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Quality Reporting Data Architecture (QRDA) Suitability Analysis

Lantana Consulting Group

NIST National Institute of Standards and Technology • U.S. Department of Commerce

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Executive Summary

This document analyzes the suitability of Quality Reporting Data Architecture (QRDA) to meet its purpose and to support the US Department of Health and Human Services' (HHS) Meaningful Use. It is part of the Healthcare Information Technology (HIT) Standards Analysis Project carried out by Lantana Consulting Group for the National Institute of Standards and Technology (NIST). We applied the methodology described in the "Healthcare Information Technology Standards: General Suitability Analysis," also prepared for NIST. In addition, we focused on whether QRDA meets the current and projected data requirements of Meaningful Use.

QRDA specifies the framework for quality reporting. QRDA, together with Clinical Document Architecture (CDA) templates, can standardize quality reporting as well as measure-defined data elements.

QRDA is a relatively new standard that is not fully specified; however, it is well suited for its purpose. CDA Release 2 is the base standard for QRDA, hence it is suitable for transmitting clinical quality measure data for current and future Meaningful Use requirements. CDA templates, implemented in QRDA, complement the National Quality Forum (NQF)'s Quality Data Model (QDM) building-block approach for creating eMeasures and make possible a tight coupling between the QRDA and Health Quality Measures Format (HQMF) standards.

While we found that QRDA is suitable, we identified a number of areas for improvement: QRDA requirements should be accompanied by corresponding Schematron rules to support testing and validation, unless other test methods are widely available. The specification itself requires further development and balloting to support aggregate-level reporting. Inconsistencies between QRDA and HQMF must be reconciled, and clarification must be provided for QRDA's reuse of templates from other CDA implementations. Improvements in testability and error handling along with the creation of a certification program and a reference implementation should encourage a wide range of vendors to implement the standard.

Introduction

This document assesses the suitability of the Health Level Seven (HL7) Quality Reporting Data Architecture (QRDA) specification[1] to support US Department of Health and Human Services' (HHS) Meaningful Use.[2] It is part of the Healthcare Information Technology (HIT) Standards Analysis Project carried out by Lantana Consulting Group for the National Institute of Standards and Technology (NIST). For that project, we assessed four standards for suitability: QRDA, HL7 Continuity of Care Document (CCD), ASTM Continuity of Care Record (CCR), and HL7 Version 2 Biosurveillance.

Suitability analysis can be thought of as a "fitness for purpose" study. Before we could assess the fitness of QRDA, we defined the goals of QRDA and then aligned those with Meaningful Use.

We assessed QRDA by applying each criterion defined in the "Healthcare Information Technology Standards: General Suitability Analysis"[3]. We also assessed QRDA for its suitability in reporting the Stage 1 Meaningful Use clinical quality measures.

QRDA Summary of Purpose

QRDA is a relatively new HL7 standard, released in 2009. It specifies a framework for quality reporting and standardizes the representation of measure-defined data elements for interoperability between organizations.

QRDA defines three types of quality measure reports:

- QRDA Category I is a patient-level report; it contains raw data for one patient and for one or more quality measures. There is no assertion about the status of quality compliance.

- QRDA Category II is a multi-patient report; each report contains data for a set of patients for one or more quality measures.

- QRDA Category III Calculated Report is an aggregate report. A Category III report contains only calculated population data, whereas Category I and II reports contain data for an individual patient.

The QRDA Category I report is a HL7 Draft Standard for Trial Use (DSTU), while QRDA Category II and Category III are currently published for comments only.

Clinical Document Architecture Release 2 (CDA R2)[4] is the base standard for QRDA. QRDA further constrains CDA R2 and reuses CDA templates, including those for CCD wherever possible.

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[1] *HL7 Implementation Guide for CDA Release 2 Quality Reporting Document Architecture (QRDA) Draft Standard for Trial Use*, March 2009.

[2] http://healthit.hhs.gov/portal/server.pt?open=512&objID=2996&mode=2 (accessed March 2011)

[3] Lantana Consulting Group. Healthcare Information Technology Standards: General Suitability Analysis, May 2011. Related document prepared for NIST.

[4] Dolin et al. 2005. See References for complete information.

QRDA and Meaningful Use

The ultimate goal of Meaningful Use is to achieve significant improvements in care. The objectives of Meaningful Use are to (1) improve quality, efficiency, safety, and reduce health disparities; (2) engage patients and families; (3) improve care coordination; (4) improve population and public health; and (5) ensure adequate privacy and security protections for personal health information.

QRDA's goal is to support quality reporting, which is aligned with the Meaningful Use goals of improving quality and reducing health disparities, and improving population and public health (see Figure 1: Meaningful Use and QRDA purposes).

QRDA standardizes the representation of measure-defined data elements to enable interoperability between all of the stakeholder organizations. QRDA supports the exchange of (1) patient-level quality data from a provider system to a quality data measurement and reporting facility and (2) population-level quality data from a measurement and reporting facility to quality data recipients.

