



NIST GCR 11-939

Quality Reporting Data Architecture (QRDA) Standards Action Plan

Lantana Consulting Group

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Executive Summary

This document is the action plan to improve the suitability of *Health Level Seven (HL7) Implementation Guide for CDA Release 2 – Quality Reporting Document Architecture (QRDA) Release 1* for quality reporting. Lantana Consulting Group prepared this report for the National Institute of Standards and Technology (NIST) to accompany the related “QRDA Suitability Analysis”.

While we believe that QRDA is suitable for Meaningful Use (MU) quality reporting, we identified areas in which the standard should be improved. This report discusses the actions to be taken to improve QRDA in these areas: enhancements to the standard itself; improvements in testability, testing, and validation, and error handling; and the creation of a certification program and a reference implementation. QRDA needs to be more fully aligned with the National Quality Forum’s Quality Data Model and HL7’s Health Quality Measures Format (eMeasures) standard. QRDA Category II and III must be fully specified and balloted. Better definitions of testable conformance statements are needed. Specific Schematron rules and a reference implementation can improve testing and validation. A QRDA-specific certification will further encourage the adoption of the QRDA standards.

If acted upon, these recommendations will enhance QRDA’s potential to become a single standard that supports all quality reporting use cases.

Introduction

This document is the action plan to enhance the suitability of Quality Reporting Document Architecture (QRDA) for quality measure reporting as required by the Department of Health and Human Services' Stage 1 Meaningful Use. Lantana Consulting Group prepared this report for the National Institute of Standards and Technology (NIST) to accompany the related "QRDA Suitability Analysis"¹.

This plan recommends actions for all improvements identified in the "QRDA Suitability Analysis". These actions will solve the issues discussed in the suitability analysis and they may also encourage more rapid adoption of the QRDA standard.

We do not duplicate our analysis in this document, but do refer to it wherever applicable. It must be decided who will manage the action plan and which (if any) of the items should be carried out and by whom.

Any mention of commercial products or organizations in this report is for information only; it does not imply recommendation or endorsement by Lantana or NIST.

¹ Both QRDA reports were prepared under contract number SB134110SE0911.

Our recommendations for the QRDA standard fall into five general categories: enhancements to the standard, testability, testing and validation, error handling, and certification.

Enhancements to the Standard

Enhancements to QRDA will better support its goals and align it with the Continuity of Care Document (CCD)², Quality Data Model (QDM)³, and the HL7 Health Quality Measures Format (HQMF) eMeasures standard⁴. We recommend the following actions:

QRDA and eMeasures

- Improve the QRDA implementation guide to be more prescriptive and describe exactly how it aligns with CCD, QDM, and eMeasure.

The QRDA and eMeasure standards are two important components of a larger quality framework. The eMeasure specification formalizes the representation of the quality measure, and QRDA formalizes the output of patient quality data. QRDA was developed before the eMeasure specification and the QDM-based building-block approach to eMeasure. Hence, there are some inconsistencies that need to be reconciled including: 1) misalignment between the representation of patient data in a QRDA vs. the representation of corresponding criteria in an eMeasure; and 2) misalignment between the representation of patient data in QRDA vs. CCD documents.

- Build eMeasures and QRDA in parallel and to be consistent with the capabilities inherent in Meaningful Use-certified EHRs. This notion is consistent with the perspective from Centers for Medicare and Medicaid Services (CMS). The upcoming version of the “CMS Measures and Measure Management Systems Blueprint” has an eMeasure Specifications chapter⁵. The eMeasure Specifications contain both the specification of a measure and its corresponding transmitting formats, including QRDA Category I.
- Refine QRDA and use the HL7 balloting process to make the QRDA and HQMF implementation guides as consistent as possible. An HL7 HQMF US Realm Implementation Guide is currently under development; it describes the QDM-based building-block approach for developing an eMeasure in detail. We need to align QRDA while balloting both guides through HL7.

QRDA Category II and Category III

² *HL7 Implementation Guide: CDA Release 2 – Continuity of Care Document (CCD)*: A CDA implementation of ASTM E2369-05 Standard Specification for Continuity of Care Record© (CCR) April 01, 2007 available through HL7: <http://www.hl7.org>

³ National Quality Forum, Quality Data Model Web site.

http://www.qualityforum.org/Projects/h/QDS_Model/Quality_Data_Model.aspx

⁴ *HL7 Version 3 Standard: Representation of the Health Quality Measures Format (eMeasure), Release 1*, Draft Standard for Trial Use, March 2010.

