

Extending the HL7/LOINC Document Ontology Settings of Care

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Abstract

Given federal mandates recommending document standards, increasing numbers of electronic clinical documents being created, and local initiatives/projects using clinical documents, there is a growing need to better represent clinical document metadata. The HL7/LOINC Document Ontology (DO) was developed to provide a standard representation of clinical document attributes with a multi-axis structure. Prior studies have demonstrated the need for extension of DO axes values and proposed new values for some axes, but significant gaps remain for representing the DO “Setting” axis. This study aimed to extend the “Setting” axis by combining the current values in the DO with values from 5 other sources. Evaluation and refinement by subject matter experts over a series of four iterative sessions resulted in a reorganized hierarchy with 254 additional values from a baseline of 20. Incorporating a comprehensive set of “Settings” in DO provides better representation of clinical information across the healthcare ecosystem.

Introduction

Federal initiatives like the Centers for Medicare & Medicaid Services (CMS) Electronic Health Record (EHR) Incentive Program along with standards and certification efforts led by the Office of the National Coordinator for Health Information Technology (ONC) have propelled the adoption and use of EHR systems¹. These efforts have also led to dramatic increases in usage of electronic clinical documents, some of which are associated with requirements to use document standards for exchange of particular types of clinical information and for certain public health reporting use cases. With continuous increasing volumes of clinical documents, there is a need for better document metadata representation to promote standardization and reduce local customization. Availability of a comprehensive representation schema is critical to fit the needs of providers and the full set of inter-professional partners and sites in health care and also to facilitate their future retrieval and use for clinical care and research.

The HL7/LOINC Document Ontology (DO) is an ontology for the representation and standardization of clinical documents in a hierarchical structure comprising of five axes: *Kind of Document (KOD)*, *Type of Service (TOS)*, *Setting*, *Subject Matter Domain (SMD)* and *Role*. The purpose of the DO is to support exchange of clinical documents across organizations, systems, and other stakeholders and to facilitate retrieval and reuse of documents for research and other secondary uses. Each DO axis is comprised of a set of values. A valid document specification with the DO consists of specification of the KOD axis and at least one additional DO axis. A select combination of valid DO specifications that have been precoordinated have assigned LOINC codes.

Several researchers have explored the application of DO and have proposed extensions to value sets, which have been incorporated by the LOINC Committee. A recent study that attempted mapping of data items from a large clinical repository to DO concluded that document attributes do not always link consistently with DO axes and recommended that additional values for certain axes, particularly for *Setting* and *Role* are needed². This study addresses that recommendation and focuses on one axis of DO – the *Setting* axis.

The objective of this study was to create a comprehensive representation of care settings that combines the current values in DO with values from other representative sources. As emphasis shifts from traditional care in hospitals and office visits to care coordination, care management, and care within home and other nontraditional healthcare settings, healthcare is being offered in places that have been typically outside the scope of traditional health delivery which likely requires better representation in DO. As an additional potential benefit, this study is poised to benefit a wide range of secondary uses of documents for research, quality initiatives and population health management.

Background

Meaningful Use recommendations for document standards specify the HL7 Clinical Document Architecture (CDA) and HL7 Consolidated CDA (C-CDA)³. Both structure and semantics of a clinical document are guided by CDA, which is an XML-based standard⁴. C-CDA is a consolidation of various CDA templates to facilitate implementation³.

The implementation guide for C-CDA that contains a library of CDA templates is available from HL7⁵. A companion guide was created by the ONC Standards and Interoperability Framework Initiative to offer guidance on implementation of certification criteria which required HL7 C-CDA⁶.

The HL7 CDA header contains the context of a clinical document and facilitates exchange across and within institutions as well as retrieval for various purposes. The CDA body holds the actual facts pertaining to the document. The CDA header comprises of document information, encounter data, service actors and service targets. Document information includes a unique identifier that is drawn from the realm of clinical LOINC codes, which are guided by the HL7/LOINC Document Ontology⁷. Figure 1 includes a sample XML showing a portion of a C-CDA header that includes the LOINC code “34133-9” for “summarization of episode note” (the value for the LOINC System axis is “{Setting}” indicating that a particular setting is not designated).

