



NIST GCR 11-936

CCR Suitability Analysis

Lantana Consulting Group

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

By
Lantana Consulting Group

May 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-SE-0881 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.



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Acknowledgments

This analysis was produced and developed by Lantana Consulting Group for the National Institute of Standards and Technology (NIST), under contract number SB134110SE0881.

We appreciate the information and insights by several healthcare experts who answered our e-mail questionnaire or took part in phone interviews. Those who participated in the Continuity of Care Record (CCR) phone interviews were Anthony LaRocca, Sage Software; Ben Hamlin, National Committee for Quality Assurance (NCQA); David Parker, Evolvent; George Cole, Allscripts; Austin Kreisler, SAIC; Paul Klinker, Harris; Tone Southerland, Greenway; and Steve Waldren, American Academy of Family Physicians (AAFP).

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Table of Contents

EXECUTIVE SUMMARY.....	6
INTRODUCTION.....	7
CCR Summary of Purpose.....	7
CCR and Meaningful Use.....	8
CCR and CCD.....	9
STAKEHOLDER INTERVIEWS.....	10
CCR 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?.....	13
Does the standard support the use of 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?.....	14
Are there unambiguous definitions of what is testable?.....	14
Are there automated test tools and test suites?.....	14
Are there reference implementations for the standard?.....	14
Has the standard been implemented by a range of vendors?.....	15
Is there documented existence of errors, including estimates of the severity?.....	17
Is there a defined and effective process for handling errors?.....	17
Do industry associations endorse the standard?.....	17
Is the standard used in more than one country?.....	18
Is certification available for developers and architects?.....	18
CCR SUITABILITY SUMMARY	19
MEANINGFUL USE ANALYSIS.....	20
Meaningful Use: Vocabulary Set.....	20
Meaningful Use: Core Set.....	21
Meaningful Use: Menu Set.....	25

CONCLUSIONS.....	27
REFERENCES.....	29
ACRONYMS AND ABBREVIATIONS.....	31

List of Figures

FIGURE 1: MEANINGFUL USE AND CCR.....	8
FIGURE 2: CCR XML SMOKING STATUS EXAMPLE 1.....	21
FIGURE 3: CCR XML SMOKING STATUS EXAMPLE 2.....	22
FIGURE 4: MEANINGFUL-USE COMPLIANT CCR XML SMOKING STATUS EXAMPLE.....	23

List of Tables

TABLE 1: CCR STANDARD-SPECIFIC INTERVIEW QUESTIONS.....	10
TABLE 2: CCR CRITERIA MATRIX.....	19
TABLE 3: MEANINGFUL USE VOCABULARY SET SUPPORTED BY CCR.....	20
TABLE 4: MEANINGFUL USE CORE SET SUPPORTABLE BY CCR.....	24
TABLE 5: MEANINGFUL USE MENU SET SUPPORTABLE BY CCR.....	26

Executive Summary

This document analyzes the suitability of the ASTM Continuity of Care Record (CCR) 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).

We applied the methodology described in the "Healthcare Information Technology Standards: General Suitability Analysis" document, also prepared for NIST. The CCR standard meets some of the defined suitability criteria required. To meet all the criteria, a number of deficiencies should be corrected. Chief among them are the needs for constraint and extensibility mechanisms and for a profile of the CCR standard that meets the functionality requirements of Meaningful Use.

Introduction

This document analyzes how the ASTM¹ Continuity of Care Record (CCR) standard supports 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). In this project, we assessed the suitability of four standards: CCR, Quality Reporting Data Architecture (QRDA), Continuity of Care Document (CCD), and Health Level Seven (HL7) V2 Biosurveillance. These findings are reported in separate documents.

CCR documents may be prepared, transmitted, and viewed in multiple ways, including email or PDF (portable document format) files. This analysis applies only to structured electronic documents containing Extensible Markup Language (XML) coding. With XML coding, a CCR may be transmitted and viewed as an element in an HL7 message or a Clinical Document Architecture (CDA) compliant document. This analysis applies to the former, the non-CDA XML encoding.

CCR Summary of Purpose

A CCR document is an exchange object between electronic health record (EHR) systems rather than a clinical document that should be stored. CCR communicates

... the most relevant administrative, demographic, and clinical information 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.”²

The CCR data set includes a summary of the patient's health status (for example problems, medications, allergies) and basic information about insurance, advance directives, care documentation, and the patient's care plan.

CCR was not designed to be long-lived. It is a summary of relevant patient data as determined by the physician based on the expected use of that data. As stated by Peters et al. (2005):

The ASTM CCR is not, however, a ‘clinical document’ – such as a Clinical Note, Encounter Note, History & Physical, or Discharge Summary, each of which are medical legal documents, generated and signed by one or more directly responsible clinical authors.

The best way to understand a ASTM CCR is as a collection of data from many clinical documents—documents such as Clinic Notes, H&Ps, Discharge Summaries, Prescriptions, Orders, Results documents, Operative Reports, Procedure Notes, etc. The ASTM CCR is what physicians or clinical or administrative health care providers generate either on scratch paper, in our heads, or in another document such as an H&P or Discharge Summary when they

¹ Originally called American Society for Testing Materials

² ASTM Standard E2369 - 05e1. *Standard Specification for Continuity of Care Record (CCR)*, 2005. <http://www.astm.org/Standards/E2369.htm>, Section 1.1 of the Abstract.

