Implementation Guide

USPSTF Statin Use for the Primary Prevention of CVD in Adults

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# Introduction

The Agency for Healthcare Research and Quality (AHRQ) has elected to sponsor a project that will help to generate a systematic and replicable process for transforming patient-centered outcomes research (PCOR) findings into shareable and standards-based clinical decision support (CDS) artifacts. A CDS artifact is the template for defining how decision support is provided for a given clinical situation, often including triggers, logic, operations, recommendations and actions, and supporting evidence. A main outcome of this project will be an online Repository for storing and accessing CDS artifacts. It is hoped that this publicly available Repository will promote the usage of CDS in everyday clinical settings, and that it will serve as the linchpin for connecting high-quality CDS to the United States healthcare community.

## Background

The purpose of the CDS Connect Repository is to store and provide access to CDS artifacts, including text and computable versions of the decision logic; suggested trigger events; text recommendations and suggested actions; and metadata, including original evidence links, decisions made in creating the artifact, sponsoring clinical organizations, and keywords*.* It is envisioned that it may at some point become a home for user feedback and experience data as well. The CDS Connect Repository enables users to search easily for desired artifacts, to explore their contents, and to facilitate their transfer into and use in locally used electronic health records (EHRs), CDS services, and other technology tools.

The concept of a CDS repository was introduced in the HHS-sponsored Roadmap for National Action on Clinical Decision Support1 (2006). Subsequent efforts, including the CDS Consortium (2008), Advancing CDS contract (2010), National Quality Forum CDS Expert Panel (2011), Health eDecisions (2012), and the National Academy of Medicine Optimizing Strategies for CDS project, among others, have advanced the concept of shared CDS. The CDS Connect project advances the goal of shareable CDS by establishing an actual public repository of CDS that can be contributed to and consumed by many stakeholders.

With further development, additional features are projected for the Repository, including—

* making several types of CDS available (such as alerts, order sets, intelligent data presentations, relevant evidence and knowledge; tools for shared decision-making with patients).
* providing several options for displaying and using repository information.
* allowing users to subscribe to artifact updates.
* allowing users to review and rate artifacts in the Repository and provide usage data.

These features will enhance the quality, validity, and value of the Repository, and create a climate of mutual ownership of artifacts across the CDS and EHR user community. The provenance and sponsorship of any artifact is visible and searchable in the Repository.

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

This document is intended to provide information about the generation, implementation, and routine operation of the USPSTF Statin Use for the Primary Prevention of Cardiovascular Disease in Adults artifact. Various audiences may find this information helpful, including:

* **Clinicians and** **Quality Leaders** at healthcare organizations and practices who wish to implement, test, and execute CDS related to this topic in their EHRs and other health information tools.
* **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.
* **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 structured logic and Clinical Quality Language (CQL) in their own work.
* **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 mature CQL artifacts.

# Implementing and Using the Artifact

## Description and Purpose of the Artifact

This artifact helps providers and patients decide on the use of statin drugs for primary prevention of cardiovascular disease (CVD), per the recommendation by the U.S. Preventive Services Task Force2 (USPSTF).

## Summary of the Clinical Statement

The USPSTF recommendation served by this artifact states:

1. Adults without a history of CVD (i.e., symptomatic coronary artery disease or ischemic stroke) use a low- to moderate-dose statin for the prevention of CVD events and mortality when all the following criteria are met: 1) they are aged 40 to 75 years; 2) they have 1 or more CVD risk factors (i.e., dyslipidemia, diabetes, hypertension, or smoking); and 3) they have a calculated 10-year risk of a cardiovascular event of 10 percent or greater(Grade B recommendation).[[1]](#footnote-1)6
2. Although statin use may be beneficial for the primary prevention of CVD events in some adults with a 10-year CVD event risk of less than 10 percent, the likelihood of benefit is smaller, because of a lower probability of disease and uncertainty in individual risk prediction. Clinicians may choose to offer a low- to moderate-dose statin to certain adults without a history of CVD when all the following criteria are met: 1) they are aged 40 to 75 years; 2) they have 1 or more CVD risk factors (i.e., dyslipidemia, diabetes, hypertension, or smoking); and 3) they have a calculated 10-year risk of a cardiovascular event of 7.5 percent to 10 percent (Grade C recommendation).[[2]](#footnote-2)7

## Primary Use Cases

In the primary use case, the decision logic and recommendations are intended for use by providers delivering care in an outpatient setting, supplied as an Event-Condition-Action alert (a common alert, reacting to an event). Typical scenarios include:

1. **Any time that the patient’s record is opened by a clinician’s direct action**

Dr. Alfa is going through the records of his patients to be seen this afternoon, and is currently reviewing the record of Ms. Bravo, a scheduled patient. When the record is opened in the EHR, the CDS logic described herein executes to determine whether to recommend that Ms. Bravo begin taking statins. The relevant recommendations and suggested actions (RSAs) could appear immediately in a box on the EHR screen for the clinician’s review and action, or could be posted to a To-Do list visible in the patient’s record.

