



**HL7 FHIR® Guidance:**  
**Quality Reporting,**  
**Release 1- US Realm**

October 2020

**HL7 Informative White Paper**

**Sponsored by:**  
**Clinical Quality Information Work Group**

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Logical Observation Identifiers Names & Codes (LOINC)	Regenstrief Institute
International Classification of Diseases (ICD) codes	World Health Organization (WHO)
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# The Case for FHIR-based Quality Measurement and Reporting

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## Overview

There has been an increased emphasis on care quality measurement over the last decade. The United States pays a high price for healthcare yet falls behind other nations based on quality, morbidity and mortality. The healthcare industry as a whole is transitioning to focus on value as defined by cost-effective high quality care. To this end, clinical measures have been created which can be used as part of a “virtuous cycle” of continuous quality improvement, where the results of quality measurement can be used to improve care.

This white paper makes the case that using HL7® Fast Health Interoperability Resources (FHIR®) for quality measurement specification, distribution, evaluation, and reporting provides many benefits that enable positive change in the clinical quality improvement ecosystem, including reducing reporting burden, increasing the accuracy and fidelity of reporting results, shortening the reporting cycle, and accelerating the overall clinical quality improvement lifecycle. The intended audiences for this white paper are those actively involved in quality measurement

use cases, including but not limited to clinicians, EHR vendors, application developers, quality measure developers, government policy and program stakeholders, clinical and specialty society registry stewards, and researchers.

FHIR is a next generation health data standards framework created by HL7. It combines the best features of HL7's v2, v3, and CDA® product lines while leveraging the latest web standards and applying a tight focus on implementability. FHIR specifies a base standard for exchanging health data and can be applied to a wide range of use cases, including quality measurement. It is often necessary to make changes to the base FHIR resources in order to meet these specialized needs. In the case of clinical quality measurement, HL7 workgroups continually develop FHIR implementation guides to meet evolving industry needs. Currently, there are several existing FHIR implementation guides that inform and support quality reporting, and this paper references many of them.

Together, this white paper and the FHIR implementation guides it references are intended to solve current challenges and reduce burden throughout the clinical quality measurement lifecycle. Many of the most burdensome challenges currently faced by stakeholders are rooted in a lack of interoperability across systems and use cases. In the current ecosystem, clinical data necessary for accurate quality measurement is exchanged using a variety of methods, standards, and data models. There is often a disconnect between the information necessary to execute clinical quality measurement and the way that information is recorded, stored, and presented within electronic health records, administrative claims filing systems, registries, and elsewhere, which makes the sharing and analyzing of data for quality measurement difficult. Here we will demonstrate how FHIR can be used to alleviate such challenges by aligning quality measurement with other healthcare data exchange.

The guidance herein is primarily based on input from US-based participants. Specifically the FHIR Quality Measure and Data Exchange for Quality Measures Implementation Guides are both deemed to be applicable to what HL7 references as US Realm. There are no restrictions on the use of this material in the international realm and findings may be applicable outside the US. The authors welcome input from the global community.

## Background

Since their inception in 2009, the [Quality Data Model](#) (QDM), a Centers for Medicare and Medicaid Services (CMS) published conceptual data model for quality measurement, and the HL7 [Health Quality Measure Format](#) (HQMF) have provided a conceptual basis for the specification of electronic Clinical Quality Measures (eCQMs). Beginning in 2014, the Clinical Quality Framework Initiative was launched to identify, develop, and harmonize standards that promote integration and reuse of clinical data elements, their respective metadata, and reuse of logic expressions in CDS and eCQMs. Specifically, to enable knowledge interoperability, from discovery to delivery and back, and at scale, the initiative focused on defining a platform and model-independent mechanism for sharing the logic required to support CDS and CQM use cases. The resulting logic specification, Clinical Quality Language (CQL), allows logic to be

expressed and shared using a specified data model bound to standard terminologies. CMS is currently distributing eCQM specifications using CQL to express logic, with QDM as the data model, bound to standard terminologies including ICD, CPT, SNOMED, LOINC, RxNorm, and others.

One of the primary motivations for identifying separate specifications for the logic and data model was to allow the logic and data model specifications to evolve independently and to enable flexibility in selecting a data model. Furthermore, by focusing on evolving and separating the logic specification first, implementations could focus on updating their engines or translation paths while holding the current data model (QDM) relatively constant under that change. This architectural approach further enables more flexibility in adopting data model changes, up to and including entirely different data models.

## Quality Improvement Ecosystem – Standards

As the health data standards landscape continues to evolve, it has become clear that FHIR has reached critical mass, and that there are clear opportunities to reduce transformation and implementation burden and complexity, while simultaneously enabling richer knowledge interoperability use cases, across the full clinical quality improvement lifecycle, and specifically for quality measurement. To set this in the larger context, Figure 1 represents the overall Quality Improvement Ecosystem:

