Health Information and Quality Authority

An tÚdarás Um Fhaisnéis agus Cáilíocht Sláinte

National standard diagnosis dataset and clinical document architecture (CDA) template

January 2016

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.

One of the areas currently being addressed by the Health Information Directorate is the area of developing common 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 a diagnosis standard which can be transformed into electronic documents using an international standard known as the Health Level 7 (HL7) Clinical Document Architecture (CDA) Standard. This Standard will define the HL7 CDA template for diagnosis.

[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.

Table of contents

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 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 EHR including the Commission for Patient Safety and Quality Assurance(1) and most recently, the Department of Health's eHealth Strategy for Ireland (2013)(2).

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

[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 development of patient summary records, i.e. summaries of key clinical information that can be derived from an EHR (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 CDA is an appropriate standard to use for the exchange of clinical documents. The HL7 CDA is a document 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 diagnosis that informs a HL7 CDA template (See Appendix 1 for detailed information on the CDA standard and templates) for diagnosis that can be reused in different document types such as national patient summaries. A diagnosis is defined by the Australian National eHealth Transition Authority (NEHTA)[4] as:

Any healthcare condition which may impact on the physical, mental, or social well-being of an individual that may require diagnostic, therapeutic or educational action. A diagnosis is based on scientific evaluation of physical signs, symptoms, history, laboratory test results and procedures.

The National Health Service (NHS) in England is using an electronic record called the Summary Care Record (SCR) to support patient care and 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 diagnosis such as diabetes or epilepsy. Summary care records generated from GP practice management systems have been used in emergency department and acute hospital settings and improve patient safety and the effectiveness and efficiency of patient care[5].

2 Background

Under the Health Act 2007, the Health Information and Quality Authority (HIQA) is charged with setting standards for health information which includes standards for the communication of health information between care providers. To date HIQA has published several standards in this regard, namely:

- 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 published standards to support ePrescribing called the *ePrescription Dataset and Clinical Document Architecture Standard (2015)* [10]. This standard 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 diagnosis 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. The diagnosis standard is part of a collection of standards, including the adverse reaction 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 diagnosis which can be reused throughout different clinical document types. For example, a CDA template for diagnosis can be reused in both a patient referral document and a patient's discharge summary document. This standard describes a dataset for a diagnosis 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 a diagnosis. 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 diagnosis 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 diagnosis 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 health care
- more efficient national planning
- improved research through the provision of more timely, and higher 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 diagnosis was developed after analysis of several datasets developed in other jurisdictions. In Australia, the National eHealth Transition Authority (NEHTA) published a detailed specification used to record all information about diagnosis that is required to support direct clinical care of an individual. Diagnosis datasets from two of the main standards developments organisations for communication standards, OpenEHR and HL7 were also included in this analysis. The specifications that were used include:

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

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

The draft 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 diagnosis 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 Diagnosis was developed in conjunction with the members of the Authority's eHealth Standards Advisory Group (eSAG) and a targeted consultation was undertaken. The Authority published a consultation document *Draft National Standard for a Diagnosis 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 adverse reaction as both standards are part of a suite of specifications that HIQA has developed. The 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.

