Health Information and Quality Authority

An tÚdarás Um Fhaisnéis agus Cáilíocht Sláinte

National standard adverse reaction dataset and clinical document architecture (CDA) template

January 2016

Safer Better Care

About the Health Information and Quality Authority

The Health Information and Quality Authority (HIQA) is an independent authority established to drive high quality and safe care for people using our health and social care services in Ireland. HIQA's role is to develop standards, inspect and review health and social care services and support informed decisions on how services are delivered.

HIQA aims to safeguard people and improve the safety and quality of health and social care services across its full range of functions.

HIQA's mandate to date extends across a specified range of public, private and voluntary sector services. Reporting to the Minister for Health and the Minister for Children and Youth Affairs, HIQA has statutory responsibility for:

- **Setting Standards for Health and Social Services –** Developing person-centred standards, based on evidence and best international practice, for health and social care services in Ireland.

- **Regulation –** Registering and inspecting designated centres.

- **Monitoring Children's Services –** Monitoring and inspecting children's social services.

- **Monitoring Healthcare Safety and Quality –** Monitoring the safety and quality of health services and investigating as necessary serious concerns about the health and welfare of people who use these services.

- **Health Technology Assessment –** Providing advice that enables the best outcome for people who use our health service and the best use of resources by evaluating the clinical effectiveness and cost-effectiveness of drugs, equipment, diagnostic techniques and health promotion and protection activities.

- **Health Information** – Advising on the efficient and secure collection and sharing of health information, setting standards, evaluating information resources and publishing information about the delivery and performance of Ireland's health and social care services.

Overview of Health Information function

Health is information-intensive, generating huge volumes of data every day. Health and social care workers spend a significant amount of their time handling information, collecting it, looking for it and storing it. It is therefore imperative that information is managed in the most effective way possible in order to ensure a high-quality, safe service.

Safe, reliable healthcare depends on access to, and the use of, information that is accurate, valid, reliable, timely, relevant, legible and complete. For example, when giving a patient a drug, a nurse needs to be sure that they are administering the appropriate dose of the correct drug to the right patient and that the patient is not allergic to it. Similarly, lack of up-to-date information can lead to the unnecessary duplication of tests – if critical diagnostic results are missing or overlooked, tests have to be repeated unnecessarily and, at best, appropriate treatment is delayed or at worst not given.

In addition, health information has a key role to play in healthcare planning decisions – where to locate a new service, whether or not to introduce a new national screening programme, and decisions on best value for money in health and social care provision.

Under section (8)(1)(k) of the Health Act 2007, the Health Information and Quality Authority (HIQA) has responsibility for setting standards for all aspects of health information and monitoring compliance with those standards. In addition, under section 8(1)(j), HIQA is charged with evaluating the quality of the information available on health and social care, making recommendations in relation to improving the quality, and filling in gaps where information is needed but is not currently available.

Information and communications technology (ICT) has a critical role to play in ensuring that information to drive quality and safety in health and social care settings is available when and where it is required. For example, it can generate alerts in the event that a patient is prescribed medication to which they are allergic. Further to this, it can support a much faster, more reliable and safer referral system between the patient's general practitioner (GP) and hospitals.

Although there are a number of examples of good practice, the current ICT infrastructure in Ireland's health and social care sector is highly fragmented with major gaps and archives of information which prevent the safe and effective transfer of information. This results in service users being asked to provide the same information on multiple occasions.

Information can be lost, documentation is poor, and there is over-reliance on memory. Equally, those responsible for planning our services experience great difficulty in bringing together information in order to make informed decisions.

Variability in practice leads to variability in outcomes and cost of care. Furthermore, we are all being encouraged to take more responsibility for our own health and wellbeing, yet it can be very difficult to find consistent, clear and trustworthy information on which to base our decisions. As a result of these deficiencies, there is a clear and pressing need to develop a coherent and integrated approach to health information, based on standards and international best practice.

HIQA has a broad statutory remit, including both regulatory functions and functions aimed at planning and supporting sustainable improvements.

Through its health information function, HIQA is addressing these issues and working to ensure that high-quality health and social care information is available to support the delivery, planning and monitoring of services. A key requirement is the ability to accurately and consistently identify service users. Hence, one of the areas currently being addressed through this work programme is the development of a national standard demographic dataset and guidance for use in health and social care settings in Ireland.

One of the areas currently being addressed by the Health Information Directorate is the area of developing common Clinical Document Architecture (CDA) templates[1] that can be used in national clinical documents. In order to electronically exchange clinical documents between healthcare providers, HIQA, in conjunction with stakeholders, developed an adverse reaction standard which can be transformed into electronic documents using an international standard known as the Health Level 7 CDA standard. This standard will define the Health Level 7 CDA template for an adverse reaction.

[1] A CDA template defines additional syntax rules that constrain the overall CDA syntax and semantics, to more tightly define the rules for a specific kind of CDA document (or portion of a CDA document). See http://www.cdapro.com/know/25110.

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1 Introduction

Communication between eHealth[2] systems including electronic health records (EHR)[3] needs to be standardised in both structure and semantics to achieve the safe exchange of information that can be used in a meaningful way, that is to say, semantic interoperability. Semantic interoperability is only possible when a number of factors are in place such as: healthcare providers sharing the same metadata, information models that can be safely mapped between systems, consistent datasets at a national level and, when appropriate, eHealth interoperability standards are in place.

One of the critical success factors for the delivery of eHealth systems is a commitment to employ interoperability standards. While a number of countries had set out to establish a national electronic health record (EHR) as the ultimate goal of their eHealth strategies, the emphasis for many has now shifted more towards focusing on the development of eHealth building blocks, including interoperability standards. Some of the different types of interoperability standards that may enable semantic interoperability include messaging, terminology and data definition standards for the exchange of data such as the:

- Health Level Seven (HL7) v2.x messaging standards
- Clinical terminologies such as SNOMED CT for coding clinical information
- openEHR archetypes that define datasets that represent medical concepts such as an adverse reaction and diagnosis
- HL7 Clinical Document Architecture (HL7 CDA) standards for sharing clinical documents.

In the Irish context, many reports and strategies have highlighted the need for a national electronic health record. This includes the Commission for Patient Safety and Quality Assurance(1) and most recently, the Department of Health's eHealth Strategy for Ireland (2013)(2).

[2] (Electronic Health) "eHealth can benefit citizens, patients, health and care professionals but also health organisations and public authorities. eHealth - when applied effectively - delivers more personalised 'citizen-centric' healthcare, which is more targeted, effective and efficient and helps reduce errors, as well as the length of hospitalisation. It facilitates socio-economic inclusion and equality, quality of life and patient empowerment through greater transparency, access to services and information and the use of social media for health"… European Union eHealth Action Plan 2012-2020.

[3] An electronic health record (EHR) is a longitudinal record of patient health information across multiple care settings.

The Health Service Executive (HSE) has recently established the Office of the Chief Information Officer who is responsible for implementing the eHealth Strategy. The Office of the Chief Information Officer is charged with the delivery of technology to support healthcare across Ireland and have published the Knowledge and Information Strategy (2015)[3] in this regard.

The development of patient summary records, that is to say, summaries of key clinical information that can be derived from an electronic health record (or other clinical information system) is also highlighted in the eHealth Strategy as one of the key priority projects to enable the implementation of eHealth. Patient summaries can include the most pertinent information for medication, diagnosis, medical history, laboratory reports, referral letters and discharge summaries, and are often exchanged as clinical notes or documents. The HL7 Clinical Document Architecture (CDA) is an appropriate standard to use for the exchange of clinical documents. The HL7 CDA is a standard that specifies the structure and semantics of clinical documents for the purpose of exchange between healthcare providers and patients.

This document specifies a dataset for adverse reactions that informs the development of a HL7 CDA template (See Appendix 1 for detailed information on the CDA standard and templates) that can be reused in different document types such as national patient summaries.

An adverse reaction (which includes allergic reactions) is defined by the Australian National eHealth Transition Authority[4] as:

> An adverse reaction is defined as a "harmful or undesirable effect associated with exposure to any substance or agent, including food, plants, animals, venom from animal stings or a medication at therapeutic or sub-therapeutic doses".

The National Health Service (NHS) in England use an electronic record called the summary care record to support patient care. This electronic record contains key information from GP records. It provides authorised healthcare staff with faster, secure access to essential information about a patient. A summary care record includes information on adverse reactions such as a reaction to penicillin or peanuts. Summary care records generated from GP practice management systems have been used in emergency department and acute hospital settings to improve patient safety and the effectiveness and efficiency of patient care[5].

There is a difference between an adverse reaction and an allergy. A patient can have an adverse reaction (nausea) to penicillin or an allergy (anaphylactic reaction) to penicillin. An allergy is considered an example of an adverse reaction.

2 Background

Under the Health Act 2007, HIQA is charged with setting standards for health information. This includes standards for the communication of health information between health and social care providers. To date HIQA has published several standards in this regard including:

- General Practice Messaging Standard (2014)[6]
- National Standards for Patient Referral Information (2011)[7]
- National Standards for Patient Discharge Summary Information (2013)[8]
- National Standard Demographic Dataset and Guidance for use in health and social care settings in Ireland (2013)[9].

