Evaluation of HL7 Continuity of Care Document as the Foundation for an International Virtual Medical Record Standard for Clinical Decision Support

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Abstract

To facilitate interoperable clinical decision support (CDS), Health Level 7 (HL7) is developing a standard information model for CDS known as the virtual medical record (vMR). Recently, several CDS initiatives have developed their own vMRs based on the HL7 Continuity of Care Document (CCD). However, it is unclear whether the CCD has sufficient breadth of coverage for an international vMR standard. Thus, the HL7 vMR project team analyzed the CCD's coverage of 130 data elements identified in an earlier study as being used by 20 CDS systems from four countries. The CCD was capable of expressing 96% of the CDS data elements, but 20% of the data elements could only be covered by extending the CCD with non-standard entries. Thus, while the CCD can serve as the foundation for an international vMR standard, the CCD has important gaps that will need to be addressed in the emerging HL7 vMR standard.

Introduction

A central rationale for investing in health information systems is enabling improved healthcare through clinical decision support (CDS), which entails providing clinicians, staff, patients or other individuals with knowledge and person-specific information, intelligently filtered or presented at appropriate times, to enhance health and health care.[1] When automatically delivered to clinicians as actionable care recommendations within their routine clinical workflows, computer-based CDS interventions have significantly improved clinical practice in over 90% of randomized controlled trials.[2]

Despite significant promise, CDS interventions are not widely implemented.[1] While there are many reasons for this limited deployment of CDS systems, an important challenge is the lack of a standard information model for CDS upon which interoperable knowledge resources can be developed. Within the Arden Syntax CDS community, for example, this problem has long been identified as the "curly braces problem" due to the implementation-specific nature of the information models contained within curly braces in Arden Syntax medical logic modules.[3]

In recognizing this problem, a number of CDS implementers have proposed the definition and adoption of a common information model for CDS, which has generally been referred to as a virtual medical record (vMR).[4-9] To address this need, the HL7 CDS Work Group is actively developing an international vMR standard. As an important step in this process, the HL7 vMR project team previously identified a representative set of clinical data elements required for CDS through a formal analysis of the data needs of 20 CDS systems across four nations.[10] Active work on an HL7 vMR standard has been ongoing since, with an initial round of balloting in 2010[11] and additional rounds of balloting scheduled for 2011.

Because an HL7 standard necessarily takes a substantial amount of time and consensus-building to establish, a variety of CDS implementers, including several members of the HL7 vMR project team, have implemented their own vMRs to meet the needs of their CDS initiatives. For many of the recent initiatives, these vMRs have been based on the information content of the HL7 Continuity of Care Document (CCD),[12] which is a standard representation format for patient summary data that has gained increasing importance in the United States due to its designation as a standard information exchange format by federal Meaningful Use regulations.[13] The CCD represents a series of constraints placed on Release 2 of the HL7 Clinical Document Architecture (CDA),[14] which is a generic representation format for clinical documents. CDS initiatives that are using vMRs based on the CCD include the CDS Consortium,[15] the Distributed Decision Support and Knowledge Management Repository (DDSS/KMR) initiative,[16] and OpenCDS.[17]

Basing the vMR on the CCD has many potential benefits, including (i) widespread support for the CCD format by a variety of electronic health record (EHR) systems due to Meaningful Use regulations; (ii) the ability to leverage the significant information modeling effort that went into defining the CCD; and (iii) alignment with other HL7 information models due to the CCD's use of a common HL7 modeling pattern known as the "clinical statement pattern." Moreover, the fact that many of the current-generation vMRs are based on the CCD indicates that it is a promising foundation for an international vMR standard. At the same time, however, it is unclear whether the information contained in a CCD covers the full breadth of information needed for an international vMR standard. Thus, in order to inform the further specification of an HL7 vMR standard, the vMR project team analyzed the degree to which the CCD covers the collective CDS data needs identified from our previous analysis of commercial and academic systems from across 20 institutions and four countries.[10] The findings of this present analysis, and the implications for the development of the HL7 vMR standard, are discussed below.

Methods

Objective and Scope. The objective of this analysis was to identify the degree to which the CCD covers the input data elements required by CDS systems to generate patient-specific inferences. CDS outputs (e.g., care recommendations) were considered out of scope, as the original CDS data needs analysis focused solely on CDS inputs. If the CCD can cover the majority of CDS data needs, our intention is to reuse components of the CCD, and in particular its clinical statements, in the to-be-developed HL7 vMR standard. Because EHR systems are increasingly supporting use of the CCD standard, we hope that our leveraging of the CCD in this manner will lower the data interoperability barrier for EHR systems and other health information systems as they develop vMR-based CDS capabilities.

Identification of Required vMR Data Elements. Data elements required for the vMR were determined through a previous analysis of the data used by 20 CDS systems across four nations to generate patient-specific inferences. This analysis identified 131 data elements as being in use by the 20 CDS systems. Details of this analysis are available in a prior publication.[10] For this analysis, we removed one of the original data elements from consideration – concept taxonomies, such as the set of ICD9 codes that identify diabetes mellitus or the set of NDC codes that identify beta-blockers. We made this decision because such concept taxonomies were deemed to be out of scope for our current vMR modeling efforts, which are focused on the modeling of data utilized by CDS knowledge resources rather than on the modeling of the CDS knowledge resources themselves and their associated terminology resources. Thus, a total of 130 data elements served as the target of our analysis of the CCD's coverage of CDS data needs.