Figure 1: Sample XML for C-CDA with Select Header Portion and Document Code⁸

```
<code
  codeSystem="2.16.840.1.113883.6.1"
  codeSystemName="LOINC"
  code="34133-9"
  displayName="Summarization of Episode Note"/>
```

The current model of DO was started by the HL7 Document Ontology Task Force (DOTF) and later continued through a joint effort with the LOINC Committee. The current DO is available as part of the LOINC User’s Guide, which is updated biannually⁹. LOINC codes in the Document Ontology class (DOC.CLINRPT) and values from various axes can be downloaded as part of the LOINC Document Ontology file, which has been publicly available since the LOINC 2.44 release¹⁰. An implementation guide for HL7/LOINC Clinical Document Ontology has been released as of September 2013 as a Draft Standard for Trial Use (DSTU)⁸. As mentioned, this 5 axis model uses multiple classes under each axis requiring specification of the *KOD* axis and at least one of the other four axes. Though *Setting* is not a required component for a valid document specification, it is often included in clinical document names to help distinguish between important classes of documents. Initial development of DO with relevant background is described by Frazier *et al.*¹¹.

In related work, detailed analysis of the *Subject Matter Domain (SMD)* axis was conducted by Shapiro *et al.*¹² who mapped a set of inpatient document titles and showed that 56% of documents were classified as “not specified” with respect to values on the DO SMD list. This study created a new polyhierarchical *SMD* structure by combining the values from the DO SMD axis with values from American Board of Medical Specialties (ABMS), thereby increasing the coverage of SMD significantly. Veterans Administration (VA) has also contributed to expansion of the *Type of Service (TOS)* axis, which characterizes the kind of service or activity provided to the patient or subject of the service where sub-classes under this axis include evaluations, consultations, and summaries. More specifically, the VA work expanded the Compensation and Pension Examination value set that is under Disability Examination and part of the Evaluation and Management sub-class, and these are now available as part of DO⁹.

Other pertinent studies have focused on mapping of document names from inpatient settings to DO and attempted to understand DO in depth and precoordination of its axes with LOINC. Document names from two large institutions were mapped to DO, and LOINC codes were identified based on mapping by Chen *et al.*¹³. This study showed that a majority of document names could be assigned a LOINC code, but granularity was often lost. The work highlighted strengths and limitations of DO and LOINC codes for representation of documents.

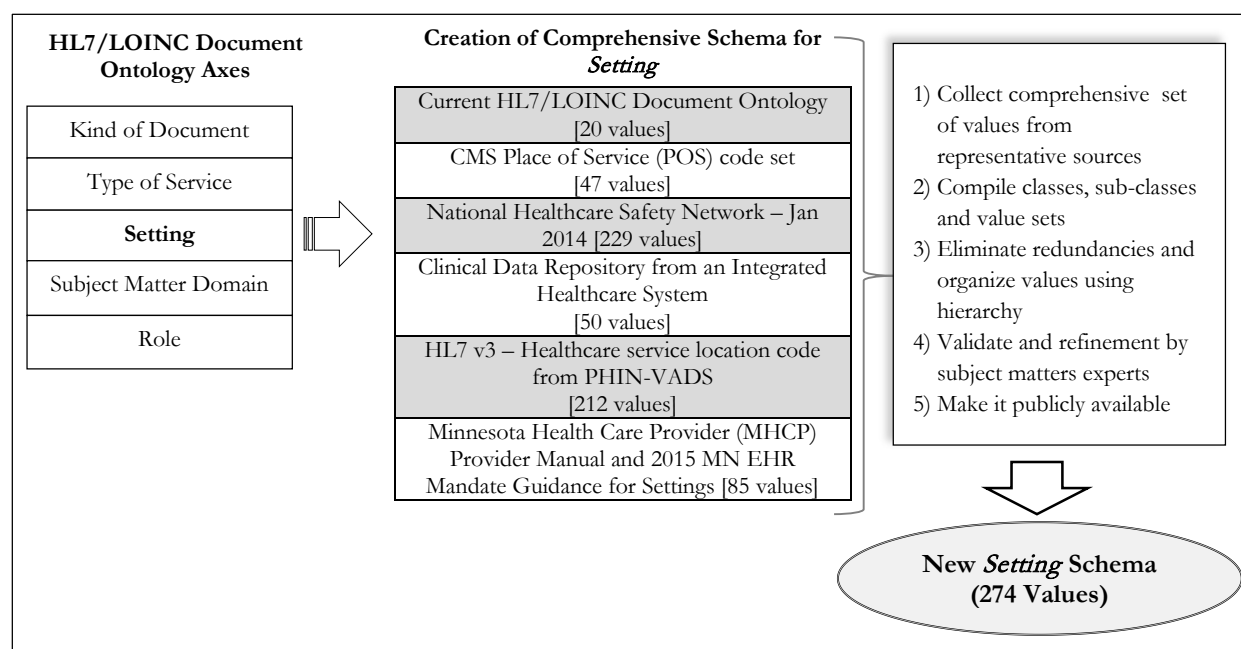
Comparison of the three versions of DO in their adequacy to represent document names in an inpatient setting was done by Hyun *et al.*¹⁴. Dugas *et al.*¹⁵ examined 86 document types from an inpatient information system and their coverage using LOINC codes. Usage of LOINC codes for document exchange across inpatient settings of two campuses of a hospital was explored and coverage of DO on clinical document titles was evaluated as part of process by Li *et al.*¹⁶. Hyun and Bakken¹⁷ extracted section headings from nursing documents and then identified DO components and mapped them to LOINC as a potential model for representing this class of texts. Most recently, Wang *et al.*² evaluated the adequacy of DO for representing clinical documents in a data repository from an integrated health delivery system which contained data from legacy and current EHR systems and is used for multiple purposes including research. A common theme across these studies was the need for extension of attribute values of the LOINC