HIQA also published standards to support electronic prescribing, or ePrescribing, called the *ePrescription Dataset and Clinical Document Architecture Standard (2015)* [10]. This standard on adverse reaction dataset and CDA specification will utilise components of the ePrescription dataset. For example, data elements for a patient and healthcare practitioner have already been verified and approved in the ePrescription dataset and will be reused for the purpose of the adverse reaction standard.

3 Purpose

The exchange of standardised electronic documents such as shared patient summaries and other document types like ePrescribing documents are key building blocks for interoperability between eHealth systems. This adverse reaction Standard is part of a collection of standards, including the diagnosis standard, which HIQA is developing to support eHealth priority areas such as national patient summaries.

The purpose of this Standard is to specify CDA templates for adverse reactions which can be reused throughout different clinical document types. For example, a CDA template for adverse reactions can be reused in both a patient referral document and a patient's discharge summary document. This Standard describes a dataset for an adverse reaction and subsequently provides a technical specification (see Appendix 2) and CDA specification for use in clinical documents (see section 8). The scope of this Standard is to define a dataset that contains a list of maximal data elements for an adverse reaction. This means that the Standard can be modified to satisfy specific clinical scenarios and use cases when required, for example, optional data elements can be omitted from the dataset when being implemented.

4 Benefits

The development of a standard dataset for adverse reactions and a corresponding CDA template is an important step towards improving the delivery of safe, person-centred care. The development of CDA templates that are common across different document types reduces the work effort in creating new adverse reaction datasets and CDA templates each time an electronic clinical document is designed and needs to be shared. Common CDA templates for patient summaries can be used in eHealth systems.

eHealth systems can enhance the quality, accessibility and efficiency across all healthcare services through the secure, timely, accurate and comprehensive exchange of clinical and administrative data offering a number of benefits including:

- better and safer care
- improved integration and sharing of health information to enable patient-centred integrated care
- more cost-effective delivery of healthcare
- more efficient national planning
- improved research through the provision of more timely, and high-quality information
- reduction in medication errors
- more timely access by health professionals to the right medical information at the right time
- improved support for patient self-management.

5 Methodology

A draft dataset for adverse reactions was developed after analysis of several datasets developed in other jurisdictions. In Australia, the National eHealth Transition Authority published a detailed specification used to record all information about adverse reactions that is required to support direct clinical care of an individual. Adverse reaction datasets from two of the main standard development organisations for communication standards, OpenEHR and HL7 were also included in this analysis. The specifications that were used include:

- NETHA, Detailed Clinical Model Specification Adverse Reaction, Version (2011)[4]
- OpenEHR, Archetypes – Adverse Reaction, Clinical Knowledge Manager (2015)[11]
- HL7 FIHR Standard Allergy Intolerance, DSTU 1 (v0.0.82)[12]

Relevant datasets previously developed by HIQA such as the demographic dataset and the referrals and discharge summary datasets referred to in section 2 above were also reviewed and reused in this Standard where appropriate. A final dataset was developed in collaboration with HIQA's eHealth Standards Advisory Group (eSAG).

The dataset was then extended into a technical specification and finally developed into a HL7 CDA template. Key international CDA implementation guides were researched including:

- National eHealth Transition Authority (NEHTA) Event Summary - CDA Implementation Guide v1.3 (2015)[13]
- European Patients Smart Open Services (epSOS), *Work Package 3.9 – Appendix B1/B2 epSOS Semantic Implementation Guidelines*. (2011)[14]
- HL7 Implementation Guide for CDA Release 2: Consolidated CDA Templates for Clinical Notes DSTU R2 (2014)[15]
- Integrating the Healthcare Enterprise. *Patient Care Coordination Technical Framework, Volume 1 and Volume 2- Revision 5* (2013)[16].

This Standard used the epSOS specification for the development of the adverse reaction CDA template. The epSOS project was a large scale cross border collaboration that developed and carried out a pilot of patient summaries using the CDA standard. This draft standard has been reviewed by the eHealth Standards Advisory Group (eSAG).

This Standard uses the SNOMED CT clinical terminology, HL7 FHIR (Draft Standard for Trial Use) to define value sets in the technical and CDA specifications which are exemplar values.

5.1 Targeted consultation

The draft National Standard for Adverse Reactions was developed in conjunction with the members of the Authority's eHealth Standards Advisory Group and a

targeted consultation was undertaken. HIQA published a consultation document *Draft National Standard for an Adverse Reaction Dataset and Clinical Document Architecture (CDA) Template.*

The draft standard for consultation was published in October 2015 for a five week period which ran until November 2015. A consultation feedback form was included which outlined eight questions (see Appendix 3). The consultation feedback also included questions on the standard for diagnosis as both standards are part of a suite of specifications that HIQA has developed. This consultation form was made available on HIQA's website together with the consultation document itself.

In order to engage with as many people as possible, targeted emails were sent to 45 stakeholders inviting them to participate in the targeted consultation.

A total of 13 submissions were received, submitted by email and online correspondence. Eight respondents completed the online form and five respondents submitted their comments by email. Of the 13 submissions, seven were submitted on behalf of organisations and six were submitted in a personal capacity.

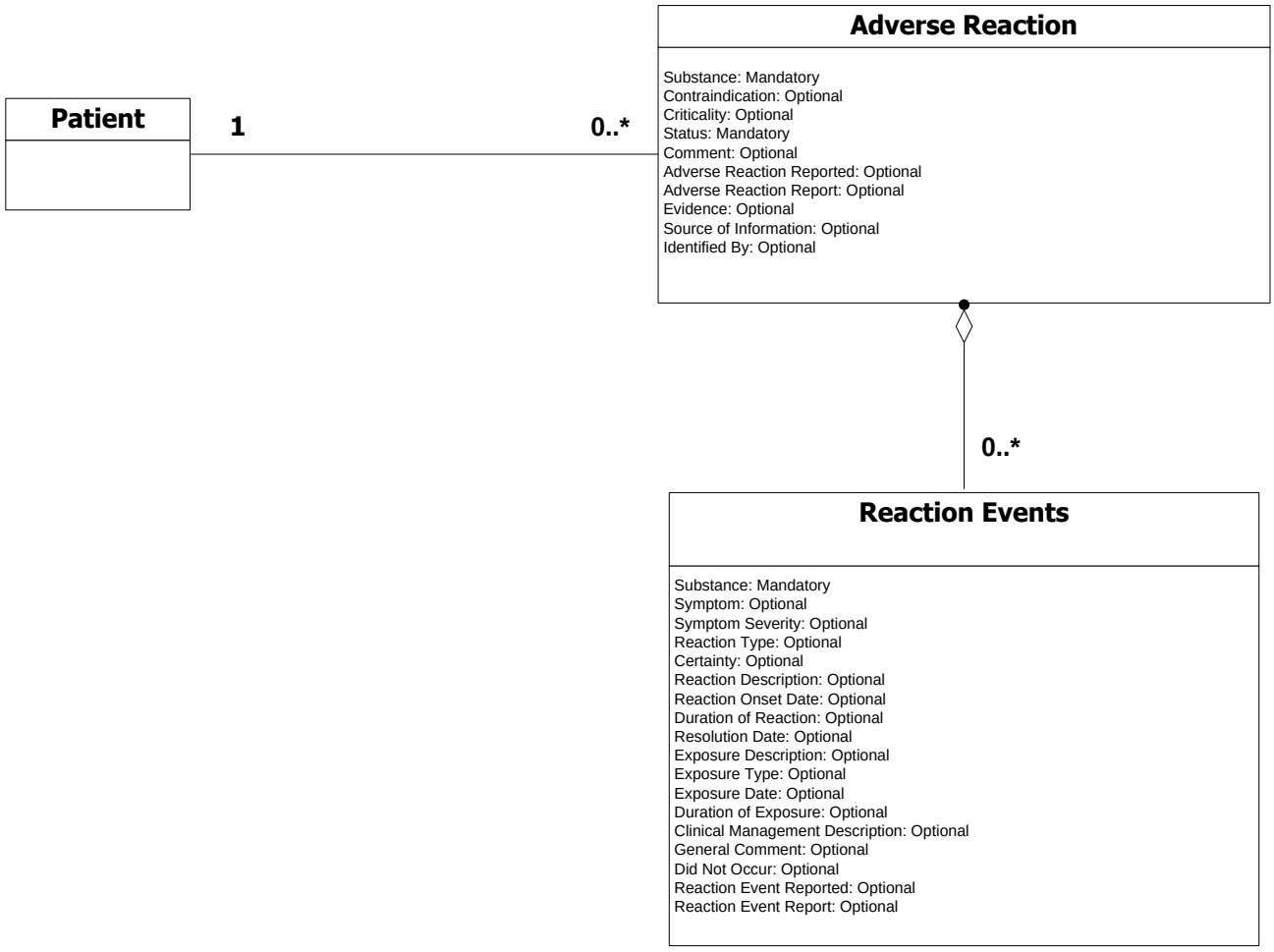
Appendix 4 outlines the organisations that made a submission. Each submission was read in its entirety and broken down into general comments and individual items that directly relate to the data items in the standard. Appendix 4 provides a review of the qualitative comments made and the changes to the standard that were agreed as a result of the submissions received. The Standard has been reviewed and approved by the eHealth Standards Advisory Group and the Executive Management Team and HIQA's Board.