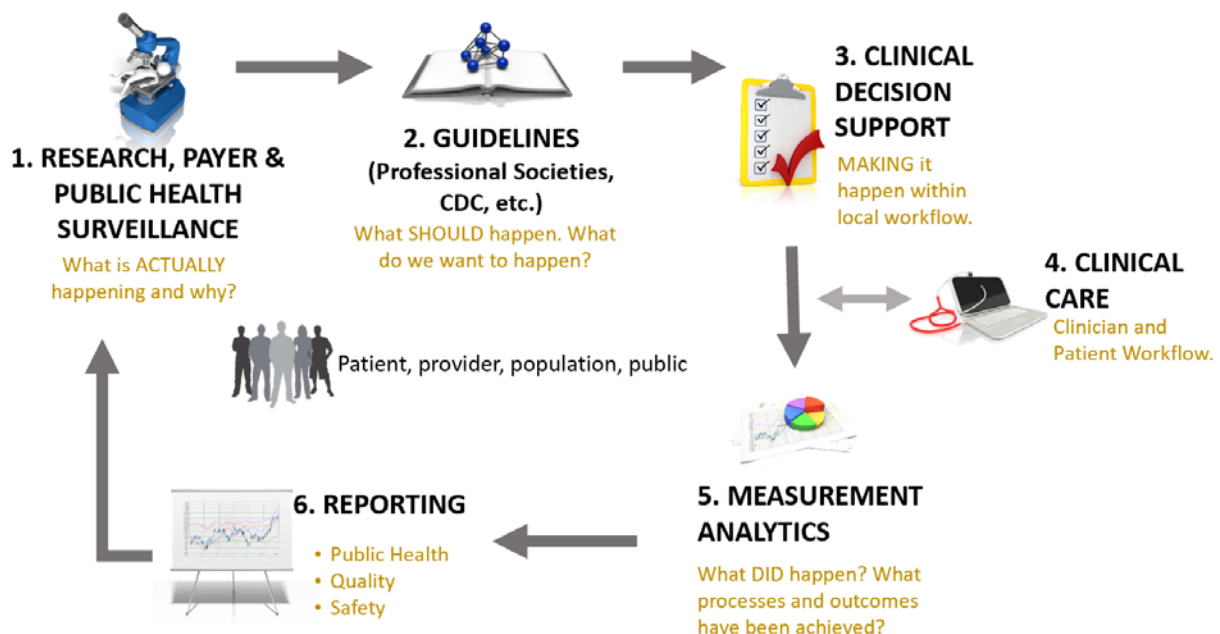


Figure 1. Quality Improvement Ecosystem.

Figure 1 depicts a learning health system initiating with information about existing disease prevalence, incidence and outcomes represented by research, payer and public health

surveillance (step 1). Professional societies, specialty society registries, public health and governmental authorities such as the Centers for Disease Control and Prevention (CDC) and others author guidelines based on known evidence (step 2). Clinical provider sites and informaticists create artifacts to incorporate clinical recommendations and actions within clinical workflows to provide cognitive support, i.e., ideally, they provide clinical decision support (CDS) (step 3) and evaluate the local implementation activity needed to make these artifacts impactful for direct clinical care for both clinicians and patients (step 4). These clinical provider sites and informaticists further collect data from clinical care, performing measurement analytics to evaluate processes and outcomes to improve the effectiveness of the CDS artifacts (step 5). For example, they attempt to determine whether the clinical care delivered was consistent with the guideline intent and achieved the desired outcomes. Organizations further report results to public health authorities, payers, quality reporting organizations and safety programs (step 6). Information gained from aggregate reporting further provides evidence to re-evaluate guideline recommendations. This ecosystem supports better care for individual patients and populations, and to improve safety and care processes for patients and providers.

Figure 2 shows the interactions among the various stakeholders and interactions between them that make up this ecosystem:

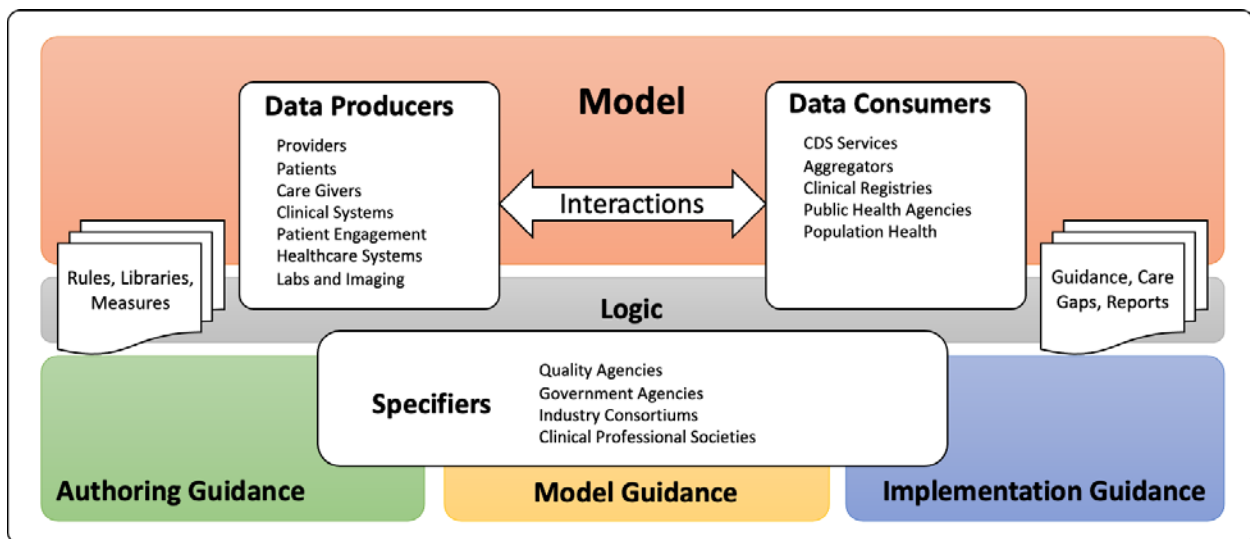


Figure 2. The Quality Measurement Standards Landscape.

The landscape includes three stakeholders: Data Producers are those individuals, organizations or processes that capture data in the process of performing health-related activities. Data Consumers are those organizations that receive individual and aggregate data and results of data analytics. Specifiers are those organizations that create electronic clinical or digital quality measures (eCQMs, dQMs) that translate the clinical research and guideline information into clear human and machine-readable expressions to retrieve information to evaluate the effectiveness, efficiency, safety, timeliness, patient-centeredness and equity of clinical processes and outcomes. The standards landscape includes the basic information model, considered here as Fast Health Interoperability Resources (FHIR) that provides a basis for

sharing different kinds of data among various healthcare providers (i.e., data interchange). This FHIR model includes a foundation, methods for implementing and sharing information, administrative concepts, clinical care, financial and workflow resources, and clinical reasoning resources to enable measurement and CDS artifacts. Each of these artifacts requires a basic method for expressing logic and guidance for how they are best authored, implemented and how they use the FHIR model consistently and accurately. The specifier stakeholder uses the guidance to create the artifacts that the data producers use to retrieve existing data and report information to the data consumers.

Standards and specifications enable the precise description of and guidance for the various use cases found throughout this ecosystem. In particular, many of the projects in the Clinical Quality Information and CDS work groups are focused on supporting quality improvement use cases. Figure 3 shows how implementation guides based on the standards landscape interact with the Quality Improvement Ecosystem shown in Figure 1.

