

Essential Similarities and Differences Between the HL7 CDA/CRS and ASTM CCR

Overview and Ballot Status

The HL7 Clinical Document Architecture (CDA) is a document architecture standard designed to represent medical legal health care encounter documents in a standardized format. CDA r2 (Release 2) was balloted and approved in June 2005. The HL7 Care Record Summary (CRS) was proposed as a special use-case of the CDA as a care record summary like the CCR (see below). The CRS ballot did not pass and the CRS has now been reconfigured as a Discharge Summary, a medical legal document, and a Referral Document, a quasi-medical legal document, for the IHE HIMSS demonstration.

The ASTM Continuity of Care Record (CCR) was designed and implemented as a standard for a comprehensive data summary that aggregates data from multiple sources, health care records, medical legal documents, and health care encounters to form a comprehensive overall clinical picture of a patient's current and relevant historical health care status. It is officially balloted and approved as ASTM Standard E2369-05.

Intended Use

The intended use for the CDA/CRS is for point-to-point/trading partner-to-trading partner exchange of documents (provider-to-provider or institution-to/from-provider), particularly medical legal documents.

The intended uses for the CCR are:

1. As a detailed health care summary that a provider can generate and give to the patient at the end of a health care encounter (inpatient, outpatient, or ambulatory care). This can be either in paper or electronic form.
2. As a data extract from an EHR, HIS (Hospital Information System), ePrescribing system, data registry, or a PHR (Personal Health Record) so that a patient health care summary can be transferred to another system, such as an EHR, HIS, or PHR.
3. To break down barriers to EHR adoption through facilitating the ability of an EHR purchaser to change to another EHR vendor, if desired, by exporting the critical medical information so that all future encounters on the system will have required summary information. The CCR is intended to increase adoption of EHRs by reducing the risk of choosing the 'wrong' EHR and reducing the cost of sales and number of providers who are unable to make decisions by reducing concern over the financial health and future of an EHR company. The CCR can also facilitate incremental pathways to an EHR by allowing a practice or provider to begin with an electronic prescribing system or immunization tracking system and then export the data from those systems when a full EHR is implemented.
4. As a model for EHR and PHR data and data objects.
5. As a complete patient health care summary to accompany medical legal and administrative documents for patient admission, discharge, or transfer to/from a health care facility.

6. As a detailed patient health care summary generated by a patient's providers that a pharmacist can use to review allergies, adverse reactions, test results, problems/diagnoses, and a complete medication list to optimize drug therapy and assure patient safety.
7. As a comprehensive data aggregation vehicle for submitting data to repositories, reporting, and regulatory purposes to support quality measures, public health, and health care research.
8. As a core production architecture for EHRs, PHRs, ePrescribing systems, registries, and health care data repositories and RHIOs.

Security, Confidentiality, and Privacy

CDA/CRS security is being defined as transactional security – for example, SSL as used for the Internet where a document is sent from a website to an end-user or from the end-user to the website. A CDA/CRS, for example would have a known health care sender and a known health care recipient who would have agreed to the security mechanisms needed for that exchange. CDA/CRS security is focused on securing the transaction.

Since the CCR is a summary record produced by a physician, patient, or institution/system that exists in its own right, irrespective of who its intended target is, it must be secure and confidential at all times, not just during a transaction. In most instances where a CCR is generated, the entity generating the CCR will be giving it to the patient or a data source and will not know who the patient will see next – in other words they will not know the next end-user of the CCR. A CCR, therefore, needs to exist as a secure and confidential document in its own right regardless and in addition to the technical transport security mechanism through which it might be sent. CCR security is focused on securing the data so all transactions, even open Internet transactions and data on portable digital media, such as USB drives, are secure.

Support for Interoperability

The CDA was designed to support 'incremental' semantic operability. As defined by the HL7 Structured Documents Technical Committee, 'What this means is that there is a range of complexity allowed within the specification and users must set their own level of compliance.' In addition, the CDA and CRS explicitly allow local extensions and configurability.