6 Model for adverse reactions

This section will illustrate the model for adverse reactions. Section 7 describes the dataset for adverse reactions and section 8 will specify the CDA template.

The adverse reaction dataset consists of three classes namely the patient, the adverse reaction and adverse reaction event(s). A patient can have zero to many adverse reactions. In addition, a patient can have zero to many reaction events to an adverse reaction. Figure 1 below outlines a data model for a patient's adverse reactions.

Figure 1. Data model for an adverse reaction and reaction event



7 Dataset for adverse reactions

A dataset is a collection of related sets of information that is composed of separate elements but can be manipulated as a unit by a computer. An adverse reaction dataset is essential to provide information about an individual's adverse reaction(s) to substances including allergies to food, drugs and so on. If all healthcare providers use the same data model and dataset then information about adverse reactions can be shared. Each of the classes and associated attributes are described in the dataset in the following Table 1 which define the name, definition, optionality and usage of each data element.

7.1 Adverse Reaction

An adverse reaction is used to provide information about specific reactions to a substance. Adverse reactions include allergies, intolerance and sensitivities.

Table 1. Adverse reaction

Name	Definition	Optionality	Usage
1.1 Substance	Identification of the substance that the patient has a susceptibility to an allergy upon exposure to the substance.	Mandatory	The substance that caused the allergy to occur. Example of a substance could include peanut, penicillin and so on.
1.2 Contraindication	Indication to suggest that the substance should not be administered to this individual.	Optional	A flag indicating that a clinician has identified there is a risk to the patient of a serious reaction upon further exposure to the substance. Record as true if the clinician recommends that exposure to or administration of the substance should be prevented in future.
1.3 Criticality	The criticality of an adverse reaction.	Optional	This represents a clinical judgment about the potential severity of a reaction if the patient is exposed to the substance. Examples include fatal, high, medium and low.
1.4 Status	The status of the adverse reaction.	Mandatory	The status of the adverse reaction. Example values include suspected, confirmed and refuted.
1.5 Comment	Additional comments about the adverse reaction that are not captured in other fields.	Optional	Additional narrative about the adverse reaction not captured in other fields, including reason for

Name	Definition	Optionality	Usage
			flagging an absolute contraindication, instructions related to future exposure or administration of the substance.
1.6 Adverse reaction Reported	A field to indicate whether the adverse reaction was reported to a regulatory body.	Optional	Flag field used to indicate if the substance was reported to a regulatory body.
1.7 Adverse reaction report	The report that was submitted to the regulatory authority.	Optional	The report that was submitted to the regulatory authority.
1.8 Evidence	Non-subjective evidence that supports the adverse reaction occurred for the patient.	Optional	This could include laboratory reports, radiology reports or other investigations which supports confirmation of the adverse reaction. This information can be supported by multimedia formats such as image, signal, sound, vox and video.
1.9 Source of information	The person who provided the information about the adverse reaction.	Optional	This could be a patient, GP, healthcare professional and so on.
1.10 Patient	The individual who experienced the adverse reaction.	Mandatory	Refer to common templates document.[4]
1.11 Identified by	The healthcare practitioner who identifies the patient's susceptibility to the adverse reaction.	Optional	Refer to common templates document.

[4] HIQA will make available a common templates document which contains supplementary material needed to implement a document standard. This specifies header information for documents such as subject of care and healthcare provider details that are common to all clinical documents.

7.2 Reaction events

The details about reaction event(s) which occurred in response to exposure to a substance. This grouping may repeat as a patient may have multiple reaction events to an allergen.

Table 2. Reaction event

Name	Definition	Optionality	Usage
2.1 Substance	Identification of the actual substance considered to be responsible for the reaction event.	Mandatory	The substance identified as being the causative agent of the reaction event. Examples include a medication trade name or identification of a specific food.
2.2 Symptom	A description of the symptoms of the reaction.	Optional	Captures the symptoms experienced when exposed to the substance. Examples of a symptom to a substance could include a rash, nausea, vomiting or anaphylactic reaction.
2.3 Symptom severity	The severity of the symptom as determined by the healthcare practitioner.	Optional	An assessment of the severity of the reaction event as evaluated by the healthcare practitioner. Examples include: severe, serious, moderate or minor.
2.4 Reaction type	The type of reaction event as determined by the healthcare practitioner.	Optional	A subjective assessment of the type of reaction event as evaluated by the healthcare practitioner. Examples include: 1. Allergy 2. Idiosyncrasy 3. Interactions

Name	Definition	Optionality	Usage
			4. Intolerance / sensitivity 5. Side effect
2.5 Certainty	The degree of certainty that the substance was the cause of the reaction event as determined by the healthcare practitioner.	Optional	The degree of certainty about the cause of the reaction event as evaluated by a healthcare practitioner. Examples could include certain, probably, unlikely.
2.6 Reaction description	Narrative description of the reaction event including anatomical reaction details.	Optional	Narrative description of the reaction to the substance.
2.7 Reaction onset date	Record of the date or time (or both) of the onset of the reaction.	Optional	The date or time (or both) of the onset of the reaction.
2.8 Duration of reaction	The amount of time that the reaction event was present.	Optional	The amount of time that the reaction event was present.
2.9 Resolution date	Record of the date and, or time or estimated date/time when the reaction event resolved.	Optional	Record of the date and, or time or estimated date/time when the reaction event resolved.
2.10 Exposure description	Description about exposure to the substance.	Optional	Narrative description of the exposure to the substance. This can include details relating to the timing and route of administration of a medication.
2.11 Exposure type	The type of exposure that caused the reaction event.	Optional	A coded value for the type of exposure including drug administration, immunisation, coincidental, Environmental Exposure.
2.12 Exposure date	Record of the date and, or time of the earliest or initial exposure to the substance.	Optional	Record of the date and, or time of the earliest or initial exposure to

Name	Definition	Optionality	Usage
			the substance.
2.13 Duration of exposure	The amount of time of exposure to the substance.	Optional	The amount of time of exposure to the substance.
2.14 Clinical management description	Description about the clinical management provided.	Optional	Used to describe details about clinical management provided to manage or treat the reaction event.
2.15 General Comment	General comments about the reaction event.	Optional	General comments about the reaction event including any instructions or medications that may have been given to the patient.
2.16 Did not occur	Field to indicate that a specific reaction to a substance did not occur when the patient was exposed to the substance.	Optional	Flag field used to indicate that the reaction details detailed above did not occur when the patient was exposed to the substance detailed above.
2.17 Reaction event reported	A field to indicate whether the reaction event was reported to a regulatory body.	Optional	Flag field used to indicate whether the reaction event was reported to a regulatory body.
2.18 Reaction event report	The report that was submitted to the regulatory authority.	Optional	The report that was submitted to the regulatory authority.
2.19 Patient	The individual who experienced the reaction event.	Mandatory	Refer to common templates document.
2.20 Identified by	The healthcare practitioner who identifies the patient's reaction event.	Optional	Refer to common templates document.

8 CDA specification

This section defines the Clinical Document Architecture (CDA) specification for an adverse reaction clinical concept and is based on the dataset defined in section 7. Section 8.1 provides guidance on how to interpret the CDA adverse reaction specification. Section 8.2 details the CDA specification for adverse reactions. The rules and background information on the CDA are provided in Appendix 1.

8.1 Description of the CDA specification tables

The specification is defined using a table structure as illustrated in Table 3 below. The purpose of each of the columns is explained in this section.

Table 3. Attribute table for defining CDA documents, sections and entries

Num	Data Element	CDA xpath expression	Optionality/ Cardinality	HL7 v3 Data Type	Vocabulary

1. The 'number' column

The 'number' column contains a unique number that identifies the data element and is used for reference purposes.

2. The 'data element' column

The data element defines the name of the field.

3. The 'CDA Xpath expression' column

The CDA Xpath expression is used to search through an XML document and locates and extracts information from the nodes (any part of the document, such as an element or attribute) in that document. This is used to help in the implementation of a CDA specification and corresponds to the XML representation required for implementation.

4. The 'optionality and cardinality (Opt/Card)' column

The optionality, as well as the cardinality, information is associated with each data element in the table. The optionality used for this specification is based on the optionality included in the epSOS specification. The optionality descriptions and acronyms are included in Table 4.

Table 4. Optionality used in the CDA Adverse Reaction specification

Value	Meaning
R	Required - the mapped CDA element shall be present and shall not contain the nullFlavor attribute.
RNFA (or R use NullFlavor)*	Required Null Flavor Allowed - the mapped CDA element shall be present and it may contain the nullFlavor attribute. In some cases, the recommended nullFlavor value is also indicated.
O	Optional - the mapped CDA element may be omitted unless required by the CDA and/or by the template specifications.
NA	Not applicable since the data element is not applicable in the respective document.

