Implementation Guide

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

Agency for Healthcare Research and Quality
5600 Fishers Lane
Rockville, MD 20857
www.ahrq.gov

Contract No. 75FCMC18D0047

Prepared by:

CMS Alliance to Modernize Healthcare (The Health FFRDC)
A Federally Funded Research and Development Center

AHRQ Publication 18(20)-0007-3-EF
Updated January 2020

Disclaimer of Conflict of Interest

None of the investigators has any affiliations or financial involvement that conflicts with the material presented in this report.

Funding Statement

This project was funded under contract/grant number 75FCMC18D0047 from AHRQ, U.S. Department of Health and Human Services. The opinions expressed in this document are those of the authors and do not reflect the official position of the Agency for Healthcare Research and Quality (AHRQ) or the U.S. Department of Health and Human Services.

Suggested Citation

CMS Alliance to Modernize Healthcare (The Health FFRDC). CMS's Million Hearts® Model Longitudinal ASCVD Risk Assessment Tool for Shared Decision Making. Implementation Guide. Prepared under Contract No. 75FCMC18D0047. AHRQ Publication No. **18(20)-0007-3-EF**. Rockville, MD: Agency for Healthcare Research and Quality; December 2019.

Acknowledgments

Specifically, we want to thank and recognize:

- Agency for Healthcare Research and Quality (AHRQ) leadership team, including Dr. Edwin Lomotan, Steve Bernstein, and Shafa Al-Showk
- Clinical Decision Support (CDS) Connect Work Group members
- Patient-Centered Clinical Decision Support Learning Network
- MITRE CDS Connect Project Team
- Million Hearts® Model Leadership Team

Record of Implementation Guide Changes

Date	Action	Notes
October 2017	Published *Implementation Guide*	
January 2020	Updated the *Implementation Guide* based on annual artifact updates	Updated the *Implementation Guide's* Introduction and Background content, revised the flow of the content to enhance readability, added evidence specifications and a semistructured representation of the artifact to Appendix A, and updated a small portion of the decision log.

Contents

Figures

Tables

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: 1) demonstrate CDS Connect infrastructure, and 2) 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, a *Pilot Report* is included 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 computer coded, it has not been field tested in 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 that is required to translate narrative clinical practice guidelines into human-readable logic. Of note, CDS Connect artifacts are not "standalone" and are not intended to be completely plug-and-play (i.e., 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. It is expected that artifacts will be customized and adapted to local clinical and IT environments.

This *Implementation Guide* provides information and guidance to individuals who are considering 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 1) the CDS Connect Repository to host and share CDS artifacts; 2) 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; and 3) 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 is notable because it 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.[1] 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 over three dozen metadata fields to describe their work, including the artifact's purpose, clinical uses, publisher and 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, coded logic. Individuals who are interested in developing CDS logic expressions similar to 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 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 electronic health record (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. **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.
4. **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,[2] 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.[3]

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:

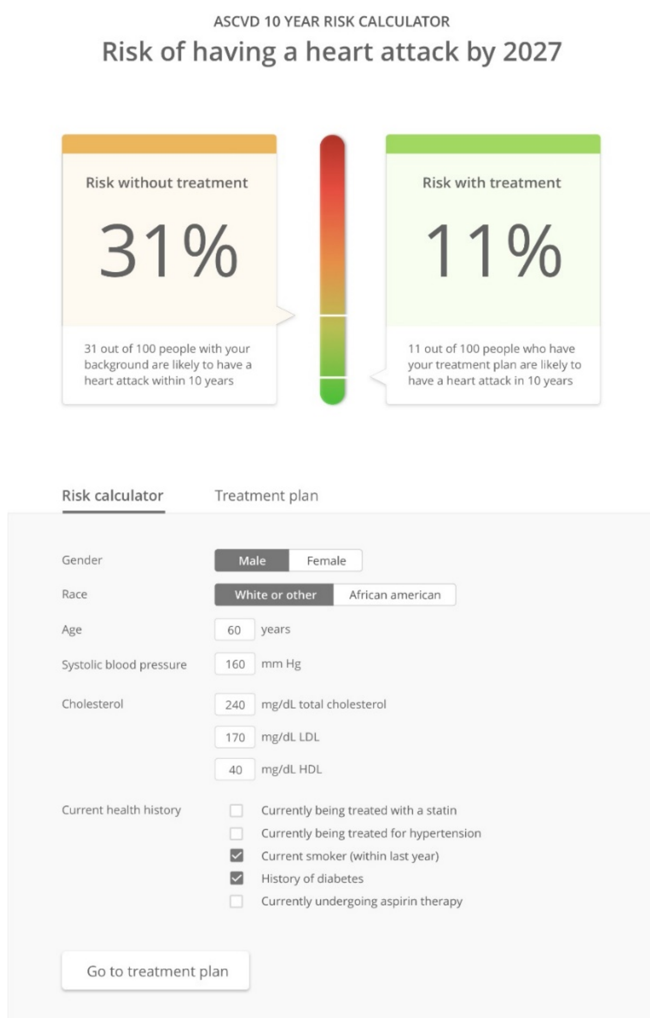
1. Calculation of a baseline 10-Year ASCVD risk assessment score, prior to initiation of any new therapies to address this risk.
2. Prospective estimations of ASCVD risk in support of shared decision making while considering the benefits of therapies, alone or in combination.
3. Calculation of updated 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 doing 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 listed above, 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, such as cholesterol-lowering CDS algorithms that make use of the risk score as part of their calculation.