Figure 1: Meaningful Use and QRDA purposes
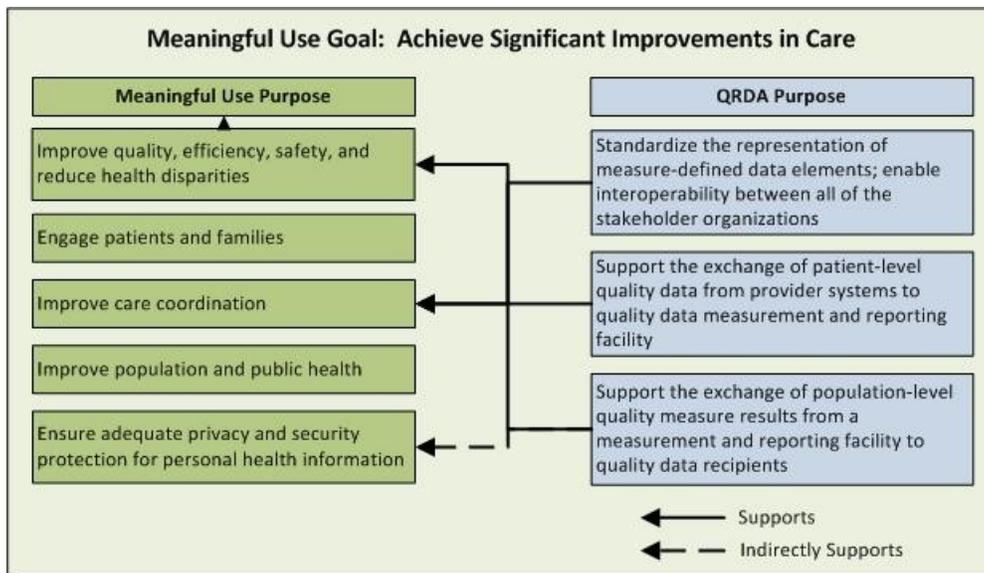
Stakeholder Interviews

The "Healthcare Information Technology Standards: General Suitability Analysis" describes our interviews with experts in HIT standards development, quality reporting, and standards implementation to evaluate the maturity, robustness, and suitability of QRDA.

We asked the following questions specific to QRDA during stakeholder interviews.

Table 1: QRDA Standard-Specific Interview Questions

Question block ID	Interview Questions

QRDA	• Please briefly describe your experience with QRDA to help us understand the basis for your answers to the following questions.
	
	 • How well is QRDA meeting its primary purpose?
	
	 • Are there errors or ambiguities in QRDA that mean it's harder than it should be to implement and use? Do you have examples?
	
	 • Consider the primary purpose of QRDA:
	     o What are some measurable criteria that should be assessed to ensure it is meeting this purpose?
	     o In what ways does it not meet its purpose?
	     o What makes QRDA testable?
	
	 • Where is "suitability" or "fitness for purpose" lacking or present in QRDA? For instance, here are some potential areas:
	     o Conveyance of all data needed by a processing entity to compute a provider's or organization's score on one or more quality measures
	     o Data reuse, whereby data having been originally communicated in a CCD (or other CDA document) is analyzed against a quality criterion, and is repackaged as part of a QRDA report
	     o Conveyance of other aggregation data not directly part of the quality measure (metadata)
	     o Ability to improve the quality feedback loop
	
	 • Please discuss the one feature about QRDA that most supports the Meaningful Use ultimate goal of achieving significant improvements in health care.

The interviews included senior developers as well as government-level directors. We received good, general information based on their experience implementing standards and their wide-ranging knowledge about standards quality. Unfortunately, we received no information on QRDA specifically as the interviewees are not familiar with the standard.

QRDA Suitability Analysis

We applied the questions defined in the "Healthcare Information Technology Standards: General Suitability Analysis" to QRDA.

Is the standard based on a stable, well-vetted data model?

QRDA is an implementation of CDA R2, a standard approved by the American National Standards Institute (ANSI) in May 2005. Since its release, CDA R2 has been widely implemented internationally and it is a foundational standard selected by, amongst others, the Healthcare Information Technology Standards Panel (HITSP). It was recognized by the Secretary of Health and Human Services, and was designated as a key standard within the Final Rule for electronic health record (EHR) technology[5]. Numerous HL7 implementation guides and Integrating the Healthcare Enterprise (IHE) profiles define the use of CDA in healthcare exchange scenarios.

Following HL7 practice, QRDA is defined in an implementation guide that declares constraints on the CDA-base standard for quality reporting purposes. Like all CDA documents, QRDA documents derive their machine-processable meaning from the HL7 Reference Information Model (RIM) and use the HL7 Version 3 (V3) Data Types. The RIM was developed in a collaborative process that engaged a broad range of experts, both clinical and technical, within HL7. The RIM is a robust, implementable standard (as demonstrated by the many implementation guides and profiles) and it applies to a large number of clinical data exchange use cases within the healthcare domain. The RIM has demonstrated stability over other models by its longevity (approximately 15 years).[6] The RIM and HL7 V3 foundation components, such as data types and vocabulary, are documented in a clear and understandable way that passes muster with the experts who reviewed it.

Given the global adoption by both vendors and healthcare providers of both the RIM and CDA R2, we conclude that QRDA is based on a stable, well-vetted data model.

Does the standard have a clear, robust vocabulary-binding syntax?

Vocabulary binding is essential to a standard's success. The correct interpretation of an exchanged message relies upon correct message syntax and correct data semantics. While syntactic correctness is defined by the standard format, semantics are defined by vocabulary binding. Clear, robust vocabulary binding defines unambiguous links between a data field and medical vocabulary systems. A data field can be valued only with one specific code or one selected from a "value set" of codes in the specified vocabulary system.

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[5] Department of Health and Human Services. *Health Information Technology: Initial Set of Standards, Implementation Specifications, and Certification Criteria for Electronic Health Record Technology; Final Rule*, 45 CFR Part 170. http://edocket.access.gpo.gov/2010/pdf/2010-17210.pdf

[6] National Cancer Institute Center for Biomedical Informatics and Information Technology (CBIIT). *CBIIT SAIF Implementation Guide*, March 10, 2011 Working Draft. (accessed March 2011) https://wiki.nci.nih.gov/display/SAIF/3.1+-+Overview+of+CBIIT+SAIF+Information+Framework?focusedCommentId=39297400

The vocabulary-binding syntax defined by the HL7 vocabulary work group has been through extensive review and has been improved through numerous rounds of balloting; it is widely used in the RIM and CDA documents throughout the world. This clear and robust binding syntax is a foundation for expressing the complex requirements of the QRDA.