Analysis of CCD for Coverage of Required Data Elements. For each of the 130 data elements identified as being required for the 20 CDS systems, vMR project team members reviewed the HL7 CCD standard[12] to identify the degree to which the CCD covered the data element. The CCD was considered to have covered a data element if (i) the data element was explicitly included in the CCD (henceforth referred to as "direct coverage") or (ii) the data element was not explicitly included in the CCD, but it could be represented using an extension mechanism allowed by the CCD, such as through the addition of a related Observation not specifically identified in the standard (henceforth referred to as "indirect coverage"). In the case of indirect coverage, a potential approach to representing the required data element within the CCD was identified. Also, for both types of coverage, the sections of the CCD and CDA Release 2 standards encapsulating the data element were recorded. Following the abstraction of the CCD coverage information, summary statistics were generated regarding the proportion of required CDS data elements covered by the CCD, both through direct and indirect means.

Of note, additional constraints to the CCD have been defined by a variety of relevant stakeholders, including Integrating the Healthcare Enterprise (IHE)[18] and the U.S. Health Information Technology Standards Panel (HITSP).[19] For the purposes of this analysis, we only considered the foundational HL7 CCD standard, for two reasons. First, these additional constraints on the CCD sometimes conflict with one another, although this issue is currently being addressed by an active effort to harmonize conflicts and overlaps among CDA-based specifications and in particular the CCD-related specifications.[20] Second, we only considered the HL7 CCD standard due to our focus on developing an international standard. Country-specific versions, such as a U.S.-focused vMR with close ties to HITSP standards, will be developed as needed based on the international vMR standard.

Results

Table 1 provides a detailed analysis of the CCD's coverage of the 130 data elements identified as being required for CDS through our prior analysis.[10] Further details regarding these data elements, including definitions, examples, and example uses within CDS systems, are available on the HL7 vMR project wiki.[21] Of the 130 CDS data elements, 99 (76%) were directly covered by the CCD, 26 (20%) were indirectly covered by the CCD, and five (4%) were not covered by the CCD.

With regard to the 26 CDS data elements that were not directly covered by the CCD but could be expressed by extending the CCD using permissible but non-standard data entries, many of these data elements related to date and time elements required for CDS but not explicitly covered in the CCD (e.g., when a problem was noted by the observer, as opposed to when the problem was clinically relevant or active). Other data elements that were indirectly covered by the CCD included such data elements as a patient's age group and the medication class to which a specific drug belongs.

With regard to the CDS data elements not covered by the CCD, all five data elements were data required for understanding the clinical context within which CDS is provided: the type of CDS system user (e.g., MD, RN, or patient), the user's preferred language, the type of individual receiving the CDS information (e.g., MD, RN, patient), the language of the information recipient, and the task context for a CDS session. Of note, all five data elements are represented in a standard manner within the HL7 Context-aware Information Retrieval (Infobutton) standard.[22]

Table 1. Data elements needed for CDS and coverage by CCD.

Data Element (DE)	**CCD Coverage***	**Path to CCD Element Covering CDS DE and Relevant Sections of CCD and CDA Standards^**
Demographic DEs		
Patient Gender	Direct	recordTarget/patientRole/patient/administrativeGenderCode (CDA 4.2.2.11, CCD 2.5)
Patient Race(s)	Indirect	Direct coverage of up to one race in recordTarget/patientRole/patient/raceCode (CDA 4.2.2.11, CCD 2.5). However, need potentially many race(s) to be specified. Multiple races could be indirectly specified in Observations in ../entry/ observation (CDA 4.3.6.3, CCD 1.2).
Patient Birth Date	Direct	recordTarget/patientRole/patient/birthTime (CDA 4.2.2.11, CCD 2.5)
Patient Age	Indirect	../entry/observation (CDA 4.3.6.3, CCD 1.2). Computable from birth date.
Patient Age Group	Indirect	../entry/observation (CDA 4.3.6.3, CCD 1.2). Computable from birth date.
Postal Address(es)	Direct	recordTarget/PatientRole/addr (CDA 4.2.2.11, CCD 2.5)
Primary Care Provider	Direct	documentationOf/serviceEvent/performer (CDA 4.2.3.2, CCD 3.17)
Moved out of Area	Indirect	../entry/observation (CDA 4.3.6.3, CCD 1.2)
Encounter DEs		
Location Type Code(s)	Indirect	../entry/encounter/entryRelationship/observation (CDA 4.3.6.3, CCD 1.2)
Encounter Location	Direct	../entry/encounter/participant (CDA 4.3.6.2, CCD 3.15.2.2)
Provider Type Code(s)	Direct	../entry/encounter/participant/participantRole/code and ../entry/encounter/performer/ assignedEntity/code. Multiple performers and participants allowed (CDA 4.3.6.2, CCD 3.15.2.1)
Encounter Status	Indirect	CCD directly covers completed encounters (CCD 3.15.2.1) and pending appointments as a part of the plan of care (CCD 3.16). Missed appointments could be indirectly covered using Observations (../entry/observation; CDA 4.3.6.3, CCD 1.2).
Date/Time Interval	Direct	../entry/encounter/effectiveTime (CDA 4.3.6.2, CCD 3.15.2.1)
Encounter Identifier	Direct	../entry/encounter/id (CDA 4.3.6.2, CCD 3.15.2.1)
Encounter Note(s)	Indirect	../entry/encounter/entryRelationship/observation (CDA 4.3.6.3, CCD 1.2). Use CCD comment template (CCD 4.3, template ID 2.16.840.1.113883.3.88.11.83.11).
Procedure DEs		
Procedure Code	Direct	../entry/procedure/code (CDA 4.3.6.6, CCD 3.14)
Procedure Site Code	Direct	../entry/procedure/targetSiteCode (CDA 4.3.6.6, CCD 3.14)
Procedure Modifier Code	Direct	../entry/procedure/code/qualifier (CDA 4.3.6.6, CCD 3.14)
Date/Time Interval	Direct	../entry/procedure/effectiveTime (CDA 4.3.6.6, CCD 3.14)

