

Electronic Clinical Quality Measures (eCQMs) Specification, Testing, Standards, Tools, and Community

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This document addresses specification of electronic clinical quality measures (eCQMs), a subset of digital quality measures (dQMs), the standards and tools used in specifying and testing eCQMs, and the eCQM community. eCQMs can promote greater consistency, improve uniformity in defining clinical concepts and logic across quality measures, and increase comparability of performance results. This document supplements the information in the Blueprint content on the CMS MMS Hub, Measure

Specification , Measure Testing, CMS Tools , and External Resources.

1 Background

Collecting and reporting accurate health care performance data has historically been a highly structured and time-consuming manual process. To limit the need for extensive record reviews required by chartabstracted measures, early quality measures used routinely available claims data. Subsequently, clinically-enhanced measures provided increased relevance by supplementing claims information with electronically available laboratory results and pharmaceutical usage data. Increasing use of electronic health records (EHRs) (1) and other electronic clinical systems, which are a source of the desired data, has the potential to provide access to a significantly greater set of clinical information. By utilizing electronic data captured during the routine process of clinical care, the eCQM has become a critical component of the quality reporting framework. When unambiguously represented as eCQMs, quality measures can guide the collection of EHR and other electronic clinical data, which the system can then assemble into quality reports, and submit to organizations such as CMS. CMS considers using the data routinely collected through EHRs and other electronic clinical systems an essential tool for reducing burden. The EHR and other electronic clinical systems hold significant promise for improving the measurement of health care quality. They can make available a broad range of reliable and valid data elements (i) for quality measurement with a lower burden of data collection. Because there is direct extraction of clinical data from standardized machine-readable fields, the industry considers EHR and other electronic clinical systems the authoritative source of clinical information and legal record of care.

Digital quality measures (dQMs) are the parent to eCQMs. CMS aims to transition incrementally to dQMs in all CMS quality reporting and value-based purchasing programs. The 2023 Inpatient Prospective Payment System (IPPS) proposed rule notes CMS's first step towards the transition is for eCQM reporting using Fast Healthcare Interoperability Resources® (FHIR®) standards. CMS drafted a <u>Digital Quality Measure Strategic Roadmap</u>, found on the <u>Electronic Clinical Quality Improvement</u> (eCQI) Resource Center. See section 2.1.5 for more information on FHIR.

The design of eCQMs includes queries to retrieve the necessary information from the EHR's and other electronic clinical data's repositories and generate quality data reports. From there, <u>measured entities</u> (or their proxy) transmit individual and/or aggregate patient quality data to the appropriate agency using <u>Quality Reporting Document Architecture (QRDA)</u> Category I (individual patient data) or Category III (aggregate patient data) reports. As the nation makes progress toward ubiquitous <u>health information technology (IT)</u> adoption, much of the success of health IT will rely on standardized electronic representation of quality measures and clinical decision support (CDS).

eCQM developers need to be knowledgeable of several tools and resources:

- The <u>CMS Measures Management System (MMS) Hub</u> The Blueprint <u>content</u> is part of the <u>CMS MMS Hub</u>. The Blueprint content contains important information regarding the evaluation of the <u>scientific acceptability</u> (i.e., <u>validity</u> and <u>reliability</u>) of eCQMs, which is based on some unique assumptions and special considerations, including
 - the types of clinical data typically encoded using standardized terminology (i.e., a <u>code</u> <u>system()</u>) in EHR and other electronic clinical systems
 - the impact on workflow and <u>data fidelity</u> for measured entities needing to map local codes to standard terminologies used in an eCQM
- Quality Data Model (QDM) The QDM is an information model used to define clinical concepts in a standardized format to enable electronic quality performance measurement. Find more information on QDM in section 2.1.2.
- Measure Authoring Tool (MAT) The MAT is a web-based tool enabling measure developers to author eCQMs in Clinical Quality Language (CQL) (I) /QDM or CQL/FHIR (I), using the QDM data elements or FHIR data elements, CQL, and other standards. Authoring eCQMs in the MAT helps measure developers standardize the eCQM representation, provides validation (I), Expression Logical Model (ELM) translation, and real time access to value sets (I) and direct reference codes (I) via the Value Set Authority Center (VSAC). Find more information on the MAT in section 2.2.1.
- <u>Clinical Quality Language (CQL)</u> CQL is a Health Level Seven International® (HL7®) standard providing the ability to express human-readable logic structured sufficiently for processing a query electronically. Find more information on CQL in section 2.1.3.
- Value Set Authority Center (VSAC) The National Library of Medicine (NLM) provides the VSAC in collaboration with the Office of the National Coordinator for Health Information Technology (ONC) and CMS. Requiring a free Unified Medical Language System® (UMLS®) license for access, the VSAC provides searchable and downloadable access to all official versions of value sets used by each of the eCQM releases used in CMS and other quality reporting programs (e.g., The Joint Commission). eCQM developers may author, and must publish value sets in the VSAC for CMS eCQMs. Find more information on the VSAC in section 2.2.5.
- <u>Bonnie</u> Bonnie is a software tool allowing eCQM developers to test and verify the behavior of their eCQM logic. Find more information on Bonnie in section 2.2.4.
- ONC Project Tracking System (Jira) ☐— Jira ① is an issue tracking system licensed by ONC. It is a collaboration platform supporting the implementation of health IT by providing a space in which internal and external users can transparently log, prioritize, and discuss issues with appropriate subject matter experts (SMEs) on a host of topics. Find more information about Jira in Appendix A.
- <u>eCQI Resource Center</u> The <u>eCQI Resource Center</u> is a website providing eCQI resources and connections. It is the source of truth for specifications of eCQMs in CMS programs and the CMS QRDA Implementation Guides (IGs). It also provides information on standards for eCQI, education, and links to other resources.

Measure Collaboration (MC) Workspace ☐ - The MC Workspace, located on the eCQI Resource
Center, brings together a set of interconnected resources, tools, and processes to promote
transparency and better interaction across interested party communities developing,
implementing, and reporting eCQMs. Find more information on the MC Workspace in section
4.1.

The <u>data source</u> for eCQMs is electronic data, primarily the EHR, whose goal is interoperable transfer of data. Therefore, there is no manual intervention in data storage, collection, and calculation needed for quality measures.

The value-added benefits of eCQMs include

- using clinical data to assess the outcomes of treatment by measured entities
- reducing the burden of manual abstraction and reporting for measured entities
- fostering the goal of access to real-time data for point-of-care quality improvement and clinical decision support

1.1 Components of an eCQM

There are three parts of an eCQM (Figure 1): the data model, expression logic, and the structure. CMS eCQM specifications use standards when specifying the three components to assist with implementation of the eCQM via certified EHR technology (CEHRT[©]).

1.2 Encoding Information for an eCQM

Measure developers author eCQMs to conform to the current HL7 CQL-based HQMF standard for representing a health quality measure as an electronic extensible markup language (XML) document. eCQM specifications use patient/encounter-level or accountable entity-level information coded in a format intended for extraction from EHRs and other electronic clinical systems.

