CMS Presents Quality Measurement Using HL7® FHIR® 101
Questions & Answers

Centers for Medicare & Medicaid Services (CMS) Webinar Qs&As
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Q: What is my first step to get started? I am a physician and it seems confusing, but I know we have to do this.
A: It would depend on your specific use case(s). However, be on the lookout for regulations. If you are asking about the Office of the National Coordinator for Health Information Technology (ONC) requirements for Fast Healthcare Interoperability Resources® (FHIR®) in health information technology (IT) module certification or their interoperability rules, please visit the ONC website. For CMS quality reporting requirements, at this time there are not any requirements for FHIR reporting of quality measures. CMS finalized use of FHIR in other use cases through the Interoperability rule. To get started on quality reporting, I recommend attending education sessions and review the Electronic Clinical Quality Improvement (eCQI) Resource Center and look for additional educational opportunities and for any proposed rules that reference FHIR.

Q: What strong skill does one need to understand and utilize FHIR?
A: FHIR is a standard for healthcare data exchange maintained and published by Health Level Seven International® (HL7®) that addresses use cases across the healthcare domain and from multiple perspectives. The skill set that you need to use FHIR depends on what your role is in implementing FHIR. FHIR "designers" need a different set of skills than FHIR "implementers," and a different set of skills again than FHIR "integrators" and "consumers." There are introductions on the Welcome to FHIR webpage from the perspective of each of these roles that are helpful in answering this question.

Q: Does the Office of the National Coordinator for Health Information Technology (ONC) Cures Act Final Rule reference the US Core Implementation Guide based on FHIR R4?
A: Yes, in May 2020, the ONC 21st Century Cures Act Interoperability, Information Blocking, and the ONC Health IT Certification Program final rule adopted the HL7FHIR US Core Implementation Guide (IG) Standard for Trial Use (STU) 3.1.0. In October 2020, ONC published an interim final rule that adopted the updated US Core Implementation Guide (IG) 3.1.1. The US Core IG is based on FHIR version R4 and includes a set of profiles designed to support and enable the broad range of interoperability use cases. There is also the Quality Improvement (QI) Core IG that builds on and extends the profiles in US Core to drive quality improvement. There are some FHIR resources profiled in QI-Core that not yet specified in US Core. The measure developer and clinical decision support communities proposed these additional profiles based

on experience with specific use cases. Note that QI-Core also further constrains some US Core profiles to assure retrieval of expected information for measure reports and clinical decision support. Experience with the additional QI-Core profiles may provide sufficient usage and maturity to encourage additions to US Core in the future.

Q: Does the new ONC Cures Edition certification criteria for certified electronic health record technology (CEHRT) require health IT module developers and vendors to use FHIR?
A: This is a question for ONC. Please refer to the new ONC Certification of Health IT criterion §170.315(g)(10) Standardized API for patient and population services.

Q: Do you have a timeline as to when CMS will adopt FHIR for use in quality measures and reporting?
A: CMS continues to test FHIR for use in quality measures and reporting. CMS plans to use information learned from this testing to inform any future timelines for adoption into CMS programs. At this time, there is not a timeline for FHIR adoption. If you attended last year's CMS Quality Conference, the announcement from the Administrator that FHIR is the direction CMS plans to go, but all timelines are based on thorough testing.

Q: How many translations of eligible professional/eligible clinician eCQMs are in the FHIR standard?
A: There are currently 10 complete translations of eligible professional/eligible clinician eCQMS specified in FHIR and an additional 18 are in progress. All of these FHIR-based eCQMs are draft measures. Through exploration and testing we are trying to understand all the technical implications of eCQMs operating in the FHIR environment.

Q: Will CMS provide at least a couple years of lead time for vendors to update their systems from Health Quality Measure Format (HQMF) to FHIR?
A: CMS will propose any changes in rulemaking, allowing for public comment and feedback. Any timeline would incorporate time for vendors to update their systems.

Q: What is the level of EHR vendor support for eCQM reporting via FHIR at this time?
A: Support varies by the specific EHR vendor.

Q: Will FHIR increase interoperability through normalized data, making it easier and cheaper to map data to disparate systems?
A: FHIR supports a broad range of use cases across the entire healthcare domain. There is nothing in the base specification that did not obtain consensus agreement among all of the participating parties. The consensus process is challenging and the more stakeholders involved, the more challenging it is. FHIR stakeholders can increase interoperability by increasing agreement among the stakeholders and FHIR provides a way to formally characterize those agreements. For example, two parties can build their formal agreements in FHIR and achieve interoperability between their two systems. But to get interoperability between a third system, you need to bring the third one in and achieve agreement about sharing data with all three

systems. FHIR provides a framework to express those agreements formally and to support a community in reaching those kinds of agreements. So yes, FHIR will increase interoperability, but achieving the required consensus still takes significant effort. The FHIR framework enables semantic interoperability, but it does not guarantee it.

Q: Does the ability to create profiles restrict data interoperability?
A: Profiles enable interoperability using the FHIR framework. If you do not share a profile covering your exchange then you do not have interoperability because, in the base specification, the codable elements are not binding on most of the elements contained within the specification. There are example bindings for encounter type, and if you exchange an encounter and assign a code to a data element, then it will mean something to only you. Someone else is expecting a different code assigned to that data element so there is no interoperability. The profiles give you a way to say with a partner that when we exchange encounters, we both agree that we are going to use these codes to talk about encounter types and lock down the variability in those bindings.