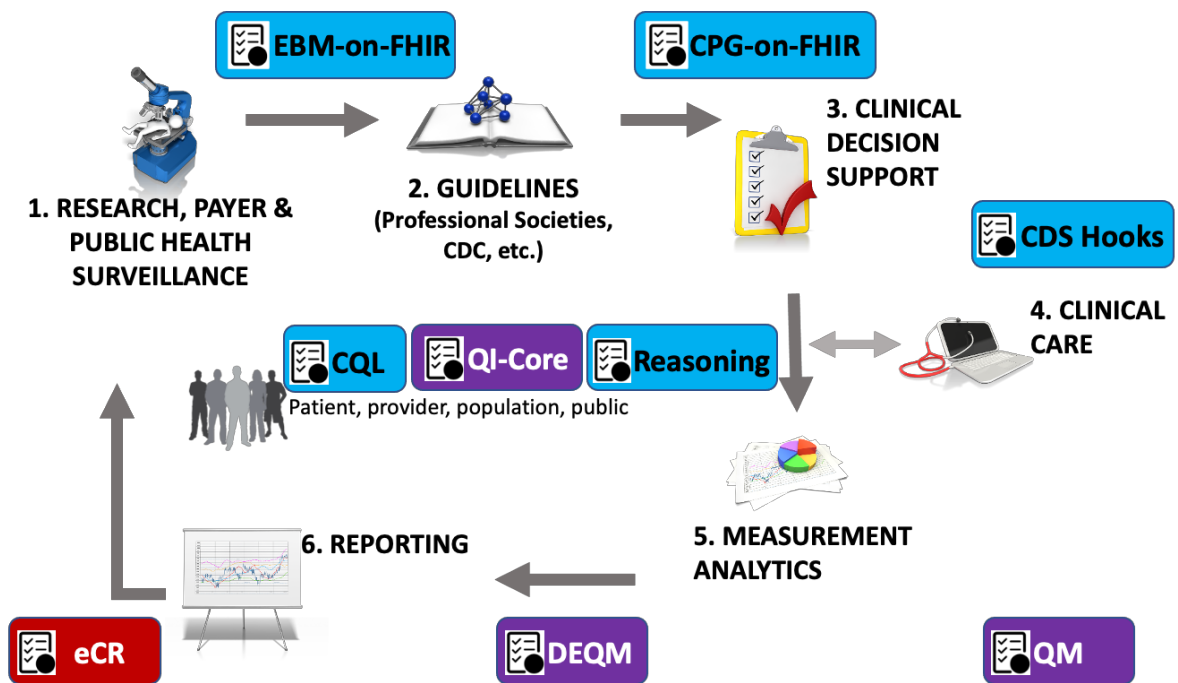
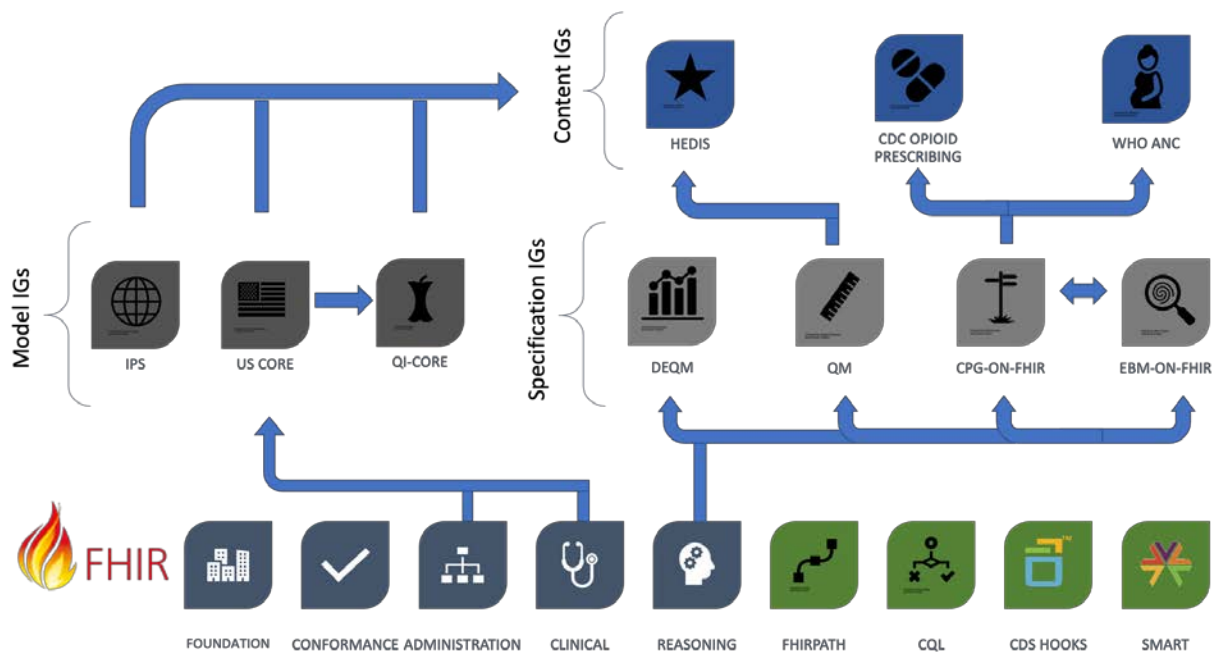


Figure 3. Quality Improvement Ecosystem with Standards Overlay.

Figure 3 shows the interfacing of standards with the ecosystems beginning with Evidence-based Medicine-on-FHIR (EBM-on-FHIR) which defines standard metadata to assist authors in citing provenance and strength of evidence and recommendations directly in guideline artifacts. Clinical Practice Guidelines on FHIR Implementation Guide (CPG-on-FHIR) provides guidance for authors to create human and machine-readable artifacts that implementers can use to implement CDS and eQMs without requiring significant re-interpretation at each clinical site. Clinical Decision Support Hooks (CDS Hooks) provides a mechanism for clinical system implementers to provide the clinical evidence to directly impact clinical care delivery for patients

and clinicians based on established workflow triggers. The Quality Measure Implementation Guide (QM) provides guidance for authoring electronic and digital clinical quality measures (eCQMs / dQMs). Data Exchange for Quality Measures (DEQM) provides guidance for reporting individual and aggregate clinical performance data to reporting recipients; this guidance includes the ability to provide information about gaps in care delivery based on the specified measures. Electronic Case Reporting (eCR) provides standard guidance for implementers to report known clinical disease incidence and exposures directly to public health. All of these artifacts use basic standards infrastructure, Clinical Quality Language (CQL) providing expression capability; Quality Improvement Core (QI-Core) providing guidance for using FHIR consistently for quality measures and CDS artifacts such that the data requests remain consistent with the method by which clinical sites share clinical data for routine care; Clinical Reasoning (Reasoning) provides the basic infrastructure for defining a quality measure or CDS artifact using FHIR.