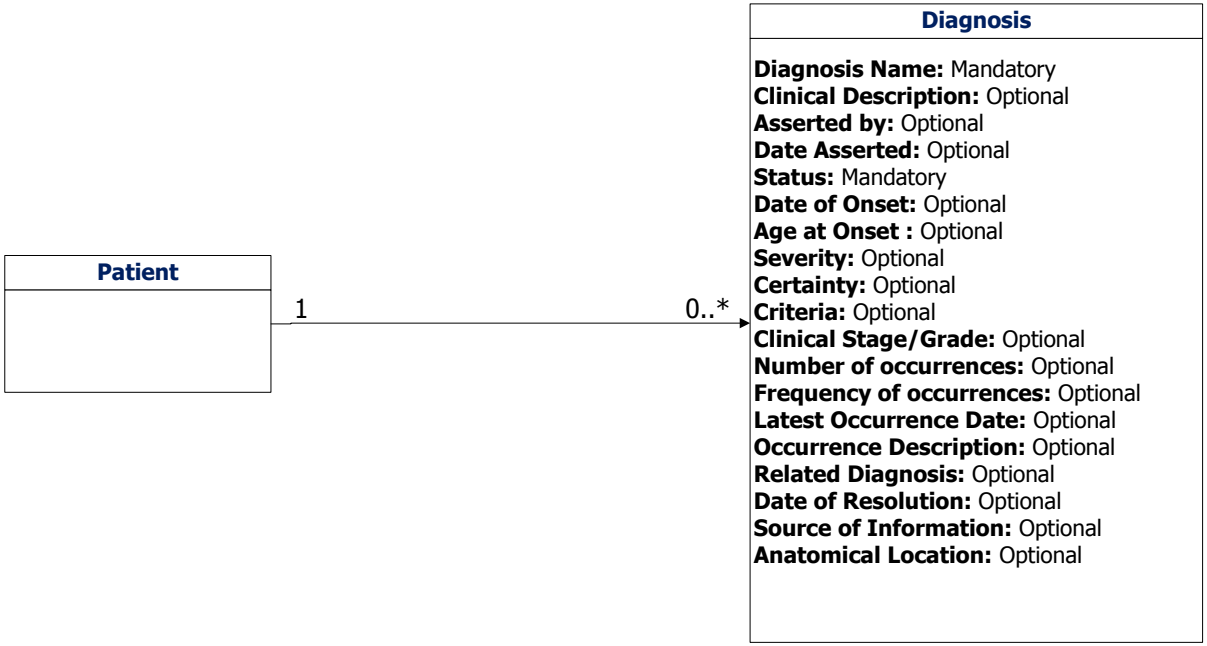
Appendix 4 outlines the organisations that made a submission. Each submission was read in its entirety and broken down into general comments and individual items that directly relate to the data items in the standard. Appendix 4 provides a review of the qualitative comments made and the changes to the 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 diagnosis

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

The diagnosis model consists of the patient and the diagnosis classes. A patient can have zero to many diagnosis. Figure 1 below outlines a data model for a patient's diagnosis.

Figure 1. Data model for a diagnosis



7 Dataset for diagnosis

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. A diagnosis dataset is essential to provide information about an individual's diagnosis. A diagnosis is defined as any healthcare condition which may impact on the physical, mental or social well-being of an individual that may require diagnostic, therapeutic or educational action.

A diagnosis is based on scientific evaluation of physical signs, symptoms, history, laboratory test results and procedures. If all healthcare providers use the same data model and dataset then information about a diagnosis can be shared. Each of the classes and associated attributes are described in the dataset in Table 1 below which define the name, definition, optionality and usage of each data element.

Table 1. Diagnosis dataset

Name	Definition	Optionality	Usage
1.1 Diagnosis name	Identification of the condition or diagnosis.	Mandatory	The name of the diagnosis given to the patient that is determined by the healthcare practitioner.
1.2 Clinical description	Narrative description or comments about clinical aspects of the diagnosis.	Optional	Additional narrative about the diagnosis not captured in other fields.
1.3 Asserted by	The details of the healthcare practitioner who makes the diagnosis.	Optional	The details of the healthcare practitioner who makes the diagnosis. See section 7.3.
1.4 Date asserted	The date the healthcare practitioner makes the diagnosis.	Optional	The date the healthcare practitioner makes the diagnosis.
1.5 Status	The status of the diagnosis.	Mandatory	The status of the diagnosis categorised as provisional, working, confirmed or refuted.
1.6 Date of onset	Estimated or actual date the diagnosis began, in the opinion of the healthcare practitioner.	Optional	The estimated or actual date when the condition was first detected/suspected/entered.
1.7 Age at onset	The age of the person at the estimated time or actual date the diagnosis began.	Optional	The age of the person at the estimated time or actual date the diagnosis began.

Name	Definition	Optionality	Usage
1.8 Severity	A subjective assessment of the severity of the diagnosis as evaluated by the healthcare practitioner.	Optional	A subjective assessment of the severity of the diagnosis as evaluated by the healthcare practitioner. Coding of the symptoms with a coding system is preferred where possible. Examples include: severe, serious, moderate or minor.
1.9 Certainty	The level of confidence in the identification of the diagnosis.	Optional	A subjective assessment of the certainty of the diagnosis as evaluated by the healthcare practitioner.
1.10 Criteria	The criteria on which the diagnosis is based.	Optional	The criteria on which the diagnosis is based.
1.11 Clinical stage/grade	Clinical stage or grade of a diagnosis.	Optional	Clinical stage or grade of a diagnosis.
1.12 Number of occurrences	Cumulative number of occurrences or exacerbations of the diagnosis.	Optional	Cumulative number of occurrences or exacerbations of the diagnosis.
1.13 Frequency of the diagnosis	The frequency or estimated frequency of occurrences or exacerbations of the diagnosis.	Optional	The frequency or estimated frequency of occurrences or exacerbations of the diagnosis.
1.14 Latest occurrence date	The date of the last occurrence or exacerbation of the diagnosis.	Optional	The date of the last occurrence or exacerbation of the diagnosis.

