MAIN COMMITTEE BALLOT REPORT E31 (05-02) 04/19/05

BALLOT ISSUE DATE: 03/17/05 CLOSING DATE: 04/16/05 NEXT COMMITTEE MEETING IS 05/16/05 IN SALT LAKE CITY, UT
THESE ITEMS APPEAR ON APRIL 2005 SOCIETY REVIEW

STAFF MANAGER: DANIEL G SMITH

COMMITTEE OFFICERS:

CHAIRMAN	C PETER WAEGEMANN
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M/S SEC	KATHLEEN M HUNTER

SUBCHAIRMAN (2800)

	NO OF ITEMS	BALLOTS SENT	BALLOTS RETURNED	PERCENT RETURN
E31	1	259	165	63.70
E31.2800	1	135	86	63.70

Please note that only voting members are counted in the tally of ballots. Also note that negative votes and comments from voting and non-official voting members shall be considered in accordance with the "Regulations Governing ASTM Technical Committees". Ballot report information and statements accompanying negative votes and comments shall not be reproduced or circulated in whole or part, outside if ASTM Committee activities, except with the approval of the Chairman of the committee having jurisdiction and President of the Society.

ITEM	SUB	ACTION		AFF	NEG	ABST	PCNT
001	28	SPECIFICATION FOR CONTINUITY OF CARE RECORD (CCR)	E31	98.00	12.00	55.00	89.09**
		TECHNICAL CONTACT : CLAUDIA TESSIER					
		WORK ITEM: WK4363					
			E31.2800	55.00	10.00	21.00	84.61

NEGATIVE VOTERS:

(MAIN ONLY)		KAREN VAN HENTENRYCK
(MAIN/SUB)		GLEN F MARSHALL
(MAIN/SUB)		JOHN T DONNELLY
(MAIN/SUB)		ROBERTO RUGGERI
(MAIN/SUB)		COREY A SPEARS
(MAIN/SUB)		DAVIN S HILLS
(MAIN/SUB)		CHARLES PARISOT
(MAIN/SUB)		THOMSON KUHN
(MAIN/SUB)		DOUGLAS R HORNER
(MAIN/SUB)	#*	KEITH W BOONE
(MAIN/SUB)	#*	VASSIL PEYTCHEV
(MAIN/SUB)		FREIDA HALL
(MAIN ONLY)	*	DIDI DAVIS
(MAIN ONLY)		CHRISTIE W SMITH
(MAIN/SUB)		JOHN C DURHAM

NON-OFFICIAL VOTING MEMBER:# INDICATES SUB; * INDICATES MAIN

** ITEM DID NOT ACHIEVE THE REQUIRED 90% AFFIRMATIVE VOTE

MAIN COMMITTEE BALLOT REPORT E31 (05-02) 04/19/05

ITEM	SUB	ACTION	AFF	NEG	ABST	PCNT
001	28	COMMENTS:				
		(MAIN ONLY) DONALD A NELSON				
		(MAIN/SUB) * THOMAS M KURIHARA				
		(MAIN ONLY) * BARRY R HIEB MD				
		(MAIN ONLY) GEOFFREY SHORTEN				
		(MAIN/SUB) LORI R FOURQUET				
		(MAIN/SUB) #* TED BLIZZARD				
		(MAIN/SUB) SHELLEY Y DI GIACOMO				
		(MAIN/SUB) THOMAS E SULLIVAN				
		(MAIN/SUB) DON JORGENSON				
		(MAIN/SUB) #* SAMI AITA				
		(MAIN/SUB) LLOYD DEVINEY				
		(MAIN/SUB) ROBERT A RUDY				
		(MAIN/SUB) JOHN RITTER				
		(MAIN ONLY) * MICHAEL SPILLANE				
		(MAIN/SUB) DIANE P FABIAN				
		(MAIN/SUB) * GEORGE E COLE				
		(MAIN/SUB) LYMAN DENNIS				
		(MAIN/SUB) #* KEN MILLER				
		(MAIN ONLY) * STASIA KAHN				

NON-OFFICIAL VOTING MEMBER:# INDICATES SUB; * INDICATES MAIN

Negative

Date:	4/18/2005
Ballot Number:	E31 (02-05) Close Date: APRIL 16, 2005
Item Number:	001 SPECIFICATION FOR CONTINUITY OF CARE RECORD (CCR) (DTN 31E WK4363 (CONCURRENT WITH .2800) TECHNICAL CONTACT: MS CLAUDIA TESSIER CTESSI@ATTGLOBAL.NET (202) 659-2699
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File Attachment:	000172368_E310205_1.doc
Statement:	

Negative

Date:	4/14/2005
Ballot Number:	E31 (02-05) Close Date: APRIL 16, 2005
Item Number:	001 SPECIFICATION FOR CONTINUITY OF CARE RECORD (CCR) (DTN 31E WK4363 (CONCURRENT WITH .2800) TECHNICAL CONTACT: MS CLAUDIA TESSIER CTESSI@ATTGLOBAL.NET (202) 659-2699
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Statement:	

See attached file.

Comments on ASTM E31.28 Continuity of Care Record (CCR) Ballot

Glen F. Marshall

Overview

While I strongly support the purpose and objectives of the CCR, the current ballot document is not ready for adoption. Substantive revisions are necessary.

It would be most helpful if the content specifications, the XML schema, and use-case specific implementation guide were balloted as separate standards. This would promote rapid adoption of the CCR content while allowing time for maturing the electronic data model and its use cases.

Major Negative Items

In general, resolving these items requires substantive revision to the CCR ballot and re-balloting.

Procedural

Were ASTM procedures followed in developing this ballot? In particular, was the CCR ballot officially approved by the E31.28 committee prior to being sent to E31 for approval? If not, then this ballot must be re-issued following ASTM procedural requirements.

Section 1.3.2

"Interchange of CCR between otherwise incompatible EHR systems"

- IF CCR is to be incorporated in EHR systems, issues of long-term validity of the data need to be addressed. Use cases for EHR are not in Annex C. State the use cases here and in more detail in Annex C.

Section 1.4.2 (and in Annex C "Security and Privacy section")

As worded, this section is not implementable and speculates on ASTM E31.20 standards work that is not done. Please remove this section *or* include the following additional elements:

- XSL for canonicalization of XML for digital signing, per W3C standards. At a minimum, a default XSL for signing the entire XML document must be provided.

- Please provide detailed specifications for encryption. It is not clear what methods are to be used. Please provide normative references. This is required for interoperability.

- If the EHR use cases are incorporated in Annex C, the relevant effects on encryptions – having unknown destinations for EHR data – needs to be accommodated. Alternatively, explicitly remove this requirement for storage of CCR data in EHR systems.

- Remove speculative references to work that is not done by E31.20 yet. This includes the suggested interim solutions (based on "cooperative agreements between send and receiver") pending such work.

- Please explain what a "SAML digital certificate" is. The current SAML standard (version 2.0) does not have such a specification. Alternatively, remove this reference.

- Restate the requirement, stated in Annex C page 6, regarding no data to be contained within XML attributes. This cannot apply to XML digital signatures, which do have data in attributes.

Section 4.3 and 4.4

If the examples stated in sections 4.3 and 4.4 are intended to be normative or to inform any normative use cases, please reword them as such.

Section 5.1.1.4 and 5.1.1.5 (and as used in Annex C)

The term "role" is unclear and must be differentiated. This is especially true if "role" is to be used for determining data access rights within a healthcare IT system. This will require the addition of elements and coded vocabularies in the CCR definition. The differentiators among the meanings of role include:

- Functional role in relationship to clinical workflow

- Structural role in relationship to attributes predefined by a healthcare provider or government regulations.

- Care role in relationship to the patient

- Regulated role as determined professional licenses or certifications.

Annex B

The XML schema is not valid. Specific problems found:

- Line 258, 591, 1001, 1820 – type refinement content type incompatible with the content type of the base type.

- Lines 633, 646, 661, 1800-1803, 1811-1818, 1820 – element definitions contains directly, indirectly or implicitly element declarations with same names and target namespace but with different type definitions.

Comments on ASTM E31.28 Continuity of Care Record (CCR) Ballot

Glen F. Marshall

Annex C – Missing elements

Although Annex C is an implementation guide, no clear use cases have been stated. For this standard to be appropriately evaluated as an implementation guide, and be applied to actual implementations, use cases must be stated.

Annex C, on page 5, states that compliance validation must be done against both the implementation guide and the .xsd (Annex B). Please state the mechanism for compliance checking against the implementation guide. These should be use case specific.

A default XSL for displaying the CCR in a web browser needs to be provided. Since there is no standard default or canonical display format for XML, a standard to enable direct viewing of the data is required.

Implementations need to include a standard means to validate signatures and decrypt data, when data is digitally signed or encrypted. This should be deferred to the E31.20 committee, however.

Annex C – Specifications

Page 6 -The restriction regarding no data to be contained within XML attributes cannot apply to XML digital signatures, which have data in attributes. Please restate this restriction so it does not apply to any standards that are referenced by or incorporated in the CCR.

Page 9 - Controlled vocabularies: Require the non-optional use of registered (e.g., have an OID assigned) controlled vocabularies where they exist to promote interoperability. Where CCR specifies novel vocabularies, register them with an OID. Provide normative references (suggestion: do this in a table) to the vocabularies used. This is necessary for supporting EHR (archival storage) use cases for long-term semantic interoperability among IT systems.

Page 10 – Remove references to DICOM, IHE, HL7, NCPDP, and ASTM work. As worded this is an evaluation opinion that is subject to changing facts. Instead, state the use case that the CCR solves.

Minor Negative Items

In general, these items require technical correction to the CCR ballot, and are not individually substantive enough to require a re-ballot. However, the cumulative effect of these corrections may be large enough to require a re-ballot.

Procedural

Annex C, on page 4, notes that there changes to the content from the first CCR standard. However, these have not been identified. It is therefore not clear if there are compatibility issues between the prior version to this one.

Comments on ASTM E31.28 Continuity of Care Record (CCR) Ballot

Glen F. Marshall

Section 1.3

Normative references needed for terms used: "HL7 CDA" (which version?), "secure e-mail," "PDF file," "HTML file," and "word processing document." These terms are not specific enough to be understood. Since the defining standards are subject to revision, the current referenced version need to be identified.

Section 1.3.2

"Interchange of CCR between otherwise incompatible EHR systems":

- Since CCR is not a document, per section 1.3.1, it is not clear how it relates to EHR systems that are document collections. Please clarify.