1. **As automatic surveillance prior to the start of a clinician encounter** (particularly in a primary care, cardiology, geriatric, or internal medicine practice)

Ms. Bravo arrives for a scheduled appointment and is registered into the encounter. This registration automatically triggers the CDS logic of this artifact. RSAs are made available as a message to the clinician’s Inbox or a To-Do item in the patient’s record.

1. **As automatic surveillance run at a fixed time the night before the practice opens each day**

Dr. Charlie’s practice automatically runs a review each evening on all patients to be seen the following day. This review sets up face-sheets and requests charts for the intake personnel to use the next day. As part of this review, the computer scans each patient for several health maintenance gaps, including using this CDS artifact to check for appropriate use of statins. When the CDS logic determines that a patient merits a statin recommendation, the RSAs are made available via an Inbox message to the provider or a To-Do item on the patient’s chart. The recommendation can also be printed as part of the patient’s visit face-sheet.

## Additional Use Cases

Additional use cases make use of the decision logic and recommendations, but may require adjustments for a different workflow, type of user, or mode of operation. Additional use cases for this artifact could include:

1. **Population health:** Inclusion in a requested or periodic screening scan of an entire patient panel or population.

Dr. Charlie’s practice is running a quarterly quality screen to find patients in need of various health maintenance and promotion services. The CDS logic is run as a report for all patients in the practice. RSAs for appropriate patients appear on each patient’s individual To-Do list, and are also compiled into an overall report that can be addressed by population health or care management workers.

1. **Patient self-care/family caregivers can use the artifact as part of self-assessment or health maintenance programs:**

Mr. Delta runs an overall general health self-assessment or cardiac risk self-screen as part of a self-care program. RSAs can be compiled into a list and presented immediately with the assessment results, or can be delivered as a secure message to the patient on a self-care website.

1. **Data-driven screening:** The recommendations could change when relevant data changes, including a new LDL/HDL result; new diagnosis of diabetes; new diagnosis of ASCVD.

Ms. Epsilon, a patient, had a new cholesterol blood test panel done as part of a recent visit; when the test is run, this CDS logic runs to see if any change in recommendations is indicated. In this case, the LDL has gone up to 195, whereas her previous high was 155; the guideline thus recommends that she be placed on a statin if she has not already been taking one. RSAs are made available as a message to the provider’s general In-Box and to the To-Do section of the patient chart.

## Recommendations and Suggested Actions

The recommendations, warnings, and suggested actions provided by this CDS artifact can be found in detail under **“Potential Intervention(s) and Action(s)” in the Semi-Structured Representation Section of the artifact**. In summary, they include:

1. Recommendations for statin use in appropriate patients, encouraging shared decision making between the provider and patient.
2. Recommendation to consider statin use in patients with less strong risk score, encouraging shared decision making between the provider and patient.
3. Notification if the patient meets exclusion criteria, or only some inclusion criteria.
4. Notification if data are missing (such as a patient with no LDL recorded).
5. Suggested action: order for a statin medication.
6. Suggested action: document any new medications being used.
7. Educational interventions: links to relevant recommendation statements, original references to the guideline, shared decision making tools, and patient education tools.
8. Exception: Document why the provider and patient have decided on a management strategy differing from the recommendation.
9. Suggested exceptions could include:
	1. Patient has known adverse reactions to statins.
	2. Patient is likely to have adverse reactions to statins.
	3. Patient has understood the recommendation but elects not to take a statin.

# Guideline Interpretation and Clinical Decisions

It is often necessary to interpret or adjust clinical guidelines to make them suitable for computation. In addition, the CDS Connect Cholesterol Management Work Group provided insight to clarify exclusions, inclusions, and parameters specified in the guideline statement, outlined in the original reference describing the guideline, or deemed to be otherwise important to the proper application of the guideline as CDS. Decisions outlined in Appendix B explain, in detail, how source content text was interpreted and representations were defined during artifact creation.

Some of the more meaningful interpretations and decisions to ensure patient safety are as follows:

1. Exclude patients with familial hypercholesterolemia and patients with LDL-C > 190 mg/dL. These concepts are excluded by the USPSTF guideline statement, as these scenarios are deemed to possibly prompt a higher need for statins than this guideline recommends.
2. Exclude pregnant and breastfeeding patients.
3. Exclude patients with end-stage renal disease and patients undergoing dialysis.
4. Exclude patients with cirrhosis.

# Artifact Manifest

The USPSTF Statin Use for the Primary Prevention of CVD in Adults artifact is comprised of eight distinct files listed in **Table 1** (below).

