

## Implementation Guide

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# **CMS's Million Hearts® Model Longitudinal ASCVD Risk Assessment Tool for Shared Decision Making**

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- Clinical Decision Support (CDS) Connect Work Group members
- Patient-Centered Clinical Decision Support Learning Network
- MITRE CDS Connect Project Team
- Million Hearts<sup>®</sup> Model Leadership Team

## Record of Implementation Guide Changes

Date	Action	Notes
October 2017	Published <i>Implementation Guide</i>	
January 2020	Updated the <i>Implementation Guide</i> based on annual artifact updates	Updated the <i>Implementation Guide</i> 's Introduction and Background content, revised the flow of the content to enhance readability, added evidence specifications and a semi-structured representation of the artifact to Appendix A, and updated a small portion of the decision log.
April 2021	Updated the <i>Implementation Guide</i> based on annual artifact updates	Applied minor edits to improve clarity, noted new CDS Connect Commons library for FHIR R4, and recommended CDS Connect CQL Testing Framework tool for CQL validation.

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# Introduction

Clinicians today face an unending stream of new research findings, new or updated clinical practice guidelines, and best practices identified by peers that they must incorporate into daily practice. Transforming these large volumes of research into actionable knowledge that can be integrated into clinical care is a lengthy and expensive process that stretches the limits of what any one healthcare system can reliably accomplish on its own. The CDS Connect project, sponsored by the Agency for Healthcare Research and Quality (AHRQ), provides an opportunity for healthcare organizations to share evidence-based knowledge expressed as clinical decision support (CDS), enabling other organizations to leverage the publicly available expressions. The ability to share CDS expressions enhances efficiency by removing the need for subsequent organizations to start CDS development from “scratch.” It also contributes to a learning health community where CDS developers and implementers collaborate and enhance the shared resources.

Each year, the CDS Connect team develops CDS artifacts (i.e., CDS logic expressions) and contributes the body of work to the [CDS Connect Repository](#) to demonstrate CDS Connect infrastructure and publicly share the CDS. Some of the artifacts developed by the project team go on to be piloted in a clinical setting. When this occurs, the project team includes a Pilot Report with the artifact to describe CDS integration, testing, and implementation details, along with end-user feedback. Future implementers can leverage the insight outlined in the report to inform their implementation.

Other artifacts, like this one, are published one step earlier in the CDS development process (i.e., they are published as a human-readable logic statement that aligns with an evidence-based source, as opposed to a computer-coded version of the evidence). Because this artifact has not been fully coded, it has not been field-tested in electronic health record (EHR) systems or other technologies currently in use. However, the human-readable artifacts provide a valuable starting point for healthcare organizations that seek to develop CDS due to the sizeable amount of research and analysis required to translate narrative clinical practice guidelines into human-readable logic. CDS Connect artifacts are not “standalone” and are not intended to be completely plug-and-play; healthcare systems will need to integrate each artifact with components of their health information technology (IT) system for the artifact to work. Implementers should conduct extensive testing—including clinical testing in real-life workflows—of all artifacts. The project team expects that artifacts will be customized and adapted to local clinical and IT environments.

This Implementation Guide provides information and guidance to individuals considering their potential use of this artifact. The main intent of this document is twofold: 1) to provide insight on how the human-readable logic expression can be used to improve patient care, and 2) to provide information on how to transform the human-readable logic expression into interoperable logic code and integrate the CDS logic with a health IT system.

## Background

To facilitate AHRQ's vision, the CDS Connect project team created—

- The CDS Connect Repository to host and share CDS artifacts.
- The CDS Authoring Tool, which enables CDS developers to create CDS logic using Clinical Quality Language (CQL), a Health Level 7 (HL7) standard expression language.
- Several open-source prototype tools to facilitate creating, testing, sharing, integrating, and implementing evidence-based, interoperable CDS in health IT systems.

The use of CQL in CDS Connect systems and CDS development provides the ability to express logic that is human-readable, yet structured enough to process a query electronically.

Furthermore, CQL is an interoperable format that eases integration with health IT systems.<sup>1</sup>

CQL allows logic to be shared between CDS artifacts, and eventually with electronic clinical quality measures (eCQMs), in support of improving healthcare quality.

The CDS Connect Repository hosts and shares CDS artifacts across a wide array of clinical topics. The Repository provides contributors with more than three dozen metadata fields to describe their work, including the artifact's purpose, clinical uses, publisher, sponsoring organization, reference material from which the CDS was derived, human-readable logic, and decisions made while creating the artifact. It also enables contributors to upload the coded logic expression, test data, technical files, and reports.

