Health IT Standards Committee

A Public Advisory Body on Health Information Technology to the National Coordinator for Health IT

Implementation Workgroup

Constraining the CCDA

Liz Johnson, co-chair
Cris Ross, co-chair
August 20, 2014

Workgroup Members

Member	Organization
Liz Johnson, co-chair	**Tenet Healthcare Corporation**
Cris Ross, co-chair	**Mayo Clinic**
Anne Castro	BlueCross BlueShield of South Carolina
John Derr	JD & Associates Enterprises, Inc.
Joe Heyman	Whittier IPA
David Kates	NAVINET
Udayan Mandavia	iPatientCare
Wes Rishel	
John Travis	Cerner Corp.
Micky Tripathi	MA eHealth Collaborative
Kevin Brady, ex officio	NIST
Michael Lincoln, ex officio	Veterans Health Administration

Discussion items

- Charge
- Challenges and solutions
- Recommendations

Charge

- Determine whether there are usability challenges with the CCDA v1.1 specification and associated implementation guidance (currently adopted in ONC's certification program) that hinder interoperability
- If there are challenges that hinder interoperability, how can ONC most effectively address these issues, including through future versions of the certification program?

Review of CCDA Challenges and Solutions

- July 9, 2014
  - ONC presentation
- July 29, 2014
  - User experience presentations
    - Emily Richmond, Practice Fusion
    - Don Sepulveda, GE
    - Udayan Mandavia and Arnaz Bharucha, iPatientCare
    - Charles Curran, McKesson - RelayHealth
    - Matt Reid, American Medical Association
    - Micky Tripathi, Massachusetts eHealth Collaborative

Two Types of Challenges Identified

1. Challenges with the transport of structured data due to vagueness in standards or testing processes

2. Usability difficulties related to transferred data

Summary of CCDA Challenges (I)

- Wide implementation variation across EHR vendors
- Current standards and implementation guides allow too much variability
- Summary documents is left up to EHR vendor discretion, too much information shared
  - Need pertinent clinical summary of a patient or most relevant data (should be up to provider discretion)
  - Stage 2 requires content for 17 different data elements, no instructions for when an element is not present
    - NullFlavor fields are available, but examples and implementation guidance is lacking

Summary of CCDA Challenges (II)

- Certification focuses on the creation and transport of CCDA, not intake
  - Testing needed for appropriate conformance to common vocabularies (e.g. SNOMED, LOINC, RxNorm)
  - Variation in how no known medication intolerances and no known environmental or substance allergies are handled
  - CCDA does not handle data versioning; therefore, data correction in the case of errors requires manual intervention
  - Many CCDA instances have more specificity in the narrative section than in the discrete data section

Summary of Solutions

- Need more detailed and constrained specifications that include clinical use cases to address common issues, such as:
  - Handling of current and non-active medications
  - Problems
  - Allergies
  - Comingling of the terms medication intolerances and environmental/substance allergies
  - Use cases (e.g., ambulatory, inpatient, ED visit, specialist referral, nursing home ToC, HIE and quality data aggregation)
- Publish conformance tools to optimize and validate real world instances of CCDA
  - Establish a site for public samples of CCDA documents, sections, and entries
- Evaluate standard and implementation guidance that separates clinically relevant narrative content from discrete information
  - Allow the opportunity for greater physician and patient discretion regarding what to include in the narrative

Recommendations

- Near-term, practical action is needed that is not disruptive and helps improve interoperability using CCDAs
- More detailed and constrained specifications are needed that include clinical use cases to address common issues
- Conformance tools need to be published to optimize and validate real world instances of CCDA, establishing a site for public samples of CCDA documents, sections, and entries
- Evaluate standards and implementation guidance that separates clinically relevant narrative content from discrete information
- Recommend that ONC and the HITSC Steering Committee identify the appropriate mechanism to conduct a more in-depth review of CCDA challenges for improvement or potential replacement (e.g. FHIR)
  - Workgroup is supportive of collaborating with other FACA workgroups to form a joint group to conduct this review