- Interchange as stated requires semantic interoperability – beyond the XML data definitions. It is not clear now this level of interoperability is to be achieved by CCR. Clarification needed *or* remove this statement.

Sections 1.4.1 and 2.1 (and in Annex C "Security and Privacy section")

This section is too vaguely worded. There are missing references to existing ASTM E31 standards that adequately cover this requirements. Please insert the ASTM E31 security standards references in section 2.1 and state in section 1.4.1 the requirements of those standards as related to CCR.

Section 2.1 – ASTM Standards

The text refers to additional ASTM standards and concepts that are subject to ASTM standards, e.g., E2084 for digital signature. Please state these references.

The prior CCR standard, balloted in May 2004, is mentioned in this document. Please provide a reference to that document.

Section 2.2 – Other Referenced Documents

Although HL7, ASC X12N, and NCPDP standards are mentioned in the text, they are not cited as normative references. This is required, including version references.

Although the HIPAA act is cited, the implementing CFR rules are not. The HIPAA act is not a standard, but the HIPAA CFR rules are. This needs to be corrected.

Internationalization: If this standard is to be applied internationally, appropriate references to non-US standards need to be included. This is especially true for ASC X12N standards and HIPAA rules. If CCR is for the US only, please clearly state so.

References in the text made to X.509 and SAML needs to be cited here.

Comments on ASTM E31.28 Continuity of Care Record (CCR) Ballot

Glen F. Marshall

Section 4.4.6

The wording "appropriate modifications for confidentiality" is vague. Either provide normative references or eliminate this section.

Section 5.1.1.2

What is the precision of "exact time"? Please specify. Precision to the second is probably sufficient.

Section 5.1.1.3.1

Define "federated or distributed identification system" and reference any standards that support this requirement.

Annex B

The XML schema has syntactic errors that need to be fixed. Specific problems found:

- Lines 1381, 1414, and 1423 specify invalid regular expressions

Annex C

The lack of section numbering makes references to specific sections very difficult for implementers. Please number all sections.

Page 10 – Remove reference to lack of standards for patient summaries. This is an opinion that is arguable. It does not belong in normative work.

Page 10-11 – Remove references to ongoing cooperative work among ASTM, HL7, NCPDP, and ASC X12N. This is speculative. Only cite any completed work.

Negative

Date:	4/18/2005
Ballot Number:	E31 (02-05) Close Date: APRIL 16, 2005
Item Number:	001 SPECIFICATION FOR CONTINUITY OF CARE RECORD (CCR) (DTN 31E WK4363 (CONCURRENT WITH .2800) TECHNICAL CONTACT: MS CLAUDIA TESSIER CTESSI@ATTGLOBAL.NET (202) 659-2699
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File Attachment:	000284702_E310205_1.doc
Statement:	

Comments from John Donnelly re. CCR Ballot

This document contains my comments on the Continuity of Care Record (CCR) Ballot issued March 17, 2005 by ASTM E31.28.

In general, the objective of the CCR is both sound and grounded in an industry-wide need for improving the information exchange process for referral documentation between two health care provider organizations or practices. The subcommittee of ASTM E31.28 has done an excellent job of building an initial foundation for an xml-based solution to address this information exchange need and from a clinical content perspective have successfully engaged physician societies to partake in the content specification. However, there are a number of items that prevent me from casting an affirmative vote for approving the CCR ballot as a standard at this time.

For starters, specifically regarding the preparation of the CCR for ballot:

- Role of the V-TAG in the Development of the Current CCR Schema
  The last version of the schema that was reviewed by the V-TAG was from Dec 2004. At that time, it was my understanding that the task at hand was to get the Implementation Guide & Data Spreadsheet in sync with the Dec CCR schema version. Apparently there was a re-direction decided in that there was considerable revision work done on the schema definition itself in the interim (almost doubled the lines of code) that I nor other members of the V-TAG were aware of. This speaks to a break-down in the process of review & validation of the proposed CCR ballot by the very group organized to prepare it for release. The work of the V-TAG group was incomplete and a number of the discussion points raised by this group back in Dec are still present in the current schema.

Next are a number of issues surrounding the XML schema in Annex B of the document that makes it difficult or impossible to deploy in the real world.

1. The schema syntax has a number of errors in its definition that prevent the schema from passing validation routines of standard xml tools (e.g. there are a numerous definitions, e.g. Function, whereby an element can optionally contain a variety of child elements which can also occur 0-infinite times. This creates ambiguities in the encoding options that a vendor's product would need to complete in order to correctly represent or map this element in its own code. It needs to be better defined to identify a minimum content of at least one choice.)

2. The demarcation of any security-related elements belonging to the standard of another E31 sub-committee (ie E31.20) from this CCR standard and how/where these two standards intersect is unclear. Also the use of digital signatures as elements within this CCR document appears to overlap with, but not follow specifications recommended by ASTM E31 standards such as E1762(95) or E2084

3. In the real world, a problem is associated with a single patient. However, in family History, the CCR has created a possibly many-to-many relationship between patients and problems.

4. According to this standard, a CCR document can contain nothing other than from/to and patient information, with no clinical content according to the schema or implementation guide. Similar medical documents are required to contain specific sections, and explicitly indicate if/when information is present. This serves to complicate the coding needed for potential importation of the CCR content into a vendor's EMR data base.

5. The specification of the Plan of Care Section is insufficient to capture the myriad elements of this clinical information. The current schema appears to reflect that the Plan of Care is comprised solely of a list of Orders.

6. Regarding vocabularies, the CCR standard does not specify in explicitly how vocabularies are to be identified. Two vendor's products can then choose differently how they identify any given vocabulary (e.g SNOMED CT vs SNOMED_CT).

7. The reference to SNOMED CT and LOINC as the preferred standard for vocabularies fails to consider the deployment of the encoding schema recently decided on by the DOD for use in their world-wide CHCSII system, namely MEDCYN, as a viable alternative to these standards.

In addition to the flaws with the schema and/or supportive documentation noted above, there are a number of other issues with regards to the deployment of this standard in the industry itself that need to be addressed.

- There is still an open debate as to whether the CCR document is indeed a clinical document or not. In accordance with other standards defined by ASTM and other SDO's, it appears that it is and will be used as a clinical document.

- The CCR standard includes a schema that competes with existing standards for the XML syntax (HL7 CDA Release 2.0). Although there are valid arguments that could substantiate that this standard is in actuality a better representation of the clinical elements for addressing known use cases in the healthcare industry, the industry does not need two independently administered standards for the specification of EHR data. These efforts need to be tightly harmonized if not consolidated.

  My suggestion is to leverage the effective relationship with clinician societies (MMS, AAFP,AAP, etc) in nurturing their ownership of the information "content" of the CCR but do not include anything related to the electronic communication of this content in the standard itself. That is, the XML schema specified (and ultimately deployed in the industry for storing and transferring EHR data) should be an external reference to this standard with the appropriate data mappings of CCR "content" to EHR schema being specified in an Annex.

Negative

Date:	4/11/2005
Ballot Number:	E31 (02-05) Close Date: APRIL 16, 2005
Item Number:	001 SPECIFICATION FOR CONTINUITY OF CARE RECORD (CCR) (DTN 31E WK4363 (CONCURRENT WITH .2800) TECHNICAL CONTACT: MS CLAUDIA TESSIER CTESSI@ATTGLOBAL.NET (202) 659-2699
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File Attachment:	000294545_E310205_1.doc
Statement:	
see attachments	

Ballot Response

BALLOT: SPECIFICATION FOR CONTINUITY OF CARE RECORD (CCR) (DTN 31E WK4363 (CONCURRENT WITH .2800)
BALLOTER: Roberto Ruggeri, Microsoft Corporation

BALLOT VOTE: **NEGATIVE**

Rationale

In order of priority from the most important:

- Lack of openness in the standard development process:
  - no email distribution list is present
  - no central store for information/collaboration
  - no clear and documented process for accepting changes in the CCR schema
  - no meeting minutes or regular meeting calls
- Lack of a clear statement on where integration/interoperability with HL7 is going sends the wrong message to the industry. This will ultimately make implementation harder for vendors that will have to support multiple standards that do not interoperate. I'm not asking ASTM to adopt HL7 or vice versa, but to model the same concepts is a similar manner so that the two can be mapped and provide mapping guidelines as part of the implementation guide.
- The CCR XSD schema is wrong and would not validate with several XML parsers, including XMLSpy.

Negative

Date:	4/18/2005
Ballot Number:	E31 (02-05) Close Date: APRIL 16, 2005
Item Number:	001 SPECIFICATION FOR CONTINUITY OF CARE RECORD (CCR) (DTN 31E WK4363 (CONCURRENT WITH .2800) TECHNICAL CONTACT: MS CLAUDIA TESSIER CTESSI@ATTGLOBAL.NET (202) 659-2699
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File Attachment:	000392014_E310205_1.doc
Statement:	

Negative

Date:	4/18/2005
Ballot Number:	E31 (02-05) Close Date: APRIL 16, 2005
Item Number:	001 SPECIFICATION FOR CONTINUITY OF CARE RECORD (CCR) (DTN 31E WK4363 (CONCURRENT WITH .2800) TECHNICAL CONTACT: MS CLAUDIA TESSIER CTESSI@ATTGLOBAL.NET (202) 659-2699
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Statement:

Age - Units are not restrictive. Implementation guide specifies that Units should be restricted to Days, Weeks, Months, and Years but xsd does not support that restriction. page 83 of E31000000205001.pdf document.
DateTime - Type is not restrictive for ResultType complex type. On page 134 in table 12 of E31000000205001.pdf document it states:
" At a minimum, the DateTime of collection or physiological measurement should be included. Additional times such as when the was run, sent, or recorded can be included if and when pertinent."
How does one EMR vendor specify "when the was run, sent, or recorded..." ? Is it supposed to specified as:
Date Run
....

or

Run
....
What I am getting at is that to make this data interoperable there needs to be more restrictions. The way schema is right now is that it will be useful as far as taking data in a standard format and cary it around but when it comes to importing it it will be difficult and messy to import data from one EMR to another EMR. This problem with interoperability was shown at HIMSS Ambulatory Showcase. Everyone had to look at each others data and make sure that all of their types and the way data was layed out matched everyone else's. One of CCR's goals was to make data interoperable. To make it interoperable there needs to be more restrictions. Ristrictions may not be possible to put in place everywhere for every piece of data but restrictions should be put in place where it is possible.