The CDS Authoring Tool provides a user-friendly interface for creating standards-based CDS logic using simple forms. The logic developed by the tool is expressed using HL7 Fast Healthcare Interoperability Resources® (FHIR) and CQL. It empowers organizations that have limited access to software engineers with the ability to express evidence-based guidelines as accurate, tested, and coded logic. Individuals who are interested in developing CDS logic expressions like this artifact can use the tool to develop new CDS logic in the clinical domain of their choice. The interoperable format of the logic facilitates sharing and integration with a wide range of health IT systems.

The CDS Connect team also developed several prototype tools, including one that facilitates CQL testing (CQL Testing Framework) and one that facilitates integration of the CQL code with a health IT system (CQL Services). The CQL Testing Framework allows CQL authors to develop and run test cases for validating CQL-based CDS logic. This framework allows CQL developers to identify bugs in the CDS logic early in the development cycle, when it is less costly to fix. In addition, these test cases enable developers to demonstrate the expected behavior of the CDS logic to bolster trust in the coded expressions. Vendors and integrators may also choose to use the CQL Testing Framework to test any site- or product-specific modifications to this artifact's CQL. CQL Services is an open-source service framework for exposing CQL-based logic using the HL7 CDS Hooks application programming interface. This capability allows implementers to integrate CQL-based CDS into systems that do not yet support CQL natively.



## Scope, Purpose, and Audience of This Implementation Guide

This document is intended to provide information about the development and implementation of CMS’s Million Hearts® Model Longitudinal Atherosclerotic Cardiovascular Disease (ASCVD) Risk Assessment Tool for Shared Decision Making artifact, referred to as the “Shared Decision Making ASCVD Risk” artifact in this document. Various audiences may find this information helpful, including:

1. **Clinicians and Quality Leaders** at healthcare organizations and practices who wish to implement, test, and execute CDS related to this topic in their EHR and other health IT tools.
2. **Patients and Family Caregivers** who wish to have active CDS to help them direct self-care activities or who are interested in the process of CDS development and implementation for shared decision-making more generally.
3. **Healthcare Systems** interested in promoting patient experience to facilitate patient engagement and a patient’s ability to manage their health, while enabling value-based care and quality.
4. **CDS Developers and Informaticists** who may have suggestions, additions, or seek to add CDS artifacts on similar topics, or who want to make use of well-developed semistructured logic in their own work.
5. **Organizations or Individuals** interested in developing their own CDS artifacts, who may find this document helpful as a guideline for the process by which clinical guidelines are translated into semistructured artifacts.

## Implementing and Using This Artifact

### Artifact Description

This artifact extends the use of the CMS’s Million Hearts® Model Longitudinal ASCVD Tool for Baseline 10-Year ASCVD Risk artifact. It provides the ability to calculate and display the base 10-Year ASCVD risk score for an individual to help when considering initiating or optimizing therapy for primary prevention of ASCVD,<sup>2</sup> and utilizes the 2013 American College of Cardiology (ACC)/American Heart Association (AHA) pooled cohort equation (PCE) to calculate the risk for developing a first-time “hard” ASCVD event, defined as: nonfatal myocardial infarction (MI), coronary heart disease (CHD) death, nonfatal stroke, or fatal stroke.<sup>3</sup>

The Shared Decision Making ASCVD Risk artifact addresses the second of three clinical scenarios where CMS’s Million Hearts® Model Longitudinal ASCVD Risk Assessment Tool might be used—

1. Calculation of a baseline 10-Year ASCVD risk assessment score, prior to initiation of any new therapies to address this risk.
2. Prospective estimations of ASCVD risk in support of shared decision making while considering the benefits of therapies, alone or in combination.