Name	Definition	Optionality	Usage
1.15 Occurrence description	A narrative description, including outcomes and other key details, about occurrences or exacerbations of the diagnosis.	Optional	A narrative description, including outcomes and other key details, about occurrences or exacerbations of the diagnosis.
1.16 Related Diagnosis	Identification of other diagnoses that have a relationship to the diagnosis.	Optional	Other diagnosis that can be linked to the diagnosis.
1.17 Date of resolution	The date or estimated date that the diagnosis was resolved.	Optional	The date or estimated date that the diagnosis resolved or went into remission, as indicated or identified by the healthcare professional.
1.18 Source of information	The person who provided the information that came to the diagnosis being made.	Optional	This could be a patient, GP, healthcare professional, and so on.
1.19 Anatomical location	The anatomical location relating to the diagnosis.	Optional	The anatomical location relating to the diagnosis.
1.20 Patient	The subject of care who has the diagnosis.	Mandatory	The subject of care who has the diagnosis.

8 CDA specification

This section defines the CDA specification for a diagnosis clinical concept and is based on the dataset defined in section 7. Section 8.1 provides guidance on how to interpret the CDA diagnosis specification. Section 8.2 details the CDA specification for diagnosis. The background information on the CDA is provided in Appendix 1.

8.1 Description of the CDA specification tables

The specification is defined using a table structure as illustrated in table 2 below. The purpose of each of the columns is explained in this section.

Table 2. Table structure for defining CDA documents, sections and entries

Number	Data Element	CDA xpath expression	Optionality and 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 elements 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 3 below:

Table 3. Optionality used in the CDA diagnosis 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 4 below:

Table 4. Cardinality used in the CDA diagnosis 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 that there are optionally many (more than one) additional identifiers.

5. The 'HL7 v3 data type' column

* Note use of US English spelling.

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 3.

6. The 'vocabulary' column

The vocabularies/terminologies that are used throughout this specification include epSOS value sets that are sourced and SNOMED CT.

8.2 CDA Template for diagnosis

Table 7 below outlines the CDA level 3 templates for diagnosis.

Table 7. CDA level 3 templates for diagnosis

Number	Data element	CDA XPath expression	Optionality and cardinality	HL7 V3 data type	Vocabulary
1.1	Diagnosis Name	entry/act[templateId/@root='1.3.6.1.4.1.19376.1.5.3.1.4.5.2']/ entryRelationship[@typeCode='SUBJ']/ observation[templateId/@root='1.3.6.1.4.1.19376.1.5.3.1.4.5']/value/@code	RNFA 1..1	CD	Suggested value set for diagnosis name is epSOSIllnessesandDisorders 2.16.840.1.113883.6.90 that uses SNOMED CT as the source terminology system.
1.2	Clinical description	entry/act[templateId/@root='1.3.6.1.4.1.19376.1.5.3.1.4.5.2']/ entryRelationship[@typeCode='SUBJ']/ observation[templateId/@root='1.3.6.1.4.1.19376.1.5.3.1.4.5']/value/@displayName	O 0..*	ST	N/A
1.3	Asserted By	Refer to common header templates document.			
1.4	Date Asserted	Refer to common header templates document.			
1.5	Status	entry/act[templateId/@root='1.3.6.1.4.1.19376.1.5.3.1.4.5.2']/entryRelationship[@typeCode='REFR']/observation[templateId/@root='1.3.6.1.4.1.19376.1.5.3.1.4.1.1']/value/@code	R 1..1	CD	The value set to be used is epSOSstatusCode, OID 1.3.6.1.4.1.12559.11.10.1.3.1.42.15. Refer to Appendix 46Table 11 for suggested values.
1.6	Date of onset	entry/act[templateId/@root='1.3.6.1.4.1.19376.1.5.3.1.4.5.2']/effectiveTime[@ xsi:type='IVL_TS']/low	O 0..1	IVL_TS	N/A