Looking at the latest xsd and previous xsd designs it looks like there has been put a lot of thought into object oriented design of xsd. I think that more work needs to be done with xsd to make data as interoperable as possible.

It looks like there are quite a few enumeration simple types are defined in xsd but are not utilised anywhere in xsd itself. Those simple types are:
ActorRoleEnum
PaymentProviderEnum
DirectiveEnum
ProblemTypeEnum
RiskFactorEnum
AlertTypeEnum
ProductTypeEnum
YesNo
TestTypeEnum
...etc
Lets take ProblemTypeEnum for example. It looks like in the previous xsd spec ProblemType was and enumeration and now it is not an enumeration in the current xsd. Maybe I am missing something but I thought that work was being done to make xsd more restrictive but by the looks of the current xsd it looks like it is less restrictive than the previous version of xsd that was used for HIMSS Ambulatory Showcase.

Page 63 of document E31000000205001.pdf makes me think that current CCR xsd does not meet following paragraphs description:
" The CCR is an interoperability content standard for data expression and exchange, on paper as well as between healthcare information systems, and strict adherence to this Implementation Guide and the accompanying CCR XML Schema (.xsd) are required to support efficient interoperability. Unlike many other standards in use in healthcare, there are no end-user or vendor configurable fields in the CCR. Data optionality, cardinality, enumeration, and specificity of mapping are tightly controlled. Data content, their expression, and where exactly they must be placed are explicitly defined. In many instances the exact, enumerated allowed and required content is also explicitly spelled out."

Having Types all over the place that are none restrictive makes xsd not meet requirements of above paragraph.
The major objection to the CCR specification is its lack of recognition of existing object-oriented format specifications for the purposes of healthcare data exchange. The CCR specification will have the most impact if it is limited to the content of the snapshot, and reuses existing standards for the format of the interchange.

Negative

Date:	4/11/2005
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Item Number:	001 SPECIFICATION FOR CONTINUITY OF CARE RECORD (CCR) (DTN 31E WK4363 (CONCURRENT WITH .2800) TECHNICAL CONTACT: MS CLAUDIA TESSIER CTESSI@ATTGLOBAL.NET (202) 659-2699
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File Attachment:	000404878_E310205_1.doc
Statement:	

BALLOT RESPONSE
Draft Standard Specification for the Continuity of Care Record (CCR)
April 10, 2005

Thomson M. Kuhn
American College of Physicians
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General

Negative - This Standard ballot must explicitly identify everything in the standard that has been added, deleted, or modified in any substantive way since the previous balloted version. This ballot must be re-drafted and re-submitted for balloting. I have identified several such items below, but there are likely to be more. It seems extremely likely that substantive changes will slip through unnoticed by balloters.

Negative - The XML schema in Annex B is invalid. Attempting to validate the schema results in at least 11 fatal errors in one tool I tried. Without a valid schema, it is impossible to review the technical accuracy of the schema or the Implementation Guide. The ballot must be re-submitted for balloting with a valid schema.

ANNEX C Page 9.
In an ideal world all data expression in healthcare would be to a level of detail and standardization such that data from any system representing a specific concept would be identical to data from another disparate system representing the exact same concept.

Negative – The goal of semantic interoperability should be more important than ownership or personal preferences. There is a global standard for clinical documents – the CDA. The CDA already specifies the XML structures and the vocabulary for most of the content in the ASTM CCR ballot. Why would we bother to create our own variants on these structures and vocabularies and then try to map them? In the case of vocabulary, if you use different terms than the CDA standard specifies, just how do you go about mapping them? Why put all vendors through the bother of having to support the processing of two different document types? Wherever possible, the elements, structures and vocabularies specified in the CDA should be used as-is or further restricted in the CCR. Wherever an appropriate element, structure, or vocabulary is not specified in the CDA, the CCR requirements should be submitted to the HL7 Structured Documents Technical Committee for addition to CDA.

Standard

Note: The negatives below apply not just to the standard, but also to Annexes A, B, and C. These negatives should be considered in each context. My goal was to reduce the redundancy and length of this document.

1.2.1 Any examples offered in this standard are not to be considered normative.

Negative – The examples offered must not violate the definition of the CCR. See 4.3.3.

1.3.1 The CCR XML schema or .xsd (see Annex B) is defined as a data object that represents a snapshot of a patient's relevant administrative, demographic, and clinical information at a specific moment in time. The CCR XML is not a persistent document, and it is not a messaging standard.

Comment – Don't we mean that the XML Document is defined as a data object?

Negative – If the CCR is not a persistent document or a message, we must define exactly what it is. As it stands, this non-definition is ambiguous from a legal perspective.

3.1.53 xsd—The XML schema.

Comment – This should say "An XML schema". More specifically a W3C schema. There are plenty of other schema standards such as Schematron and Relax NG.

4.3.3 Personal health record: A person may keep copies of his/her CCRs and supplement them, for example, with alternative medicine information and other personal health information.

Negative – This example explicitly violates the definition of the CCR. The CCR is not a persistent document. See 1.3.1 and 3.1.36. It is a violation of the CCR standard to collect and save CCRs as documents.

5.1 The CCR consists of three core components: the CCR Header, the CCR Body, and the CCR Footer.

Negative – There are no CCR Header or CCR Footer structures defined in CCR. All elements that are mentioned in the text as being part of the header or footer actually appear as children of ContinuityofCareRecord, along with Body. While this may be just a convenience for discussion, it is confusing. We should clearly

identify the uses of these terms. They can not be identified as core components if they do not exist.

5.1.1.1 Unique Identifier of the CCR, generated by the originating entity/system uniquely identifies each explicit instance of a CCR.
5.1.1.1.1 The uniqueness of the ID is defined within the generating system and must be unique to and within each CCR but it not considered unique across the universe of CCRs

Negative – The Unique Identifier has been added to this version of the standard without being balloted. This Standard ballot must explicitly identify everything in the standard that has been added, deleted, or modified in any substantive way since the previous balloted version.

The Unique Identifier should be unique across the universe of CCRs. There are relatively simple ways to do it. It eliminates the possibility of a serious error. It has the added benefit of identifying the originating institution uniquely. It would reduce the effort required by the receiver to uniquely identify the CCR. The root should be specified as a UUID or an OSI Object Identifier (OID) that uniquely identifies the scope of the extension, and where the extension is an identifier that is unique within the scope of the root identifier for this version of the document. Organizations that wish to use OIDs must properly registering their OID root, and ensure uniqueness of the OID roots used in identifiers. There are a large number of mechanisms to obtain OID roots for free, or for a reasonable fee. ASTM could maintain a registry page for CCR users. Another useful resource lists the many ways to obtain a registered OID Root for free or a small fee, anywhere in the world, located at:
http://www.dclunie.com/medical-image-faq/html/part8.html#UIDRegistration

5.1.1.2 Date/Time refers to the exact time the data on a specific patient were aggregated to create a CCR, which is not necessarily the time the CCR was transmitted, printed, or sent.

Negative - The CCR Transmission Date has been removed from this version of the standard without being balloted. This Standard ballot must explicitly identify everything in the standard that has been added, deleted, or modified in any substantive way since the previous balloted version. The transmission date is at least as valuable as the creation date. CCR Transmission Date was required for electronic transmission in the previous version of the standard.

5.1.1.3 Patient identifies the person to which the CCR refers.

Negative - Preferred Mode of Contact and Language have been removed from this version of the standard without being balloted. This Standard ballot must explicitly identify everything in the standard that has been added, deleted, or modified in any substantive way since the previous balloted version. Both elements are useful and should not be removed.

5.1.1.6 Purpose defines the specific reason that a CCR is generated, such as patient admission, transfer, consult/referral, or inpatient discharge.

Negative – Reason and Reason attributes have been removed from this version of the standard without being balloted. This Standard ballot must explicitly identify everything in the standard that has been added, deleted, or modified in any substantive way since the previous balloted version. Reason was a required element in the previous version.

5.1.2.2 Advance Directives contains data defining the patient's advance directives and any reference to any existing supporting documentation and the physical location of that documentation, such as a durable power of attorney for healthcare.

Negative – We have reversed ourselves on the optionality of Advance Directives with no indication in the document. Advance Directives was a required section in the previous ballot, and a negative vote requesting optionality was unanimously found not persuasive. The change in optionality must be explicitly indicated in the standard and in each annex. Further the reason for this change must be explained in the Standard and in Annex C.

E31.28 Electronic Health Record Subcommittee Minutes
April 6, 2004
Point #14 – Page 17 the advance directives section should be optional. There are many conceivable uses for a CCR where it does not make sense to require an advance directive.
The subcommittee found this point not persuasive because the subcommittee feels that the advance directives should be required so that the next practitioner can know the information. If there is no advanced directive, the author of the CCR must state "none" and this is stated in the specification Annex A.
Subcommittee vote count: 23-0-0

5.1.3 CCR Footer contains the following sections:

Negative – The CCR Footer and its components have been added to this version of the standard without being balloted. This Standard ballot must explicitly

identify everything in the standard that has been added, deleted, or modified in any substantive way since the previous balloted version.

Annex A

Negative- Changes from the balloted version of the standard are not identified in any way. This makes it impossible for a balloter to perform a thorough and responsible review.

<PatientKnowledge>

Negative – This element includes a <Reason> element that is not included in Annex B or C.

Annex B

Negative – The schema is invalid. This makes it impossible for a balloter to perform a thorough and responsible review of Annex B and Annex C. No XML-based standard can possibly be considered, let alone approved, without a valid schema.

Negative – In addition to a valid schema, an XML-based standard should include a valid sample document and a stylesheet or other such technology that fully tests candidate documents for full conformance to the entire implementation guide, not just a simple XML validation by a parser.

Annex C

Page 4.
The implementation guide includes explicit requirements for implementation using specific XML tags some of which represent changes to the content from the first CCR standard.

Negative – The changes to the content are not identified as such. This Standard ballot must explicitly identify everything in the standard that has been added, deleted, or modified in any substantive way since the previous balloted version.

Page 5. CCR Principles and Structure
The CCR is defined as a data object . . .

Negative - Industry standard practice is that it is inappropriate to attempt to define a data object using an XML schema. If indeed the CCR is a data object,

there are industry best practices to describe or define it - UML and IDL are two of them. What is more, there is an ANSI standard for modeling healthcare information (using UML), and it is the HL7 RIM. For the sake of full interoperability in healthcare, the HL7 RIM must be used to model all healthcare data objects.