Table : Artifact Manifest

| Filename | Purpose | Author(s) |
| --- | --- | --- |
| USPSTF\_Statin\_Use\_for\_Primary\_Prevention\_of\_CVD\_in\_Adults\_FHIRv102.cql | CQL representation of the United States Preventive Services Task Force (USPSTF) statin therapy recommendation for adults aged 40 to 75 years without a history of cardiovascular disease (CVD) who have 1 or more CVD risk factors (i.e., dyslipidemia, diabetes, hypertension, or smoking) and a calculated 10-year CVD event risk score of 7.5% or greater.  | Rute Martins, Chris Moesel, Sharon Sebastian |
| USPSTF\_Statin\_Use\_for\_Primary\_Prevention\_of\_CVD\_in\_Adults\_FHIRv102.json | JSON representation of the United States Preventive Services Task Force (USPSTF) statin therapy recommendation for adults aged 40 to 75 years without a history of cardiovascular disease (CVD) who have 1 or more CVD risk factors (i.e., dyslipidemia, diabetes, hypertension, or smoking) and a calculated 10-year CVD event risk score of 7.5% or greater. | Rute Martins, Chris Moesel, Sharon Sebastian |
| CDS\_Connect\_Commons\_for\_FHIRv102.cql | Common CQL functions that may be called by CDS Connect artifacts | Rute Martins, Chris Moesel, Sharon Sebastian |
| CDS\_Connect\_Commons\_for\_FHIRv102.json | JSON representation of common CQL functions that may be called by CDS Connect artifacts | Rute Martins, Chris Moesel, Sharon Sebastian |
| CDS\_Connect\_Conversions.cql | A library that supports conversions from one unit to another | Rute Martins, Chris Moesel, Sharon Sebastian |
| CDS\_Connect\_Conversions.json | JSON representation of a library that supports conversions from one unit to another  | Rute Martins, Chris Moesel, Sharon Sebastian |
| FHIRHelpers.cql | Common CQL functions used to convert CQL data elements to FHIR and back again | Rute Martins, Chris Moesel, Sharon Sebastian |
| FHIRHelpers.json | JSON representation of common CQL functions used to convert CQL data elements to FHIR and back again | Rute Martins, Chris Moesel, Sharon Sebastian |

## Artifact Relationship Diagram

Clinical Quality Language developers are encouraged to refactor commonly used functions into their own files. The diagram in Figure 1 shows the relationships between the files included in this artifact (as described above). In this case, the USPSTF\_Statin\_Use\_for\_Primary\_Prevention\_of\_CVD\_in\_Adults\_FHIRv102 file includes several libraries. When implementing this artifact, please ensure that all files are present and the filenames have not been modified.

Figure : Artifact Relationship Diagram



# Testing

The USPSTF Statin Use for the Primary Prevention of CVD in Adultsartifact was tested using an automated testing framework written in Node.js. This framework accepted test cases in a .csv (comma-separated value) file, executed the artifact against each test case, and reported the success or failure of each test case. Test cases were developed to investigate efficacy for basic expected functionality and to test the expected inclusion and exclusion criteria. A selection of the test data used for this artifact is included in Appendix A. Implementers should review their organizational priorities and develop a similar testing framework (and test cases) prior to implementation in a production system.

# Implementation Checklist

Boxwala et al.3 developed a multi-layered knowledge representation framework for structuring guideline recommendations as they are transformed into CDS artifacts. The framework defines four “layers” of representation:

1. **Narrative** text created by a guideline or Clinical Quality Measurement (CQM) developer (e.g., the recommendation statement described as a sentence).
2. **Semi-structured** text that describes the recommendations 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 in to 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.

This artifact is a **structured** representation of medical knowledge that contains code files that represent the source content (e.g., recommendation statement).

Figure : CDS Artifact Maturity Process



Prior to incorporating this artifact in a production setting, implementers should consider the following items:

* Analyze the purpose, clinical statement, and use case 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 the “clinical considerations” section of this document (including the cited 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 structured, computable CDS artifact.
* Technical staff should read through each of the files in the artifact manifest to understand their respective purposes and how they can be successfully incorporated into a clinical information technology (IT) system. At the time of publication, many commercial off-the-shelf (COTS) EHR systems are unable to use CQL files natively and require a separate application to convert CQL code such that it can be used in those EHR systems. Implementers should work with vendors of their respective health IT products to understand their readiness to implement CQL code and any potential adverse impacts to existing functionality. In a pilot setting, developers have worked around existing EHR limitations by implementing a web service wrapper around a CQL execution engine. This is a non-trivial amount of work with two primary components:
	+ a CQL execution engine with a RESTful web service designed to accept requests for CQL execution and to respond with the calculated results, and
	+ modifications to the EHR system such that it will
		- trigger RESTful events to call the CQL execution engine,
		- interpret the response,
		- and reflect the CQL-generated recommendations and suggested actions in the EHR user interface.
* After incorporation into a development environment, the artifact should be exhaustively tested against predefined test cases. Additionally, testing should be conducted to ensure that implementation of the artifact has no adverse effect on the processing efficiency of the health IT system.
* Documentation and training materials for clinical staff should be drafted and distributed. These training materials should include descriptions of modified functionality, directions for interacting with CDS rules (if different than in the current system), and contact information for assistance if functionality does not meet expectations.