Table 1 (continued). Data elements needed for CDS and coverage by CCD.

Data Element (DE)	CCD Coverage*	Path to CCD Element Covering CDS DE and Relevant Sections of CCD and CDA Standards^
Procedure Status	Direct	../entry/procedure/statusCode (CDA 4.3.6.6, CCD 3.14)
Procedure Identifier	Direct	../entry/procedure/id (CDA 4.3.6.6, CCD 3.14)
Associated Enc. ID	Direct	../entry/procedure/entryRelationship/encounter/id (CDA 4.3.6.6, CCD 3.14)
Procedure Note	Indirect	../entry/encounter/entryRelationship/observation (CDA 4.3.6.3, CCD 1.2). Use CCD comment template (CCD 4.3, template ID 2.16.840.1.113883.3.88.11.83.11).
Procedure Note Type	Indirect	../entry/encounter/entryRelationship/observation/code (CDA 4.3.6.3, CCD 1.2). Extend CCD comment template to add comment type as modifier to comment.
Problem Observation DEs		
Problem Identifier	Direct	../entry/act/id or ../entry/act/entryRelationship/observation/id (CDA 4.3.6.3, CCD 3.5.2.1)
Problem Observation Date/Time	Indirect	../entry/act/effectiveTime and ../entry/act/entryRelationship/observation/ effectiveTime do not refer to the actual date/time when the observation was made, but rather when the problem was a concern and the biological timing, respectively (CDA 4.3.6.3, CCD 3.5.2.1). The desired DE could be represented indirectly using a related observation nested within the problem observation or problem act (CDA 4.3.6.3, CCD 1.2). Or, potentially, the problem observation date/time could be inferred from the effectiveTime of a related encounter.
Problem Observer Type	Direct	../entry/act/performer/assignedEntity/code or ../entry/act/entryRelationship/ observation/performer/assignedEntity/code (CDA 4.3.6.3, CCD 3.5.2.1)
Associated Enc. ID	Direct	../entry/act/entryRelationship/encounter/id or ../entry/act/entryRelationship/ observation/entryRelationship/encounter/id (CDA 4.3.6.6, CCD 3.5.2.1)
Problem Observation Type	Direct	../entry/act/entryRelationship/observation/code (CDA 4.3.6.6, CCD 3.5.2.1.2)
Problem Code	Direct	../entry/act/entryRelationship/observation/value (CDA 4.3.6.6, CCD 3.5.2.1.2)
Problem Class(es)	Indirect	../entry/act/entryRelationship/observation/entryRelationship/observation/value (CDA 4.3.6.3, CCD 1.2). Use Problem Class template as modifier to Problem Observation.
Problem Modifier	Direct	../entry/act/entryRelationship/observation/negationInd (CDA 4.3.6.6, CCD 3.5.2.1.2)
Problem Status	Direct	../entry/act/entryRelationship/observation/entryRelationship/observation/value (CDA 4.3.6.6, CCD 3.5.2.1.2)
Status Time Interval	Direct	../entry/act/entryRelationship/observation/effectiveTime (CDA 4.3.6.6, CCD 3.5.2.1.2)
Observation Method	Direct	../entry/act/entryRelationship/observation/methodCode (CDA 4.3.6.3, CCD 3.5.2.1.2)
Medication Observation DEs		
Observation Identifier	Direct	../entry/substanceAdministration/id (CDA 4.3.6.8, CCD 3.9.2)
Observation Date/Time	Indirect	../entry/substanceAdministration/entryRelationship/observation/value (CDA 4.3.6.8, CCD 3.9.2)
Observer Type	Direct	../entry/substanceAdministration/performer/assignedEntity/code (CDA 4.3.6.8, CCD 3.9.2)
Associated Enc. ID	Direct	../entry/substanceAdministration/entryRelationship/encounter/id (CDA 4.3.6.8, CCD 3.9.2)
Observation Type	Direct	../entry/substanceAdministration/moodCode (CDA 4.3.6.8, CCD 3.9.2.1)
Medication Code	Direct	../entry/substanceAdministration/consumable/manufacturedProduct/ manufacturedMaterial/code (CDA 4.3.6.8, CCD 3.9.2.1)
Medication Class(es)	Indirect	../entry/substanceAdministration/entryRelationship/observation/value (CDA 4.3.6.8, CCD 3.9.2.1). HITSP has a recommended approach for this information.
Medication Dose	Direct	../entry/substanceAdministration/doseQuantity and ../entry/ substanceAdministration/administrationUnitCode (CDA 4.3.6.8, CCD 3.9.2.1)
Medication Route	Direct	../entry/substanceAdministration/routeCode (CDA 4.3.6.8, CCD 3.9.2.1.1)
Medication Rate	Direct	../entry/substanceAdministration/doseQuantity and ../entry/ substanceAdministration/administrationUnitCode (CDA 4.3.6.8, CCD 3.9.2.1.1)
Coverage Time Interval	Direct	../entry/substanceAdministration/effectiveTime (CDA 4.3.6.8, CCD 3.9.2.1.1)