Does the standard support reusable modules, such as templates or data types?

QRDA specifies a framework for quality measure reporting. The measure data that can go into a QRDA report are potentially limitless. It is not within the scope of QRDA to define how every possible measure data element should be represented; however, QRDA clearly states that measure data should reuse CCD and other CDA implementation-guide templates where possible. Templated CDA, which we discuss in detail in "Templated CDA: Key Concept for Interoperability"[7] prepared for NIST, is an example of a strictly defined architecture for compatible reuse.

As EHR vendors become familiar with structured documents and the CCD as part of the Office of National Coordinator (ONC) certification process, they will be able to reuse CDA and CCD templates for rapid development and implementation of QRDA systems.

Does the standard have a well-defined constraint mechanism?

The HL7 V3 standard has a well-defined constraint mechanism supported by CDA. The standard defines constraints on the RIM, data types, vocabularies, implementation guides, et cetera. Along with extensibility, constraints provide a clear set of rules for producing local variants to meet realm-specific requirements while preserving the global applicability of the V3 standard.[8]

As a US-realm implementation guide based on the CDA R2 base standard, QRDA Release 1 uses the HL7 V3 standard constraint mechanism. It meets the needs of quality reporting requirements in the US.

Does the standard have a well-defined extensibility mechanism?

The base CDA R2 standard has a well-defined extensibility mechanism. Implementations may use namespace extensions to include additional Extensible Markup Language (XML) elements and attributes that are not in the CDA schema. These extensions cannot change the meaning of any of the standard data items, and document recipients must be able to faithfully render the CDA document while ignoring extensions.

For vocabulary binding to a domain, the HL7 V3 standard allows an Extensibility Qualifier to be associated with the coded entry. The Extensibility Qualifier has two possible values: CNE (coded no extensions), and CWE (coded with extensions). CWE allows the code set to be expanded to meet local implementation needs. When a coded attribute is sent in a message, local concepts or

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[7] Lantana Consulting Group. Templated CDA: Key Concept for Interoperability. May 2011. Related document prepared for NIST.

[8] *HL7 International Localization Task Force Report Version 2b*. http://www.e-osiris.it/documenti/s_HL7/HL7IntlLocalizationReport_v2b.doc (accessed March 2011)

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free text may be sent in place of a standard code if the desired concept is not represented in the standard vocabulary domain.

An additional extensibility feature of the CDA standard is the inclusion of generic classes, such as act and participant. The act class can be used if no more specific class is available for the use case. "Teach cast care" is an example. While "teach cast care" is defined in some code systems as a procedure, it does not fit the HL7 definition of procedure: "an Act whose immediate and primary outcome (post-condition) is the alteration of the physical condition of the subject",[9] nor is teaching an observation. The act class can represent this in CDA such that it is semantically interpretable across systems. The generic participant can represent any participants not explicitly mentioned by other classes that were involved with the patient or the situation being documented. For example, there is no "Next of Kin" participant, but the generic participant can use standard modeling and codes to represent detailed information about such a participant.

These well-documented extensibility mechanisms support unanticipated use cases within the quality reporting domain and provide flexibility until specific use cases can be brought to HL7 and incorporated into a future release.

Are there unambiguous definitions of what is testable?

Unambiguous definitions of what is testable directly relate to the implementability of a standard. As a CDA R2 implementation guide, a QRDA instance can be validated for its structural correctness by the CDA R2 XML schema.

Conformance statements define the enforceable aspects of an HL7 specification. Conformance statements are constructed from common language statements and keywords to ensure semantic interoperability across standards and wire formats. These statements guide the coding and information content of a given template. CDA implementation guides contain different types of conformance statements such as parent-to-child constraints, document-tree conditional constraints, and template-specific vocabulary constraints. The "CCD Coverage Report"[10] describes the types of constraints and their testability.

Not every CDA and QRDA conformance statement is testable; ambiguity and inconsistency in the application of some statements create "fuzziness" about what is testable. The ONC's Standards and Interoperability (S&I) CDA Consolidation project[11] is clarifying and documenting those conformance statements that are fully machine testable, those that require human intervention, and those that cannot be evaluated by a machine-driven process. The "CCD Coverage Report" analyzes the CCD specification from the perspective of validation, looking at the limits of automated testing and assessing various approaches to it. The conclusions and recommendations in that report provide valuable information for developing strategies that will improve testability of CCD and other CDA standards, including QRDA.

[9] HL7 V3 RIM Definitions http://www.hl7.org/v3ballot/html/welcome/environment/index.html Normative Vocabulary for the RIM, actClass, Procedure (PROC). Note: Access Requires download of the V3 Ballot
[10] Lantana Consulting Group. CCD Coverage Report, May 2011. Related document prepared for NIST.
[11] http://jira.siframework.org/wiki/display/SIF/CDA+Consolidation+Project

Are there automated test tools and test suites?

NIST provides a test package that contains the Schematron rules for validating a document against the guidelines specified in QRDA. Any off-the-shelf XML tool, such as XML Spy, can apply the Schematron rules to validate QRDA instances. QRDA Schematron rules are not currently available.

Are there reference implementations?

The "Healthcare Information Technology Standards: General Suitability Analysis" describes two types of implementations: reference implementations and real-world implementations. A reference implementation is a fully instantiated software solution that is a reference for software developers. There is no reference implementation for QRDA yet.

