A Rebuttal to Wes Rishel's Gartner Report 'Two Versions of Continuity of Care Record Offer Different Approaches to Interoperability' – *and a Proposal for Rapid Progress on Interoperability*

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Disclosure

The authors wish to disclose up front they are directly affiliated with the ASTM as lead authors in the drafting of the ASTM CCR Standard Specification, and that Wes Rishel, as acknowledged in his paper, is a member of the HL7 Board of Directors and one of the lead authors of the HL7 CDA HIPAA Claims Attachment Implementation Guide. It is also important to state that the authors of this document have an unfair advantage in this discussion, having had access to the latest versions of the standards for the ASTM CCR and HL7 CDA (CDA r2) at the time this document is written. Mr. Rishel's Gartner Research Report was published prior to the release of the ASTM CCR ballot and thus was based on prior versions of that standard. The authors and Mr. Rishel have worked together extensively in the health care information systems industry, particularly in the standards arena with both ASTM and HL7, but also with X12, NCPDP, and with the Federal Government, and have the highest regard for each other and for our respective professional opinions. This paper is written in response to a Research Report by Wes Rishel of Gartner, Inc. titled *Two Versions of Continuity of Care Record Offer Different Approaches to Interoperability*.

Key Points at Issue

A recent Research Report by Wes Rishel of Gartner, Inc. titled *Two Versions of Continuity of Care Record Offer Different Approaches to Interoperability* encouraged user and implementers of computer-based patient record systems to put their support behind a single standard and XML format to represent clinical data in support of continuity of care. Mr. Rishel further recommended that the standard that should be adopted by the industry for these purposes should be the Clinical Document Architecture (CDA) version of a Continuity of Care Record from the standards development organization (SDO) Health Level 7 (HL7) and not the Continuity of Care Record (CCR) standard from the standards development organization ASTM International (ASTM). Mr. Rishel postulated that, 'Because the Clinical Document Architecture version offers a greater ability to leverage existing code and skills across many document types, it is the preferable approach.'

This paper is a rebuttal to Mr. Rishel's position and defines the distinct and unique characteristics, use cases, and utility of both the HL7 CDA and ASTM CCR standards. The paper also demonstrates the need for both approaches, working together, yet maintaining them as separate concepts and expressions of data at this stage in the evolution of standards that promote seamless and relevant clinical information exchange. The ultimate intention is to utilize these vehicles in support of the interoperability of electronic health record systems and the clinical continuity tools needed to assure safe and effective patient care.

In our view the HL7 CDA and the ASTM CCR are not 'two versions' of the same thing. They are designed to address very different issues. We also believe there exist fundamental misunderstandings surrounding each of these standards. The HL7 CDA, represents a clinical document architecture standard, and seems generally well understood by certain vendors and specialists in health care informatics. The ASTM CCR represents a standard patient care record summary and in contrast, the fundamentals and history surrounding it are far less well understood.

The History of the ASTM Continuity of Care Record

The Continuity of Care Record (CCR) was developed by ASTM at the request in May 2003 of Tom Sullivan, MD, and the Massachusetts Medical Society (MMS) with additional sponsorship coming later from the American Academy of Family Physicians (AAFP), the American Academy of Pediatrics (AAP), the American Medical Association (AMA), the Healthcare Information Management and Systems Society (HIMSS), the Mobile Healthcare Alliance (MoHCA), the Patient Safety Institute, the American Healthcare Association, and the National Association for the Support of Long term Care.

Work on the standard got underway in 2003 under the auspices of ASTM Technical Committee E31 on Healthcare Informatics and was specifically assigned to Subcommittee E31.28 Electronic Health Records chaired by Claudia Tessier of the MoHCA and Tom Sullivan, MD, of MMS who formed a CCR Workgroup. Security, confidentiality, and privacy work for the standard was assigned to ASTM Subcommittee E31.20 Security and Privacy chaired by Lori Forquet and Dale Miller.

The initial work of the ASTM CCR Workgoup involved a conversion from a printed form into an XML schema (.xsd) of the Patient Care Referral Form (PCRF) designed and mandated by the Massachusetts Department of Public Health for use in the transfer of patients primarily from the inpatient setting to nursing or longterm care facilities. Ted Blizzard from the MMS and Tom Sullivan, MD did this work with Roberto Ruggeri from Microsoft. David C. Kibbe, MD, from the AAFP, in August of 2003 then suggested generalizing the purpose of the CCR to include all the data elements necessary to express a comprehensive health care summary of a patient's complete health care status at any given point in time – aka a 'snapshot.' This was done with the extensive participation and expertise of the sponsoring organizations, the members of E31, as well as the EHR, PHR, HIS, and ePrescribing vendors who are members of E31. From this start the subcommittee undertook a detailed analysis – discussed later in this paper, of the ideal XML architecture and approach.

An initial demonstration of the ASTM CCR, using the original XML schema as an example, was tested by several vendors at the IHE 'Connectathon' in San Diego in January 2004 and introduced as a prototype at the HIMSS Annual Conference in February 2004 in Orlando. Following the HIMSS 2004 Annual Conference, HL7's Board and ASTM International agreed with the assistance of Bill Braithwaite, MD, to issue a Memorandum of Understanding (MOU) to coordinate efforts to harmonize the CCR standard and the pertinent parts of the CDA. The MOU was signed in September 2004 and states that both SDOs want the standards to be interoperable.

Also following the HIMSS 2004 Annual Conference CCR demonstration, a new schema was defined with the extensive assistance of a cross section of EHR vendors and Microsoft's health care group. A preliminary Implementation Guide was written in March 2004 and a comprehensive demonstration involving thirty (30) EHR vendors exchanging CCRs via USB 'thumb-drives' was held at the Medical Record Institute's Towards an Electronic Patient Record (TEPR) Conference in May 2004. Immediately following the TEPR conference, the initial CCR specifications were balloted under the ASTM, ANSI accredited consensus process and passed as a formal standard in May 2004.[1]

Following the May 2004 meeting, work began immediately on a comprehensive Implementation Guide and revisions to the core CCR XML schema (.xsd) starting with a proposal from Roberto Ruggeri and Raj Krishnan from Microsoft to normalize the schema. In addition, Pat Wise of HIMSS arranged for Integrating the Healthcare Enterprise (IHE) to coordinate a second demonstration of the ASTM CCR, in conjunction with the HL7 CDA at the HIMSS 2005 Annual Conference. IHE assisted ASTM E31.28 in defining a constrained version of the ASTM CCR and then established a technical framework and 'Integration Profile' for the ASTM CCR for HIMSS 2005. Keith Boone from Dictaphone and an IHE member formed a Technical Advisory Group (TAG) for ASTM E31.28 and the CCR with the assistance of Ted Blizzard of MMS. The TAG held telephone conference calls with participating EHR, PEHR, and ePrescribing vendor representatives to the ASTM CCR TAG through the fall of 2004 to finalize the CCR XML schema (.xsd).

[1] www.astm.org, Technical Committee E31 Healthcare Informatics.

The ASTM CCR XML schema (.xsd) was finalized in late 2004 and the standard, a data element spreadsheet, and the .xsd were conformed and a detailed Implementation Guide was completed. Feedback from the IHE/HIMSS ASTM CCR and HL7 CDA demonstration at the HIMSS 2005 Annual Conference was incorporated into this work. In addition, through the summer and fall of 2004, the author, Alan Zuckerman, MD, and Peter Kaufman, MD worked with the NCPDP SIG Standard Industry Task Group to conform the CCR XML schema (.xsd) with proposed changes to the NCPDPScript ePrescribing standard to allow the expression of essentially any inpatient, outpatient, or long term care medication order or prescription in both NCPDP Script and the ASTM CCR.