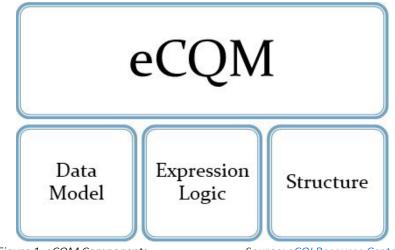


Figure 1. eCQM Components

Source: eCQI Resource Center

Current standards for coding of information for eCQMs consists of three components:

- Computable representations of the eCQM contain important details about the measure, the
 definition of the data elements, and the underlying logic of the measure calculation. The files
 include
 - O HQMF XML syntax (.xml). The HQMF includes a header and a body. The header identifies and classifies the document and provides important metadata about the measure. <u>The MAT User Guide</u> ○, Chapter 6: Measure Details, discusses the metadata, which populates the header. The HQMF body contains eCQM sections (e.g., definitions, <u>population criteria</u> ○, <u>supplemental data elements</u> ○).
 - Shared CQL libraries (.cql, .xml, and .json). The shared libraries are the basic units of sharing CQL. They consist of a foundation of CQL statements used within a measure. Every measure has at least one main CQL library referenced from HQMF.
 - CQL file (.cql). The CQL file provides the expression logic for <u>data criteria</u>, population criteria, and supplemental data elements. Refer to section 2.1.1. It provides a formal description of the computable content in the measure and organized into libraries for reusing or sharing between measures and other artifacts. Refer to section 2.1.3.
 - Expression Logical Model (ELM) XML document (.xml). ELM provides a machinereadable representation of the measure's logic in XML. The intent of the ELM file is for machine processing and provides the information needed to retrieve data from an EHR automatically.
 - ELM JavaScript Object Notation (JSON) file (.json). The JSON file is the ELM file in JavaScript Notation, as opposed to XML.
- **Human-readable representation** of the eCQM displays the eCQM content in a format easily read by humans directly in a web browser, Hypertext Markup Language (HTML) file (.html). This file does not include the underlying HQMF syntax, but the narrative content at the top of the HTML is an extraction from the HOMF header.
- Value sets and direct reference codes (DRCs) convey specific coded value(s) allowed for the data elements within the eCQM. Identification of value sets is via an object identifier (OID) and each value set includes several metadata elements describing the inclusion and exclusion criteria for the codes in the set. The value set includes a list of codes (i.e., the value set expansion code set) acceptable or valid for a specific data element in the measure, descriptors of those codes, the derivation of the codes from the code system, and the version of that code system. DRCs are specific codes referenced directly in the eCQM logic to describe a data element or one of its attributes. Find value sets and DRCs in the VSAC.

1.3 Unique Features of Developing eCQMs

The measure development process for eCQMs does not differ significantly from the process used for non- eCQMs. The measure conceptualization process is the same for eCQMs as for measures developed using other data sources. While processes are alike with respect to defining measure metadata and measure components for each measure scoring type (e.g., process (e.g., proportion (e.g., processos (e.g., pro

components and standard terminologies to assemble the data criteria. eCQMs are based on information that should exist in a structured format in electronic clinical systems such as EHRs. In principle, all information should be available and accessible without impacting the normal clinical workflow; hence, it is essential to consider carefully how, by whom, and the context of the desired information for capture.

eCQM developers can use the <u>MC Workspace</u> as a vehicle for interested party feedback. They should share suggested eCQM concepts in the <u>eCQM Concepts</u> module allowing for feedback in refining the suggested eCQM concept. The <u>eCQM Testing Opportunities</u> module provides a space for eCQM developers to announce opportunities to test eCQMs at any stage of the Measure Lifecycle.

Evaluation of the scientific acceptability (i.e., validity and reliability) of eCQMs is based on some unique assumptions and special considerations:

- eCQM evaluation is based on use of only data elements expressed using the QDM.
- Quality measures based on electronic clinical systems should significantly reduce measurement errors due to manual abstraction, coding issues, and inaccurate transcription errors, thereby improving reliability and validity.
- eCQMs are subject to some of the same potential implementation issues as non-eCQMs, which could result in low evaluation ratings for the reliability and validity of data elements and measure scores.
- There is a requirement for careful analysis, such as through systematic <u>audits</u> of patient data used in reporting (<u>Pronovost</u>, <u>Wu</u>, <u>& Austin</u>, <u>2017</u> □) to avoid the potential, unintended consequences of selecting infrequently or inconsistently captured data elements. For example, updates to problem lists may not occur in a timely manner or not reconciled to remove or resolve inactive health concerns. Therefore, using information from problem lists may not necessarily provide valid and reliable data. Since eCQMs rely on accurately maintained, specifically encoded data in the EHR or other clinical software, increased attention to improved clinical workflow and routine data capture is essential.
- Examples of potential sources of error that may occur as a result of implementation include
 - EHR or other clinical software system structure or programming not complying with standards for data fields, coding, or exporting data, such as administrative, laboratory, radiology, and pharmacy systems.
 - Data fields used in different ways or multiple ways to enter the same data. For example, variation in clinical workflow resulting in entries made into the EHR fields other than those used to retrieve data to calculate the eCQM resulting in data captured in clinical software fields different from those programmed to retrieve data to calculate the eCQM.
 - Inaccurate interpretation of data by natural language processing (NLP) software used to analyze information from text fields.
 - Variability in the mapping of data encoded using a non-standard (local) terminology to the

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¹ It is possible to use data not in a structured field in conjunction with natural language processing (NLP) software or similar tools.

² eCQM specifications, as defined by QDM data elements, do not designate where (e.g., Problem List) in the EHR to extract the data.

standard terminology expected by the eCQM.

- Data format issues such as string vs numerical data and data in binary large object (BLOB) of text (text blob ①) or pdf.
- Although there is the assumption of data element reliability (repeatability) with computer programming of an eCQM, the requirement is to evaluate the reliability of the measure score with empirical evidence.

To test data element validity, the measure developer should

- Compare the electronic extract with the manual abstract.
- Ensure NLP is correct (if using NLP).

In addition, measure developers must consider several features, e.g., the types of clinical data typically encoded using standardized terminology (i.e., a code system) in EHRs and other clinical software systems and the impact on workflow and data fidelity for measured entities needing to map local codes to standard terminologies used in an eCQM.

eCQM development is a community effort promoting the early and frequent engagement of patients, caregivers, measured entities, and implementers throughout the process. See section 4, Engaging in the eCQM Community. While the community-type approach is the goal of any measure development effort, eCQMs are different since health IT standards organizations and the EHR and other clinical software system vendor community should inform eCQM development. Doing so allows for a better overall assessment of industry readiness and drives a more informed approach to technical specifications to better support and facilitate eCQM implementation. Given the many different EHR and other clinical software systems products available, it is critical for eCQM specifications not only be compatible with EHR products and other clinical software systems, but also impose a minimal, commensurate burden on the measured entities.

2 Standards and Tools for eCQMs

eCQM specification development and maintenance has evolved into a highly structured process requiring input from multiple interested parties (e.g., CMS, NLM, measure steward) as well as use of multiple standards-based guidance documents and tools. The tools used to implement the standards discussed in this document during eCQM development and maintenance include measure authoring and information gathering tools (e.g., MAT, VSAC), testing tools (e.g., Bonnie), and the ONC Project Tracking System (Jira) (refer to Appendix A). The standards-based guidance and tools described here apply to de novo eCQMs, respecified eCQMs, and eCQM maintenance.