‘review’ the patient chart or charts. The ASTM CCR is an aggregation of all of the pertinent data from all the documents in the chart(s) and the compilation and parsing of that data into a uniform and easily interpreted format—the CCR. [...]

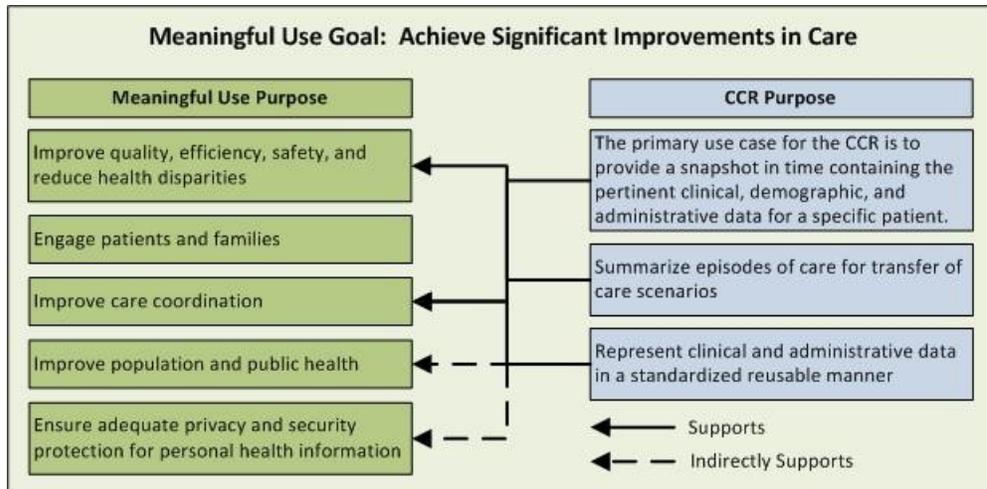
To reiterate, the ASTM CCR is not a ‘clinical document;’ the ASTM CCR is an aggregation of clinical and administrative data from multiple documents from multiple disparate sources.

CCR and Meaningful Use

The primary objective of Stage 1 Meaningful Use is to leverage technology to achieve significant improvements in patient care. The 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.³

CCR supports the Meaningful Use goals of improving quality, efficiency, safety, and coordination and reducing health disparities (the first and third goals listed above). CCR helps transmit automated healthcare information with minimal workflow disruption for practitioners, and allows data to be exchanged between otherwise incompatible EHR systems, although aggregation of that data is not feasible without using a profile.

Figure 1: Meaningful Use and CCR



³ Department of Health and Human Services. *Medicare and Medicaid Programs; Electronic Health Record Incentive Program; Final Rule – Stage One Meaningful Use Objectives* 42 CFR Parts 412, 413, 422 et al. <http://edocket.access.gpo.gov/2010/pdf/2010-17207.pdf>

CCR and CCD

CCR is closely related to HL7's Continuity of Care Document (CCD). CCD—a collaborative effort between HL7 and ASTM^{4,5}—is essentially a CDA implementation of the medical information in a CCR. The major concepts within the two formats are similar and can be mapped accurately and transformed reliably where the variability in each specification is constrained. A general mapping is not feasible.

⁴ <http://www.hl7standards.com/blog/2010/03/10/ccd-and-ccr-the-discussion-continues/>

⁵ <http://projectpophealth.org/glossary.html>

Stakeholder Interviews

As described in the “Healthcare Information Technology Standards: General Suitability Analysis”⁶ also prepared for NIST, we interviewed experts in HIT standards development, quality reporting, and standards implementation to supplement our own experience and knowledge of CCR. The table below lists the [questions](#) that guided the discussion on CCR.

We also reviewed material on the web and communicated privately with implementers, members of the CCR design committee, and the ASTM Staff Liaison for Committee E31.

Table 1: CCR Standard-Specific Interview Questions

Question block ID	Interview Questions
[CCR]	<ul style="list-style-type: none"> • Please briefly describe your experience with CCR to help us understand the basis for your answers to the following questions. • The primary purpose of CCR is to transmit summary data. How well is CCR meeting its primary purpose? • Are there errors or ambiguities in CCR that mean it is harder than it should be to implement and use? Do you have examples? • Consider the primary purpose of CCR: <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 CCR testable? • Where is “suitability” or “fitness for purpose” lacking or present in CCR? 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 of disparate systems to send uniform data to a central repository) ○ Others? • Please discuss the one feature about CCR that most supports the Meaningful Use ultimate goal of achieving significant improvements in health care.

Senior developers and government-level directors who had some experience with the CCR standard and its implementation provided insight. Most people with CCR experience also had

⁶ Lantana Consulting Group. Healthcare Information Technology Standards: General Suitability Analysis, May 2011. Related document prepared for NIST.

experience with the CCD. Thus, many of their comments should be viewed as comparisons of the two standards.

CCR is generally seen to be relatively easy to understand and implement. It is defined in one document and it was designed to meet one specific use case. It is not modular and there are no related standards using the same model or XML conventions.

