



NIST GCR 11-941

Continuity of Care (CCD) Suitability Analysis

Lantana Consulting Group

NIST GCR 11-941

Continuity of Care (CCD) Suitability Analysis

*Prepared for
National Institute of Standards and Technology
Gaithersburg Md 20899-8202*

By
Lantana Consulting Group

June 2011

U.S. Department of Commerce
John E. Bryson, Secretary

National Institute of Standards and Technology
Patrick D. Gallagher, Under Secretary for Standards and Technology and Director

This publication was produced as part of contract SB1341-10-CN-0085 with the National Institute of Standards and Technology. The contents of this publication do not necessarily reflect the views or policies of the National Institute of Standards and Technology or the US Government.



**Continuity of Care Document (CCD)
Suitability Analysis**

June 2011

**Prepared by Lantana Consulting Group
for
National Institute of Standards and Technology**

Lantana Consulting Group

PO Box 177

East Thetford, VT 05043

www.lantanagroup.com

Liora Alschuler

Chief Executive Officer

liora.alschuler@lantanagroup.com

Bob Dolin, MD, FACP

President and Chief Medical Officer

bob.dolin@lantanagroup.com

Rick Geimer

Chief Technology Officer

rick.geimer@lantanagroup.com

Lauren Wood, Ph.D.

Senior Project Manager

lauren.wood@lantanagroup.com

Gaye Dolin, RN, MSN

Senior Nurse Informaticist

gaye.dolin@lantanagroup.com

Jingdong Li, MD

Chief Architect

jingdong.li@lantanagroup.com

Yan Heras

Senior Medical Informaticist

yan.heras@lantanagroup.com

Bob Yench

Principal Consultant

bob.yench@lantanagroup.com

Kate Hamilton

Senior Information Analyst

kate.hamilton@lantanagroup.com

Susan Hardy

Senior Technical Editor

susan.hardy@lantanagroup.com

Acknowledgments

This analysis was produced and developed by Lantana Consulting Group for the National Institute of Standards and Technology (NIST) under contract number SB134110CN0085.

We appreciate the information and insights by several healthcare experts who answered our e-mail questionnaire or took part in phone interviews. To comply with regulations, fewer than 10 private-sector experts took part in discussions about each standard, although the total number of experts we talked to exceeded 10. They were Anthony LaRocca, Sage Software; Ben Hamlin, National Committee for Quality Assurance (NCQA); Dave Perry, Lovelace Clinic Foundation; David Dobbs, Science Applications International Corporation (SAIC)/Biosense; Carl Dvorak, Epic; George Cole, Allscripts; David Kibbe, American Academy of Family Physicians (AAFP); Austin Kreisler, SAIC; Mark Stine, Medplus; Paul Klinker, Harris; Dan Pollock, Center for Disease Control and Prevention (CDC); Rick Moore, NCQA; Tone Southerland, Greenway; Steve Waldren, AAFP; and Thanos Tsiolis, Epic.

Any mention of commercial products or organizations in this report is for information only; it does not imply recommendation or endorsement by Lantana or NIST.

Table of Contents

EXECUTIVE SUMMARY.....	6
INTRODUCTION.....	7
CCD Summary of Purpose.....	7
CCD and Meaningful Use.....	7
Additional Considerations.....	9
STAKEHOLDER INTERVIEWS.....	10
CCD SUITABILITY ANALYSIS.....	12
Is the standard based on a stable, well-vetted data model?.....	12
Does the standard have a clear, robust vocabulary binding syntax?.....	12
Does the standard support reusable modules, such as templates or data types?.....	13
Does the standard have a well-defined constraint mechanism?.....	13
Does the standard have a well-defined extensibility mechanism?.....	13
Are there unambiguous definitions of what is testable?.....	14
Are there automated test tools and test suites?.....	15
Are there reference implementations?.....	15
Is there documented existence of errors, including estimates of the severity?.....	16
Is there a defined and effective process for handling errors?.....	16
Do industry associations endorse the standard?.....	16
Has the standard been implemented by a range of vendors?.....	17
Is the standard used in more than one country?.....	17
Is certification available for developers and architects?.....	18
CCD SUITABILITY SUMMARY	19
MEANINGFUL USE ANALYSIS.....	20
Meaningful Use: Vocabulary Set.....	20
Meaningful Use: Core Set.....	20
Meaningful Use: Menu Set.....	22

CONCLUSIONS.....	24
REFERENCES.....	25
ACRONYMS AND ABBREVIATIONS.....	28

List of Figures

FIGURE 1: MEANINGFUL USE AND CCD	8
--	---

List of Tables

TABLE 1: CCD-SPECIFIC INTERVIEW QUESTIONS.....	10
TABLE 2: SELECTION OF COUNTRIES USING CDA OR CCD	17
TABLE 3: SELECTION OF COUNTRIES WITH CDA OR CCD EXPERIMENTAL PROJECTS.....	18
TABLE 4: CCD CRITERIA RESULTS MATRIX.....	19
TABLE 5: MEANINGFUL USE VOCABULARY SUPPORTED BY CCD.....	20
TABLE 6: MEANINGFUL USE CORE SET AND CCD SUPPORT.....	21
TABLE 7: MEANINGFUL USE MENU SET AND CCD SUPPORT	22

Executive Summary

This document analyzes the suitability of the Health Level Seven (HL7) Continuity of Care Document (CCD) specification to support the US Department of Health and Human Services' (HHS) Meaningful Use. It is part of the Healthcare Information Technology (HIT) Standards Analysis Project carried out by Lantana Consulting Group for The National Institute of Standards and Technology (NIST).

Lantana Group developed a general methodology to assess the suitability of a standard and has applied this methodology to CCD. This methodology is described in the “Healthcare Information Technology Standards: General Suitability Analysis” document, prepared for NIST under this contract.