A new ASTM CCR Standard was then released for ballot under the ASTM consensus process March 17th, 2005. The ballot period is thirty (30) days with a closing date of April 17th and a ballot reconciliation meeting of ASTM E31.28 and the E31 Main Committee is scheduled for April 26th, 2005 in Washington, DC.

Harmonization of the ASTM CCR with the HL7 CDA has been underway since 2004 with an initial presentation of an ASTM CCR as a CDA template at the HL7 meeting in Acapulco on October 21st, 2004, by Liora Alschuler, Roberto Ruggeri, Ted Blizzard, and others. Further harmonization work is scheduled for April 2005 between HL7 and ASTM with the intent of rapid harmonization. In addition, ASTM and NCPDP are currently pursuing a Memorandum of Understanding (MOU) to formalize work already underway between NCPDP and ASTM, as discussed above, with a target delivery of a new NCPDPScript standard (the SIG segment) by June or July 2005 for use in the planned CMS ePrescribing demonstration projects of both 'Foundation' and 'Advanced' standards scheduled for January 2006. The NCPDPScript text string (EDIFACT) standard and the ASTM CCR XML are specifically designed to map with one-hundred percent (100%) conformance.

The Design of the ASTM Continuity of Care Record (CCR)

The CCR represents a comprehensive summary and snapshot of a patient's relevant current and historical health care data at the time any instance of the CCR is generated. The CCR is designed to support the following core use cases, although this list is not considered exhaustive or intended to limit the potential use of the CCR to these cases.

The CCR is designed to support:

- Transfer of a patient's care under one health care provider to care under another health care provider, as in a referral from a primary care giver to a subspecialist.
- Transfer of core patient data to/from an Electronic Health Record (EHR) to/from another EHR.
- Transfer of core patient data to/from an EHR to/from a Personal Electronic Health Record (PEHR).
- Printing to paper or saving to portable digital media core patient data for the patient's own use or for the patient to be able to physically transfer their data from one health care provider to another, whether or not either health care provider used an EHR.

- Transfer of core patient data to/from an Electronic Health Record (EHR) to/from a Hospital Information System (HIS) or a departmental system such as a Laboratory Information System (LIS) or Radiology Information System (RIS).
- Extraction of all of the core patient data contained in an EHR when a health care provider wishes to replace an installed EHR within their practice setting with a different EHR. This feature is considered attractive as an 'insurance policy' in the event an EHR vendor ceases business or support for a specific product for a reason beyond the control of the products' end-users and the end-users need to switch to an alternative EHR solution.

The ASTM CCR is an XML document, but the use of the word 'document' refers technically to the XML as a document, consistent with the use of the term 'document' in the general computer industry. The ASTM CCR is not, however, a 'clinical document' – such as a Clinical Note, Encounter Note, History & Physical, or Discharge Summary, each of which are medical legal documents, generated and signed by one or more directly responsible clinical authors.

The best way to understand a ASTM CCR is as a collection of data from many clinical documents – documents such as Clinic Notes, H&Ps, Discharge Summaries, Prescriptions, Orders, Results documents, Operative Reports, Procedure Notes, etc. The ASTM CCR is what physicians or clinical or administrative health care providers generate either on scratch paper, in our heads, or in another document such as an H&P or Discharge Summary when they 'review' the patient chart or charts. The ASTM CCR is an aggregation of all of the pertinent data from all the documents in the chart(s) and the compilation and parsing of that data into a uniform and easily interpreted format – the CCR. This is illustrated in *Figure 1*. To reiterate, the ASTM CCR is not a 'clinical document;' the ASTM CCR is an aggregation of clinical and administrative data from multiple documents from multiple disparate sources.

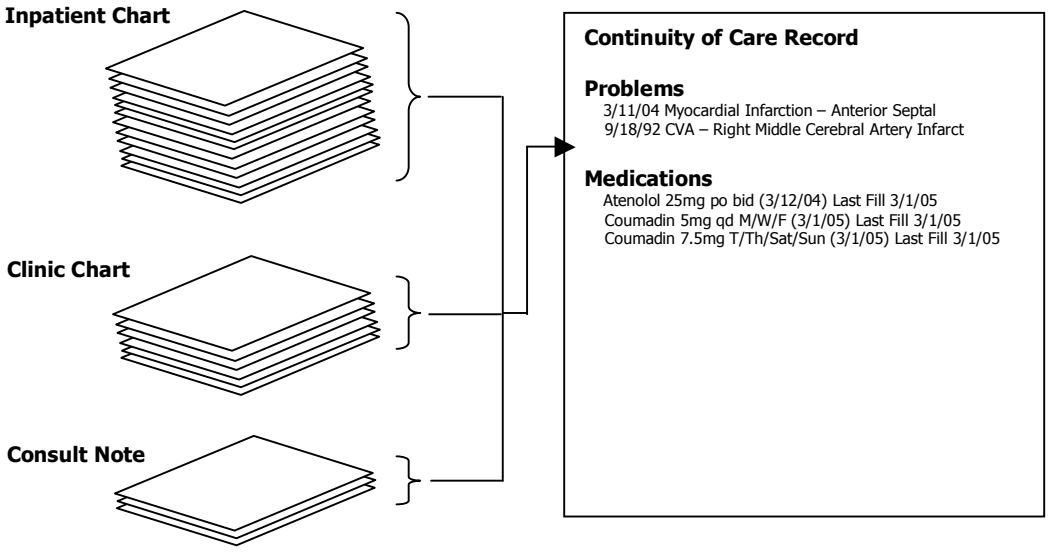

Figure 1 – **The Core Concept of the ASTM Continuity of Care Record (CCR)**

Another good way to look at the ASTM CCR is as the 'Patient Summary' or 'Patient Overview' within EHRs and/or PEHRs. Essentially most EHRs treat data very much like the CCR does. EHR data entry tends to be through the generation of clinical documents. Those documents are stored in the EHR database, but at the same time some of the information in those documents is broken out into a set of tables that define the various clinical concepts health care providers need to support clinical decision making.

A 'problem list' in most EHRs is stored in a table that is derived from data entered into documents. If an EHR end-user wants to look at the patient's problem list, the EHR does not query all the documents; the EHR queries the 'problem list table.' This is true for the medications list, the allergies/adverse reactions list, the outstanding orders, and a core set of additional administrative and clinical data sets. Each EHR architecture does this differently, but the principle is generally the same. One of the key advantages of EHRs for real-time clinical decision-making by physicians is that EHRs automate the aggregation of pertinent data in this fashion, a process that is painstaking, time consuming, and susceptible to errors of omission in the world of the paper chart.

The ASTM CCR takes this paper and EHR-based data aggregation approach and instantiates it into a uniform, standardized, and highly constrained format using XML. The data model used is an object-oriented model, with each critical clinical or administrative concept defined as an object and each of its attributes defined as data attributes.

This leads to a set of core ASTM CCR XML principles:

1) The CCR structure and architecture are object-oriented.
    a) The CCR is an XML document that is defined as an XML Document Object.
    b) The CCR Document Object is constructed from a set of discrete XML building blocks, which are defined as Data Objects.
    c) The Data Objects are contained within Sections, such as Medications, Immunizations, Problems, and Procedures, in the CCR Document Object.
    d) Each discrete Medication, Immunization, Problem, Procedure represents a discrete data object within the CCR.
    e) A Medication List or Problem List, therefore, represents a list of discrete Data Objects, within a specific Section and within the CCR Document Object (the CCR itself).