We discussed two issues in some depth. One is that what is rendered to the clinician on screen is completely up to the receiver of a CCR document. One interviewee thought this allows a system to render information in a consistent format regardless of where it was sourced or what the source clinician intended. Other interviewees were concerned that this could create incomplete and medically dangerous documents. Some providers use free-form text while others provide structured information. Some style sheets show all information, including what is in free-form text, but in one case the style sheet worked only when all the structured elements were complete—without all elements, no information was shown.

The other issue was that although CCR recommends the use of code sets, it also allows free text.

CCR Suitability Analysis

This section applies to CCR the suitability criteria defined in the “Healthcare Information Technology Standards: General Suitability Analysis”.

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

CCR was developed by ASTM International Technical Committee E31 on Healthcare Informatics in Subcommittee 31.25 on Healthcare Data Management, Security, Confidentiality, and Privacy⁷. ASTM is a recognized international standards developing organization (SDO) with a consensus-driven approach. Membership is open to all who can pay the membership fee. This SDO structure typically makes it possible for any interested experts to take part in the development of a standard to ensure it meets the needs of the community. In this case, ASTM E31 did have a large number of healthcare experts working on the design of CCR. As of March 2011, CCR is listed as an ACTIVE standard under the jurisdiction of E31.25 (although the latest version was published in 2005).

CCR has a data model insofar as an XML document with a structure that conforms to a specific schema has a data model. Using the World Wide Web Consortium Document Object Model (W3C DOM), all information units within an XML document can be represented by data objects within a software application. Annex A2.2 of the CCR standard refers to this:

- (2) The CCR Document Object is constructed from a set of discrete XML building blocks, which are defined as Data Objects.
- (3) The Data Objects are contained within Sections, such as Medications, Immunizations, Problems, and Procedures, in the CCR Document Object.
- (4) Each discrete Medication, Immunization, Problem, Procedure represents a discrete data object within the CCR.

The CCR XML object model could be applied to use cases within a restricted area, where such use cases are essentially variations on a theme of CCR. Application to other, more extensive use cases would require significant work to develop a consistent underlying conceptual model, if the resulting standards were to be properly compatible with each other. Such a conceptual model would also make it easier to relate the XML data model to the models required for healthcare IT implementations. The XML schema for CCR can represent some of object relationships, but cannot represent all of the constraints required. Other, more formal ways of describing the data model, such as the Unified Modeling Language (UML)⁸ in combination with the Object Constraint Language (OCL), can represent additional relationships and constraints. Even this method, however, does not represent all constraints; the rest must be expressed in natural language.

A number of experts participated in the development of CCR and it did go through more than one cycle of ANSI ballot, so the XML data model was well vetted, but it remains limited. It does not

⁷ <http://www.astm.org/COMMIT/SUBCOMMIT/E3125.htm>

⁸ <http://www.uml.org>

have an underlying conceptual model and does not cover all the necessary relationships and constraints.

There is currently no active development of CCR. Although the standard could therefore be described as “stable” (or more precisely, unchanging), we believe that true stability results from ongoing testing against the applicable use cases to ensure that a standard continues to meet those defined needs.

Thus we conclude that the CCR standard is not based on a stable, well-vetted data model, since the standard is not being monitored in case it needs to be updated.

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

Although the CCR standard recommends the use of controlled vocabularies, it does not mandate them. Information can be coded using SNOMED CT, ICD-9 CM, ICD-10, CPT, LOINC, and RxNorm, or described using simple natural-language text strings.

The standard contains the phrase “using the most recent codes at the time CCR is generated” for many of the coding recommendations. This increases the variability among different implementations. Even if the same coding system is used, the different implementations may update their codes at different rates. The standard recommends that problems, procedures, products, and agents be coded “to as granular a level as possible”, which can also create mismatches through different interpretations of what is, or should, be possible.

In addition, the standard does not completely describe how code systems should be represented. The definition of the XML element <CodingSystem> allows many choices in the way the content can be encoded (e.g., "SNOMED CT", "SCT", or "SNOMEDCT" would each be a valid CCR representation of the SNOMED CT code system). This makes it difficult to validate, compare, or aggregate the data encoded in a CCR.

In conclusion, while CCR does offer some support for the use of vocabularies and code sets, this support is minimal and without sufficient guidance to be maintained and relied upon.

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

CCR was designed to meet a single use case and does not support the concept or use of reusable modules. The CCR standard contains XML elements that could be used as “building blocks” for other standards, but this is not defined in the CCR standard. Many of these structures are reused within the CCR standard itself (e.g., the Immunization section reuses structures defined in the Medications section), but the use of these elements in any other standard would have to be considered carefully to avoid unintended consequences.

Thus, the CCR standard does not support the use of reusable modules. Implementers are faced with implementing CCR as a stand-alone interchange format.

Does the standard have a well-defined constraint mechanism?

A constraint mechanism restricts the original standard to meet specific business and content needs, such as for specific use cases or geographic locations.

CCR data elements and structures are optional. It does not have a defined mechanism to constrain optionality or create agreement on profiles between users.

The CCR standard does not have a well-defined constraint mechanism.

Does the standard have a well-defined extensibility mechanism?