semantic model, more specific LOINC codes and limitations with precoordination, and the recommendation to expand the value sets for certain DO axes, particularly for *Setting* and *Role*.

Methods

This study involved creation of a comprehensive representation of the *Setting* axis in the HL7/LOINC Document Ontology (DO). The methodology comprises of five main components: (1) collection of a comprehensive set of values from representative sources; (2) compilation of classes, sub-classes, and value sets for the *Setting* axis; (3) elimination of redundancies and organization of values into an extended hierarchy; (4) validation and refinement by subject matters experts; and (5) a resulting publicly available hierarchy for sharing the resultant value set with the broader community. Figure 2 details the methodology for the proposed expansion.

Figure 2: Methodology for Creation of Comprehensive Schema for *Setting* in Document Ontology



The current value set for *Setting* in DO⁹ is comprised of 20 values that are organized into 12 classes with 8 sub-classes for two of the classes, leading to 20 overall values for document representation. The first step in the process was to examine the value sets for *Setting* in the secure local research-oriented clinical data repository, including large numbers of clinical documents, which was established in a partnership between the University of Minnesota and its affiliated integrated healthcare system, Fairview Health Services. Prior work of the authors examined the representation of documents in this repository and demonstrated inadequacy of the *Setting* axis in DO². Next, other valid sources were identified that could contribute to representation of *Setting* values. The Place of Service (POS) code set¹⁸ from CMS was identified and selected, as CMS is the largest insurer and provider of healthcare services in the US. In order to find corresponding value sets for a Medicaid source, values were obtained from the Minnesota Health Care Plans (MHCP) provider manual¹⁹ and the 2015 Minnesota Electronic Health Record mandate guidance²⁰ on settings. Other sources incorporated in this study were the HL7 version 3 (v3) code set²¹ for representation of settings, which was retrieved from the Public Health Information Network (PHIN) Vocabulary Access and Distribution System (PHIN-VADS). Since the HL7 codes were based off of the National Healthcare Safety Network (NHSN), the current version of NHSN codes (Jan 2014 release)²² was also incorporated. Compilation of all these values resulted in classes and sub-classes of 327 values.

Once all value sets from the six sources including DO were obtained, redundancies were identified and eliminated. Table 1 shows some examples of values across sources and consensus arrived by subject matter experts as part of an iterative review process.

Table 1. Mapping Examples of Different Classes Across Sources

Current HL7/LOINC Document Ontology (LOINC User's Guide – Dec 2013)	CMS Place of Service (POS) code set – Nov 2012 version	Clinical Data Repository from an Integrated Healthcare System – June 2013	National Healthcare Safety Network (NHSN) – Jan 2014 release	HL7 v3 – Healthcare service location code set from PHIN-VADS (2010 version)	Minnesota Health Care Provider (MHCP) Provider Manual and 2015 MN EHR Mandate Guidance for Settings (2013)	Subject Matter Expert (SME) Consensus
Office	Office	Office				Office
			Physician's Office	Physician's Office		
Hospital						Inpatient setting
	Inpatient Hospital	Inpatient Hospital			Inpatient Hospital	
			Inpatient location			
Ambulatory Surgical Center	Ambulatory Surgical Center	Ambulatory Surgical Center	Ambulatory Surgical Center	Ambulatory Surgical Center	Ambulatory Surgical Center	Ambulatory Surgical Center
Urgent Care Center			Urgent Care Center	Urgent Care Center		Urgent Care Center
	Urgent Care Facility	Urgent Care Facility				
					Urgent Care Clinic	
						Public Health - Public Health Clinic - State Agency: Health - Prison Infirmary - Mass Immunization Center
	Public Health Clinic	Public Health Clinic				
					State Agency – Health	
			School or Prison Infirmary	School or Prison Infirmary		
	Mass Immunization Center	Mass Immunization Center				

