Centers for Medicare & Medicaid Services

Quality Reporting Document Architecture

Informative Document

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1. Introduction

This document represents key concepts behind the Quality Reporting Document Architecture (QRDA) and its relationship to the Meaningful Use Stage 2 (MU2), It provides initial guidance for implementers, providers, and state agencies.

1.1 Overview of QRDA

The Health Level Seven International (HL7) QRDA is a standard document format for the exchange of electronic clinical quality measure (eCQM) data. QRDA reports contain data extracted from electronic health records (EHRs) and other information technology systems. QRDA reports are used for the exchange of eCQM data between systems for a variety of quality measurement and reporting initiatives, such as the Centers for Medicare & Medicaid Services (CMS) EHR Incentive Program: Meaningful Use Stage 2 (MU2).[1]

The Office of the National Coordinator for Health Information Technology (ONC) adopted QRDA as the standard to support both QRDA Category I (individual patient) and QRDA Category III (aggregate) data submission approaches for MU2 through final rulemaking in September 2012.[2] CMS and ONC subsequently released an interim final rule in December 2012 that replaced the QRDA Category III standard adopted in the September 2012 final rule with an updated version of the standard.[3]

QRDA Category I and III implementation guides (IGs) are Draft Standards for Trial Use (DSTUs). DSTUs are issued at a point in the standards development life cycle when many, but not all, of the guiding requirements have been clarified. A DSTU is tested and then taken back through the HL7 ballot process to be formalized into an American National Standards Institute (ANSI)-accredited normative standard.

1.2 QRDA Templates

QRDA is a constraint on the HL7 Clinical Document Architecture (CDA), a document markup standard that specifies the structure and semantics of clinical documents for the purpose of exchange.[4] To streamline implementations, QRDA makes use of CDA templates, which are business rules for representing clinical data consistently. Many QRDA templates are reused from the HL7 Consolidated CDA (C-CDA) standard[5], which contains a library of commonly used templates that have been harmonized for MU2. Templates defined in the QRDA Category I and III IGs enable consistent representations of quality reporting data to streamline implementations and promote interoperability.

[1] CMS, EHR Incentive Program Final Rule (2012), http://www.gpo.gov/fdsys/pkg/FR-2012-09-04/pdf/2012-21050.pdf
[2] ONC, HIT Standards and Certification Final Rule (2012), http://www.gpo.gov/fdsys/pkg/FR-2012-09-04/pdf/2012-20982.pdf
[3] CMS, HIT Revisions to 2014 EHR Certification Criteria and EHR Incentive Program (2012), http://www.gpo.gov/fdsys/pkg/FR-2012-12-07/pdf/2012-29607.pdf
[4] HL7, CDA Release 2, 2005. http://www.hl7.org/implement/standards/product_brief.cfm?product_id=7
[5] HL7 Implementation Guide for CDA Release 2: IHE Health Story Consolidation, DSTU Release 1.1—US Realm. http://www.hl7.org/implement/standards/product_brief.cfm?product_id=258

1.3 QRDA Category I (Individual Patient) Reports

A QRDA Category I report is an individual patient quality report. Each report contains quality data for one patient for one or more eCQMs, where the data elements in the report are defined by the particular measure(s) being reported. A QRDA Category I report contains raw applicable patient data (e.g., the specific dates of an encounter, the clinical condition) using standardized coded data (e.g., ICD-9-CM, SNOMED CT®). When pooled and analyzed, each report contributes the quality data necessary to calculate population measure metrics.[6]

The QRDA Category I DSTU was published in 2009. At the conclusion of the first trial use period, work began on the QRDA Category I, DSTU Release 2, published in July 2012. The second release incorporates a framework for coupling QRDA with the National Quality Forum (NQF) Quality Data Model (QDM), a domain-analysis model that supports consistent definition of clinical concepts recurring across quality measures.[7] This framework allows users to create QDM-based QRDAs that correspond with QDM-based eCQMs.

1.4 QRDA Category I Errata

During a DSTU period, inaccuracies may be identified warranting corrections to the specification. The resulting errata updates are limited to corrections that preserve the original intent of the specification, such as those that address misspellings or incongruent conformance statements. Errata updates to the IG and corresponding supporting materials (e.g., sample files) are published in an errata package.