The CCR disallows end-user or vendor configurable fields and thus all customization and variation is forbidden. This does increase interoperability (the given reason for not allowing any customizable fields), but at the cost of excluding related use cases that were not considered when the standard was developed, such as use in international locales.

The CCR standard does not have a well-defined extensibility mechanism and does not provide a method for localization.

Are there unambiguous definitions of what is testable?

The CCR defines both required and optional items, as well as many recommended items with “either/or” optionality. As an example of the latter, the <Code> element may contain code systems (recommended), simple text strings, or a combination of both.

The CCR states that “Adherence only to the CCR XML schema is necessary, but not sufficient to support interoperability.” XML schema validation is a necessary baseline test but it is not a sufficient test mechanism. XML schema can test for the correct spelling of element and attribute names, the presence of required XML elements or attributes, and basic XML well-formedness. XML schema testing is limited for those items that are optional or have alternatives. For example, XML schema validators cannot test that the code system being referenced has the correct name, or that the various values used within an element of type CodedDescriptionType are consistent.

The CCR standard does not have unambiguous definitions of what is testable.

Are there automated test tools and test suites?

Open Health Data provides an open source ASTM CCR validation tool, available at <https://github.com/openhealthdata/CCR-Validator>. It was most recently updated in February 2011 and appears to have two regular developers. It was developed to meet the NIST conformance test procedure for electronic information.⁹ The tool includes validation rules for the use of CCR within the federal regulations for Meaningful Use.

There was a web interface to this tool at <http://chit.dyndns.org/ValidationService/> for testing purposes, but when last checked in April 2011, the site was not available.

The CCR standard does have a validation tool.

Are there reference implementations for the standard?

There are currently no reference implementations of CCR EHR or personal health record (PHR) applications created during the development of the CCR standard.

⁹ http://healthcare.nist.gov/docs/170.304.f_ElectronicCopyOfHealthInformation_v1.0.pdf

Has the standard been implemented by a range of vendors?

CCR is based on a simple XML data model, with an XML schema. Several tools are available that will automatically take XML schemas and produce data objects for software development, thus making the process of exporting a CCR document from an EHR or PHR relatively easy.

According to the e-CareManagement blog¹⁰:

The ASTM CCR standard is more likely to be used in ambulatory settings:

- By organizations that have not yet adopted any standard (e.g., early stage companies)
- To support new business models
- In disruptive applications [...]
- Where the implementers are highly sensitive to incremental costs of IT resources and view the CCR as a “better, faster, cheaper” alternative.

The ONC Certified Health IT Product List¹¹ includes over 250 vendors that can create and/or display CCR documents. The commercial implementations of CCR include:

GoogleHealth supports a subset of CCR, detailed at https://code.google.com/apis/health/ccrg_reference.html. Google has a number of partners who integrate their solutions with Google Health listed at <http://www.google.com/intl/en-US/health/about/profiles.html>.

Microsoft HealthVault can transform HealthVault information items into and out of CCR documents (<http://msdn.microsoft.com/en-us/healthvault/dd797577>). Microsoft Amalga is an enterprise data aggregation system that can transfer information to a patient’s HealthVault record. This is implemented at New York Presbyterian Hospital.

Allscripts Enterprise EHR (formerly TouchWorks EHR) exports CCR. (<http://www.allscripts.com/resources/docs/stimulusPackage/CriteriaforSelectinganEHR.pdf>)

eClinicalWorks (<http://www.eclinicalworks.com/products-technology.htm>) is implemented at Children’s National Medical Center of Washington D.C.

Solventus (<http://www.solventus.com>)

NextGen (<http://www.nextgen.com/index.asp>)

Allutia from Doctor–Patient Health Records (DHRPHR) (<http://allutia.com/>)

Chartware (<http://www.chartware.com>)

Good Health Network (<http://www.ghnetwork.com/index.html>)

Records For Living (<http://www.recordsforliving.com/>)

¹⁰ <http://e-caremanagement.com/the-third-rail-in-hitech-implementation-please-dont-make-us-all-speak-latin/>

¹¹ <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.

Digital Clinic from Medico System Inc (<http://www.medicosystem.com>)

MedCommons (<http://home.medcommons.net/index.html>)

Clinical Portal from Lawson (<http://www.lawson.com>)

CareProfile from Availity (<http://www.availity.com>) is used by many Blue Cross and Blue Shield providers

Google and Microsoft are household names, though not (until recently) big players in health care. Allscripts, on the other hand, is well known in the HIT world. However, the information that one of their products exports CCR documents came from private communication with a senior developer; it is not listed on the Allscripts web site. This is not exceptional because HIT vendors seldom mention the standards that are implemented in their systems or give any details on the extent to which those standards are used. It is therefore difficult to definitively answer the question of commercial vendor implementation.