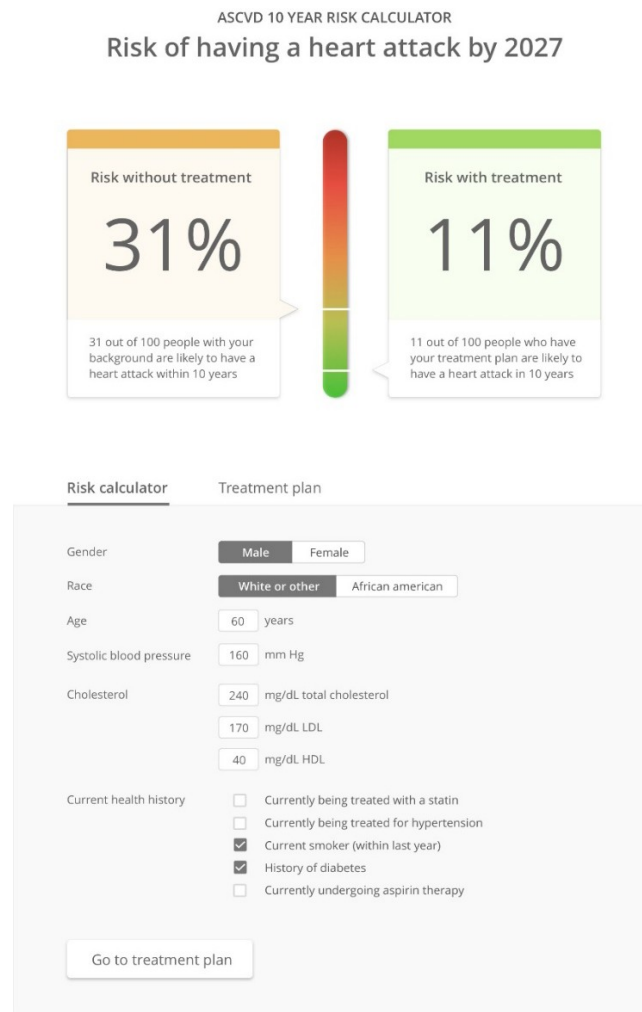
3. Calculation of updated risk after preventive therapies have been initiated.

## Preventive Health Scenarios Supported by This Artifact

The three ASCVD risk calculations in this family of artifacts are primarily for use by clinicians and patients performing assessment and treatment planning in a primary care or cardiology practice setting. The artifact is suitable for producing an intelligent data display. An implementation of this CDS artifact can produce: 1) a “calculator” view of the parameters used in the calculation, with opportunity for the user to correct or adjust any values; and 2) a calculated risk score, displayed on the screen and potentially available for other CDS artifacts (e.g., cholesterol-lowering CDS algorithms) that make use of the risk score as part of their calculation.

A typical calculator view created by the implementer of the artifact might look like **Figure 1** where the score is prominently displayed, while the supporting parameters are filled in automatically from EHR data or adjusted manually.

**Figure 1: Sample Implementation of an ASCVD 10-Year Risk Calculator Display**



Compared to the Baseline risk assessment calculator display, the notional Shared Decision Making display in **Figure 2** shows not only the risk based on current parameters, but also the modification of anticipated risk if statins, hypertension treatment, aspirin therapy, and/or smoking cessation were to be initiated.

**Figure 2. Notional Extension to the 10-Year ASCVD Risk Calculator with Prospective Therapies Selected**



By turning on and off the various checkboxes for these interventions, the clinician and patient can work together (or, in alternative use cases, the patient can work alone) to understand how much each intervention and each combination of interventions can reduce their risk.

The Shared Decision Making calculator interaction is typically performed after a Baseline risk calculation has been completed, although it can be performed at any time.

Preventive health scenarios that this artifact supports include:

- **Upon request, typically as part of a patient encounter**
  - Ms. Bravo, a 55-year-old African-American nondiabetic patient with hypertension, comes in for a regular annual checkup. She has not had an ASCVD risk calculation done previously. Her clinical practitioner launches the risk calculator. Using data from Ms. Bravo's EHR, the algorithm executes; a calculator view is displayed on screen, showing all relevant parameters and her calculated risk score of 31 percent. In some implementations, this view also allows manual adjustment of parameters that might not have been fully or correctly captured, such as smoking status. Ms. Bravo and her clinician can then manipulate the boxes in the calculator for statins, aspirin, blood pressure control,

and smoking cessation to see how her risk would change. Through this exercise, they can begin to decide together which interventions to consider, while weighing treatment side effects and lifestyle impact.

- **Upon request, after use of another CDS artifact run during a visit**
  - A different CDS artifact is run against Mr. Delta's data to consider whether a statin recommendation is indicated. If that artifact produces a positive recommendation for statin use, then Mr. Delta and Dr. Charlie could ask to see this risk calculator, so they can see more clearly the impact of using statins on his overall cardiac risk.

Note that some of the shared decision-making interventions will not affect the risk score if they are already in place (i.e., if the patient is already a nonsmoker or already on statins, aspirin, or blood pressure treatment). In this case, the calculator should have the indicated boxes checked (as shown in Figures 1 and 2) and display a warning if the user tries to modify these parameters.

