1 Introduction

1.1 Purpose

The Institute of Medicine (IOM) defines quality as: “The degree to which health services for individuals and populations increase the likelihood of desired health outcomes and are consistent with current professional knowledge.” [1](http://build.fhir.org/ig/cqframework/cqf-measures/introduction.html#fn:1) For care quality to be evaluated, it must be standardized and communicated to the appropriate organizations. To that end, this Implementation Guide has been written to provide guidance for authoring electronic clinical quality measures (eCQMs), clinical quality measures specified in a standard electronic format and designed to use structured, encoded data present in the electronic health record.[[1]](#footnote-1) This implementation guide references the following standards for creating eCQMs:

* Fast Healthcare Interoperability Resources (FHIR) STU3 [2](http://build.fhir.org/ig/cqframework/cqf-measures/introduction.html#fn:2)

To avoid variation in use of FHIR Resources and metadata consistently across eCQMs and clinical decision support (CDS) a quality-related implementation guide based on a logical data model is essential. In the US Realm, eCQM developers can use FHIR Quality Improvement Core (QICore) and Quality Improvement Clinical Knowledge (QUICK) as the data model to maintain consistency.

* Clinical Quality Language (CQL) R1.4 [3](http://build.fhir.org/ig/cqframework/cqf-measures/introduction.html#fn:3)

Although the specification is based on the 1.4 version of CQL, backwards-compatible future versions of CQL can be used as well. In addition, if necessary, the 1.2 and 1.3 versions of CQL can be used without loss of functionality for this Implementation Guide.

Note that this implementation guide is based on FHIR STU3, as that is the first version with the Clinical Reasoning module, which provides the necessary support for representing and reporting quality measures. Future versions of this implementation guide will address the use of R4 and later versions of FHIR.

Except where noted, material from the base FHIR specification, and in particular the Clinical Reasoning module, is not repeated here.

As features and functionality are identified by this implementation guide that apply more broadly, those features may be promoted to the base FHIR specification.

1.2 Structure of this Guide

This implementation guide is structured as follows:

1. Introduction - This section, providing narrative introduction and background material
2. Overview - Provides an overview of quality measurement
3. Measure Conformance - Provides detailed guidance and conformance requirements for measures
4. Composite Measures - Discusses composite measure calculation and representation approaches
5. Using CQL - Provides guidance and conformance requirements for the use of CQL within measures

In addition, there are appendices for examples, references, acknowledgements, and a glossary.

1.3 Structure of this Volume

// TODO: UPDATE THIS SECTION

This implementation guide is divided into 6 chapters. Chapters 2 - 6 describe how to construct a FHIR-based eCQM file and follow the structure of FHIR Clinical Reasoning (metadata, data criteria, population criteria, stratification criteria).

Chapter 1 provides an introduction to this IG, gives a brief history of the IG, describes some of the standards upon which this IG was built, and briefly references other standards and tools present in the ecosystem of which this IG is part.

Chapter 2 provides an overview of FHIR Clinical Reasoning structure, how to reference CQL documents within the FHIR Clinical Reasoning structure, and how to specify control variables (measure period).

Chapter 3 describes how to reference terminology (codes and valuesets) in CQL and the accompanying Clinical Reasoning structure. Chapter 4 describes how to construct the CQL to reference libraries, definitions, terminology in the eCQM.

Chapter 5 discusses measure scoring types, how to specify population criteria in the eCQM and how to specify measure populations in CQL. There are also sections discussing stratification, inclusion of supplemental data, and defining risk adjustment variables.

Chapter 6 contains a discussion of composite measures and FHIR Clinical Reasoning-based examples of composite measures.

1.4 Audience

The audience for this IG includes software developers of measure authoring tools such as the US Centers for Medicare and Medicaid Services (CMS) Measure Authoring Tool (MAT); measure developers who will specify clinical quality measures using FHIR and CQL; software developers and implementers who will implement the quality measures specified in FHIR and CQL in their institutions or in their vendor products; institutions and organizations who wish to use FHIR and CQL to express and implement quality measures within their health systems; and local, regional, and national quality reporting agencies who wish to receive and process quality reporting documents that are based on measures specified in FHIR and CQL.

1.5 Approach

The approach taken here is consistent with balloted IGs for Fast Healthcare Interoperability Resources (FHIR). These publications view the ultimate implementation specification as a set of formal artifacts, including profiles, extensions, and terminologies. The base FHIR specification provides for the representation of quality measures using the Measure resource, as well as guidance on quality reporting within the Clinical Reasoning module. IGs such as this add constraints to the base resources and guidance through profiles and conformance requirements that further define and restrict the sequence and cardinality of elements in the FHIR resources and the vocabulary sets for coded elements.

This IG is STU1 of the FHIR Quality Measure IG. Section 1.8 describes the development of this STU.