We believe that CCD addresses its intended purpose to provide a snapshot in time of a patient's pertinent clinical, demographic, and administrative data. We believe CCD—with its underlying, stable HL7 Clinical Document Architecture (CDA) standard—supports the overall Meaningful Use goal of achieving significant improvements in care. We do identify improvements in testability and testing tools, error handling, and certification that can enhance the adoption of CCD. In addition, improved documentation will mitigate some of the problems presented by layered constraints, a problem that is not inherent to CCD but which has developed through the management of the standard across diverse organizations.

Introduction

This document presents an analysis of the suitability of the Health Level Seven (HL7) Continuity of Care Document (CCD) specification to support US Department of Health and Human Services' (HHS) Meaningful Use.¹ It is part of the Healthcare Information Technology (HIT) Standards Analysis Project carried out by Lantana Consulting Group for the National Institute of Standards and Technology (NIST). We assessed four standards for suitability: CCD, ASTM Continuity of Care Record (CCR), HL7 Quality Reporting Document Architecture (QRDA), and HL7 V2 Biosurveillance.

CCD² is an implementation guide as defined and developed by HL7. CCD uses the CCR standardized data set³ to constrain the HL7 Clinical Document Architecture Release 2 (CDA R2) standard for a patient summary document.

CDA and the data element modeling within CCD are based on the HL7 Reference Information Model (RIM) within the constraints of the CDA Refined Message Information Model (RMIM). CCD data elements reuse previously developed domain models and clinical statements also based on the RIM; many of these data elements and clinical statement models are now defined as reusable templates.

CCD Summary of Purpose

CCD provides a summary or snapshot of the status of a patient's health and healthcare in HL7 CDA format. The CCD implementation guide states that CCD inherits the goal of CCR, which is:

...to communicate the most relevant administrative, demographic, and clinical facts about a patient's healthcare, covering one or more healthcare encounters. It provides a means for one healthcare practitioner, system, or setting to aggregate all of the pertinent data about a patient and forward it to another practitioner, system, or setting to support continuity of care. The primary use case for the CCD is to provide a patient summary containing the pertinent clinical, demographic, and administrative data for a specific patient.

Based on this goal, the HHS Office of the National Coordinator (ONC) cites CCD as a means to achieve Meaningful Use.

CCD and Meaningful Use

¹ <http://healthit.hhs.gov/portal/server.pt?open=512&objID=2996&mode=2> (accessed March 2011)

² *HL7 Implementation Guide: CDA Release 2 – Continuity of Care Document (CCD)*, April 01, 2007 §; 1.1. Scope

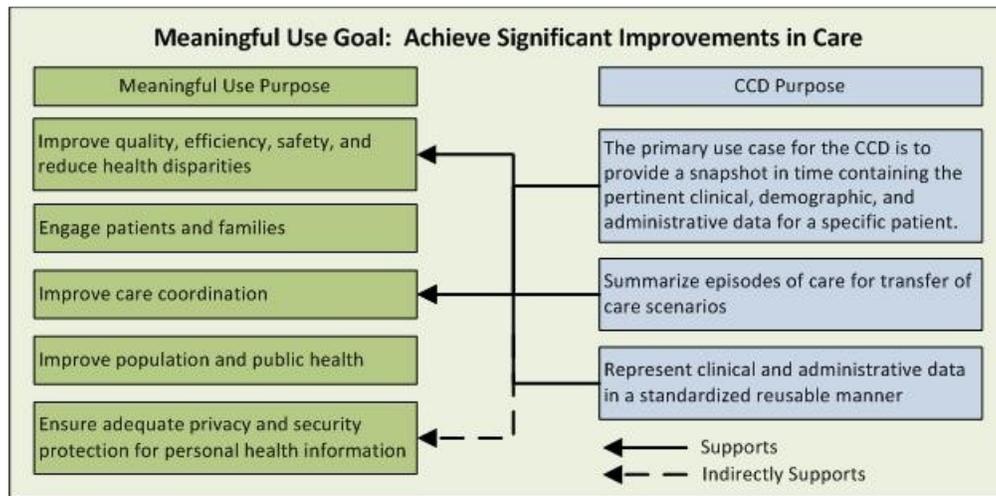
³ ASTM Standard E2369 - 05e1. *Standard Specification for Continuity of Care Record (CCR)*. DOI: 10.1520/E2369-05E01. 2005. <http://www.astm.org/Standards/E2369.htm>

The primary objective of Stage 1 Meaningful Use is to leverage technology to achieve significant improvements in patient care. Meaningful Use goals are to (1) improve quality, efficiency, and safety and reduce health disparities; (2) engage patients and families, (3) improve care coordination; (4) improve population and public health; and (5) ensure adequate privacy and security protections for personal health information.⁴ The [Meaningful Use and CCD](#) diagram illustrates the relationship of CCD's goals with those of Stage 1 Meaningful Use.

CCD supports the Meaningful Use goals of improving quality, efficiency, safety, and coordination and reducing health disparities (the first and third goals listed above) through exchange of reusable standardized templates for clinical, demographic, and administrative data. With standardized representation of these data elements, the receiving system can understand them without prior negotiation. Custom interfaces are not required and care providers have instant access to patient information from disparate systems. With instant access to pertinent patient data, providers can improve care quality and safety for everyone as well as equality in care for low-income patients who have no single source of medical care.⁵

CDA supports adequate privacy and security indirectly. It has a `confidentialityCode` element that can be leveraged by a properly designed and implemented privacy and security system.