2.1 eCQM Standards

The information container for an eCQM is HQMF using the QDM for the data model and CQL for the logic expressions (Figure 2). QDM data criteria specify only the data of interest (e.g., clinical concepts, concept details/attributes) for the eCQM. CQL expressions capture interrelationships between data criteria, such as "starts after end of," or identified subsets of data, such as min, max, last, and first. The standards used to develop eCQMs are HQMF, QDM, and CQL. The standard used to report eCQMs is QRDA. A brief discussion of each element follows.

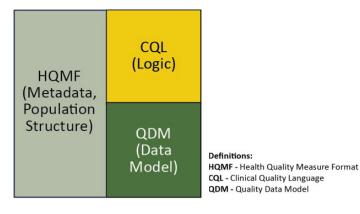


Figure 2. eCQM Information Structure

2.1.1 Health Quality Measure Format (HQMF)

HQMF is an HL7 standard for representing a health quality measure as an electronic XML document.³ Through standardization of a measure's structure, metadata, definitions, and logic, the HQMF provides quality measure consistency and unambiguous interpretation. HQMF is a component of a larger end-to-end quality framework, which has evolved to a normative HL7 standard. HQMF/CQL-defined eCQMs are queries that can automatically capture data from the EHR data repositories. Health care facilities can use the data captured for measures to create QRDA reports. From there, transmission of individual and/or aggregate patient quality data to the appropriate agency can occur.

Published as a standard for trial use (STU) in 2009, the HQMF Release 1 (R1) is the underlying structured representation used by the CMS MAT for eCQMs developed through June 2014. HL7 updated HQMF to STU Release 2.1 (R2.1) in 2015 and updated to a normative standard in January 2017. The normative standard is the version currently in use.

The components of an HQMF document include a header and a body. The header identifies and classifies the document and provides important metadata about the measure such as general descriptions; numerator and <a href="mailto:denominator statements; the measure steward, measure type, and measure scoring; guidance; and definitions, as well as information about whether the measure is CMS consensus-based entity (CBE)-endorsed. The human readable HTML body displays the eCQM sections (see the MAT User Guide):

- population criteria
- definitions
- functions

³ Refer to eCQI Resource Center pages for eligible hospital/critical access hospital and eligible professional/eligible clinician measures, for upto-date examples of how eCQMs appear as XML, JSON, and HTML documents.

- terminology
- data criteria (QDM data elements)
- supplemental data elements
- risk adjustment (i) variables

Population criteria should include narrative descriptions and all sections should contain formally encoded HQMF entries. For more information on the quality measures encoded in HQMF, refer to the HL7 HQMF IGs.

Any eCQM intended for submission to CMS for review and for submission to the CMS CBE for endorsement must be in HQMF. When measure developers author their eCQMs in the MATC, they assure a machine-readable, standards-based representation. Developed under contract with CMS, the MAT aids in the creation of eCQMs using CMS-required standards. See section 2.2.1.

2.1.2 Quality Data Model

The QDM is a standard information model adopted by CMS describing the data needed to represent information necessary for electronic quality assessment. The Health Information Technology Expert Panel (HITEP) initially established the QDM in 2009. CMS is now the QDM sponsor.

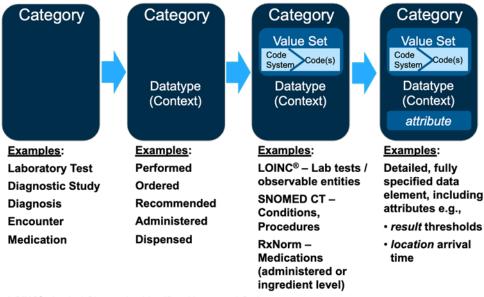
The QDM allows definition of a data element: the smallest possible unit of information with precise meaning to communicate the data required within a quality measure. Each data element contains

- A QDM category: a single clinical concept identified by a value set.
- A QDM datatype: the context for use of each category to describe a part of the clinical care process.
- Values: a single code or list of codes used to define the specific data element. For values requiring coded data, there are code system recommendations used for a data element's category (e.g., SNOMED CT, Logical Observation Identifiers Names and Codes, RxNorm). For more information about code systems, refer to the <u>Code Systems, Vocabularies, and Terminologies</u> section of the <u>CMS MMS Hub</u> and the <u>United States Core Data for Interoperability</u>.
- A QDM attribute provides specific detail about a QDM datatype further constraining the concept.
- QDM entities represent a concept used to specify details about the actor (or performer) of any QDM datatype. An eCQM can use the entities to provide further information required for an individual or organization actor to meet the measure's criteria.

The measure developer can specify a data element by selecting a QDM category, the expected QDM datatype for the category with respect to electronic clinical data, a value or value set drawn from an appropriate code system, and all necessary attributes. Refer to section 4.1, MC Workspace, for more information on the <u>eCQM Data Element Repository</u> (DERep). Figure 3 shows the QDM data element structure.

- QDM category e.g., Laboratory Test
- QDM datatype e.g., "Laboratory Test, Performed"

- Value set e.g., High Density Lipoprotein (HDL)
- QDM data element e.g., Laboratory Test, Performed: HDL
- QDM attribute



LOINC® - Logical Observation Identifiers Names and Codes

Figure 3. QDM Data Element Structure

Find information about current and prior QDM versions on the <u>eCQI Resource Center</u>.

The QDM User Group previously was the body making recommendations for changes to the QDM. With the evolving transition from the QDM to the FHIR model, CMS has broadened the focus and renamed the QDM User Group to the Quality Data Implementation (QDI) User Group. This group will ensure interested party collaboration in data model guidance, development, maintenance, and harmonization between quality and clinical decision support (CDS) standards. Technical questions and comments related to the QDM and QDI should go to the QDM <u>Jira project</u>. The <u>QDI User Group Charter</u> outlines the mission, purpose, scope, and responsibilities of the QDI User Group.

2.1.3 Clinical Quality Language

CQL is a clinically-focused and author-friendly <u>HL7 standard</u> enabling precise eCQM specifications. CQL provides the ability to express human-readable logic structured sufficiently for processing a query electronically. The evolution of CQL enables greater flexibility of expression and the <u>CQL Style Guide</u> helps with consistency across eCQMs.

The CQL specification provides a machine-readable representation, ELM, which provides a more streamlined format for automated sharing of executable eCQM logic. "The ELM file provides the semantics necessary to retrieve the correct data from the EHR" (MAT User Guide , p. 87).

The <u>CQL Formatting and Usage Wiki</u> serves as a collaborative workspace for the development of CQL formatting conventions and usage patterns for the representation of logic within quality measures. All users have the rights to submit edits and add comments and concerns.

The CQL Style Guide provides examples to standardize expression of measure concepts across eCQMs

and define a uniform "look and feel" to eCQM logic using CQL. The *CQL Style Guide* focuses on a set of common best practices implemented across CQL-based eCQMs in CMS quality reporting programs and also promotes the use of consistent language within the framework of CQL, including libraries, aliases, definitions, functions, and conventions. Refer to the <u>eCQM Logic Quality Assurance Checklist</u> to help with review of eCQM logic.