## **Preventive Health Scenarios Supported With Customization of the Semistructured Expression**

An additional preventive health scenario that could be supported by enhancing portions of this artifact to make them directly accessible by a patient is as follows:

- **Patient self-care/family caregivers as part of self-assessment or health maintenance**
  - Mr. Delta, a 62-year-old White man, runs an overall general health self-assessment or cardiac risk self-screen as part of a self-care program. The risk score display, showing his current risk, is presented as part of the assessment. In addition, he can use the shared decision-making features to learn how various recommended interventions would impact his overall cardiac risk.

## **CDS Interventions and Suggested Actions**

The Artifact Semistructured Logic section of [Appendix A](#) illustrates the CDS logic that generates the display of interventions and recommendations. At a very high level, the recommendations and interventions pertinent to each risk calculator artifact includes the following:

1. Notify the user if the patient is excluded either due to age (less than 40 or greater than 79) or a history of ASCVD.
2. Notify the user that, even though the algorithm is executing, it may not be fully valid or may need to be adjusted for patients with familial hypercholesterolemia, or for patients who are not White or African American.
3. Display the ASCVD risk calculation as either a calculator view or data view.
4. Populate the calculator with known parameters from EHR data, while indicating which parameters (if any) could not be obtained.
5. Allow the user to modify parameters in the calculator.
6. If applicable, notify the user that certain parameters (including total cholesterol, HDL cholesterol, and systolic blood pressure) were out of the validated range and have been adjusted to the nearest in-range value.

7. Display the ASCVD risk score as derived from the collected and entered parameters.
8. Document the ASCVD risk score in the patient's record. This is not a standard EHR data element; each implementation currently must identify where this is stored in the record for applications that make use of the score and for documenting that a score was performed.

Items specific to shared decision making:

1. Allow the user to manipulate the controls pertinent to possible interventions.
2. Display the adjusted risk if the selected interventions were done.
3. Document any interventions that were decided upon by the patient with the clinician (or without the clinician, in the case of patient self-use of the artifact).
4. Provide information resources to the patient outlining benefits, risks, effects, and evidence behind each type of intervention (regardless of whether the patient has already initiated that intervention) to aid further decision making.

## Evidence Source for Artifact Development

The 2017 ACC/AHA Special Report is the evidence-based source of this artifact.<sup>2</sup> The Million Hearts® Model Longitudinal ASCVD Risk Assessment Tool uses the ACC/AHA 2013 PCE, providing sex- and race-specific 10-year estimates of ASCVD risk. The equations are intended for use in patients 40 – 79 years of age who have not had ASCVD.<sup>3</sup> The risk calculations have been validated in a broadly representative sample of U.S. White and African-American individuals.

The Baseline calculation allows for estimate of initial baseline risk based on key parameters, including age, gender, race, total and high-density lipoprotein (HDL), systolic blood pressure, smoking within the past year, presence of diabetes, and treatment for high blood pressure.

The Shared Decision Making calculation scores the change in estimated risk that would be associated with institution of one or more preventive interventions, including smoking cessation, aspirin therapy, blood pressure control, and statin therapy, if these have not already been started.

The Updated Risk calculation compares the original baseline risk with the updated risk reflecting instituted interventions and their impact on measures such as LDL cholesterol and systolic blood pressure. According to the ACC/AHA Special Report:

Using the [Updated Risk] artifact, the patient and clinician can see the projected absolute risk reduction associated with initiation and continuation of each therapy, or combinations of therapies, and weigh this in the context of other considerations, including patient preferences for taking medications, potential adverse drug reactions or interactions, and where they see the most bang for the buck.<sup>2</sup>

The Updated Risk calculates risk reduction in part by formulas that assign coefficients for the impact of *changes* in key values such as LDL cholesterol, rather than risk based on the absolute value of the parameter. However, it provides guardrails so that the Updated Risk

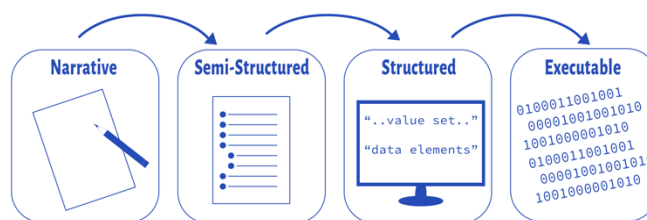
cannot be more than the Baseline risk calculation would have been if the new parameters had been incorporated.

Additional reference information can be found in the textual metadata section that describes this artifact in the CDS Connect Repository.

## Artifact Development Plan

Boxwala et al. developed a multilayered knowledge representation framework for structuring guideline recommendations as they are transformed into CDS artifacts.<sup>4</sup> The framework defines four “layers” of representation, as depicted in **Figure 3**.