As shown in Table 1, this process also included identifying synonyms and the need for “preferred terms.” For example, “office” is used currently in the DO, CMS POS, and MHCP; however, “physician’s office” is used in HL7 v3 and NHSN, which were meant to represent the same setting. From this, a consensus decision was made by the subject matter experts to keep the current “office” value and eliminate “physician’s office” in light of the variety of inter-professional office settings, including non-physician provider offices. Also, some settings in NHSN were deemed irrelevant to this study which focuses on document representation. This phase of selection and redundant value harmonization reduced the total number of values to 274, which were then organized into a hierarchy.

A series of iterative sessions with 4 subject matter experts (2 providers, 1 public health provider, and 4 informaticians) was held where the hierarchy was constructed, refined, and validated. In particular, three of experts were experienced with the DO and biomedical standards evaluation. The reviewers looked at the following aspects of the sources and value sets in placing them into the hierarchy, including: (1) relative granularity of values, (2) representation of current content, and (3) need for additional layers in the hierarchy. Experts reviewed the value sets independently and also together to compare proposed revisions. This process was repeated iteratively four times until there was consensus amongst the experts. As a final step, the proposed final list was made available publicly for use by the larger community.

Results

The processes resulted in the creation of a comprehensive *Setting* value set with compilation of values from relevant and representative sources which included: current HL7/LOINC Document Ontology [20 values], CMS Place of Service (POS) code set [47 values], National Healthcare Safety Network [229 values], clinical data repository setting value set from an integrated healthcare system [50 values], HL7 v3 – healthcare service location code from PHIN-VADS [212 values] and Minnesota Health Care Provider (MHCP) provider manual and 2015 MN EHR mandate guidance for settings [85 values]. Using the methodology described, this resulted in the creation of a final proposed list of 274 values. Table 2 provides a comparison of the current hierarchy in DO for *Setting* with proposed extended hierarchy.

Table 2: Comparison of Values across Current and Proposed HL7/LOINC Document Ontology for Settings

<i>Current HL7/LOINC Document Ontology Values [includes all classes and sub-classes]</i>	<i>Proposed Extended Hierarchy for Settings of Care [displays main classes only]</i>
Ambulance	Inpatient setting
Birthing center	Critical care unit
Emergency department	Step down unit
Hospital	Mixed acuity unit
Intensive care unit	Operating room
Long term care facility	Ward
Custodial care facility	Inpatient psychiatric facility
Nursing facility	Hospice
Skilled nursing facility	24 hour observation area
Unskilled nursing facility	Hyperbaric oxygen center
Outpatient	Emergency department
Ambulatory surgical center	Outpatient setting
Office	Acute setting
Outpatient hospital	Clinic (non-acute) setting
Urgent care center	Other outpatient setting
Patient's home	Long term care facility
Pharmacy	Skilled nursing facility
Rehabilitation hospital	Unskilled nursing facility/Custodial care facility
Telehealth	Intermediate care facility
Telephone encounter	Behavioral health facility
	Rehabilitation center
	Birthing center
	Telehealth
	Telephone encounter
	Mobile
	Transport
	Pharmacy
	Laboratory
	Public Health
	Community
	Home

The current DO axis has 12 main classes and 8 sub-classes, whereas the study's proposed axis has 14 main classes and 17 sub-classes and also includes additional value sets. The representation of 274 values with the extended hierarchy comprises of Inpatient setting [n=97], Emergency department [n=2], Outpatient setting [n=93], Long term care facility [n=17], Behavioral health facility [n=5], Rehabilitation center [n=4], Birthing center [n=3], Telehealth [n=1], Telephone encounter [n=1], Mobile [n=8], Pharmacy [n=1], Laboratory [n=11], Public Health [n=21] and Community [n=10].