Table 1 (continued). Data elements needed for CDS and coverage by CCD.

Data Element (DE)	CCD Coverage*	Path to CCD Element Covering CDS DE and Relevant Sections of CCD and CDA Standards^
Refill Information	Direct	../entry/substanceAdministration/entryRelationship/supply/repeatNumber and ../entry/substanceAdministration/entryRelationship/supply/quantity (CDA 4.3.6.9, CCD 3.9.2.1.2)
Medication Status	Direct	../entry/substanceAdministration/statusCode (CDA 4.3.6.9, CCD 3.9.2.1.1)
Medical Equipment Observation DEs		
Observation Identifier	Direct	../entry/supply/id (CDA 4.3.6.9, CCD 3.10.1)
Observation Date/Time	Direct	../entry/supply/effectiveTime (CDA 4.3.6.9, CCD 3.10.1)
Observer Type	Direct	../entry/act/performer/assignedEntity/code or ../entry/act/entryRelationship/observation/performer/assignedEntity/code (CDA 4.3.6.3, CCD 3.5.2.1)
Associated Enc. ID	Direct	../entry/act/entryRelationship/encounter/id or ../entry/act/entryRelationship/observation/entryRelationship/encounter/id (CDA 4.3.6.6, CCD 3.5.2.1)
Observation Type	Direct	../entry/supply/classCode (CDA 4.3.6.9, CCD 3.9.2.4)
Equipment Code	Direct	../entry/supply/participant/participantRole/playingDevice/code (CDA 4.3.6.9, CCD 3.10.1)
Family History Observation DEs		
Observation Identifier	Direct	../entry/organizer/component/observation/id (CDA 4.3.6.3, CCD 3.6.2.1)
Observer Type	Direct	../entry/organizer/component/observation/performer/assignedEntity/code (CDA 4.3.6.3, CCD 3.6.2.1.2)
Associated Enc. ID	Direct	../entry/organizer/component/observation/entryRelationship/encounter/id (CDA 4.3.6.6, CCD 3.6.2.1.2)
Relationship to Patient	Direct	../entry/organizer/component/observation/subject/relatedSubject (CDA 4.3.6.5, CCD 3.6.2.2)
Relative Demographics	Direct	../entry/organizer/component/observation/subject/relatedSubject (CDA 4.3.6.5, CCD 3.6.2.2)
Relative Age of Death	Direct	../entry/organizer/component/observation/entryRelationship/observation/value (CDA 4.3.6.5, CCD 3.6.2.2)
Relative Problem(s)	Direct	../entry/organizer/component/observation/value (CDA 4.3.6.5, CCD 3.6.2.2)
Relative's EHR data	Direct	../entry/organizer/component (CDA 4.3.6.5, CCD 3.6.2.2)
Adverse Reaction Observation DEs		
Observation Identifier	Direct	../entry/act/id or ../entry/act/entryRelationship/observation/id (CDA 4.3.6.3, CCD 3.5.2.1)
Observation Date/Time	Indirect	DE could be represented indirectly using a related observation nested within the problem observation or problem act (CDA 4.3.6.3, CCD 1.2). Or, potentially, the observation date/time could be inferred from the effectiveTime of a related encounter.
Observer Type	Direct	../entry/act/performer/assignedEntity/code or ../entry/act/entryRelationship/observation/performer/assignedEntity/code (CDA 4.3.6.3, CCD 3.5.2.1)
Associated Enc. ID	Direct	../entry/act/entryRelationship/encounter/id or ../entry/act/entryRelationship/observation/entryRelationship/encounter/id (CDA 4.3.6.6, CCD 3.5.2.1)
Causative Agent Type	Indirect	../entry/act/entryRelationship/observation/entryRelationship/observation/code (CDA 4.3.6.8, CCD 3.9.2.1). HITSP recommends a specific approach.
Causative Agent Code	Direct	../entry/act/entryRelationship/observation/participant/participantRole/playingEntity/code (CDA 4.3.6.3, CCD 3.8.2.3)
Agent Class(es)	Indirect	../entry/act/entryRelationship/observation/entryRelationship/observation/code (CDA 4.3.6.8, CCD 3.9.2.1). HITSP recommends a specific approach.
Reaction Code	Direct	../entry/act/entryRelationship/observation/entryRelationship/observation/code (CDA 4.3.6.3, CCD 4.3.8.4)
Reaction Severity	Direct	../entry/act/entryRelationship/observation/entryRelationship/observation/code (CDA 4.3.8.4, CCD 3.8.2.2)
Reaction Date/Time	Direct	../entry/act/entryRelationship/observation/entryRelationship/effectiveTime (CDA 4.3.8.4, CCD 3.8.2.2)
Reaction Status	Direct	../entry/act/entryRelationship/observation/entryRelationship/observation/code (CDA 4.3.8.4, CCD 3.8.2.2)