2.1.4 Quality Reporting Document Architecture

After eCQM specification, testing, and implementation, the EHR and electronic clinical system implementers use the CQL queries to retrieve the necessary information from the EHR's data repositories and generate quality measure reports. eCQM reporting (i.e., the transmission format) is another important component of the quality reporting end-to-end framework. Transmission of individual and aggregate patient quality measure data to the appropriate agency uses QRDA Category I (i.e., individual patient data) and Category III (i.e., aggregate patient data) reports. Both QRDA Category I and Category III are HL7 standards for reporting quality measures.

QRDA is an HL7 Clinical Document Architecture (CDA)-based standard. As such, the QRDA conforms to the HL7 CDA standard. The HL7 QRDA IGs⁴ describe the constraints on the CDA. CMS further constrains the base QRDAs and publishes IGs and schematrons for CMS reporting. Schematrons provide technical instructions to validate the constraints and rules specific to the QRDA.

Each QRDA Category I report contains quality data for one patient for one or more quality measures. For each QDM datatype, there is a one-to-one mapping of each QRDA Category I template to its corresponding HQMF template specified in the HL7 CQL-based HQMF IG. This tight coupling helps to streamline the end-to-end process from eCQM specification to eCQM reporting.

Like a QRDA Category I report, a QRDA Category III report also contains a Measure section listing the reported eCQM(s) and a Reporting Parameters section providing information about the reporting/performance period. However, instead of reporting individual patient data, the report includes an aggregated summary for all patient populations relative to a measure (i.e., a total count of patients who meet the denominator population criteria of a measure within a measured entity over a specific period of time).

⁴ QRDA I - http://www.hl7.org/implement/standards/product_brief.cfm?product_id=35 —, QRDA III - http://www.hl7.org/implement/standards/product_brief.cfm?product_id=286

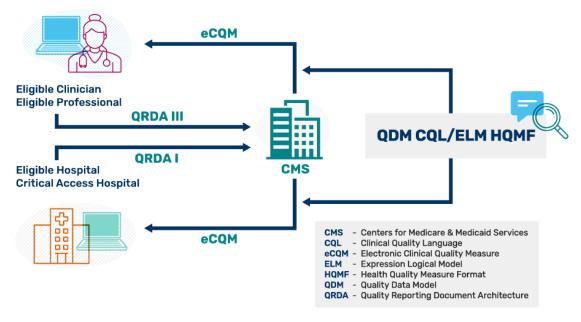


Figure 4. Connections between Standards

As depicted in Figure 4, measured entities receive the measure specifications, expressed in HQMF using QDM and CQL, and then report results to CMS using QRDA as specified by CMS programs.

2.1.5 Emerging Standards

The 21st Century Cures Act (Public Law [P.L.] 114-255), and the subsequent ONC 21st Century Cures Act and CMS Interoperability and Patient Access final rules, emphasize interoperability of health information. As a result, HL7's FHIR and associated standards are undergoing testing for possible adoption by CMS. CMS supports the use of FHIR as the standard for health care quality data exchange and will continue testing prior to implementing FHIR-based application programming interfaces (APIs) for the transmission and receipt of quality measure data. Most of these standards arose from harmonizing CDS standards and eCQM standards. A goal is to use the same standards for CDS and eCQMs. Figure 5 provides a crosswalk from current standards to potential future standards.

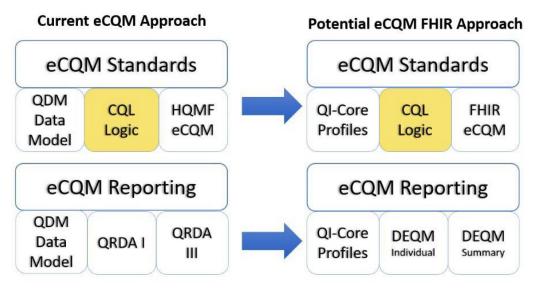


Figure 5. Potential Future of eCQM Standards

The basic building block of FHIR is resources. All exchangeable content is a resource. The FHIR specification has multiple modules, such as foundation, terminology, clinical, medications, and clinical reasoning. The <u>Clinical Reasoning module</u> is for CDS and quality measures. CQL is an expression logic and eCQMs are knowledge artifacts within Clinical Reasoning.

Quality Improvement (QI)-Core is a logical model bringing together the QDM and the <u>virtual Medical</u>

<u>Record</u> (vMR), the common reference model for CDS. QI-Core is FHIR version-specific. A bidirectional mapping of the QDM and QI-Core data elements is available in the <u>QI-Core IG</u>.

<u>Data Exchange for Quality Measures (DEQM)</u> is a framework for exchanging quality information and quality measure reporting. The goal of the DEQM framework is to enable automatic data collection and submission. Development of the DEQM framework used QRDA.

For more information on FHIR, see the <u>HL7 FHIR</u> website. For more information about FHIR in quality measures, see the <u>eCQI Resource Center</u>.

2.2 Tools for Developing eCQMs

Using eCQM-friendly tools provides standardization in developing eCQMs. This standardization will facilitate implementation by minimizing measured entity burden.

Figure 6 shows the connections among eCQM standards and the tools used to help develop and test eCQMs.

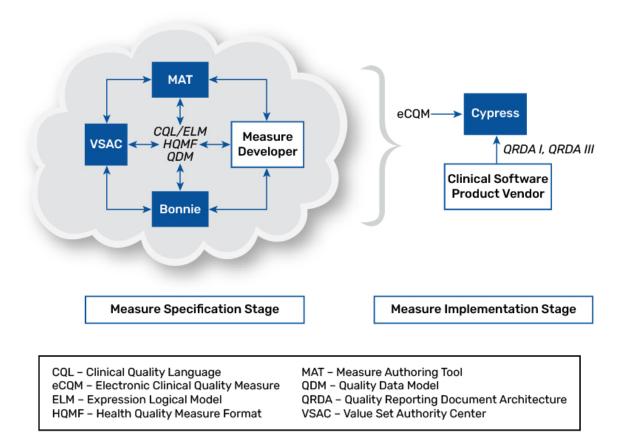


Figure 6. Tools for eCQM Development

2.2.1 Measure Authoring Tool

The <u>MAT</u> is a web-based authoring tool required for developing and maintaining eCQMs for CMS programs. The requirement is to ensure eCQM developers are using the established health IT standards and clinical terminology code systems needed for eCQM implementation. The MAT currently supports two standards, QDM and FHIR. Specifically, the MAT enables measure developers to author eCQMs in CQL/QDM or CQL/FHIR using the QDM data elements, FHIR data elements, CQL, and other standards to meet future measure authoring requirements.

For QDM, the MAT provides the capability to express complex eCQM logic and export eCQM packages. The eCQM package includes a human-readable document users can view in a web browser, the CQL-based HQMF eCQM, an eCQM HQMF XML document, and ELM XML document, and a corresponding ELM JSON file. For FHIR, the MAT also provides several artifacts, including a human-readable document users can view in a web browser and a FHIR-based measure bundle available in JSON and XML. Measure developers use both Bonnie and the MAT to promote test-driven development.

The <u>MAT User Guide</u> , Chapter 6: Measure Details, summarizes the eCQM metadata in the display order as generated from the MAT.

A MAT account is free and is available for anyone completing the application process. The MAT requires a valid Healthcare Quality Information System (HCQIS) Access Roles and Profile (HARP) ID. Measure developers who do not have a HARP ID should register on the HCQIS Access Roles and Profile page.

