Health Information and Quality Authority

An tÚdarás Um Fhaisnéis agus Cáilíocht Sláinte

Draft National Standard for a Procedure Dataset and Clinical Document Architecture (CDA) Template – Draft for consultation

September 2016

About the Health Information and Quality Authority

The Health Information and Quality Authority (HIQA) is the independent Authority established to drive high quality and safe care for people using our health and social care services. HIQA's role is to promote sustainable improvements, safeguard people using health and social care services, support informed decisions on how services are delivered, and promote person-centred care for the benefit of the public.

The Authority's mandate to date extends across the quality and safety of the public, private (within its social care function) and voluntary sectors. Reporting to the Minister for Health and the Minister for Children and Youth Affairs, the Health Information and Quality Authority has statutory responsibility for:

- **Setting Standards for Health and Social Services** – Developing person-centred standards, based on evidence and best international practice, for those health and social care services in Ireland that by law are required to be regulated by the Authority.

- **Supporting Improvement –** Supporting health and social care services to implement standards by providing education in quality improvement tools and methodologies.

- **Social Services Inspectorate** – Registering and inspecting residential centres for dependent people and inspecting children detention schools, foster care services and child protection services.

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

- **Health Technology Assessment** – Ensuring the best outcome for people who use our health services and best use of resources by evaluating the clinical and cost effectiveness of drugs, equipment, diagnostic techniques and health promotion activities.

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

Overview of Health Information function

Healthcare 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 (the Authority) has responsibility for setting standards for all aspects of health information and monitoring compliance with those standards. In addition, under section 8(1)(j), the Authority is charged with evaluating the quality of the information available on health and social care and 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 silos of information which prevents the safe, 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, understandable 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. A robust health information environment will allow all stakeholders, the general public, patients and service users, health professionals and policy makers to make choices or decisions based on the best available information. This is a fundamental requirement for a high reliability healthcare system.

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. 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, the Authority in conjunction with stakeholders developed a procedure template standard which can be used 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 procedures.

[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). **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 i.e. 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 a procedure,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 the Department of Health's eHealth Strategy for Ireland (2013)(2).

The HSE established the Office of the Chief Information Officer (OCIO) who are responsible for implementing the eHealth Strategy. The OCIO are charged with the delivery of technology to support healthcare across Ireland and have 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 systems) 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 the most 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 standard specifies a national dataset for procedures. The dataset is then extended to a technical specification and a HL7 CDA template (See Appendix 1 for detailed information on the CDA standard and templates). A HL7 CDA template for procedures can be reused in different document types i.e. national patient summaries, discharge summaries.

A procedure is defined by the Australian National eHealth Transition Authority (NEHTA)[4] as:

> "A clinical activity carried out for therapeutic, evaluative, investigative, screening or diagnostic purposes".

2. Background

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

- General Practice Messaging Standard (2014)[5]
- National Standards for Patient Referral Information (2011)[6]
- National Standards for Patient Discharge Summary Information (2013)[7]
- National Standard Demographic Dataset and Guidance for use in health and social care settings in Ireland (2013)[8]
- National Standards for Diagnoisis (2016)[15]
- National Standards for Adverse Reaction (2016) [16].

3. Purpose

The purpose of this draft standard is to create a CDA template for procedures which can be reused throughout different clinical document types. This is a minimum dataset that could be displayed in a patient summary or a national summary care record. The exchange of standardised electronic documents such as shared patient summaries and other document types like ePrescription documents are key building blocks for interoperability between eHealth systems. This standard is part of a suite of standards, including the adverse reaction and diagnosis standards that HIQA has developed to support eHealth priority areas such as national patient summaries. For example, a CDA template for procedures can be reused in both a patient referral document and a patient's discharge summary document. This standard describes a dataset for a procedure and provides a technical specification (see Appendix 2) and CDA specification for use in clinical documents (see Section 8).

4. Benefits

The development of a standard dataset for procedures 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 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 through ePrescribing
- more timely access by health professionals to the right medical information at the right time
- improved support for patient self-management.