The CCR was designed to require and enforce explicit semantic interoperability. The EHR and PEHR vendors have demanded that there be universal compliance with a defined syntax, semantic content, and explicit structure to all CCRs and that no local extensions or configurability be allowed. The vendors as well as the clinical providers, as represented by the medical specialty societies, have defined the level of completeness and specificity to enforce this.

Please refer to the section below on *Vocabulary and Semantic Interoperability* to understand an overarching constraint on the CDA, CRS, and CCR regarding data interoperability.

Data and Structural Architecture

The CDA and CRS are based on the HL7 Reference Information Model (RIM). The RIM is a data model that defines health care data objects using an OMG (Object Management Group) Entity-Relation (ER) model. The RIM is the basis for all emerging HL7 standards. The RIM is a conceptual model and not a production database model. The CDA and CRS are intended as expressions of intact documents and are not explicitly designed for filtering and providing views onto data.

The CCR is based on an XML-based object-relational data model that represents complex health care data as highly constrained and highly specific data objects. The CCR object-relational data model is a production database model designed for EHRs, PHRs, data repositories, and RHIOs. The CCR is built from discrete data objects so that those data objects can be filtered, viewed, and organized without changing the information content or integrity while at the same time facilitating reuse of selected portions of the data for disparate decision processes.

XML

The CDA and CRS use an XML syntax modeled and defined for Version 3.x HL7 messaging. It is an HL7-specific syntax that maps to the RIM that predominantly uses XML tag attributes to contain structured data and coding, and uses tags to contain text-based data. The CDA and CRS store the human readable formatting information in the XML document. In addition, the narrative data in the CDA and CRS are not required to match the structured data.

The CCR uses an XML syntax based on W3C-compliant rules used within the general computer industry and is intentionally non-health care specific to optimize the use of general computer industry XML tools and skill sets. In contrast to the HL7 CDA and CRS, the ASTM CCR explicitly prohibits the use of XML tag attributes to contain data – all data in the CCR must be tagged. This prohibition reflects general use within the general computer and Internet industries and optimizes the performance of XML parsers and processing. All of the XML and tags within the CCR are human as well as machine-readable and the CCR stores human readable text as text strings or structured data and allows selection of standardized XSLTs (transforms) for formatting text or structured data. Narrative in the CCR is absolutely required to exactly and explicitly match its structured representation so that human readable and machine-readable data are always identical and synchronized.

Data Specificity

The CDA (r2/Level 2) and CRS support free text and an intermediate level of structured data. CDA Level 3 (under development) is intended to support a detailed level of structured data and clinical decision support.

The CCR supports an explicit level of structured and free text data mapping, specificity, and coding to drive clinical decision support. The CCR is built to support real-time as well as retrospective clinical and administrative decision support.

Harmonization

HL7 and ASTM have a Memorandum of Understanding (MOU) in place to coordinate efforts to harmonize the CDA and CCR. Current efforts involve ASTM and HL7 working to make CCR data objects and specificity fully able to be expressed in the CDA. This will involve bringing the CDA to Level 3 and defining tag and tag attribute sets within HL7 XML syntax to express CCR objects. Out of this work a set of XSLTs (XML transforms) will be created that will support the seamless transformation of data from HL7 XML syntax to CCR XML syntax. The intent is for these transforms (XSLTs) to allow transformation with no data loss.

Additional coordination and harmonization work is underway between HL7 and ASTM on XML security. HL7 and ASTM are also working closely with NCPDP to define the new SIG extensions to NCPDP Script to support ePrescribing.

Vocabulary and Semantic Interoperability

To reach true data interoperability, vocabularies and semantic interoperability need to be defined and tightly controlled. The CDA (Version 3, under development) and the CCR are designed to support detailed semantic interoperability. There is a lack of definition, agreement, and constraint, however, on existing health care vocabularies within the health care industry, which prevents CDA (Version 3, under development) and the CCR from providing constrained (interoperable) semantics. ASTM, HL7, NCPDP, and X12 are all coordinating efforts with SNOMED and other entities to define interoperable vocabularies and semantics. Note that this involves constraining and controlling the unfettered use of vocabularies and the explosion of terms within vocabularies as much as defining vocabularies. The lack of vocabulary standardization, and even more importantly, constraints, is a critical barrier to overall health care standard harmonization and true interoperability.