The MAT staff then processes the application for approval. Individuals receive a notification after creation of their new MAT user ID. Individuals who have a current MAT account should use the same email address previously used with the MAT when registering for a HARP ID.

2.2.2 Measure Authoring Development Integrated Environment (MADIE)

MADIE orings together the eCQM development and testing processes within a single application. MADIE can generate eCQMs using FHIR and CQL following the QM IG and CQL in addition to eCQMs using QDM and CQL. MADIE allows eCQM developers to transition their eCQMs to QI-Core. MADIE provides eCQM logic testing and verification also available via Bonnie.

2.2.3 CQL-to-ELM Translator

The <u>CQL-to-ELM Translator</u> is a specification describing a formal mechanism for translating the high-level CQL syntax into the canonical ELM representation. The intent of the reference implementation is for use by eCQM authoring tools in support of clinical quality framework implementations to enable uniform and automatically translated CQL output into ELM XML or JSON documents. This in turn enables sharing and distribution to support implementation, integration, translation, and execution of CQL-based artifacts. The MAT uses the CQL-to-ELM Translator for validation of syntactically correct CQL content.

The Translator is an artifact of the HL7 CQL specification maintained by the CMS eCQM Standards contractor. The Translator is open source and available on GitHub.

2.2.4 Bonnie

Bonnie is a web-based tool used by eCQM developers to test eCQM logic during the measure development process. This process, known as test-driven development, utilizes measure developer-created test cases (i.e., synthetic patient data) to mimic real-world patient scenarios. The intent is to

assess the accuracy, completeness, and coverage of the eCQM logic prior to finalizing the technical specification. This approach, when coupled with real-world clinical site feasibility, reliability, and validity testing, minimizes specification errors during eCQM implementation.

The main goal of the Bonnie application is to reduce the number of defects in eCQMs by providing a robust and automated testing framework. The Bonnie application allows measure developers to load eCQMs they have constructed using the MAT. Measure developers build a synthetic patient test deck for each eCQM from the clinical elements defined during the measure construction process. By using eCQM logic as a basis for building synthetic patients, measure developers can quickly and efficiently create a test deck for an eCQM. A test deck is a group of test cases evaluating each part of the eCQM's logic. The Bonnie application helps measure developers execute the eCQM logic against the constructed patient test deck and evaluate whether the logic aligns with the intent of the eCQM. Bonnie also shows which sections of the eCQM the test deck has tested, allowing measure developers to ensure testing of all logic in the eCQM. Refer to the Bonnie User Guide (for QDM-based eCQMs) or the Bonnie FHIR User Guide (for FHIR-based eCQMs) for more information.

Bonnie currently has three environments, <u>Bonnie Prior</u>, which supports QDM 5.5, <u>Bonnie Proper</u>, which supports QDM 5.6, and <u>Bonnie FHIR</u>, which supports FHIR. Each requires a valid HARP ID. Measure developers who do not have a HARP ID should register on the <u>HCQIS Access Roles and Profile</u> page. Users also must have a valid Bonnie account in any environment they wish to use. Users can register via the Bonnie tool. The Bonnie help desk receives the request and processes the request for approval. Individuals receive a notification after account approval.

2.2.5 Value Set Authority Center

The <u>VSAC</u> of value sets for CMS eCQM data elements. NLM coordinates and curates terminology used by the different code systems—e.g., SNOMED CT, Current Procedural Terminology (CPT)— used by measure developers for authoring eCQMs. The *VSAC* requires a free UMLS license for access and provides searchable and downloadable access to all official versions of value sets used by each of the eCQM releases in CMS and other quality reporting programs (e.g., The Joint Commission). Measure developers use the *VSAC* to author the value sets used in eCQMs.

The VSAC is not specific to eCQMs, but its use is a requirement for CMS eCQMs.

2.3 Cypress Certification Tool

<u>Cypress</u> is an open-source testing tool used by health IT vendors to certify their EHRs and health IT modules (CEHRT) for calculating eCQMs. Cypress is an official testing tool for the ONC Health IT Certification Program. Testing involves Cypress generating synthetic patient records for the subset of published eCQMs selected for certification and testing the ability of the EHR systems and health IT modules to accurately record, import, calculate, filter, and report eCQMs.

Starting in 2019, Cypress fully integrated the Cypress Validation Utility + Calculation Check (CVU+) into the Cypress application. The CVU+ facilitates real world testing, providing health IT vendors the ability to perform tests using their own test patients. The CVU+ supports validation with the CMS QRDA IGs, as well as performs eCQM calculation with measure logic highlighting. Health IT vendors may use the CVU+ functionality as they update their systems to adopt the latest eCQM versions and associated standards.

3 eCQM Testing

When evaluating an eCQM's readiness for implementation and adoption, the measure developer uses eCQM testing to assess the extent to which an eCQM meets the measure properties of feasibility, validity, and reliability. Measures developed based on data extracted from the EHR and other electronic clinical systems must still meet the evaluation criteria just like any other measure.

As with other types of measures, testing eCQM properties is an iterative process, with the purpose of refining and revising the eCQM until resolution of all quality issues. The goal is to produce a reliable and valid eCQM ready for implementation. eCQM testing is possible after completion of the eCQM specification in the MAT, export of the eCQM package, and their provision to the testing team.

Measure developers should perform early feasibility testing prior to electronic specification in the MAT to test the reasonableness of collecting expected data elements during common workflow practice and to determine whether there is capture of data elements within an EHR system or other electronic clinical system. Post-MAT, the measure developer tests the validity and reliability to confirm the electronically specified measure meets its intended purpose; the measure produces consistent, repeatable results; and the logic is not ambiguous. As EHR and other electronic clinical systems become more generally available and more integrated, additional documented clinical information may also become widely available for measure use.

However, a multitude of EHR systems and other electronic clinical systems are in use today, particularly in the ambulatory care setting, and measure developers must manage this diversity when developing eCQM specifications for use across EHR systems. To address this issue, measure developers are to author eCQMs in the MAT and specify eCQMs using the QDM and CQL. The use of the MAT, CQL, and the QDM promote standards-based, consistent, reliable, and valid eCQMs when extracted across diverse, certified EHR systems. However, standards also raise new considerations when testing eCQMs including specification accuracy in EHRs, EHR validity testing , measure score and data element testing, testing of respecified measures, and feasibility testing. The different types of testing uncover different information about the extent of feasibility, reliability, and validity of the measure properties. Testing identifies ambiguities in the eCQM logic, potential barriers to implementation, and reasonableness of the data elements specified in the eCQM.

For eCQMs, reliability and validity testing need to verify the testing showed evidence of

- adequate agreement between electronic extraction and manual abstraction
- use of appropriate codes and taxonomies
- use of appropriate QDM datatypes

Measure developers should test data elements in non-structured fields at the patient/encounter/accountable entity data elements. If desiring CMS CBE-endorsement, the measure developer submits the testing results to the CMS CBE.

Measures originally specified using data sources other than an EHR (i.e., paper patient records or claims data) can be respecified for use with EHRs. However, even if these measures have previously received approval by CMS and show adequate reliability and validity in the original measure, measure developers should assess the eCQMs for reliability and validity.