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 Figure 4. FHIR-based Knowledge Representation Specifications

Figure 4, FHIR-based Knowledge Representation Specifications depicts four categories of specifications, with representative examples of each category, illustrating how the various pieces can be used together to deliver shareable clinical reasoning artifacts such as quality measures and decision support rules.

- The foundational standards on the bottom row of the diagram include FHIR layers , as well as expression language and integration standards including FHIRPath, Clinical Quality Language (CQL), CDS Hooks, and SMART.
  - FHIR includes five layers of concepts, each shown as an icon on the bottom row of the diagram.



- Foundation layer – defines the core data exchange protocol.
  - Conformance layer – defines how resources, profiles, and terminologies are represented and used.
  - Administration layer – defines individuals, locations, organizations, and encounters.
  - Clinical layer – defines clinical information such as observations, medications, procedures, and orders.
  - Reasoning layer – provides definitional artifacts like plan and activity definitions, libraries, and measures.
- FHIRPath is a simple, yet powerful, model-independent expression language that is used extensively throughout FHIR to describe paths to elements on resources, and to define invariants on profiles.
- Clinical Quality Language (CQL) is a superset of FHIRPath that provides an author-friendly format for the description of clinical logic, as well as a machine-friendly format for processing the logic.
- CDS Hooks is an HL7 standard specification for integrating decision support services with clinical systems. It is primarily focused on clinician-facing remote decision support within an EHR.
- SMART-on-FHIR (SMART) is an HL7 standard specification for integrating clinical applications into EMRs using FHIR.
- The middle row on the left of the Figure 4 shows the Model Implementation Guides (IGs), typically derived from FHIR Administration and Clinical resources such as Patient, Encounter, and MedicationRequest. These Model IGs are typically built to address a broad range of use cases, focused on a particular target realm or domain.
  - International Patient Summary (IPS) is a set of internationally applicable FHIR profiles used to share an extract of essential patient healthcare information across international boundaries. As a result, it forms an excellent foundation for expressing universally applicable content guidelines such as the WHO Antenatal Care (WHO ANC).
  - US Core is a set of profiles focused on enabling exchange of the US Clinical Data for Interoperability (USCDI) and is supported by a broad range of EMR vendors within the US.
  - QI-Core is a set of profiles that derives from US Core to enable quality improvement use cases such as quality measurement and decision support within the US.
- The middle row on the right of the Figure 4 shows the Specification Implementation Guides, which derive from the FHIR Clinical Reasoning resources to provide implementation guidance and conformance requirements for the creation, distribution, evaluation, and maintenance of shareable clinical knowledge. These include the Quality Measure IG (QM), Data Exchange for Quality Measures (DEQM), the Clinical Practice Guidelines IG (CPG-on-FHIR), and Evidence-based Medicine on FHIR (EBM-on-FHIR).
  - Quality Measure IG (QM) provides guidance on and conformance requirements for the use of the FHIR Reasoning resources, Measure and Library, to create and share clinical quality measures.

- Data Exchange for Quality Measures (DEQM) provides guidance for reporting quality measures.
- Clinical Practice Guidelines IG (CPG-on-FHIR) demonstrates how to build shareable computable guideline content.
- Evidence-Based Medicine on FHIR (EBM-on-FHIR) provides interoperability (standards for data exchange) for those producing, analyzing, synthesizing, disseminating and implementing clinical research (evidence) and recommendations for clinical care (clinical practice guidelines). It specifies resources and patterns for the exchange of data involved in evidence-based medicine including study results, quality of evidence and strength of recommendation and relevant context, environmental surveys, and systematic reviews.
- In the top row of Figure 4, the Content Implementation Guides are FHIR Implementation Guides. These IGs are not necessarily balloted as HL7 standards; rather, they use the FHIR publication toolchain to support authoring and distribution as depicted in the rest of the diagram. The content is stewarded by separate authorities such as quality agencies and guideline developers; groups that have their own governance and maintenance policies. The content IGs conform to the specification IGs on the right of row 2, and typically make use of the model IGs on the left of row 2 to define content focused on a particular realm.
  - HEDIS IG contains Healthcare and Effectiveness Data and Information Set (HEDIS) quality measures expressed using FHIR Reasoning Measure and Library resources and conforming to the Quality Measure IG (QM) profiles.
  - CDC Opioid Prescribing IG contains decision support content to streamline guideline implementation regarding the use of opioids for chronic pain in clinical settings.
  - World Health Organization Antenatal Care (WHO ANC) IG contains decision support content to streamline guideline implementation regarding antenatal care.

Within this larger context, this white paper identifies the benefits, and highlights the challenges, associated with the use of the FHIR-based quality measurement and reporting specifications defined as part of this overall quality framework. More specifically, this paper makes the case that although there are benefits to identifying, building, and maintaining a quality measurement-focused model like QDM, the benefits of using an interoperable framework such as FHIR for Quality Measurement offers more advantages over a data model that is confined to a single use case.

## The Case for FHIR-based Quality Measurement

FHIR represents the evolving and future method for data interchange for clinical use. Thus, it represents a good approach for sharing the same data (i.e., re-use) for public health reporting, for healthcare analytics used to measure improvements in structure, process and outcomes. The rationale is that FHIR fulfills the following eleven desirable qualities of an information modeling framework for use in information exchange. Each of these qualities is discussed in its own section below:

### 1. Expressivity

FHIR supports a broad range of use cases, including not only clinical data, but claims, labs, research, public health, and other applications from across the healthcare domain

2. Alignment

FHIR is developed with a focus on implementation, providing alignment with existing clinical information systems and clinical workflows, greatly reducing the burden of semantic transformation

3. Fitness (Representational Bias)

A common data model for logic expression and data transport/exchange further reduces the opportunities for mis-aligning semantics between distinct models resulting in unintended inference/interpretation. FHIR can serve as data model for both logic expression and data representation/exchange

4. Liquidity

FHIR is an API-based approach, enabling applications as well as reporting capabilities and knowledge assets to be portable and fungible

5. Community

FHIR is a diverse and dedicated community, bringing expertise and experience to bear not only on how the specification is built, but how it is used – particularly around clinical use