QRDA has not yet been widely implemented. The Centers for Medicare and Medicaid Services (CMS) has the only real-world implementation that we are aware of. In 2009, CMS contracted Iowa Foundation for Medical Care (IFMC) to implement QRDA for the Physician Quality Reporting System (PQRS).[12] This implementation used the QRDA Category I (patient-level) report and reused several CCD templates, such as Problems, Procedures, and Payers. The CMS "Alternative Reporting Mechanisms: Physician Qualtiy Reporting System" web page lists several related documents.[13]

Is there documented existence of errors, including estimates of the severity?

Errors exist in any standard; the question is whether the important ones have been found and fixed. A good standard has lists of errors that contain only minor and no severe, known errors. The lists of errors should include change requests and error logs, as well as errors documented in published errata. A lack of a list of known errors may indicate that the standard has not been widely enough implemented, or that errors discovered during implementation were not made public.

HL7 maintains a log of errors and comments on all DSTUs, including QRDA[14]. The log contains open issues known at the time of publication and comments logged since then by NIST on conformance test requirements.

The published CMS and IFMC implementation of QRDA did not mention any specific errors. It did suggest two additional components and features for QRDA: (1) include Schematron files with the QRDA publication for easier adoption of the standard by the user community; and (2) generate OIDs for providers.

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[12] Velamuri S. QRDA-technology overview and lessons learned. *J Healthc Inf Manag.* 2010 Summer; 24(3):41-8. Note: PQRS was originally called the Physician Quality Reporting Initiative (PQRI), but it is not the same as the PQRI Registry XML Specification; throughout this document, we use PQRS to refer to CMS' reporting system and PQRI for the XML specification.

[13] https://www.cms.gov/PQRI/20_AlternativeReportingMechanisms.asp (accessed March 2011)

[14] http://www.hl7.org/dstucomments/showdetail.cfm?dstuid=39

QRDA's base CDA R2 standard does have documented errors, all of which are minor. The CDA R2 Errata page on the HL7 wiki[15] (last modified April 14, 2009) records sixteen errors. Seven of the errors are related to the sample CDA instance released with the standard, and are not related to the CDA R2 standard itself. The other nine errors are minor, such as the need for more clarification or improved readability. The errors are easy to address and do not affect the overall quality of the standard.

Is there a defined and effective process for handling errors?

HL7 maintains a log of errors and comments on all DSTUs, including QRDA. HL7 itself has a well-defined error-reporting process. The QRDA standard recommends reusing CDA templates wherever possible. The HL7 Structured Document Working Group (SDWG) maintains publicly accessible errata wiki pages for the CDA R2 standard and for CCD.

Do industry associations endorse the standard?

QRDA was adopted by the Healthcare Information Technology Standards Panel (HISTP). HITSP C105 constrains QRDA to support the communication of patient-level quality data for analysis and measurement.[16] IHE includes QRDA in the IHE Performance Quality Report profile development effort.[17] In addition to the HITSP and IHE adoption, CMS's definition of eMeasure encompasses both the Health Quality Measure Format (HQMF)[18] used in electronic specification of the measure and the corresponding QRDA for the measure. The CMS Physician Quality Reporting System (PQRS)[19] accepts quality reports in QRDA Category I format.

Has the standard been implemented by a range of vendors?

As previously noted ("Are there reference implementations?"), the CMS/IFMC implementation for the PQRS program is the only published real-world implementation of QRDA that we are aware of. Even though QRDA is not yet implemented by a range of vendors, it was tested successfully as part of the HITSP Interoperability Demonstration during the Integrating the Healthcare Enterprise (IHE) Connectathon and Healthcare Information and Management Systems Society (HIMSS) Interoperability Showcase.[20] The reuse of CDA and CCD templates in QRDA should lead to rapid implementation and development of QRDA.

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[15] http://wiki.hl7.org/index.php?title=CDA_R2_Errata. (accessed March 2011)

[16] HITSP. *Patient Level Quality Data Component Using HL7 Quality Reporting Document Architecture (QRDA Component. Version 1.0* (HITSP/C105). http://www.hitsp.org/ConstructSet_Details.aspx?&PrefixAlpha=4&PrefixNumeric=105 (accessed March 2011).

[17] http://wiki.ihe.net/index.php?title=Performance_Quality_Report

[18] *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

[19] CMS Alternative Reporting Mechanisms: Physician Quality Reporting System Web site. https://www.cms.gov/PQRI/20_AlternativeReportingMechanisms.asp (accessed March 2011)

[20] http://www.ahima.org/downloads/pdfs/advocacy/AHIMAStandardsCertIFRResponseLetter_Final.pdf

Is the standard used in more than one country?

QRDA was developed to meet the quality reporting use cases in the United States. Even though QRDA itself has not been used in other countries, its parent standard, CDA R2, has been widely adopted and implemented in many countries. As noted in the section on constraint mechanisms, QRDA preserves the global applicability of the HL7 V3 standard. QRDA specifies a quality reporting framework and uses the templated CDA strategy. Similar quality reporting implementation guides for other realms could be developed following the same approach to meet quality reporting needs in different countries.

Is certification available for developers and architects?

If certification for a standard is available for developers and architects, it indicates that the standard is relatively mature and that there is a proven, repeatable process for implementers to successfully implement the standard. It also indicates that the certifying body considers the standard important and stable enough to justify the expense of developing the certification criteria.