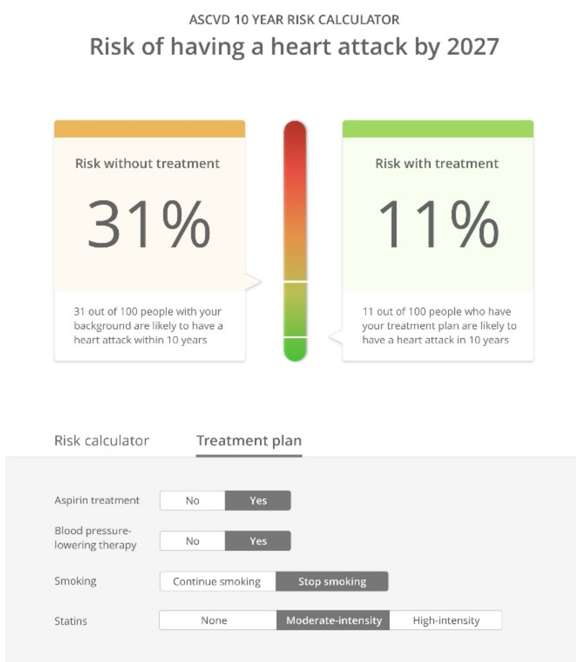
A typical calculator view might look like **Figure 1** where the score is prominently displayed while the supporting parameters, whether filled in automatically from EHR data or adjusted manually.

Figure 1: ASCVD 10-Year Risk Calculator Display



Compared to the Baseline risk assessment calculator display, the 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 done, although it can be done 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 requests the risk calculator to execute. Using data from Ms. Bravo's EHR, the algorithm executes, and 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, and 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.

- **As part of another CDS artifact run during a visit**
    - A different CDS artifact is being run against Mr. Delta's data to consider whether a statin recommendation is indicated. If that artifact produces a positive recommendation for statin use, 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; already on statins, aspirin, or blood pressure treatment). In this case, the calculator should have the indicated boxes checked (as in the visual example above) and warn 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 is as follows:

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

CDS Interventions and Suggested Actions

The CDS logic that generates the display of CDS interventions and recommendations is pictured in the Artifact Semistructured Logic section of Appendix A. At a very high level, the interventions and recommendations pertinent to each risk calculator artifact includes the following:

1. Notify the user if the patient is excluded, because of 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 patients who are not white or African American.
3. Display the ASCVD risk calculation as a calculator view or data view.
4. Populate the calculator with known parameters from EHR data, while indicating which parameters could not be obtained, if any.
5. Allow the user to modify parameters in the calculator.

6. 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, and currently each implementation 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 the patient with information resources that outline benefits, risks, effects, and evidence behind each of the possible selected interventions, to further aid decision making.