# Potential Reuse Scenarios

CQL code within this artifact was developed to enact a clinical guideline, but there are portions of the CQL code that are expected to be useful for other purposes.

* The CDS\_Connect\_Commons\_for\_FHIRv102, FHIRHelpers, and CDS\_Connect\_Conversions libraries included in the artifact define commonly used functions in CQL files and are not specific to the USPSTF Statin Use for the Primary Prevention of CVD in Adults artifact. They are expected to be used with any other CQL file that could benefit from those functions.
* Selected code blocks from USPSTF\_Statin\_Use\_for\_Primary\_Prevention\_of\_CVD\_in\_Adults\_FHIRv102 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).

# General Information About CQL

The USPSTF Statin Use for the Primary Prevention of CVD in Adults artifact is composed of several files, but the primary focus of the artifact is the introduction of CQL files that can be used by any health care organization to properly identify populations of patients that require a specific message or clinical intervention. CQL is a data standard governed by Health Level 7® (HL7) that is currently a Standard for Trial Use (STU). CQL expresses logic in a human-readable document that is also structured enough for electronic processing of a query. It can be used within both the CDS and CQM domains.

If you would like to learn more about CQL, there are a few resources (care of the [eCQI Resource Center](https://ecqi.healthit.gov/cql)) that you should review:

* [CQL STU Release 1 at HL7](http://www.hl7.org/implement/standards/product_brief.cfm?product_id=400)
* [CQL Tools on GitHub](https://github.com/cqframework/clinical_quality_language)
* [CQL Formatting and Usage Wiki](https://github.com/esacinc/CQL-Formatting-and-Usage-Wiki/wiki)
* [CQL Online](http://cql-online.esacinc.com/)
* [CQL Q&As on the eCQI Resource Center](https://ecqi.healthit.gov/cql/CQ-Qs%26As)

Appendix A: Test Data

In conjunction with a custom Node.js testing framework, the following data tables were used to test the USPSTF Statin Use for the Primary Prevention of CVD in Adults artifact:

Table : USPSTF Statin Basic Tests

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **TestCase** | **Patient** | **age** | **ASCVDRiskScore** | **issued** | **LDL** | **HDL** | **issued** | **SmokingStatus** | **Diabetes** | **StatinStatement** | **RESULT: MeetsInclusionCriteria** | **RESULT: MeetsExclusionCriteria** | **RESULT: ShouldStartStatin** | **RESULT: ShouldDiscussStatin** | **RESULT: Errors** | **RESULT: Recommendation** | **RESULT: Rationale** |
| Grade B Recommendation | female | 43 | 32.44 |   | 170 | 37 |   | current | + |   | TRUE | FALSE | TRUE | FALSE | <null> | ~Start | ~moderate amount |
| Grade C Recommendation | male | 41 | 7.86 |   | 145 | 45 |   | someday |   |   | TRUE | FALSE | FALSE | TRUE | <null> | ~Discuss | ~small amount |
| Not Included | male | 47 | 1.4 |   | 112 | 58 |   | never |   |   | FALSE | FALSE | <null> | <null> | <null> | ~does not meet inclusion criteria | ~The USPSTF guideline applies |
| Excluded | female | 43 | 32.44 |   | 170 | 37 |   | current | + | + | TRUE | TRUE | <null> | <null> | <null> | ~meets exclusion criteria | ~This USPSTF guideline should not be used |
| Missing Data Error | female | 43 |   |   | 170 | 37 |   | current | + |   | <null> | FALSE | <null> | <null> | ~ERROR: Inadequate | <null> | <null> |
| Old Data Error | female | 43 | 32.44 | 5/12/10 | 170 | 37 |   | current | + |   | <null> | FALSE | <null> | <null> | ~ERROR: Inadequate | <null> | <null> |
| Missing Data Warning | female | 43 | 32.44 |   | 170 |   |   | current | + |   | TRUE | FALSE | TRUE | FALSE | ~WARNING: Adequate | ~Start | ~moderate amount |
| Old Data Warning | female | 43 | 32.44 |   | 170 | 37 | 2/1/11 | current | + |   | TRUE | FALSE | TRUE | FALSE | ~WARNING: Adequate | ~Start | ~moderate amount |