HL7 has not offered certification for any of the specific CDA R2 implementation guides, nor is any specific QRDA certification available; however, HL7 has offered a "Certified CDA Specialist" certification test since January 2007. The number of certified HIT professionals each year has been climbing, with close to 300 HIT professionals receiving CDA certification in the past four years.

The CDA Academy[21] offers hands-on, weeklong CDA training in the US.

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[21] http://www.cdaacademy.com

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QRDA Suitability Summary

The following matrix summarizes the results of applying the criteria to the QRDA standard. One criterion is not applicable to QRDA; the standard meets most other criteria, with caveats for testability and test tools. QRDA lacks a specific error-handling process, certification program, and reference implementation.

Table 2: QRDA Criteria Matrix

Criteria	Results	Notes
Is the standard based on a stable, well-vetted data model?	Yes	
Does the standard have a clear, robust vocabulary-binding syntax?	Yes	
Does the standard support reusable modules, such as templates or data types?	Yes	
Does the standard have a well-defined constraint mechanism?	Yes	
Does the standard have a well-defined extensibility mechanism?	Yes	
Are there unambiguous definitions of what is testable?	Yes	Testable conformance statements are needed. Current projects will further clarify and document testability.
Are there automated test tools and test suites?	Yes	General test tools are available, but QRDA Schematron or other rule sets are required.
Are there reference implementations?	No	
Is there documented existence of errors, including estimates of the severity?	No	Open issues known at the time of QRDA publication and NIST comments on conformance test requirements are documented. Minor errors are documented for the parent standard CDA R2.
Is there a defined and effective process for handling errors?	Yes	HL7 has a well-defined process, and there is a publicly accessible HL7 DSTU comments page for QRDA.
Do industry associations endorse the standard?	Yes	Endorsed by HISTP and IHE. Uptake by CMS.
Has the standard been implemented by a range of vendors?	No	To date, there is only one implementation for QRDA Category I, but the widespread use of its parent standard CDA R2 should enable rapid development.
Is the standard used in more than one country?	NA	The parent standard, CDA R2, is used in more than one country.

Criteria	Results	Notes
Is certification available for developers and architects	No	Certification is available for the parent standard CDA R2.

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Meaningful Use Analysis

The QRDA standard specifies the framework for quality reporting. In the following sections, we examine QRDA's suitability for CMS-required data as defined in Stage 1 Meaningful Use measure specifications.

Stage 1 Meaningful Use requires that eligible professionals report on six total measures: three required core measures (substituting alternate core measures where necessary) and another three selected from 38 additional clinical quality measures (CQMs). All of the Stage 1 Meaningful Use CQMs are endorsed by NQF. NQF has converted these measures from a paper-based format to an electronic format through a "retooling" process using the HQMF standard (see below).

QRDA and eMeasure

HQMF is an HL7 standard for representing a quality measure in an electronic format[22]. Measures that are specified using HQMF are called eMeasures. Both HQMF (eMeasure) and quality reporting are components of a larger quality framework, as shown in the Quality Framework figure below. Ideally, in this end-to-end framework, providers can push a button and import these eMeasures into their EHRs. The eMeasures will then query the EHRs' data repositories and generate reports for internal use or for external reporting to quality organizations such as CMS. The generated reports will be the corresponding QRDA reports for a measure. The eMeasure and QRDA figure shows that HQMF (eMeasure) specifies the measures that will query EHRs; QRDA specifies how to report the queried results from EHRs. HQMF is not a CDA R2 implementation guide, but, rather, has a peer-to-peer relationship with CDA.

eMeasures provide the rules for determining if a particular patient is included in a population, such as initial patient population (IPP), denominator population (DENOM), or numerator population (NUM). QRDA contains sufficient data elements to determine if the patient meets IPP, DENOM, or NUM criteria, so a quality organization can do its own aggregation. QRDA lets sites send quality reports that have individual patient-level or aggregate-level data. For a given eMeasure, it is possible to generate different QRDA reports based on different reporting goals. The base CDA R2 standard for QRDA provides a wide scope of coupling mechanisms between eMeasures and QRDA.

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[22] *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