<http://www.hl7.org/v3ballot/html/domains/uvqm/uvqm.html>

⁵ CMS Measures and Measure Management Systems Blueprint, Version 8.0. To be released in fall, 2011.

- Push the standard development effort for QRDA Category II and Category III to provide a single standard that meets all quality reporting use cases.
- Ballot QRDA Category II and Category III in a timely manner for potential adoption by the Stage 2 Meaningful Use.

QRDA Category I is an HL7 Draft Standard for Trial Use (DSTU), but Category II and Category III are in HL7 comments-only status. The CMS Physician Quality Reporting System (PQRS) currently accepts submission of both summary- and patient-level data through both the Physician Quality Reporting Initiative (PQRI) Registry XML Specification and QRDA Category I format, respectively. It would be better if all input comes through a single standard: QRDA; different standards within the same quality program will cause unnecessary overhead to the quality programs and participants.

As stakeholder interests in QRDA continue to grow with the Stage 1 Meaningful Use quality measure reporting requirements, we anticipate that new requirements and new use cases will surface, which should be carefully reviewed through the ballot process.

QRDA Category I

- Update the QRDA Category I specification to align with the templates developed through the Clinical Document Architecture (CDA) consolidation project⁶ for consistency across all CDA implementation guides.
- Describe how to define a QRDA Category I report using the same QDM-based building-block approach for developing eMeasures. Defining both QRDA reports and eMeasures based on the QDM maximizes the coupling between the two specifications.
- Distinguish QRDA Category I from CCD/Continuity of Care Record (CCR). Both CCD and CCR carry single-patient data for transition of care. As a result, CCD and CCR contain some, but not all, of the data needed to determine whether or not a particular patient meets the population criteria within a particular measure. For instance, the Meaningful Use Emergency Department measures assess wait time in the Emergency Department (ED) for those patients who are subsequently admitted to the hospital. Typical summary documents include a list of hospitalizations, possibly with dates for each hospitalization, but would not contain details on ED arrival time, decision to admit time, etc. On the other hand, QRDA Category I carries quality data tailored to a specific measure or measure set. As such, QRDA and CCD/CCR overlap considerably in data content. As more quality measures are retooled to become eMeasures, quality reporting will require data elements that are with more variety and broader extent. QRDA Category I has the capability of supporting such growth, while CCD/CCR will be limited by their intended purposes.
- Promote the adoption of quality reporting tools such as popHealth—an open source Meaningful Use Clinical Quality Measure (CQM) reporting tool⁷. popHealth accepts patient data via either the Healthcare Information Technology Standards Panel (HITSP) C32 or CCR XML standards. It calculates whether the patient meets numerator or

⁶ CDA Consolidation Project. <http://jira.siframework.org/wiki/display/SIF/CDA+Consolidation+Project>
⁷popHealth – An open source quality measure reference implementation. <http://projectpophealth.org>

denominator criteria for 44 Meaningful Use outpatient ambulatory measures. With simple modification, popHealth will import QRDA Category I instances, make calculations, apply appropriate validations, and submit aggregate quality reports using QRDA Category II or Category III. Tools such as popHealth allow CMS to collect aggregate rather than individual data and let CMS verify that the EHR is correctly computing populations.

Testability

QRDA specifies the framework for quality reporting and reuses the CDA templates where possible. QRDA's conformance statements constrain the CDA R2 standard and define the QRDA payload. Testability can be improved by refining these conformance statements as defined in the "CCD Coverage Report"⁸ and creating a template library for QRDA data elements as defined in "Templated CDA: Key Concept for Interoperability"⁹.

We recommend the following actions:

- Re-write QRDA conformance statements into multiple, discrete conformance statements with a consistent style, each of which are individually testable.
- Develop a standard style of prose guidance when discrete testable conformance statements require additional guidance for untestable real-world requirements.
- Create a template library for QRDA data elements; the template library for QRDA should be part of the centralized template library for all CDA templates.

The CDA Consolidation Project¹⁰ is addressing conformance and testability. Should future iterations of QRDA adopt this consistent approach, it will simplify the definition of what is testable and the requirements for validation and run-time validation versus certification.

Templated CDA is a key technology underlying QRDA and other HL7 CDA implementation guides. Such template libraries (databases) support both standards development and implementation. A template library will improve quality assurance, consistency, and Schematron testing.