Evidence Source for Artifact Development

The 2017 ACC/AHA Special Report is the evidence-based source of this artifact.[2] The Million Hearts® Model Longitudinal ASCVD Risk Assessment Tool uses the ACC/AHA 2013 PCE, providing sex- and race-specific10-year estimates of ASCVD risk. The equations are intended for use in patients 40 – 79 years of age who have not had ASCVD.[3] 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 calculations calculates 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 calculation compares the original Baseline risk score with the Updated risk score based on interventions that have been instituted and their impact on measures including low density lipoprotein (LDL) cholesterol and systolic blood pressure.

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.[4] The framework defines four “layers” of representation, as depicted in **Figure 3** and described here:

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 SMEs. 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 puts forward the information below as suggested “best practices” for developing semistructured logic representations of evidence:

- Analyze the purpose, clinical statement, and preventive health scenario sections of this document to ensure that your organization understands and 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 below 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 information technology products.
3. The ability (or willingness to learn how) to develop code in several languages, at a minimum CQL and 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

Generation of 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, there are many Systematized Nomenclature of Medicine-Clinical Terms (SNOMED-CT) and International Classification of Diseases, Tenth Revision, Clinical Modification (ICD-10-CM) codes that 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, implementers may create their own value sets through VSAC (e.g., 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 any additional meaning beyond the value set title. Be prepared to inspect the value sets to determine their fitness for purpose.
2. There are many competing value sets for what appear to be the same clinical concepts in VSAC. Investigate the alternatives and decide on value set usage based on the context of the clinical guideline. While part of the reason for using standard value sets is that they are maintained and keep up with changing usage patterns, 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 or 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 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:

- CQL Release 1 STU3
- CQL on the Electronic Clinical Quality Information (eCQI) Resource Center
- CQL Tools on GitHub
- CQL Execution Engine (CoffeeScript) on GitHub *
- CQL Evaluation Engine (Java) on GitHub *
- CQL Online
- CQL Runner *

* These websites do not support the use of Internet Explorer, and recommend using Google Chrome, Microsoft Edge, or Firefox.

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, FHIRHelpers, and CDS_Connect_Conversions libraries included in existing CQL artifacts define commonly used functions in CQL files and 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 multiple 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, to allow for the CQL execution service to receive properly formatted patients.
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

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 held 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. Specifically, 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, 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 should not be underestimated. Based on pilot efforts, the item with the largest amount of uncertainty and longest lead time (and thus the driver of the project timeline) has been 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, as previous teams can be re-used or similar resources can be brought on to backfill open team positions.
2. Over time, more 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 will develop a familiarity with the constituent parts of the translation effort, regardless of their area of expertise.

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® 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

Semistructured inclusion and exclusion logic and examples of the CDS interventions are as follows:

Inclusion logic:

10-Year ASCVD risk score >=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

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 semistructured 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

Concept	Definition and/or Rationale
“ASCVD”	Arteriosclerotic cardiovascular disease. Implementers might consider representing ASCVD as a grouped value set that includes diagnosis and procedure concepts that reflect signs and symptoms of the disease (e.g., myocardial infarction, ischemic vascular disease) and procedures that imply underlying ASCVD (e.g., coronary artery bypass grafts, percutaneous coronary interventions, carotid interventions).
“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 numerous 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 the Tso et al. journal article titled, "Automating Guidelines for Clinical Decision Support: Knowledge Engineering and Implementation" that outlines a methodology for knowledge translation.[5] 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), whereas the ACC/AHA guidelines do not require the presence of a risk factor. Based on Cholesterol Management Work Group feedback and to more closely align with the ACC/AHA Special Report, risk factors were not added to inclusion logic. Local implementers can add these specifications if desired, 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 felt the benefit of calculating ASCVD risk for Hispanic individuals using the PCE outweighs the chance that it may slightly over- or underestimate ASCVD risk, and providers can and 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 40 – 79-year-old individuals every 4 – 6 years, which is specified in the CDS logic. 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[3] 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, 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 (because 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; therefore, the true score may be higher than 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 SBP and lab values). If patient data is outside the defined range, 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). Per 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	Per 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, since 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 *and* 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 (i.e., if highly abnormal or unreasonable 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. Since lipid profile results, SBP and smoking status are inputs to ASCVD risk assessment, a 6-year lookback supports a calculation that will most accurately reflect risk. If the most recent result of any of these items is > 6 years old 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.