Table : USPSTF Statin Exclusion Tests

| **TestCase** | **Patient** | **age** | **ASCVDRiskScore** | **LDL** | **HDL** | **MI** | **CABG** | **FamilialHypercholesterolemia** | **system** | **code** | **PregnancyCondition** | **PregnancyObservation** | **BreastfeedingCondition** | **BreastfeedingObservation** | **ESRD** | **Dialysis** | **Cirrhosis** | **StatinStatement** | **StatinOrder** | **RESULT: MeetsInclusionCriteria** | **RESULT: MeetsExclusionCriteria** | **RESULT: ShouldStartStatin** | **RESULT: ShouldDiscussStatin** | **RESULT: Errors** |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Not Excluded | female | 50 | 11.79 | 190 | 45 |   |   |   |   |   |   |   |   |   |   |   |   |   |   | TRUE | FALSE | TRUE | FALSE | <null> |
| Not Included but Excluded | female | 50 | 7 | 130 | 45 | + |   |   |   |   |   |   |   |   |   |   |   |   |   | FALSE | TRUE | <null> | <null> | <null> |
| High LDL | female | 50 | 11.79 | 191 | 45 |   |   |   |   |   |   |   |   |   |   |   |   |   |   | TRUE | TRUE | <null> | <null> | <null> |
| CVD | female | 50 | 11.79 | 190 | 45 | + |   |   |   |   |   |   |   |   |   |   |   |   |   | TRUE | TRUE | <null> | <null> | <null> |
| CVD Procedure | female | 50 | 11.79 | 190 | 45 |   | + |   |   |   |   |   |   |   |   |   |   |   |   | TRUE | TRUE | <null> | <null> | <null> |
| Familial Hypercholesterolemia | female | 50 | 11.79 | 190 | 45 |   |   | + |   |   |   |   |   |   |   |   |   |   |   | TRUE | TRUE | <null> | <null> | <null> |
| Familial Hypercholesterolemia ICD-10 Concept | female | 50 | 11.79 | 190 | 45 |   |   | + | urn:oid:2.16.840.1.113883.6.90 | E78.01 |   |   |   |   |   |   |   |   |   | TRUE | TRUE | <null> | <null> | <null> |
| Pregnancy Condition | female | 50 | 11.79 | 190 | 45 |   |   |   |   |   | + |   |   |   |   |   |   |   |   | TRUE | TRUE | <null> | <null> | <null> |
| Pregnancy Observation | female | 50 | 11.79 | 190 | 45 |   |   |   |   |   |   | + |   |   |   |   |   |   |   | TRUE | TRUE | <null> | <null> | <null> |
| Breastfeeding Condition | female | 50 | 11.79 | 190 | 45 |   |   |   |   |   |   |   | + |   |   |   |   |   |   | TRUE | TRUE | <null> | <null> | <null> |
| Breastfeeding Observation | female | 50 | 11.79 | 190 | 45 |   |   |   |   |   |   |   |   | + |   |   |   |   |   | TRUE | TRUE | <null> | <null> | <null> |
| End Stage Renal Disease | female | 50 | 11.79 | 190 | 45 |   |   |   |   |   |   |   |   |   | + |   |   |   |   | TRUE | TRUE | <null> | <null> | <null> |
| Dialysis | female | 50 | 11.79 | 190 | 45 |   |   |   |   |   |   |   |   |   |   | + |   |   |   | TRUE | TRUE | <null> | <null> | <null> |
| Cirrhosis | female | 50 | 11.79 | 190 | 45 |   |   |   |   |   |   |   |   |   |   |   | + |   |   | TRUE | TRUE | <null> | <null> | <null> |
| Statin Statement | female | 50 | 11.79 | 190 | 45 |   |   |   |   |   |   |   |   |   |   |   |   | + |   | TRUE | TRUE | <null> | <null> | <null> |
| Statin Order | female | 50 | 11.79 | 190 | 45 |   |   |   |   |   |   |   |   |   |   |   |   |   | + | TRUE | TRUE | <null> | <null> | <null> |

Table : USPSTF Statin Inclusion Tests

| **TestCase** | **Patient** | **age** | **ASCVDRiskScore** | **LDL** | **HDL** | **SmokingStatus** | **Diabetes** | **Hypertension** | **system** | **code** | **display** | **RESULT: MeetsInclusionCriteria** | **RESULT: MeetsExclusionCriteria** | **RESULT: ShouldStartStatin** | **RESULT: ShouldDiscussStatin** | **RESULT: Errors** |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Too Young | female | 39 | 11.79 | 190 | 45 | current |   |   |   |   |   | FALSE | FALSE | <NULL> | <NULL> | <NULL> |
| Too Old | female | 76 | 11.79 | 190 | 45 | current |   |   |   |   |   | FALSE | FALSE | <NULL> | <NULL> | <NULL> |
| Score Too Low | female | 50 | 7 | 190 | 45 | never |   |   |   |   |   | FALSE | FALSE | <NULL> | <NULL> | <NULL> |
| No Risk Factors | female | 50 | 11.79 | 129 | 45 | never |   |   |   |   |   | FALSE | FALSE | <NULL> | <NULL> | <NULL> |
| LDL Factor | female | 50 | 11.79 | 190 | 45 | never |   |   |   |   |   | TRUE | FALSE | TRUE | FALSE | <NULL> |
| HDL Factor | female | 50 | 11.79 | 129 | 39 | never |   |   |   |   |   | TRUE | FALSE | TRUE | FALSE | <NULL> |
| Smoking Factor | female | 50 | 11.79 | 129 | 45 | current |   |   |   |   |   | TRUE | FALSE | TRUE | FALSE | <NULL> |
| Diabetes Factor | female | 50 | 11.79 | 129 | 45 | never | + |   |   |   |   | TRUE | FALSE | TRUE | FALSE | <NULL> |
| Hypertension Factor | female | 50 | 11.79 | 129 | 45 | never |   | + |   |   |   | TRUE | FALSE | TRUE | FALSE | <NULL> |
| Secondary Hypertension Factor | female | 50 | 11.79 | 129 | 45 | never |   | + | urn:oid:2.16.840.1.113883.6.90 | I12.9 | Benign renal hypertension w o failure | TRUE | FALSE | TRUE | FALSE | <NULL> |