5. Methodology

The draft dataset for procedures was developed after analysis of several datasets developed in other jurisdictions. In Australia, the National eHealth Transition Authority (NEHTA), now named the Australian Digital Health Agency, published a detailed specification used to record all information about procedures that is required to support direct clinical care of an individual. Procedure datasets from two of the main standards developments organisations for communication standards, OpenEHR and HL7 were also included in this analysis. The standards and specifications that were analysed include:

- NETHA, Detailed Clinical Model Specification Procedure, Version 3.1 (2011)[4]
- OpenEHR, Archetypes Procedures, Clinical Knowledge Manager[9]
- HL7 FIHR Standard Procedures, DSTU2 [10].
- European Patients Smart Open Services (epSOS), *Work Package 3.9 – Appendix B1/B2 epSOS Semantic Implementation Guidelines*. (2011)[11]

Relevant datasets previously developed by HIQA such as the demographic dataset, referrals and discharge summary datasets were also reviewed and reused 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 developed into a HL7 CDA template. Key international CDA implementation guides were reviewed to inform the CDA standard including:

- National eHealth Transition Authority (NEHTA) Event Summary - CDA Implementation Guide v1.3 (2015)[12]
- European Patients Smart Open Services (epSOS), *Work Package 3.9 – Appendix B1/B2 epSOS Semantic Implementation Guidelines*. (2011)[11]
- HL7 Implementation Guide for CDA Release 2: Consolidated CDA Templates for Clinical Notes DSTU R2 (2014)[13]
- Integrating the Healthcare Enterprise. *Patient Care Coordination Technical Framework, Volume 1 and Volume 2- Revision 5* (2013)[14]

This standard used the epSOS specification for the development of the procedure CDA template. epSOS was a large european initiative to facilitate cross border

transfer of electronic patient summary documents and electronic prescriptions and electronic dispensing. The epSOS project re-used information and specifications from other leading organisations who are considered experts in the area of CDA implementations. The epSOS project reused the HL7 CDA Standard, the HL7 clinical care document (CCD) specification and the IHE PCC.

5.1 Next Steps

There will be a five week consultation on the *Draft National Standard Procedure Dataset and Clinical Document Architecture (CDA)* which will take place from 09 September 2016 to 14 October 2016. All submissions from the consultation will be reviewed and will inform the development of the final draft of the standard. Following the targeted consultation, the draft standard will then be reviewed by the eHealth Standards Advisory Group, HIQA's Executive Management Team and the Board of HIQA. Finally, the standard will be sent to the Minister for Health for mandate.

5.2 Targeted Consultation

This document presents for targeted consultation the proposed *Draft National Standard for a Procedure Dataset and Clinical Document Architecture (CDA)* for use in health and social care settings in Ireland for a period of five weeks. HIQA will consider and review all submissions received during the consultation process. Following this process, HIQA will finalise the standards.

The closing date for receipt of submissions is 14 October 2016 at 5 pm.

How to make a submission

A number of consultation questions have been prepared for your consideration when reviewing the standards. These questions are grouped together in the consultation feedback form. They are not intended, in any way, to limit feedback, and any other comments are welcome. There are three ways to tell us what you think:

- Complete the online consultation feedback form by clicking here. This will bring you to an online version of the consultation feedback form.
- Your comments can be submitted by downloading and completing the consultation feedback form available here and emailing your completed forms to technicalstandards@hiqa.ie.

- You can print off a copy of the feedback form at http://www.hiqa.ie and post it to us at:

Health Information and Quality Authority
Draft National Procedures Standard
George's Court
George's Lane
Smithfield
Dublin 7
D07 E984.

For further information or if you have any questions you can talk to the consultation team by calling (01) 8147685.

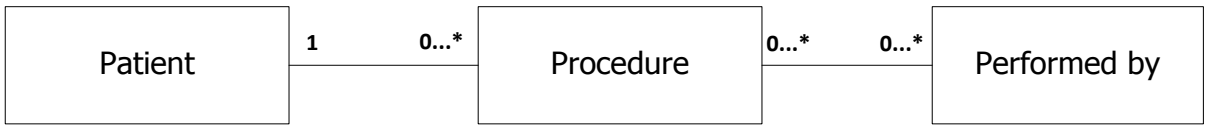
How we will use your comments

Following the consultation, HIQA will analyse the submissions and as a result may make further amendments to the document. We will present the main amendments in a separate statement of outcomes document which we will publish. This is your opportunity to participate in the development of standards. We wish to thank you in advance for taking the time to submit your comments.

6. Model for Procedures

This section will illustrate the model for procedures. Section 7 describes the dataset for procedures and section 8 will specify the CDA procedures template. The data model for procedures consists of the patient and the procedures classes. A patient can have zero to many procedures . Figure 1 below outlines a data model for a patient's procedures.

Figure 1 Model for a procedure



7. Dataset for Procedures

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 procedures dataset is essential to provide information about an individual's procedures. A procedure is defined as a clinical activity carried out for the therapeutic, evaluative, investigative, screening or diagnostic purposes. If all healthcare providers use the same data model and dataset then information about procedures can be shared. Each of the classes and associated attributes are described in the dataset in tables 1 below which define the name, definition, optionality and usage of each data element.