Table 1 (continued). Data elements needed for CDS and coverage by CCD.

Data Element (DE)	CCD Coverage*	Path to CCD Element Covering CDS DE and Relevant Sections of CCD and CDA Standards^
Laboratory Result Observation DEs		
Observation Identifier	Direct	../entry/organizer/component/observation/id (CDA 4.3.6.3, CCD 3.13)
Observer Type	Direct	../entry/organizer/component/observation/performer/assignedEntity/code (CDA 4.3.6.3, CCD 3.13)
Associated Enc. ID	Direct	../entry/organizer/component/observation/entryRelationship/encounter/id (CDA 4.3.6.3, CCD 3.13)
Test Type	Direct	component/structuredBody/component/section/code (CDA 4.3.6.3, CCD 3.13) CCD requires value to be "Relevant diagnostic tests and/or laboratory data" or "Vital signs", with no further classification allowed.
Test Status	Direct	../entry/organizer/component/observation/statusCode (CDA 4.3.6.3, CCD 3.13)
Test Code	Direct	../entry/organizer/component/observation/code (CDA 4.3.6.3, CCD 3.13)
Specimen Location Code	Indirect	../entry/organizer/component/observation/entryRelationship/observation/value May potentially be represented using qualifier attribute of ../entry/organizer/component/ observation/specimen/specimenRole/playingEntity/code (CDA 4.3.6.3, CCD 1.2)
Specimen Type Code	Direct	../entry/organizer/component/observation/specimen/specimenRole/playingEntity/ code (CDA 4.3.6.3, CCD 3.13)
Collection Date/Time	Direct	../entry/organizer/component/observation/effectiveTime (CDA 4.3.6.3, CCD 3.13)
Value	Direct	../entry/organizer/component/observation/value (CDA 4.3.6.3, CCD 3.13)
Normal Range	Direct	../entry/organizer/component/observation/referenceRange/value (CDA 4.3.6.3, CCD 3.13)
Interpretation	Direct	../entry/organizer/component/observation/interpretationCode (CDA 4.3.6.3, CCD 3.13)
Nested Observations	Direct	../entry/organizer/component/observation/entryRelationship/observation (CDA 4.3.6.3, CCD 3.13)
Observer Identifier	Direct	../entry/organizer/component/observation/performer/assignedEntity/id (CDA 4.3.6.3, CCD 3.13)
Observation Note	Indirect	../entry/organizer/component/observation/entryRelationship/observation (CDA 4.3.6.3, CCD 1.2). Use CCD comment template (CCD 4.3).
Note Type	Indirect	../entry/organizer/component/observation/entryRelationship/observation/code (CDA 4.3.6.3, CCD 1.2). Extend CCD comment template to add comment type.
Physical Finding Observation DEs		
Observation Identifier	Direct	../entry/organizer/component/observation/id (CDA 4.3.6.3, CCD 3.12 and 3.13)
Observation Date/Time	Direct	../entry/organizer/component/observation/effectiveTime (CDA 4.3.6.3, CCD 3.12 and 3.13)
Observer Type	Direct	../entry/organizer/component/observation/performer/assignedEntity/code (CDA 4.3.6.3, CCD 3.12 and 3.13)
Associated Enc. ID	Direct	../entry/organizer/component/observation/entryRelationship/encounter/id (CDA 4.3.6.3, CCD 3.12 and 3.13)
Finding Type	Direct	component/structuredBody/component/section/code (CDA 4.3.6.3, CCD 3.12 and 3.13) CCD requires value to be "Relevant diagnostic tests and/or laboratory data" or "Vital signs", with no further classification allowed.
Finding Code	Direct	../entry/organizer/component/observation/code (CDA 4.3.6.3, CCD 3.12 and 3.13)
Patient Position Code	Indirect	../entry/organizer/component/observation/entryRelationship/observation/value (CDA 4.3.6.3, CCD 1.2)
Finding Location Code	Direct	../entry/organizer/component/observation/targetSiteCode (CDA 4.3.6.3, CCD 3.12 and 3.13)
Value	Direct	../entry/organizer/component/observation/value (CDA 4.3.6.3, CCD 3.12 and 3.13)
Normal Range	Direct	../entry/organizer/component/observation/referenceRange/value (CDA 4.3.6.3, CCD 3.12 and 3.13)

Table 1 (continued). Data elements needed for CDS and coverage by CCD.