Figure 1: Meaningful Use and CCD



⁴ Department of Health and Human Services. *Medicare and Medicaid Programs; Electronic Health Record Incentive Program; Final Rule – Stage 1 Meaningful Use Objectives*, 42 CFR Parts 412, 413, 422 et al. <http://edocket.access.gpo.gov/2010/pdf/2010-17207.pdf>

⁵Schwartz and Artiga. *Health Insurance Coverage and Access to Care for Low-Income Non-Citizen Adult*. <http://www.kff.org/uninsured/upload/7651.pdf>

Additional Considerations

We considered three external initiatives related to the CCD during analysis:

1. **Healthcare Information Technology Standards Panel *HITSP/C32 Summary Documents Using HL7 Continuity of Care Document (CCD) Component (July 2009)*.**⁶
The selection of CCD for exchanging clinical summaries in Meaningful Use is bound by the constraints and guidance in HITSP's C32 specification. C32 does not alter the fundamental function of CCD; it adds US-specific constraints to the exchange of summary documents. In other words, C32 constrains CCD just as CCD constrains CDA. C32 also requires many of the IHE constraints described below.
2. **Integrating the Healthcare Environment (IHE).** The IHE Patient Care Committee (PCC) developed the PCC Technical Framework⁷, and created three integration profiles⁸. One of these profiles—the Medical Summary Document—identifies the functional components of a distributed healthcare environment and defines a coordinated set of transactions for the exchange of CCD/CDA. It is an implementation framework for CCD and not a standard, but it does constrain CCD. As noted above, C32 requires compliance with many of the Medical Summary Document constraints.
3. **The CDA Consolidation Project.** This joint HL7/IHE/Health Story⁹ project was launched in December 2010 with support from the ONC as a Standards and Interoperability Framework Initiative¹⁰. It is a US-realm reconciliation of differences across several CDA-based implementation guides and profiles—including CCD—developed by HL7, IHE, and the Health Story Project. It will enhance CCD's suitability by harmonizing templates, removing discrepancies, and developing simpler, easier-to-use documentation. The result will improve semantic interoperability in healthcare data exchanges.

⁶ <http://www.hitsp.org/Handlers/HitspFileServer.aspx?FileGuid=e1b99525-a1a5-48f6-a958-4b2fc6d7a5c7>

⁷ IHE Technical Framework: http://www.ihe.net/Technical_Framework/index.cfm#pcc

⁸ *IHE Patient Care Coordination (PCC) Technical Framework Volume 2 Revision 6.0*, August 2010.
http://www.ihe.net/Technical_Framework/upload/IHE_PCC_TF_Rev6-0_Vol_2_2010-08-30.pdf

⁹ <http://healthstory.com/>

¹⁰ The S&I Framework Initiative: CDA Consolidation Project.
<http://jira.siframework.org/wiki/display/SIF/CDA+Consolidation+Project>

Stakeholder Interviews

The “Healthcare Information Technology Standards: General Suitability Analysis”¹¹ describes the interviews we held with experts in HIT standards development, quality reporting, and standards implementation to evaluate the maturity, robustness, and suitability of CCD.

We asked the following questions specific to CCD during these stakeholder interviews.

Table 1: CCD-Specific Interview Questions

Question block ID	Interview Questions
CCD	<ul style="list-style-type: none"> • Please briefly describe your experience with CCD to help us understand the basis for your answers to the following questions. • The primary purpose of CCD is to transmit summary data; how well is CCD meeting its primary purpose? • Are there errors or ambiguities in CCD that mean it’s harder than it should be to implement and use? Do you have examples? • Consider the primary purpose of CCD: <ul style="list-style-type: none"> ○ What are some measurable criteria that should be assessed to ensure it is meeting this purpose? ○ In what ways does it not meet its purpose? ○ What makes CCD testable? • Where is “suitability” or “fitness for purpose” lacking or present in CCD? For instance, here are some potential areas: <ul style="list-style-type: none"> ○ Narrative Interoperability or immediate, accurate rendering in a receiving system ○ Data reconciliation ○ Data reuse ○ Third party aggregation of data (e.g. ability for disparate systems to send uniform data to a central repository) ○ Others? • Please discuss the one feature about CCD that most supports the Meaningful Use ultimate goal of achieving significant improvements in health care.

The interviews included senior developers experienced with the CCD standard and its implementation. They provided excellent insights into CCD and its use in a range of clinical data exchanges.

Although we were asking about CCD, the HITSP/C32 specification is foremost in the minds of stakeholders because Meaningful Use mandates its use. Many interviewees mentioned the

¹¹ Lantana Consulting Group. Healthcare Information Technology Standards: General Suitability Analysis, May 2011. Related document prepared for NIST.

difficulty of dealing with the constraints layered upon CCD through HITSP/C32 and IHE PCC. This layering of constraints is not inherent to CCD itself, but it is confusing and a barrier to adoption of the full C32 specification for Meaningful Use. At the same time, interviewees appreciated the specificity provided by C32 for the US realm.

Another general theme was the appreciation of CCD as part of a “family” of clinical document standards that are derived from a common set of concepts and reusable templates. Once implementers learn CDA, they know how to implement the related standards with only incremental effort. This reliance on a foundational architecture is a major “win” within the implementation community.

CCD Suitability Analysis

This section applies the questions defined in the “Healthcare Information Technology Standards: General Suitability Analysis” to CCD.

Is the standard based on a stable, well-vetted data model?

The CCD is an implementation of CDA R2, an American National Standards Institute (ANSI) approved standard since May 2005. CDA R2 has been widely implemented internationally, and HITSP selected it as a foundational standard. There are numerous HL7 implementation guides and IHE profiles that define the use of CDA in healthcare exchange scenarios.

Following HL7 practice, the CCD is defined in an implementation guide that declares constraints on the CDA base standard for summary reports. Like all CDA documents, CCD documents derive their machine processable meaning from the HL7 Reference Information Model (RIM) and use the HL7 Version 3 Data Types. The RIM was developed in a collaborative process engaging a broad range of experts, both clinical and technical within HL7. The RIM is a robust, implementable standard (as demonstrated by the many implementation guides and profiles), and it is applicable to a large number of clinical data exchange use cases within the healthcare domain. The RIM has demonstrated stability over other models by virtue of its longevity (approximately 15 years) and ongoing maintenance and evolution.¹² The RIM and HL7 Version 3 foundation components, such as data types and vocabulary, are documented in a clear and understandable way that passes muster with the group of experts that reviewed it.

Given the global adoption by vendors and healthcare providers of both the RIM and CDA, we conclude that the CCD is based on a stable, well-vetted data model.

Does the standard have a clear, robust vocabulary binding syntax?