7.2 Procedure Dataset

Name	Definition	Optionality	Usage
1.1 Procedure name	The name of the procedure (to be) performed.	Mandatory	A coded value for the name of the procedure. Examples include an Appendectomy or Caesarean Section
1.2 Description	Narrative description about the procedure.	Optional	Captures a narrative description of the procedure. Examples can include description about performance, findings, failed attempt or cancellations.
1.3 Urgency	The urgency of the procedure	Optional	Describes details about the urgency of the procedure. This free text data element is currently a placeholder for further structured data that is as yet undefined.
1.4 Body site	Identification of the body site for the procedure.	Optional	This element may be present to indicate the target site of the procedure. This free text data element is currently a placeholder for further structured data that is as yet undefined about the procedure.
1.5 Outcome	Outcome of procedure performed.	Optional	A coded value for the result of the procedure. Suggested codes could include: Successful, Unsuccessful, and Partially Successful.

1.6 Complication	Details about any complication arising from the procedure.	Optional	Details about any complication arising from the procedure. Could be linked to a diagnosis or rules such as report a complication within 30 days of the completion of a procedure.
1.7 Date/time	The date and/or time on which the procedure is intended to be performed.	Optional	The date and time (or both) of the procedure.
1.8 Multimedia	Multimedia representation of a performed procedure.	Optional	Inclusion of any multimedia file to support the recording of the procedure, for example, a link to a video of the procedure performed or a drawing of the wound/surgery.
1.9 Comment	Additional narrative about the activity or care pathway step not captured in other fields.	Optional	General comments about the procedure including any instructions that may have been given to the patient.
1.10 Device	Structured information about any device used during the procedure.	Optional	This data element describes details about the device that was used during the procedure. This free text data element is currently a placeholder for further structured data that is as yet undefined.
1.11 Information Provided by/Sourced By	The individual who provides information to the healthcare practitioner.	Optional	This could be the patient or a relative or carer of the patient.

1.12 Performed By	The healthcare practitioner who performs the procedure.	Optional	This field refers to the type of healthcare practitioner who performs the procedure.

Table 1 - Procedure Dataset

8. CDA Standard

This section defines the CDA specification for a procedure and is based on the dataset defined in 7.1. Section 8.1 provides guidance on how to interpret the CDA diagnosis specification. Section 8.2 details the CDA standard for procedures. 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: 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 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

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 Procedure

Table 5 below outlines the CDA level 3 templates for procedure (epSOS CDA template Procedure Entry 1.3.6.1.4.1.19376.1.5.3.1.4.19)

Number	Data element	CDA XPath expression	Optionality/ Cardinality	HL7 V3 Data Type	Vocabulary
1.1	Procedure name	entry/procedure[templateId/@root= '1.3.6.1.4.1.19376.1.5.3.1.4.19']/code/@displayName	RNFA [1..1]	CD	See Appendix 4, value set 1.
1.2	Description	entry/procedure[templateId/@root= '1.3.6.1.4.1.19376.1.5.3.1.4.19']/code/@displayName	Optional [0..1]	ST	N/A
1.3	Urgency	entry/procedure[templateId/@root=’ 1.3.6.1.4.1.19376.1.5.3.1.4.19’]/value/@code	Optional [0..1]	ST	N/A
1.4	Body site	entry/procedure[templateId/@root=’ 1.3.6.1.4.1.19376.1.5.3.1.4.19’]/text/reference/@value	Optional [0..1]	ST	N/A
1.5	Outcome	entry/procedure[templateId/@root=’ 1.3.6.1.4.1.19376.1.5.3.1.4.19’]/value/@code	Optional [0..1]	CD	See Appendix 4, value set 2.
1.6	Complication	entry/act[templateId/@root=’ 1.3.6.1.4.1.19376.1.5.3.1.4.19’]/text/reference/@value	Optional [0..*]	CD	See Appendix 4, value set 3.
1.7	date/time	entry/procedure[templateId/@root= '1.3.6.1.4.1.19376.1.5.3.1.4.19']/effectiveTime/low	Optional [0..1]	TS	N/A

1.8	Multimedia	entry/procedure [templateId/@root=’ 1.3.6.1.4.1.19376.1.5.3.1.4.19’]/text/reference/@value	Optional [0...*]	ED	N/A
1.9	Comment	<text><reference value='#comment'/></text>	Optional [0..1]	ST	N/A
1.10	Device	entry/procedure [templateId/@root=’ 1.3.6.1.4.1.19376.1.5.3.1.4.19’]/value/@code	Optional [0...*]	CD	N/A
1.11	Location Performed	Custodian/Organisation/name	Required [1..1]	ON	N/A

Table 2 - CDA specification for Procedures

Appendix 1 Clinical Document Architecture Overview

1 Clinical Document Architecture (CDA) Standard

The 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 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 enable 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, 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.