Data Element (DE)	CCD Coverage*	Path to CCD Element Covering CDS DE and Relevant Sections of CCD and CDA Standards^
Interpretation	Direct	../entry/organizer/component/observation/interpretationCode (CDA 4.3.6.3, CCD 3.12 and 3.13)
Nested Observations	Direct	../entry/organizer/component/observation/entryRelationship/observation (CDA 4.3.6.3, CCD 3.12 and 3.13)
Finding Status	Direct	../entry/organizer/component/observation/statusCode (CDA 4.3.6.3, CCD 3.12 and 3.13)
Finding Note	Indirect	../entry/organizer/component/observation/entryRelationship/observation (CDA 4.3.6.3, CCD 1.2). Use CCD comment template (CCD 4.3).
Note Type	Indirect	../entry/organizer/component/observation/entryRelationship/observation/code (CDA 4.3.6.3, CCD 1.2). Extend CCD comment template to add comment type.
Goal Observation DEs		
Observation Identifier	Direct	../entry/observation/id (CDA 4.3.6.3, CCD 3.16.2.1)
Observation Date/Time	Indirect	../entry/observation/entryRelationship/observation/value (CDA 4.3.6.3, CCD 1.2)
Observer Type	Direct	../entry/observation/performer/assignedEntity/code (CDA 4.3.6.3, CCD 3.16.2.1)
Associated Enc. ID	Direct	../entry/observation/entryRelationship/encounter/id (CDA 4.3.6.3, CCD 3.16.2.1)
Goal Focus Code	Direct	../entry/observation/code (CDA 4.3.6.3, CCD 3.16.2.1)
Value	Direct	../entry/observation/value (CDA 4.3.6.3, CCD 3.16.2.1)
Other Observation DEs		
Observation Identifier	Direct	../entry/observation/id (CDA 4.3.6.3)
Observation Date/Time	Indirect	../entry/observation/entryRelationship/observation/value (CDA 4.3.6.3, CCD 1.2) Base observation's effectiveTime does not necessarily refer to when observation was made.
Observer Type	Direct	../entry/observation/performer/assignedEntity/code (CDA 4.3.6.3)
Associated Enc. ID	Direct	../entry/observation/entryRelationship/encounter/id (CDA 4.3.6.3)
Observation Type	Direct	component/structuredBody/component/section/code (CDA 4.3.6.3)
Obs. Focus Code	Direct	../entry/observation/code (CDA 4.3.6.3)
Value	Direct	../entry/observation/value (CDA 4.3.6.3)
Interpretation	Direct	../entry/observation/interpretationCode (CDA 4.3.6.3)
Nested Observations	Direct	../entry/observation/entryRelationship/observation (CDA 4.3.6.3)
Patient Affiliation DEs		
Affiliated Entity Type	Direct	For payors: ../entry/act/entryRelationship/act/performer/assignedEntity/code (CDA 4.3.6.1, CCD 3.1.2.1) For providers (persons and organizations): documentationOf/serviceEvent/performer/functionCode (CDA 4.2.3.2, CCD 3.17)
Entity Identifier	Direct	For payors: ../entry/act/entryRelationship/act/performer/assignedEntity/id (CDA 4.3.6.1, CCD 3.1.2.1) For providers (persons and organizations): documentationOf/serviceEvent/performer/assignedEntity/id (CDA 4.2.3.2, CCD 3.17)
Obs. Date/Time	Indirect	For payors, could be made available under ../entry/act/entryRelationship/act/ entryRelationship/observation/value (CDA 4.3.6.1, CCD 3.1.2.1) For providers (persons and organizations), could be made available under ../entry/observation/entryRelationship/observation/value (CDA 4.3.6.3, CCD 1.2)
Affiliation Status	Indirect	For payors, could be made available under: ../entry/act/entryRelationship/act/ entryRelationship/observation/value (CDA 4.3.6.1, CCD 3.1.2.1) For providers (persons and organizations), could be made available under ../entry/observation/entryRelationship/observation/value (CDA 4.3.6.3, CCD 1.2)
Status Time Interval	Direct	For payors: ../entry/act/entryRelationship/act/participant/time (CDA 4.3.6.1, CCD 3.1.2.1) For providers (persons and organizations): documentationOf/serviceEvent/performer/time (CDA 4.2.3.2, CCD 3.17)

Table 1 (continued). Data elements needed for CDS and coverage by CCD.