Number	Data element	CDA XPath expression	Optionality and cardinality	HL7 V3 data type	Vocabulary
1.7	Age of onset	entry/act/[templateId/@root='1.3.6.1.4.1.19376.1.5.3.1.4.5.2']/observation[templateId/@root='1.3.6.1.4.1.19376.1.5.3.1.4.5']/[code/@code='445518008]/value/@code	O 0..1	PQ	Age at onset of clinical finding SCT code is 445518008. @value is the actual age.
1.8	Severity	entry/act[templateId/@root='1.3.6.1.4.1.19376.1.5.3.1.4.5.2']/entryRelationship[@typeCode='SUBJ']/observation[templateId/@root='1.3.6.1.4.1.19376.1.5.3.1.4.1']/value/@code	O 0..1	CD	The severity codes to be used are epSOSSeverity, OID 1.3.6.1.4.1.12559.11.10.1.3.1.42.13. Refer to Appendix 6 Table 12 for suggested values.
1.9	Certainty	entry/act[templateId/@root='1.3.6.1.4.1.19376.1.5.3.1.4.5.2"]/ entryRelationship[@typeCode='SUBJ']/observation[templateId/@root='1.3.6.1.4.1.19376.1.5.3.1.4.5 ']/value/@code	O 0..1	CD	See Value Set in Appendix 6 Table 13 for suggested values.
1.10	Criteria	entry/act[templateId/@root='1.3.6.1.4.1.19376.1.5.3.1.4.5.2']/entryRelationship[@typeCode='SUBJ']/observation[templateId/@root='1.3.6.1.4.1.19376.1.5.3.1.4.2']/text/reference/@value	O 0...*	ST	N/A.
1.11	Clinical stage/grade	entry/act[templateId/@root='1.3.6.1.4.1.19376.1.5.3.1.4.5.2']/entryRelationship[@typeCode='SUBJ']/observation[templateId/@root='1.3.6.1.4.1.19376.1.5.3.1.4.2']/ text/reference/@value	O 0...*	ST	N/A
1.12	Number of occurrences	entry/act[templateId/[@root='1.3.6.1.4.1.19376.1.5.3.1.4.5.2']/quantity/low@value entry/act[templateId/[@root='1.3.6.1.4.1.19376.1.5.3.1.4.5.2']/quantity/high@value	O 0..1	PQ	N/A
1.13	Frequency of the diagnosis	entry/ProblemAct[templateId/[@root='1.3.6.1.4.1.19376.1.5.3.1.4.5.2']/ effectiveTime	O 0..1	TS IVL_TS PIVL_TS EIVL_TS SXPR_TS	N/A

Number	Data element	CDA XPath expression	Optionality and cardinality	HL7 V3 data type	Vocabulary
1.14	Latest occurrence date	entry/act[templateId/@root='1.3.6.1.4.1.19376.1.5.3.1.4.5.2']/effectiveTime/high	O 0..1	TS	N/A
1.15	Occurrence description	entry/act[templateId/@root='1.3.6.1.4.1.19376.1.5.3.1.4.5.2']/entryRelationship[@typeCode='SUBJ']/observation[templateId/@root='1.3.6.1.4.1.19376.1.5.3.1.4.5']/text/reference/@value	O 0..*	ST	N/A
1.16	Related Diagnosis	entry/act[templateId/@root='1.3.6.1.4.1.19376.1.5.3.1.4.5.2']/ entryRelationship[@typeCode='SUBJ']/observation[templateId/@root='1.3.6.1.4.1.19376.1.5.3.1.4.5']/value/@code	O 0..*	ST	N/A
1.17	Date of resolution	entry/act[templateId/@root='1.3.6.1.4.1.19376.1.5.3.1.4.5.2']/effectiveTime/effectiveTime[2][@xsi:type='IVL_TS']/high	O 0..1	TS	N/A
1.18	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='1.3.6.1.4.1.19376.1.5.3.1.4.5']/text/reference/@value	O 0...*	ST	N/A
1.19	Anatomical location	entry/act[templateId/@root='1.3.6.1.4.1.19376.1.5.3.1.4.5.2']/entryRelationship[@typeCode='SUBJ']/observation[templateId/@root='1.3.6.1.4.1.19376.1.5.3.1.4.5']/text/reference/@value	O 0...*	ST	N/A
1.20	Patient	Refer to common header templates document.[1]			

[1] [1] 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.