The cardinality rules that may be used for sections and data elements are described in Table 5 below.

Table 5. Cardinality used in the CDA adverse reaction specification

Value	Meaning
0..1	The section or data element may have zero or one instance.
1..1	The section or data element may have one and only one instance.
0..*	The section or data element may have zero or more instances.
1..*	The section or data element may have one or more instances.

For example, the cardinality of a Primary Patient Identifier is [1...1]. This is a one-to-one relationship which means that we require the Primary Patient Identifier. A cardinality of [0...*] means that there are optionally many (more than one) additional identifiers.

* Note US English spelling.

5. The 'HL7 v3 data type' column

Each data element has a datatype associated with it. This column indicates the HL7 v3 data type that must be used for the field. Information about HL7v3 data types may be found in Appendix 5.

6. The 'vocabulary' column

The vocabularies and or terminologies that are used throughout this specification include exemplar value sets taken from the epSOS specification, SNOMED CT, HL7 FIHR and user-defined (see Appendix 6).

8.2 CDA specification for adverse reactions

Table 6 and Table 7 below outline the CDA level 3 templates for adverse reactions.

Table 6. CDA specification for adverse reactions

Number	Data element	CDA XPath expression	Optionality/ cardinality	HL7 V3 data type	Vocabulary
1.1	Substance	Allergy and Intolerance Concern Entry Content Module 1.3.6.1.4.1.19376.1.5.3.1.4.5.3 entry/act[templateId/@root= '2.16.840.1.113883.10.20.1.27']/entryRelationship[@typeCode="SUBJ"]/observation[templateId/@root="1.3.6.1.4.1.19376.1.5.3.1.4.6"]/participant[@typeCode="CSM"]/participantRole[@classCode="MANU"]/playingEntity[@classCode="MMAT]/code/@displayName	RNFA 1..1	ST	If the substance is a medicine the World Health Organization (WHO) ATC code system should be used. Code system OID is 2.16.840.1.113883.6.73 . If not, the suggested values are epSOSAllergenNoDrugs 2.16.840.1.113883.6.96 See Appendix 6 Table 1 for suggested values for substance.
1.2	Contraindication	Allergy and Intolerance Concern Entry Content Module	O 0..1	INT	See Appendix 6 Table 2 for

Number	Data element	CDA XPath expression	Optionality/ cardinality	HL7 V3 data type	Vocabulary
		1.3.6.1.4.1.19376.1.5.3.1.4.5.3 entry/act[templateId/@root= '2.16.840.1.113883.10.20.1.27']/entry Relationship[@typeCode="SUBJ"]/obse rvation[templateId/@root='1.3.6.1.4.1. 19376.1.5.3.1.4.6']/value/[@xsi:type=' BL']/@code			suggested values for contraindication.
1.3	Criticality	Allergy and Intolerance Concern Entry Content Module 1.3.6.1.4.1.19376.1.5.3.1.4.5.3 entry/act[templateId/@root= '2.16.840.1.113883.10.20.1.27']/entry Relationship[@typeCode="SUBJ"]/obse rvation[templateId/@root='1.3.6.1.4.1. 19376.1.5.3.1.4.6']/code/@code	O 0..1	CD	See Appendix 6 Table 3 for suggested values for criticality.
1.4	Status	Allergy and Intolerance Concern Entry Content Module 1.3.6.1.4.1.19376.1.5.3.1.4.5.3 entry/act[templateId/@root= '2.16.840.1.113883.10.20.1.27']/entry Relationship[@typeCode="SUBJ"]/obse rvation[templateId/@root='1.3.6.1.4.1. 19376.1.5.3.1.4.6']/entryRelationship[	R 1..1	CD	See Appendix 6 Table 4 for suggested values for status.

Number	Data element	CDA XPath expression	Optionality/ cardinality	HL7 V3 data type	Vocabulary
		@typeCode='REFR']/observation[templ ateId/@root='2.16.840.1.113883.10.2 0.22.4.28']/value/@code			
1.5	Comment	Allergy and Intolerance Concern Entry Content Module 1.3.6.1.4.1.19376.1.5.3.1.4.5.3 entry/act[templateId/@root= '2.16.840.1.113883.10.20.1.27']/entry Relationship[@typeCode="SUBJ"]/obse rvation[templateId/@root='1.3.6.1.4.1. 19376.1.5.3.1.4.6']/entryRelationship[@typeCode='SUBJ']/observation[templ ateId/@root='1.3.6.1.4.1.19376.1.5.3. 1.4.2']/text/reference/@value	O 0..1	ST	N/A
1.6	Adverse reaction Reported	Allergy and Intolerance Concern Entry Content Module 1.3.6.1.4.1.19376.1.5.3.1.4.5.3 entry/act[templateId/@root= '2.16.840.1.113883.10.20.1.27']/entry Relationship[@typeCode="SUBJ"]/obse	O 0..1	INT	N/A

Number	Data element	CDA XPath expression	Optionality/ cardinality	HL7 V3 data type	Vocabulary
		rvation[templateId/@root='1.3.6.1.4.1.19376.1.5.3.1.4.6']/value/[@xsi:type='BL']/@code			
1.7	Adverse reaction report	Allergy and Intolerance Concern Entry Content Module 1.3.6.1.4.1.19376.1.5.3.1.4.5.3 entry/act[templateId/@root='1.3.6.1.4.1.19376.1.5.3.1.4.5.2']/entryRelationship[@typeCode='SUBJ']/observation[templateId/@root='1.3.6.1.4.1.19376.1.5.3.1.4.6']/text/reference/@value	O 0..1	ST	N/A
1.8	Evidence	Allergy and Intolerance Concern Entry Content Module 1.3.6.1.4.1.19376.1.5.3.1.4.5.3 entry/act[templateId/@root='1.3.6.1.4.1.19376.1.5.3.1.4.5.2']/entryRelationship[@typeCode='SUBJ']/observation[templateId/@root='1.3.6.1.4.1.19376.1.5.3.1.4.6']/text/reference/@value	O 0..1	ST	N/A

Number	Data element	CDA XPath expression	Optionality/ cardinality	HL7 V3 data type	Vocabulary
1.9	Source of information	entry/act[templateId/@root='1.3.6.1.4.1.19376.1.5.3.1.4.5.2']/entryRelationship[@typeCode='SUBJ']/observation[templateId/@root="1.3.6.1.4.1.19376.1.5.3.1.4.6']/text/reference/@value	O 0...*	ST	N/A
1.10	Patient	Refer to common templates document.			
1.11	Identified By	Refer to common templates document.			

Table 7. CDA template for reaction events

Number	Data element	CDA XPath expression	Optionality/ cardinality	HL7 V3 data type	Vocabulary
2.1	Substance	Allergy and Intolerance Concern Entry Content Module 1.3.6.1.4.1.19376.1.5.3.1.4.5.3 entry/act[templateId/@root='2.16.840.1.113883.10.20.1.27']/entryRelationship[@typeCode="SUBJ"]/observation[templateId/@root="1.3.6.1.4.1.19376.1.5.3.1.4.6"]/participant[@typeCode="CSM"]/participantRole[@classCode="MANU"]/playingEntity[@classCode="MMAT]/code/@displayName	RNFA 1..1	ST	If the substance is a medicine the WHO ATC code system should be used. Code system OID is 2.16.840.1.113883.6.73 If not the suggested values are epSOSAllergenNoDrugs 2.16.840.1.113883.6.96 See Appendix 6 Table 1 for suggested values for substance.
2.2	Symptom	Allergy and Intolerance Concern Entry Content Module 1.3.6.1.4.1.19376.1.5.3.1.4.5.3 entry/act[templateId/@root='2.16.840.1.113883.10.20.1.27']/entryRelationship[@typeCode="SUBJ"]/observation[templateId/@root='1.3.6.1.4.1.19376.1.5.3.1.4.6']/entryRelationship[@	RNFA 1..1	ST	epSOSReactionAllergy 2.16.840.1.113883.6.96 See Appendix 6 Table 5 for suggested values for symptom.

Number	Data element	CDA XPath expression	Optionality/ cardinality	HL7 V3 data type	Vocabulary
		typeCode="MFST"]/observation[templateId/@root='2.16.840.1.113883.10.20.1.54']/value/@displayName			
2.3	Symptom Severity	Allergy and Intolerance Concern Entry Content Module 1.3.6.1.4.1.19376.1.5.3.1.4.5.3 Severity Entry Content Module 1.3.6.1.4.1.19376.1.5.3.1.4.1 entry/act[templateId/@root='2.16.840.1.113883.10.20.1.27']/entryRelationship[@typeCode="SUBJ"]/observation[templateId/@root='1.3.6.1.4.1.19376.1.5.3.1.4.6']/entryRelationship[@typeCode="SUBJ"]/observation[templateId/@root='1.3.6.1.4.1.19376.1.5.3.1.4.1']/value/@code	O 0..1	CD	See Appendix 6 Table 6 for suggested values for symptom severity.
2.4	Reaction type	Allergy and Intolerance Concern Entry Content Module 1.3.6.1.4.1.19376.1.5.3.1.4.5.3 entry/act[templateId/@root='2.16.840.1.113883.10.20.1.27'	RNFA 1..1		See Appendix 6 Table 7 for suggested values. epSOSAdverseEventType 2.16.840.1.113883.6.96.