Following the publication of QRDA Category I, DSTU Release 2 in July 2012, inaccuracies were identified that necessitated an errata package. The QRDA errata package includes the original July 2012 publication of QRDA in addition to the following resources:

1. Corrections to non-normative content, such as edited Extensible Markup Language (XML) representations in figures, spelling mistakes, and broken links.
2. A QRDA template library that contains corrections to normative content.
3. A spreadsheet containing a list of changes that detail all normative and non-normative errata updates approved by the HL7 Structured Documents Work Group (SDWG) in December 2012.

1.5 QRDA Category III (Aggregate) Reports

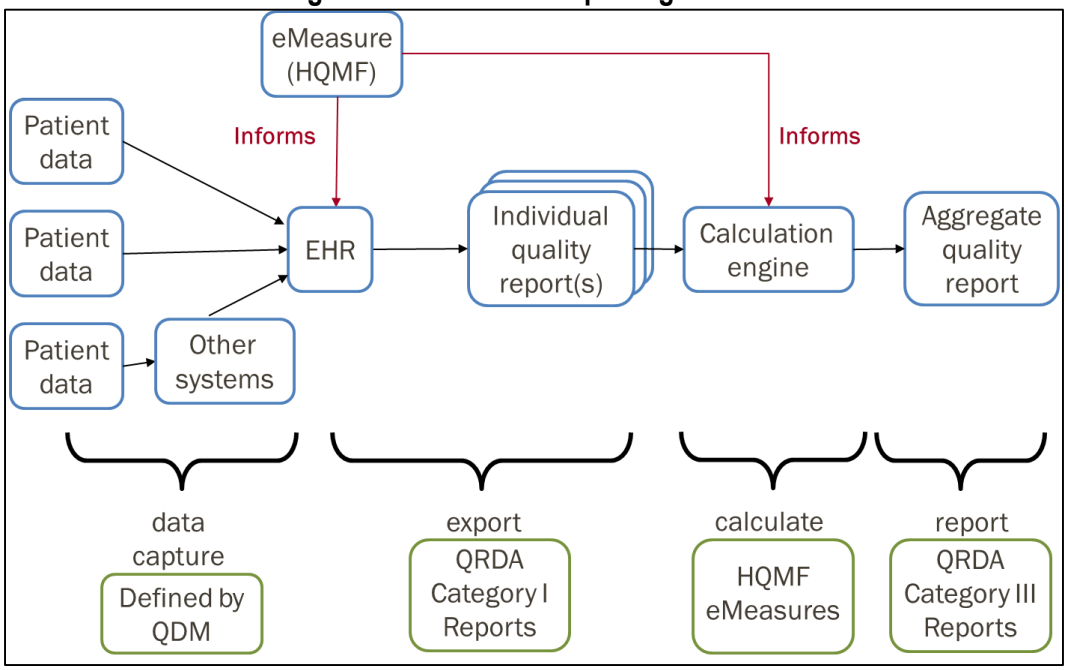
A QRDA Category III report is a standard structure to use in reporting aggregate quality measure data. Each report contains aggregate quality data for one provider for one or more eCQMs. Aggregate reports, such as those detailed in the QRDA Category III DSTU, are used in several ways. Quality reporting gives organizations the statistical information needed to track diseases, monitor quality of healthcare delivery, track the results of particular measures over time, and determine results from specific populations for those measures. Using quality query systems, researchers can ask questions of the data residing in health information systems and receive relevant data that are stripped of all patient identifiers, protecting patients and healthcare providers from the risks of inadvertent privacy loss.[8] QRDA Category III, DSTU Release 1, was published in December 2012.