Appendix 1 — Clinical document architecture overview

1 Clinical document architecture (CDA) Standard

The Health Level Seven (HL7) clinical document architecture (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 HL7 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 provide 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 by incrementally 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, UK and 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

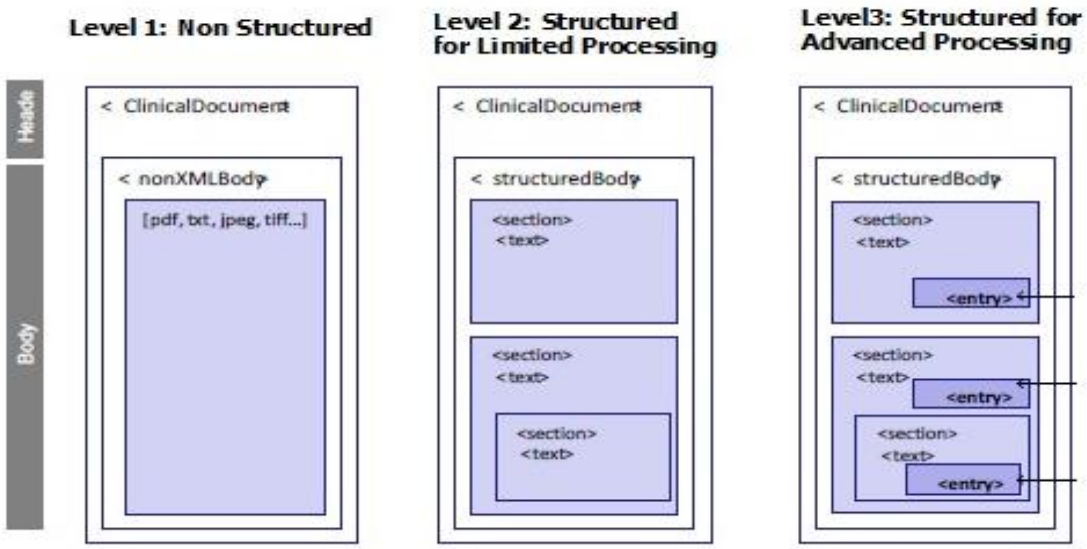
A CDA clinical document is divided into a header and a body. The purpose of the header is to hold metadata about the clinical report which set the context for the document, enable clinical document exchange across and within institutions, facilitate clinical document management. The header also

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 2). 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, i.e. 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 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, i.e. 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 template ID indicating that a document conforms to both the CDA generic model and the constraints specified in an implementation guide. The template ID, which could be an OID or locally defined, is used to indicate which template is being used.

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 diagnosis

Name	Definition	Optionality	Cardinality	Data type	Coding systems and value domains
1.1 Diagnosis Name	Identification of the condition or diagnosis.	Mandatory	1..1	Codeable Text	This free text data element is currently a placeholder for further structured data that is as yet undefined. It will link to SNOMED CT. This value set includes all SNOMED CT clinical findings (concepts with an is-a relationship with 404684003). A SCT reference set will be defined which includes a list of codes and all its children.
1.2 Clinical description	Narrative description or comments about clinical aspects of the diagnosis.	Optional	0..*	Text	N/A
1.3 Asserted By	Refer to common header templates document.				
1.4 Date Asserted	Refer to common header templates document.				
1.5 Status	The status of the diagnosis.	Mandatory	1..1	Codeable Concept	The following HL7 FIHR value set should be used: provisional | working | confirmed | refuted. Refer to Appendix 6 Table 1 for suggested value set.

Name	Definition	Optionality	Cardinality	Data type	Coding systems and value domains
1.6 Date of onset	Estimated or actual date the diagnosis began, in the opinion of the healthcare practitioner.	Optional	0..1	Date	N/A
1.7 Age at onset	The age of the person at the estimated time or actual date the diagnosis began.	Optional	0..1	Date/Age	N/A
1.8 Severity	A subjective assessment of the severity of the diagnosis as evaluated by the healthcare practitioner.	Optional	0..1	Codeable Concept	Link to SNOMED CT value set. This value set (should this be reference set) includes the following SNOMED CT "Severity" concepts. Refer to Appendix 6 Table 2 for suggested value set.
1.9 Certainty	The level of confidence in the identification of the diagnosis.	Optional	0..1	Codeable Concept	Link to SNOMED CT value set. Refer to Appendix 6 Table 3 for suggested value set.
1.10 Criteria	The criteria on which the diagnosis is based.	Optional	0..*	Codeable Text	This free text data element is currently a placeholder for further structured data that is as yet undefined.
1.11 Clinical stage/grade	Clinical stage or grade of a diagnosis.	Optional	0..*	Text	N/A