The public domain Veterans Health Information Systems and Technology Architecture (VistA) also supports CCR, using the tools for CCR/CCD support to communicate with other EHRs.¹²

There are also a number of open source implementations—many related to VistA:

VistA-Edge Practice Management System (<http://sourceforge.net/projects/vista-edgepms/>)

vxVista (<http://www.docstorsys.com/dss-vxOpenSource.html>)

popHealth (<http://projectpophealth.org/>)

OpenVista (<https://medsphere.org/index.jspa>)

Indivo (<http://indivohealth.org/>)

WorldVistA (<http://worldvista.org/>)

PatientOS (<http://www.patientos.org/>)

ClearHealth (<http://www.clear-health.com/>)

Two viewing implementations are Android Continuity of Care Record Viewer, ACCReV, and a free stylesheet for transforming a CCR XML document to HTML (hypertext markup language), available at <http://sourceforge.net/projects/ccr-resources/files/>.

A 2008 list of implementations at <http://www.ccrstandard.com/ccrstandardimplementationsanddeployments>, includes some that no longer exist. However, the CCR standard has been implemented by a range of vendors, small and large, open source and commercial.

¹² "Opensource CCR and CCD support for VistA based systems Project Update (Powerpoint slideshow)" - <http://groups.google.com/group/ccd-ccr-project/web/CCR-CCD-Update-090219.ppt> (Information from <https://secure.wikimedia.org/wikipedia/en/wiki/VistA>, last accessed March 17, 2011.)

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

There are implementation-specific discussion lists for Google Health¹³ and open-source Vista CCD/CCR tools¹⁴, but we were unable to find any general error or discussion lists for CCR implementers available to the public. Email requesting a subscription to the CCR Acceleration Group¹⁵ went unanswered for a month before being acknowledged.

We don't know of any specific errors in the CCR standard; however we also don't know if this is because there are no errors, or because the implementers have not reported them, or because reports of any errors are not made public.

Is there a defined and effective process for handling errors?

We are not members of ASTM. As non-members, we were unable to discover what formal process exists, if any, for notifying ASTM International Technical Committee E31 of any errors in the CCR standard. The ASTM web site gives no obvious process. Private communication indicates that emails to ASTM are routed to technical contacts with no tracking.

The CCR standard does not have a well-described process for handling errors.

Do industry associations endorse the standard?

The description of CCR (dated 2005) lists a number of organizations as co-leaders with ASTM in the standard's development and adoption. They are the Massachusetts Medical Society, HIMSS, the American Academy of Family Physicians (AAFP), the American Academy of Pediatrics, the American Medical Association (AMA), the Patient Safety Institute, the American Health Care Association, the National Association for the Support of Long Term Care, the Mobile Healthcare Alliance (MoHCA), the Medical Group Management Association (MGMA) and the American College of Osteopathic Family Physicians (ACOFP).

We were unable to find a current list of industry associations endorsing CCR. However, the fact that the CCR standard is listed as a component of the Meaningful Use Final Rule is an endorsement by the Department of Health and Human Services.

Of the industry associations that endorsed the CCR in 2005, a number of them have references to CCR on their web sites indicating continued interest. Chief among these are the Massachusetts Medical Society, HIMSS, the American Academy of Pediatrics, and AAFP (which hosts the "Unofficial FAQs About the ASTM CCR Standard"¹⁶ although it appears the FAQs—frequently asked questions—had not been updated for some time when we checked in March 2011).

Thus, the CCR standard was endorsed at its creation by industry associations, some of whom still appear to endorse it, and has since been endorsed by a US Federal department as part of Stage 1 Meaningful Use.

¹³ <https://groups.google.com/group/googlehealthdevelopers>

¹⁴ <https://groups.google.com/group/ccd-ctr-project>

¹⁵ <http://www.centerforhit.org/online/chit/home/project-ctr/astm/ccraccel.html>

¹⁶ <http://www.centerforhit.org/online/chit/home/project-ctr/astm/unofficialfaq.html>

Is the standard used in more than one country?

We found two descriptions of non-US CCR implementations. One is a press release from a Bangkok hospital that implemented CCR to allow US patients to connect to their personal Microsoft HealthVault accounts.¹⁷

The other is the Singapore General Hospital piloting the use of the CCR standard for continuity in care transfers. The current status of the pilot project is unknown.¹⁸

We also found a research pilot project undertaken by the Helmholtz Institute in Bavaria, Germany, where they are mapping the CCR to ISO EN 13606 for trial in a healthcare network.¹⁹

There are some university courses in informatics and research institute papers that cite the CCR as a standard to watch, but we were not able to find concrete evidence for actual implementations.

While there is some indication of implementations outside the US, it was not sufficient for us to conclude that the CCR standard is in widespread use in more than one country or endorsed as a local, regional, or national standard in any country outside the US.

Is certification available for developers and architects?

We have not found any professional certification programs for developers or software architects with expertise in the CCR standard. We followed our standard research procedures, including asking members of the ASTM E31 committee and the ASTM staff liaison for E31 if they knew of any certification programs.

There is a CCR workshop listed on the ASTM web site, but there are no dates listed and the description has not been updated for some time. The workshop can only be found by searching the web site; it is not in the current course listing.

We conclude that no professional certification program for developers or software architects is available for the CCR standard.

¹⁷ http://7thspace.com/headlines/323806/global_leaders_team_up_to_give_portable_health_information_to_medical_travelers.html

¹⁸ <http://www.ccrstandard.com/ccrstandardimplementationsanddeployments>

¹⁹ <http://www.helmholtz-muenchen.de/en/bymedconnect/home/index.html>

CCR Suitability Summary

This following matrix summarizes how the suitability criteria can be applied to the CCR standard.

