

National E-Health Transition Authority  
Project #4

Adverse Reaction and Alert  
Archetype Representations

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## DOCUMENT CONTROL

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Program	National E-Health Transition Authority (NEHTA)
Project	NEHTA Clinical Data Standards (CDS) (formerly Clinical Information Program)
Project Manager	Dr Frida Cheok

Document Title	Adverse Reaction and Alert Archetype Representations		
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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 (based on ISO/IEC 11179).
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 PREFACE

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The purpose of this document is to inform and support the final report (**Project Report: Priority Event Summaries and Code Sets, and Jurisdictional Gap Analysis**) for NEHTA Projects #1 to #4.

This document contains Adverse Reaction and Alert archetypes which were developed collaboratively by the National Centre for Classification in Health (NCCCH) and the NEHTA Clinical Data Standards group (CDS) based upon the relevant NEHTA technical specifications.

The *openEHR* Foundation has adopted a model for expressing clinical information according to agreed archetypal representations. Archetypes are created for a number of purposes such as:

- Human Communication: to enable domain concepts to be modelled in a formal way by domain experts;
- Specialised Searching: also to compare data to specialised archetypes, or "predicates".

Archetypes can be used directly for the computational purposes described below. The key benefits of archetypes include:

- Knowledge-enabled systems: the separation of information and knowledge concerns in software systems, allowing future-proof software to be built;
- Knowledge-level interoperability: the ability of systems to reliably communicate with each other at the level of knowledge concepts;
- Domain empowerment: the empowerment of domain specialists to define the informational concepts they work with, and have direct control over their information systems;
- Intelligent Querying: to be used at runtime to enable the efficient querying of data based on the structure of archetypes from which the data was created.

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, *openEHR* 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 information exchange and messaging standards, archetypes can be used to provide a standardised representation of clinical information for interoperability between clinical information systems.

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 *openEHR* Reference Model), they provide a more formal expression of data specifications than traditional paper-based specifications. They permit exporting to Archetype Definition Language (ADL) or XML for direct use by software systems. A human readable representation of the Adverse Reaction and Alert archetypes is presented in this document.


## ADVERSE REACTION ARCHETYPE




*Entity:* EVALUATION




<b>Concept description:</b>	<b>Identification:</b>
<p>A harmful or undesirable response to a substance/agent.</p> <p>An adverse reaction may occur within a variable timeframe after exposure to an agent/substance and may range from minor reactions like a skin rash to serious and life-threatening events such as anaphylaxis. Exposure may be by ingestion, inhalation, injection or direct contact. An adverse reaction includes allergies, intolerances and sensitivities. An adverse reaction does not include poisoning, medical errors or mishaps that may occur during surgical or medical care as these are generally classified as an adverse event.</p>	<p><i>Id:</i> openEHR-EHR-EVALUATION.adverse_reaction_data_group_CIP_EB.v2</p> <p><i>Reference model:</i> openEHR_EHR</p>

### Data

Structure = TREE, ordered

Concept	Description	Constraints	Values
<p><b>T</b></p> <p>Adverse reaction presence</p>	An indication of the results of enquiry regarding the existence or non existence of a harmful or undesirable response to an agent/substance, as determined by a healthcare provider.	<i>Text</i> 1..1	Internal; 'Present', 'Absent', 'Nil known'
<p><b>T</b></p> <p>Information provided by</p>	A category specifying the source of the subject of care's health information.	<i>Text</i> 0..1	Internal; 'Carer', 'Device', 'Healthcare provider', 'Other', 'Subject of care'
<p><b>T</b></p> <p>Agent type</p>	The category of the agent/substance that classifies the adverse reaction.	<i>Text</i> 0..1	Internal; 'Animal', 'Chemical', 'Drug', 'Environment', 'Food', 'None known'
<p><b>T</b></p> <p>Agent description</p>	The agent/substance causing the adverse reaction, as determined by a healthcare provider.	<i>Text</i> 1..1	Terminology; New constraint
<p></p> <p>DateTime:Exposure</p>	The date or date and time that exposure to an agent/substance occurred.	<i>DateTime</i> 0..1	Allow all