Name	Definition	Optionality	Cardinality	Data type	Coding systems and value domains
1.12 Number of occurrences	Cumulative number of occurrences or exacerbations of the diagnosis.	Optional	0..1	Integer	N/A
1.13 Frequency of the diagnosis	The frequency or estimated frequency of occurrences or exacerbations of the diagnosis.	Optional	0..1	Quantity	N/A
1.14 Latest occurrence date	The date of the last occurrence or exacerbation of the diagnosis.	Optional	0..1	Date	N/A
1.15 Occurrence description	A narrative description, including outcomes and other key details, about occurrences or exacerbations of the diagnosis.	Optional	0..*	Text	N/A
1.16 Related Diagnosis	Identification of other diagnoses that have a relationship to the diagnosis.	Optional	0..*	Codeable Text	This free text data element is currently a placeholder for further structured data that is as yet undefined. It will link to SNOMED CT. This value set includes all SNOMED CT clinical findings (concepts with an is-a relationship with

Name	Definition	Optionality	Cardinality	Data type	Coding systems and value domains
					404684003). A SCT reference set will be defined which includes a list of codes and all its children.
1.17 Date of resolution	The date or estimated date that the diagnosis was resolved.	Optional	0..1	Date	N/A
1.18 Source of information.	The person who provided the information that came to the diagnosis being made.	Optional	0..1	Codeable Text	This free text data element is currently a placeholder for further structured data that is as yet undefined. It will link to SNOMED CT.
1.19 Anatomical location	The anatomical location relating to the diagnosis	Optional	0..*	Text	N/A
1.20 Patient	Refer to common header templates document.				

Appendix 3 — Consultation questions

The Authority asked for responses to the following eight questions. Questions 2-4 are specific to the Diagnosis 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. HIQA welcomed all submissions and would like to thank all those who contributed. The organisations that made submissions to the targeted consultation include:

- 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 the Diagnosis 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 the individual data items of the dataset and CDA specification.

4.2 Changes to Dataset and CDA specification

There was one change that was made to the diagnosis dataset. Table 1 below outlines the change that was made to the data items of the diagnosis standard.

Table 1. Changes to draft standards for diagnosis

Number (as defined in dataset/CDA specification)	Data item	Change agreed
1.7	Age of Onset	Change Definition and Usage in dataset and technical specification from "The age of the person at the time of resolution or remission of the diagnosis" to "The age of the person at the estimated time or actual date the diagnosis began".

4.3 Feedback on consultation questions for diagnosis

Question 2, 3 and 4 of the consultation form related to the Adverse Reaction dataset.

2. 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?

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

"All appropriate data items are included. Must ensure that Diagnosis Name uses SNOMED CT as the source terminology".

"Flexibility to reduce to minimal data is a good feature. The small number of mandatory fields will improve compliance. Nothing more to add".

3. Do the definitions provided in the Diagnosis 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.

"Definitions are adequate".

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

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

All respondents were satisfied with the content of the CDA specification.

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, that 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 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 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 datatypes used in the diagnosis 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.

HL7 v3 Data Type	Name	Description
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) and so on. 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 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.

HL7 v3 Data Type	Name	Description
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 uses 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 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.

Value Set 1: Status (HL7 FIHR)

Table 1. Value set for status of diagnosis

Code	Descriptor/display name	Source	Map to SNOMED CT CODE
P	Provisional	HL7 FIHR	Y
W	Working	HL7 FIHR	Y
C	Confirmed	HL7 FIHR	Y
R	Refuted	HL7 FIHR	Y

Value Set 2: Severity

The Value Set is used for all problems and allergies in the Patient Summary to indicate the severity of the problem (or Allergy). The source Code System is SNOMED CT 2.16.840.1.113883.6.96. (epSOSSeverity. 1.3.6.1.4.1.12559.11.10.1.3.1.42.13)

Table 2. Value set for Problem severity

Code	Descriptor/display name	Source	Map to SNOMED CT CODE
442452003	Life threatening severity. Is this the same as Fatal?	SNOMED-CT	N/A
349915008	Low grade	SNOMED-CT	N/A
255604002	Mild	SNOMED-CT	N/A
371923003	Mild to moderate	SNOMED-CT	N/A
6736007	Moderate	SNOMED-CT	N/A
371924009	Moderate to severe	SNOMED-CT	N/A
24484000	Severe	SNOMED-CT	N/A
399166001	Fatal	SNOMED-CT	N/A

Suggested values for this specification which are a subset of the epSOS value set are highlighted in navy in Table 2. An additional code Fatal (qualifier value) is required for the HIQA value set which was not previously in the epSOS value set.