The CCR essentially consists of three core components:

1) A Set of Header Sections
2) A Set of Body Sections
3) A Set of Footer Sections

The Header Sections define:

- <CCRDocumentObjectID>
- <DateTime>

- <Patient>
- <From>
- <To>
- <Purpose>

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

- <Insurance>
- <AdvanceDirectives>
- <Support>
- <FunctionalStatus>
- <Problems>
- <FamilyHistory>
- <SocialHistory>
- <Alerts>
- <Medications>
- <MedicalEquipment>
- <Immunizations>
- <VitalSigns>
- <Results>
- <Procedures>
- <Encounters>
- <PlanOfCare>
- <HealthCareProviders>

- The Footer Sections contain the normalized links within the CCR for:

  - <Actors>
  - <References>
  - <Comments>
  - <Signatures>

The CCR core XML structure is represented in *Figure 2*.[2]

[2] This XML diagram is generated with XMLSpy from Altova (www.xmlspy.com). It is extracted, with permission, from the ASTM Draft Standard Specification for the Continuity of Care Record (CCR)1, Version 1a (March 2005). This document is not an ASTM standard; it is under consideration within an ASTM technical committee but has not received all approvals required to become an ASTM standard. It shall not be reproduced or circulated or quoted, in whole or in part, outside of ASTM committee activities except with the approval of the chairman of the committee having jurisdiction and the president of the society. Copyright ASTM, 100 Barr Harbor Drive, West Conshohocken, PA 19428-2959. All rights reserved."

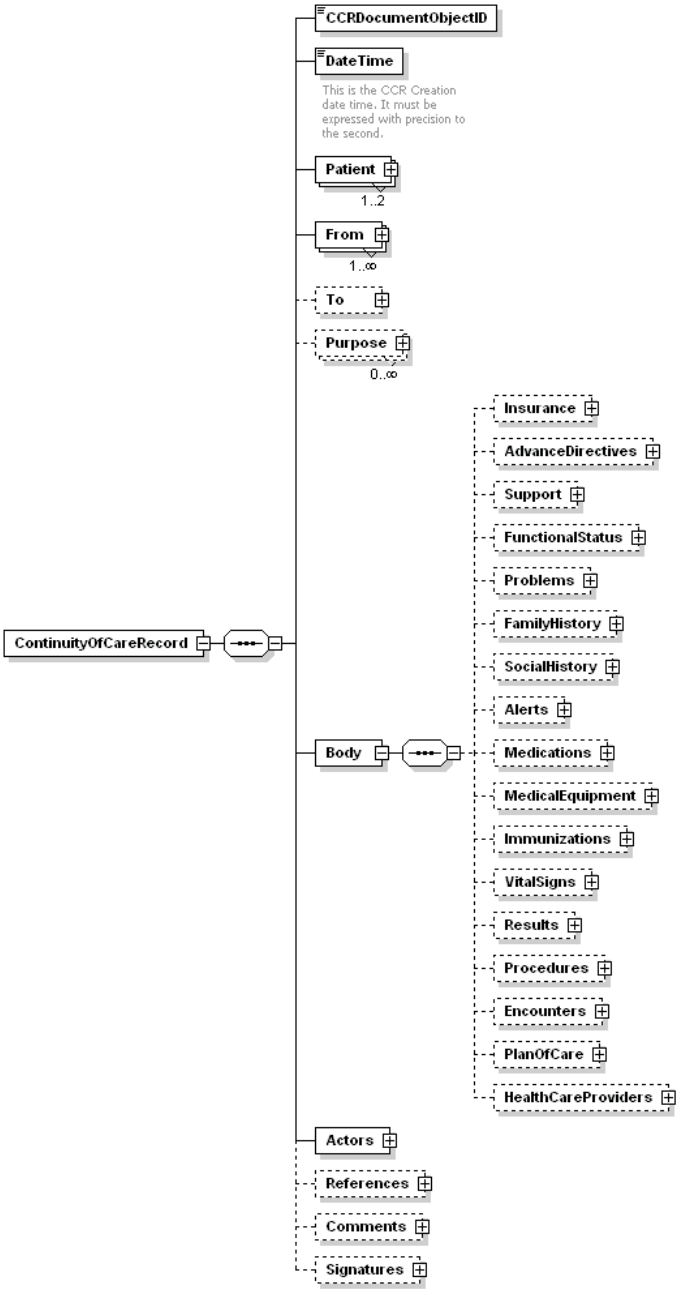

Figure 2 – **Overall XML Structure of the ASTM CCR**

The ASTM CCR Standard and its Implementation Guide define the expression of patient-specific health care data within this core ASTM CCR XML framework and in the 'sections' that are data containers for comprehensive patient data.

Within these sections/content containers, data within the ASTM CCR are intended to be expressed in as much detail as possible. The ASTM CCR is designed to promote highly structured and coded information to support not only data exchange, but also to support complex data expression as well as both human and automated clinical decision support,

through the use of alerts, reminders, performance measures and sophisticated data analysis. In a simplified description, the ASTM CCR 'Alerts' are oriented toward patient safety considerations of constant and immediate importance, whereas CCR 'Reminders,' embedded in the ASTM CCR Plan of Care section are oriented toward Clinical Quality Improvement (CQI), disease management, and longer term considerations.

The Key Differences Between the HL7 CDA and the ASTM CCR

The 'Technical Addendum' to this paper describes in detail the technical analysis and design that went into building the ASTM CCR, including explicitly why the CCR does not use the HL7 CDA or CDA XML. In addition to the technical differences between the XML design and data architecture approaches taken by HL7 and the ASTM CCR Workgroup, it is important to define the exact intent and use of each standard. It is also important to look at how potentially complementary they are, and how harmonization will benefit the entire health care industry.

The HL7 CDA standard was the result of work begun in the late 1990's by HL7's XML Special Interest Group. The work of this Special Interest Group influenced the use of XML for HL7 Version 3 (called the 'Kona' proposal initially) and out of this group the CDA effort, under the chairs Bob Dolin, MD and Liora Alschuler originated. The intent of the CDA was to define a common document architecture and ontology or a description of relationships among clinical documents using XML. The goal was to support the expression and exchange of the many and varied clinical documents between and among incompatible health care information systems in a uniform format.

Early discussions concerning the CDA revolved around specific use cases as well as what the real structure and best technical representation of data should be within a document. There were essentially two views – the first is that a document is a data container and the second is that documents, particularly clinical documents, are made from building blocks. The 'building block' view represented by EHR vendors, was that documents are constructed from modular building blocks, often defined as 'data objects,' which is similar to how many EHRs are designed and built. The 'data container' view represented by laboratory, imaging, and HIS system vendors, was that documents are containers, which actually a closer match to their architectures.

Out of that early debate, the container view prevailed and CDA Version 1.0 was defined as a container of text documents. This persists in Version 3 Release 2 (CDA r2) with the added support for both text and structured representation of the same data. CDA r2 is essentially a system for automated filing of dictated or text-based narrative notes with support for a secondary inclusion of encoded parameters to provide some structure and encoding to the text. CDA r2 also contains more sophisticated XML tagging, considerable extensibility, and some added restrictions. One of those restrictions is that within a CDA, XML from another schema cannot be used. In other words the CDA defines that any XML within the CDA must be compliant with the CDA XML schema. On the other hand, as mentioned earlier, anyone can expand the CDA schema to include local extensions as tags (elements) to meet local needs.

The current focus of the HL7 CDA is to define templates for specific document types within the CDA. Wes Rishel's Gartner Report contrasts a template for a 'continuity of care record' within the CDA (developed for the 2005 HIMSS Annual Conference) with the ASTM CCR as currently balloted and described in the Implementation Guide.

Mr. Rishel makes a number of key points to highlight the differences:

1) The CDA supports 'incremental interoperability' including everything from a pure text string representation of data all the way up to a full 'computable interoperability.' The ASTM CCR does not and 'would have to be expanded dramatically to create fully computable interoperability.'
2) The ASTM CCR does not support full semantic interoperability. The CDA does.
3) The ASTM CCR XML schema is 'ad hoc' while the CDA XML schema is not.
4) The CCR is easier to implement, but programmers that have already programmed for documents in CDA format will find the HL7 version easier than programming for a schema that is particular to the ASTM CCR.