Table 2: CCR Criteria Matrix

Criteria	Results	Notes
Is the standard based on a stable, well-vetted data model?	Partial	The XML schema is a simple data model. The model is unchanging rather than stable, as it is not maintained.
Does the standard have a clear, robust vocabulary binding syntax?	No	
Does the standard support use of reusable modules, such as templates or data types?	No	
Does the standard have a well-defined constraint mechanism?	No	
Does the standard have a well-defined extensibility mechanism?	No	
Are there unambiguous definitions of what is testable?	No	
Are there automated test tools and test suites?	Yes	
Are there reference implementations for the standard?	No	
Has the standard been implemented by a range of vendors?	Yes	
Is there documented existence of errors, including estimates of the severity?	No	
Is there a defined and effective process for handling errors?	No	
Do industry associations endorse the standard	Yes	
Is the standard used in more than one country?	Partial	Some pilot projects have been announced
Is certification available for developers and architects?	No	

Meaningful Use Analysis

This section analyzes CCR based on the stricter requirements for Stage 1 Meaningful Use. These criteria “establish the required capabilities and related standards and implementation specifications that certified electronic health record (EHR) technology will need to include”²⁰. Systems must implement the specifications and functionality in a secure way to satisfy the Final Rule for Stage 1 Meaningful Use.

Meaningful Use: Vocabulary Set

In the CCR standard, the choice of coding system is optional. This is not the case for Meaningful Use; the coding systems listed in the table below must be used by health plans and healthcare clearinghouses, as well as any healthcare provider transmitting an electronic transaction²¹. The CCR supports most of the Meaningful Use coding systems as well as plain text.

In addition, the CCR standard does not completely describe how code systems should be represented. The XML element <CodingSystem> allows many choices in the way the content can be encoded. For example, the string “SNOMED CT” could be used, or the string “SNMD”. The former is recommended, but not required.

Table 3: Meaningful Use Vocabulary Set Supported by CCR

Item	Vocabulary	Supported by CCR?
Problem List	ICD9-CM, SNOMED CT	Yes, with no guidance on how to represent specific code systems
Procedures	CPT-4, ICD-9-CM: Procedures, HCPCS	SNOMED CT, LOINC (preferred); recent CPT (allowed), with no guidance on how to represent specific code systems
Labs	LOINC	Yes, with no guidance on how to represent specific code systems
Medications	RxNorm	Yes, with no guidance on how to represent specific code systems
Immunizations	HL7 CVX - Vaccines Administered	Yes, with no guidance since you can put in anything you want. You’re supposed to put in the type and then the value.
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, with no guidance since you can put in anything you want.

²⁰ http://healthit.hhs.gov/portal/server.pt/community/healthit_hhs_gov_standards_ifr/1195, accessed March 2011

²¹ Department of Health and Human Services, 45 CFR Parts 160 and 162, *Health Insurance Reform: Standards for Electronic Transactions*

Meaningful Use: Core Set

The Core Set of functionality is defined as that which every certified EHR system must provide for Meaningful Use. The CCR standard does provide a way to encode much of the data to be transmitted, though not all. It is important to remember that the scope for CCR is a transitory document for transferring information from one system to another. Some of the Meaningful Use criteria are outside the CCR scope.

Where our notes in the [Meaningful Use Core Set](#) table state “can be stored as free-form information”, this means that although there is a recommended place—and perhaps a specific XML element—for some of the Meaningful Use information within the CCR document, the content of each of those elements is generic, not specific. The CCR specification has 17 sections at the body level, each designed for a particular type of information. Many of those sections contain generic elements and attributes with names such as <Text> or <Type> or <CodedDescriptionType> that are used to encode the information. Thus the items required, in particular for demographic information, can be represented in several ways. The standard states, for example, that “5.1.2.7 Social History contains data defining the patient’s occupational, personal (for example, lifestyle), social, and environmental history and health risk factors, as well as administrative data (ADT) such as marital status, race, ethnicity, and religious affiliation”²² but does not specify any more details on how the marital status and risk factors should be represented.

To illustrate this, the following two figures provide alternate methods, each of which could be used to represent a patient’s smoking status.

²² ASTM Standard E 2369 – 05 *Standard Specification for Continuity of Care Record (CCR)*

Figure 2: CCR XML smoking status example I

```
<SocialHistory>
  <SocialHistoryElement>
    <CCRDataObjectID>abc</CCRDataObjectID>
    <Type>
      <Text>Smoking</Text>
      <Code>
        <!-- code for Cigarette consumption (observable entity) -->
        <Value>230056004</Value>
        <CodingSystem>SNOMED CT</CodingSystem>
      </Code>
    </Type>
    <Source><Actor><ActorID>xyz</ActorID></Actor></Source>
    <Episodes>
      ...
    </Episodes>
  </SocialHistoryElement>
  ...
</SocialHistory>
```

Figure 3: CCR XML smoking status example 2

```
<SocialHistory>
  <SocialHistoryElement>
    <CCRDataObjectID>abc</CCRDataObjectID>
    <Type>
      <Text>Smokes</Text>
    </Type>
    <Source><Actor><ActorID>xyz</ActorID></Actor></Source>
    <Episodes>
      ...
    </Episodes>
  </SocialHistoryElement>
  ...
</SocialHistory>
```

Since there are different ways to represent the same information, combining information from multiple CCR documents is difficult unless the systems creating those documents all make the same coding style choices.