Data Element (DE)	CCD Coverage*	Path to CCD Element Covering CDS DE and Relevant Sections of CCD and CDA Standards^
CDS Context DEs		
CDS System User Type	Not covered	
User Preferred Language	Not covered	
Info Recipient Type	Not covered	ClinicalDocument/informationRecipient/intendedRecipient/informationRecipient does not have a mechanism for noting this information about the recipient
Info Recipient Language	Not covered	ClinicalDocument/informationRecipient/intendedRecipient/informationRecipient does not have a mechanism for noting this information about the recipient
Task Context	Not covered	
DEs for All Orderable Items (e.g., Meds, Labs)		
Orderable Item Status	Direct	../entry/[clinicalStatement]/statusCode

*Direct = DE explicitly included in the CCD; Indirect = DE not explicitly included in CCD, but could be represented using an extension mechanism allowed by the CCD. ^CCD element represents the relative path relative to the ClinicalDocument root node. ../entry is shorthand for component/structuredBody/component/section/entry. CCD section references are to HL7 CCD standard.[12] CDA section references are to the HL7 CDA Release 2 standard,[23] which is the foundational model constrained by the CCD.

Discussion

Summary of Findings. In this study, we analyzed the HL7 CCD standard to evaluate the extent to which it covered 130 data elements identified as being required for CDS through a prior analysis of 20 CDS systems from four countries. This analysis revealed that the CCD was capable of representing over 95% of the data elements. However, 20% of the data elements were not directly covered by the CCD and required the addition of permissible but non-standard data entries, such as adding a nested observation to existing CCD elements. Of the five data elements not covered by the CCD, all were covered by the HL7 Infobutton standard.[22]

Distinction between CCD and vMR. Based on our present analysis, an apparent conclusion may be that the CCD could be used "as is" for the vMR. However, we have found that there are difficulties with using the CCD itself as the vMR, for several reasons. First, the CCD uses a highly nested, complex data structure that makes it difficult for knowledge engineers to easily comprehend, whereas the vMR is being defined in a "flattened" structure that is more intuitive (and therefore safer) for knowledge engineers to use. The CCD's nested structure is also relatively slow for computation – an important factor if we want to enable real-time CDS. Second, because the CCD's focus is on documentation rather than on inferencing, it has significant quantities of information that are unnecessary for CDS (e.g., human-readable formatted text and document section headers). Finally, as identified by our analysis, there are data elements required for CDS that are only indirectly covered or not covered at all.

Study Strengths. As one important strength, the CDS data needs that served as the target of the analysis were identified through a survey of a large number of diverse CDS systems, including mature home-grown and commercial CDS systems from four countries.[10] This diversity minimized the chances that important data elements were overlooked. Second, the CDS data needs survey included only actual CDS systems and their data needs. Consequently, we minimized the possibility of including data elements not truly useful for CDS. Third, the analysis distinguished between data elements that were covered directly and indirectly by the CCD. This distinction provides nuanced insights into how the CCD can be used to support the data needs of CDS systems. Finally, this study provides a solid basis for establishing an international vMR standard based on the CCD.

Study Limitations. As one limitation, this study did not consider the additional CCD constraints defined by HITSP, which are important considerations in the United States.[24] However, as the ultimate purpose of the present work is to develop an international HL7 vMR standard, we limited our analysis to the internationally accepted CCD standard. Moving forward, we plan to define the vMR in a manner that takes into consideration HITSP's constraints on the CCD and CDA, as well as other relevant constraints defined by IHE and HL7.[20] As another limitation, we did not consider CDS outputs within the scope of the analysis. As described in the Methods section, this was due to the lack of a gold standard target to which to compare the CCD. However, we do plan to address this issue in the future following the identification of required data elements for CDS outputs. Finally, this study did not consider

CDS data needs beyond those identified through the survey of CDS systems.[10] However, we felt it was best to ground our analysis on actual CDS data needs rather than on theoretical data needs that may arise in the future, as standards developed based on theoretical needs can quickly become overly complex and difficult to implement.

Implications and Future Directions. The results of our analysis indicate that the CCD can in fact serve as the foundation for an international vMR standard. At the same time, our finding that many of the CDS data needs required the use of permissible but non-standard CCD data entries indicates that the representation of these data elements requires the specification of additional, standard constraints on the CCD. Furthermore, the inability of the CCD to represent some data elements indicates the need for additional standard information models to be incorporated into the vMR. Besides the HL7 Infobutton standard,[22] the HL7 Pedigree model[25] may need to be incorporated. This incorporation of the HL7 Pedigree model may be needed as the CCD does not support the specification of a full pedigree, which may be required for some types of advanced CDS based on family history.

At present, the HL7 vMR project team is using the results of the present analysis to specify an HL7 vMR standard which heavily leverages the CCD and supports the deterministic transformation of a CCD instance into a vMR instance. Moreover, model constraints are being defined to deal with the CDS data elements that are not directly covered by the CCD, and additional models including the HL7 Infobutton standard[22] and the HL7 Pedigree standard[25] are being incorporated into the vMR. Furthermore, the vMR project team is in the process of leveraging model simplification tooling originally developed to simplify CDA-based models such as the CCD,[26] so that the resulting HL7 vMR is capable of semantic interoperability with complex information models such as the CCD while being accessible to a wide range of CDS implementers. Finally, members of the HL7 vMR project team are actively implementing prototypes of the emerging HL7 vMR standard in order to ensure the practical utility of the standard. For example, OpenCDS[17] currently utilizes a CCD-based vMR and will provide an open-source reference implementation of the emerging HL7 vMR standard moving forward.