1.6 Scope

This IG is a conformance profile, as described in the “Conformance” [4](http://build.fhir.org/ig/cqframework/cqf-measures/introduction.html#fn:9) section of the HL7 FHIR specification. The base resource for this IG is the HL7 FHIR Measure and Library resources and associated guidance within the Clinical Reasoning module. This IG does not describe every aspect of quality reporting in FHIR. Rather, it defines profiles and constraints on the base Measure and Library resources used in a FHIR Quality Measure. Additional optional Measure and Library elements, not included here, can be included and the result will be compliant with the specifications in this guide. The FHIR Data Export for Quality Measurement (DEQM) implementation guide specifies needs for FHIR-related quality reporting.

1.7 Conventions

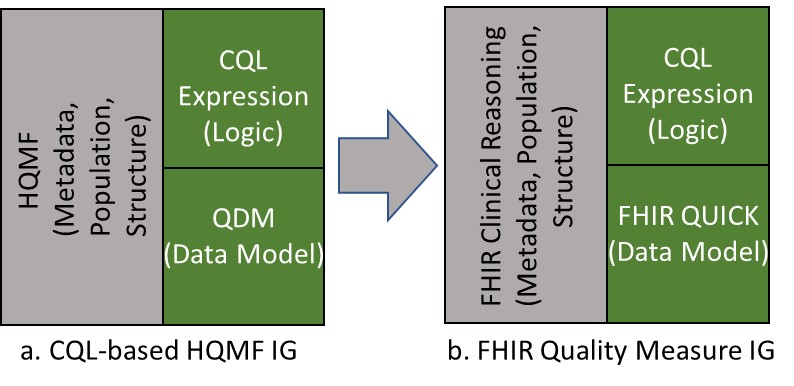
The keywords SHALL, SHALL NOT, SHOULD, SHOULD NOT, MAY, and NEED NOT in this document are to be interpreted as defined in RFC 2119. Unlike RFC 2119, however, this specification allows that different applications may not be able to interoperate because of how they use optional features. In particular

* SHALL: an absolute requirement for all implementations
* SHALL NOT: an absolute prohibition against inclusion for all implementations
* SHOULD/SHOULD NOT: a best practice or recommendation to be considered by implementers within the context of their particular implementation; there may be valid reasons to ignore an item, but the full implications must be understood and carefully weighed before choosing a different course
* MAY/NEED NOT: truly optional; can be included or omitted as the implementer decides with no implications

1.8 Background

This Implementation Guide (IG) defines an approach to using CQL with the FHIR Measure and Library resources for definition quality measures. The guidance here is drawn from Health Quality Measures Format Release 1 Normative (HQMF) [5](http://build.fhir.org/ig/cqframework/cqf-measures/introduction.html#fn:4), as well as the CQL-Based HQMF IG.

This Implementation Guide is the successor of the CQL-based HQMF IG STU4 (Figure 2a).

Figure 2: Relationship between CQL-based HQMF and FHIR Quality Measure IG’s.

1.8.1 Clinical Quality Language R1.4

Clinical Quality Language R1.4 (CQL) is an HL7 standard for trial use (STU) [3](http://build.fhir.org/ig/cqframework/cqf-measures/introduction.html#fn:3). It is part of the effort to harmonize standards between electronic clinical quality measures (eCQMs) and clinical decision support (CDS). CQL provides the ability to express logic that is human readable yet structured enough for processing a query electronically.

1.8.2 QDM based HQMF IG R1.4

The QDM based HQMF IG R1.4 [6](http://build.fhir.org/ig/cqframework/cqf-measures/introduction.html#fn:5) published October 2016 described how to construct an HQMF measure using QDM data elements and QDM logic (Figure 2a). That IG was built using QDM version 4.3.

1.8.3 CQL based HQMF IG R1 STU3

The first version of the CQL-based HQMF IG was released in September 2015 and was intended to be used in conjunction with the pre-existing QDM-based HQMF R1 IG. Since 2015, the community and the standards evolved and the current version of QDM (v5.4) no longer contains expression logic, ceding this functionality to CQL. The CQL-based HQMF IG is the sole guide describing how to use QDM, CQL, and HQMF in combination (Figure 2a).

A result of replacing QDM-based logic with CQL is that all QDM logic elements previously encoded in HQMF were replaced with CQL. This means that QDM data criteria specify only the data of interest (e.g. value sets, effective time, properties) for the eCQM, and the previous use of QDM expressions that captured interrelationships between data criteria (such as “starts after end of”) or identified subsets of data (such as min, max, last, and first) are now represented with CQL expressions. This IG documents the full approach in detail starting in Chapter 2.

This document, FHIR Quality Measure IG covers the use of FHIR Clinical Reasoning, CQL, FHIR QICore and QUICK, and other emerging approaches to define eCQMs.

1.8.4 HQMF

HQMF is a structured document markup standard\* “…for representing a health quality measure as an electronic document. A quality measure is a quantitative tool to assess the performance of an individual or organization’s performance in relation to a specified process or outcome via the measurement of an action, process, or outcome of clinical care. Quality measures are often derived from clinical guidelines and are designed to determine whether the appropriate care has been provided given a set of clinical criteria and an evidence base.” [5](http://build.fhir.org/ig/cqframework/cqf-measures/introduction.html#fn:4) [7](http://build.fhir.org/ig/cqframework/cqf-measures/introduction.html#fn:a)

HQMF is now a normative HL7 V3 based standard that defines a header for classification and management of the quality measure as well as important metadata. HQMF also defines a document body that carries the content of the quality measure. Itstandardizes a measure’s structure, metadata, definitions, and logic, the HQMF ensures measure consistency and unambiguous interpretation.