**Figure 3. CDS Artifact Maturity Process**



1. **Narrative** text created by a guideline or clinical quality measure (CQM) developer (e.g., the recommendation statement described as a sentence).
2. **Semistructured** text that describes the recommendation logic for implementation as CDS, often created by clinical subject-matter experts. It serves as a common understanding of the clinical intent as the artifact is translated into a fully structured format by software engineers.
3. **Structured** code that is interpretable by a computer and includes data elements, value sets, and coded logic.
4. **Executable** code that is interpretable by a CDS system at a local level. This code will vary for each site.

The CDS Connect team suggests the following “best practices” for developing semistructured logic representations of evidence.

- Analyze the purpose, clinical statement, and use case sections of this document to ensure that your organization agrees with the intended goals of the clinical guideline on which this artifact is based.
- Review [Appendix A](#) (the decision log) to ensure that your organization understands and agrees with the decisions made during the process to convert the underlying clinical guideline to a semistructured CDS artifact.

Future implementers of this artifact can follow the activities described in the next section to enhance this artifact to the structured stage.

## **Form a Cross-Functional Team**

Translating this semistructured representation of medical knowledge into a structured representation using CQL code requires a combination of skills that are not commonly possessed by a single individual—

1. A clinical background that includes working knowledge of the underlying clinical guideline and its application in medical practice.
2. Familiarity with standard terminologies (e.g., RxNorm) and their implementation in health IT products.
3. The ability (or willingness to learn how) to develop code in several languages, at a minimum CQL and likely one other language, to be used for the execution of test scripts.

Each of these skillsets will be necessary at various points in the CQL development process, with some tasks being done synchronously and others done asynchronously. The team should plan to meet at least weekly to evaluate status and collaborate on joint tasks.

## **Identify Appropriate Value Sets and Codes**

Generating a structured CDS artifact begins with the identification of existing value sets or codes that can be used to represent the clinical concepts in the semistructured artifact. For example, if a semistructured artifact mentions “diabetes” as part of its logic, then many Systematized Nomenclature of Medicine-Clinical Terms (SNOMED-CT) and International Classification of Diseases, Tenth Revision, Clinical Modification (ICD-10-CM) codes could be used to represent a patient with an active condition of “diabetes” in an EHR. Implementers should review the Value Set Authority Center (VSAC) to determine whether existing value sets are sufficient to express each clinical concept in an artifact. VSAC provides a website and an application programming interface (API) with access to all official versions of vocabulary value sets contained in Centers for Medicare & Medicaid Services (CMS) electronic Clinical Quality Measures (eCQMs). If a clinical concept in the semistructured artifact cannot be expressed using existing value sets, then implementers may create their own value sets through VSAC. For example, a value set for “familial hypercholesterolemia” was created as part of MITRE’s work for another artifact posted on the CDS Connect Repository.

Implementers should be forewarned—reviews of existing value sets are primarily manual processes, and comparison of content across value sets is difficult:

1. Many value sets are missing purpose statements, or the existing purpose statements are vague and don’t include additional meaning beyond the value set title. Be prepared to inspect the value sets to determine their fitness for purpose.
2. Many competing value sets appear to address the same clinical concepts in VSAC. Investigate the alternatives and decide on value set usage based on the context of the clinical guideline. Part of the reason for using standard value sets is that they are

- maintained and keep up with changing usage patterns; nonetheless, it would also be prudent to validate the chosen value set against codes that are in use at the implementation site(s).
3. VSAC does not show whether a value set is actively maintained or deprecated. For example, a value set last updated in 2014 may not be current. To infer whether a value set is current, one must determine if the value set is used in any of the latest eCQMs—and if not, why.
    - a. The eCQM itself may have been removed/retired. It is unclear what happens to the value sets in this scenario.
    - b. The value set has been harmonized or replaced by a similar value set in the eCQM. This information is likely noted in the eCQM release notes (if one can find the version where the change was made) but is not carried over to the VSAC.

## Review Existing CQL Libraries and Develop CQL

In developing CQL code, implementers should follow the lead of the semistructured artifact. Begin by establishing the inclusion and exclusion criteria for the artifact in CQL. When the population of patients is established, model the subpopulations that will contribute to various recommendations laid out in the semistructured artifact. Use those subpopulations to generate recommendations. Finally, build any clinically relevant warnings or error messages into the CQL code. Generally, most errors and warnings are related to missing or outdated data in a patient's medical record.