Appendix B: Decision Log

The decision log was generated per procedures published by Tso et al.,4 which incorporates and extends steps that Shiffman et al.5 outlined for translating clinical practice guidelines to CDS. Brief descriptions of the steps in this process are included in the following table:

Table : Definitions of Shiffman's Steps

| **Decision Category** | **Definition** |
| --- | --- |
| **Select Guidelines**  | Choosing specific guidelines and specific recommendations within the selected guidelines to be implemented  |
| **Markup**  | Identifying and tagging guideline knowledge components relevant to operationalization  |
| **Atomize**  | The process of extracting and refining single concepts from the narrative text recommendations  |
| **Deabstract**  | The process of adjusting the level of generality at which a decision variable or action is described to permit operationalization  |
| **Disambiguate**  | The process of establishing a single semantic interpretation for a recommendation statement  |
| **Build Executable Statements**  | Arranging the atomized, de-abstracted, and disambiguated decision variables and actions into logical statements that can be translated readily into computable statements  |
| **Verify Completeness**  | The process of making sure that each recommendation provides guidance in all situations that a clinician is likely to face  |
| **Add Explanation**  | A facility to describe the reasoning behind recommendations  |
| **Identify Origin**  | Identifying a source or origin in the clinical environment for each decision variable  |
| **Insert Recommendations**  | Identifying an insertion point in the care process for each recommended action  |
| **Define Action Type**  | Categorizing guideline-recommended activities per predefined action types  |
| **Define Associated Beneficial Services**  | Linking action types to associated beneficial services that offer design patterns for facilitating clinical care  |
| **Design User Interface**  | Selecting and grouping user interface elements to best deliver CDS output  |

Artifact Recommendation Statements

**Grade B Recommendation Statement**

The USPSTF recommends that adults without a history of CVD (i.e., symptomatic coronary artery disease or ischemic stroke) use a low- to moderate-dose statin for the prevention of CVD events and mortality when all of the following criteria are met: 1) they are aged 40 to 75 years; 2) they have 1 or more CVD risk factors (i.e., dyslipidemia, diabetes, hypertension, or smoking); and 3) they have a calculated 10-year risk of a cardiovascular event of 10% or greater.

**Grade C Recommendation Statement**

Clinicians may choose to offer a low- to moderate-dose statin to certain adults without a history of CVD when all of the following criteria are met: 1) they are aged 40 to 75 years; 2) they have 1 or more CVD risk factors (i.e., dyslipidemia, diabetes, hypertension, or smoking); and 3) they have a calculated 10-year risk of a cardiovascular event of 7.5% to 10%.