Number	Data element	CDA XPath expression	Optionality/ cardinality	HL7 V3 data type	Vocabulary
		]/entryRelationship[@typeCode="SUBJ"]/observation[templateId/@root='1.3.6.1.4.1.19376.1.5.3.1.4.6']/code/@code			
2.5	Certainty	Allergy and Intolerance Concern Entry Content Module 1.3.6.1.4.1.19376.1.5.3.1.4.5.3 entry/act[templateId/@root='2.16.840.1.113883.10.20.1.27']/entryRelationship[@typeCode="SUBJ"]/observation[templateId/@root="1.3.6.1.4.1.19376.1.5.3.1.4.6"]/code/@code	O 0..1	CD	The use of the WHO-UMC system for standardised case causality assessment [UMC2011a] See Appendix 6 Table 8 for suggested values.
2.6	Reaction description	Allergy and Intolerance Concern Entry Content Module 1.3.6.1.4.1.19376.1.5.3.1.4.5.3 entry/act[templateId/@root='2.16.840.1.113883.10.20.1.27']/entryRelationship[@typeCode="SUBJ"]/observation[templateId/@root='1.3.6.1.4.1.19376.1.5.3.1.4.6']/text/reference/@value	O 0..1	ST	N/A

Number	Data element	CDA XPath expression	Optionality/ cardinality	HL7 V3 data type	Vocabulary
2.7	Reaction onset date	Allergy and Intolerance Concern Entry Content Module 1.3.6.1.4.1.19376.1.5.3.1.4.5.3 entry/act[templateId/@root='1.3.6.1.4.1.19376.1.5.3.1.4.6']/effectiveTime[@xsi:type='IVL_TS']/low	O 0..1	TS	N/A
2.8	Duration of reaction	Allergy and Intolerance Concern Entry Content Module 1.3.6.1.4.1.19376.1.5.3.1.4.5.3 entry/act[templateId/@root='1.3.6.1.4.1.19376.1.5.3.1.4.6']/ effectiveTime[1][@xsi:type='IVL_TS']/low/@value entry/act[templateId/@root='1.3.6.1.4.1.19376.1.5.3.1.4.6']/effectiveTime[1][@xsi:type='IVL_TS']/high/@value	O 0..1	IVL_TS	N/A
2.9	Resolution date	Allergy and Intolerance Concern Entry Content Module 1.3.6.1.4.1.19376.1.5.3.1.4.5.3 entry/act[templateId/@root='1.3.6.1.4.1.19376.1.5.3.1.4.6']	O 0..1	TS	N/A

Number	Data element	CDA XPath expression	Optionality/ cardinality	HL7 V3 data type	Vocabulary
		/effectiveTime[@ xsi:type='IVL_TS']/high			
2.10	Exposure description	Allergy and Intolerance Concern Entry Content Module 1.3.6.1.4.1.19376.1.5.3.1.4.5.3 entry/act[templateId/@root= '2.16.840.1.113883.10.20.1.27']/entryRelationship[@typeCode ="SUBJ"]/observation[templat eId/@root='1.3.6.1.4.1.19376. 1.5.3.1.4.6']/text/reference/@v alue	O 0..1	ST	N/A
2.11	Exposure type	entry/act[templateId/@root='1 .3.6.1.4.1.19376.1.5.3.1.4.5.2'] /entryRelationship[@typeCode ='SUBJ']/observation[template Id/@root='1.3.6.1.4.1.19376.1 .5.3.1.4.5']/text/reference/@va lue	O 0..1	ST	See Appendix 6 Table 9 for suggested values.
2.12	Exposure date	Allergy and Intolerance Concern Entry Content Module 1.3.6.1.4.1.19376.1.5.3.1.4.5.3 entry/act[templateId/@root=' 1.3.6.1.4.1.19376.1.5.3.1.4.6'] /effectiveTime[@	O 0..1	TS	N/A

Number	Data element	CDA XPath expression	Optionality/ cardinality	HL7 V3 data type	Vocabulary
		xsi:type='IVL_TS']/low			
2.13	Duration of exposure	Allergy and Intolerance Concern Entry Content Module 1.3.6.1.4.1.19376.1.5.3.1.4.5.3 entry/act[templateId/@root='1.3.6.1.4.1.19376.1.5.3.1.4.6']/ effectiveTime[1][@ xsi:type='IVL_TS']/low/@value entry/act[templateId/@root='1.3.6.1.4.1.19376.1.5.3.1.4.6']/ effectiveTime[1][@ xsi:type='IVL_TS']/high/@value	O 0..1	IVL_TS	N/A
2.14	Clinical management description	Allergy and Intolerance Concern Entry Content Module 1.3.6.1.4.1.19376.1.5.3.1.4.5.3 entry/act[templateId/@root='2.16.840.1.113883.10.20.1.27']/entryRelationship[@typeCode="SUBJ"]/observation[templateId/@root='1.3.6.1.4.1.19376.1.5.3.1.4.6']/text/reference/@value	O 0..1	ST	N/A

Number	Data element	CDA XPath expression	Optionality/ cardinality	HL7 V3 data type	Vocabulary
2.15	General Comment	Allergy and Intolerance Concern Entry Content Module 1.3.6.1.4.1.19376.1.5.3.1.4.5.3 entry/act[templateId/@root= '2.16.840.1.113883.10.20.1.27']/entryRelationship[@typeCode ="SUBJ"]/observation[templat eId/@root=' 1.3.6.1.4.1.19376.1.5.3.1.4.2']/text/reference/@value	O 0..1	ST	N/A
2.16	Did not occur	entry/act[templateId/@root= '2.16.840.1.113883.10.20.1.27']/entryRelationship[@typeCode ="SUBJ"]/observation[templat eId/@root='1.3.6.1.4.1.19376. 1.5.3.1.4.6']/value/[@xsi:type ='BL']/@code	O 0..1	INT	See Appendix 6 Table 10 for suggested values.
2.17	Reaction event reported	Allergy and Intolerance Concern Entry Content Module 1.3.6.1.4.1.19376.1.5.3.1.4.5.3 entry/act[templateId/@root= '2.16.840.1.113883.10.20.1.27']/entryRelationship[@typeCode ="SUBJ"]/observation[templat eId/@root='1.3.6.1.4.1.19376.	O 0..1	INT	See Appendix 6 Table 11 for suggested values.

Number	Data element	CDA XPath expression	Optionality/ cardinality	HL7 V3 data type	Vocabulary
		1.5.3.1.4.6']/value/[@xsi:type ='BL']/@code			
2.18	Reaction event report	Allergy and Intolerance Concern Entry Content Module 1.3.6.1.4.1.19376.1.5.3.1.4.5.3 entry/act[templateId/@root= '2.16.840.1.113883.10.20.1.27']/entryRelationship[@typeCode ="SUBJ"]/observation[templat eId/@root='1.3.6.1.4.1.19376. 1.5.3.1.4.6']/text/reference/@v alue	O 0..1	ST	N/A
2.19	Patient	Refer to common templates document.			
2.20	Identified by	Refer to common templates document.			

Appendix 1 — Clinical document architecture overview

1 Clinical document architecture (CDA) standard

The Health Level Seven (HL7) CDA standard is an internationally recognised standard which has been implemented in many countries. The CDA standard facilitates the exchange and unambiguous interpretation of clinical documents such as prescriptions, referrals and discharge summaries. CDA supports a combination of free text for human readability and adds structure and coding to the document to enable machine processing. The CDA standard can be processed by unsophisticated applications making it easy to render in web browsers so end-users can view the clinical document. They can also be integrated into clinical information systems so the data can be reused.

2 CDA characteristics

The international standards organisation Health Level Seven (HL7) developed the CDA standard to facilitate the exchange and unambiguous interpretation of clinical documents such as prescriptions, referrals and discharge summaries. CDA supports a combination of free text for human readability and adds structure and coding to the document to enable machine processing.

HL7 defines clinical documents as historical, human readable healthcare records that combine data and free text. The following list describes the characteristics of an electronic clinical document as defined by the CDA standard:

- Persistent - A clinical document continues to exist in an unaltered state, for a period defined by local and regulatory requirements.
- Stewardship - A clinical document is maintained by an organisation entrusted with its care.
- Potential for authentication - A clinical document is a collection of information that is intended to be legally authenticated.
- Context - A clinical document establishes the default context for its content.
- Wholeness - Authentication of a clinical document applies to the whole and does not apply to portions of the document without the full context of the document.
- Human readability - A clinical document is human readable.