Page 6. The Body Sections contain the <Patient> data, within the following Sections:

Negative – This standard must allow for additional user-defined sections that may be required due to care, patient safety, or regulatory issues. Examples of possible additional sections might include chief complaint, associated complaints, admitting diagnosis, reason for visit, pre-surgical diagnosis, and post-surgical diagnosis.

Page 9.
Comment - All mentions of Figure 2 should be changed to Figure 1.

Page 11. CodedDescriptionType

Negative - Without any constraints on allowable <Attribute> values, there exists the potential for uncontrolled post-coordination, with no way to compare against pre-coordinated SNOMED codes.

Page 13. CodedDescriptionType
Example 4 is not considered ideal, as it represents a compromise data representation using a text string and structured representation of exactly the same data. This representation may seem the most flexible, but it inherently leads to data inexactitude and redundant data representation.

Negative – A fundamental requirement of the CCR must be that the receiver sees the CCR displayed in a form as close as possible to what the sender saw. Also, providing human readable text for all coded elements in CCR provides a sanity check on possible coding errors. This approach is ambiguous in terms of what a clinician actually saw and intended to say, since there will always be discrepancies between narrative and coded entries. The Text element should be required within CodedDescriptionType. No guidance is provided for the quite common case where a sentence or paragraph can only be partially encoded. How should this be tagged and how should this be rendered for the receiver.

Page 18. All CCR Object IDs:

The first character must be from the set A-Z, a-z.

Negative – Requiring the first character to be alpha precludes the use of universal identifier systems such as UUID or OSI Object Identifiers (OID). This standard should not prevent the use of universal identifier systems.

Page 28. CCRDocumentObjectID

Negative – The Unique Identifier should be unique across the universe of CCRs. There are relatively simple ways to do it. It eliminates the possibility of a serious error. It has the added benefit of identifying the originating institution uniquely. It would reduce the effort required by the receiver to uniquely identify the CCR. The root should be specified as a UUID or an OSI Object Identifier (OID) that uniquely identifies the scope of the extension, and where the extension is an identifier that is unique within the scope of the root identifier for this version of the document. Organizations that wish to use OIDs must properly registering their OID root, and ensure uniqueness of the OID roots used in identifiers. There are a large number of mechanisms to obtain OID roots for free, or for a reasonable fee. ASTM could maintain a registry page for CCR users. Another useful resource lists the many ways to obtain a registered OID Root for free or a small fee, anywhere in the world, located at:
http://www.dclunie.com/medical-image-faq/html/part8.html#UIDRegistration

Page 41, 97, and others. Reference and Comment

Negative – The Reference and Comment elements have entirely different models depending on where they appear in the document. This results in unnecessary confusion and introduces the possibility of error. All elements should always have only a single model with local constraints on that model. Where different models are used for the same element, one of the models should be given a different element name.

Page 58. FamilyHistory

The CCR supports a one-to-many relation from <Problem> to <FamilyMember> and from <FamilyMember> to <Problem>. The preferred usage in the CCR, however, is to list each <Problem> as a discrete entity and then list all family members who have or have had that problem.

Negative – FamilyMember is a sibling, not a child of Problem. Given a FamilyHistory section with lots of Problem elements and lots of FamilyMember elements, how does one sort out which problems go with which family members?

Should we repeat all appropriate FamilyMember(s) following each Problem? The IG must provide guidance if not change the model.

Page 61. SocialHistory

Negative – Description is a sibling, not a child of Type. Given a SocialHistory section with lots of Type elements and lots of Description elements, how does one sort out which types go with which descriptions? The IG must provide guidance if not change the model.

Negative – No guidance is provided as to how to tag data concerning Marital Status, Race, Ethnicity, and Religious Affiliation. If semantic interoperability is truly our priority, values for these data should be restricted to the appropriate HL7 vocabularies. Otherwise, how will we be able to compare data?

Page 65. Alert

Negative – Reaction is a sibling, not a child of Agent. Given a Agent section with lots of Reaction elements and lots of Agent elements, how does one sort out which Reactions go with which Agents? The IG must provide guidance if not change the model.

Page 93. <Telephone>

Negative – This standard should specify the use of IETF RFC 2806 for the format of telephone numbers. This will reduce the effort required to implement the dialing function in applications.

Issues Not Addressed in Annex C – Negative

In the reconciliation process for the previous ballot, the following items were identified as needing to be addressed in the IG. These items have not been addressed. Both items must be added to the standard and to the IG.

E31.28 Electronic Health Record Subcommittee Minutes
April 6, 2004

Point #5 - There should be a filed indicating the language that is used to create the CCR. It should not be assumed that all CCRs use English.
The subcommittee found this point not persuasive because this is not appropriate for this standard because the language translation issue is an implementation issue and will be addressed in the implementation guide as part of the XML Header.
Subcommittee vote count: 23-0-1

Point #6 – There should be a field indicating the current version of the CCR that this document represents. It is almost certain that there will be subsequent versions of the CCR and the user will need to know which version this particular document represents.
The subcommittee found this point not persuasive because this is an implementation or workflow issue. The XML header in the implementation guide will have a version header but this issue should not be addressed within this standard.
Subcommittee vote count: 24-0-1

Vocabulary

Negative – At least the following elements and types should draw their codes and values from the appropriate HL7 vocabulary. True semantic interoperability must be valued over proprietary concerns. There are likely to be many other elements that could be dealt with this way.

CodeType
Attribute
LinkRelationship
SequenceModifier
ActorRole
CodedDescriptionType
Indication
Type
Status
Problem
Severity
Agent

Negative

Date:	4/11/2005
Ballot Number:	E31 (02-05) Close Date: APRIL 16, 2005
Item Number:	001 SPECIFICATION FOR CONTINUITY OF CARE RECORD (CCR) (DTN 31E WK4363 (CONCURRENT WITH .2800) TECHNICAL CONTACT: MS CLAUDIA TESSIER CTESSI@ATTGLOBAL.NET (202) 659-2699
Member's Name:	DOUGLAS R HORNER
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Email Address:	HORNER@MIEWEB.COM
File Attachment:	000408211_E310205_1.doc
Statement:	

Negative Vote Comments
Medical Informatics Engineering April 8, 2005:

- The CCR depends on a global code right now to define many items, when their isn't a set definition of many of the items needing to be coded.
    - For example, how would a CCR definitively code a specific date about insurance coverage? There are no codes in SNOMED to cover this, and we are not aware of another global standard to use to define this type of element. If a sender just use the free form text, other systems won't have any idea what "Start of Coverage" means, if the receiving system understands it as another term in their system.
- No date of death on Actor/Person types (I'd imagine the CCR data could be sent for patients post-mortem). While we realize that the cause/date of death can be linked to as a part of a problem, searching through Problems/HealthStatuses doesn't seem like the most straightforward way of finding "date of death" for a patient.
- Need of a "miscellaneous" part of the body. Basically could be a section like the others, with 1 to infinity number of records, where all that is being sent is a CCRDataObjectID, DateTime's, Coded Description Type, and a value attribute. This would allow for transferring data not specified elsewhere in the CCR, but needing to be transferred, and would be recognized by the receiving system (because of previous arrangements between the sender and receiver). For example, patient financial information for a free clinic.
- IDs in Insurance Type is not very straight forward, doesn't match the layout (which has "IDNumber")
- ActorRoleEnum is mentioned as being used in many places in the documentation, but the XSD does not use it, only lists it.
    - As well, the ActorRoleEnum list of values is not complete at all. First, the family member on family history says it will use it, but, there are no family member types listed. Second, this is used for linking up things that are not people in some places, and there are no entities listed in the Enum (i.e. pharmacy, hospital, etc).

Negative

Date:	4/14/2005
Ballot Number:	E31 (02-05) Close Date: APRIL 16, 2005
Item Number:	001 SPECIFICATION FOR CONTINUITY OF CARE RECORD (CCR) (DTN 31E WK4363 (CONCURRENT WITH .2800) TECHNICAL CONTACT: MS CLAUDIA TESSIER CTESSI@ATTGLOBAL.NET (202) 659-2699
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Phone Nr:	7812293677 Fax Nr:
Email Address:	KEITH.BOONE@DICTAPHONE.COM
File Attachment:	000414961_E310205_1.doc
Statement:	

Negative

Date:	4/18/2005	
Ballot Number:	E31 (02-05)	Close Date: APRIL 16, 2005
Item Number:	001 SPECIFICATION FOR CONTINUITY OF CARE RECORD (CCR) (DTN 31E WK4363 (CONCURRENT WITH .2800) TECHNICAL CONTACT: MS CLAUDIA TESSIER CTESSI@ATTGLOBAL.NET (202) 659-2699	
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File Attachment:	000417540_E310205_1.doc	

Statement:

The CCR specification claims to be a core data set of the most relevant administrative, demographic, and clinical information facts about a patients healthcare, covering one or more healthcare encounters. The need for defining such a data set for the purposes of interoperability is well recognized, and a specification to satisfy that need is a valuable contribution to the world of healthcare IT.

The specification further describes the primary use of the CCR as providing a snapshot in time of the patients pertinent clinical, demographics, and administrative elements. This implies that the CCR can and should be utilized in many different use cases (and it is stated explicitly that the CCR applies to all healthcare settings).

Given the general nature of the CCR, it becomes necessary for the specification to be general and at an abstract level. This is emphasized by the claim that the CCR is not a persistent document, and it is not a messaging standard.

Given the above goals and claims, this ballot response is negative, based on the fact that the specification often contradicts its goals, and the technical and logical inconsistencies in the document make it unacceptable as a standards specification.
Please see the attached document for more details.

NEGATIVE BALLOT RESPONSE TO

SPECIFICATION FOR CONTINUITY OF CARE RECORD (CCR) (DTN 31E K4363 (CONCURRENT WITH .2800))

Vassil Peytchev
Lead Technical Advisor
Epic Systems Corporation

1 Overview

The CCR specification claims to be "a core data set of the most relevant administrative, demographic, and clinical information facts about a patient's healthcare, covering one or more healthcare encounters." The need for defining such a data set for the purposes of interoperability is well recognized, and a specification to satisfy that need is a valuable contribution to the world of healthcare IT.

The specification further describes the primary use of the CCR as providing a snapshot in time of the patient's pertinent clinical, demographics, and administrative elements. This implies that the CCR can and should be utilized in many different use cases (and it is stated explicitly that the CCR applies to all healthcare settings).

Given the general nature of the CCR, it becomes necessary for the specification to be general and at an abstract level. This is emphasized by the claim that the CCR is "not a persistent document, and it is not a messaging standard."