Decision Logs

Table : Decisions Based on "Atomized" Components of the Recommendation Statement

| **Recommendation Statement** | **"Atomized" Word or Phrase** | **Interpretation** |
| --- | --- | --- |
| Grade B  | USPSTF | U.S. Preventive Services Task Force  |
| Grade B  | "recommends" | offer or provide this service, implement as "Start" if initiation of treatment is occurring based on a shared decision between the provider and the patient (e.g., start low-moderate intensity statin based on outcome of shared decision between patient and provider) |
| Grade C | "may choose to offer" | implement as "discuss" (i.e., discuss low-moderate intensity statin) |
| Grade B  | "adults" | individuals 40-75 years of age |
| Grade C | "certain adults" | select individuals 40-75 years of age that meet established criteria |
| Grade B and C | "without a history of" | without documented evidence of |
| Grade B and C | "CVD" | Cardiovascular disease, specifically "symptomatic coronary artery disease or ischemic stroke.” For the purposes of this artifact, CVD is represented by a grouped value set that represents an array of conditions and procedures that would only occur if a patient has CVD. High-level concepts include:"Diagnosis: "Ischemic Vascular Disease" "Diagnosis: Myocardial Infarction" "Procedure, Performed: CABG Surgeries" "Procedure, Performed: PCI" "Procedure, Performed: Carotid Intervention"  |
| Grade B | "use" | prescribe or start  |
| Grade B and C | "low intensity statin"  | Simvastatin 10 mg, Pravastatin 10-20 mg, Lovastatin 20 mg, Fluvastatin 20-40mg, Pitavastatin 1 mg |
| Grade B and C | "moderate intensity statin" | Atorvastatin 10-20 mg, Rosuvastatin 5-10mg, Simvastatin 20-40 mg, Pravastatin 40-80 mg, Lovastatin 40 mg, Fluvastatin XL 80 mg, Fluvastatin 40 mg twice daily, Pitavastatin 2-4 mg |
| Grade B | "for the prevention of" | to maintain health in order to avert disease and death |
| Grade B | "mortality" | death |
| Grade B and C | "when all of the following criteria are met" | all 3 of the inclusion criteria must evaluate as true (i.e., - aged 40 to 75 years; - >=1 CVD risk factors - 10-yearCVD risk of 7.5% to 10% |
| Grade B and C | "aged 40 to 75" | adults who are 40 years old based on their date of birth (DOB) at the time of calculation through 75 years old based on their DOB at the time of calculation |
| Grade B and C | "1 or more" | any one of the specified risk factors or any combination of 2 or more specified risk factors (>=1 risk factor) |
| Grade B and C | "CVD risk factors" | Dyslipidemia, Diabetes, Hypertension, or Smoking |
| Grade B and C | "Dyslipidemia" | abnormal blood cholesterol, represented HDL-C < 40 mg/dL or LDL-C > 130 mg/dL |
| Grade B and C | "Diabetes" | Type 1 and Type 2 Diabetes |
| Grade B and C | "Hypertension" | high blood pressure |
| Grade B and C | "Smoking" | cigarette smoker |
| Grade B and C | "calculated 10-Year risk"  | level of risk determined by populating the pooled cohort equation created by the American College of Cardiology/American Heart Association (ACC/AHA) with patient data (e.g., age, sex, systolic blood pressure) to calculate a patient's risk of having a heart attack or stroke within the next 10 years |
| Grade B | "10% or greater" | >=10% |
| Grade C | "7.5% to 10%" | >=7.5% and <10% |

Several decisions were made outside the scope of the atomized words and phrases in the recommendation statements. These additional decisions were made based on the best available clinical knowledge and were encountered at various stages in the artifact development process.

Table : Additional Decisions

| **Decision Category** | **Concept** | **Rationale**  |
| --- | --- | --- |
| Verify completeness | Known Familial Hypercholesterolemia added as an Exclusion | The USPSTF recommendation does not include individuals who have familial hypercholesterolemia, since they may be more likely to require statin use.  |
| Verify completeness | LDL-C lab result > 190 mg/dL added as an Exclusion | The USPSTF recommendation does not apply to individuals with an LDL-C > 190 mg/dL, since they may be more likely to require statin use.  |
| Verify completeness | Diagnosis of Active Pregnancy as an Exclusion | Statins are not indicated for pregnant women (per Cholesterol Management Work Group recommendation based on their medical expertise). |
| Verify completeness | Pregnancy Observation as an Exclusion | Statins are not indicated for pregnant women (per Cholesterol Management Work Group recommendation based on their medical expertise). Since EHRs can capture pregnancy as a diagnosis *or* an observation, this concept was added to exclusion logic during early pilot testing. |
| Verify completeness | Diagnosis: Breastfeeding added as an Exclusion | Statins are not indicated for women who are breastfeeding (per Cholesterol Management Work Group recommendation based on their medical expertise) |
| Verify completeness | Diagnosis of End Stage Renal Disease (ESRD) added as an Exclusion | Statins are not indicated for individuals who are diagnosed with ESRD (per Cholesterol Management Work Group recommendation based on their medical expertise). Aligns with ACC/AHA thoughts on contraindications for statin use. |
| Verify completeness | Actively undergoing dialysis added as an Exclusion | Statins are not indicated for individuals who are diagnosed with ESRD (per Cholesterol Management Work Group recommendation based on their medical expertise), and active dialysis is an indication of ESRD. Active is evaluated by having a dialysis treatment within the past 7 days. |
| Verify completeness | Diagnosis of Active Cirrhosis added as an Exclusion | Statins are not indicated for individuals with severe liver disease represented by Diagnosis: Active Cirrhosis (per Cholesterol Work Group recommendation based on their medical expertise). Per the work group, not all liver conditions clearly exclude a recommendation for statin therapy (e.g., Hepatitis B and C).  |
| Verify completeness | Already receiving a Statin added as an Exclusion  | Providers do not need to be presented with a notification to consider the prescription of a low or moderate intensity statin if the patient is already receiving a statin. Per the Cholesterol Management Work Group, they did not feel that it was worthwhile to suggest a low-moderate statin if the patient was on a high intensity statin because it would be too hard to create logic to determine the subtle nuances in patient condition (e.g., patient was prescribed a high intensity statin for LDL of 220 mg/dL and the high intensity statin has now brought the LDL down to 150 mg/dL) |
| **Logic constraints to ensure clinical relevance:** |
| Verify completeness | MOST RECENT for lab values and smoking status as a qualifier to ensure clinical relevance | The most recent values are most reflective of the patient's current condition. Use of the MOST RECENT values 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). |
| Verify completeness | Lookback of 6 years for lab values, smoking status, and ASCVD risk as a qualifier to ensure clinical relevance | The ACC/AHA recommends assessment of ASCVD risk every 4-6 years. Results older than 6 years may not reflect the patient's current condition as accurately. Since lipid profile results 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.  |
| **Exclusions that were considered, but not included in CDS logic at this time** |
| Consider completeness | Statin allergy and intolerance | Cholesterol Management Work Group physicians felt that providers should determine if a statin is withheld based on these concepts, since allergies and intolerance of statins are very rare. |
| Consider completeness | Rhabdomyolysis | Initially, Cholesterol Management Work Group physicians felt that providers (versus CDS exclusion logic) should determine if a statin is withheld based on the intensity, duration, and cause of this condition. After a second discussion and review of the value set, they recommended that Active or Relapsed Rhabdomyolysis be added to exclusion logic. If possibly, this concept and value set will be incorporated during a mid-pilot update to the logic.  |
| Consider completeness | Statin allergy and intolerance | Cholesterol Management Work Group physicians felt that providers should determine if a statin is withheld based on these concepts, since allergies and intolerance of statins are very rare. |
| Consider completeness | Rhabdomyolysis | Initially, Cholesterol Management Work Group physicians felt that providers (versus CDS exclusion logic) should determine if a statin is withheld based on the intensity, duration, and cause of this condition. After a second discussion and review of the value set, they recommended that Active or Relapsed Rhabdomyolysis be added to exclusion logic. If possibly, this concept and value set will be incorporated during a mid-pilot update to the logic.  |
| Consider completeness | ALT > 150  | Per the Cholesterol Management Work Group, an elevated ALT (i.e., > 3x's upper limit of normal or 150) can signify "severe liver disease." This concept may be added to CDS exclusion logic mid-pilot for evaluation. |
| Consider completeness | Condition: Dependent on Dialysis | Although dialysis procedures are not always captured in outpatient primary care settings, at times the diagnosis "Dependent on Dialysis" may be recorded. This scenario was identified during pilot testing and may be added to CDS exclusion logic mid-way through the CDS pilot. |

