield data such as the following:

Test component	Result	Normal Range	Abnormal Result
Haemoglobin [Hb]	165	130-180g/L	
Red Cell Count [RCC]	4.8	4.5-6.5 X 10^{12}/L	
Packed Cell Volume [PCV]	0.45	0.40 – 0.54	
Mean Cell Volume [MCV]	88 fL	80 – 100 fL	

Mean Cell Haemoglobin [MCH]	26 pg	27-32 pg	*
Mean Cell Haemoglobin [MCHC]	320 g/L	300-350 g/L	
Leucocyte (White cell) count [WCC]	6.2 X 10^9/L	4.0-11.0 X 10^9/L	*
Leucocyte differential count			
- Neutrophils	3.3 X 10^9/L	2.0-7.5 X 10^9/L	
- Eosinophils	0.12 X 10^9/L	0.04-0.4 X 10^9/L	
- Basophils	0.02 X 10^9/L	<0.1 X 10^9/L	*
- Monocytes	0.4 X 10^9/L	0.2-0.8 X 10^9/L	
- Lymphocytes	1.9 X 10^9/L	1.5-4.0X 10^9/L	
Leucocyte differential count at different ages			
Platelet Count	220 X 10^9/L	150-400 X 10^9/L	
Erythrocyte Sedimentation Rate [ESR]	7 mm/hour	2-14 mm/hour	
Reticulocyte Count	33 X 10^9/L	10-100 X 10^9/L	

Table 6 - Pathology test results

Table 6 (above) could simply be captured in an EHR as an unstructured 'blob' of data, such as a scanned image or PDF file. It could be stored, formatted for presentation on a clinician's screen as HTML, or it could be represented in its fine-grained structure, suitable for querying and for decision support. In order to support fine-grained structures, data specifications need to be more sophisticated than can be rendered readily on paper for human consumption. Specifications better matched to software would need to be used to capture such fine-grained detail. *open*EHR archetypes are currently the technology of choice for describing these complex clinical structures.

Electronic Health Record

The event summary should be able to be versioned within the EHR to allow the event summary to be revised after the initial contribution to the EHR. Each version should be reproducible retrospectively including attestation details of each version.

There are issues regarding the process of providing diagnostic investigation results to a shared EHR without the requesting provider releasing the result for shared use. The need to access the diagnostic investigation summaries from a shared EHR for emergency use has been identified. This would require the Diagnostic Investigation – Pathology summary being sent directly to the shared EHR from the Pathology provider. This will require consumer consent and the ability for the ordering provider to authorise the release of the summary for shared use. However, in the case of an emergency, an emergency over-ride authority could allow access to the event summary that has yet to be authorised for shared use. Additionally, to cater for long term unauthorised event summaries and providers with limited authorising capabilities, an automatic release of the diagnostic investigation summary after a reasonable period of time could be provided.

eHealth Messaging

A HL7 V3 message is being drafted within the HL7 organisation. It is expected that this Laboratory message will provide sufficient support for the entire Diagnostic Investigation – Pathology summary.

8.13 Diagnostic Imaging

Electronic Health Record

There are issues regarding the process of providing diagnostic investigation results to a shared EHR without the requesting provider releasing the result for shared use. The need to access the diagnostic investigation summaries from a shared EHR for emergency use has been identified. This would require the Diagnostic Investigation – Imaging summary being sent directly to the shared EHR from the Diagnostic

Imaging provider. This will require consumer consent and the ability for the ordering provider to authorise the release of the summary for shared use. However, in the case of an emergency an emergency override authority could allow access to the event summary that has yet to be authorised for shared use. Additionally, to cater for long term unauthorised event summaries and providers with limited authorising capabilities, an automatic release of the diagnostic investigation summary after a reasonable period of time could be provided.

8.14 Alerts

Alerts are an important function of many clinical information systems. The scope of any one alert is often of particular concern to designers of such systems. Different audiences, and different clinical contexts need to process different alerts differently. Such contexts such as geographical, organisational, provider role, provider discipline, patient demographics, current functional status all affect whether, and how, a particular alert needs to be provided. Much of this context will be available to systems already. How systems process such context is an implementation issue. The current NEHTA data specifications provide the ability to categorise alerts into broad types, namely:

- Administrative;
- Clinical or Medical;
- Home Environment;
- Impairment and/or Disability;
- Infectious Risk;
- Legal;
- Safety and Security;
- Special Mental Health; and
- Special Needs and/or Preferences.

Such specification groupings are designed to assist developers of clinical information systems in the task of providing relevant, context-sensitive alerts to clinicians.

8.15 Adverse Reaction

Adverse reactions cover reactions to a range of different 'agents'. These agents can include medications, in which case any reactions are often referred to as adverse drug reactions. The NEHTA specifications currently do not treat adverse drug reactions as a special case of general adverse reactions. Later releases of the specification, based on archetypes may do so. An issue arises as to the terminology used to identify the agent. There is currently a specified value domain for agent description, developed in conjunction with the National Centre for Classification in Health (NCCH), which covers agents other than medications. This situation will be resolved when NEHTA specifies a specified terminology for medications, through the current Australian Medicines and Devices Terminology (AMDT) project. In the interim, the use of local drug terminologies to describe adverse reaction agents is supported.