6. Extensibility

FHIR has a well-defined and flexible mechanism for supporting coordinated exchange of use-case specific information, without undermining core interoperability

7. Conformance

FHIR has a rich conformance framework for describing and validating exchanges and ensuring interoperability

8. Tooling

FHIR has a well-developed and well supported set of open source and vendor tooling for authoring, modeling, developing, publishing, and implementing

9. Agility

FHIR has a rich set of publication tooling to support development and implementation of use cases through specifications, implementation guides, and supplements

10. Reusability

FHIR provides a foundation for sharing content both within and across use cases, increasing opportunities for reusable content across guidelines, decision support rules, quality measures, case reporting, and workflow applications

11. Implementability

FHIR directly supports expression of quality measurement use cases with the Measure and MeasureReport resources

## Expressivity

Across the Clinical Quality Ecosystem, there is a need for fully and accurately expressing explicit meaning for data elements within logic expression as well as mechanisms for data exchange including transport, messaging, and reporting. Expressivity addresses the scope-breadth and depth- of information that can be represented in a data model. Variety (diversity,

range), extent (specificity, fidelity), and quantity of concepts expressed are key criteria on which to assess the expressivity of a data model. Expressivity addresses whether explicit, unambiguous meaning can be sufficiently represented in a model. Alignment addresses closeness of data semantics across use cases, most importantly existing systems of record. Fitness addresses how closely data semantics convey or express real-world concepts.

As a clinical conceptual data model, QDM has primarily (and initially exclusively) focused on clinical content that would be available within a patient's medical record and required for a specific set of quality measures. However, claims data is an important aspect of many types of healthcare quality measures, and more recent versions of QDM and enable flexibility in selecting a data model have begun to include basic coverage information. As a general-purpose framework for healthcare data exchange, FHIR supports a rich and expanding set of use cases, including payment, coverage, claims, and plan eligibility and enrollment. Quality measures that use FHIR can begin using resources and profiles developed from these use cases to more easily integrate clinical and claims data in the same measures to address critical use cases across clinical and financial spectrum as well as leverage key information from a broader set of data sources (clinical, claims, registry, etc.), often even in combination, to more comprehensively address the information need (e.g. did a patient receive a critical service such as a colonoscopy, mammogram, or an HbA1c laboratory test).

As one example, the FHIR resources are richly interconnected, supporting not only the description of clinical and other patient-related data, but also the relationships among those data elements such as the performance of an Encounter or Procedure, the target of a Communication, or the beneficiary of Coverage. These relationships are a critical aspect of establishing relevant criteria in a quality measure but have traditionally been expressed using timing relationships between the data elements, rather than direct references expressed in the information model.

In addition, quality measurement use cases involving both claims and clinical data (sometimes referred to as Hybrid Measures) are an important use case that can begin to be met with the administrative and payment-related resources in FHIR, specifically the Claim and Coverage resources to support describing insurance plan participation.

And finally, this richness supports the ability to formally define provider attribution criteria, whereas traditional approaches have relegated that to narrative descriptions in program guidance. This lack of formal representation has been a source of implementer burden and confusion, and recent efforts have begun to address this more formally; with FHIR, the data elements required to more fully express these criteria are available in currently published versions of the specification. Attribution is but one use case that clearly requires a combined perspective on clinical and financial/administrative data.

## Alignment

FHIR was primarily designed as a healthcare interoperability standard with a heavy focus on implementability. The FHIR development process has always included real-world

implementation as part of developing, validating, and publishing the standard<sup>1</sup>. As a result, the FHIR data model is closely aligned with what existing clinical information systems support, especially for the more mature FHIR resources. This alignment reduces transformation burden, implementation and development effort, time, and cost, as well as the potential for error through semantic misalignment. In addition, alignment reduces the need for transformation logic, which leads to more fidelity in the exchanged data and higher quality data available for use in all aspects of healthcare, including quality measurement.

In considering whether to continue development of a use-case specific conceptual data model for quality measurement, this alignment question is key to reducing implementer burden.<sup>2</sup> Enabling data exchange between systems requires a common model. The more different systems involved in the exchange, the more effort is required to transform data to and from that common model. In the case of FHIR, implementer systems are already performing this transformation from their internal data models to FHIR. Retaining a conceptual data model specific to quality measurement, such as QDM, on top of that introduces another layer of mapping and transformation that must be developed, tooled, authored, implemented, and subsequently maintained over time. And the more layers of mapping and transformation involved, the greater the chance for errors, semantic misalignment, and loss of fidelity.

Figure 5 and Figure 6 provide examples of alignment concerns.

QDM	or exists ( ["Procedure, Performed": "Pneumococcal Vaccine Administered"] PneumococcalVaccineGiven where PneumococcalVaccineGiven.relevantDatetime on or before end of "Measurement Period"
FHIR	or exists ( ["Procedure": "Pneumococcal Vaccine Administered"] PneumococcalVaccineGiven where PneumococcalVaccineGiven.status = 'completed' and PneumococcalVaccineGiven.performed as Period on or before end of "Measurement Period"

Figure 5. CMS127 description of the procedure to administer pneumococcal vaccine using QDM and FHIR.

Figure 5 compares QDM and FHIR representations of the pneumococcal vaccination procedure. Both phrases use the same value set composed of SNOMED CT and CPT procedure codes referencing the pneumococcal vaccine procedure. The phrase expressed in QDM assumes the implementer understands that “Procedure, Performed” empirically means a completed procedure as compared to a procedure that is planned, in progress, cancelled or completed. eCQMs that use “Procedure, Performed” require that the implementer correctly map to relevant completed immunization procedures to retrieve data for the measure. The FHIR expression specifically notes that the required data is a procedure with a status of completed and it uses the same model with which the implementer should share the same information when communicating among practitioners and registries such that there is no additional mapping required to retrieve data for the measure.

<sup>1</sup> The FHIR Maturity model illustrates this commitment to implementation as a critical factor in the development of the specification: <http://hl7.org/fhir/versions.html#maturity>

<sup>2</sup> A conceptual data model establishes the business use case requirements for the entities, their attributes, and their relationships, but it does not define the structure of the data elements or the relationships between them.