Appendix C: Acronyms

|  |  |
| --- | --- |
| ACA | Affordable Care Act |
| AHRQ | Agency for Healthcare Research and Quality |
| CAMH | CMS Alliance to Modernize Healthcare |
| CDS | Clinical Decision Support |
| CMS | Centers for Medicare & Medicaid Services |
| COTS | Commercial Off-the-Shelf |
| CQL | Clinical Quality Language |
| CQM | Clinical Quality Measurement |
| CVD | Cardiovascular Disease |
| eCQI | Electronic Clinical Quality Information |
| EHR | Electronic Health Record |
| FAR | Federal Acquisition Regulation |
| FFRDC | Federally Funded Research and Development Center |
| FHIR | Fast Healthcare Interoperability ResourcesTM |
| HDL | High-Density Lipoprotein |
| HHS | Department of Health and Human Services |
| HL7 | Health Level 7® |
| IT | Information Technology |
| LDL | Low-Density Lipoprotein |
| ONC | Office of the National Coordinator for Health Information Technology |
| PCOR | Patient-Centered Outcomes Research |
| PCORI | Patient-Centered Outcomes Research Institute |
| RSAs | Recommendations and Suggested Actions |
| USPSTF | U.S. Preventive Services Task Force |

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[6] U.S. Preventive Services Task Force. June 2016. Grade Definitions. Retrieved from <https://www.uspreventiveservicestaskforce.org/Page/Name/grade-definitions>

[7] U.S. Preventive Services Task Force. June 2016. Grade Definitions. Retrieved from <https://www.uspreventiveservicestaskforce.org/Page/Name/grade-definitions>

1. 6 Grades are assigned based on the Levels of Certainty Regarding Net Benefit (LOC). Grade B recommendations reflect a High LOC, meaning the available evidence usually includes consistent results from well-designed, well-conducted studies in representative primary care populations. Additional information is available at [USPSTF Grade Definition](https://www.uspreventiveservicestaskforce.org/Page/Name/grade-definitions#grade-definitions-after-july-2012) [↑](#footnote-ref-1)
2. 7 Grades are assigned based on the Levels of Certainty Regarding Net Benefit (LOC). Grade C recommendations reflect a Moderate LOC, meaning available evidence is sufficient to determine the effects of the preventive service on health outcomes, but confidence in the estimate is constrained by certain factors. Additional information is available at [USPSTF Grade Definition](https://www.uspreventiveservicestaskforce.org/Page/Name/grade-definitions#grade-definitions-after-july-2012) [↑](#footnote-ref-2)