Vocabulary binding is essential to a standard's success. The correct interpretation of an exchanged message relies upon correct message syntax and correct data semantics. While syntactic correctness is defined by the standard format, semantics are defined by vocabulary binding. Clear, robust vocabulary binding defines unambiguous links between a data field and medical vocabulary systems. A data field can be valued only with one specific code or one selected from a “value set” of codes in the specified vocabulary system.

CCD has a clear, robust vocabulary binding syntax as it uses HL7 vocabulary binding syntax and the HL7 RIM. The HL7 RIM is more expressive than other current and emerging models with respect to semantics and vocabulary critical to healthcare interoperability. The vocabulary binding syntax defined by the HL7 Vocabulary Work Group has been extensively reviewed and improved through numerous rounds of balloting, and is in wide use in the HL7 RIM and CDA implementations throughout the world, including CCD.

¹² *CBIT SAIF Implementation Guide*, March 30, 2011.

<https://wiki.nci.nih.gov/display/SAIF/CBIT+SAIF+Implementation+Guide>

Does the standard support reusable modules, such as templates or data types?

The CCD implementation guide was the prototype implementation of a concept called Templated CDA. This concept defines sets of uniquely identified conformance statements that can apply to a document, a section, or a clinical statement. Section and clinical statement templates by their nature are reusable; multiple documents can reuse section templates and multiple sections can reuse clinical statement templates. Once someone can understand and support a given template, they can understand and process that template no matter where they encounter it.

As vendors of electronic health records (EHR) become familiar with structured documents and the CCD as part of the ONC certification process, they can reuse CDA and CCD templates for rapid implementation of solutions to exchange clinical information with consistent representation.

Does the standard have a well-defined constraint mechanism?

The HL7 V3 standard has a well-defined constraint mechanism to be applied to the RIM, data types, and vocabulary supported by CDA, and thus by the CCD. This constraint mechanism provides the International Committee a clear set of rules for producing local variants on the HL7 V3 standard. This meets realm-specific localization requirements but preserves the global applicability of the V3 standard.¹³

The CCD is a US realm implementation guide based on the CDA R2 base standard and was developed following the HL7 V3 standard constraint mechanism. CCD meets the needs of patient summary documents requirements in the US while allowing for localization and preserving the global applicability of the V3 standard.

Does the standard have a well-defined extensibility mechanism?

The CCD is derived from the base CDA R2 standard, which has a well-defined extensibility mechanism. As clearly stated in the CDA standard, it is permissible to use namespace extensions to include additional XML elements and attributes that are not included in the CDA schema. These extensions cannot change the meaning of any of the standardized data elements, and document recipients must be able to render the CDA document faithfully while ignoring extensions.¹⁴

For vocabulary binding to a domain, the HL7 V3 standard allows an extensibility qualifier to be associated with the coded entry. The extensibility qualifier has two possible values: CNE (coded no extensions), and CWE (coded with extensions). The CWE extensibility qualifier expands the code set to meet local implementation needs: when a coded attribute is sent in a message, local concepts or free text may be sent in place of a standard code if the desired concept is not represented in the standard vocabulary domain.

An additional extensibility feature of the CDA standard is the inclusion of generic classes such as act and participant. The act class can be used if no more specific class is available for the use case. “Teach cast care” is an example. While “teach cast care” is defined in some code systems

¹³ HL7 International Localization Report. <http://www.docstoc.com/docs/57624000/HL7-V3-Localization>

¹⁴ *CDA Normative Web Edition*, § 1.4 CDA Extensibility. http://www.hl7.org/documentcenter/private/standards/cda/r2/cda_r2_normativewebedition.zip

as a procedure, it does not fit the HL7 definition of procedure: “an Act whose immediate and primary outcome (post-condition) is the alteration of the physical condition of the subject”,¹⁵ nor is teaching an observation. The act class can represent this in CDA such that is semantically interpretable across systems. The generic participant can represent any participants not explicitly mentioned by other classes that were involved with the patient or the situation being documented. For example, there is no “Next of Kin” participant, but the generic participant can use standard modeling and codes to represent detailed information about such a participant.

These namespace extensions, code extensibility qualifiers, and generic classes provide much flexibility in the standard until the use case is brought to the HL7 and incorporated into a future release if appropriate. These well-documented extensibility mechanisms support unanticipated use cases as well as local exchange requirements.

Are there unambiguous definitions of what is testable?

The methods for declaring conformance to the CCD and the obligations of the instance creator and receiver are stated within the CCD implementation guide¹⁶ and the base CDA R2 specification. The implementation guide explains the use of conformance statements.

Conformance statements are constructed from common language statements and keywords adopted across the HL7 community to ensure semantic interoperability across standards and wire formats. These statements provide detailed guidance for the coding and information content of a given template.

The CCD was one of the earliest guides (2007) to use these techniques; it is in the midst of a revision to harmonize the format and intent of the conformance statements. Some of the current statements are not enforceable by a machine-based validation approach; they require a juried review or are more appropriately included as guidance. The ONC’s Standards and Interoperability (S&I) CDA Consolidation project¹⁷ will further clarify and document those conformance statements that are fully machine testable; those that require human intervention; and those that cannot be evaluated by a machine-driven process. The project will provide the desired crisp definitions (with examples) for each of these categories.

The “CCD Coverage Report”¹⁸, also prepared by Lantana for NIST, analyzes the CCD specification from the perspective of validation, looking at the limits of automated testing and assessing various approaches to it. The conclusions and recommendations in that report provide valuable information to develop strategies that will improve testability of CCD and other CDA standards.

¹⁵ HL7 V3 RIM Definitions <http://www.hl7.org/v3ballot/html/welcome/environment/index.html> Normative Vocabulary for the RIM, actClass, Procedure (PROC). Note: Access Requires download of the V3 Ballot

¹⁶ *HL7 Implementation Guide: CDA Release 2 – Continuity of Care Document (CCD)*, §1.4 Asserting Conformance to this Guide

¹⁷ <http://jira.siframework.org/wiki/display/SIF/CDA+Consolidation+Project>

¹⁸ Lantana Consulting Group. CCD Coverage Report, May 2011. Related document prepared for NIST.