QDM	exists ( ["Immunization, Administered": "Pneumococcal Vaccine"] PneumococcalVaccine where PneumococcalVaccine.relevantDatetime on or before end of "Measurement Period"
FHIR	exists ( ["Immunization": "Pneumococcal Vaccine"] PneumococcalVaccine where PneumococcalVaccine.status = 'completed' and PneumococcalVaccine.occurrence as dateTime on or before end of "Measurement Period"

Figure 6. CMS127 description of the actual administration of pneumococcal vaccine using QDM and FHIR.

Figure 6 compares QDM and FHIR representations of the pneumococcal vaccine that was administered and the timing. Both phrases use the same value set composed of CVX (vaccine administered) codes, i.e., codes that specifically identify pneumococcal vaccines and not the procedure to administer them. The phrase expressed in QDM assumes the implementer understands that “Immunization, Administered” empirically means a completed administration as compared to a planned, or cancelled administration. It also assumes the implementer understands what is meant by relevantDatetime, i.e., the time the vaccine administration occurred. eCQMs that use “Immunization, Administered” require that implementers correctly map to relevant completed immunization administration to retrieve data for the measure. The FHIR expression specifically notes that the required data is an immunization with a status of completed and its timing, HIT implementers which use a proprietary internal data model are mapping their representations to FHIR for a variety of use cases (e.g., communicating among practitioners and registries). Using FHIR for eCQMs can leverage this FHIR representation, whereas using QDM (or any model tailored specifically for quality measurement) for eCQMs requires an extra step of conversion.

## Fitness (Representational Bias)

Semantic fitting deals with the alignment of the semantics or meaning that can be conveyed, represented, or expressed in the data model. Overfitting, underfitting, and misfitting can all create unnecessary complexity and worse, inadvertent, or even unexpected variation in the intended versus interpreted meaning of information resulting from the inferences of clinical business logic. The following examples represent misalignment between the source and target of representations of information across use cases and/or from domain entity/concept to the expression of information.

- Overfitting occurs when there is more extensive expressivity in the data model than is required to accurately represent domain entities and concepts within the information carrier (data model) resulting in ambiguity and leading to misinterpretation. For example, QDM differentiates Procedure from Intervention based on conceptual distinctions yet both map to the FHIR Procedure resource.
- Underfitting occurs when a data model does not or cannot represent ample concepts to carry the information required to sufficiently describe the domain of interest. For example, QDM defines entities (Patient, Care Partner, Organization, and Practitioner) to allow expressions to reference the performer of one activity, e.g., Encounter, should be the same performer of another activity, e.g., Physical Exam. However, the entities are not fully specified to allow the Encounter participant to be an organization and the Physical Exam

performer to be a practitioner who is a member of that referenced organization. FHIR enables such expressivity using PractitionerRole.organization. In addition, QDM's approach to underfitting requires a new version to incorporate any changes. FHIR allows extensions to add required elements in advance of new version availability.

- Misfitting occurs when there is misalignment between the source and target representations of a mapping. For example, a misfit occurs when a concept in one domain, such as Physical Exam, can be interpreted as describing actions such as dilated retinal examination (addressed with the FHIR Procedure resource), or as findings, i.e., the result of the dilated retinal examination (addressed with the FHIR Observation resource). QDM requires interpretation by expression authors and implementers; this ambiguity can lead to incorrect data retrievals. FHIR enables the expression authors and implementers to more clearly understand intent, improving the certainty of expected data retrieves.

FHIR and QI-Core are designed to express the data semantics for the use cases of clinical care, delivery, and supporting financial processes as well as the full lifecycle of Clinical Quality Improvement, respectively. This tight bond with the existing clinical systems ensures good “fitness” for semantic representation and ultimately valuable and actionable application of Quality Measurement and related CDS interventions and other CQI use cases such as Case Reporting and Knowledge Discovery. While FHIR is not free from overfitting, underfitting and misfitting, the process used to produce FHIR tends to minimize these concerns by its focus on healthcare and interoperability.

## Liquidity

This same semantic alignment and appropriate fitting through FHIR also facilitates the re-use of knowledge assets developed for quality measurement across other high-value use cases such as integration with clinical workflow via CDS Hooks, or data enrichment and insight delivery via SMART-on-FHIR applications, surveillance and reporting to professional societies, payers, and research or government entities, or even for direct use within systems that support write access in their FHIR services.

For example, decision logic content (i.e., the shareable and computable criteria) that is developed from the same guidelines used to inform the quality measurement specifications can be operationalized at the point-of-care using applications that can deliver that content, driving performance improvement in support of quality measurement. Inclusion and exclusion criteria for measure populations often overlap with “Condition” criteria in common CDS Event-Condition-Action Rules, eligibility criteria for clinical Pathways (derived from CPGs), cohort definitions (“triggers”) and supporting data elements for [Electronic Case Report](#) (eCR).<sup>3</sup> In this example, eCR provides the opportunity for shared logic and data elements (raw and inferred) across these use cases has the potential to increase consistency within the CQI lifecycle and

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<sup>3</sup> Electronic Case Report (eCR) supports public health surveillance and delivery of relevant public health information to clinical care to provide complete and timely case data, support disease / condition monitoring, and assist in outbreak management and control.

likewise makes possible much more expedient best practice (knowledge) discovery-to-delivery translational and implementation endeavors.

In addition, the existence of API-based access to clinical systems has already been a driver for clinical quality and analytics use cases beyond quality reporting and measurement, and the types of exchanges enabled (such as incremental data submission throughout a given measurement period) are already driving standardization around care management processes such as Gaps in Care identification, closure, and potentially even prevention.

## Community

The FHIR specification benefits from a broad and ever-expanding community of stakeholders from across the healthcare industry<sup>4</sup>. As a focused data model, QDM currently has a representative set of stakeholders from within the quality measurement community, but as the use cases for quality measurement expand, so must that representation across the clinical care and healthcare delivery domain. By using FHIR, quality measurement joins the already vibrant community contributing to the shape and supported use cases of the FHIR resources and implementation guidance. This brings clinical practice and quality measurement in closer alignment in terms of data, information, and knowledge (business logic) assets as well as process, governance, and focus/prioritization.