[6] HL7, QRDA Category I DSTU, Release 2 (2012), http://www.hl7.org/implement/standards/product_brief.cfm?product_id=35
[7] NQF, QDM, 2012. http://www.qualityforum.org/QualityDataModel.aspx#t=1&s=&p
[8] HL7, QRDA Category III DSTU, Release 1, 2012. http://www.hl7.org/implement/standards/product_brief.cfm?product_id=286

2. End-to-End Quality Reporting Process

Quality measurement processes are driven by organizational needs and characteristics. One key to success in using data from EHRs for quality reporting is understanding the reporting process within the workflow patterns of a variety of provider institutions. This section describes a generalizable end-to-end quality reporting process, as depicted in Figure 1.

Figure 1: End-to-End Reporting Process



2.1 Data Capture

Standardization of data and data formats provide tremendous opportunities to aggregate quality measurement data from clinical sources. ONC certification requirements under MU2 mandate that EHR vendors demonstrate the ability to capture the data necessary to reliably calculate and report eCQM data using standardized formats. The use of standard data models for clinical data and quality reports reduces data-entry burden and supports data reuse.

2.2 Export

EHRs and other electronic systems export the appropriate data to include in individual patient-level QRDA Category I reports. When pooled and analyzed, each report contributes the quality data necessary to calculate population measure metrics for QRDA Category III reports. QRDA Category I reports can be transmitted directly to quality measurement organizations (such as CMS) that request the submission of raw patient data.

2.3 Calculate

Inherent in this step of the end-to-end quality reporting processes is the capability of the end-user to validate the data and ensure the consistency of the measure calculations. The consistency and completeness of these calculations will be strengthened by the continued refinement of standards, definitions, and tools that enable the import of standardized data reports and that create queries against an EHR database.

Calculation engines (e.g., popHealth) are informed by eMeasures, the Healthcare Quality Measure Format (HQMF) representation of the eCQM. These types of tools can consume QRDA Category I reports, calculate eCQM results based on the criteria defined by an eMeasure specification, and produce a corresponding QRDA Category III report.

In some circumstances, a data intermediary (e.g., data warehouse, registry, Joint Commission, performance measurement system vendor, or health information exchange) may accept QRDA Category I (individual patient) reports, calculate the aggregate results, and transmit the data using a QRDA Category III (aggregate) report. This model decentralizes data storage. It also provides the opportunity for data intermediaries to offer rapid feedback and supportive services to providers.

2.4 Report

QRDA reports communicate clinical information between senders and recipients of quality measurement data. The data contained in a QRDA report represent eCQM data in a standard format that can be automatically consumed and operated on by recipient databases. QRDA Category III reports contain aggregate eCQM data from individual patient data in QRDA Category I reports.

3. QRDA Implementation Resources

A variety of resources exist to support implementation of QRDA Category I and Category III reports.

3.1 QRDA IGs

IGs are a set of business rules for consistently implementing a standard for a specific use. QRDA IGs make use of templates that describe how to represent clinical data consistently using CDA. Many of the templates included in the QRDA IGs are drawn from the HL7 C-CDA standard [9], which contains a library of commonly used templates that were harmonized from existing CDA templates developed across several organizations.

- *HL7 Implementation Guide for CDA R2: Quality Reporting Document Architecture—Category I (QRDA) DSTU Release 2 (US Realm).* July 2012. http://www.hl7.org/implement/standards/product_brief.cfm?product_id=35
- *HL7 Implementation Guide for CDA Release 2: Quality Reporting Document Architecture—Category III (QRDA III), DSTU Release 1 (US Realm).* November 2012. http://www.hl7.org/implement/standards/product_brief.cfm?product_id=286

Errata or enhancement requests for the QRDA IGs may be submitted as DSTU comments through HL7.

- HL7 QRDA I, DSTU Release 2 Comments page http://www.hl7.org/dstucomments/showdetail.cfm?dstuid=80
- HL7 QRDA III, DSTU Release 1 Comments page http://www.hl7.org/dstucomments/showdetail.cfm?dstuid=90

3.2 CMS eCQM Resources

CMS resources for Eligible Hospitals (EHs) and Eligible Professionals (EPs) eCQM reporting are available through http://cms.gov/. Resources include program-specific guidance for QRDA implementations, the *CMS EP Programs QRDA Category I DSTU Release 2 Supplementary Implementation Guide for 2014* and the *CMS EP Programs Category III Release 1 Implementation Guide for 2014*.