The conclusion of the report is that the HL7 CDA is the preferred approach to implement a 'continuity of care record.'

It is important to deal with each of these points explicitly and then step back and discuss what we are really trying to do with both the HL7 CDA and the ASTM CCR and why they both exist and what work needs to be done going forward to address the real requirements for document and data interoperability in health care and to be consistent with the spirit and explicit intent of the ASTM/Hl7 MOU on harmonization..

To address *Points 1* and *2* together:

It is incorrect to state that the ASTM CCR does not support full semantic interoperability: In fact, the ASTM CCR and the CDA *both* support full semantic and computational interoperability. The CDA utilizes the HL7 Reference Information Model (RIM) to accomplish this. The ASTM CCR uses an explicit object-oriented data model using an XML-defined data object-attribute approach (<CodedDescriptionType>) to accomplish this (see the Technical Addendum to this document). The ASTM CCR, as an object-oriented data model, supports hierarchically nested sub objects with their own discrete and fully encoded attributes such as episodes within problem, fulfillment within medication, test within result to offer essential and required data richness and clinical relevance. In addition, the CCR supports full expression of complex data types across all pertinent administrative and clinical data to map a patient's exact current clinical status. The HL7 CDA and the RIM need to be expanded significantly to cover the breadth and depth of relevant data explicitly defined in the CCR.

To address *Point 3*:

The ASTM CCR XML schema is anything but 'ad hoc.' The ASTM CCR XML schema (.xsd) represents the explicit use of XML as an object description language to fully define clinical and administrative data as data objects supporting text or structured representation.

The ASTM CCR XML schema is also mapped to HL7 standards, including 2.x ADT and results messages, to NCPDScript, and to X12. This allows explicit, efficient, and straightforward mapping of legacy data and non-XML messaging and data standards to and from the ASTM CCR XML data model to support across the board interoperability between all health care information systems, not just between 'trading partners.' The ASTM CCR XML schema also explicitly follows general computer industry XML standards, specifically those of the W3C. The HL7 CDA is mapped to other HL7 XML standards and to the RIM, but not explicitly to the widely utilized standards of the other SDOs, and the HL7 use of XML deviates from accepted general computer industry practice. The ASTM CCR XML approach has been vetted extensively with the EHR, PEHR, ePrescribing, and HIS systems vendors and their technical teams and has been extensively tested as a data extraction and data import tool within the architectures of several leading EHR, PEHR, and ePrescribing vendors.

To address *Point 4*:

The ASTM CCR is easier to implement. This is not because it is simpler or less complete than the HL7 CDA. The CCR is not less complete than the CDA – they are designed for different purposes. The ASTM CCR is easier to implement because:

1) The ASTM CCR XML schema follows accepted industry practice in the use of XML. In particular all data in the ASTM CCR are contained within tags (elements). This makes data mapping and the generation of both 'writes from' and 'queries to' widely variable data models and architectures much easier. An instantiation of the CCR becomes very straightforward, computationally efficient, and logical.
2) All CCR tags are both machine and human readable. None are algorithmically derived. They fall in a logical order relative to the data and data attributes. This markedly simplifies the essential interchange between vendor and institutional clinical and technical teams in designing and implementing clinical systems. The data, tags, and tag attributes in the HL7 CDA require transformation to be human readable.
3) The ASTM CCR Implementation Guide is highly constrained defining only one way to implement specific data objects within the CCR, and allowing no local extensions or deviations from the standard. This markedly simplifies implementation, testing, and interoperability assurances.
4) The ASTM CCR mimics the general architecture of many EHRs and PEHRs which look at data as objects and use an object-oriented model. Mapping to and from the EHR is very straightforward into or out of an EHR architecture.
5) The ASTM CCR maps to ANSI and de facto standards in common use for EHRs and HISs such as HL7 2.x, NCPDPScript/Surescripts (XML), RxHub, and X12.

Mr. Rishel also makes the point that the HL7 CDA is in use already in the United States. However, its only current use is at the Mayo (Clinic) Health Systems, which uses a proprietary approach to XML in the EHR they have developed with IDX. It is not in full production use at this time. Implementations of the HL7 CDA in Europe are primarily using earlier versions of the CDA (prior to CDA r2) and tend to use the CDA as a text container, not as a structured and computationally interoperable document format.

A prevailing and inaccurate criticism of the ASTM CCR in comparison to the HL7 CDA is that the CDA is more complete and more comprehensive. In point of fact, at the time this paper is written, the HL7 CDA does not currently contain the clinical or administrative data richness of the ASTM CCR or map to the ASTM CCR. The HL7 CDA also does not map to NCPDPScript or X12. The CCR maps to both these standards and was explicitly designed to do so. The ASTM CCR also maps to HL7 2.x ADT and Results string messages as well as HL7 Version 3. In addition, the ASTM CCR Header and its internal representation of individuals (<Actors>) provides full support for Master Person (Patient) Identification (MPI) functions for explicit mapping of identity between disparate systems.

The core difference, however, is that the HL7 CDA and the ASTM CCR were designed for two very different purposes. To define these explicitly:

- The HL7 CDA was designed as a 'Clinical Document Architecture' to define a uniform XML representation of clinical documents – Clinic Notes, H&Ps, Discharge Summaries, Results documents, Operative Reports, Procedure Notes, etc. These are medical legal documents, originating from the authorship of one or more clinicians, signed by the author(s), and a permanent part of the medical legal patient record. The HL7 CDA is expressly designed to model multiple disparate documents and document types and is therefore highly configurable and by necessity inexact in its data representation. It is optimized to support the interoperability of document expression, by rigidly defining the representation and some of the relationships among these documents. It takes a 'generic' approach to documents.
- The ASTM CCR was designed as a clinical and administrative content extract of pertinent and relevant data from multiple disparate clinical documents, patient records, and administrative sources. It standardizes the expression of those data in XML to represent the clinical status of a patient at a specific point in time. The ASTM CCR is explicitly designed to support human and computer decision support and while it fully supports free text data, it is optimized and highly constrained to support exact data representation and data interoperability.

If we refer back to *Figure 1*, the HL7 CDA and the ASTM CCR sit on the two sides of that diagram. The HL7 CDA represents the documents and their relationships and the ASTM CCR represents the summary extraction of data across those documents, even across different sites and document sources.

There is also a key difference in expression and architectural intent. Referring back to the description earlier in this paper, the HL7 CDA represents a 'data container' while the ASTM CCR represents a set of explicitly mapped and defined data objects as 'building blocks'. These are not incompatible concepts or approaches, but harmonization is required to make them consistent and fully interoperable.

All HL7 CDA documents could, for example, be constructed with the ASTM CCR data objects as building blocks. For example, a clinical note has a structured or free text Reason for Encounter/Chief Complaint and a generally text-based History of Present Illness. Yet, all other sections map exactly to ASTM CCR data objects to generate a Past Medical History, Review of Systems, Physical Exam, Medication List, Diagnoses/Assessment, and a Plan of

Care. This holds true for H&Ps, Discharge Summaries, Consult Notes, Results documents, Procedure Notes, etc.

All that is needed is XML conformance and an agreement on the appropriate data representation architecture. The ASTM CCR Workgroup would certainly advocate an object-oriented approach using XML as the object description language. This is in keeping with the common use of XML in all other major industries, but it represents a deviation for the use of XML in the HL7 CDA.

The Real, Underlying Problem

The real problem in health care standards is that we refuse in the health care industry to really focus on the true problems and step up to the plate to address them. The controversy over the HL7 CDA and the ASTM CCR represented in Wes Rishel's paper and in all the concomitant discussions at HL7, IHE, ASTM, HIMSS, EHRVA, CCHIT IG Workgroup, PEHRC, and among the vendors is symptomatic of the disease.