Whenever possible, developers should reuse existing CQL libraries or code snippets. Aside from the existing artifacts in the CDS Connect Repository, developers can review the following resources for guidance on developing CQL:

- [HL7 CQL Specification](#)
- [CQL on the Electronic Clinical Quality Information \(eCQI\) Resource Center](#)
- [CQL Tools \(e.g., CQL-to-ELM Translator\) on GitHub](#)
- [CQL Execution Engine \(JavaScript\) on GitHub](#)
- [CQL Evaluation Engine \(Java\) on GitHub](#)

CQL code from other artifacts have been developed to enact specific clinical guidelines, but portions of that code may be helpful for translation of unrelated future into CQL:

1. The CDS\_Connect\_Commons\_for\_FHIRv102, CDS\_Connect\_Commons\_for\_FHIRv401, FHIRHelpers, and CDS\_Connect\_Conversions are four libraries included in existing CQL artifacts define commonly used functions in CQL files; they are not specific to any clinical guideline. They can be used with any other CQL file that could benefit from those functions.
2. Selected code blocks from existing artifacts could be copied and reused in other CQL files. For example, some have expressed interest in the definition of pregnancy (based on the existence of either a condition code or observation code).

Implementers may face challenges due to the current lack of tooling available for development



and testing of CQL code. More-mature languages tend to have multiple tools associated with them, but CQL is an emerging language. MITRE developed a [CDS Authoring Tool](#) that allows users unfamiliar with CQL syntax and structure to create CQL with a graphical user interface.

## **Review and Test Developed CQL**

After CQL representations of artifacts have been developed, they should be thoroughly reviewed for technical and clinical accuracy. The CQL logic should be both clinically meaningful and minimally prescriptive to allow flexibility in implementation by a variety of organizations. Developers should refactor logic that is not specific to the artifact (e.g., unit conversions) into included libraries. Test cases should be developed and executed against the CQL, with special attention paid to logic coverage, edge cases, negative cases, and clinical relevance.

Review and testing of a CQL artifact should be composed of (at a minimum) two components: automated execution of test cases and manual review of the artifact.

### **Automated Execution of Test Cases**

A test suite should be acquired, built, or adapted from existing software to allow for automated test cases to be run. The test suite will require—

1. A synthetic patient generator that allows the CQL execution service to receive properly formatted patient records.
2. An orchestration module that accepts test data (patient data and expected results) as raw input and then:
  - a. Calls the synthetic patient generator to generate patient records.
  - b. Sends that patient data to the execution service.
  - c. Receives and interprets the response from the execution service.
  - d. Compares the actual results against the expected results and generates a report.

The CDS Connect project provides an open source [CQL Testing Framework](#) tool; authors and implementers may find it useful for developing and executing CQL logic test suites.

### **Manual Review of the Artifact**

After sufficient automated testing, the cross-functional team should review (line-by-line) the developed CQL code to ensure that all parts of the semistructured artifact have been accurately captured. At a minimum, this manual review should be conducted twice per artifact (one initial review and a final review) with all team members present to comment on the suitability of the CQL code.

During review, the team should match up the semistructured artifact to the developed CQL code to identify any gaps between the two items. Implementers should be wary of naming conventions; code-commenting conventions; and inclusion, exclusion, and subpopulation filters. This review may also be useful to determine gaps in the semistructured artifact. If patients fall

into multiple categories in the CQL code based on the semistructured guidelines, then the semistructured artifact may need to be revisited.

## **Expected Timeline**

Implementers should expect the first translation of a semistructured artifact into CQL code to take several months. With properly established teams, workflows, and supporting applications, this time should become progressively shorter. Under idealized conditions, preliminary CQL code may be generated quickly, but this does not include proper testing and validation in a clinical setting. Proper testing in a clinical setting is imperative to understand the utility of developed CQL, and its impact should not be underestimated. In pilot efforts, the item with the largest amount of uncertainty and longest lead time (and, thus, the driver of the project timeline) was the identification and build process for proper value sets to be used in an artifact.

Each subsequent effort will benefit from productivity gains in several areas.

1. Team formation is likely to be simpler; previous teams can be re-used, or similar resources can be brought on to backfill open team positions.
2. Over time, additional value sets will be established on VSAC and existing value sets will become more well-defined, decreasing the amount of research time necessary.
3. Developers will be able to leverage existing CQL libraries and re-use snippets of code from existing CQL artifacts.
4. Once established, CQL testing frameworks should be simpler to use in subsequent translation efforts.
5. Over time, all team members (regardless of their area of expertise) will develop a familiarity with the constituent parts of the translation effort.