The CCR can satisfy the Stage 1 Meaningful Use requirement of using the Center for Disease Prevention and Control (CDC) National Health Interview Survey (NHIS) codes for the smoking status²³ by making use of two features. Information can be encoded with a generic element if there is no specific element available for it, and coding systems other than the recommended ones can be used. The next figure shows a version of the above example that is closer to the intent of Meaningful Use.

²³ Available at http://www.cdc.gov/nchs/nhis/tobacco/tobacco_recodes.htm

Figure 4: Meaningful-Use compliant CCR XML smoking status example

```
<SocialHistory>
  <SocialHistoryElement>
    <CCRDataObjectID>abc</CCRDataObjectID>
    <Type>
      <Text>Smoking Status</Text>
      <Code>
        <!-- code for Current some day smoker -->
        <Value>2</Value>
        <CodingSystem>SMKSTAT2</CodingSystem>
      </Code>
    </Type>
    <Source><Actor><ActorID>xyz</ActorID></Actor></Source>
    <Episodes>
      ...
    </Episodes>
  </SocialHistoryElement>
  ...
</SocialHistory>
```

Thus CCR's method of encoding much of the information in a relatively free-form manner makes it difficult to aggregate the information and lowers the interoperability between systems (the implementers of the systems need to agree on details that aren't specified in the standard), but allows unforeseen use cases.

In conclusion, the CCR supports the Meaningful Use data set, though not necessarily in a form that makes aggregation of the data easy. In the table below we list the Core Set criteria and whether they are supportable by the CCR. If CCR were profiled so that the many choices and options were reduced to a set that matches the Meaningful Use requirements, it would have a wider range of applicability.

Table 4: Meaningful Use Core Set Supportable by CCR

Core Set Criteria	Supportable by CCR?
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.)	Except for date and cause of death, which have specific elements, all can be stored as free-form information within <SocialHistoryElement> elements in the <SocialHistory> element.
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.)	All except the growth charts can be stored as free-form information within <Results> elements in the <VitalSigns> element. The growth charts could be put in as images, but there is no specific support for them.
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.	Diagnoses: Yes, in the <Problem> element. Medications: Yes, in the <Medications> element, including the allergies. Smoking status: Yes, in the <SocialHistory> element.
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.
Provide patients with an electronic copy of their discharge instructions at time of discharge from the hospital, upon request.	No. “Since the CCR is a core data set of selected, relevant information, it is not a discharge summary” ²⁴
Provide patients with an electronic copy of their health information (including diagnostics test results, problem list, medication lists, medication allergies) upon request.	Yes.
Generate and transmit permissible prescriptions electronically (does not apply to hospitals).	Yes.
Provide Computerized Provider Order Entry for Medication Orders.	No.
Implement drug-drug and drug-allergy interaction checks. Functionality must be enabled for these checks for the entire reporting period.	No. It has the drug data, but not the decision support.

²⁴ ASTM Standard E 2369 – 05 *Standard Specification for Continuity of Care Record (CCR)*, page 1

Core Set Criteria	Supportable by CCR?
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.	No.
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.	Yes, where relevant. The CCR specification includes security and privacy considerations as requirements, but does not discuss what would be entailed in a security risk analysis.
Report clinical quality measures to CMS or states. For 2011, provide aggregate numerator and denominator through attestation. For 2012, electronically submit measures.	Some ²⁵ . Pophealth imports CCR documents and then uses that data to compute the numerator and denominator. Some quality measures require data that isn't in the CCR (e.g., discharge medication).

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 on [Meaningful Use Menu Set Supported by CCR](#)). The current expectation is that Stage 2 Meaningful Use will require certified systems to have all of the items in the Menu Set.

For many of these items, the EHR system could use data encoded in the CCR as input to the required functionality, but in many cases that use is not directly supported by the standard. The CCR can encode information for six of the twelve Menu Set items, with some caveats. The recording physician must be aware of the proposed use of the information to ensure that all relevant information is included. The relevant information can be coded within a CCR document in more than one way, so that the CCR must be profiled to support data aggregation and secondary use.

²⁵ For an example, see <http://projectpophealth.org/faq.html - standards>

Table 5: Meaningful Use Menu Set Supportable by CCR

Menu Set Criteria	Supportable by CCR?
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.	No.
Incorporate clinical laboratory test results into EHRs as structured data.	Yes.
Generate lists of patients by specific conditions for use for quality improvement, reduction of disparities, research or outreach.	The CCR could supply data to an EHR for this calculation if it were appropriately profiled.
Use EHR technology to identify patient-specific education resources and provide those to the patient as appropriate.	No.
Perform Medication reconciliation between care settings.	Yes. The definitions used for medication reconciliation are not precise, so the CCR can supply data. A profiled CCR would, of course, be better.
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 (this was the original intent for the CCR).
Submit electronic immunization data to immunization registries or immunization information systems.	Not applicable, since MU requires HL7 V2 messaging.
Submit electronic syndromic surveillance data to public health agencies.	Not applicable, since MU requires HL7 V2 messaging.
For hospitals, record advanced directives for patients 65 years or older.	Yes.
For hospitals, submit electronic data on reportable laboratory results to public health agencies.	Not applicable, since MU requires HL7 V2 messaging
For professionals, send reminders to patients (per patient preference) for preventative and follow-up care.	No.
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

The CCR standard is well known in HIT. It was designed to transfer of relevant records when a patient moves from one provider to another. CCR is a relatively simple standard to understand. The number of implementations show that it is considered suitable for HIT use. It is generally considered sufficient for ambulatory settings²⁶ and for giving patients access to their health information²⁷.