The controversy is not about doing the right thing clinically or otherwise. This is about two well respected standards development organizations (SDOs) and the many dedicated volunteers who provide the essential professional expertise that enables convening groups to advance proposals intended to benefit commerce and the common good. Inevitably and sadly, the human and social forces within SDOs that work together to achieve success in the marketplace of ideas, also lead to competitive activities, and power politics. These competitive battles have nothing to do with what we all need to improve patient care. They are major distractions that waste the energy that should be redirected toward true collaboration in this industry. This should not be about our organizational affiliations, our business models, our titles, our roles, or our reputations.

Let's editorially modify that last sentence. This is about our reputations. We all deserve to lose every shred of our reputations and all respect if we cannot rise above our divergent opinions, our biases, and our egos to define standards that work, that are simple to implement, that address core industry needs, that are incorruptible, and that demand highly constrained implementation. We seem to have lost all ability to argue a critically important issue with civility and at least the minimal consideration of apolitical fair play.

Concerning the HL7 CDA, the ASTM CCR, and all outstanding health care interoperability standards issues, let's cut through the layers of hyperbole and get to the core of what we all need to do.

Defining a Real Solution

The problem with much of the health care information systems industry is that the train has already left the station. There are too many competing architectural and systems approaches. In addition, our institutions and we refuse to part with so many archaic systems because we have expended enormous resources building and maintaining them. . If we are ever going to achieve data interoperability we are going to have to define a data intermediary that can be exchanged between these completely disparate systems that represent data they

can each produce and data they can each accept. This seems obvious and even self evident, but why can we not get there?

First everyone wants it done their way, and second if it cannot be done their way they want to make sure that their special needs are met. This means we end up with standards that are conceptually and technically sound, but they are so accommodating and configurable that they are no longer standards. They are certainly not interoperability standards!

The ASTM CCR Workgroup is sincerely trying to address this conundrum whether others see that or not. Not only is there a real interest in making the standard technically good and clinically complete, there is an absolute commitment, driven by the EHR vendors, to make the CCR standard exacting and highly controlled.

The ASTM and specifically the ASTM CCR Workgroup are not competing with HL7 or with the HL7 Technical Committee defining the CDA. It's time to define an approach to standardization and interoperability that gives a uniform set of solutions to the industry. It is also not about HL7 and ASTM at all. It is about getting HL7, ASTM, NCPDP, X12, DICOM, and the key vocabulary/terminology players at the table and defining a uniform and cooperative architecture and approach to interoperability.

The Best of All Worlds

The concept of the Clinical Document Architecture (CDA) seems on the surface like a good one. Almost everything we do in health care is stored as a document. The problem with that view, however, is that it represents a replication of the paper world. The main reason all health care transactions are still managed with a document-centric perspective is for medical legal purposes and to allow for the storage and retrieval of data in at least a semi-structured approach for clinical care, support for billing, and for regulatory compliance and quality. Thus, we are forced, if even just for medical legal reasons to maintain a document-centric approach. That is not, however, the only nor is it the optimum way to define or managing clinical or administrative data in a 21st century information age environment.

In the current and future health care IT world, we want to work with data, information and knowledge primarily and documents secondarily.

From a purely clinical view and particularly from a human or machine-based clinical decision support perspective, the most important thing we need to define and standardize is the data. An object-oriented approach is what we need. This is state-of-the-art in the computer industry, but more importantly this is how humans and computers think of and utilize data in clinical decision making. We think of a diagnosis (object) and its particular features and modifiers (attributes) such as its location, severity, extent, acuity, etc., just as we think about a medication (object) and its dose, route, frequency, etc. (attributes). We do the same when we think about the symptoms and signs associated with a physical finding or result (objects) and their various descriptors (attributes).

Any health care document is made up of these objects, not the other way around. A *diagnosis* can be part of the Assessment Section of a Clinic Note or an H&P or the Past Medical History Section, or as a Discharge Diagnosis of a Discharge Summary. That *diagnosis* can

also be the indication for a procedure or medication or therapy, or the result of a test. It can also be a *diagnosis* on a health care claim or on an authorization request. In other words the *diagnosis* is a building block used in multiple places in multiple documents.

What is critical for us to face in health care is that the expression of that *diagnosis* should be the same no matter where it is used. For example, if it is expressed in XML, that XML expression should be the same in any clinical document, on an order or prescription, in a results message, or on a health care claim or authorization request. We know this but why can we not deal with it? We also know that this holds true for all clinical concepts and entities – symptoms, findings, medications, allergies/adverse reactions, advance directives, etc., etc., etc., etc…

XML is an ideal way to express objects, attributes, and relations and is ideal to express all clinical concepts and all administrative ones such as name (object) – attributes Given, Family, etc.

Any clinical or administrative document or message can be built from what turns out to be a limited number of building blocks, and this also holds true for any clinical or administrative system-to-system message.

Why do we express *patient name* differently in an HL7 message, an NCPDPScript prescription, an X12 claim, a DICOM message, or an ASTM CCR? Why does each EHR vendor represent it differently in each application?

We need to stop this madness and reverse the biblical legacy of the Tower of Babel brought about by an excess of pride and unwillingness to work together and solve these problems.

HL7, ASTM, NCPDP, DICOM, and X12 need to drop any prideful and defensive postures and work together. We all need to define the building blocks and the XML to express them. All health care SDOs need to redouble their efforts to use a uniform approach to XML schema design. This XML approach needs to conform with generally accepted practice across industries that have not been subverted to meet the 'special needs' of health care.

Individual SDOs need to do the following:

1) HL7 would ideally redefine all of its messages and standards as CDA documents – they all are documents anyway, particularly results and ADT messages. The CDA then needs to be reconfigured to be an XML container for building blocks. Rather than defining hundreds of document types and templates, a finite set of document formats (Clinic Note, SOAP Note, H&P, Discharge Summary, Procedure Note, Result Document, Image Report, etc.) needs to be defined and the appropriate building blocks assigned to the right container. Closely related document types can be tweaked and conformed in groups. All future work then can be focused on the building blocks and not the container. HL7 3 goes away – all results are legal clinical findings and are treated as documents in the paper chart as well as by EHRs and PEHRs. HL7 would manage all the text-based clinical and results documents (CDAs) to conform to the common XML architecture – that's their special expertise.

2) NCPDP (already underway) would ideally redefine NCPDPScript to reflect a building block approach. NCPDP then should take the commonly agreed upon XML approach and building blocks and define a prescription, refill request, and other relevant documents that conform to the common XML architecture – that's their specialty.
3) X12 wlould ideally define claims and supporting documents taking a building block approach and take the commonly agreed upon XML approach and modular blocks. They then should redefine the 837 and other claims processing documents to conform to the common XML architecture. X12 can manage the claims documents – that's their special expertise.
4) DICOM would ideally take the commonly agreed upon XML approach and building blocks and define an image report and work with all the other SDOs on how to correctly map image and multimedia links within the common XML approach. DICOM can manage image reports and images/multimedia – that's their specialized expertise and IHE is the organization to help carry this out.
5) ASTM would ideally define the building blocks and clinical extensions with the specialty societies and associations (most are already defined in the ASTM CCR) and the CCR to conform to the commonly agreed upon XML approach for a patient record summary. ASTM can manage the building blocks, the CCR, and security (XML security) – that's their specialized expertise.

All the SDOs can then cooperate and pick a common set of terminologies to express the concepts within the building blocks – one terminology per building block (knowing that the transition to one terminology per building block would be a gradual one). In other words, a diagnosis in a Clinical Note (HL7 CDA), a prescription (NCPDPScript), a health care claim (X12 837), an image report (DICOM) or a CCR (ASTM) would be identical. In other words the diagnosis would have the same XML tagging, the same terminology, and use the same code set or sets (ICD-9 CM for billing, for example and SNOMED CT for exactness).