# Appendix A. Decision Log

## Artifact Semistructured Logic

This artifact provides the ability to calculate a prospective 10-Year ASCVD risk estimate when preventive therapy is being considered by a clinician and patient (i.e., aspirin, blood pressure-lowering therapy, statin, tobacco cessation, or combinations thereof).

It addresses the second of three clinical scenarios where CMS's Million Hearts<sup>®</sup> Model Longitudinal ASCVD Risk Assessment Tool might be used—

1. Calculation of a baseline 10-Year ASCVD risk assessment score.
2. Prospective estimations of ASCVD risk in support of shared decision making while considering the benefits of therapies, alone or in combination.
3. Calculation of updated ASCVD risk after preventive therapies have been initiated.

Semi-structured inclusion and exclusion logic and examples of the CDS interventions are as follows:

### Inclusion logic:

10-Year ASCVD risk score  $\geq 5$  percent

### Exclusion logic:

History of ASCVD

### Examples of the CDS intervention:

Display age

Display gender (male/female)

Display race (White/African American/other)

Display total cholesterol, MOST RECENT within past 6 years (measured in milligrams/deciliter [mg/dl])

Display LDL cholesterol, MOST RECENT within past 6 years (measured in mg/dl)

Display HDL cholesterol, MOST RECENT within past 6 years (measured in mg/dl)

Display treatment with statin (yes/no) – determined by an active statin medication order

Display systolic blood pressure (SBP), MOST RECENT within past 6 years (measured as millimeters of mercury [mmHg])

Display treated for high blood pressure (yes/no – determined by a diagnosis of hypertension and an active anti-hypertensive medication)

Display diabetes (yes/no)

Display current smoker within the last year (yes/no)

Display aspirin therapy (yes/no – determined by an aspirin medication)

Calculate prospective risk scores

Display prospective risk scores

## Concept Definition Decision Log

**Table 1** defines many of the terms used in the semi-structured CDS representation to provide clarity on what each logic concept means and why it was expressed as listed. These concepts were informed or derived from text in the evidence-based source.

**Table 1. Concept Definition Decision Log**

Concept	Definition and/or Rationale
“facilitate”	Enable unlimited calculations based on scenarios (i.e., therapies) entered in the ASCVD risk tool.
“provider-patient discussion”	Encourages shared decision making about the benefits and harms of specific therapies so the patient can make an informed decision.
“after”	The trigger for this artifact is calculation of an ASCVD risk score.
“10-year risk”	Risk of showing evidence of ASCVD within the next 10 years.
“one or more therapies”	One or more of the following: smoking cessation, hypertension treatment, statin therapy, or aspirin therapy.

## Artifact Development Decision Log

The Artifact Development Team made several decisions while translating the evidence and developing the semistructured representation of this artifact. **Table 2** provides insight on those decisions. The table lists a “Decision Category,” which was informed by a Tso et al. journal article, titled “Automating Guidelines for Clinical Decision Support: Knowledge Engineering and Implementation,” that outlines a methodology for knowledge translation.<sup>5</sup> It also lists the high-level “Concept” related to the entry and the “Rationale” for each decision.

**Table 2. Artifact Development Decision Log**

Decision Category	Concept	Rationale
Reconcile multiple guidelines	Presence of CVD risk factors as a requirement to calculate 10-year risk	The U.S. Preventive Services Task Force (USPSTF) guidelines recommend the calculation of 10-year risk only in the presence of 1 or more risk factors (e.g., smoking, hypertension); the ACC/AHA guidelines do not require the presence of a risk factor. Based on Cholesterol Management Work Group feedback and in an effort to more closely align with the ACC/AHA Special Report, risk factors were not added to inclusion logic. Local implementers can add these specifications based on their organization’s policy and practice.
Implementation guidance	Use of the Longitudinal ASCVD Tool (i.e., PCE) on Hispanic individuals	The Cholesterol Management Work Group found the benefit of calculating ASCVD risk for Hispanic individuals using the PCE outweighs the chance that it may slightly overestimate or underestimate ASCVD risk; providers should use their judgement on how the risk score might be adjusted for each unique individual. Consider adding a notification that caveats the risk score if the patient is Hispanic during structured specification of this artifact.
Implementation guidance	Age specification in the Inclusion logic	The ACC/AHA recommends 10-year ASCVD risk assessment for eligible individuals aged 40 – 79 to be conducted every 4 – 6 years (as specified in the CDS logic). The upper and lower age parameters can be changed during implementation if a risk score is needed for an individual outside this age range. Refer to the ACC/AHA Special Report and ACC/AHA Guideline on the Assessment of Risk <sup>3</sup> for additional information.
Verify completeness of logic	History of ASCVD as an exclusion	The PCE calculates the risk of developing ASCVD within the coming 10 years. If an individual already has ASCVD, then use of the calculator is not indicated.