<p><b>T</b></p> <p>Agent description certainty</p>	<p>Used to indicate the degree of confidence that the agent/substance referred to in the agent description has caused the adverse reaction, as determined by a healthcare provider.</p>	<p><i>Text</i> 0..1</p>	<p>Internal; 'Certain', 'Conditional/Unclassified', 'Possible', 'Probably/Likely', 'Unassessable/Unclassifiable', 'Unlikely'</p>
<p><b>T</b></p> <p>Adverse reaction type</p>	<p>The type of reaction experienced by the subject of care to an agent/substance, as determined by a healthcare provider</p>	<p><i>Text</i> 0..1</p>	<p>Internal: 'Allergy', 'Intolerance', 'Sensitivity'</p>
<p></p> <p>REACTION DETAILS</p>	<p>Details of one or more reactions to the agent.</p>	<p><i>Cluster</i> 0..1</p>	
<p><b>T</b></p> <p>Adverse reaction description</p>	<p>The symptoms and/or signs experienced or exhibited by the subject of care as a consequence of the adverse reaction to a specific agent/substance, as determined by a healthcare provider.</p>	<p><i>Text</i> 0..1</p>	<p>Terminology; New constraint</p>
<p></p> <p>Severity</p>	<p>Clinical judgement of the degree of seriousness of an observed or reported event.</p>	<p><i>Ordinal</i> 0..1</p>	<p>0: mild 5: disabling 10: life threatening</p>
<p></p> <p>DateTime:Start</p>	<p>The date or date and time that the issue in question commenced.</p>	<p><i>DateTime</i> 0..1</p>	<p>Allow all</p>
<p><b>T</b></p> <p>Adverse reaction status</p>	<p>An indication of whether the stated adverse reaction is considered an active or inactive health issue, as determined by a healthcare provider.</p>	<p><i>Text</i> 0..1</p>	<p>Internal; 'Active', 'Inactive'</p>
<p><b>T</b></p> <p>Adverse reaction outcome</p>	<p>The state of well-being of the subject of care after experiencing the adverse event and being treated for it, if required.</p>	<p><i>Text</i> 0..1</p>	<p>Internal; 'Death as an overall outcome of the adverse reaction', 'Death as the primary reaction to the agent', 'Death unrelated to the adverse event', 'Not yet recovered', 'Recovered with sequelae', 'Recovered without sequelae', 'Unknown'</p>

 <p><b>HEALTHCARE PROVIDER IDENTIFICATION: Reporter</b></p>	<p>Details pertaining to the healthcare provider or organisation who is reporting the issue.</p>	<p><i>Any</i> 1..1</p>	
 <p><b>DateTime:Recorded</b></p>	<p>The date or date and time that information was recorded in this clinical record.</p>	<p><i>DateTime</i> 1..1</p>	<p>Allow all</p>
 <p><b>Adverse reaction note</b></p>	<p>Free text comments relevant to the event in question.</p>	<p><i>Text</i> 0..1</p>	<p>Text;</p>


## ALERT ARCHETYPE

Entity: EVALUATION

Concept description:	Identification:
Information pertaining to a subject of care that may: -need special consideration by a healthcare provider before making a decision about his/her actions to avert an unfavourable healthcare event; or -need consideration and/or action by a healthcare provider or facility in relation to the care and safety of the subject of care, staff and/or other individuals; or -notify the healthcare provider of special circumstances that may be relevant in delivering care and/or interacting with the subject of care.	<i>Id:</i> openEHR-EHR-EVALUATION.alert_EB.v1 <i>Reference model:</i> openEHR_EHR

## Data

Structure = LIST, ordered

Concept	Description	Constraints	Values
<b>T</b> Alert type	The category of the alert that classifies the alert description.	<i>Text</i> 1..1	Internal; 'Administrative', 'Clinical or medical', 'Home environment', 'Infectious risk', 'Safety and security', 'Special mental health', 'Special needs and/or preferences'
<b>T</b> Information provided by	A category specifying the source of the subject of care's health information.	<i>Text</i> 0..1	Internal; 'Carer', 'Device', 'Healthcare provider', 'Other', 'Subject of care'
<b>T</b> Alert description	Details of the nature of the alert.	<i>Text</i> 1..1	Terminology; *
 DateTime:Start	The date or date and time that the issue in question commenced.	<i>DateTime</i> 0..1	Allow all

<p><b>T</b></p> <p>Alert certainty</p>	<p>Used to indicate the degree of confidence concerning the nature of the alert.</p>	<p><i>Text</i> 0..1</p>	<p>Internal; 'Certain', 'Conditional/Unclassified', 'Possible', 'Probably/Likely', 'Unassessable/Unclassifiable', 'Unlikely',</p>
<p><b>T</b></p> <p>Alert active status</p>	<p>An indication of whether the alert is considered an active or inactive issue, as determined by a healthcare provider.</p>	<p><i>Text</i> 0..1</p>	<p>Internal; 'Active', 'Inactive'</p>
<p></p> <p>DateTime:Action next review</p>	<p>The date or date and time the next action is due to be reviewed.</p>	<p><i>DateTime</i> 0..1</p>	<p>Allow all</p>
<p></p> <p>DateTime:End</p>	<p>The date or date and time that the issue in question ceased.</p>	<p><i>DateTime</i> 0..1</p>	<p>Allow all</p>
<p></p> <p><i>HEALTHCARE PROVIDER IDENTIFICATION: Reporter</i></p>	<p>Details pertaining to the healthcare provider or organisation who is reporting the issue.</p>	<p><i>Any</i> 1..1</p>	
<p></p> <p>DateTime:Recorded</p>	<p>The date or date and time that information was recorded in this clinical record</p>	<p><i>DateTime</i> 1..1</p>	<p>Allow all</p>
<p><b>T</b></p> <p>Alert note</p>	<p>Free text comments relevant to the event in question.</p>	<p><i>Text</i> 0..1</p>	<p>Text;</p>