Are there automated test tools and test suites?

CCD is supported by a number of testing venues (Certification Commission for Health Information Technology [CCHIT]¹⁹, Project Laika²⁰, Lantana Consulting Group²¹, NIST²²) that provide a range of interfaces for developers to validate CCD and other CDA document instances. These venues offer both interactive web pages for manual submission of an instance and web services interfaces for programmatic access.

The most common means to date for the automated testing of CCD instances is through the use of the International Organization for Standardization (ISO) Schematron. This method was first used for CDA instances in an application developed in 2006 by Alschuler Associates, LLC (now Lantana Consulting Group) in response to a request from the Electronic Health Record Vendors Association (EHRVA, now the EHRA).

NIST has further refined and expanded this schematron approach to support implementation testing in support of HITSP's selection of CDA and CDA-based implementation guides. Today, the NIST validation suite is the "gold standard" used by the implementation community, despite the lack of a governance process to vet all rules and resulting validation tests for completeness and accuracy. This "not for production use" is clearly identified on the NIST and other organizations' web pages.

There is no detailed peer review of the Schematron statements used to enforce the concepts of a conformance statement. Detailed peer review of Schematron statements would improve accuracy of these valuable tools.

Additionally, the CDA Consolidation project has an ancillary goal of creating a new, model-driven approach to testing. While this technique holds promise, it has yet to be proven and widely implemented. See the "CCD Coverage Report" for a full review of CCD test options.²³

Are there reference implementations?

To date, reference implementations have not been developed concurrently with the development of CDA based standards. Pilots may be planned and identified when the scope of the standard is defined and approved; however, they may be in proprietary systems and thus are not publicly available. There is currently no publicly available reference implementation of a CDA/CCD in an EHR.

We believe, however, that the existing proprietary implementations coupled with the current industry demonstration projects and certification processes serve as hardy evidence of implementations of CCD that could be used as reference for implementers should they become accessible.

¹⁹ Certification Commission for Health Information Technology: <http://www.cchit.org/>

²⁰ Project Laika: <http://laika.sourceforge.net/>

²¹ Lantana Consulting Group Validator: <https://www.lantanagroup.com/validator/>

²² National Institute for Standards and Technology Validator: <http://xreg2.nist.gov/cda-validation/validation.html>

²³ Lantana Consulting Group. CCD Coverage Report, May 2011. Related document prepared for NIST.

Is there documented existence of errors, including estimates of the severity?

HL7 has a well-defined error reporting process. The organizations that contributed to C32 host different processes.

HITSP Public Comment tracking system captures issues related to all HITSP artifacts. It reports issues that relate to the C32 and CCD as well as other CDA-based profiles selected by HITSP (QRDA, etc.).

The HL7 Structured Documents Working Group has maintenance responsibility for the CCD implementation guide and maintains a publicly accessible CCD errata wiki²⁴.

Both HL7 and IHE host mailing lists where suspected errors and proposed solutions can be discussed.

IHE captures Change Proposals for IHE specifications that are evaluated by their technical communities.

Errors on the lists mentioned above that cannot be resolved are recorded either on the HL7 wiki or in the IHE change control process.

Is there a defined and effective process for handling errors?

The CDA Consolidation project is addressing many of the issues recorded through forums described in the previous section, focusing first on those items that will affect the support of Meaningful Use.

The HL7 processes deal with CCD and CDA and are well-defined. C32 and ONC resolution processes have not yet been fully defined. The multi-organization CDA Consolidation project may set a precedent for cross-organization collaboration in development of a formal process for error handling and maintenance, however, this is yet to be confirmed.

Do industry associations endorse the standard?

The CDA and CCD have been endorsed and adopted by many industry associations. The following are a selection of organizations known to endorse and/or implement CDA:

ONC HHS via the Meaningful Use Final Rule

EHRA

Health Story Project

HITSP

²⁴ HL7 Wiki CCD Errata page. http://wiki.hl7.org/index.php?title=CCD_Errata

Has the standard been implemented by a range of vendors?

As demonstrated at the HIMSS Interoperability Showcase over the past five years, all major vendors have implemented the CDA and CCD standards. Many medium and small vendors are now implementing CDA and CCD to prepare for Meaningful Use certification. The ONC-certified Health IT Product List site provides a list of vendors that can create and/or display CCDs²⁵.

Is the standard used in more than one country?

CCD was developed to meet the needs of the US realm, but CCD or its base standard CDA has also been cited as the basis for the exchange of clinical data in a number of countries. The next two tables list some of the countries with existing or experimental CDA or CCD projects. A Google map, “Where in the World is CDA and XDS”²⁶, shows some of the CDA implementations around the world.

Table 2: Selection of Countries Using CDA or CCD

Country	Organization or Product
Germany	SCIPHOX
Finland	Aluetietojärjestelmä
Greece	HYGEIAnet/WebOnColl
Japan	MERIT-9 (MML)
Canada	e-MS
France	Dossier Médical Personnel
Italy	TeleMed Escape
Argentina	Hosp. Italiano de Buenos Aires
England	National Program for HIT
Turkey	Ministry of Health - Saglik-Net network

²⁵ <http://onc-chpl.force.com/ehrcert/ehrproductcriteriasearch>. Click on “Inpatient Practice Type” or “Ambulatory Practice Type”. Click on “Search by Criteria Met”. Scroll down and select “) Exchange clinical information and patient summary record”. Click on “Search Matching Products”. Scroll down to view results.

²⁶ <http://www.google.com/maps/ms?ie=UTF8&oe=UTF8&source=embed&msa=0&msid=110535847732151766411.00047b0b46314e91435c9>

Table 3: Selection of Countries with CDA or CCD Experimental Projects

Country	Organization or Product
Korea	Kyungpook National University
Israel	IBM Haifa Research Lab
New Zealand	GP2GP Patient Records Transfer
Australia	The Royal Marsden NHS
Wales	Wales' National Architecture Design Board
Switzerland	IHE Suisse' initiative

Is certification available for developers and architects?