3.1 ECQM VALIDITY

Validity testing for the eCQM confirms the intent of the measure, ensures eCQM logic is not ambiguous and expected test patients fall in the correct populations (e.g., using Bonnie), determines whether there is alignment between data elements and national standards, and checks calculated scores from automated extraction for accuracy. These items are in addition to the <u>validity testing criteria</u> for other types of measures, which evaluate whether the measure assesses what it purports to measure.

Ideally, <u>CEHRT</u> uses clinical information recorded in discrete machine-readable fields, which potentially reduces errors in measure data elements arising from manual abstraction or coding errors. However, eCQMs need evaluation during <u>measure testing</u>. Examples of factors that can affect validity include

- Complex specifications, which may make an eCQM more susceptible to varying data field interpretation by different users.
- Users may enter information into EHR fields other than those from which the vendor extracts data for eCQM reporting.
- Even small errors in the eCQM specifications, such as omission of codes for commonly
 documented concepts in value sets, can reduce the capture of appropriate patients in the
 eCQM's denominator.

Respecified eCQMs require a subjective evaluation of the human-readable document of the eCQM to confirm the intent of the measure is unchanged from the original specification. An example of a subjective evaluation includes confirmation by the steward for a respecified measure the eCQM preserves the intent of the original paper or claims-based measure equivalent "at face value." A subjective evaluation for a de novo eCQM includes confirmation by a clinical working group or Technical Expert Panel (TEP) that the eCQM concepts reflect the intent. Measure level (i.e., face) validity testing may involve iterative discussions with the measure steward or clinical working group/TEP to ensure maintenance of the original intent of the measure concept in the eCQM. However, face validity alone is insufficient. Measure developers must perform empirical data element validity unless there is a justifiable reason (see <u>Measure Selection</u>).

Refer to the CMS <u>CBE Measure Partnership for Quality Measurement (PQM) Endorsement and Maintenance</u> and the Blueprint content on the *CMS MMS Hub*, <u>Validity</u>, for more information and guidance on validity testing.

3.1.1 Measure Logic Validity

Measure developers should perform an objective evaluation of eCQM logic to confirm whether the eCQM can correctly identify patients intended for inclusion in or exclusion from the numerator, denominator, and other relevant populations of the eCQM. The test aims to ensure expression of the logic of the eCQM is without ambiguity, to validate the eCQM's "development against a base set of synthetic patient records with known expectations for calculating against the implemented measures" (Bonnie User Guide , p.6). Testing may identify potential differences in the interpretation of measure logic encoded in the eCQM. Measure developers should test and verify the logic of their eCQM using the Bonnie tool. If the measure developer does not use Bonnie, they must show evidence of 100% coverage of the eCQM logic using simulated data.

3.1.2 Data Element Validity

Measure developers should conduct an objective evaluation of whether data elements electronically extracted from an EHR/electronic clinical system are comparable to similar data elements manually abstracted by the reviewers. The terminology section (e.g., eCQM HTML) containing the relevant value sets is the baseline for the automatic extraction. This testing method applies to respecified and de novo eCQMs.

The measure developer should collect data elements from test site EHRs/electronic clinical system through electronic extraction and compare them to a manual EHR/electronic clinical system abstract to assess validity of the electronic extraction. They should perform this comparison to determine whether the eCQM provides the same results for numerator inclusion/exclusion and denominator inclusions as the manual abstraction. If testing identifies discrepancies, the presumption is visual review of the manually abstracted data elements is correct, serving as the gold standard.

The guide for this data element validity design is the rationale that electronic extraction of EHR/electronic clinical system data cannot detect values entered as free text as opposed to structured data, while manual abstraction will usually capture both free text and structured data and, therefore, be more complete and accurate. Data elements demonstrating a pattern of disagreement between the results from visual abstraction and electronic extraction may arise either because documentation of some data required for the measure is in the EHR/electronic clinical system in a format the electronic extraction did not capture, or there are problems with the composition of the eCQM query.

For eCQM data elements, adequate demonstration of validity is either an observation of

 adequate agreement between data elements electronically extracted and data elements manually abstracted from the EHR

OR

• complete agreement between the known values from a simulated QDM-compliant data set and the elements obtained with application of the eCQM specifications to the data set

CMS CBE guidance further clarifies the expectation measure developers rely on data from structured data fields or demonstrate unstructured data are both reliable and valid.

3.1.3 Standards Conformance Validation

To help ensure accuracy of data elements, measure developers should validate the content of the extensible markup language (XML), using one of three types of validation.

• Syntactic validation—This method of accuracy validation ensures the XML content follows (i.e., conforms to) specific constraints required by the HL7 HQMF standard and the XML patterns based on the QDM. The MAT has these quality-checking processes built into the application. The MAT uses the <u>CQL-to-ELM Translator</u> for validation of syntactically correct CQL content. The Translator provides validation of CQL expressions based on the <u>CQL grammar files</u>, which are part of the HL7 CQL standard. If no syntax errors exist in a CQL file, the Translator converts the CQL file into the respective ELM XML and JSON content based on the <u>ELM XML schema</u>.

To help a measure developer avoid pitfalls violating conformance requirements in CQL-based HQMF, the MAT provides various levels of validation within the tool to help guide users in creating syntactically correct CQL-based HQMF before they package their eCQMs. Built into the MAT are various preventions including

- Provision of correct model (i.e., QDM) and version within the CQL workspace CQL syntax error and warning checking with highlighting. The MAT does not allow a user to package an eCQM if CQL syntax errors are present.
- Provision of default CQL expressions: "Measurement Period" parameter and the four CMS Supplemental Data Element definitions (i.e., Ethnicity, Race, ONC Administrative Sex, and Payer). Based on the CQL-based HQMF IG, these expressions must meet certain requirements.
- Duplicate identifier checking. No two library-level identifiers (e.g., definition names, function names, local identifiers for codes and value sets) may have the same name within a library.
- Filtering of definitions for population workspace based on the user-provided patient-based indicator for the measure.
- O Population grouping help/notifications to offer guidance to users so they use correct type and number of populations within a measure group based on the user-provided measure score (i.e., cohort, CV, proportion, or ratio).
- Expression return type validation.
- HL7 International Organization for Standardization (ISO)-based Schematron. This method is
 a possible mechanism for validating XML written outside the MAT. However, it may not
 include all components built into the MAT. For additional resources and information on the
 ISO Schematron, including technical specifications, see the ISO[™] website.
- Narrative validation. The MAT output includes a human-readable document viewable in a standard web browser in HTML. When viewed in a web browser, the measure developer can assess the extent to which the machine-generated criteria correctly reflect the original measure criteria under development. When the measure developer validates correctness of the human-readable format, this is narrative validation.

3.2 eCQM Reliability

Testing for reliability involves experts assessing the human-readable format (i.e., HTML) of the eCQM for clarity and alignment to standard specifications. A reliable measure is reproducible and consistently implemented within and across organizations. Reliability allows for comparability of results. Three ways of testing reliability of an eCQM are to evaluate the measure for clarity, logic ambiguity, and data element alignment with standard specifications supporting consistent implementations. Measure developers should use the Bonnie tool to test logic. Clarity and alignment assessments can be visual and subjective. This testing is in addition to and does not replace statistical reliability testing. For more information on reliability testing, see the Blueprint content on the CMS MMS Hub, Reliability.