Conclusion

The CCD is a suitable foundation for an international vMR standard. However, there are important information gaps that need to be addressed through further constraints and the use of complementary information models such as the HL7 Pedigree model.

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References

1. Osheroff JA, Teich JM, Middleton B, Steen EB, Wright A, Detmer DE. A roadmap for national action on clinical decision support. J Am Med Inform Assoc. 2007;14(2):141-5.

2. Kawamoto K, Houlihan CA, Balas EA, Lobach DF. Improving clinical practice using clinical decision support systems: a systematic review of trials to identify features critical to success. BMJ. 2005;330(7494):765-8.

3. Choi J, Lussier YA, Mendoca EA. Adapting current Arden Syntax knowledge for an object oriented event monitor. AMIA Annu Symp Proc. 2003:814.

4. Johnson PD, Tu SW, Musen MA, Purves I. A virtual medical record for guideline-based decision support. AMIA Annu Symp Proc. 2001:294-8.

5. Huang C, Noirot LA, Heard KM, Reichley RM, Dunagan WC, Bailey TC. Implementation of virtual medical record object model for a standards-based clinical decision support rule engine. AMIA Annu Symp Proc. 2006:958.

6. Jenders RA, Dasgupta B. Challenges in implementing a knowledge editor for the Arden Syntax: knowledge base maintenance and standardization of database linkages. Proc AMIA Symp. 2002:355-9.

7. Boaz D, Shahar Y. A framework for distributed mediation of temporal-abstraction queries to clinical databases. Artif Intell Med. 2005 May;34(1):3-24.

8. Kolesa P, Spidlen J, Zvarova J. Obstacles to implementing an execution engine for clinical guidelines formalized in GLIF. Stud Health Technol Inform. 2005;116:563-8.

9. Sonnenberg FA, Hagerty CG. Computer-interpretable clinical practice guidelines. Where are we and where are we going? Yearb Med Inform. 2006:145-58.

10. Kawamoto K, Del Fiol G, Strasberg HR, Hulse N, Curtis C, Cimino JJ, et al. Multi-national, multi-institutional analysis of clinical decision support data needs to inform development of the HL7 Virtual Medical Record standard. AMIA Annu Symp Proc. 2010;2010:377-81.

11. Virtual medical record (vMR) for clinical decision support – domain analysis model, May 2010 ballot. Available from: http://www.hl7.org/v3ballot2010may/html/welcome/downloads/v3ballot_dam_vmr_2010MAY.zip.

12. HL7 implementation guide: Continuity of Care Document (CCD) release 1. Available from: http://www.hl7.org/documentcenter/private/standards/cda/igs/HL7_CCD_final.zip.

13. Meaningful Use. Available from: http://healthit.hhs.gov/portal/server.pt?open=512&objID=1325&parentname=CommunityPage&parentid=1&mode=2.

14. Dolin RH, Alschuler L, Boyer S, Beebe C, Behlen FM, Biron PV, et al. HL7 Clinical Document Architecture, Release 2. J Am Med Inform Assoc. 2006 Jan-Feb;13(1):30-9.

15. Middleton B. The clinical decision support consortium. Stud Health Technol Inform. 2009;150:26-30.

16. Socratic Grid project home page. Available from: http://socraticgrid.org/dashboard.action.

17. OpenCDS home page. Available from: http://www.opencds.org.

18. Siegel EL, Channin DS. Integrating the Healthcare Enterprise: a primer. Part 1. Introduction. Radiographics. 2001;21(5):1339-41.

19. Health Information Technology Standards Panel. Available from: http://www.hitsp.org/.

20. CDA Consolidation Project. Available from: http://jira.siframework.org/wiki/display/SIF/CDA+Consolidation+Project.

21. HL7 vMR Project CDS data needs analysis. Available from: http://wiki.hl7.org/index.php?title=Image:HL7vMR_Cross_Institutional_CDS_Data_Needs_Analysis_vFinal.zip.

22. HL7 Context-aware Information Retrieval (Infobutton) standard. Available from: http://www.hl7.org/v3ballot2010may/html/domains/uvds/uvds_Context-awareKnowledgeRetrieval(Infobutton).htm.

23. HL7 Clinical Document Architecture, Release 2.0. Available from: http://www.hl7.org/documentcenter/private/standards/cda/r2/cda_r2_normativewebedition2010.zip.

24. Component C32 - HITSP summary documents using HL7 Continuity of Care Document (CCD) component. Available from: http://www.hitsp.org/ConstructSet_Details.aspx?&PrefixAlpha=4&PrefixNumeric=32.

25. HL7 version 3 standard: Clinical Genomics; Pedigree, Release 1. Available from: http://www.hl7.org/v3ballot2009sep/html/domains/uvcg/uvcg_Pedigree.htm#POCG_DO000000UV-Pedigree-ic.

26. HL7 GreenCDA Project Wiki. Available from: http://wiki.hl7.org/index.php?title=GreenCDA_Project.