While not focused narrowly on the CCD itself, HL7 offers certification in CDA through a testing process. The certification makes no distinction among different roles within an implementing organization.

HL7 provides training for CDA at its worldwide working group meetings and educational summits; these are primarily one-to-two day lecture-based classes aimed at a high level understanding of CDA.

The CDA Academy²⁷ offers hands-on, weeklong training in the US.

²⁷<http://www.cdaacademy.com>

CCD Suitability Summary

The following matrix summarizes the results of applying suitability criteria to the CCD standard. All findings were positive with caveats in testability, test tools, C32 error handling, and certification.

Table 4: CCD Criteria Results Matrix

Criteria	Results	Notes
Is the standard based on a stable, well-vetted data model?	Yes	
Does the standard have a clear, robust vocabulary binding syntax?	Yes	
Does the standard support reusable modules, such as templates or data types?	Yes	
Does the standard have a well-defined constraint mechanism?	Yes	
Does the standard have a well-defined extensibility mechanism?	Yes	
Are there unambiguous definitions of what is testable?	Yes	Improvement is needed in the creation of testable conformance statements. Current projects are working to further clarify and document what is fully machine testable.
Are there automated test tools and test suites?	Yes	Schematron rules underlying these test tools need public vetting for accuracy.
Are there reference implementations?	No	Existing implementations coupled with the current industry demonstration projects and certification processes could serve as references for CCD implementers
Is there documented existence of errors, including estimates of the severity?	Yes	
Is there a defined and effective process for handling errors?	Yes	HL7 has a well-defined process. The error-handling process for C32 was defined by HITSP but has not been maintained by the current ONC.
Do industry associations endorse the standard?	Yes	
Has the standard been implemented by a range of vendors?	Yes	
Is the standard used in more than one country?	Yes	
Is certification available for developers and architects?	Partial	There is certification for CDA, but not for CCD specifically. Training should be available at multiple levels. There should be distinct certification for developers vs. architects.

Meaningful Use Analysis

Here we evaluate CCD based on specific Stage 1 Meaningful Use criteria.

Meaningful Use: Vocabulary Set

CCD specifies coding systems in some instances and recommends optional coding systems in others. Users can also use plain text. Meaningful Use requires use of the coding systems listed in the table below²⁸. The table compares vocabulary requirements for CCD and Meaningful Use.

Table 5: Meaningful Use Vocabulary Supported by CCD

Item	Vocabulary	Supported by CCD?
Problem List	ICD9-CM, SNOMED CT	Yes
Procedures	CPT-4, ICD-9-CM: Procedures, HCPCS	SNOMED CT, LOINC (preferred); CPT (allowed)
Labs	LOINC	Yes
Medications	RxNorm	Yes
Immunizations	HL7 CVX - Vaccines Administered	Yes
RACE/Ethnicity	The Office of Management and Budget Standards for Maintaining, Collecting, and Presenting Federal Data on Race and Ethnicity, Statistical Policy Directive No. 15, October 30, 1997	Yes

Meaningful Use: Core Set

Every certified EHR system must provide a Core Set of functionality. Stage 1 Meaningful Use provides no guidance as to how the Core Set criteria are to be supported, so flexibility is allowed in Stage 1. The table below shows the Core Set criteria and whether CCD can meet the criteria or provide or receive information in support of the EHR function

²⁸ Department of Health and Human Services, 45 CFR Parts 160 and 162, *Health Insurance Reform Standards for Electronic Transactions*. <http://edocket.access.gpo.gov/2010/pdf/2010-17210.pdf>

Table 6: Meaningful Use Core Set and CCD Support

Core Set Criteria	Supported by CCD?
Record patient demographics (preferred language, insurance type, gender, race and ethnicity, date of birth, and date and cause of death in the event of mortality.)	Yes, supported per C32 guidance
Record vital signs and chart changes (height, weight and blood pressure and calculate and display body mass index (BMI) for ages 2 and over; plot and display growth charts for children 2–20 years, including BMI.)	Yes, supported per C32 guidance
Maintain up-to-date problem list of current and active diagnoses. Maintain an active medication list. Maintain an active medication allergy list. Record smoking status for patients 13 and older.	Yes, supported per C32 guidance
Provide patients with clinical summaries for each office visit: clinical summary is an after-visit summary that provides a patient with relevant and actionable information and instructions containing, but not limited to, the patient name, provider’s office contact information, date and location of visit, an updated medication list and summary of current medications, updated vitals, reason(s) for visit, procedures and other instructions based on clinical discussions that took place during the office visit, any updates to a problem list, immunizations or medications administered during visit, summary of topics covered/considered during visit, time and location of next appointment/ testing if scheduled, or a recommended appointment time if not scheduled, list of other appointments and testing patient needs to schedule with contact information, recommended patient decision aids, laboratory and other diagnostic test orders, test/laboratory results (if received before 24 hours after visit), and symptoms.	Yes, supported per C32 guidance
Hospitals must provide patients with an electronic copy of their discharge instructions at time of discharge, upon request.	Not applicable. A CCD is not a discharge summary, but applicable CCD entry templates could be used with a discharge summary.
Provide patients with an electronic copy of their health information (including diagnostics test results, problem list, medication lists, medication allergies) upon request.	Yes, supported per C32 guidance
Generate and transmit permissible prescriptions electronically (does not apply to hospitals).	Yes, supported per C32 guidance
Computerized Provider Order Entry for Medication Orders.	Not applicable
Implement drug-drug and drug-allergy interaction checks. Functionality must be enabled for these checks for the entire reporting period.	This functionality is supported by CCD when Level 3 coding is available
Implement capability to electronically exchange key clinical information among providers and patient-authorized entities. Must perform at least one test of the EHR’s capacity to electronically exchange information.	Yes
Implement one clinical decision support rule and track compliance with that rule. One rule must be implemented.	Yes, supported by CCD when Level 3 coding is available

Core Set Criteria	Supported by CCD?
Protect electronic health information created or maintained by the certified EHR technology through the implementation of appropriate technical capabilities. Conduct or review a security risk analysis in accordance with the requirements under 45 CFR 164.308(a)(1) and implement security updates as necessary and correct identified security deficiencies as part of its risk management process.	Not applicable
Report clinical quality measures to Centers for Medicare and Medicaid Services (CMS) or states. For 2011, provide aggregate numerator and denominator through attestation. For 2012, electronically submit measures.	Yes, supported by CCD when Level 3 coding is available

Meaningful Use: Menu Set

The Meaningful Use Menu Set lists additional criteria for certified EHR systems. These systems must provide a specified percentage of the functionality listed in the Menu Set (see the table below). The current expectation is that Stage 2 Meaningful Use will require certified systems to have all of the items in the Menu Set.