9 EVENT SUMMARY CONTEXT - HEADERS

Because of the dual purpose of event summaries, that of direct point - point communication between providers, versus that of a contribution to a shared EHR, there is a requirement for some additional context information to be provided to service these needs. This additional information can be provided in a 'header' section of an event summary.

Event summaries sent between health care providers require contextual information related to the health care setting, the provider names and organisations and details pertaining to the relevant subject of care to ensure that the event summary can 'stand alone', i.e. it does not require this additional information to be sourced from elsewhere before it can be interpreted by the recipient provider(s). For example, for a discharge summary being sent from a hospital to a GP, it is insufficient to provide only the hospital's identifier (Unit Record number) as the sole identifier of the subject of care. Even if Australia were to have a unified, single subject of care identifier, then this would still be deemed insufficient information in the event summary for the recipient provider(s) to unambiguously identify the subject of care. Name, sex and age are usually all required data items to be included in the discharge summary.

Similarly with healthcare provider information, a single identifier may be insufficient for a recipient of a discharge summary to identify the sender, and the sender's location at the time of issue. Additional name and contact details should be provided in cases where the event summary may need to stand alone, for immediate interpretation by the receiving clinician.

The NEHTA data specifications provide generic data groups for client and provider, based on Australian Standards AS5017 (current draft) and AS4846:2004.

The exact specification of header information in an event summary will need to be informed by both the context for use, and the messaging technology and business processes involved. NEHTA has undertaken considerable analysis in the potential use of header information, with particular reference to HL7 CDA Release 2 and with the emerging CEN 13606 standard. Finalisation and release of data elements to support given implementations will also need to be consistent with the emerging National Health Identifier and Provider Indexes being established by NEHTA, as well as the consent framework supporting eHealth information storage and exchange.

10 DATATYPES

Each data element is represented according to a predefined datatype, as listed in Appendix A.

The datatype, together with any associated value domain specification, determine the set of permissible values that a data element can contain. Any piece of data that represents a value of a defined data element is interpreted according to its datatype. Independent upon the context of use, e.g. in a specific message, or in an application user interface, or in a database, the specific data value is expected to conform to the datatype of the data element.

11 NAMING CONVENTIONS AND IDENTIFIERS

11.1 Design Time versus Runtime Names

Design time names refer to *metadata* names within data specifications and are coined because they are developed during system development and design. The names of data groups, data elements and value domains in the NEHTA data specifications are considered as design time names. These names are therefore unique in the data specifications or the knowledgebase that stores them, but may not be unique in the data where runtime names may be applied. For example, discharge summary might have two independent entries for a medication item – both having run-time names of 'Prescribed medication' that appear in two different sections: 'Current Medications' and 'Prescribing History'. In general, design time names are indicative of the semantics or meaning of the data and as such, the design time names should be encouraged to be used as run-time names as well. Design time names and/or metadata item identifiers (see Section 11.2.1) may be transferred with data at runtime to ensure that the *meaning* of the data is communicated between systems.

Runtime names are generated by the software applications as field entry 'labels' at runtime or when the application generates the form/screen for data entry (see Section 7.2), and/or when applications assign specific names to data that gets recorded. These names are usually unique in the data and therefore, can be used for querying data items, e.g. in the form of *paths*.

For the design time name 'Alert', the run time name of 'Alert (local)' may be given to alerts relevant to a local healthcare setting. For example, an alert for community setting only may include 'Family dog in yard' However, the overall underlying meaning of the name 'Alert' remains the same, but is renamed to provide further contextual meaning. However, since the NEHTA data item names on their own are intended for re-use in different contexts, and whilst it is achievable to obtain fully qualified names from the names of data items within a hierarchical path (i.e. the names of 'Instances' under 'Relationships' for a NEHTA data specification) more 'user-friendly' names may need to be developed for use at runtime. For example, 'MEDICATIONS.PRESCRIPTION.MEDICATION ITEM.PRODUCT.Actual medicine name' may have a run-time name of 'Prescribed medication name'.

11.2 Metadata Item versus Data Item Identifiers

11.2.1 Metadata Item Identifiers

NEHTA *metadata* item identifiers are unique alphanumeric strings used to refer to any given version of a data group, data element or value domain specification. These may be used by systems to control versioning of event summary specification entries. Unique identifiers may also be required for fully qualified data items, which can be done by using the combination of the metadata item identifier and metadata item version number for each of the items, i.e. event summary data group, data element and value domain specifications that make up a fully qualified metadata item. The identifier that results from this can also be considered as globally unique within the knowledge base of specifications. For example, a fully qualified data item name might be:

'HOSPITAL DISCHARGE EVENT SUMMARY.MEDICATIONS.PRESCRIPTION.MEDICATION ITEM.PRODUCT.Actual medicine name' (see Section 11.1 for use of names), and its (globally) unique identifier might be:

'ES-101.V1_DG-500.V1_DG-909.V1_DG-932.V1_DE-610.V1' – with each identifier and version number group delimited by an underscore.