It's time to get rid of any political agendas and biases, cooperate on standards, bring all the key stakeholders and technical talent to the table, and do the work together. Once the building blocks, document containers, security, and terminologies are defined and implemented, then the specialized work, licensing, and management of each respective part of the overall standard can go back to each SDO.

No one will lose with this scenario, the standards work can be done exceedingly quickly, and even though it has traditionally taken years for any new standards to fully permeate the industry, a single, cooperative, interoperability approach at this critical juncture in the industry would be rapidly adopted by all players.

TECHNICAL ADDENDUM[3]

The CCR was designed from the ground up to support detailed data representation and both human and computer-based clinical decision support. The essential goals of the ASTM CCR are to improve patient care and patient safety and to decrease health care costs. These goals can only be accomplished if the correct clinical and administrative information in as complete a form as possible is available to physicians and other health care providers at the point of care.

The other profound influence on the ASTM CCR development process was a series of strict requirements from the EHR vendor community. The first requirement was that the CCR standard had to be extremely explicit and constrained. This was felt to be essential to the EHR vendors so that all entities that generated a CCR were forced to implement and generate a CCR in exactly the same way. The objective is that any CCR generated by any system could be readable by any other system without reference back to or any knowledge of the original system. The EHR vendor community also felt very strongly that the CCR had to utilize established standards from the general computer industry and not deviate from those standards to fit the 'special interests' of health care. The EHR development teams from all of the leading EHR vendors who participated in the ASTM CCR authoring process expressed extreme frustration with the lack of standards for data interoperability in health care and even more frustration with the interoperability standards that do exist – particularly X12's 837 claims standard and the archaic ASTM and HL7 ADT and laboratory data standards.

The problem the EHR vendors have with the existing 'interoperability' standards is not with the standards themselves. These standards are all extremely well defined, well designed, and generated through strict consensus processes by HL7, X12, and ASTM. The problem is with the variability allowed in implementation of those standards to support local and provider-to-provider trading partner variability. An ASTM or HL7 laboratory message from one institution or reference laboratory is usually not identical or conformant to a message from another institution or reference laboratory. For hospital information systems this has always been a problem, but a local one. For EHR vendors it is a global problem because in any given community, EHRs have to interact with multiple hospital and reference laboratory systems for any given physician practice. This is also a problem for EHR vendors who sell across geographical markets as they are currently forced to do custom interfaces with each deployment of their products. We need to forgive the EHR vendors for their skepticism of standards, but recent historical experience is also on their side. For example, there was a strong hope under the HIPAA legislation that the X12 837 claims standard would finally allow a uniform electronic claim across all payers. The standard is very comprehensive and well designed. The problem, once again, is not with the 837 standard, it was with a decision to allow Medicare Third Party Administrators (TPAs) to vary the implementation and use of the fields within the standard to meet their 'local' needs. Every EHR, Practice Management

[3] Portions of the text in this Addendum were extracted, with permission, from the ASTM Draft Standard Specification for the Continuity of Care Record (CCR)1, Version 1a (March 2005). This document is not an ASTM standard; it is under consideration within an ASTM technical committee but has not received all approvals required to become an ASTM standard. It shall not be reproduced or circulated or quoted, in whole or in part, outside of ASTM committee activities except with the approval of the chairman of the committee having jurisdiction and the president of the society. Copyright ASTM, 100 Barr Harbor Drive, West Conshohocken, PA 19428-2959. All rights reserved.

System (PMS), and HIS vendor is now in the unenviable position of having to write individual X12 837 implementations for each TPA – an expensive, painful, and in the opinion of the EHR vendors, unnecessary complication.

The demand, therefore to the ASTM CCR Workgroup was that the CCR standard, and specifically the CCR Implementation Guide, had to require all vendors to implement the CCR in exactly the same manner. This requirement also fit the core use cases for the CCR, which are very different than trading partner interoperability needs, since most clinical use cases for the CCR do not involve trading partner arrangements. For example, a CCR generated from an EHR or HIS vendor and given to the patient can be taken to any other provider that sees that patient. With the patient's permission the data can be uploaded into that new provider's EHR or HIS. There is no technical, regulatory, legal, or other requirement that the EHR/HIS of the generating provider must have with any trading partner or recipient EHR/HIS. The transactions and data transport are solely at the personal and legal discretion of the patient. It is critical, for all these reasons, that the there be only one way to implement and use a CCR.

The ASTM CCR Workgroup received feedback from the EHR vendor community that the CCR XML had to be compliant with data standards as well as with general practice in the use of XML within the general software industry. XML is widely used outside of health care and has become the de facto standard in the supply chain industries, as well as in the financial services, banking, and mortgage industries. XML as eXtensible Business Reporting Language (XBRL) is under consideration as a regulatory requirement for financial reporting with the Securities and Exchange Committee (SEC).[4] All of these industries follow general and established practice in the use of XML, primarily as defined by the W3C. Standards of practice cover the use of tags (elements), tag attributes, and rules about what should and should not be expressed with XML, including security practices, confidentiality, and privacy of data and data transport.

The ASTM CCR Workgroup, members of whom have been or are concurrently involved in the HL7 CDA standard work, looked extensively at the use of XML in HL7 Version 3 and the HL7 CDA. A decision not to use HL7 CDA or HL7 Version 3 XML approach was made after careful consideration due to a number of technical reasons:

1) HL7 Version 3 and CDA XML use both tag attributes and tags as data containers. This is valid and allowed under the W3C XML standards, but is not considered ideal XML usage. XML is derived from SGML and tag attributes were originally defined for processing instructions and not for data. The problem with a mixed data model such as used in HL7 XML is that it is inefficient to process and somewhat confusing to implement and read. Both the ASTM CCR and the HL7 CDA are intended to be human readable in their raw XML forms. Data that are primarily in tag attributes or restricted to tags as content are generally human readable, as long as the tag attribute and/or tag names are readable. Data that are mixed in tag attributes and tag content are less easily readable. The ASTM CCR Subcommittee discussed the merits surrounding the use of tag attributes along with tags for data representation. It was decided after careful consideration that the use of tags alone was more in line with

[4] www.sec.gov Proposed Rules.

the general computer and software industry. A persuasive example was the Securities and Exchange Commission (SEC) XML standard for financial reporting, which restricts data to tag content.[5] The SEC is particularly interested in accuracy and explicit expression of information, two extremely critical considerations for the CCR XML development group. Another persuasive argument involved processing efficiency. XML parsers are very efficient at parsing data as tag content, but somewhat less so with data in tag attributes, and even less so with a mixed tag attribute and tag content approach such as HL7 Version 3 has chosen. Marc Overhage, MD of Regienstrief Institute and the current CEO of the Indianapolis Health Exchange Network, stated at a recent eHI Lab Connectivity Workgroup meeting in Washington, DC, that after trying to process HL7 Version 3 XML messages, they had made an explicit decision not to support it, preferring the older HL7 2.4 messages, which are archaic string messages.