As a specific example of the benefits of engaging the FHIR community, a recent measurement use case involves representation of the nutrition orders for a patient. However, the NutritionOrder resource within FHIR has a low maturity level, so measure developers were able to reach out to the stewards of the resource through the Orders and Observations HL7 Work Group to bring their use case to a forum for discussion. Specifically, the measurement use case involved identifying a newborn infant's exclusive consumption of breast milk, with no other nutrients or liquids. However, the only available resource in FHIR R4 is NutritionOrder. FHIR R4 addresses NutritionOrder with a maturity level of 2 with limitation for use for acute care diet orders including individual nutrients. FHIR R5 work is progressing to increase maturity and address ambulatory nutrition prescriptions. FHIR R5 will also include new NutritionIntake to capture the event of consuming food or fluid and NutritionProduct analogous to the Medication resource to enable detailed description of dietary products. C-CDA currently includes specification of acute care setting diet orders (Nutrition Order) and ambulatory setting diet orders (Nutrition Recommendation). FHIR R5 NutritionIntake will more clearly address the use case described.

## Extensibility

Evolving use cases, regulatory and implementation environments as well as advances in medical knowledge and the practice of care will require that the information model evolve over time to support additional content and concepts (semantics). Particularly, the ability to extend

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<sup>4</sup> The FHIR Credits page illustrates the breadth and depth of this community: <http://hl7.org/fhir/credits.html>



and constrain via profiling such as in QI-Core (or US-Core) enables adaptation of the data model to improve “Fitting” to the use cases and domain.

The FHIR framework provides a well-established and flexible mechanism for defining additional constraint-based definitions and data concepts, as well as a process for achieving consensus for inclusion in implementation guidance. The consensus-based process allows for new concepts to be promoted up to base specifications where appropriate. Figure 7 illustrates this landscape:

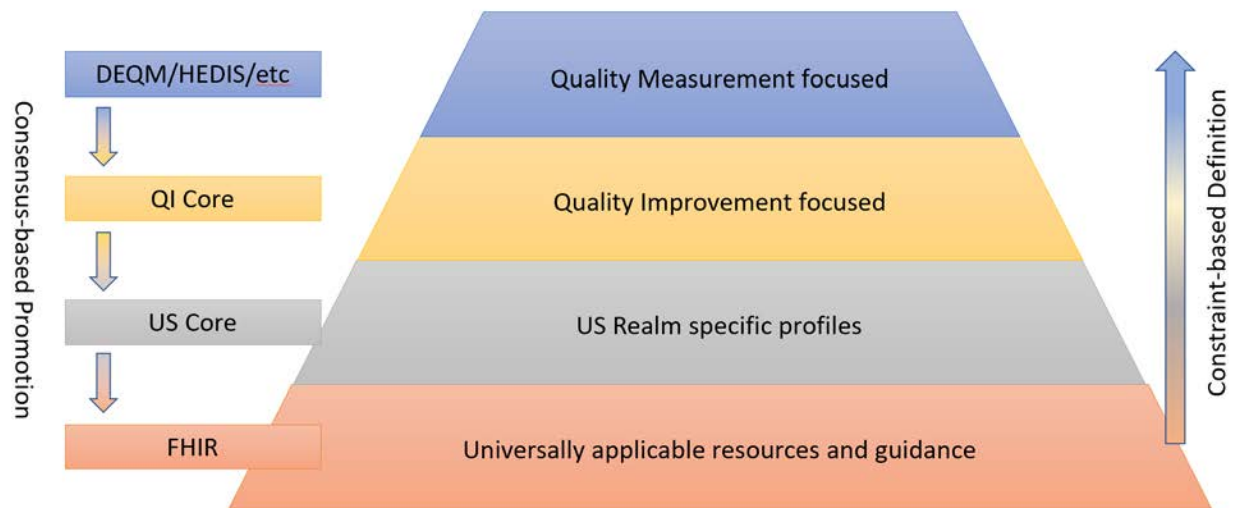


Figure 7. Data Model Standards Landscape Diagram. Each layer builds on the previous layer while adding constraints and focus for the various use cases.

As new use cases are proposed, Figure 7 shows FHIR as the basic platform specification supporting the ability to describe extended information that is not defined by the base standard. Using profiles and implementation guidance, that extended information is still specified in a formal way that enables conformance checking. Moving up the diagram involves constraint-based definition to capture the use-case specific requirements and moving down the diagram involves submitting feedback to base implementation guides and specifications and achieving consensus where appropriate for content that is more broadly applicable.

As an example of this process, some quality measurement use cases rely on identifying whether a particular diagnosis was present on admission. This information is not currently represented within the Encounter or Condition resources in FHIR. Figure 8 shows the QI-CoreEncounter profile extension to represent this information:

diagnosis	S	0..*	BackboneElement	
qicore-encounter-diagnosisPresentOnAdmission	S	1..1	CodeableConcept	onAdmission <b>URL:</b> <a href="http://hl7.org/fhir/us/qicore/StructureDefinition/qicore-encounter-diagnosisPresentOnAdmission">http://hl7.org/fhir/us/qicore/StructureDefinition/qicore-encounter-diagnosisPresentOnAdmission</a> <b>Binding:</b> <a href="#">ExampleDiagnosisOnAdmissionCodes</a> (required)

Figure 8. QI-CoreEncounter extension for diagnosisPresentOnAdmission.

Recognizing that this information is more broadly applicable than just quality measurement, this extension is being submitted as feedback to the US Core profiles, and ultimately the base FHIR specification itself to support capturing that data as a first-class data element.

## Conformance

As an interoperability framework, the FHIR specification provides mechanisms not only for describing the expected content of an exchange, but for validating that the resources involved in the exchange conform to the expected profiles.

The FHIR conformance framework supports the following types of conformance validation:

- Structure - Validation that data elements conform to structural requirements (i.e. resource and data element names)
- Cardinality - Validation that data elements are present in the expected cardinalities (e.g. 0..1, 1..1, 1..\* and others)
- Constraint - Validation that data elements satisfy expression-based constraints (e.g. if a name is present, a contact point must be as well)
- Terminology - Validation that codes used for data elements are from specific code systems and value sets
- Relationship - Validation that references between data elements conform to expected profiles.
- Capability - Description of capabilities such as search, profile support, terminology capabilities and operations.

These conformance capabilities provide a robust framework for the validation of healthcare exchange, and quality measurement use cases can make use of this framework to ensure data quality, consistency, and correctness. Profiles and implementation guidance can also serve more focused exchange partners, such as enabling knowledge-sharing within institutions, provider organizations, or other groups with highly focused needs.