Appendix I: Summary of Challenges from July 9, 2014 Meeting

Summary of Challenges Coding/Vocabulary

1. Mismatches between codes (different code systems have different levels of granularity)
   - Recommendation: When communicating codes also communicate the code display name and the code system
2. Vocabulary is too broad for some data elements
   - Recommendation: Create a LOINC subset or value set and further constrain LOINC to those that are adequate for the procedure
3. Unable to distinguish between code system and value set globally unique ISO identifier (OID) in HL7 message
   - Recommendation: State whether a value set in a CCDA is static or dynamic (effects the processes that the vendor sets up to update)

Summary of Challenges: NullFlavor and Header

4. Missing information and inconsistent use of nullFlavor
   - Recommendation: Make it very explicit to the vendors if you don't know the information, where that knowledge is supposed to be communicated, and how the information looks
5. Header: Significant variability in how information is sent makes it difficult for the receiver to integrate information in a local system and use it in a meaningful way (e.g., marital status, gender, language, birth place, postal codes, etc.)

Summary of Challenges: Result Section

7. Result codes disparities (receiver maintains only a LOINC code but receives a SNOMED CT code, difficult for the receiving system to integrate the code)
    - Recommendations: Need consistency in representation of that lab data
8. No guidance on the units and the value representation for lab results
9. Interpretation code and reference frames missing
10. Method code or the method that was used to perform the diagnostic test has a may binding (you can provide that method if you want or you don't have to if you don't want)
    - Recommendation: Update current free text field which makes it very difficult to normalize and integrate

Summary of Challenges: Allergies and Medications

11. Reaction severity often missing for allergic reactions
    - Recommendations: Reduce variability of how the information can be provided in terms of severity and optionality of whether or not it is provided
12. Medication codes provided but nothing to display name or code system name
    - Difficult to express quantities for compound medications
    - Route and interval timing not provided
    - Variability in the use of brand name, generic name and ingredient names and associated formulations

NPRM Feedback

NPRM Proposal: ONC proposed to create a new "cross-vendor" exchange requirement. Specifically, ONC proposed to require EHR technology certified to ToC to demonstrate that it can successfully electronically process validly formatted CCDAs no less than 95% of the time (performance standard).

Implementation Workgroup Comments

- Difficult to understand how the performance standard could be tested for certification.
- It would seem minimally that a library of derivative CCDAs would have to be available or a testing tool capable of generating the same would need to be available for vendors to prepare

Other Stakeholder Comments

- Questioned the likelihood that the proper set of testing documents could be collected, which would prevent efficient testing and development.
- Commenters believed that the 95% threshold would be impractical, time consuming, and expensive to implement, given the wide variation in Consolidated CDA implementation.
- Commenters supported constraining the CCDA as a better way to achieve ONC's stated goals

Appendix II: User Experience Presentations
July 28, 2014

Emily Richmond, Practice Fusion

- Challenges
  - Current standards and implementation guides allow variability, resulting in different interpretations when configured
  - Challenging interoperability scenarios include
    - Patient matching using CCDAs across different settings
    - Ability to display, parse, and ingest data from CCDAs generated by external systems
    - Using data from a CCDA for quality measure calculations
- Solutions
  - Greater interoperability requires stricter and more clearly defined standards with less implementation flexibility
  - Require all sections, even when there are no data
  - The required metadata or metadata necessary for utilization of the data should be strictly defined for all coded data elements
  - The presence of numeric personal unique identifiers (HIC, SSN) that would facilitate patient matching should be required

Don Sepulveda, GE Healthcare

- Challenges
  - CCDA documents are interoperable at the document level
  - When data adhere to standards, they can be parsed, but standards are not always followed.
- Solutions
  - To improve interoperability, standards should be enforced
  - Narrative sections do not necessarily present useful clinical summaries, especially for referrals and ToC