Given the above goals and claims, this ballot response is negative, based on the fact that the specification often contradicts its goals, and the technical and logical inconsistencies in the document make it unacceptable as a standards specification.

2 General Problems

2.1 Object representation approach (negative vote)

The specification represents the CCR via a W3C XML schema. While XML is often used to serialize objects represented in different object-oriented software architectures for both persistence and transfer between systems and applications (e.g. both Microsoft's .NET framework and Sun's Java platform have mechanisms for this), the W3C XML schema language is not designed to be the primary representation of objects. If the CCR specification would follow common industry practices for object-oriented design, it would use an object representation language like UML or IDL to describe the CCR data objects. If the specification insists on representing the data objects via XML, then a specific XML object representation language needs to be defined and used.

2.2 Specification of an XML format (negative vote)

The specification fails to distinguish between object representation using XML, and data formatting using XML. In fact, the specification contradicts itself. Section 1.3 states:

> To ensure interchangeability of electronic CCRs, this standard specifies XML coding that is required when the CCR is created in a structured electronic format. This specified XML coding provides flexibility that will allow users to prepare, transmit, and view the CCR in multiple ways, e.g., in a browser, as an element in a Health Level 7 (HL7) message or CDA compliant document, in a secure email, as a PDF file, as an HTML file, or as a word processing document. It will further permit users to display the fields of the CCR in multiple formats.

On one hand the specified XML coding is required, on the other users can prepare and transmit the CCR in multiple ways. It is clear that if the CCR is to fulfill its objective to apply to all care settings, and in various use cases, the specification needs to limit itself to describing the data objects in the CCR (i.e. the content). The format should be left to implementation guides for specific use cases (preferably using existing standards for formatting of healthcare information for the purposes of exchange).

2.3 Implementation guide is lacking use cases (negative vote)

Appendix C is presumably an implementation guide, but it lacks specific use cases for the use of CCR. If the CCR is to be used in all care settings, then use cases for these care settings need to be defined (based on common medical practices), and implementation guides prepared for the particular use cases. This will allow constraints specific to a use case to be defined formally (see 2.4).

2.4 Appendix C lacks formal constraints (negative vote)

It seems that Appendix C is meant to further constrain the CCR schema, which is a recognition of the limitations of the W3C XML schema language when it is used to describe objects and their attributes in a meaningful way without first defining the semantic foundations underlying these objects. What Appendix C lacks is a formal way to define these additional constraints. There are multiple ways to define additional constraints on XML content, among which are Schematron schemas, RelaxNG schemas, and XSLT transforms using XPath expressions.

2.5 Inconsistencies regarding persistence of the CCR (negative vote)

Section 1.3.1 states that “The CCR XML [sic] is not a persistent document…” As long as the CCR specification limits itself to content, this is by definition true. Section 1.1, however, states that the CCR “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 the continuity of care.” This, coupled with the statement in 1.1.2 that “[w]hen prepared in a structured electronic format, strict adherence to the .xsd [sic] (Annex B) and the Implementation Guide (Annex C) is required to support standards-compliant interoperability,” implies that the CCR, formatted using the XML defined in the specification, will be used in electronic transfers between systems and settings. The lack of use cases shouldn’t prevent an observer to notice that there are likely no systems or organizations, which will allow such electronic

transfers without requiring that the CCR persists both at the source and at the destination, as well as in points in between (e.g. in registries in the context of RHIOs).

Once the need for persistence is established, it is necessary for organizations and systems to treat persisted CCR information in a standardized way. In addition to the content of the CCR, this requires other attributes and metadata, commonly associated with a document paradigm. If these additional attributes are not standardized, interoperability will suffer. Note that these inconsistencies will cease to exist if the CCR specification does not attempt to define the format used for information exchange, and refers to existing standards for that purpose.

2.6 Standards developing process (negative vote)

I became a member of ASTM sub-committee E31.28 in November 2004 with the purpose to contribute to the development of the CCR specification. From that time until the ballot was announced, I didn't receive any communications regarding the work on the specification. When I inquired on the status of the specification, I was told that there is no special mailing list or group that I need to join, and the only additional information I received was that the vendor advisory group (V-TAG) was having discussions. By the time I contacted them, there were no more conference calls being held.

My understanding of the ASTM process is that a ballot document has to be approved by the subcommittee members before it can be submitted for voting. Even if I am incorrect in my understanding, the lack of communications between the authors of the specification and the sub-committee members is indicative of a closed process, contrary to the practices expected from an ANSI accredited SDO.

It is also unclear what the relationship of this specification is to the ballot that had taken place in March/April of 2004. From the lack of any materials available to ASTM members, it seems that the current ballot is a clean slate replacement of the previous one. If this is the case, this should be clearly indicated. If this is not the case, then changes from the previous version need to be made obvious.

3 Detailed problems

3.1 The CCR W3C XML Schema is not valid (negative vote)

The CCR schema in Appendix B is not valid. Since different validators have different level of compliance with the W3C Schema specification, it is necessary to check several tools to make sure that the schema is indeed valid. The schema fails validation using one of the industry standard tools, the Xerces parser. There are three types of errors:

- Invalid patterns in the definition of the DateTimeType complex data type.
- Definition of elements with the same name, but with different data types
- Improper type derivations

3.2 Requirement to use only elements (negative vote)

The specification states that

All data within the CCR must be contained within XML tagged elements.
No data are allowed in the CCR to be contained within XML tag attributes.

There are two problems with such a requirement. The first one is that the specification doesn't distinguish between data and metadata. An example would be the children of a <Code> tag – the <value> tag is the data, and the <CodeType> and <Version> tags are the metadata, or descriptions of the data. It is common practice to represent metadata as XML attributes, and text data as elements.

The second problem with such a requirement is that it is completely arbitrary, and has no reasonable explanation behind it. There are no technical reasons behind it (unless the promotion of particular technology, product, or vendor is the reason for it, although this is hard to imagine). The W3C schema language itself is an example of how attributes are used to define complex XML structures. Also, some of the elements in the schema are defined to be of the ID and IDREF data types. The W3C schema specification states about both of these data types (http://www.w3.org/TR/xmlschema-2/): "For compatibility … this datatype should be used only on attributes." Deviating from a W3C schema recommended practice seems to be contrary to the stated goal for the use of XML to promote interoperability.

3.3 Inability to convey concepts (negative vote)

The complex type CodedDescriptionType can have an ObjectAttribute child. The Attribute child of ObjectAttribute is supposed to convey a concept like Diagnosis (see example 6 in Appendix C). In Appendix B, the type of the Attribute element is xs:string, which means that any free text can be used as its value. In order to promote interoperability, concepts need to allow for coded descriptions. This is just one example of content defined as free text in places where semantic meaning is very desirable.

3.4 PersonNameType is vague and ambiguous (negative vote)

A person's name is one of the main attributes used in determining his or her identity. The PersonNameType specifies unbounded Given, Middle (even though middle names are usually given names), and Family elements, as well as unlimited suffixes, titles, and nicknames. The nickname element also lacks a type. There are no other specifications on the use of names, and Appendix C does not refer to PersonName in any way.

3.5 Format of ObjectID (negative vote)

The description of Object IDs on page 17 of Appendix C restricts the format to alpha-numeric plus dash, underscore, and period, and requires that all IDs start with an alpha character. There is no reasoning provided for this latter requirement, and it prevents the use of UUIDs and OIDs – the two main mechanisms for generation unique IDs

3.6 CodeType vs. CodingSystem (negative vote)

The examples for CodedDescriptionType show CodeType as one of the children of the Code element. The schema specifies that the children of the Code element are Value, CodingSystem, and Version, and the discussion of CodeType in Appendix C supports that naming.

3.7 Redundant element definitions (negative vote)

Several elements are defined multiple times without any indication for such a need. For example, just within few lines from each other, there is the globally defined reference ID

```
<xs:element name="ReferenceID" type="xs:IDREF"/>
```

followed by

```
<xs:element name="Reference">
            <xs:complexType>
                  <xs:sequence>
                        <xs:element name="ReferenceID"
type="xs:IDREF">
                              <xs:annotation>

<xs:documentation>This is an xs:IDREF to the
ReferenceObjectID in the References Section of the
CCR.</xs:documentation>
                              </xs:annotation>
                        </xs:element>
                  </xs:sequence>
            </xs:complexType>
</xs:element>
```

This is just one example showing the somewhat ad-hoc nature of the schema design, something which is hard to avoid if the W3C schema language is used to describe complex object relationships.

4 Suggestions for resolving the major issues with the current CCR specification

The major objective of the CCR specification is to define a data object describing the snapshot of healthcare information about a particular patient. Defining the content of the CCR is a major step towards interoperability and is an effort necessary for sharing information between systems. It is important to recognize that object-oriented format specifications for the purposes of healthcare data exchange already exist, and some of them are ANSI approved standards. The CCR specification will have the most impact if it is limited to the content of the snapshot, and reuses existing standards for the format of the interchange by referring to implementation guides for particular use cases.

4.1 Decide on, and define an object description format

In order to provide the most generally applicable description of the CCR, the specification needs to use an industry standard object description language and methodology. This will ensure consistency and will relieve the CCR working group members of the need to reinvent the complex building blocks of the specification. One candidate is the Unified Modeling Language (UML - http://www.uml.org/), which is a general-purpose language for describing object-oriented models. Another choice could be

the HL7 Version 3 Reference Information Model (which is built using UML), and the design process associated with it. The advantage of the RIM is that it is healthcare information specific, it has passed several consensus driven ballots, and it is an ANSI standard.

4.2 Remove the requirements for data formatting from the specification

The main part of the specification and Appendix A will need only minor modifications – the use of a new object description format (see 4.1), and the removal of references to the current XML format as required for creation and sharing will bring the specification to a form ready for ballot. Appendix B will not be necessary, or can be replaced by a "Readers Guide" to provide an introduction to the new object description format. The detailed constraints that the CCR needs in the general case, which are currently in Appendix C, will then have to be incorporated in the main specification body and in Appendix A.

4.3 Create use-case oriented implementation guides

As the specification states in section 1.5, the CCR grew out of the Patient Care Referral Form (PCRF), which covers a specific use case in a particular care setting. While the content of the CCR is designed for all care settings, different use cases will have their own specific requirements. This necessitates the creation of implementation guides for specific use cases. One example of such an implementation guide is the CDA-based Care Record Summary, which is currently under ballot, and which can cover the use cases where a persistent document is needed to represent the CCR. Other guides can cover use cases where message-based interoperability is better suited, or even direct object communication between systems is used (e.g. RMI in Java or .Net Remoting). These implementation guides will drive the adoption of the CCR specification, which ultimately will improve interoperability, and patient care.