CDA allows for different levels of detail to be added to clinical documents. Level one enables implementers to develop documents that are displayed and presented to clinicians in a readable format, but provides very little coded information to support machine processing of the document. More complex documents can be created that are coded for machine processing using level two and three. Level one is considered relatively easy to implement and will ensure that clinical documents are brought up to a standard format. Over time, it is possible for implementers to add greater levels of sophistication incrementally by adding in more structure and coding to the clinical document. This feature is referred to as the 'migration path' and provides a flexible approach to CDA implementation.

Several countries have adopted CDA as the basis for their standards-based health information exchange architecture. Countries who have undertaken CDA projects include Australia, Canada, Germany, Greece, Finland, Japan, the UK and the US. Implementers can refine the generic CDA specification by defining the structure and coding requirements to meet their local requirements.

In summary, the key benefits of CDA documents are listed below. CDA documents:

- are machine computable and human readable.
- provide a standardised display of clinical information without loss of clinical meaning.
- provide assurance of clinical quality and safety more effectively than message-based interfaces by storing and displaying the clinical data as entered by the clinician.
- support legal attestation by the clinician (requiring that a document has been signed manually or electronically by the responsible individual).
- can be processed by unsophisticated applications (displayed in web browsers).
- provide a number of levels of compliance to assist with technical implementation and migration.

3 CDA document structure

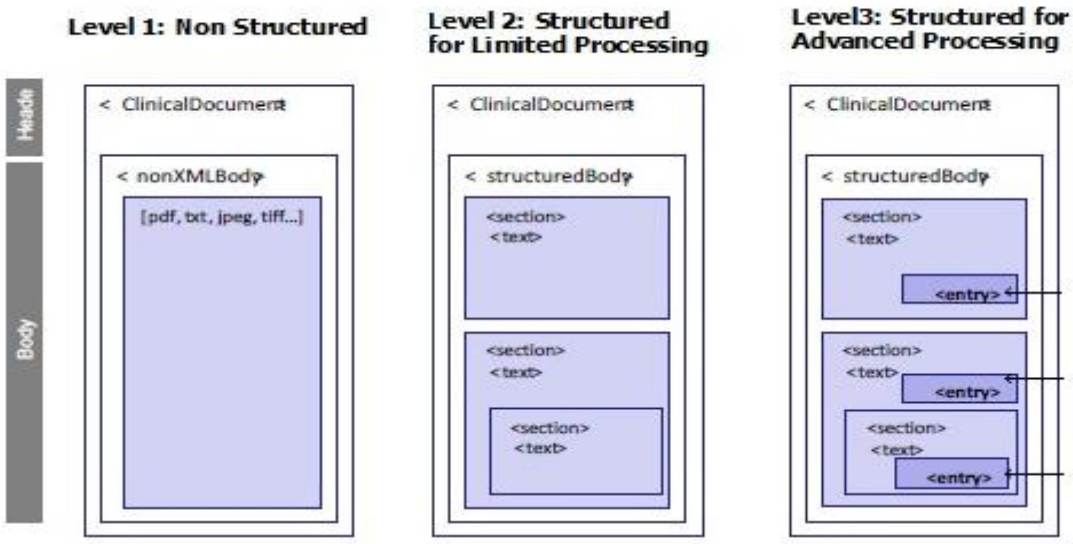
A CDA clinical document is divided into a header and a body. The purpose of the header is to hold metadata about the clinical report which set the context for the document, enable clinical document exchange across and within institutions, facilitate clinical document management. The header also facilitates compilation of an individual patient's clinical documents into a lifetime electronic patient record.

The header identifies and classifies the document and provides information on the authentication, the clinical visit, the patient, and the involved providers.

The purpose of the body of a CDA document is to carry the clinical report created by the healthcare practitioner. As previously mentioned, CDA allows for different levels of detail to be added to clinical documents (see Figure 1 below). Level one implementations have a coded document header and the human readable content is added to the body of the document as text. When implementing levels two and three, structured information is added by identifying CDA concepts known as sections and entries. Sections are used to identify headings within the clinical document and entries are used to identify lower level detail. In the context of this specification there is one section identified (the medication section) and each prescription item is implemented as an entry.

Sections can be coded using a vocabulary like LOINC or SNOMED CT. When the body of the document is structured using sections, and those sections are coded, HL7 would call that a Level 2 CDA document. A section may have a number of entries. Entries are machine readable representations of the clinical content and constitute a level 3 CDA document. An example of coding at the level 3 could be for a "prescription item". When the body of the document is structured using entries, and those sections are coded, HL7 would call that a Level 3 CDA document.

Figure 1. HL7 CDA document levels (adapted from epSOS)



4 CDA templates

The HL7 CDA object model (RMIM) is very generic. To use the CDA model for a specific use case, such as a discharge summary document, it is necessary to use HL7 templates. HL7 templates are constraints on the CDA object model, which means that they narrow the scope of the generic model. For example, a generic model for the identification of a patient may state that a patient must have one or more identifications. However, a template could be defined to state that a patient must have exactly one national patient identifier. HL7 templates are documented in an implementation guide.

Template definitions can be generated at the document-level, section-level and entry-level such as patient identification, provider organisation or an observation entry respectively.

HL7 templates are required to have a unique identifying number known as template ID. This template ID is used in clinical documents associated with patient records to indicate the document conforms to both the CDA generic model and the constraints specified in an implementation guide.

Each template has a set of metadata to describe the purpose and use of the template, allowing templates to be stored in repositories which can be queried. This makes it possible for templates to be shared internationally.

Appendix 2 — Technical specification

Table 1. Technical specification for adverse reactions

Name	Definition	Optionality	Data type	Cardinality	Coding system/value set
1.1 Substance	Identification of the substance that the patient has a susceptibility to an allergy upon exposure to the substance.	Mandatory	CodeableText	1..1 (parent adverse reaction)	This free text data element is currently a placeholder for further structured data that is as yet undefined. It will link to SNOMED CT reference set.
1.2 Contraindication	Indication to suggest that the administration of the substance should not be administered to this individual.	Optional	Integer	0..1	The following value set should be used and includes: True/False/Unknown.
1.3 Criticality	The criticality of an adverse reaction.	Optional	CodeableText	0..1	The following value set should be used: fatal | high | medium | low (HL7 FIHR).
1.4 Status	The status of the adverse reaction.	Mandatory	CodeableText	1..1	The following value set should be used: suspected | confirmed | refuted | resolved (HL7 FIHR).
1.5 Comment	Additional comments about the adverse reaction that are not captured in	Optional	Text	0..1	N/A

Name	Definition	Optionality	Data type	Cardinality	Coding system/value set
	other fields.				
1.6 Adverse reaction Reported	A field to indicate whether the adverse reaction was reported to a regulatory body.	Optional	Codeable Concept/Coded	0..1	The following value set should be used and includes: True/False/Unknown
1.7 Adverse reaction report	The report that was submitted to the regulatory authority.	Optional	Text	0..1	N/A
1.8 Evidence	Non subjective evidence that supports the adverse reaction occurred for the patient.	Optional	Text	0..*	N/A
1.9 Source of information.	The person who provided the information about the adverse reaction.	Optional	Codeable Text	0..1	This free text data element is currently a placeholder for further structured data that is as yet undefined. It will link to SNOMED CT.
1.9 Patient	Refer to common templates document				
1.10 Identified By	Refer to common templates document				

Table 2. Technical specification for reaction events

Name	Definition	Optionality	Data type	Cardinality	Coding system/value set
2.1 Substance	Identification of the actual substance considered to be responsible for the reaction event.	Mandatory	CodeableText	1..1	This free text data element is currently a placeholder for further structured data that is as yet undefined. It will link to one or more SCT reference sets.
2.2 Symptom	A description of the symptoms of the reaction.	Optional	Codeable text	0..*	This free text data element is currently a placeholder for further structured data that is as yet undefined. It will link to Clinical Findings Foundational Ref Set (NEHTA).
2.3 Symptom severity	The severity of the symptom as determined by the healthcare practitioner.	Optional	CodeableText	0..1	This free text data element is currently a placeholder for further structured data that is as yet undefined. It will link to the following value set : severe | serious | moderate | minor (HL7 fihr)

Name	Definition	Optionality	Data type	Cardinality	Coding system/value set
2.4 Reaction type	The type of reaction event as determined by the healthcare practitioner.	Optional	CodeableText	0..1	This free text data element is currently a placeholder for further structured data that is as yet undefined. It will link to the following value set (examples from NEHTA): 1. Allergy 2. Idiosyncrasy 3. Interactions 4. Intolerance / sensitivity 5. Pseudoallergy / anaphylactoid reaction 6. Side effects
2.5 Certainty	The degree of certainty that the substance was the cause of the reaction event as determined by the healthcare practitioner.	Optional	Coded Text	0..1	NEHTA Adverse Reaction Certainty Values EXAMPLES 1. Certain 2. Probable 3. Unlikely. The use of the WHO-UMC system for standardised case causality assessment [UMC2011a]
2.6 Reaction description	Narrative description of the reaction event including anatomical reaction details.	Optional	Text	0..1	N/A
2.7 Reaction	Record of the	Optional	DateTime	0..1	N/A