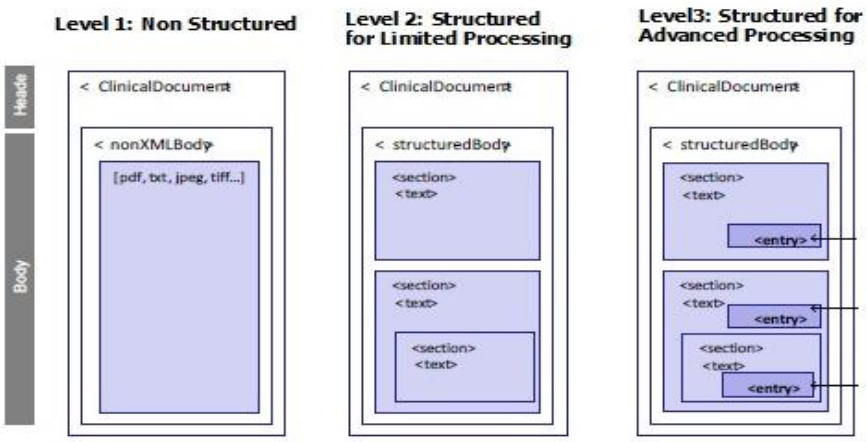


Figure 2: HL7 CDA document levels (Adapted from epSOS)

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 is 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 templateID indicating that a document conforms to both the CDA generic model and the constraints specified in an implementation guide. The templateID, 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 6 Technical Specification for procedure

Name	Definition	Optionality	Cardinality	Data Type	Coding Systems and Value Domains
1.1 Procedure name	The name of the procedure (to be) performed.	Mandatory	1..1	Coded Text	See Appendix 4, value set 1. This includes epSOSProcedures 2.16.840.1.113883.6.96.
1.2 Description	Narrative description about the activity or care pathway step for the identified procedure.	Optional	0..1	Text	N/A
1.4 Urgency	The urgency of the procedure	Optional	0..*	Text	N/A
1.5 Body site	Identification of the body site for the procedure.	Optional	0..1	Text	N/A
1.6 Outcome	Outcome of procedure performed.	Optional	0..1	Codeable Text	See Appendix 4, value set 2.
1.7 Complication	Details about any complication arising from the procedure.	Optional	0..*	Codeable Text	See Appendix 4, value set 3.
1.8 date/time	The date and/or time on which the procedure is intended to be performed.	Optional	0..1	DateTime	N/A
1.9 Multimedia	Mulitimedia representation of a performed procedure.	Optional	0..*	EncapsulatedData	N/A
1.10 Comment	Additional narrative about the activity or care pathway step not	Optional	0..1	Text	N/A

	captured in other fields.				
1.11 Device	Structured information about any device used during the procedure.	Optional	0..*	CodedText	N/A
1.12 Subject: Refer to common header templates document					
1.13 Performed/Identified By: Refer to common header templates document					
1.14 Information Provided by/Sourced by: Refer to common header templates document					
1.15 Location Performed: Refer to the name of custodian in CDA standard					

Appendix 3 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 7: 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 an interval: it does not matter whether the base type is discrete or continuous. It 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 (e.g. 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 IVL TS (Interval Timestamp) has to be fully formed, whereas a regular timestamp can be truncated.

Appendix 4 Value Sets

The following tables provide exemplar values for these value sets.

Value Set 1: Procedure Name

The suggested value set that can be used to indicate the procedure name is (get OID from SNOMED). This includes epSOSProcedures 2.16.840.1.113883.6.96.

Value Set 2: Outcome

The following suggested value set can be used to indicate the outcome of the procedure. The source Code System is SNOMED CT 2.16.840.1.113883.6.96.

Table 8: Outcome values

Code	Descriptor/Display Name	Source
385669000	Successful	SNOMED CT
385671000	Unsuccessful	SNOMED CT
385670004	Partially Successful	SNOMED CT

Value Set 3: Complication

The suggested value set that can be used to indicate the complication of the procedure is (get OID from SNOMED) taken from the Condition/Problem/Diagnosis Codes.

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