The table below shows whether CCD could meet the Menu Set criteria or provide or receive information in support of the EHR function.

Table 7: Meaningful Use Menu Set and CCD Support

Menu Set Criteria	Supported by CCD?
Implement drug formulary checks. Drug formulary check system must be implemented and access at least one internal or external drug formulary during the reporting period.	Yes, supported by CCD when Level 3 coding is available
Incorporate clinical laboratory test results into EHRs as structured data.	Yes, supported by CCD when Level 3 coding is available
Generate lists of patients by specific conditions for use for quality improvement, reduction of disparities, research or outreach.	Yes, supported by CCD when Level 3 coding is available
Use EHR technology to identify patient-specific education resources and provide those to the patient as appropriate.	Not applicable
Perform Medication reconciliation between care settings.	Yes, supported by CCD when Level 3 coding is available
Provide summary of care record for patients referred or transitioned to another provider or setting. Transition of care means the movement of a patient from one setting of care (hospital, ambulatory primary care practice, ambulatory, specialty care practice, long-term care, home health, rehabilitation facility) to another.	Yes

Menu Set Criteria	Supported by CCD?
Submission of electronic immunization data to immunization registries or immunization information systems.	Yes
Submission of electronic syndromic surveillance data to public health agencies.	Yes, supported by CCD when Level 3 coding is available
For hospitals - record advanced directives for patients 65 years or older.	Yes, supported by CCD when Level 3 coding is available
For hospitals - submission of electronic data on reportable laboratory results to public health agencies.	Not applicable
For professionals - Send reminders to patients (per patient preference) for preventative and follow-up care.	Not applicable
For professionals - Provide patients with an electronic copy of their health information (including diagnostics test results, problem list, medication lists, medication allergies) upon request.	Yes

Conclusions

CCD's purpose is to provide a snapshot in time of the pertinent clinical, demographic, and administrative summary data for a specific patient. Unambiguous communication of summary data is achieved through the use of a stable well-vetted data model coupled with a formal vocabulary binding syntax. Data elements are modeled as templates, which are modular reusable constraints applied against the base CDA model. CDA templates are computable artifacts, from which schematron validation rules can be generated. As a result, CCD instances can be tested not only for conformance to the base CDA standard, but also for conformance against the invoked templates. CCD has been widely adopted, and is widely supported across the United States. The base CDA standard is widely used across the globe.

We identified areas in which CCD can be improved to further ease its adoption for Meaningful Use; these are testability, testing and validation, error handling for C32, certification, and documentation. Testability will be improved as model-driven CDA development techniques such as those described in “Templated CDA: Key Concept for Interoperability,”²⁹ evolve. Model-driven development will improve our ability to generate schematron and other testing and validation artefacts. Improved error handling processes for C32 will help ensure that errors are corrected at the source, such that revisions cascade to all down-stream artefacts. Certifying individuals not only in CDA, but also in CCD, will improve the consistency of technical implementations. Improved documentation, particularly the creation of an implementation guide that flattens the multiple layers of indirection across multiple documents, can dramatically lower the learning curve. The accompanying “CCD Standards Action Plan”³⁰ provides our recommendations in each of these areas.

We conclude that CCD fulfills its intended purpose, and that it can be improved. It also supports a broader set of requirements because it is built upon the base standard, the CDA. CCD supports the Meaningful Use goal of achieving significant improvements in care.

²⁹ Lantana Consulting Group. Templated CDA: Key Concept for Interoperability, May 2011. Related document prepared for NIST.

³⁰ Lantana Consulting Group. CCD Standards Action Plan, June 2011. Related document prepared for NIST.

References

ASTM Standard E2369 - 05e1. *Standard Specification for Continuity of Care Record (CCR)*. DOI: 10.1520/E2369-05E01. 2005. <http://www.astm.org/Standards/E2369.htm>

CBIIT SAIF Implementation Guide, March 30, 2011.
<https://wiki.nci.nih.gov/display/SAIF/CBIIT+SAIF+Implementation+Guide>

CDA Consolidation Project.
<http://jira.siframework.org/wiki/display/SIF/CDA+Consolidation+Project>

CDA Normative Web Edition. § 1.4 CDA Extensibility.
http://www.hl7.org/documentcenter/private/standards/cda/r2/cda_r2_normativewebedition.zip

Curran, Patrick. *Conformance Testing An Industry Perspective*, Sun Microsystems. 2003.
Available from: <http://www.nist.gov/itl/vote/upload/6-Curran.pdf>

Department of Health and Human Services, *Health Insurance Reform: Standards for Electronic Transactions*. 45 CFR Parts 160 and 162.