Name	Definition	Optionality	Data type	Cardinality	Coding system/value set
onset date	date or time (or both) of the onset of the reaction.				
2.8 Duration of reaction	The amount of time that the reaction event was present.	Optional	Duration	0..1	N/A
2.9 Resolution Date	Record of the date and, or time or estimated date/time when the reaction event resolved.	Optional	DateTime	0..1	N/A
2.10 Exposure description	Description about exposure to the substance.	Optional	Text	0..1	N/A
2.11 Exposure type	The type of exposure that caused the reaction event.	Optional	CodeableText	0..1	This free text data element is currently a placeholder for further structured data that is as yet undefined. It will link to Code System URL: http://hl7.org/fhir/exposureType/ Value Set
2.12 Exposure date	Record of the date and/or time	Optional	DateTime	0..1	N/A

Name	Definition	Optionality	Data type	Cardinality	Coding system/value set
	of the earliest or initial exposure to the substance.				
2.13 Duration of exposure	The amount of time of exposure to the substance.	Optional	Duration	0..1	N/A
2.14 Clinical management description	Description about the clinical management provided.	Optional	Text	0..1	N/A
2.15 General Comment	General comments about the reaction event.	Optional	Text	0..1	N/A
2.16 Did not occur	Field to indicate that a specific reaction to a substance did not occur when the patient was exposed to the substance.	Optional	Codeable Concept/Coded	0..1	The following value set should be used and includes: True/False/Unknown
2.17 Reaction event reported	A field to indicate whether the reaction event was reported to a	Optional	Codeable Concept/Coded	0..1	The following value set should be used and includes: True/False/Unknown

Name	Definition	Optionality	Data type	Cardinality	Coding system/value set
	regulatory body.				
2.18 Reaction event report	The report that was submitted to the regulatory authority.	Optional	Text	0..1	N/A
2.19 Patient	Refer to common templates document.				
2.20	Refer to common templates document.				

Appendix 3 — Consultation questions

As part of the public consultation, the Health Information and Quality Authority asked for responses to the following eight questions. Questions 5-7 are specific to the Adverse Reactions Standard.

1. Benefits - Are there benefits in having a Diagnosis and Adverse Reaction Dataset and Clinical Document Architecture specification and, if so, what are the main benefits?

2. Diagnosis dataset - Have all of the appropriate data items been included in the Diagnosis dataset? Would you leave out any of the data items listed? Would you suggest additional data items?

3. Diagnosis dataset - Do the definitions provided in the Diagnosis dataset in the consultation document adequately explain each of the data items? If not, please suggest improvements?

4. Diagnosis CDA specification - Are there any alterations needed for the Diagnosis clinical document architecture specification? If so, please suggest improvements?

5. Adverse Reaction dataset - Have all of the appropriate data items been included in the Adverse Reaction dataset? Would you leave out any of the data items listed? Would you suggest additional data items?

6. Adverse Reaction dataset - Do the definitions provided in the Adverse Reaction dataset in the consultation document adequately explain each of the data items? If not, please suggest improvements?

7. Adverse Reaction CDA specification - Are there any alterations needed for the Adverse Reactions clinical document architecture specification standard? If so, please suggest improvements?

8. Please provide any general feedback you wish to give below.

Appendix 4 — Statement of outcomes

A total of 13 submissions were received during the consultation process. The Health Information and Quality Authority (HIQA) welcomed all submissions and would like to thank all those who contributed. The organisations that made submissions to the targeted consultation include the:

- The Irish Pharmacy Union
- The Health Service Executive
- Complete GP Ltd.
- DMF Systems Ltd.
- Mater Misericordiae University Hospital

Submissions were also made by individuals in a personal capacity. All submissions have received an acknowledgement of their contribution. All submissions to the consultation informed the development of the final national standard.

4.1 Changes to Adverse Reaction Draft Standard

Each submission received was read in its entirety, analysed and a decision was made to either include or exclude responses to the Standard. A rationale for inclusion or exclusion of a response was given. The responses received were identified as a qualitative comment or as feedback that related to individual data items of the dataset and CDA specification.

4.2 Changes to Dataset and CDA specification

Table 1 outlines the changes that were made to the data items of the adverse reaction Standard.

Table 1. Changes to draft standards for adverse reactions

Number (as defined in dataset/CDA specification)	Data item	Change agreed
1.1	Substance	Change terminology in vocabulary section in CDA specification from "Allergenic Agent" to "Substance".
1.8	Evidence	Change Usage from "This could include laboratory reports, radiology reports or other investigation which supports confirmation of the adverse reaction" to "This could include laboratory reports, radiology reports or other investigations which supports confirmation of the adverse reaction. This information can be supported by multimedia formats such as image, signal, sound, vox and video".
2.1	Substance (Reaction Type)	Change terminology in vocabulary section in CDA specification from "Allergenic Agent" to "Substance".
2.11	Exposure Type	Change Usage and Update Value set Exposure Type to include value "Environmental Exposure".
2.15	General Comment	Change Usage from "General Comments about the reaction event including any instructions that may have been given to the patient" to "General Comments about the reaction event including any instructions or medications that may have been given to the patient".

4.3 Feedback on consultation questions for adverse reaction

Questions 5, 6 and 7 of the consultation form related to the Adverse Reaction dataset.

5. Have all of the appropriate data items been included in the Adverse Reaction dataset? Would you leave out any of the data items listed? Would you suggest additional data items?

Overall respondents were satisfied that appropriate data items were included in the adverse reaction dataset. Some of the feedback comments included:

"The document is comprehensive and complete. Actual initial or pilot implementation may highlight some areas for improvement".

"All appropriate data items included. No deletions or additions proposed".

6. Do the definitions provided in the Adverse Reaction dataset in the consultation document adequately explain each of the data items? If not, please suggest improvements?

Overall respondents were satisfied with the dataset definitions. Suggestions were made to change the optionality of some data items. Some of the feedback comments are included below:

"The definitions adequately describe the data items".

"Some of the more technical definitions could possibly be substituted with worked examples".

7. Are there any alterations needed for the Adverse Reactions clinical document architecture specification standard? If so, please suggest improvements?

All respondents were satisfied with the CDA specification. One response noted that in order to implement the CDA specification in practice it is necessary to consider the use case in question:

"Depends on use case. For reporting to regulatory agency, the extra fields specified above need inclusion".

4.4 Overall themes

Qualitative comments were identified during the analysis. The following comments below illustrate a sample of the comments made by respondents. The overall consensus from respondents is that the development of draft standards for diagnosis and adverse reactions, which can be reused throughout different document types, is highly beneficial. The standards can facilitate the unambiguous sharing of information between providers.

Samples of the comments are provided below categorised under the following themes: benefits, coding and alignment with national ICT agenda.

- **Benefits**

"A specification will in time if integrated with EPR systems will facilitate the sharing of patient information between healthcare providers and provide for greater continuity and optimisation of patient care".

"Improved sharing of information, improved discipline in diagnosis, reduced avoidable adverse reactions, improved accuracy of data for research".

"yes - very beneficial provides for standardisation of detection, reporting and training to the benefit of the patient".

"On a practical basis, having a standardised mechanism to specify the indication and indication status for a specific treatment would facilitate part of the prescription assessment process. Ideally this would mean that any treatment would be tied to an indication".

"One issue of importance is that the agreed DARD & CDA are implementable within the hospital and national health IT application frameworks that are in place or planned".

- **Coding information**

"There is a benefit for the correct transfer of CODED diagnosis and Reactions and some indication to EHR systems as to what information to collect. Uncoded Diagnosis has a very limited benefit".

"I believe the Diagnosis MUST BE CODED. All GP Practice management systems, if certified, must use either ICPC-2 or ICD10. SNOMED has not yet been made available and NO standard should be created until it is made available to companies to include it in their EHR. Because either ICPC-2 or ICD10 is mandated in all Hospitals and GP practices in Ireland the specification should indicate how to code one of those Diagnosis. If a Diagnosis is transferred into our EHR we use the coding when prescribing to put up warning messages. This cannot be done with just a text diagnosis. I would also mandate that just a Text diagnosis should never be allowed".

"I note that Diagnosis name will in the interim be a free text field which may be necessary prior to a terminology standard being adopted. It should be noted that free text may lead to ambiguity currently associated with paper notes. E.g. Ulcer may be written, is this a duodenal, peptic, venous or other type of ulcer?".

Appendix 5 — HL7 v3 data type

Each data element has a data type associated with it. A description of the HL7 data types used in the Adverse Reaction CDA template is outlined below.