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Figure 2: Quality framework
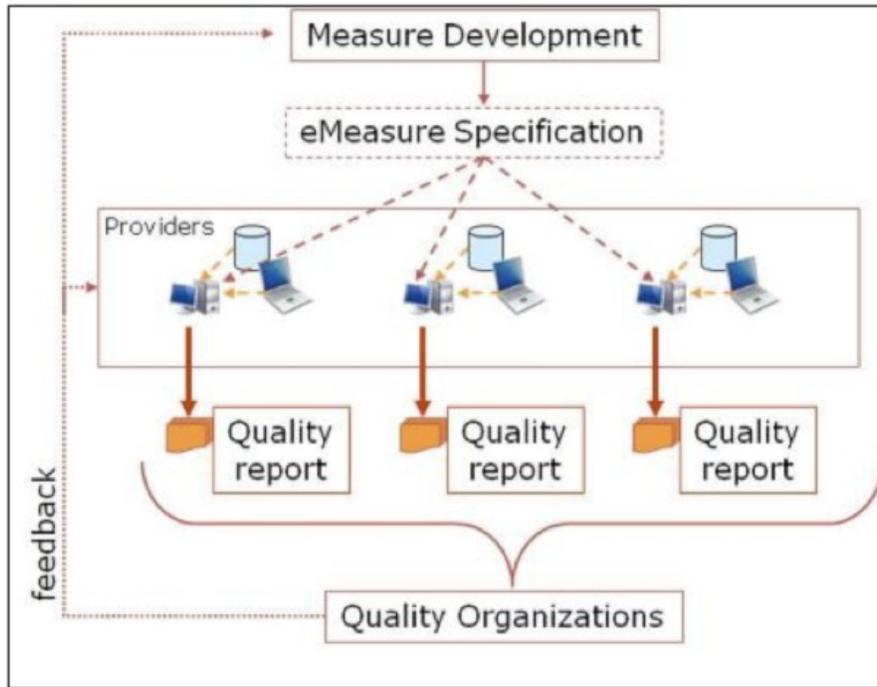
Figure 3: eMeasure and QRDA
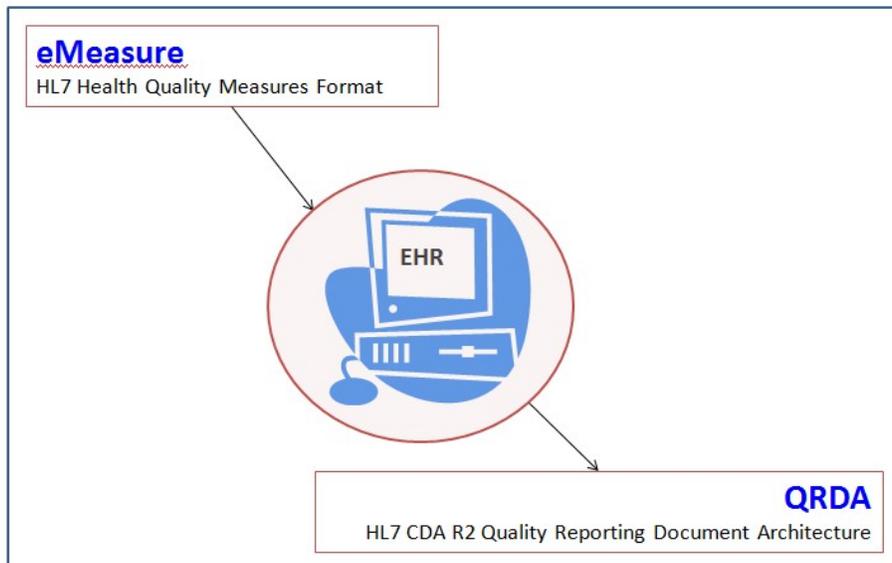
QDM Building-Block Approach to eMeasures

In 2010, Lantana worked with NQF to develop a building-block approach to consistently construct eMeasures.

Reusable building blocks are derived from the Quality Data Model (QDM, formerly known as Quality Data Set) defined by the Health Information Technology Expert Panel (HITEP). The QDM clearly defines concepts used in quality measures and clinical care; it automates EHR use.[23] QDM Version 2.1[24] describes the data elements and their context in four levels of information: standard elements, quality data types, quality data elements, and data flow attributes. A standard element such as *diagnosis of diabetes* takes on additional meaning when used with a quality data type, such as *active diagnosis,* to form a quality data element *active diabetes diagnosis* (see the Quality Data Model figure).

Figure 4: Quality Data Model
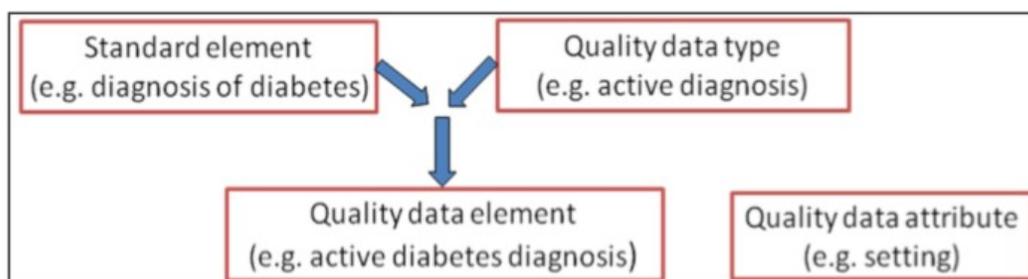
QDM Version 2.1 lists about 80 quality data types and quality data attributes for measure development. These quality data types include diagnoses, procedures, findings, medications ordered, care plans, et cetera. We converted each quality data type and quality data attribute in the QDM into an XML pattern modeled on the HL7 V3 RIM. Coupled with a code list, the quality data type becomes a quality data element. We assembled data criteria (using Boolean and other logical and numeric operators) into population criteria, thereby creating a formal and computer-processable representation of a quality measure. See the Building-block approach to eMeasures figure below.

We used this building block approach to develop all of the Stage 1 Meaningful Use clinical quality measures—such as NQF 0421 *Adult Weight Screening and Follow Up* and NQF 0028 *Tobacco Use Assessment and Tobacco Cessation Intervention.* As an example, active diagnosis of pregnancy is part of the exclusion criteria in NQF 0421. To represent it in eMeasure, we bound the XML pattern that was developed for the quality data type of *active diagnosis* to the SNOMED code for pregnancy, and turned the pattern into a quality data element for *active diagnosis:*

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[23] http://www.qualityforum.org/Projects/h/QDS_Model/Quality_Data_Model.aspx (accessed March 2011). Note: this discussion is based on QDM Version 2.1; NQF has published Version 3.0, with a comment period from April 20, 2011 to May 26, 2011. Version 3.0 changes some of the terminology for elements and data types, but the concepts remain the same. Page 5 of the Version 3.0 overview document (avaliable from the above link) lists the changes from 2.1.

[24] *National Quality Forum, Quality Data Set Model, Version 2.1*, September 2010. Available at http://www.qualityforum.org/Projects/h/QDS_Model/Quality_Data_Model.aspx

pregnancy. We then assembled the quality data element *active diagnosis: pregnancy* with other data criteria to form the exclusion criteria.