2) Data as tag attributes also do not support a rich object-attribute hierarchy, as data are limited to one level of attribute-class relationship – a tag's content and its tag attributes. For true object representation and specifically for accurate and discrete data encoding (semantic representation), multi-level attributes and embedding are needed. An example, which will be explored later in this document, is the expression of a diagnosis in both a 'roll-up' code set such as ICD9-CM as well as a discrete encoding nomenclature such as can be supported with SNOMED CT. The CCR requires explicit encoding of data to support clinical and administrative decision support.
3) The HL7 CDA XML allows expression of text formatting in the XML. This is consistent with general industry practice in HTML, but is not allowed in SGML and is discouraged or not allowed in XML as implemented in many industries. All formatting in XML is intended to be external and contained within XSLT scripts, which is general practice in the computer industry. The CDA, as a container of free text document content has a specific justification, perhaps, but formatting is excluded from the CCR in line with general XML rules and usage.
4) Under HL7 Version 3 and the CDA, XML tags are not required to be constrained. In the CDA, for example, the standard explicitly states, 'In order to support local extensibility requirements, it is permitted to include additional XML elements and attributes that are not included in the CDA schema.'[6] This conflicts with the requirement from the vendors participating in the ASTM CCR development process that no local extensibility of the XML could be allowed or the core goal of interoperability would be compromised.
5) A number of HL7 CDA tag and attribute names are algorithmically generated from the RIM and the HL7 Development Framework and do not correspond to recognizable clinical or administrative terms, or at least the relationship, even according to the CDA standard, to clinical concepts is 'unclear.'[7] One of the core requirements for the CCR was that it would be humanly readable and that readability has to extend to tags.
6) HL7 CDA tags are 'generalized' allowing extensive customized configurations such as the expression of new 'sections' or data without extensions or revisions to the

[5] www.xbrl.org
[6] HL7 Clinical Data Architecture, Release 2.0.
[7] HL7 Clinical Data Architecture, Release 2.0.

CDA XML schema (.xsd). This generalization of tags (elements) provides a lot of flexibility and extensibility, that may be required in modeling disparate documents and document types, but this flexibility (and potential ambiguity) is inconsistent with the requirement from vendors that the CCR as a patient record summary be explicit and highly constrained in its expression of data to support interoperability.

The CCR uses an object-oriented approach to data modeling and used XML as its object-description model. This led to extensive discussion on the representation of object-attribute relations in XML, in addition to the problems encountered with object representation in HL7 CDA XML and the RIM, as discussed above. The issue the ASTM CCR Workgoup addressed involved whether or not 'mixed-content' would be allowed. Mixed-content is the embedding of XML tags within other tags and allows rich expression of object-attribute relations, but unless its use is explicitly constrained it can lead to parsing and data reconciliation problems. It was also recognized that some of Microsoft's XML tools and implementations did not support mixed content. These considerations led to the decision not to allow mixed content in the ASTM CCR. This decision supports the need for interoperability across all XML tools and platforms, as well as supporting stronger constraints on data expression.

The following rules define the requirements of CCR XML:

1) All data must to be content of tags (elements).
2) No data are allowed in tag attributes. Tag attributes are reserved for processing instructions, only.
3) All tags must be humanly readable and correspond to easily and clearly understandable concepts using recognizable terms.
4) All use of XML should conform to W3C XML best practices and correspond to general usage within the overall computer industry.
5) CCR XML will follow an explicit object-oriented approach and will use tags and tag hierarchies as the object description language for the expression of all data as objects, and all data attributes as object attributes. Mixed content is not allowed in the schema.
6) CCR XML cannot contain data formatting instructions. All formatting must be defined in XSLT scripts.
7) CCR XML is highly and explicitly constrained to support complete data interoperability. No local extensions are allowed and all CCRs must conform to the ASTM CCR schema (.xsd) and to the ASTM CCR Implementation Guide. In addition generalized tag names are not allowed. All tags, including sections within the CCR Body must be explicitly named, and, as defined above, humanly readable.

There was considerable discussion concerning the constraints the above rules place on core CCR extensibility. It was decided that specific 'CCR Extensions' would be defined, as needed, by special interest groups and organizations and that any changes to the XML schema would have to go through a vote of the ASTM E31 Committee as part of the normal ASTM balloting process. The intent was the preservation and protection of explicit interoperability.

Every effort was then made to make the CCR as comprehensive and accurate as possible in expressing all of the core administrative and clinical data required for good patient care and in all settings where human and computer-based clinical decision support is appropriate. To further the work of the committee, CCR Extensions are currently underway in long term Care and in HIV special interest groups. Using the core CCR with extensions for separate Performance Measure reporting, Public Health reporting and Disease Management and other extensions has also been considered, based on extensive clinical feedback from professional medical societies.

Expressing Data as Text or Structured Data

In an ideal world all data expression in health care 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. Currently this is not the case in health care. Therefore the ASTM CCR XML has been defined to allow a range of expression of data and data complexity. The standard strongly recommends the use of controlled vocabularies but has provided a small number of 'escape hatches' for free text where deemed absolutely necessary for those systems that cannot support discretely structured, tagged, and coded data.

As noted earlier, the ASTM CCR is set up as a Document Object that is a container for Data Objects. That Document Object is the ASTM CCR, and the Data Objects are the medications, problems, procedures, encounters, immunizations, and the like that are contained within the sections illustrated in *Figure 2*. The ASTM CCR supports the detailed parsing of any specific data object into its detailed structured components. The ASTM CCR also, as an object-oriented data model, supports hierarchically nested sub objects with their own discrete and fully encoded attributes and relationships such as episodes within problem, fulfillment within medication, test within result.

The medication *Amoxicillin* for example, would represent a data object in the ASTM CCR. Its attributes within the ASTM CCR are expressed with discrete specificity as attributes of that data object, displayed as tagged data elements in XML. *Amoxicillin*, therefore, has discrete tags for <BrandName>, <Strength>, <Form>, <Quantity>, <Dose>, <Route>, <Site>, <Indication>, <Instructions>, etc., and each of these is sub-classed with a set of tags to promote detailed data specificity. <Dose>, for example, is expressed as a <Dose> or a <Dose> range and is further sub-classed to express a <Value> and <Units>, any <Variable>, and an optional <DoseCalculation>. All of these data attributes and their content can repeat within an object, allowing, for example, the expression of a dose 'taper', 'sliding scale', 'pulse or variable dosing', 'prn' expressions, and the like. The ASTM CCR medication data object is structured to comprehensively support all prescriptions and orders. This includes inpatient as well as ambulatory or office-based medication administration, IV admixtures, home health and outpatient administration and infusions, and all instances and ways in which a medication/drug can be delivered to a patient. It also covers medication administration and dosing from the youngest neonatal patients to the oldest geriatric patients.

Similar levels of detail are supported for all data objects in the ASTM CCR, tailored to the specificity needed to express complex clinical and administrative concepts. In addition, the ASTM CCR supports detailed coding of data and detailed data attributes with standardized coding methodologies such as SNOMED CT, ICD-9 CM, ICD-10, CPT, LOINC, RxNorm, and the like.

In other words, the ASTM CCR is a comprehensive tool for the detailed and encoded object-oriented expression of patient-centric, summarized clinical data. XML is the object-description language used by the ASTM CCR to express data objects and their attributes. Ideally all systems using the ASTM CCR for interoperable exchange would express data in an object-oriented approach using XML and would conform to the standardized content detail that the ASTM CCR is capable of supporting. Unfortunately, due to the lack of any comprehensive and widely used clinical content standards for patient summaries in health care, most systems have not been either standardized or are not interoperable, and their capabilities relative to structuring data vary widely. In addition, most current systems are not object-oriented in their expression of data.

The emerging use of the DICOM imaging standards and the associated 'Integration Profiles' created though the collaboration of the members of IHE (Integrating the Healthcare Enterprise) and collaborative work between HL7, NCPDP, and ASTM have made great strides in moving the industry towards a structured approach to data. There is marked variability within the industry, however, and in order to deal with this reality, the ASTM CCR XML has been designed to allow an expression of data in a range of modalities, as follows:

- Non-specific text strings.
- Coded text strings.
- Coded or un-coded text strings with an arbitrary level of structure.
- Fully structured and coded object-oriented data expression.