Table 3 offers a snapshot of the proposed values and their hierarchical organization for three of the 14 main classes: Public Health, Community, and Mobile. The entire structure comprising of 274 values is available publicly (<http://www.bmhi.umn.edu/ih/research/nlpie/>) for dissemination to the broader community (e.g., for sharing with the LOINC Committee and other interested stakeholders).

Table 3: Snapshot of Proposed Extensions to the HL7/LOINC Document Ontology for *Setting*

Proposed Values in Select Classes		
Public Health	Community	Mobile
City/county agencies: Jails	Home	Mobile unit
City/county agencies: Human services	Home-based hospice	Mobile blood collection center
City/county agencies: Local health departments	Home hemodialysis	Mobile MRI/CT
Community mental health center	Group home	Transport service
Federally qualified health center (FQHC)	Assisted living facility	Mobile emergency services/EMS
Indian health service free-standing facility	Place of employment - worksite	Ambulance – air or water
Indian health service provider-based facility	Homeless shelter	Ambulance – land
Mass immunization center	Temporary lodging	
Migrant health clinic	Other place of service	
Military treatment facility		
Prison – Correctional facility		
Prison Infirmary		
Public health clinic		
State agency – corrections		
State agency – health		
State agency – human services		
State or local health clinic		
Tribal 638 free-standing facility		
Tribal 638 provider-based facility		
Veterans Affairs (VA)		

Discussion

In this study, we have described an effort to construct a comprehensive value set for representation of *Setting* for the HL7/LOINC Document Ontology. The methodology involved identifying additional representative and valid sources for *Setting* values, integrating these value sets to eliminate redundancies and combine synonyms, extending the existing DO hierarchy for *Setting* and organizing the values into this hierarchy, validating with subject matter experts in multiple sessions, and disseminating the results. One of the challenges encountered in this work was the effort and decisions around optimal hierarchical representation of value sets. The sessions with subject matter experts revealed the complexity of this task due to numerous places in which care is delivered across inpatient, outpatient, home, and community locations, as some of the major settings of care, and the variation in care delivery by organizational structure. Also, there were numerous redundancies and synonyms to deal with across the value sets from various sources. Expert review revealed that there are a multitude of ways to organize the setting values, depending on the specification of higher classes and the granularity of terms. One consensus was that the *Setting* axis in the current HL7/LOINC Document Ontology needs inclusion of additional settings of care to truly reflect the changing healthcare delivery landscape to accurately capture information on settings of care and facilitate representation and reuse of documents for research.

Guidelines were also developed for systematic review and organization of settings in a hierarchy. Criteria which were discussed included: (1) inclusion of specialty locations separately in a particular setting or roll them up as part of overarching settings of care such as inpatient and outpatient, (2) potential need for poly-hierarchy with a class to be included as a sub-class of various categories, (3) validity of sources for inclusion, (4) addition of other reliable sources, and (5) identification of main classes in settings of care. Multiple rounds of expert review, including both independent and combined sessions revealed the complexity in organization of the setting concept. These assessments also revealed inconsistencies in representation across sources, redundancies, and synonyms, all of which had to be addressed.

One of the limitations of this work is the difficulty in obtaining data on internal validity. Although we did have multiple rounds and exposed the data hierarchy to multiple expert stakeholders, because of the large number of values and need to leverage group wisdom about care settings, separate and independent assessments of the value sets was found to be difficult for applying inter-rater reliability measures, which are often applied to terminology coding tasks. An ongoing challenge is balancing the comprehensiveness of information in the hierarchy and associated granularity with the

practical aspects of implementation and mapping burden. This study proposes an over 10-fold extension of the *Setting* axis values from a current list of 20 to a proposed set of 274 values. More coverage in the *Setting* axis is needed, but further efforts are needed to determine the optimal set of values and their organization for uses ranging from clinical care to research.

Next steps for this study would be submission of the value sets to the LOINC Committee for a formal review as outlined in the LOINC User's guide⁹. This is a critical next step in the generalizability of this work and its applicability to *Setting* axis extension. Other ongoing work involves studying the representation of *Role* in DO as a recent study recommended the need for additional values in the *Role* axis². Ultimately, these findings need to be promoted and value sets shared as a form of external validation by other interested stakeholders, including those from the standards community. Both informal feedback and also the formal LOINC submission and review process would decide the extent of *Setting* axis expansion. As this study group and others continue to promote better representation of clinical information across providers and partners in healthcare ecosystem, the extension of DO value sets is needed to incorporate a comprehensive and reflective set of values for settings of care.

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