1.8.5 HQMF Release 1 Normative vs STU1 vs STU2

HQMF R1 STU1 was balloted in the September 2009 ballot cycle as a DSTU; it was supported by volunteer efforts and through the NQF contract with the US Department of Health and Human Services (HHS) to promote the effective use of EHR systems. The DSTU period for HQMF R1 STU1 was two years.

HQMF R1 STU2 was sponsored by the Center for Clinical Standards and Quality of CMS in partnership with HL7 and the Office of the National Coordinator (ONC). A driver for developing HQMF R1 STU2 was the need to make HQMF more amenable to automated machine processing. ONC’s Standards and Interoperability (S&I) Framework Query Health Technical Workgroup co-hosted project meetings. This IG is developed based on the normative release of HQMF R1 that was published in June of 2017 [5](http://build.fhir.org/ig/cqframework/cqf-measures/introduction.html#fn:4).

The FHIR Clinical Reasoning module replaces HQMF by defining the quality measure structure.

1.9 Other Related Tools and Standards

This section describes other tools, standards, and resources related to electronic Clinical Quality Measures as established in the US for implementation at least through 2020.

1.9.1 Quality Data Model

Volume 1 of this IG is intended to be as model agnostic as possible. However, the examples used have incorporated QDM [2](http://build.fhir.org/ig/cqframework/cqf-measures/introduction.html#fn:2). Further discussion of incorporating QDM into CQL based HQMF measures is discussed in Volume 2 of this IG.

1.9.2 Relationship to Quality Reporting Document Architecture

Volumes 2 and 3 discuss how to incorporate QDM into CQL based HQMF measures. A standard reporting mechanism for QDM based is the Quality Reporting Document Architecture [9](http://build.fhir.org/ig/cqframework/cqf-measures/introduction.html#fn:6). Further discussion of QRDA is available in Volume 2 of this IG.

1.9.3 Measure Authoring Tool

The MAT is a web-based software-authoring tool that measure developers use to create eCQMs [8](http://build.fhir.org/ig/cqframework/cqf-measures/introduction.html#fn:7). The authoring tool allows measure developers to create eCQMs in a highly structured format using the QDM and healthcare industry standard vocabularies. The MAT was developed by NQF under a contract with HHS, and has been publicly available through NQF since September 2011. All Meaningful Use Stage 2 measures are authored in MAT to ensure consistency in creating header metadata, population criteria, data criteria, etc. Effective January 2013, CMS assumed ownership of the MAT and has contracted with Health Care Innovation Services, a joint venture between Telligen and Net-Integrated Consulting for the ongoing development, maintenance, and support.

The QDM-based building-block approach to eCQMs, which is described in this IG, was implemented in the MAT. It will be updated in accordance with this guide.

1.9.4 NLM Value Set Authority Center

The Value Set Authority Center (VSAC) [10](http://build.fhir.org/ig/cqframework/cqf-measures/introduction.html#fn:10) is provided by the National Library of Medicine (NLM), in collaboration with the ONC and CMS. The VSAC currently serves as the authority and central repository for the official versions of value sets that support Meaningful Use eCQMs. Through the VSAC, NLM draws upon the UMLS Metathesaurus and its responsibility as the central coordinating body for clinical terminology standards within the HHS to assure the ongoing validity and accuracy of the value sets. NLM launched the VSAC Authoring Tool on October 31, 2013. Value sets for eCQMs can now be authored directly in VSAC. In addition, direct reference codes can be retrieved from the VSAC for use in eCQMs.

1.9.5 CMS Measures Management System Blueprint

CMS has developed a standardized approach for the development and maintenance of the quality measures it uses in its various quality initiatives and programs. The Measures Management System is composed ofa set of business processes and decision criteria that CMS-funded measure developers follow in the creation, implementation, and maintenance of quality measures. Measures developed following the Measures Management System meet the high standards required by the NQF for consensus endorsement. The full Measures Management System set of business processes and decision criteria are documented and described in A Blueprint for the CMS Measures Management System (the Blueprint). Updates to the Blueprint have been made every year since its first release in 2003.

To support the need of eCQM development, the “Measures Specifications” section was added to Version

8.0 of the Blueprint (August 2011) to guide CMS- contracted measure developers on how to develop and document an eCQM for either a retooled measure or a de novo measure. The “Measure Specifications” section has since gone through several updates and has been evolved to become the “Measure Lifecycle” section with the latest being published on CMS’ website [11](http://build.fhir.org/ig/cqframework/cqf-measures/introduction.html#fn:8).

1.9.6 HITSC Recommended Vocabularies

In 2012, the Health IT Standards Committee (HITSC) Clinical Quality Technology Workgroup and Vocabulary Task Force of the ONC published their recommendations for the use of vocabulary standards by measure developers. The list of QDM categories and their applicable HITSC recommended vocabulary standards are included in the Blueprint’s “Measure Lifecycle” section.

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