Negative

Date:	4/18/2005
Ballot Number:	E31 (02-05) Close Date: APRIL 16, 2005
Item Number:	001 SPECIFICATION FOR CONTINUITY OF CARE RECORD (CCR) (DTN 31E WK4363 (CONCURRENT WITH .2800) TECHNICAL CONTACT: MS CLAUDIA TESSIER CTESSI@ATTGLOBAL.NET (202) 659-2699
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Email Address:	freida.hall@med.va.gov
File Attachment:	000419669_E310205_1.doc
Statement:	

Negative

Date:	4/18/2005	
Ballot Number:	E31 (02-05)	Close Date: APRIL 16, 2005
Item Number:	001 SPECIFICATION FOR CONTINUITY OF CARE RECORD (CCR) (DTN 31E WK4363 (CONCURRENT WITH .2800) TECHNICAL CONTACT: MS CLAUDIA TESSIER CTESSI@ATTGLOBAL.NET (202) 659-2699	
Member's Name:	DIDI DAVIS	
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File Attachment:		

Statement:

Eclipsys agrees with the concept of the CCR and sees it as a desperately needed Healthcare industry standard. However, this ballot as submitted has several issues both at a technical and logical level. These issues will cause problems with interoperability in the near and distant futures. First of all the standard ballot does not explicitly identify everything in the standard that has been added, deleted, or modified in any way from the previously balloted version. If the CCR is to be incorporated into EHR systems such as Sunrise Clinical Manager, issues with long-term validity of data need to be addressed. There are no use cases in the implementation guide (Appendix C) to define appropriately. The term used as role in the ballot is unclear. If EHR products are to use role based security this will need to be properly defined. The implementation guide and sections 5.1.1.4 and 5.1.1.5 do not properly define how to uniquely identify the CCRs across enterprises that may use various vendor products. Section 5.5 does not properly identify how harmonization of various vocabularies are to be used by different care settings. A minimum set of specific codes for each coded entry shall be explicitly identified. Lastly the XML schema is not valid. When we attempted to validate the schema, our validation tool reported many fatal errors. The ballot must be resubmitted for balloting with a valid schema.

Negative

Date:	4/18/2005
Ballot Number:	E31 (02-05) Close Date: APRIL 16, 2005
Item Number:	001 SPECIFICATION FOR CONTINUITY OF CARE RECORD (CCR) (DTN 31E WK4363 (CONCURRENT WITH .2800) TECHNICAL CONTACT: MS CLAUDIA TESSIER CTESSI@ATTGLOBAL.NET (202) 659-2699
Member's Name:	JOHN MOEHRKE
Address:	GE HEALTHCARE
	STE 200
	W126 N7449 FLINT DR
	MENOMONEE FALLS WI 53051
Phone Nr:	2622931667 Fax Nr:
Email Address:	JOHN.MOEHRKE@MED.GE.COM
File Attachment:	000420767_E310205_1.doc
Statement:	

Negative

Date:	4/18/2005
Ballot Number:	E31 (02-05) Close Date: APRIL 16, 2005
Item Number:	001 SPECIFICATION FOR CONTINUITY OF CARE RECORD (CCR) (DTN 31E WK4363 (CONCURRENT WITH .2800) TECHNICAL CONTACT: MS CLAUDIA TESSIER CTESSI@ATTGLOBAL.NET (202) 659-2699
Member's Name:	JOHN C DURHAM
Address:	1530 NEWNAN ROAD
	CARROLLTON GA 30116
Phone Nr:	6787960789 Fax Nr:
Email Address:	JOHNDURHAM@GREENWAYMEDICAL.COM
File Attachment:	

Statement:

To whom it may concern:
I may have inadvertently sent a previous statement for John Durham. This happened when I attached a file and clicked the save statement button below the file. It is unclear whether this sent my typed statement and/ or the file. Even though I clicked save statement there appears to be no way to review what was saved. When I clicked submit it prompted me to create a new statemtn as if the other had not saved. Please make sure there is no duplicate negative vote for John Durham. I will repeat my orginal statement and file attachement and try again.

To whom it may concern:
In addition to these comments I have attached a file with the details of my concerns. My negative vote is based on issues as noted in the the attachment regarding the unclear definition of the CCR, the question of persistence and the failure of validation of the XML schema using standard industry tools. There are also a number of apparent procedural issues that those who are more familiar with the process will address. In the reconsideration I would also hope there would be a greater focus on usability and data integrity, issues especailly important to me as a physician.

Respectfully submitted,
John Durham

Affirmative with Comment

Date:	3/28/2005
Ballot Number:	E31 (02-05) Close Date: APRIL 16, 2005
Item Number:	001 SPECIFICATION FOR CONTINUITY OF CARE RECORD (CCR) (DTN 31E WK4363 (CONCURRENT WITH .2800) TECHNICAL CONTACT: MS CLAUDIA TESSIER CTESSI@ATTGLOBAL.NET (202) 659-2699
Member's Name:	DONALD A NELSON
Address:	CEDAR RAPIDS MEDICAL EDUCATION FOUNDATION 610 EIGHTH ST SE CEDAR RAPIDS IA 52401
Phone Nr:	3193694490 Fax Nr: 3193640811
Email Address:	DONALDAFNELSON@CS.COM
File Attachment:	

Statement:

3.1.29 Although the LOINC web page uses the term 'database' in
decribing the project, I think it is misleading as a definition,
especially if it does not mention what the database contains. I suggest something like this:
3.1.29 LOINCLogical Observation Identifiers Names and Codes (LOINC) is a system of universal identification codes for laboratory observations and other clinical observations (such as hemoglobin, serum potassium, or vital signs), designed to facilitate exchange and pooling of results for clinical care, outcomes, management, and research.
Source http://www.loinc.org/

3.1.30 'Messaging standard' is a generic term; we have defined it to apply only to one standard. How about:
3.1.30 messaging standardA method of representing data in communicable form for electronic data exchange, such as that defined by HL7.

3.1.34 optionality 'or not' is duplicated. "Defining whether or not something is optional."

Inplementation Guide, Age, p25. I disagree with the restrictions here:
Age > 2 Years must be expressed in years [__ Years].
Unless this system allows age to be expressed in fractional (decimal) years, there is a potentially important loss of precision. Our EMR includes items of pediatric development, such as the ability to name 4 colors. The fact that the patient met this goal at 39 months rather than 45 months is significant. But by this schema the CCR would say that this was
accomplished at age 3 years in both cases.

Affirmative with Comment

Date:	3/21/2005
Ballot Number:	E31 (02-05) Close Date: APRIL 16, 2005
Item Number:	001 SPECIFICATION FOR CONTINUITY OF CARE RECORD (CCR) (DTN 31E WK4363 (CONCURRENT WITH .2800) TECHNICAL CONTACT: MS CLAUDIA TESSIER CTESSI@ATTGLOBAL.NET (202) 659-2699
Member's Name:	THOMAS M KURIHARA
Address:	T K STDS MANAGEMENT
	3800 N FAIRFAX DR/#207
	ARLINGTON VA 22203-1759
Phone Nr:	7035169650 Fax Nr: 7035164688
Email Address:	TKSTDS@MINDSPRING.COM
File Attachment:	

Statement:

Suggest that all instances of the use of "must" be changed to "shall," if that is in accordance with the ASTM Style Guide and the meaning is "to conform and to attain a high degree of interoperability.

Affirmative with Comment

Date:	3/21/2005
Ballot Number:	E31 (02-05) Close Date: APRIL 16, 2005
Item Number:	001 SPECIFICATION FOR CONTINUITY OF CARE RECORD (CCR) (DTN 31E WK4363 (CONCURRENT WITH .2800) TECHNICAL CONTACT: MS CLAUDIA TESSIER CTESSI@ATTGLOBAL.NET (202) 659-2699
Member's Name:	BARRY R HIEB MD
Address:	GARTNERGROUP
	2515 E 7TH ST
	TUCSON AZ 85716
Phone Nr:	5203206220 Fax Nr: 5203201230
Email Address:	BARRY.HIEB@GARTNER.COM
File Attachment:	

Statement:

Recommend renumbering section 3.1 which has duplicate and skipped numbers.
Is the identification of an information system (page 154) sufficient to identify the precise source if the system is an ASP data center running 7 different hospitals on the same version of a vendor's software?
The implementation guide looks great! Congratulations to those involved in its creation. The CCR is now ready to be used to make a real contribution to interoperability in the healthcare domain.

Abstention with Comment

Date:	4/18/2005
Ballot Number:	E31 (02-05) Close Date: APRIL 16, 2005
Item Number:	001 SPECIFICATION FOR CONTINUITY OF CARE RECORD (CCR) (DTN 31E WK4363 (CONCURRENT WITH .2800) TECHNICAL CONTACT: MS CLAUDIA TESSIER CTESSI@ATTGLOBAL.NET (202) 659-2699
Member's Name:	GEOFFREY SHORTEN
Address:	LABWARE AFRICA
	PO BOX 98725
	PO BOX 98725
	SLOANE PARK 02152
	REPUBLIC OF SOUTH AFRICA
Phone Nr:	2711516871 Fax Nr: 27114635728
Email Address:	SHORTEN@LABWARE.COM
File Attachment:	

Statement:

Ther is a spelling mistake on the PDF page 53 (i.e. not page 53 of 102) - 'Resusitation' should read 'Resuscitation':

Affirmative with Comment

Date:	4/18/2005
Ballot Number:	E31 (02-05) Close Date: APRIL 16, 2005
Item Number:	001 SPECIFICATION FOR CONTINUITY OF CARE RECORD (CCR) (DTN 31E WK4363 (CONCURRENT WITH .2800) TECHNICAL CONTACT: MS CLAUDIA TESSIER CTESSI@ATTGLOBAL.NET (202) 659-2699
Member's Name:	MS LORI R FOURQUET
Address:	E-HEALTHFIGN
	1056 DURHAM RD
	WALLINGFORD CT 06492
Phone Nr:	2032940479 Fax Nr: 2032949318
Email Address:	LORI.FOURQUET@SBCGLOBAL.NET
File Attachment:	

Statement:

There should be more clarification regarding coded values either through a reference to E1633, E1384, or HL7.

