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Health informatics - Data exchange standards - HL7 clinical document architecture (release 2)

健康信息学 数据交换标准 HL7临床文档架构(版本2)

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1 Scope

This document defines the terms and definitions relating to the clinical document architecture (CDA), describes the technical artifacts of CDA, specifies the requirements for exchanging CDA documents in HL7 messages, and gives the CDA R-MIM, the CDA hierarchical description and the XML implementation of CDA.

The following are outside the scope of the document: clinical document data formats outside the exchange context, such as data formats used to store clinical documents; HL7 messages designed solely for the transmission of clinical documents; and the creation and management of documents.

The document applies to the research, development and management of clinical documents exchanged in healthcare information systems.

2 Normative references

The contents of the following documents constitute indispensable provisions of this document through normative reference in the text. For dated references, only the edition corresponding to that date applies; for undated references, the latest edition, including all amendments, applies.

The list comprises GB/T 30107-2013 Health informatics - HL7 V3 - Reference information model (ISO/HL7 21731:2006, MOD), with a note recording that the content of GB/T 30107-2013 cited here does not differ technically from the content cited from ISO/HL7 21731:2006; HL7 Vocabulary; the HL7 V3 XML Implementable Technology Specification (ITS); the HL7 Version 3 Standard: Data Types - Abstract Specification, Release 1; IETF RFC 2046 Multipurpose Internet Mail Extensions (MIME); IETF RFC 2557 MIME Encapsulation of Aggregate Documents; IETF RFC 3066 Tags for the Identification of Languages; and the XML Implementation Technology Specification - Data Types.

3 Terms and definitions

3.1 clinical document architecture, CDA: a document markup standard that specifies the structure and semantics of clinical documents for the purpose of exchange.

3.2 document type definition, DTD: an XML document type declaration that contains, or points to, the grammar for a class of documents.

3.3 healthcare professional: a person entrusted with providing healthcare services directly or indirectly to a subject of care or to a group of subjects of care. The examples given are qualified practising physicians, practising assistant physicians, pharmacists, registered

nurses, medical laboratory technicians, medical imaging technicians and village doctors. The entry is sourced from ENV 1613:1995, 3.13 and ISO 21549-7:2016, 3.9.

3.4 regulatory agency (or authorities): the collective name for the agencies or departments established by a geopolitical entity and responsible for regulating healthcare products.

3.5 reference information model, RIM: the HL7 information model from which all other information models, such as the R-MIM, and the models of messages are derived.

3.6 refined message information model, R-MIM: an information structure that represents the requirements for a set of messages.

3.7 extensible markup language, XML: a simple and very flexible text format derived from SGML (ISO 8879). A note records that XML was originally designed to meet the challenges of large-scale electronic publishing and that it plays an increasingly important role in the exchange of a wide variety of data on the web and elsewhere.

3.8 XML schema: a way of defining in detail the structure, content and semantics of an XML document; XML schemas are used to represent shareable vocabularies and allow machines to carry out rules made by people.

4 Abbreviated terms

The abbreviations listed are CDA, clinical document architecture; CE, coded with equivalents; CEN, Comité Européen de Normalisation; CNE, coded, no extension; CWE, coded with extension; DICOM, Digital Imaging and Communications in Medicine; DTD, document type definition; ED, encapsulated data; HL7, Health Level 7; LOINC, Logical Observation Identifiers Names and Codes; MIME, Multipurpose Internet Mail Extensions; R-MIM, refined message information model; RIM, reference information model; SGML, standardized generalized markup language; SNOMED, Systematized Nomenclature of Human and Veterinary Medicine; SNOMED-CT, Systematized Nomenclature of Medicine - Clinical Terms; UML, unified modelling language; W3C, World Wide Web Consortium; XML, eXtensible Markup Language.

5.1 What is CDA

Characteristics of a clinical document: a clinical document is a document about clinical observation and services and has the following characteristics. Persistence: the state of the clinical document stays unchanged for the period of time laid down by local regulatory requirements; a note records that the persistence of a clinical document has a definite scope and is unrelated to the persistence of an XML-encoded CDA document instance. Stewardship: the clinical document is maintained by an entrusted organisation. Potential for authentication: the clinical document is a set of information that can be legally authenticated. Context: the clinical document establishes a default context for its content. Wholeness: authentication of the clinical document applies to the whole document and not

to parts of the document without the full document context. Human readability: the clinical document is human readable. A CDA document is a defined and complete information object that can include text, images, sound and other multimedia content.

Benefits of CDA: CDA documents can be encoded in XML, with a note recording that when a workable alternative implementation appears, suitable conformance requirements will be published so that the syntax is not restricted to XML in future; CDA documents integrate the machine-processable meaning of the HL7 RIM and use the HL7 V3 data types; and CDA has rich expressive power and flexibility, document-level, section-level and entry-level templates being usable to constrain the general CDA specification.

Goals and design principles of CDA: the stated goals are to give priority to the provision of care to patients; to allow cost-effective control to be implemented within as wide a range of systems as possible; to support the exchange of human-readable documents between users, including users of differing technical levels; to extend the lifetime of all information encoded in CDA; to support a wide range of post-exchange processing applications; to be compatible with a variety of document creation applications; to promote exchange independent of the underlying transfer or storage mechanism; to allow designs to be prepared quickly and reasonably; and to enable decision makers to control their information needs without extending the document.

The design principles derived from those goals are that CDA is compatible with XML and the HL7 RIM; that CDA is compatible with the clinical information representations of the HL7 organisation; that the technical barriers to using CDA are minimised; that CDA specifies the representation of the instances needed for exchange; that CDA imposes minimal constraints or requirements on the document structure and content needed for exchange; that CDA can be adapted through fine-grained markup, such as highly structured text and coded data; that CDA-based document specifications can accommodate the constraints and requirements raised by professionals, commercial bodies and regulatory agencies; that document specifications for document creation and processing map to CDA where the purpose is exchange; that CDA documents are human readable and can be rendered by a general CDA style sheet written with widely available and generally deployed XML-aware browsers, print drivers and a standard style sheet language; and that open standards are used.

5.2.1 Major components of a CDA document

An example gives the major components of a prototype CDA document, showing a ClinicalDocument element containing the CDA header and a structuredBody element, within which section elements contain a text element, observation entries and a substanceAdministration entry with a nested supply entry, one observation entry containing an externalObservation, and one section nested inside another section.

A CDA document is wrapped by the ClinicalDocument element and consists of a document