3.3 eCQM Feasibility

The feasibility assessment may include discussions with SMEs such as vendors and implementers of EHR systems and evaluation of data capture in an active clinical setting. The measure developer must assess

feasibility of the eCQM concept at the time of eCQM conception and definitely prior to drafting initial eCQM specifications to ensure the data elements are available in a usable structured format and the measured entity can code using standard terminologies within the EHR/electronic clinical system. This process is critical to ensure a developed eCQM passes feasibility assessments during beta (i.e., field) testing and to avoid re-expressing eCQM concepts or replacing the eCQM after completion of a considerable amount of work. Measure developers should conduct reassessment or, at a minimum, review of previous feasibility assessments as part of maintenance.

In addition to information obtained from SMEs, measure developers should use empirical analysis to test the feasibility of data elements required for an eCQM. Feasibility considerations include

- data availability (including availability in a structured format)
- accuracy of the information in the data
- maturity of standards
- standard terminologies
- extent to which data collection and encoding will require modification and/or additional data collection to the workflow

When testing feasibility, it is important to understand the intent of the eCQM because the intent can influence the collection of data. For more information on feasibility assessment see the Blueprint content on the CMS MMS Hub, Feasibility.

Feasibility is more than a demonstration by an EHR vendor of the system's ability to capture a data element. Feasibility testing evaluates the reasonableness of collecting the expected data elements during a typical clinical workflow in an EHR system, evaluates the burden on clinicians, and determines if the system captures the data elements. When developing the feasibility testing and maintenance plan, the measure developer should carefully consider determining the threshold for feasibility. Refer to the PQM E&M website and the CMS CBE PCQM Feasibility Scorecard for more information and guidance. The CMS CBE requires the Feasibility Scorecard for endorsement of eCQMs.

3.4 Testing Multiple Sites and Multiple EHRs

Testing eCQMs at multiple sites using multiple EHRs for validity, reliability, and feasibility is important to address potential variability in reporting based on differences in local workflow process. Even multiple sites using the same EHR vendor product may show different results since the local workflow may vary and there may not be consistent entry of data into the fields expected by the vendor. Evaluate variances in results from testing at multiple sites to determine whether there is a need for changes in the eCQM logic or definition. Testing must encompass at least two EHR products.

4 Engaging in the eCQM Community

Interested parties can engage in the eCQM Community in a variety of ways. Visit the eCQI Resource Center Engage in Electronic Clinical Quality Improvement webpage for examples of opportunities.

4.1 Measure Collaboration Workspace (MC Workspace)

The <u>MC Workspace</u> is a result of the outreach CMS conducted as part of the <u>eCQM Strategy Project</u>. The goal of the <u>MC Workspace</u> is to bring together a set of interconnected resources, tools, and

processes to promote transparency and better interaction across interested party communities developing, implementing, and reporting eCQMs.

The *MC Workspace* consists of three modules to assist clinicians, eCQM developers, implementers, and submitters through the eCQM lifecycle, from initial measure concept, through development, testing, implementation, and reporting to CMS. The addition of new content will occur over time, and CMS encourages interested parties to review the *MC Workspace* and participate interactively. Goals of the *MC Workspace* are to

- provide detailed data element definitions to support implementation
- achieve harmonization ⊕ across measures, data elements, and value sets
- improve alignment of measure concepts with clinical need and newly published guidelines
- demonstrate how new measures fill existing quality reporting gaps
- increase involvement by clinical experts and EHR vendors during measure development

The three modules are

- <u>eCQM Concepts</u> ☐— The eCQM Concepts module provides users with the ability to comment on eCQM concepts suggested by others, suggest new eCQM concepts, and find links to sources to identify whether similar eCQMs exist. User feedback can help guide an eCQM developer to refine a concept and purpose of a new eCQM to better meet the needs of those interested in quality measurement.
- <u>eCQM Testing Opportunities</u> The eCQM Testing Opportunities module provides measure developers a place to announce eCQM testing opportunities and interested parties with available opportunities to participate in eCQM testing. Measure developers use testing for a variety of reasons throughout the Measure Lifecycle.
- <u>eCQM Data Element Repository</u> provides all the data elements associated with published and tested eCQMs for use in CMS quality reporting programs as well as the definitions and clinical focus for each data element. An end user can sort information by Eligible Hospital/Critical Access Hospital eCQMs, Eligible Professional/Eligible Clinician eCQMs, data element, eCQM, QDM attribute, QDM category, QDM datatype or QDM entities. The DERep makes available 4 years of data. When the eCQI Resource Center publishes a new year of data, the oldest year drops off.

Persons interested in eCQM development, testing, and implementation should <u>register</u> for an eCQI Resource Center account and engage with the MC Workspace.

4.2 Change Review Process (CRP) and eCQM Annual Update

The eCQM Annual Update process includes updates to eCQM specifications, supporting documentation, and eCQM tools, and may include updates to eCQM standards. CMS updates eCQMs annually to align with current clinical practice guidelines①, code systems, and eCQM standards, and to help ensure eCQMs remain relevant and actionable within the clinical care setting. CMS may also update eCQMs in response to end user questions or suggestions, usually submitted via the Jira CQM project . Selected issues submitted via the ONC Project Tracking System (Jira) and other means go through the CRP.

4.2.1 Change Review Process

The goal of the CRP is to work with eCQM implementers to determine the impact of an update, while minimizing measured entity and vendor burden in the collection, capture, calculation, and reporting of eCQMs. eCQM users have the opportunity to review and comment on proposed changes to the eCQM specifications through the Jira website before official adoption of changes. Measure developers then incorporate CMS-approved changes during the eCQM Annual Update. To participate in the CRP, users must have a Jira account. After posting Jira CQM project tickets for public comment, weekly digest emails serve to inform members of new issues posted for review and those issues closing soon. The CRP occurs during the fall.

4.2.2 eCQM Specifications

There are different phases to the eCQM specifications update. As part of the pre-MAT time frame, measure developers propose changes to the specifications to CMS based on the CRP feedback, e.g., changes to standards. Once CMS approves the changes, the measure developers share marked-up specifications with standards and logic SMEs, who review for accuracy. Measure developers identify any deprecated codes needing to continue in use in measure specifications (legacy codes) for look-back periods and share them with the <u>VSAC</u>. VSAC, in turn, updates the value set expansion profiles to include the legacy codes. Measure developers update the value sets using the <u>VSAC Collaboration Tool</u>.

Measure developers then input CMS-approved changes to the specifications in the MAT and export the revised packages for review and Bonnie testing. The post-MAT phase begins with the posting of the updated packages to the Jira CAU project for a second review by standards and logic SMEs. Measure developers post updated draft measure packets to the CQM Jira project for public review and comment. Measure developers finalize measure specifications based on reviews and feedback by updating the MAT packages and retesting in Bonnie. Measure developers then develop the technical release notes (TRNs), which provide an overview of technical changes in the eCQM specifications. The measure developers send the final MAT packages to VSAC, and all the final value sets move into VSAC's production environment. To view the details of the value sets, a user must have a free UMLS license The VSAC also posts the Binding Parameter Specification (BPS) document. The BPS is a record of the value set metadata information defining the value set code lists specified by published CMS eCQMs. Measure implementers and vendors can use the BPS to track versions and other parameters defining the value set code lists for each eCQM release. The eCQI Resource Center posts the measure packages, including the TRNs, and links to the value sets and BPS.