Affirmative with Comment

Date:	4/12/2005
Ballot Number:	E31 (02-05) Close Date: APRIL 16, 2005
Item Number:	001 SPECIFICATION FOR CONTINUITY OF CARE RECORD (CCR) (DTN 31E WK4363 (CONCURRENT WITH .2800) TECHNICAL CONTACT: MS CLAUDIA TESSIER CTESSI@ATTGLOBAL.NET (202) 659-2699
Member's Name:	TED BLIZZARD
Address:	MASS MEDICAL SOCIETY
	860 WINTER ST
	WALTHAM MA 02451
Phone Nr:	7814347003 Fax Nr: 7814644813
Email Address:	tblizzard@mms.org
File Attachment:	

Statement:

1)The group deserves enormous credit for the large amount of work done on the CCR. Their willingness to continuously evaluate improvements has been important.
2)Continued concerns regarding the interoperability with other health-care standards including HL7.
3)Concerns regarding the technical participation from vendors and other health-care entities.

Affirmative with Comment

Date:	4/15/2005
Ballot Number:	E31 (02-05) Close Date: APRIL 16, 2005
Item Number:	001 SPECIFICATION FOR CONTINUITY OF CARE RECORD (CCR) (DTN 31E WK4363 (CONCURRENT WITH .2800) TECHNICAL CONTACT: MS CLAUDIA TESSIER CTESSI@ATTGLOBAL.NET (202) 659-2699
Member's Name:	SHELLEY Y DI GIACOMO
Address:	837 SEDDON COVE WAY
	TAMPA FL 33602-5704
Phone Nr:	8636600781 Fax Nr: 8133180222
Email Address:	SDIGIAC1@TAMPABAY.RR.COM
File Attachment:	

Statement:

Spredsheet line 10- "To:" - to whome you are releasing data, either provider organization or specific practitioner should be required.

In the implementation guide it specifies when certain elements are valued, then a section becomes required. It seems this same consistent message should be referenced in the spreadsheet. For example, page 21 line 44 functional status- if a patient has an impaired functional status that requires immediate attention or accomodation upon transfer to another practitioner, then the information should be required. The same would be true for the section on Social History in the spreadsheet line 84. If a patient speaks an alternate language which would require immediate accomodation, then the element becomes required.

Spreadsheet sheet Section Family History Line 69. With the expanding field of genomics have we accomodated for the expression of available genomic typing data that is available.

Plan of care line 119. In the description we need to clearly define where we are in a treatment plan that is in progress. For example, if a medication is ordered 1 po tid x 10 days, the information provided should explicitly describe that the first 2 days of intervention (6 doses) are complete and the patient is to begin day 3 of treatment after transfer. Interventions that are in progress are at high risk of misinterpretation between providers.
In the implementation guide family history section, the example has a value of "yes" in the cause of death field. This is unclear to me.

Affirmative with Comment

Date:	4/18/2005
Ballot Number:	E31 (02-05) Close Date: APRIL 16, 2005
Item Number:	001 SPECIFICATION FOR CONTINUITY OF CARE RECORD (CCR) (DTN 31E WK4363 (CONCURRENT WITH .2800) TECHNICAL CONTACT: MS CLAUDIA TESSIER CTESSI@ATTGLOBAL.NET (202) 659-2699
Member's Name:	THOMAS E SULLIVAN
Address:	6 BRACKENBURY LANE
	BEVERLY MA 01915
Phone Nr:	9787295075 Fax Nr: 9787773105
Email Address:	sullivan@massmed.org
File Attachment:	

Statement:

This is a great step forward. Any minor objections can be dealt with quickly. If there are major objections, the will to improve patient safety, quality and efficiency should be strong enough to overcome differences of opinion.

Affirmative with Comment

Date:	4/18/2005
Ballot Number:	E31 (02-05) Close Date: APRIL 16, 2005
Item Number:	001 SPECIFICATION FOR CONTINUITY OF CARE RECORD (CCR) (DTN 31E WK4363 (CONCURRENT WITH .2800) TECHNICAL CONTACT: MS CLAUDIA TESSIER CTESSI@ATTGLOBAL.NET (202) 659-2699
Member's Name:	DON JORGENSON
Address:	INPRIVA INC
	220 W PROSPECT RD
	FORT COLLINS CO 80526
Phone Nr:	9704721441 Fax Nr:
Email Address:	DJORGENSON@INPRIVA.COM
File Attachment:	

Statement:

Under the Security and Privacy section of Annex C (page 26), Item 1 in the third paragraph states that the CCR should have a checksum calculated against the entire document and a W3C XML digital signature applied. Such a checksum is provided automatically (it is the digest derived from hashing) when an XML digital signature is applied. Suggested alternative language:
The CCR should have a W3C XML Digital Signature applied against the entire document.

Affirmative with Comment

Date:	4/18/2005
Ballot Number:	E31 (02-05) Close Date: APRIL 16, 2005
Item Number:	001 SPECIFICATION FOR CONTINUITY OF CARE RECORD (CCR) (DTN 31E WK4363 (CONCURRENT WITH .2800) TECHNICAL CONTACT: MS CLAUDIA TESSIER CTESSI@ATTGLOBAL.NET (202) 659-2699
Member's Name:	SAMI AITA
Address:	MEDCOMSOFT INC
	SUITE 900
	1200 EGLINTON AVE EAST
	TORONTO ON CANADA
	M3C1H9
Phone Nr:	4164438788 Fax Nr:
Email Address:	SAITA@MEDCOMSOFT.COM
File Attachment:	

Statement:

Usable Interoperability within the ASTM Continuity of Care Record (CCR) Framework

After careful analysis of the usability of the CCR transaction standard for the purposes of the highest level of clinical data interoperability and decision making, MedcomSoft believes that several requirements would be desirable for the definition of the standard and for certain technical data types.

First and foremost, CCR is currently defined as a snapshot of a patients relevant administrative, demographic, and clinical information at a specific moment in time. As a standard that meets the lowest levels of interoperability, in which a receiving system could only view the most current and relevant clinical data, this definition is correct and viable. However, to satisfy the needs of the highest levels of interoperability (Level 4), wherein a system could receive, import, incorporate and interpret clinical data, the CCR must be a complete set of patient demographic, administrative and clinical information, which could be considered the patients chart, at any given time. If CCR is going to move in the direction of full data import/export, it will need to make significant modifications to the current definition of snapshot in time, since the activities referenced within the documentation are often discrepant with this current definition. Furthermore, the standard could become more encounter-centric in the sense that all clinical data elements should be linked to encounters which would include the dates and originating provider information associated in order to qualify, organize and understand the relevance of these past data elements. This necessitates more robust internal linking of data in the CCR schema than currently exists.

The concept of the CCR being a complete patient clinical chart is a fundamental shift from the

original definition in the CCR standard, and affects the logic required for both sending and receiving information systems. In addition, data must be tagged in a manner that permits a receiving system to identify the information, in order to determine if that data exists in the system already. It also must be structured in a way that the receiving system can interpret the data.

Recommended technical requirements can be summarized as follows:

The adoption of numerical codification for codified datatypes (e.g. MEDCIN, SNOMED, LOINC based codes) is paramount in order for each data element in the CCR to be interpreted by any receiving system: whether it be for the purposes of viewing or importing data elements. For example, MEDCIN clinical codes include numerous modifiers, or attributes, each containing multiple options. A receiving system must be able to interpret each possibility for each attribute to be usable. The current XML schema allows this data to be included in a transmission. However, the use of these codesets within the current structure must be further standardized utilizing a numerically codified methodology in order for all sending and receiving systems to be compatible.

Adopting guidelines for distinct encounters is a necessity since the encounter is the focal point of any clinical chart. It defines the time and origin of any clinical data entered in system, and therefore must be uniquely identifiable. Any system attempting to import data must be able to determine if that data exists already in the system, and could verify this using the encounter as the focal point. The current XML schema allows this data to be included in a transmission, but, the definition of this portion of the CCR should be expanded to support standardized datasets in order to properly authenticate the encounter.

In order to use the CCR as an interoperable, complete chart solution, all clinical data must be assigned to a specific event or encounter. To do this, any clinical data element must link to a particular encounter, and thus an internal CCR link is required. Currently in the CCR schema, the internal CCR link does not exist in the area of CodedDescriptionType. This is a critical element that should be added to the schema to enable the tracking of information over time for any given clinical data element.

Affirmative with Comment

Date:	4/18/2005
Ballot Number:	E31 (02-05) Close Date: APRIL 16, 2005
Item Number:	001 SPECIFICATION FOR CONTINUITY OF CARE RECORD (CCR) (DTN 31E WK4363 (CONCURRENT WITH .2800) TECHNICAL CONTACT: MS CLAUDIA TESSIER CTESSI@ATTGLOBAL.NET (202) 659-2699
Member's Name:	LLOYD DEVINEY
Address:	SYMBIONT HEALTHCARE SYSTEMS
	5811 MISTY HILL COVE
	AUSTIN TX 78759
Phone Nr:	5123389873 Fax Nr:
Email Address:	LLOYD@SYMBIONT.BIZ
File Attachment:	
Statement:	

Schema Issues

1. XML Schema is invalid. Errors received by XMLSpy:

a. Two elements with the same name "DateTime" are directly, indirectly, or implicitly contained in the same particle. They must be defined with the same type name without derivations!

b. The content model of complex type 'ccr:SimpleProductType' is not a valid restriction of the content model of complex type 'ccr:StructuredProductType'.

2. //Insurance/Payer/IDs has no child elements.

3. Are there plans to define all of the restricted content in the schema rather than just some?

Reference Manual Issues

1. Table 6 on page 44 does not match schema. Payer tag is missing.

2. Example 24 is not valid according to schema.

Affirmative with Comment

Date:	4/1/2005
Ballot Number:	E31 (02-05) Close Date: APRIL 16, 2005
Item Number:	001 SPECIFICATION FOR CONTINUITY OF CARE RECORD (CCR) (DTN 31E WK4363 (CONCURRENT WITH .2800) TECHNICAL CONTACT: MS CLAUDIA TESSIER CTESSI@ATTGLOBAL.NET (202) 659-2699
Member's Name:	ROBERT A RUDY
Address:	RARE ADVISORS
	20 HOMESTEADER LANE/SUITE 201
	NEW HAVEN CT 06516-6632
Phone Nr:	2039346030 Fax Nr:
Email Address:	BOBRUDY1@JUNO.COM
File Attachment:	

Statement:

Knowing that this standard was based on the already in use Patient Care Referral Form used by Massachusetts and employs XML gives me great confidence that this standard will be widely used around the world. Congratulations to all who worked so very hard to get to this point in the approval process for this standard. I'm in awe of its completeness! Bob Rudy.