11.2.2 Data Item Identifiers

Where code values are not globally unique, such that they may only be unique within a specific '*event summary.data group.data element'*, or an archetype definition for instance (in which 'AT[code number]' is used for both archetype element names and local code values defined within a specific archetype) there may be a requirement to **allocate each code a unique code identifier** as well. This can help ensure that the distinction between any identical term names and/or identical term codes that have different meanings is maintained, and therefore, helps ensure that the appropriate term is used for a given context.

Without a unique code identifier as an explicit attribute being made available, there may be a tendency to do this in such a way that it is dependent on the implementation, i.e. terminology server, repository, and will therefore vary. For example, if a relational database is used, then the unique identifier will typically be obtained from the primary key values. In an archetype approach, the unique identifier may be derivable from the archetype ID + the 'AT[code number]' + the 'AT[number]' (for locally defined codes) or some other terminology code. If a SNOMED code is used, then the code itself is uniquely identifiable so other information such as the archetype ID is not required. This variance for instance, makes it difficult to perform queries. The query mechanism may change depending on the type of terminology used, as well as the implementation, which in addition, is neither maintainable nor feasible in their long-term use. Having a unique identifier for each code (no matter if the code value itself is globally unique or not) makes it easier and more consistent to specify and implement queries on the data such that it only has to look for the value of that single attribute. Also, the specification can be implemented in various ways without the potential to lose meaning, or lose the distinctions that have been made between codes.

It may further help to **standardise the unique code identifiers** and of course, to standardise the way a unique code identifier is generated/created. In this way, the unique code identifier will be consistent amongst all types of terminologies, which may be used at the same time. For further discussion on this issue and other NEHTA activities related to terminologies, see Section 8.4.

APPENDIX A: DATATYPES

Icon	Datatype Name	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 *without* exceptions; text with code mappings. It is viewed that a CodedText value should consist of both the text or term value, its corresponding code value, the name of the terminology and the terminology version number from which it is sourced.
	CodeableText	Coded text with exceptions; flexible datatype to support various ways of holding text - both free text, CodedText and combinations of free text and CodedText. CodeableText allows users to potentially add a new term where the existing terminology does not yet currently support. It also allows for values of the data element to be sourced from a terminology that may be able to support it in future and can supply the appropriate code values for them. The latter is known as 'late-binding' of values to codes/terminology.
	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. **Usage/Example:** "3 hours"; "6 months"; "1 year"
	Number	A whole number or positive integer, and where (according to ISO 11404) – • *integer* is the mathematical datatype comprising the exact integral values (**Usage/Examples:** 1; 50; 125).
	Boolean	A value of true or false. **Usage/Example:** An actual value entered by the user might be "yes", or could be chosen by a mouse click on an icon such as ☑
	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. **Usage/Examples:** 12:00 – 18:00; 1:30 a.m. – 6:00 p.m.
	Quantity	Used for recording many real world measurements and observations. Such a data type needs not only to provide for a magnitude value to be recorded, but also for units, precision and number of decimal places to be recorded.
	QuantityRange	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. **Usage/Examples:** Temperature range of -20 to 100 °C; 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.
	Link	This is a general link, reference or pointer to an object, data, or application that exists logically or stored electronically in a computer system. **Usage/Example:** 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 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".
	Ratio	The relative magnitudes of two Quantity values (usually expressed as a quotient). **Usage/Example:** 1/3; 1:3
	Sequence	Ordered collection of items. **Usage/Example:** A person's given names, e.g. "David Phillip Andrew" would be held as 3 items grouped in order to form a single entity.
	Set	Unordered collection of items with values that must be unique within the set.

APPENDIX B: GLOSSARY

TERM	DEFINITION
Subject of care	One or more persons schedules to receive, receiving, or having received a health service.
Clinician	A health professional who delivers health services directly to a patient/client
Client	An individual who is the subject of care
Term	Any word, phrase of symbol which represents a concept
Terminology	A set of terms representing a system of concepts within a specified domain including semantic links

APPENDIX C: ACRONYMS & ABBREVIATIONS

TERM	DEFINITION
AMDT	Australasian Medicines and Devices Terminology
AIHW	Australasian Institute of Health and Welfare
CATCH	The Australian Classification and Terminology of Community Health (development by NCCH).
CDS	Clinical Data Standards
CIS	Clinical Information System
CRG	Clinical Reference Group
DSTU	Draft Specification for Trial Use
EHR	Electronic Health Record
ICPC-2+	International Classification of Primary Care Version 2, extended vocabulary
ICT	Information and Communications Technology
ISO/IEC 11179	International standard for Metadata Registries (previously International standard for the specification and standardisation of data elements)
MBS	Medicare Benefits Schedule
NATA	National Association of Testing Authorities
NCCH	National Centre for Classification in Health
NEHTA	National E-Health Transition Authority
NHDD	National Health Data Dictionary
OMG	Object Management Group
SNOMED-CT	Systemised Nomenclature of Medicine – Clinical Terms