Figure 5: Building-block approach to eMeasures
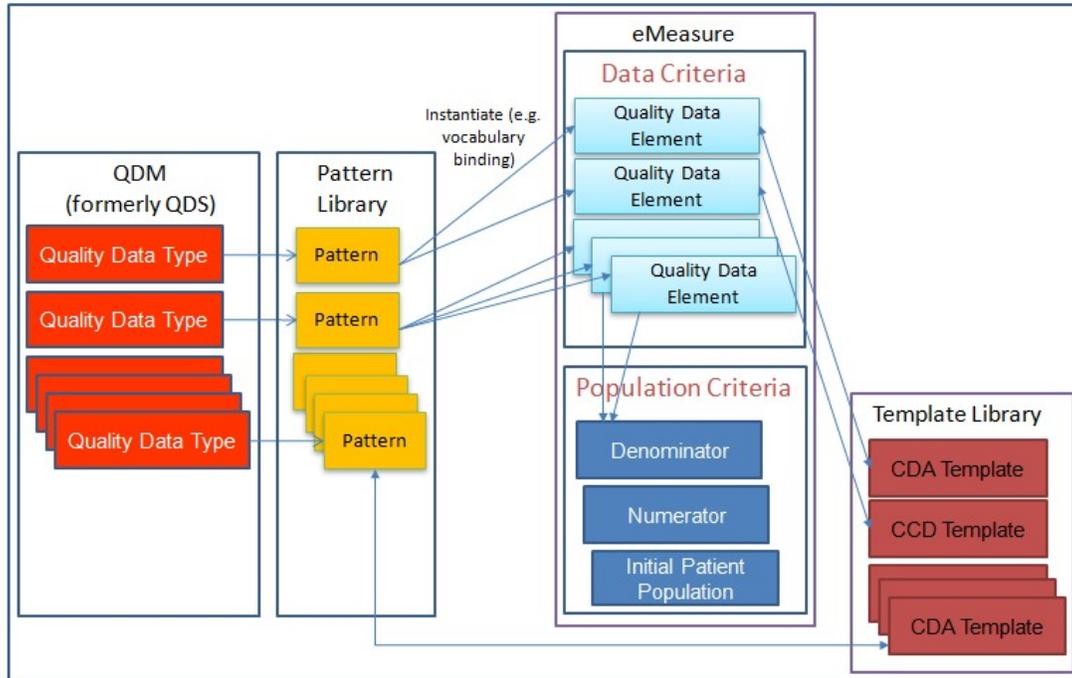
We can continue to use this QDM-based building–block approach to transform any future Meaningful Use measures into eMeasures. On occasion, we may need to create additional patterns when we encounter new quality data types for future measures. Currently, the pattern library we developed along with NQF is able to support the 113 NQF retooled measures.

All of the XML patterns in the library are based on the HL7 V3 RIM. Because of this, we assert that each XML pattern that constructs eMeasures can be automatically converted to a corresponding reusable CDA template, and each of the quality data elements can be automatically converted to a CDA template instance data. EHRs process queries based on eMeasure criteria and generate measure data. CDA templates can be derived from the corresponding patterns for the eMeasure data criteria, and these CDA templates can represent generated measure data. The CDA template instance data can then be sent in a QRDA report.

The patterns in the library support construction of NQF's 113 retooled measures to eMeasures. Thus, we should be able to generate CDA templates based on these patterns. We can use these CDA templates to represent all of the required data for the Stage 1 Meaningful Use clinical quality measures and insert them in QRDA. These reusable CDA templates will also support future CMS clinical quality reporting requirements for Meaningful Use. As we develop new patterns to support future measures, new reusable CDA templates can be generated.

QRDA was developed before the HQMF standard and the QDM-based building-block approach to eMeasure. As a result, there are inconsistencies in the representation of data elements between a QRDA and a corresponding eMeasure. These need to be reconciled.

QRDA and CCD

CCD contains some, but not necessarily all, of the data needed to determine whether a particular patient meets the population criteria within a particular measure. QRDA Category I carries quality data tailored to a specific measure or measure set. As such, QRDA and CCD partially overlap in data content. QRDA reuses CCD templates wherever possible. The QRDA specification does not currently specify how QRDA aligns with CCD or any other clinical document types; this should be included in future releases.

QRDA and PQRI Registry XML Specification

The Physician Quality Reporting Initiative (PQRI) 2009 Registry XML Specification[25] is the Stage 1 Meaningful Use standard for quality reporting defined by the final rules[26]. Unlike QRDA, which is derived from CDA R2 under the HL7 V3 paradigms, PQRI is a government-unique standard—it is not a voluntary consensus standard.

Both the PQRI Registry XML Specification and QRDA Category III support aggregate, summary-level quality reporting. The PQRI specification does not support patient-level measure data reporting; it is not the same as the CMS Physician Quality Reporting System (PQRS, formerly known as the PQRI program)[27].. The PQRS program accepts both aggregated quality reporting through the PQRI specification and individual patient-level quality reporting through QRDA Category I format.

Even though Stage 1 Meaningful Use requires only aggregate data, it is very likely that future Meaningful Use measures will require patient-level data. QRDA supports both patient-level and aggregate-level quality reports; the PQRI specification will not be able to meet this future need without significant improvements. As mentioned earlier, the Meaningful Use measures have been retooled and expressed in HQMF eMeasures. The ultimate goal is to turn these eMeasures into automatic queries on an EHRs' data repositories and to generate quality reports for the measures. The PQRI specification is not compatible with the HQMF standard, which will make it more difficult to generate reports directly based on eMeasures. The building-block approach to eMeasures and the coupling between the XML patterns and CDA templates provides significant advantages to QRDA over PQRI for patient-level quality reporting. An EHR that is certified for Stage 1 Meaningful Use can generate an electronic summary report in CCD format; it would be a familiar task for the same EHR to generate a QRDA report based on the CDA templates.