Q: Is a mapping between QI-Core and Consolidated Clinical Document Architecture (C-CDA) available?
A: There is not a specific mapping between C-CDA and QI-Core profiles, but there is an implementation guide for C-CDA on FHIR that provides a general mapping from C-CDA documents to the FHIR resources. The implementation guide would be a starting point for a C-CDA mapping to QI-Core.

Q: The QI-Core has actual metrics, so can we say that payors and healthcare providers do not have to calculate the metrics and there is automatic calculation of different types of guidelines based on other fields available through FHIR?
A: QI-Core does not provide metrics. QI-Core is a data model. It supports the description of the data elements required for quality improvement use cases in general. The FHIR community has built a set of QI-Core profiles upon multiple use cases, which is the set of data elements for expression within an eCQM, for example, but it also has input from other quality improvement use cases across the FHIR spectrum. We have tried to harmonize across the FHIR spectrum to get a broad set of data elements in QI-Core that covers these quality improvement use cases, but it is not yet complete. There will always be more specific use cases but the quality improvement stakeholders are driving towards agreement on those data elements. For that set of data elements, you can now share things like quality measures and decision support rules using those data element definitions. CMS publishes the quality measures as content that uses QI-Core to describe the data needs. Based on the elements described in QI-Core, we are exploring an approach that exchanges the data of interest for a measure, rather than exchanging the calculated metrics.

Q: Can you please talk about the balloting process? How long does it take to go through the process?
A: HL7, a standards development organization, ballots three times a year. There are well-defined and well-vetted processes and it usually takes anywhere from two to five ballot cycles

to get to a normative specification for a given standard. There are requirements around the HL7 maturity model and to get to successively higher levels of maturity you have to demonstrate successively more involved implementation, e.g., during HL7 Connectathons. You need to use prototypes and pilots and then ultimately production implementations before you can ballot a standard to a normative specification. Depending on the size of the standard you are trying to ballot, it could take at least a year or two to get from inception to balloted specification for a reasonably sized use case.

Q: Is there a clear rubric of requirements for defining maturity and moving FHIR specifications up the scale from level 0 to level 5?
A: Yes, the FHIR specification provides a concise description of maturity levels and requirements. The link is also accessible from the Maturity description in the header of every FHIR resource.

Q: Can you please address a query of discrete data fields for a population of individuals rather than an individual patient?
A: Measure developers have specified eCQMs from the patient's perspective. Measure developers focus the criteria on describing the requirements for the eCQMs in terms of the data elements for a single patient and can evaluate this in terms of a single patient in a given environment or by translating it to a model that supports population-based query. In the latter case, you need to account for the relationships between the patient and the data for each patient considered. Using a patient-focused expression of the criteria makes an eCQM easier to author and understand and it makes it more flexible to use in different contexts, like decision support for quality measurement. For example, you can use the bulk data specification to export bulk data to apply the eCQM across a population. Just because the expression of eCQMs is per patient does not mean you cannot accomplish evaluation in a population. It just means you have to apply the eCQM across that population and account for the relationships and their associated data.

Q: What does the Flag field represent?
A: Flags are for the various attributes related to how to define each element, such as whether the summary includes the element and whether it is a modifying element (i.e., it changes the meaning of the resource). There is a legend linked from the Flags header at the top of the element list in every resource that provides more detail.

Q: What happens when a FHIR data element has a red 'S' along with cardinality of 0..*?
A: The QI-Core profiles include flags and cardinality for every element (or attribute). A red 'S' indicates that an implementer must be able to support the referenced element if it is present in a measure. The red 'S' provides some assurance to a measure developer that the respective element is likely to be retrievable in a clinical system. The cardinality indicates how many of the elements can be present in the information retrieved. 0.. * means that the information retrieved is valid if the element is absent or has many representations. 0 .. 1 means that the

information retrieved is valid if the element is absent but that it may have only one response. 1.. 1 indicates that the element must be present to provide a valid response.

Q: Is there any difference between "Encounter" vs "Appointment" resource?
A: An “Encounter” resource can represent an outpatient appointment. While there is an “Appointment” resource in FHIR R4, QI-Core does NOT contain a QICoreAppointment Profile at this time. The FHIR Appointment resource contains data elements utilized by a scheduling system to make and record a scheduled appointment for an encounter. Use the FHIR "Encounter" resource to define ambulatory, emergency, home health, inpatient, and virtual encounters. Find the full list of resources in the FHIR Resource Index.

Q: What is Bonnie?
A: Bonnie is an open-source testing tool for eCQMs. It allows you to run patient-level test cases against a measure specification to verify the results intended by the measure logic. You can access Bonnie and information about Bonnie on the Bonnie website.

Q: What are some final thoughts or key takeaways from the presenters related to FHIR in quality measurement?
A: One thing I hope you got from the presentation is that eligible clinicians and eligible hospitals will have the ability to report quality measures in FHIR. In addition, the implementation of quality measure reporting in FHIR is more flexible than previous implementations, such as with the transition to Clinical Quality Language (CQL). Another key takeaway is that there is an incredible international community of stakeholders and FHIR developers that have already contributed to the FHIR specification, in general, and to the US Core specification, in particular. As a result, more specific and more detailed implementation guides are now providing very rich formal descriptions of data elements that quality measure other developers may use with this framework in quality measurement use cases. FHIR is a data model standard that enables adoption and use thereby the interoperable exchange of health information. A final key takeaway would be to utilize resources on the eCQI Resource Center website. We publish all our education sessions there and plan on providing more FHIR education sessions.

Q: Where can we sign up for notifications of future presentations like these?
A: We suggest following the Events section of the eCQI Resource Center.