## Tooling

Because of the focus on implementation, the FHIR tooling ecosystem is both well-developed and well-supported. In addition, because of a strong emphasis on open standards and technologies, this capable tooling stack is largely open source, including:

- Publication tooling to support creation and maintenance of FHIR implementation guides
- Authoring tooling to support development of profiles, example instances and test cases
- Generation tooling to support simulation of large amounts of realistic clinical data
- Open source server implementations on multiple platforms and technologies
- Open source client implementations on multiple platforms and technologies
- Terminology tooling on multiple platforms and technologies

In the development of any data exchange capability, all these types of tooling are necessary to support proper authoring, distribution, interpretation, and implementation. Extending existing conceptual data models would require closing significant gaps in tooling to support implementation.

## Agility

The FHIR publishing ecosystem has evolved over the past several years to a mature and stable technology stack, along with a broad and growing community of authoring expertise. This allows integration authors to focus on expressing their use cases, and lets stakeholders quickly see the expected results.

This agility comes with the associated challenge of versioning, in that new versions of implementation guides, as well as of the base specification itself, are released in relatively quick succession. This challenge is not inherent to FHIR; however, it is a constant feature of any changing system. What is critical is that the specifications for exchange have a mechanism to support and deal with evolution over time. Building on the shared experience of HL7 publishing, as well as the FHIR community, FHIR has a well-established and mature versioning model, both for the base specification, as well as for the implementation guides delivered on top of it.

## Reusability

Recognizing that quality measurement is part of a much broader quality improvement ecosystem, the use of consistent standards across those domains will make it easier to share content and services developed in different areas, such as decision support, research, population health management, public health reporting, registry reporting, and others. The FHIR framework supports saying things in a way that can be shared as models so that multiple groups don't have to reinvent the same content. It is distinct from, yet enhances Liquidity that highlights the FHIR API as a method to make data available and accessible to different parties for different usages. By using FHIR, support for many of these other domains are already part of, or actively being developed within, the FHIR ecosystem.

For example, the CDC Opioid Prescribing Support implementation guide developed shareable clinical logic for calculating Milligram Morphine Equivalent dose across a patient's opioid-containing prescriptions, a complex calculation which requires significant development effort as well as ongoing maintenance to ensure correct calculation and up-to-date knowledge of opioid-containing drugs. Although this calculation logic was developed as part of a decision support

implementation guide, measure developers were able to make use of this content directly to express measure population criteria.

As another example, the Da Vinci Gaps In Care use case incorporated into the DEQM IG is exploring the use of logic developed for quality measurement to support defining care gaps for use in coordinated care-management. Using the same data element descriptions already developed for the measure and expressed within the QI-Core profiles, care-gaps reporting can be built and shared using the same underlying exchange specifications. As quality reporting data is submitted periodically throughout the measurement period, receivers can detect cases that do not meet the standard of care described for a measure and notify the reporter, or otherwise initiate corrective action.

## Implementability

FHIR directly supports quality measurement use cases through the Measure and MeasureReport resources. In addition, because these are also FHIR resources, there is no impedance mismatch between the measure specification and reporting containers and the data on which they operate.

This native representation means not only that systems that already support other types of FHIR resources have a lighter lift to read and process Measure and MeasureReport resources, but that because the container (MeasureReport) is also a FHIR resource, measure data can be packaged and exchanged using the same infrastructure.

In addition, as discussed in the Alignment and Tooling sections above, the FHIR focus on implementation, together with the availability of well-supported tooling further reduces implementation burden.

Finally, the FHIR Maturity model provides a clear indication of the level of testing and development the resources and profiles involved in an implementation have received, informing investment and risk assessment.

## Conclusion

This paper has made the case that using the FHIR ecosystem offers significant advantages to the quality measurement and reporting use cases expressed by US-based stakeholders. From the breadth and depth of the information model, to the conformance-testable data exchange, to the agility and capability of the tooling, there are numerous reasons to use FHIR. That is not to say that FHIR is not without its challenges for meeting the quality measurement use case. In particular, the relatively low maturity of some of the key resources required to specify some quality measures presents a significant challenge. Even so, both the US and the global healthcare industry has already adopted FHIR and is moving forward with surprising rapidity; and this trend is only reinforced by the recent Office of the National Coordinator for Health

Information Technology (ONC) and CMS Final Rules<sup>5</sup>. A transition to FHIR-based quality measurement would represent an improvement over current production standards by aligning with this adoption to streamline processes and align with other healthcare data exchange scenarios.

## Acronyms

ANC – Antenatal Care  
API – Application Programming Interface  
CDA – Clinical Document Architecture  
CDC – Centers for Disease Control and Prevention  
CDS – Clinical Decision Support  
CDS Hooks – Clinical Decision Support Hooks  
CMS – Centers for Medicare and Medicaid Services  
CPG – Clinical Practice Guideline  
CPG-on-FHIR – Clinical Practice Guidelines on FHIR  
CPT – Clinical Procedural Terminology  
CQL – Clinical Quality Language  
CQM – Clinical Quality Measures  
CVX – Vaccine Administered Code  
DEQM – Data Exchange for Quality Measures Implementation Guide  
dQM – digital Quality Measures  
EBM-on-FHIR – Evidence-based Medicine on FHIR  
eCQM – electronic Clinical Quality Measures  
eCR – electronic Case Reporting  
FHIR – Fast Health Interoperability Resources  
FHIR R4 – FHIR Release 4  
FHIR R5 – FHIR Release 5  
HbA1c – Glycated Hemoglobin  
HEDIS – Health Effectiveness Data and Information Set  
HL7 – Health Level 7  
HL7 v2 – Health Level 7 version 2  
HL7 v3 – Health Level 7 version 3 (also called the Reference Information Model)  
HQMF – Health Quality Measures Format  
ICD – International Classification of Diseases  
IPS – International Patient Summary  
LOINC – Logical Observation Identifiers Names and Codes  
ONC – Office of the National Coordinator for Health Information Technology  
QDM – Quality Data Model

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<sup>5</sup><https://www.cms.gov/Regulations-and-Guidance/Guidance/Interoperability/index>

QI-Core – Quality Improvement Core  
QM – Quality Measure Implementation Guide  
RxNorm – US Medication Ontology  
SMART – Specific, Measurable, Attainable, Realistic, and Timely [API]  
SNOMED – Systematized Nomenclature of Medicine  
US Core – United States Core  
US Realm – United States Realm  
USCDI – United States Core Data for Interoperability  
WHO – World Health Organization