A significant amount of thought and effort has gone into mapping the ASTM CCR to string-based and other XML health care messaging standards and architectures such as NCPDP and NCPDP Script, HL7 2.x and 3.0, HL7 CDA, and X12 (specifically X12 standards such as the 837 claims standard). In general, the ASTM CCR Implementation Guide, as noted above, contains greater data specificity than some of these string-based and XML standards, but care has been taken to assure that the data needed to generate a message or document using one of these standards is fully supported within the ASTM CCR. The intent is that the ASTM CCR would be fed by data coming from messages and documents expressed in these standards and that a system could generate a message or document consistent with these standards from a ASTM CCR. In addition, to ASTM International and HL7 having a Memorandum of Understanding, for each organization to work with the other toward the goal of harmonizing HL7 and CCR content, cooperative work is ongoing with IHE and NCPDP. The Physician EHR Coalition (PEHRC - www.pehrc.org) representing 20 national specialty societies and including the American Medical Association, have also been extensively involved with the CCR initiative.

The following few examples, taken from the ASTM CCR Implementation Guide illustrate XML used to express text-based and encoded clinical data.[8]

The first place to start is with a text 'diagnosis':

```
<Text>Acute Antereoseptal Myocardial Infarction</Text>
```

Example 1 – **Diagnosis as a Simple Text String**

This same text string as an ICD-9 CM coded diagnosis would be expressed as follows:

```
<Text>Acute Antereoseptal Myocardial Infarction</Text>
<Code>
       <Value>410.1</Value>
       <CodeType>ICD-9 CM</CodeType>
       <Version>2004</Version>
</Code>
```

Example 2 – **ICD-9 CM Coded Text String Diagnosis**

The same text string coded in both ICD-9 CM and SNOMED CT would be expressed as follows:

```
<Text>Acute Antereoseptal Myocardial Infarction</Text>
<Code>
       <Value>410.1</Value>
       <CodeType>ICD-9 CM</CodeType>
       <Version>2004</Version>
</Code>
<Code>
       <Value>62695002</Value>
       <CodeType>SNOMED CT</CodeType>
       <Version>20050131</Version>
</Code>
```

Example 3 – **Diagnosis Coded in Two Different Coding Schemes**

The same diagnosis represented as both a text string and fully tagged and coded data object with ICD-9 CM and SNOMED CT coding would be expressed as follows:

```
<Text>Acute Antereoseptal Myocardial Infarction</Text>
<Code>
       <Value>410.1</Value>
       <CodeType>ICD-9 CM</CodeType>
       <Version>2004</Version>
</Code>
<Code>
       <Value>62695002</Value>
       <CodeType>SNOMED CT</CodeType>
       <Version>20050131</Version>
</Code>
<ObjectAttribute>
       <Attribute>Diagnosis</Attribute>
```

[8] All Examples and associated text are reprinted with permission from the ASTM Draft CCR Standard Specification, © 2005, ASTM International, All Rights Reserved.

```
<AttributeValue>
       <Value>Myocardial Infarction</Value>
       <Code>
              <Value>22298006</Value>
              <CodeType>SNOMED CT</CodeType>
              <Version>20050131</Version>
       </Code>
</AttributeValue>
<Attribute>Acuity</Attribute>
<AttributeValue>
       <Value>Acute</Value>
       <Code>
              <Value>53737009</Value>
              <CodeType>SNOMED CT</CodeType>
              <Version>20050131</Version>
       </Code>
</AttributeValue>
<Attribute>Site</Attribute>
<AttributeValue>
       <Value>Antereoseptal</Value>
       <Code>
              <Value>20706007</Value>
              <CodeType>SNOMED CT</CodeType>
              <Version>20050131</Version>
       </Code>
</AttributeValue>
```

***Example 4* – Diagnosis as a Coded Text String and as a Structured Representation**

Example 4 is not ideal. It represents a compromise redundant data representation using a text string and structured representation of exactly the same data. This representation may seem the most flexible, but is at risk of misinterpretation due to redundant data representation and the fact that some of the codes are more specific than others.

Example 4 represents a compromise that the ASTM CCR XML is specifically designed to address. The ASTM CCR is explicit in how this is to be done, offering no flexibility in expression, only in what content and in which forms are included. *Example 4* is a reality in how data will be expressed in many CCRs.

The ASTM CCR also supports the ideal representation of this diagnosis in XML as structured, tagged, and coded object-oriented data object using only structured and coded data as follows:

```
<ObjectAttribute>
       <Attribute>Diagnosis</Attribute>
       <AttributeValue>
              <Value>Myocardial Infarction</Value>
              <Code>
                     <Value>22298006</Value>
                     <CodeType>SNOMED CT</CodeType>
                     <Version>20050131</Version>
              </Code>
       </AttributeValue>
       <Attribute>Acuity</Attribute>
       <AttributeValue>
              <Value>Acute</Value>
              <Code>
                     <Value>53737009</Value>
```

```
                    <CodeType>SNOMED CT</CodeType>
                    <Version>20050131</Version>
                </Code>
            </AttributeValue>
            <Attribute>Site</Attribute>
            <AttributeValue>
                <Value>Antereoseptal</Value>
                <Code>
                    <Value>20706007</Value>
                    <CodeType>SNOMED CT</CodeType>
                    <Version>20050131</Version>
                </Code>
            </AttributeValue>
        </ObjectAttribute>
```

***Example 5* – Structured XML Data Object Representation of a Diagnosis**

Example 5 represents precise data representation and granular encoding that is explicit and exact. Note that the text string '**Acute Antereoseptal Myocardial Infarction**' can easily be reconstructed using a XSLT script in XML from the object-oriented representation in *Example 5*.

One problem with encoding data in health care is the variability and inexactitude of many widely used coding schemes. ICD, CPT, and NDC codes are non-specific in many instances of use, whereas SNOMED CT, LOINC, and RxNorm codes are more granular, specific and clinically meaningful. The problem in health care is that ICD, CPT, and NDC codes are often required for health care claims processing and reimbursement (in the United States), and due to these widespread uses and requirements their inclusion and representation in the CCR must be supported.

The ASTM CCR provides support for detailed object-oriented and discretely encoded data representation, while also supporting the use of a less specific code – a code such as an ICD-9 CM code in the diagnosis example, as follows:

```
        <ObjectAttribute>
            <Attribute>Diagnosis</Attribute>
            <AttributeValue>
                <Value>Myocardial Infarction</Value>
                <Code>
                    <Value>22298006</Value>
                    <CodeType>SNOMED CT</CodeType>
                    <Version>20050131</Version>
                </Code>
            </AttributeValue>
            <Attribute>Acuity</Attribute>
            <AttributeValue>
                <Value>Acute</Value>
                <Code>
                    <Value>53737009</Value>
                    <CodeType>SNOMED CT</CodeType>
                    <Version>20050131</Version>
                </Code>
            </AttributeValue>
            <Attribute>Site</Attribute>
            <AttributeValue>
                <Value>Antereoseptal</Value>
                <Code>
```

```
                        <Value>20706007</Value>
                        <CodeType>SNOMED CT</CodeType>
                        <Version>20050131</Version>
                    </Code>
                </AttributeValue>
            </ObjectAttribute>
            <Code>
                <Value>410.1</Value>
                <CodeType>ICD-9 CM</CodeType>
                <Version>2004</Version>
            </Code>
```

Example 6 – **Structured XML Data Object Representation and Roll-Up ICD Code**

This supports structuring the data as a discretely tagged XML data object, coded in SNOMED CT, with a roll-up code in ICD-9 CM for billing purposes. This is the technical approach used throughout the ASTM CCR to support text strings as well as fully structured and encoded data.

The ASTM CCR is, therefore, a highly technical but extremely facile and easy to use XML representation of all pertinent clinical and administrative data needed for both human and computer-based clinical decision making at the point of care.

The ASTM CCR's technical architecture represents an extremely logical object-oriented data model using XML as its object-description language and is consistent with generally accepted best practices for the use of XML in all other major industries.