We found, however, that the CCR standard does not satisfy many of our suitability requirements, and some that it does satisfy come with caveats. There are indeed implementations by a range of large and small vendors, and open-source implementations are also available. Many industry organizations endorsed CCR in 2005 and contributed to its development, but the ASTM stopped seeking official sponsors after the standard was published²⁸. The validation suite, although open source and regularly updated, appears to have only two regular contributors. We could find no error lists or process for reporting errors available to non-members. In private communications, E31 members said that emails to ASTM with questions are typically passed on to technical contacts and not tracked. There is a CCR Acceleration Group²⁹ that we subscribed to, but there was no email traffic in two months, making it difficult to judge how active the group is.

The CCR satisfies some of the Meaningful Use criteria, again with caveats. In many cases CCR-recommended code systems would satisfy the Stage 1 Meaningful Use criteria, but CCR also allows plain text, which falls short of the Meaningful Use standards. In other cases, such as for demographics, there are no dedicated elements or attributes in the CCR XML schema. Thus, there could be confusion over how to code those items defined by Meaningful Use, leading to a decrease in interoperability at best, and the potential of improper processing of important information. The lack of a well-defined constraint mechanism in the CCR becomes apparent here, since there is no defined process for creating a profile of the CCR for Meaningful Use.

CCR was designed for one purpose and is specific to that use case. It is not extensible, so cannot easily satisfy variations of that use case or be localized where constraints or extensions are required. As CCR is a stand-alone standard, implementers of CCR or CCR data objects cannot apply that experience to implementing other potentially related clinical-care document formats. The concepts within CCR are useful, however, and map to many of the Stage 1 Meaningful Use criteria. The concepts underlying CCR (which are the same as those in CCD) are important as illustrated by its use in PHR systems. The issues and problems documented in this analysis fall into six categories, for which specific actions are defined in the related “CCR Action Plan”³⁰.

- Refine the standard to add constraint and extensibility mechanisms, develop templates, add a vocabulary binding syntax, and define testability
- Profile the standard to define elements and vocabularies that are needed for Meaningful Use.

²⁶ <http://www.hl7standards.com/blog/2010/03/10/ccd-and-ccr-the-discussion-continues/>

²⁷ <http://jamia.bmj.com/content/18/2/118.full.html>

²⁸ Dan Smith, ASTM Staff Liaison for Committee E31, private communication

²⁹ <http://www.centerforhit.org/online/chit/home/project-ctr/astm/ccraccel.html>

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

- Create more testing tools and a reference implementation to improve testing and validation.
- Improve the process for error handling.
- Create a certification program for developers and architects.
- Create additional documentation.

If these are resolved, CCR could be considered for implementation in clinical healthcare systems to support Meaningful Use.

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Acronyms and Abbreviations

AAFP	American Academy of Family Physicians
ACOFPA	American College of Osteopathic Family Physicians
ADT	administrative data
AMA	American Medical Association
ARRA	American Recovery and Reinvestment Act
ASTM	originally called the American Society for Testing and Materials
BMI	Body Mass Index
CCD	Continuity of Care Document
CCR	Continuity of Care Record
CDA	Clinical Document Architecture
CDC	Center for Disease Prevention and Control (CDC)
CFR	Code of Federal Regulations
CPT	Current Procedural Terminology
DHRPHR	Doctor-Patient Health Records
DOM	Document Object Model
EHR	Electronic Health Record
FAQs	frequently asked questions
H&P	History and Physical
HHS	Department of Health and Human Services
HIMSS	Health Information Management and Systems Society)
HIT	Healthcare Information Technology
HL7	Health Level Seven
HTML	hypertext markup language
ICD	International Classification of Diseases
IETF	Internet Engineering Task Force
IHE	Integrating the Healthcare Environment
ISO	International Organization for Standardization
IT	Information Technology

LOINC Logical Observation Identifiers Names and Codes
MGMA Medical Group Management Association
MoHCA Mobile Healthcare Alliance
MU Meaningful Use
NIH National Institutes of Health
NHIS National Health Interview Survey
NIST National Institute of Standards and Technology
OCL Object Constraint Language
ONC Office of the National Coordinator
PDF portable document format)
PHR Personal Health Record
QRDA Quality Reporting Document Architecture
SDO standards developing organization
SNOMED CT Systematized Nomenclature of Medicine, Clinical Terms
UML Unified Modeling Language
VistA Veterans Health Information Systems and Technology Architecture
W3C World Wide Web Consortium
XML Extensible Markup Language