Testing and Validation

Schematron provides syntax validation at several levels of syntactic correctness. Implementers rely on Schematron to determine the correctness of QRDA instance generation. A better review process for Schematron rule development and creation of a reference implementation will improve testing and validation. We recommend the following actions:

- Develop and publish Schematron rules along with the QRDA standard. Many off-the-shelf XML tools can then apply these Schematron rules to validate QRDA instances.

⁸ Lantana Consulting Group. CCD Coverage Report, May 2011. Related document prepared for NIST.

⁹ Lantana Consulting Group. Templated CDA: Key Concept for Interoperability, May 2011. Related document prepared for NIST.

¹⁰ <http://jira.siframework.org/wiki/display/SIF/CDA+Consolidation+Project>

- Establish a Healthcare Information Technology (HIT) community review and consensus process as part of the development of Schematron rules so that they can be publicly vetted.
- Consider using other testing technologies to improve instance testing as identified in the “CCD Coverage Report”, such as model-driven validation and RELAX NG.
- Create one or more QRDA reference implementations. Reference implementations could be built to QRDA Category I, Category II, and Category III specifications, when we further enhance the Category I and fully specify QRDA Category II and Category III. Ideally, the reference implementations should show how to implement QRDA-based quality reporting for measures that are specified as HQMF eMeasures.
- Create a pilot real-world implementation for QRDA Category II and Category III, once they are fully specified. CMS has implemented Category I for its reporting program: Physician Quality Reporting System (PQRS). Lessons learned and experiences gained from the pilot real-world implementation will improve the QRDA standard itself and spur the growth of adoption and implementation rates of QRDA by a range of vendors.
- Improve vocabulary validation. Terminology validation is an important piece of QRDA validation. When a system receives a QRDA instance, it must validate the structural correctness of the instance and whether a correct code is received for a coded data element. Codes from dynamic vocabulary bindings are difficult to validate and require interface with terminology services. Health care often uses dynamic value sets to support new knowledge and to supply missing terms. A single go-to terminology service based on the *HL7 Version 3 Standard: Common Terminology Services, Release 2 (CTS 2)*¹¹ would mitigate this testing problem. See the “CCD Coverage Report” for a full discussion of this issue.

Error Handling

HL7 has a well-defined error-handling system. It maintains a log of errors and comments on all DSTUs, including QRDA. After aligning QRDA with the QDM, the eMeasure standard, and CCD, and then going through further HL7 ballots, a centralized errata page will be valuable.

Certification

HL7 provides certification for the CDA standard, but not in varying depths, and there is no certification for QRDA specifically. We recommend the following actions:

- Develop a certification program for proficiency in both eMeasures and QRDA. Due to the tight coupling between eMeasures and QRDA, a certification program for proficiency in both would be very valuable.
- Create several depths to the certification program so that it can be tailored to different types of audiences, such as measure developers and eMeasure/QRDA implementers.

¹¹ HL7 Version 3 Standard: Common Terminology Services, Release 2
http://www.hl7.org/documentcenter/public/standards/dstu/2009may/V3_CTS_R2_DSTU_2009OCT.pdf

Conclusions

QRDA suits its purpose for quality reporting. QRDA is robust because of the underlying, well-accepted HL7 CDA standard and the ability to represent elements in a consistent manner through vetted templates. The areas identified in this action plan, if acted upon, will better align QRDA Category I with CCD, QDM, and eMeasure; fully specify Category II and Category III for aggregate-level quality reporting; increase the rate of implementation; and prepare it for the future. The recommended actions also call for improvement in testability, testing and validation, and certification.

In summary, QRDA holds great potential to become a single standard that supports all quality reporting use cases—patient-level and aggregate-level—with the capability to grow. The QDM-based building-block approach bridges eMeasures and QRDA. The tight coupling between the two specifications provides a coherent quality reporting framework, which could enable automatic querying of EHRs based on eMeasures and generating and submitting reports in the near future.

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<http://projectpophealth.org>

Acronyms and Abbreviations

CCD	Continuity of Care Document
CCR	Continuity of Care Record
CDA	Clinical Document Architecture
CMS	Centers for Medicare and Medicaid Services
CQM	clinical quality measure
HITSP	Healthcare Information Technology Standards Panel
HL7	Health Level Seven
HQMF	Health Quality Measures Format
IT	Information Technology
MU	Meaningful Use
NIST	National Institute of Standards and Technology
PQRS	Physician Quality Reporting System
QDM	Quality Data Model (formerly known as Quality Data Set)
QRDA	Quality Reporting Document Architecture