Decision Category	Concept	Rationale
Verify completeness of logic	Caveat for individuals with familial hypercholesterolemia (FH)	Based on Cholesterol Management Work Group feedback, individuals with a history of FH should not be excluded from a risk score calculation; the PCE underestimates risk in these individuals. The score is valuable information that can guide care. Instead, the score could be caveated to indicate that the individual has FH and, as a result, the true score may be higher than that depicted by the calculated value.
Verify completeness of logic and add explanation	Facilitate calculation of ASCVD risk, when possible	The Longitudinal Tool includes parameters for several values (e.g., minimum and maximum systolic blood pressure [SBP] and lab values). If patient data is outside the defined range, then a score will not calculate. In this scenario: 1) CDS logic will replace the value with the nearest “allowable” value so the ASCVD score can be calculated; 2) the score is caveated; and 3) the provider is notified of the replacement (e.g., true SBP value = 212, SBP value used for calculation = 200). As noted by the Cholesterol Management Work Group, it is far more important to know the approximated risk score than to have no score on which to base decisions.
Deabstract (to ensure clinical relevance)	Logic definition of “diabetes” for data input to risk equation	Diabetes is defined as type 1 and type 2 based on text in the ACC/AHA guidelines. The presence of a type 1 or type 2 diabetes SNOMED-CT or ICD-10-CM code will translate as “yes” for the calculation.
Disambiguate (to ensure clinical relevance)	Logic definition of “treated for hypertension” for data input to risk equation	As noted by the Cholesterol Management Work Group, the presence of an anti-hypertensive medication in the patient record is not sufficient evidence that the patient is being treated for hypertension; some anti-hypertensive medications can be prescribed for other medical conditions. To evaluate positively as being treated for hypertension, the patient must have a diagnosis of hypertension <i>and</i> evidence that they are being treated for hypertension (e.g., an appropriate medication order).
Verify completeness of logic (to ensure clinical relevance)	MOST RECENT for lab and SBP values and smoking status to ensure clinical relevance	The most recent values are most reflective of the patient's current condition. Use of the MOST RECENT value assumes that they were recorded using best practices. If highly abnormal or unreasonable, then the results would be completed; therefore, the MOST RECENT result indicates a valid result.

Decision Category	Concept	Rationale
Verify completeness of logic (to ensure clinical relevance)	Lookback of 6 years for lab values, smoking status, and ASCVD risk to ensure clinical relevance	The ACC/AHA recommends assessment of ASCVD risk every 4 – 6 years. Results older than 6 years may not accurately reflect the individual's current condition. Lipid profile results, SBP, and smoking status are inputs to ASCVD risk assessment; as a result, a 6-year lookback supports a calculation that will most accurately reflect risk. If the most recent result of any of these items is more than 6 years old, then a notification warning or error will be presented to the provider to provide awareness and prompt updates.

## Appendix B. References

1. U.S. Department of Health and Human Services. CQL - Clinical Quality Language | eCQI Resource Center. <https://ecqi.healthit.gov/cql-clinical-quality-language>. Accessed June 16, 2019.
2. Lloyd-Jones DM, Huffman MD, Karmali KN, et al. Estimating Longitudinal Risks and Benefits From Cardiovascular Preventive Therapies Among Medicare Patients: The Million Hearts Longitudinal ASCVD Risk Assessment Tool. *Circulation*. 2017;135(13):e793-e813. doi:10.1161/cir.0000000000000467.
3. Goff DC, Lloyd-Jones DM, Bennett G, et al. 2013 ACC/AHA guideline on the assessment of cardiovascular risk: A report of the American college of cardiology/American heart association task force on practice guidelines. *J Am Coll Cardiol*. 2014;63(25 PART B):2935-2959. doi:10.1016/j.jacc.2013.11.005.
4. Boxwala AA, Rocha BH, Maviglia S, et al. A multi-layered framework for disseminating knowledge for computer-based decision support. *J Am Med Inform Assoc*. 2011;18 Suppl 1(Suppl 1):i132-9. doi:10.1136/amiajnl-2011-000334.
5. Tso GJ, Tu SW, Oshiro C, et al. Automating Guidelines for Clinical Decision Support: Knowledge Engineering and Implementation. *AMIA Annu Symp Proc*. 2016;2016:1189-1198. <http://www.ncbi.nlm.nih.gov/pubmed/28269916>. Accessed February 28, 2019.