Value Set 3: Certainty

Table 3. Value set for certainty (HL7 FIHR)

Code	Descriptor/Display Name	Source	Map to SNOMED CT CODE
S	Suspected	HL7 FIHR	Y
P	Probable	HL7 FIHR	Y
C	Confirmed	HL7 FIHR	Y

Reference List

(1) Commission on Patient Safety and Quality Assurance. *Building a Culture of Patient Safety* . 2008. Available online from: http://www.dohc.ie/publications/building_culture_patient_safety.html. Accessed on: 19 May 2011.

(2) Department of Health. *eHealth Strategy for Ireland*. 2013. Available online from: http://www.dohc.ie/publications/eHealth_Strategy_2013.html. Accessed on: 24 April 2014.

(3) Health Service Executive. *Knowledge and Information Strategy*. 2015. Available online from: http://www.ehealthireland.ie/Knowledge-Information-Plan/Knowledge-and-Information-Plan.pdf. Accessed on: 7 October 2015.

(4) National E-Health Transition Authority. *Detailed Clinical Model Specification Diagnosis*. 2011. Accessed on: 23 September 15 A.D.

(5) Health and Social Care Information Centre UK. *How the Summary Care Record benefits clinical practices*. 2015. Available online from: http://systems.hscic.gov.uk/scr/benefits. Accessed on: 7 October 15 A.D.

(6) Health Information and Quality Authority. *General Practice Messaging Standard Version 2.0*. 2011. Available online from: www.hiqa.ie.

(7) Health Information and Quality Authority (HIQA). *Report and Recommendations on Patient Referrals from General Practice to Outpatient and Radiology Services, including the National Standard for Patient Referral Information*. 2011. Available online from: http://www.hiqa.ie/publications/hiqa%E2%80%99s-gp-referral-report-published. Accessed on: 5 July 2012.

(8) Health Information and Quality Authority. *Standardising Patient Discharge Summary Information: a Draft National Data Set for Consultation*. 2013. Available online from: www.hiqa.ie.

(9) Health Information and Quality Authority. *National Standard Demographics Dataset and Guidance for use in Health and Social Care settings in Ireland*. 2013. Available online from: http://www.hiqa.ie/publications/national-standard-demographic-dataset-and-guidance-use-health-and-social-care-settings-. Accessed on: 7 October 15 A.D.

(10) Health Information and Quality Authority. *ePrescription Dataset and Clinical Document Architecture Standard*. 2015. Accessed on: 14 September 2015.

(11) OpenEHR Foundation. *Clincal Knowledge Manager*. 2015. Accessed on: 23 September 15 A.D.

(12) Health Level Seven (HL7). *HL7 FHIR Resource - Problem*. 2015. Available online from: https://www.hl7.org/fhir/. Accessed on: 7 October 15 A.D.

(13) National E-Health Transition Authority. *CDA Implementation Guide Event Summary v1.3*. 2015. Accessed on: 23 September 15 A.D.

(14) European Patients Smart Open Services. *epSOS Work Package 3.9 – Appendix B1/B2 epSOS Semantic Implementation Guidelines*. 2015. Accessed on: 23 September 15 A.D.

(15) Health Level Seven (HL7). *HL7 Implementation Guide for CDA Release 2: Consolidated CDA Templates for Clinical Notes DSTU R2*. 2015. Accessed on: 23 September 15 A.D.

(16) Integrating the Healthcare Enterprise. *Patient Care Coordination Technical Framework, Volume 1 and Volume 2- Revision 5*. 2013. Accessed on: 23 September 15 A.D.

Published by the Health Information and Quality Authority.

For further information please contact:

Health Information and Quality Authority
Dublin Regional Office
George's Court
George's Lane
Smithfield
Dublin 7

Phone: +353 (0) 1 814 7400
URL: www.hiqa.ie

© Health Information and Quality Authority 2016