Department of Health and Human Services. *Health Information Technology: Initial Set of Standards, Implementation Specifications, and Certification Criteria for Electronic Health Record Technology; Final Rule*, 45 CFR Part 170. <http://edocket.access.gpo.gov/2010/pdf/2010-17210.pdf>

Department of Health and Human Services. *Medicare and Medicaid Programs; Electronic Health Record Incentive Program; Final rule – Stage 1 Meaningful Use Objectives*, 42 CFR Parts 412, 413, 422 et al. <http://edocket.access.gpo.gov/2010/pdf/2010-17207.pdf>

Department of Health and Human Services. *Electronic Health Records and Meaningful Use* (web site). <http://healthit.hhs.gov/portal/server.pt?open=512&objID=2996&mode=2>

Dolin RH, Alschuler L, Boyer S, Beebe C, Behlen FM, Biron PV, Shabo A, (Editors). *HL7 Clinical Document Architecture, Release 2.0. ANSI-approved HL7 Standard*; May 2005. Ann Arbor, Mich.: Health Level Seven, Inc. Available through HL7 <http://www.hl7.org> or if an HL7 member with the following link:
http://www.hl7.org/documentcenter/private/standards/cda/r2/cda_r2_normativewebedition.zip

Dolin RH, Alschuler L, Boyer S, Beebe C, Behlen FM, Biron PV, Shabo A., HL7 Clinical Document Architecture, Release 2. *J Am Med Inform Assoc*. 2006;13:3039. Available at: <http://www.jamia.org/cgi/reprint/13/1/30>.

Extensible Markup Language. www.w3.org/XML.

HITSP/C32 Summary Documents Using HL7 Continuity of Care Document (CCD Component, Version 2.5, July 2009. <http://www.hitsp.org/Handlers/HitspFileServer.aspx?FileGuid=e1b99525-a1a5-48f6-a958-4b2fc6d7a5c7>

HL7 Implementation Guide for CDA Release 2 CDA for Public Health Case Reports (PHCR) Informative Standard, October 2009. Available through HL7: <http://www.hl7.org>

HL7 Implementation Guide for CDA Release 2 Quality Reporting Document Architecture (QRDA) Draft Standard for Trial Use, March 2009. Available at:
http://www.hl7.org/documentcenter/ballots/2008sep/downloads/CDAR2_ORDA_R1_DSTU_2009APR.zip

HL7 Implementation Guide for CDA Release 2: NHSN Healthcare Associated Infection (HAI) Reports, Release 2 Draft Standard for Trial Use, January 2009. Available at:
http://www.hl7.org/documentcenter/ballots/2009JAN/downloads/CDAR2L3_IG_HAIRPT_R2_DSTU_2009MAR.zip

HL7 Implementation Guide: CDA Release 2 – Continuity of Care Document (CCD): A CDA implementation of ASTM E2369-05 Standard Specification for Continuity of Care Record© (CCR) April 01, 2007 available through HL7: <http://www.hl7.org>

HL7 International Localization Report: Report from the International Task Force Committee.
<http://www.docstoc.com/docs/57624000/HL7-V3-Localization>

IHE Patient Care Coordination (PCC) Technical Framework Volume 2 Revision 6.0, August 2010. http://www.ihe.net/Technical_Framework/upload/IHE_PCC_TF_Rev6-0_Vol_2_2010-08-30.pdf

IHE Technical Framework: http://www.ihe.net/Technical_Framework/index.cfm#pcc

Lantana Consulting Group. CCD Standards Action Plan, June 2011. Related document prepared for NIST.

Lantana Consulting Group. CCD Coverage Report, May 2011. Related document prepared for NIST.

Lantana Consulting Group. Healthcare Information Technology Standards: General Suitability Analysis, May 2011. Related document prepared for NIST.

Lantana Consulting Group. Templated CDA: Key Concept for Interoperability, May 2011. Related document prepared for NIST.

LOINC®: Logical Observation Identifiers Names and Codes, Regenstrief Institute.
<http://www.regenstrief.org/loinc>

Office of the National Coordinator for Health Information Technology. Certified Health IT Product List. <http://onc-chpl.force.com/ehrcert/ehrproductcriteriasearch>

Schwartz, K and Artiga, A. *Health Insurance Coverage and Access to Care for Low-Income Non-Citizen Adult*. <http://www.kff.org/uninsured/upload/7651.pdf>

SNOMED CT®: SNOMED Clinical Terms SNOMED International Organization.
<http://www.ihtsdo.org/>

The Health Story Project: Our Vision: Comprehensive electronic clinical records that tell a patient's complete health story. <http://healthstory.com/>

The S&I Framework Initiative: CDA Consolidation Project.
<http://jira.siframework.org/wiki/display/SIF/CDA+Consolidation+Project>

Using SNOMED CT in HL7 Version 3; Implementation Guide, Release 1.5. Available through HL7 <http://www.hl7.org> or if an HL7 member with the following link:
<http://www.hl7.org/v3ballot/html/infrastructure/terminfo/terminfo.htm>

Where in the World is XDS and CDA. <http://www.google.com/maps/ms?ie=UTF8&oe=UTF8&source=embed&msa=0&msid=110535847732151766411.00047b0b46314e91435c9>

Acronyms and Abbreviations

AAFP	American Academy of Family Physicians
ANSI	American National Standards Institute
ASTM	originally American Society for Testing and Materials
CBIIT	Center for Bioinformatics and Information Technology
CCD	Continuity of Care Document
CCHIT	Certification Commission for Health Information Technology
CCR	Continuity of Care Record
CDA	Clinical Document Architecture
CDC	Center for Disease Control and Prevention
CMS	Centers for Medicare and Medicaid Services
CNE	Coded No Exceptions
CWE	Coded With Exceptions
EHR	Electronic Health Records
EHRA	Electronic Health Records Association
FR	Final Rule
HHS	US Department of Health and Human Services
HIMSS	Healthcare Information and Management Systems Society
HIT	Healthcare Information Technology
HITSP	Healthcare Information Technology Standards Panel
HL7	Health Level Seven
IG	implementation guide
IHE	Integrating the Healthcare Environment
IHE PCC	Integrating the Healthcare Environment – Patient Care Committee
ISO	International Organization for Standardization
IT	Information Technology
NCQA	National Committee for Quality Assurance
NIST	National Institute of Standards and Technology
ONC	The Office of the National Coordinator

QRDA Quality Reporting Document Architecture
R2 Release 2
RIM Reference Information Model
S&I Standards and Interoperability
SAIC Science Applications International Corporation
SAIF Service-Aware Interoperability Framework (SAIF)