- eCQM Library http://cms.gov/Regulations-and-Guidance/Legislation/EHRIncentivePrograms/eCQM_Library.html
- CQMs http://www.cms.gov/Regulations-and-Guidance/Legislation/EHRIncentivePrograms/ClinicalQualityMeasures.html

3.3 United States Health Information Knowledgebase (USHIK)

The United States Health Information Knowledgebase (USHIK) is home to the Meaningful Use portal containing specifications, artifacts, downloads, search tools, and other resources for Meaningful Use, including eCQMs, Value Sets, and Objectives for Stage 1 and Stage 2. The USHIK Meaningful Use portal provides eCQM resources at: http://ushik.ahrq.gov, under Meaningful Use.

[9] HL7 Implementation Guide for CDA Release 2: IHE Health Story Consolidation, DSTU Release 1.1—US Realm. http://www.hl7.org/implement/standards/product_brief.cfm?product_id=258

3.4 Electronic Clinical Quality Measure Specification Feedback System

The Electronic Clinical Quality Measure specification feedback system is a tool offered by CMS and Office of the National Coordinator for Health IT (ONC) for implementers to submit issues and request guidance on eCQM logic, specifications, and certification. The tool may be accessed at: http://oncprojecttracking.org/secure/Dashboard.jspa.

3.5 Trifolia Workbench HL7 Web Edition

The Lantana Trifolia Workbench HL7 Web Edition is a read-only repository of all HL7 CDA templates and IGs that have been authored using Trifolia and balloted through HL7. This tool allows users to browse templates, view their constraints, and generate Microsoft Word and HTML documentation from those templates. Users can access QRDA templates (including relationships to C-CDA templates) using HL7 non-member access to Trifolia at http://tdb.lantanagroup.com/.

3.6 Cypress

Cypress is the testing tool of EHRs and EHR modules for calculating MU2 eCQMs. The Cypress tool is open-source and freely available for use or adoption by the health information technology community, including EHR vendors and testing labs. Cypress serves as the official testing tool for the 2014 EHR Certification Program supported by ONC.

Cypress contains software for calculating all 93 MU2 eCQMs. It contains test cases that have been built to check a vendor's logic for each of the measures. Cypress also contains a tool to check the validity of a QRDA Category I or Category III report. Cypress is available at http://projectcypress.org/.

3.7 popHealth

popHealth is an open-source reference implementation software service that automates the reporting of MU2 eCQMs. It integrates with a healthcare provider's EHR system and streamlines the automated generation of summary quality measure reports on the provider's patient population. popHealth has been designed to be permissive and supports numerous data and transport standards. It is also designed to be extensible, supporting multiple standards for both input and output into the future, including QRDA. popHealth is available at http://projectpophealth.org/.

4. Frequently Asked Questions

What is the difference between QRDA Category I and Category III reports?

A: QRDA Category I reports contain quality data for an individual patient. QRDA Category III reports contain aggregated summary quality data for a specified population within a health system. Category III report data is aggregated from individual Category I reports.

What are templates?

A: Templates are business rules for representing information in a standard way. Health information technology standards, such as the HL7 CDA, often are able to convey the same data in multiple ways. Templates enable consistent representations of data to streamline implementations and promote interoperability.

What is the difference between HQMF and QRDA?

A: HQMF (Health Quality Measure Format) eMeasure specifications are used for querying quality measure data that are used in QRDA reporting. HQMF eMeasures represent quality measures in an electronic format. QRDA reports represent quality measure data at the patient and organization level. Patient data are exported from the EHR for eMeasure calculations. Those calculations are then imported into a QRDA report containing summary data for an organization.

What is a DSTU?

A: A Draft Standard for Trial Use is issued at a point in the standards development life cycle when many, but not all, of the guiding requirements have been clarified. A DSTU is intended to be tested and ultimately taken back through the HL7 ballot process to be formalized into an ANSI-accredited standard.

What is a normative standard?

A: Normative standards are formal standards accredited by ANSI.

What are errata?

A: Errata address inaccuracies in representations of HL7 balloted standards, such as misspellings, broken links, or incongruent conformance statements.