The PQRI Registry XML Specification and QRDA Category III are not comparable, although they both provide summary-level data. If we applied our general suitability criteria to the PQRI Registry XML Specification, it would not meet most of the criteria. For example, it was not

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[25] PQRI 2009 Registry XML Specifications
http://www.cms.gov/PQRS//downloads/PQRI2009RegistryXMLSpecsFinal508.pdf
[26] Department of Health and Human Services. *Health Information Technology: Initial Set of Standards, Implementation Specifications, and Certification Criteria for Electronic Health Record Technology; Final Rule*, 45 CFR Part 170. http://edocket.access.gpo.gov/2010/pdf/2010-17210.pdf
[27] CMS Alternative Reporting Mechanisms: Physician Quality Reporting System Web site.
https://www.cms.gov/PQRI/20_AlternativeReportingMechanisms.asp (accessed March 2011)

developed based on a stable and well-vetted data model; it is based on a simple XML schema. The data elements use simple data types, such as number or character. It does not have a clearly defined, robust vocabulary binding syntax.

In summary, the PQRI specification is analogous to QRDA Category III only on the surface. The PQRI specification does not support patient-level quality reporting and does not align well with the eMeasure specification. QRDA couples with the eMeasure specification nicely and supports both patient-level and aggregate summary-level quality reporting, although QRDA Category III is currently in comments-only status and needs to be fully specified and balloted through the HL7 balloting process.

QRDA Ballot Consideration

QRDA Category I is an HL7 DSTU standard; Category II and Category III are in HL7 comments-only status. QRDA Category II and III are not fully specified and have not yet been balloted, so there is no way to implement them consistently, test conformance, or constrain them formally.

A ballot for QRDA Category II and Category III is much needed so that we can define and specify them fully and obtain and address feedback from the healthcare and healthcare IT communities. Many people are working toward the goal of Stage 1 Meaningful Use reporting, so we expect that we will have a much better understanding of the use cases for Category II and III. As more institutions and vendors gain experience in reporting aggregate data, new requirements and new use cases will surface and they must be carefully reviewed through the ballot process.

Conclusions

The QRDA standard is relatively new; none of our interviewees has experience implementing it. Even though QRDA does not fully meet some of our criteria, it fits its purpose of reporting quality measures. QRDA is robust because of the underlying, well-accepted HL7 CDA standard and because it can represent elements in a consistent manner through vetted templates. QRDA is also well suited for current and future data requirements of Meaningful Use. This suitability is a result of the tight coupling between eMeasures and QRDA reports and the QDM-based building-block approach of eMeasures. The building blocks—the XML patterns—can be automatically converted to their corresponding reusable CDA templates. The coherent framework created by the coupling of eMeasures and QRDA could lead to automatic queries of EHRs and generation of reports.

Enhancements to QRDA; improvements in testability, testing and validation, and error handling; and the creation of a certification program and reference implementation should encourage a wide range of vendors to implement the standard. QRDA Category I, which handles patient-level reporting, needs Schematron rules for testing. For aggregate-level quality reporting, QRDA Categories II and III must be fully specified and balloted to become a standard for real-life implementation. Inconsistencies in data representation in some QRDA and corresponding eMeasures must be reconciled. Descriptions of how QRDA aligns with CCD are also needed.

In summary, QRDA suits its purpose and satisfies the Meaningful Use criteria. With improvements in the areas we identified, QRDA holds great potential to become a single standard that supports all patient- and aggregate-level quality reporting.

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Acronyms and Abbreviations

AAFP   American Academy of Family Physicians

ANSI   American National Standards Institute

CBIIT (National Cancer Institute) Center for Biomedical Informatics and Information
            Technology

CCD   Continuity of Care Document

CCR   Continuity of Care Record

CDA   Clinical Document Architecture

CDC   Centers for Disease Control and Prevention

CMS   Centers for Medicare and Medicaid Services

CNE   coded no extensions

CQM   clinical quality measure

CWE   coded with extensions

DENOM   denominator population

DSTU   Draft Standard for Trial Use

EHR   Electronic Health Record

HHS   US Department of Health and Human Services

HIMSS Healthcare Information and Management Systems Society

HIT   healthcare information technology

HITEP Health Information Technology Expert Panel

HITSP Healthcare Information Technology Standards Panel

HL7   Health Level Seven

HQMF Health Quality Measure Format

IFMC   Iowa Foundation for Medical Care

IHE   Integrating the Healthcare Enterprise

IPP   initial patient population

NCI CBIIT   National Cancer Institute Center for Biomedical Informatics and Information
            Technology

NCQA National Committee for Quality Assurance

NIST   National Institute of Standards and Technology

NQF   National Quality Forum

NUM   numerator population

ONC   Office of National Coordinator

PQRI   Physician Quality Reporting Initiative

PQRS   Physician Quality Reporting System (CMS system that accepts both QRDA and PQRI Registry XML input; it was originally called the Physician Quality Reporting Initiative but is not the same as the PQRI Registry XML Specification)

QDM   Quality Data Model (QDM, formerly known as Quality Data Set)

QRDA   Quality Reporting Document Architecture

R2   Release 2

RIM   Reference Information Model

S&I   Standards and Interoperability

SAIC   Science Applications International Corporation

SAIF   Service-Aware Interoperability Framework

SDWG   Structured Document Working Group

V3   Version 3

XML   Extensible Markup Language