Table 1. HL7 v3 data types

HL7 v3 Data Type	Name	Description
AD	Postal Address	Home or Office Address. A sequence of address parts.
ANY	Any	Defines the basic properties of every data.
CD	Concept Descriptor	A concept descriptor represents any kind of concept usually by giving a code defined in a code system. A concepts descriptor can contain the original text or phrase that served as the basis of the coding and one or more translations into different coding systems.
CE	Coded with Equivalents	Coded data that consists of a coded value (CV) and optionally coded values from other coding systems that identify the same concept. Used when alternative codes may exist.
CS	Coded Simple Value	Coded data in its simplest form, where only the code is not predetermined. The code system and code system version is fixed by the context in which the CS value occurs. CS is used for coded attributes that have a single HL7-defined value set.
ED	Encapsulated Data	Data that is primarily intended for human interpretation or for further machine processing outside the scope of HL7. This includes unformatted or formatted written language, multimedia data or structured information in as defined by a different standard.
EN	Entity Name	A name for a person, organisation, place or thing. A sequence of name parts, such as first name or family name, prefix, suffix.
II	Instance Identifier	An identifier that uniquely identifies a thing or an object. Examples are object identifier for HL7 RIM objects, medical record number, order id, service catalogue item id. Vehicle Identification Number (VIN) etc. Instance Identifiers are defined based on ISO object identifiers.
IVL	Interval	A set of consecutive values of an ordered based data type. Any ordered type can be the basis of

HL7 v3 Data Type	Name	Description
		an interval: it does not matter whether the base type is discrete or continuous. If the base data type is only partially ordered, all elements of the interval must be elements of a totally ordered subset of the partially ordered data type.
ON	Organisation Name	A name for an organisation. A sequence of name parts.
PN	Person Name	A name for a person. A sequence of name parts such as first name, family name, prefix, suffix. A name part is a restriction of entity name part that only allows those entity name part qualifiers applicable to person names. Since the structure of entity name is mostly determined by the requirements of person name, the restriction is very minor. This data type is of mixed content.
PQ	Physical Quantity	A dimensioned quantity expressing the result of measuring.
RTO	Ratio	A quantity constructed as the quotient of a numerator quantity divided by a denominator quantity. Common factors in the numerator and denominator are not automatically cancelled out. The data type supports quantities produced by laboratories that truly represent ratios.
SC	Character String with Code	The character string that optionally may have a code attached. The text must always be present if a code is present. The code is often local code.
ST	Character String	The character string data type stands for text data, primarily intended for machine processing (for example, sorting, querying, indexing). Used for names, symbols, and formal expressions.
TEL	Telecommunication Address	A telephone number (voice or fax), email address, or other locator for a resource mediated by telecommunication equipment. The address is specified as a Universal Resource Locator (URL) qualified by time specification and use codes that help in deciding which address to use for a given time and purpose.
TS	Timestamp	A quantity specifying a point on the axis of natural time. A point in time is most often represented as a calendar expression. Note: An

HL7 v3 Data Type	Name	Description
		IVL TS (Interval Timestamp) has to be fully formed, whereas a regular timestamp can be truncated.

Appendix 6 — Value sets

The following tables provide exemplar values for these value sets and should not be considered complete value sets.

Value Set 1: Substance

Table 1. Value set for substance (epSOSAllergenNoDrugs 1.3.6.1.4.1.12559.11.10.1.3.1.42.19)

Value	Descriptor/Display Name	Source
294461000	allergy to antibiotic agents	SNOMED-CT
294221004	allergy to muscle relaxants	SNOMED-CT
293637006	allergy to contrast media	SNOMED-CT
293913009	allergy to neuroleptics	SNOMED-CT
294020007	allergy to sympathomimetics	SNOMED-CT
294109009	allergy to antihistamines	SNOMED-CT
293816000	allergy to antidepressants	SNOMED-CT
294633002	allergy to human immune sera	SNOMED-CT
402594000	allergy to plants	SNOMED-CT
213020009	allergy to egg protein	SNOMED-CT
418545001	allergy to colouring agents, dye	SNOMED-CT
412046002	allergy to paraben	SNOMED-CT
294914009	allergy to iodine	SNOMED-CT
300910009	allergy to pollen	SNOMED-CT
419474003	allergy to mould	SNOMED-CT
300911008	allergy to animal hair	SNOMED-CT
232350006	allergy to mites	SNOMED-CT
418689008	allergy to grasses	SNOMED-CT
419788000	allergy to nickel	SNOMED-CT
91936005	allergy to penicillin	SNOMED-CT
300916003	allergy to latex	SNOMED-CT
91939003	allergy to sulfonamides	SNOMED-CT
418434002	allergy to anaesthetic agent	SNOMED-CT
161596009	allergy to serum	SNOMED-CT
294640001	allergy to vaccine	SNOMED-CT
293586001	allergy to aspirine	SNOMED-CT
295037009	allergy to captopril	SNOMED-CT
232350006	House dust mite allergy (disorder)	SNOMED-CT
416098002	Drug allergy (disorder)	SNOMED-CT
390952000	Dust allergy (disorder)	SNOMED-CT

Value Set 2: Contraindication

Table 2.

Value set for contraindication (HIQA)

Value	Descriptor/Display Name	Source	Map to SNOMED CT CODE
T	True	HIQA	Y
F	False	HIQA	Y
U	Unknown	HIQA	Y

Value Set 3: Criticality

Table 3. Value set for criticality (hl7) value set URL: http://hl7.org/fhir/vs/criticality

Value	Descriptor/Display Name	Source	Map to SNOMED CT CODE
F	Fatal	Hl7 FIHR	Y
H	High	Hl7 FIHR	Y
M	Medium	Hl7 FIHR	Y
L	Low	Hl7 FIHR	Y

Value Set 4: Status

Table 4. Value set for status (HL7)

Value	Descriptor/Display Name	Source	Map to SNOMED CT CODE
S	Suspected	Hl7 FIHR	Y
C	Confirmed	Hl7 FIHR	Y
R	Refuted	Hl7 FIHR	Y
RS	Resolved	Hl7 FIHR	Y

Value Set 5: Symptom

Table 5. Value set for Reaction Allergy (epSOSReactionAllergy 2.16.840.1.113883.6.96)

Value/Code	Descriptor/Display Name	Source	Map to SNOMED CT CODE
39579001	Anaphylaxis	SNOMED-CT	N/A
200769008	Atopic dermatitis and related conditions	SNOMED-CT	N/A
4386001	Bronchospasm	SNOMED-CT	N/A
9826008	Conjunctivitis	SNOMED-CT	N/A
43116000	Eczema	SNOMED-CT	N/A
267804004	Pruritus NOS	SNOMED-CT	N/A
70076002	Rhinitis	SNOMED-CT	N/A
247472004	Weal	SNOMED-CT	N/A
41291007	Angio-oedema	SNOMED-CT	N/A

Value Set 6: Symptom Severity

Table 6. Value set for symptom severity (HL7 FIHR)

Value	Descriptor/Display Name	Source	Map to SNOMED CT CODE
SV	Severe	Hl7 FIHR	Y
S	Serious	Hl7 FIHR	Y
M	Moderate	Hl7 FIHR	Y
M	Minor	Hl7 FIHR	Y

Value Set 7: Reaction Type

Table 7. Value set for Reaction Type (epSOSAdverseEventType 2.16.840.1.113883.6.96)

Value	Descriptor/Display Name	Source	Map to SNOMED CT CODE
419199007	Allergy to substance	SNOMED-CT	N/A
416098002	Drug allergy	SNOMED-CT	N/A
59037007	Drug intolerance	SNOMED-CT	N/A
414285001	Food allergy	SNOMED-CT	N/A
235719002	Food intolerance	SNOMED-CT	N/A
420134006	Propensity to adverse reactions	SNOMED-CT	N/A
419511003	Propensity to adverse reactions to drug	SNOMED-CT	N/A
418471000	Propensity to adverse reactions to food	SNOMED-CT	N/A
418038007	Propensity to adverse reactions to substance	SNOMED-CT	N/A

Value Set 8: Certainty

Table 8. Value set for certainty (WHO-UCM causality)

Value	Descriptor/Display Name	Source	Map to SNOMED CT CODE
C	Certain	WHO	Y
PR	Probably/Likely	WHO	Y
P	Possible	WHO	Y
UL	Unlikely	WHO	Y
C	Conditional/Unclassified	WHO	Y
UN	Unassessable/Unclassifiable	WHO	Y

Value Set 9: Exposure Type

Table 9. Value set for exposure type (HIQA)

Value	Descriptor/Display Name	Source	Map to SNOMED CT CODE
DA	Drug administration	HIQA	Y
I	Immunisation	HIQA	Y
C	Coincidental	HIQA	Y
EE	Environmental Exposure	HIQA	Y

Value Set 10: Did not occur

Table 10. Value set for did not occur (HIQA)

Value	Descriptor/Display Name	Source	Map to SNOMED CT CODE
T	True	HIQA	Y
F	False	HIQA	Y
U	Unknown	HIQA	Y

Value Set 11: Reaction event reported

Table 11. Value set for reaction event reported (HIQA)

Value	Descriptor/Display Name	Source	Map to SNOMED CT CODE
T	True	HIQA	Y
F	False	HIQA	Y
U	Unknown	HIQA	Y

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