4.2.3 Supplemental Documents

CMS develops several supplemental documents with support from numerous contractors including eCQM developers. These supplemental documents provide information to help eCQM developers create and update eCQMs and eCQM implementers prepare for the next year's standards and eCQMs. Updates to supplemental documents occur annually.

- <u>eCQM Annual Update Pre-Publication Document</u> , published prior to the publication of the updated specifications, contains technical and program changes, and the standards and code sets approved by CMS. The purpose of this document is to give implementers advance notice of upcoming changes.
- eCQM Logic and Implementation Guidance , published about the same time as the updated

eCQMs, provides general implementation guidance such as the conceptualization of specific logic and data elements, implementation, and how to use the ONC Project Tracking System (Jira) to provide feedback, track issues, and ask questions. An appendix in the eCQM Logic and Implementation Guidance document provides the standards and code systems in use for the particular reporting/performance period.

- <u>Guide for Reading eCQMs</u>, published about the same time as the updated eCQMs, describes the eCQM package contents, file naming conventions, brief descriptions of the standards, and tools used with eCQMs. There are explanations of the different sections of the human-readable HTML document with examples.
- <u>CQL Style Guide</u> , published about the same time as the updated eCQMs, provides examples to standardize expression of measure concepts across eCQMs and defines a uniform look and feel to eCQM logic using CQL. The *CQL Style Guide* focuses on a set of common best practices implemented across CQL-based eCQMs in CMS programs and also promotes the use of consistent language within the framework of CQL, including libraries, aliases, definitions, functions, and conventions.
- eCQM Flows- measure developers prepare and document eCQM flows for each eCQM. The eCQM flows are flowcharts designed to assist in interpretation of the eCQM logic and calculation methodology for reporting rates. These flows provide an overview of each of the population criteria components and associated data elements leading to the inclusions or denominator and/or numerator exclusions helping to bind or define the eCQM's quality action (numerator). The eCQI Resource Center posts the flows to the eCQM Resources tables, usually by the end of the summer after publication of the updated specifications.

4.2.4 eCQM Standards and Tools

Several of the standards used with eCQMs are HL7 standards (CQL, HQMF, QRDA). HL7 has a standards review process and any significant changes must undergo the HL7 ballot process, which can take a year or more. Smaller changes can occur outside the ballot cycle. Changes to CQL, both the base standard and the CQL-based HQMF IG, may affect the QDM and vice versa. Updates to the QDM, a non-HL7 standard, occur as necessary and changes go to the eCQI User Group for approval. Updates to CQL may also require updates to the <u>CQL-to-ELM Translator</u>, which translates high-level CQL syntax into the canonical ELM representation. The <u>MAT</u> and <u>Bonnie</u> contractor updates these tools to align with the standards, including coordinating with the VSAC team. If needed, there is user acceptance testing of the MAT and Bonnie tools. The <u>Cypress</u> tool also receives an update.

5 Key points

Collecting and reporting accurate health care performance data has historically been a highly structured and time-consuming manual process. Evolving from manually-abstracted measures, the design of eCQMs is to promote greater consistency, improve uniformity in defining clinical concepts and logic across measures, and increase comparability of performance results. To achieve these goals, processing of eCQMs must occur electronically, but still be readable to humans. eCQM specifications use patient-level information coded in a format intended for extraction from EHRs and other electronic clinical systems.

The process for developing eCQMs is largely the same as for other measures since it follows the Measure Lifecycle, but there are special considerations for measure specification and testing. To generate specifications for an eCQM, measure developers use the MAT to ensure the technical specifications align with CMS standards. eCQM standards include, for example, HQMF (which is the standard for representing a quality measure in an electronic format), QDM (a data model providing the framework for defining measure data elements), and CQL (language providing the ability to express human-readable logic structured sufficiently for processing a query electronically).

eCQMs also require some additional testing considerations compared to other measures, especially related to assessing validity, reliability, and feasibility. Further, measure developers must test eCQMs at multiple test sites and use a variety of EHR systems, which helps to account for variability in reporting based on differences in local workflows. Measure developers must also test the soundness of the measure logic using the Bonnie tool.

Once implemented, eCQMs go through an annual update process (sometimes through the change review process, or CRP) involving technical specification review, updates to codes, and communication of proposed changes to CMS and other interested parties. The annual update process ensures alignment of eCQMs in CMS programs with the latest guidelines and uses the most current and appropriate value sets and codes to define data elements.

As CMS strives to promote interoperability, eCQM standards are evolving. FHIR and associated standards are undergoing testing for possible adoption and, if implemented, will change the way to conceptualize and specify eCQMs.

APPENDIX A ONC Project Tracking System (Jira)

INTRODUCTION

CMS uses the *ONC Project Tracking System* (*Jira*) during most stages of the eCQM Lifecycle - specification, testing, implementation, and maintenance.

Jira is an Atlassian, Inc.-based collaboration platform hosted by the Department of Health and Human Service's Office of the National Coordinator for Health Information Technology (ONC) used for information sharing for eCQM-related and other projects. Jira can produce standard and customized reports to support each project.

Current content for most projects is public facing. Users must <u>create an account</u> to enter new tickets/issues or track existing tickets. Some Jira projects require an account to view tickets and further restriction of others by the project administrators. General information regarding use of the ONC Jira project trackers is available under the <u>Learning Resources</u> tab.

ECQM Specification, Testing, Implementation, and Maintenance Stages

Jira projects use a ticketing process, where generation of content is through an issue ticket. Derivation of most content is from questions submitted through tickets, comments on the issue, and a posted solution to the issue. eCQM developers can make use of several Jira projects to support each phase of the eCQM development lifecycle.

Specification Phase – Posting Measures for Public Comment

Jira has issue trackers for standards and tools for measure developers to ask questions related to the development of CQL, QDM, and Bonnie and MAT including how to use in eCQM specifications.

Testing Phase - Obtaining Feedback from the Field

eCQM developers may post draft specifications, e.g., draft specifications, to Jira in the eCQM Issue Tracker and ask implementers to test and comment on the draft specifications.

Implementation Phase – Obtaining Feedback from the Field

After implementation of eCQMs into CMS quality programs, those responsible for implementing the eCQMs into the different settings or products may have questions related to eCQM specifications. eCQM developers use the eCQM Issue Tracker (CQM) Jira project for the public to obtain further guidance and clarity on measure specifications. The measure developer or steward responds to questions from the field. Question/answer tickets provide a searchable database for end users. The eCQM Known Issues Tracker and QRDA Known Issues provide implementation information for eCQMs/QRDA with known technical issues for which a solution is under development but not yet available in a published eCQM specification. The CQL Formatting and Usage Wiki hosts the QDM Known Issues Tracker.

Measure developers and the public may have questions relating to the standards and tools used in eCQM development. There are separate Jira projects for QDM , QRDA , CQL Bonnie and MAT , and Cypress S. SMEs monitor each of these projects and respond to end user questions.

Maintenance Phase - Annual Updates

eCQM developers may post draft Annual Update specifications to Jira in the eCQM Issue Tracker and ask implementers to test and comment on the draft specifications. The standards contractor posts

draft CMS QRDA IGs for comment as part of the Annual Update. CMS-contracted measure developers should contact their Contracting Officer's Representative (COR) regarding participation in the eCQM Annual Update and obtain access as needed.

APPENDIX B References

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