What is contained in the QRDA errata package?

A: The QRDA errata package includes: 1) the QRDA DSTU; 2) an export of all templates with conformance corrections; 3) a spreadsheet detailing the errata changes; 4) corrected sample files; 5) corrected Schematron (software used to validate conformance with the standard); and 6) a read.me file.

Can QRDA be used to transmit claims-based measures (e.g., HEDIS)?

A: The MU2 certification program does not assess an EHR's ability to submit claims-based measures using QRDA Category I or III standards, although it is theoretically possible to use these specifications for the transmission of claims-based data.

How can states implement state-specific eCQMs that are not part of the MU2 program?

A: Most eCQMs can be specified to support the use of QRDA Category 1 and Category III formats. If a state wants to use its own measures in the same way, ONC can direct them to the tools required for specifying eCQMs using national formats (e.g., the HQMF).

Does QRDA allow reporting of one patient's data by one or many providers within one patient record (using one QRDA report)?

A: A QRDA Category I report is patient-specific and can contain data associated with more than one provider.

What is the difference between normative and non-normative content?

A: Normative content is the prescriptive portion of a standard that must be adhered to in order to be compliant. Non-normative content is used for communicating content, but adherence is not required for compliance. Examples of non-normative content include introductory narratives and XML representations in figures or sample files.

Are eCQMs electronically reported by vendors or providers?

A: They are reported by providers. Providers may enlist the help of a vendor processing engine.

Do we need QRDA Category I reports to create Category III reports?

A: If you have all the data and access to an HQMF processing engine, it is certainly possible to calculate content for a QRDA Category III report without first creating a QRDA Category I report.

Please explain what you mean by a calculation or processing engine.

A: An HQMF calculation or processing engine is a tool that consumes an eMeasure in HQMF format and runs it against a store of patient-level data (which could be QRDA Category I documents or data in an EHR) and calculates a result, which could be a QRDA Category III (aggregate) report. popHealth is an example of a calculation or processing engine.

How many QRDA templates exist?

A: There are well over 100 templates used in the QRDA specification. Many are reused from other specifications such as C-CDA.

How long will QRDA remain in DSTU status?

A: QRDA will likely remain a DSTU for several years.

Do we have to report initial patient population?

A: Only if it is required by the measure.

Where are the QRDA templates located?

A: They are defined in the HL7 QRDA Category I IG. Please refer to the mapping table on Page 323 in the Appendix.

Are the codes and code systems under each value set validated by the Schematron rules engine during certification?

A: For all STATIC value sets, yes. If a value set is DYNAMIC (meaning it can change over time), then typically not.

The QRDA Category I and III IGs are broad enough to cover different types of quality reporting. What can we use to guide implementations for CMS reporting programs?

A: CMS has developed program-specific guidance for QRDA implementations to meet EH and EP program reporting needs. CMS program QRDA Supplemental IGs serve as companions to the HL7 QRDA IGs and guide QRDA implementations for the CMS reporting program. CMS program QRDA IGs serve as "one-stop-shops" and define constraints specific to QRDA implementations for the CMS reporting program.

Acronyms

This section describes the acronyms used in this guide.

Acronym	Literal Translation
ANSI	American National Standards Institute
CDA	Clinical Document Architecture
CMS	Centers for Medicare & Medicaid Services
CQM	Clinical Quality Measure
DSTU	Draft Standard for Trial Use
eCQM	electronic Clinical Quality Measure
EH	Eligible Hospital
EHR	Electronic Health Record
EP	Eligible Professional
HL7	Health Level Seven
HQMF	Health Quality Measures Format
IG	implementation guide
MU, MU2	Meaningful Use, Meaningful Use Stage 2
NQF	National Quality Forum
ONC	Office of the National Coordinator for Health Information Technology
QDM	Quality Data Model
QRDA	Quality Reporting Data Architecture
QRDA-I	Quality Reporting Data Architecture Category I
QRDA-III	Quality Reporting Data Architecture Category III
USHIK	United States Health Information Knowledgebase
XML	Extensible Markup Language