Udayan Mandavia and Arnaz Bharucha iPatientCare

- Challenges
  - Some vendors do not send coded values
  - Coded values are not proper
  - The proper use of UCUM codes for unit of measurements is not validated for proper use; thus many vendors do not implement them
  - Not all vendors send allergy reactions in coded structure
  - Some vendors do not send proper precision of time
  - Incorrect application of Nullflavor
  - Frequently missing elements
  - Multiple coding systems
    - SNOMED or CPT 4 or ICD-10-PCS codes are accepted. Most EHRs use only one coding system to document data
- Solutions
  - Provide richer, more standardized samples in an online format
  - Include validation of codes and vocabulary in certification
  - Reduce the number of data elements that are optional
  - Make tools available to ensure robust document exchange in real-world and mechanisms to monitor

Charles Curran, McKesson-RelayHealth

- Challenges/limitations
  - Too much information is often shared
    - Providers aren't able to receive a pertinent summary of the clinical status of a patient or just view a subset of the data that is most relevant (e.g. medication list)
  - CCDA is poorly constrained
    - Variation in how no known medication intolerances and no known environmental or substance allergies are handled
  - CCDA does not handle data versioning; therefore, data correction in the case of errors requires manual intervention
  - Many CCDA instances have more specificity in the narrative section than in the discrete data section
  - ONC proposed performance standard of handling 95% of the received CCDAs would require intermediaries,such as RelayHealth, to accommodate all of the vendor-specific variations.
  - Most EHR vendors have defaulted to view-only solutions rather than parsing and handing discrete clinical data
- Solutions
  - Publish more detailed and constrained specifications, including clinical use cases to address common issues causing variance, such as:
    - Handling of current and non-active medications
    - Problems
    - Allergies
    - Comingling of the terms medication intolerances and environmental and substance allergies
  - Publish conformance tools to optimize and validate real world instances of CCDA and a standardized style sheet rendering of CCDA
  - Evaluate standards and implementation guidance that separates clinically relevant narrative content from the accessible discrete information
  - Use FHIR to bundle a narrative summary with accompanying discrete resources
    - Or future CCDA documents could deliver a brief clinical narrative separately from the packaging of discrete clinical data without the need to render each section's narrative text or machine abstract
  - Allow significantly more time for future phases of meaningful use and other certification-related and timeline driven regulatory programs

Matt Reid, American Medical Association

- Challenges
  - No single CCDA document template contains all of the data requirements to sufficiently comply with Meanignful Use Stage 2
  - Regarding ToC, the document templates within CCDA are considered open templates, which means in addition to the required and optional sections defined in the template, an implementer can add to the document whatever CCDA sections are necessary for his/her purposes
  - Generating the correct summary documents is left up to the discretion of the EHR vendor
  - Implementation guides are lacking and too broad
    - Stage 2 requires content for 17 different data elements, but there are no instructions for when an element is not present.
  - Certified products have to pass tests to verify that a vendor can create the data elements, but those tests do not verify that EHRs correctly produce a CCDA document where there are no data
  - NullFlavor fields are available, but good examples and implementation guidance is lacking
  - Certification testing focuses on the creation and transport of CCDA, not their intake
  - CCDA includes many reference vocabularies in its implementation, testing for appropriate conformance to common vocabularies (e.g. SNOMED, LOINC, RxNorm) should be part of certification
- Solutions
  - ONC should clarify the implementation guidance
  - Constrain optionality at a more granular level
  - Create a site for public samples of CCDA documents, sections, and entries.
  - CMS and ONC must limit future requirements to ones that are well tested and understood
  - More guidance on the use of summaries is needed - greater physician and patient discretion regarding what to include

Micky Tripathi, Massachusetts eHealth Collaborative

- Challenges
  - CCDA is an unwieldy container, but many of its problems can be overcome
  - The biggest issue is wide implementation variation across EHR vendors
    - Variation in data availability and semantic normalization that affect interoperability.
- Solutions
  - Standardized templates and implementation guidance for high frequency and high value use cases (e.g., ambulatory visit, inpatient visit, ED visit, specialist referral, nursing home ToC, HIE data aggregation, and quality data aggregation)
  - Current work in these areas must be aggressively accelerated and made widely available.
  - Certification testing focused more specifically on implementation of CCDA to support data availability and semantic normalization for high priority use cases is needed