Affirmative with Comment

Date:	4/15/2005	
Ballot Number:	E31 (02-05)	Close Date: APRIL 16, 2005
Item Number:	001 SPECIFICATION FOR CONTINUITY OF CARE RECORD (CCR) (DTN 31E WK4363 (CONCURRENT WITH .2800) TECHNICAL CONTACT: MS CLAUDIA TESSIER CTESSI@ATTGLOBAL.NET (202) 659-2699	
Member's Name:	MICHAEL SPILLANE	
Address:	HEALTHVISION	
	1601 TRAPELO RD	
	WALTHAM MA 02451	
Phone Nr:	7819068452	Fax Nr:
Email Address:	MSPILLANE@HEALTHVISION.COM	
File Attachment:	000414380_E310205_1.doc	

Statement:

Approved with comments. See attached file.

Comments on Draft Standard Specification for the Continuity of Care Record (CCR), Version 1a (March 2005)

SCHEMA ISSUES

1. The XSD Schema needs to be provided as a separate downloadable file, not as text within a PDF file. Application vendors need to integrate this schema into their applications and cannot easily obtain it from a PDF.

2. The following enumerations are not referenced within the XSD. So although they are defined the schema does not require that data validates against this list:

   ActorRoleEnum
   PaymentProviderEnum
   DirectiveEnum
   ProblemTypeEnum
   RiskFactorEnum
   AlertTypeEnum
   ProductTypeEnum
   TestTypeEnum
   NormalTypeEnum
   ReactionTypeEnum

3. Several enumerations appear to be absent based upon implementation guide references to "restricted content". They include Alert Status, Directive Status, Problem Status, Health Status, Health Status Description, Cause of Death, Patient Knowledge Description, SocialHistory Type, Social History Status, Product Status, Result Type, Procedure Status, Plan Type, Plan Status, Order Request Type, Order Request Status, Actor Status

4. Other enumerations are incomplete and do not match the description in the Implementation Guide. They include ReactionTypeEnum (missing Minimal, Critical), DirectiveEnum (missing Support Status, misspelled Tube Feeding, missing Other), AlertTypeEnum (missing Critical Result), ProductTypeEnum (missing Supplies, Device? or Medical Device?)

IMPLEMENTATION GUIDE ISSUES

1. The implementation guide should include one or more fully populated, valid CCR samples to show how to map clinical data into the XML layout. Sample should include a compound CCR (i.e., An original CCR created by one practitioner, and subsequently annotated by another practitioner.)

2. The implementation guide should include Appendices that list the full set of lookup codes/enumerations permitted throughout the CCR. The definitions of XML should reference these Appendices rather than repeat the valid choices each time.

WORKFLOW ISSUE: PULL vs PUSH of content

This ASTM standard presupposes that a CCR will be generated by a practitioner in the course of documenting or completing a patient encounter. Essentially this is a model in which a CCR is pushed from point A to point B by human intervention. The content is determined by the user. What if the workflow were revised as follows:

- SYSTEM A contains a full patient record.
- SYSTEM B contains a minimal patient record.
- A user of SYSTEM B seeks a current snapshot of the patient's clinical record and generates a request to SYSTEM A for the last N days of data.
- SYSTEM A responds by automatically creating a CCR containing the last N days of data.
- SYSTEM B receives the CCR and obtains the requested information.

- The current CCR standard does not specify a standard means to request CCR data from another system for a requested period of time.

WORKFLOW ISSUE: UPDATING AN EMR via CCR

This ASTM standard is silent on workflow issues surrounding filing CCR content into an EMR system. Receipt of numerous similar CCRs raises the question of whether the receiving system should simply continuously overwrite codified data with each new CCR. Does omission of data from a CCR imply that the receiving EMR should delete the omitted data? How can a CCR be constructed to indicate that previously transmitted data is erroneous and should be removed from the patient record?

Michael Spillane
Healthvision
Director, Clinical Product Strategy
781.906.8452 / 781.663.0348 fax
www.healthvision.com

Affirmative with Comment

Date:	4/12/2005
Ballot Number:	E31 (02-05) Close Date: APRIL 16, 2005
Item Number:	001 SPECIFICATION FOR CONTINUITY OF CARE RECORD (CCR) (DTN 31E WK4363 (CONCURRENT WITH .2800) TECHNICAL CONTACT: MS CLAUDIA TESSIER CTESSI@ATTGLOBAL.NET (202) 659-2699
Member's Name:	DIANE P FABIAN
Address:	SOURCE IT INC
	10 FLORENCE DR
	MANORVILLE NY 11949
Phone Nr:	6318780769 Fax Nr: 6318780769
Email Address:	DAISY4DEE@AOL.COM
File Attachment:	
Statement:	

Specifications 5.1.2.5 Problems
Listing problems in reverse chronological order or ranking problem according to order of importance for referral purposes may create confusion. This may need further clarification.

Affirmative with Comment

Date:	4/15/2005
Ballot Number:	E31 (02-05) Close Date: APRIL 16, 2005
Item Number:	001 SPECIFICATION FOR CONTINUITY OF CARE RECORD (CCR) (DTN 31E WK4363 (CONCURRENT WITH .2800) TECHNICAL CONTACT: MS CLAUDIA TESSIER CTESSI@ATTGLOBAL.NET (202) 659-2699
Member's Name:	GEORGE E COLE
Address:	ALLSCRIPTS HEALTHCARE SOLUTIONS INC 29 VALLEY SPRING RD NEWTON MA 02458
Phone Nr:	6179640556 Fax Nr:
Email Address:	GEORGE.COLE@ALLSCRIPTS.COM
File Attachment:	000417608_E310205_1.txt
Statement:	

CCR Ballot Comments

The organization and information containted is excellent. However, these are troubling areas:

1) no unique document identifier - according to the spec it only has to be unique within the confines of the Document Source...seems like a huge mistake; suggest use of an OID prefix to guarantee document id uniqueness.

2) no schema version number with the document - given a ccr, how do we know what schema it validates against ? Suggest adding some version number.

3) the newly proposed schema is not backwards compatible with the previous one - this is so terrible in and of itself, but without any indication in the document of the schema or version we're at a loss as to what we have.

4) one of the examples declares that the use of both text and coded data is not optimal - I disagree, since the Document Source cannot know the capabilities of the Consumers, it seems to me to be mandatory that text always be provided for elements, with coded information provided where possible.

Affirmative with Comment

Date:	4/12/2005
Ballot Number:	E31 (02-05) Close Date: APRIL 16, 2005
Item Number:	001 SPECIFICATION FOR CONTINUITY OF CARE RECORD (CCR) (DTN 31E WK4363 (CONCURRENT WITH .2800) TECHNICAL CONTACT: MS CLAUDIA TESSIER CTESSI@ATTGLOBAL.NET (202) 659-2699
Member's Name:	DENNIS LYMAN
Address:	PARTNERSHIP HEALTHPLAN OF CALIFORNIA 360 CAMPUS LN SUISUN CITY CA 94534-1400
Phone Nr:	7078634405 Fax Nr:
Email Address:	LDENNIS@PARTNERSHIPHP.ORG
File Attachment:	
Statement:	

Fine piece of work. It seems to be getting close to a mini medical record. Could it be merged with the CDA?
Lyman Dennis

Affirmative with Comment

Date:	4/18/2005
Ballot Number:	E31 (02-05) Close Date: APRIL 16, 2005
Item Number:	001 SPECIFICATION FOR CONTINUITY OF CARE RECORD (CCR) (DTN 31E WK4363 (CONCURRENT WITH .2800) TECHNICAL CONTACT: MS CLAUDIA TESSIER CTESSI@ATTGLOBAL.NET (202) 659-2699
Member's Name:	KEN MILLER
Address:	SOLVENTUS LLC
	625 OAKS DR #305
	POMPANO BEACH FL 33069
Phone Nr:	3057852264 Fax Nr:
Email Address:	KEN.MILLER@SOLVENTUS.COM
File Attachment:	

Statement:

There are numerous inconsistencies between the documented XSDand the diagrams shown in the implementation guide. For instance, the FreqDurGroup group has DateTime, Rate, Frequency, Interval, and Duration elements in the XSD, but only Frequency and Duration elements in the diagrams in the implementation guide. In fact, this causes the XSD to be invalid (according to XMLSpy) because EncounterType will have two DateTime elements implicitly defined. Also the IDs reference type does not appear to be defined in the XSD. These issues should be cleaned up before wide distribution of the XSD.
Additionally, I would suggest that the DateTime types for objects be far more tightly constrained.

Affirmative with Comment
Vote from Non-Member

Date:	4/6/2005	
Ballot Number:	E31 (02-05)	Close Date:
Item Number:	001 SPECIFICATION FOR CONTINUITY OF CARE RECORD (CCR) (DTN 31E WK4363 (CONCURRENT WITH .2800) TECHNICAL CONTACT: MS CLAUDIA TESSIER CTESSI@ATTGLOBAL.NET (202) 659-2699	
Member's Name:	KAHN, STASIA	
Address:		
	FOX PRAIRIE MEDICAL GROUP	
	2560 FOXFIELD	
	SUITE 160	
	SAINT CHARLES IL 60174	
	USA	
Phone Nr:	(630) 858-4936	Fax Nr:
Email Address:	stash5@sbcglobal.net	
File Attachment:		

Statement:

As a physician who is currently working within an EHR my comment would be that before the E31.28 committee accepts the CCR in its final format that a test CCR needs to be generated by a physician working within an exhisting EHR on a test patient. What if it takes 2, 3, 4 hours to generate that CCR. The ideas look great on paper and I read through every page. In the back of my mind I kept asking myself how long is it going to take me to make a CCR for one of my own patients. I would be willing to make a CCR on a test patient to avoid HIPPA issues. I am using Nextgen as my EHR. I think a test needs to be done before the committee meets on April 26. It would be a good idea to make several versions such as Pt transferring out of state, needs complete health record- Patient going to Florida for a weekend, just needs basic problems and medications in case of emergency-Referral to a University consultant from a private practioner, needs problem oriented data. I think that primary care physicians will be source of most CCRs. If you do decide to make test CCRs, a practicing primary care physician would be your best resource. Respctively Yours, Stasia Kahn MD