

Implementation Guide

USPSTF Aspirin Therapy for the Primary Prevention of Cardiovascular Disease and Colorectal Cancer

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- Patient-Centered Clinical Decision Support Learning Network
- MITRE CDS Connect Project Team
- U.S. Preventive Services Task Force (USPSTF) 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 semistructured 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.

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 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 that is 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.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 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 the USPSTF Aspirin Therapy for the Prevention of Cardiovascular Disease (CVD) and Colorectal Cancer (CRC) artifact, referred to as the “Aspirin Therapy” 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. **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.
5. **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.

Implementing and Using This Artifact

Artifact Description

The Aspirin Therapy artifact helps clinicians and patients decide on the use of aspirin therapy to mitigate the patient’s risk of developing CVD and/or CRC if they are between 50 – 69 years old. It provides USPSTF Grade A and Grade B recommendations for consideration by clinicians and their patients to support preventive health.

Preventive Health Scenario Supported by This Artifact

This artifact is designed as an Event-Condition-Action alert (i.e., a common alert, reacting to an event) delivered to clinicians in a primary care setting. It supports the following preventive health scenarios as currently represented:

1. **Data-driven screening, when a new 10-year ASCVD risk score is documented**
 - a. Ms. Epsilon, a 55-year-old African-American non-diabetic patient with hypertension, had a new cholesterol blood test panel done as part of a recent visit; the total cholesterol went up from 170 to 190, and the high density lipoprotein (HDL) fraction went down from 60 to 50. This changed her estimated atherosclerotic cardiovascular disease (ASCVD) risk from 8.3 percent to 10.9 percent. The CDS executed automatically when the test was performed and, with the change in risk, now issues a recommendation that she start aspirin therapy.

CDS recommendations are made available as a message to the clinician’s general inbox and to the “to do” section of the patient chart.

2. **Any time that the patient’s record is opened by a clinician’s direct action**
 - a. Dr. Alpha 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 aspirin based on her risk factors. The relevant recommendations could appear immediately in a box on the EHR screen for the clinician’s review and action, or they could be posted to a “to do” list visible in the patient’s record.
3. **As automatic surveillance performed prior to the start of a clinician encounter (particularly in a primary care, cardiology, geriatric, or internal medicine practice)**
 - a. Ms. Bravo arrives for a scheduled appointment and is registered into the encounter. This registration automatically triggers the CDS logic of this artifact. Recommendations are made available as a message to the clinician’s Inbox or a “To Do” item in the patient’s record.
4. **An automatic surveillance performed at a fixed time each night before the practice opens**
 - a. 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 aspirin. When the CDS logic determines that a patient merits an aspirin recommendation, the recommendations are made available via an inbox message to the clinician or a “to do” item on the patient’s chart. The recommendations can also be printed as part of the patient’s visit face-sheet.

Preventive Health Scenario Supported With Customization of the Semistructured Expression

Additional preventive health scenarios that could be supported by enhancing portions of this artifact are as follows:

1. **Population health:** Inclusion in a requested or periodic screening scan of an entire patient panel or population.
 - a. Dr. Charlie’s practice is running a quarterly quality screen to find patients in need of various health maintenance and promotion services. Running the CDS logic generates a report for all patients in the practice. Recommendations 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.

2. **Patient self-care/family caregivers can use the artifact as part of self-assessment or health maintenance programs.**
 - a. Mr. Delta runs an overall general health self-assessment or cardiac risk self-screen as part of a self-care program. Recommendations 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.

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 interventions and recommendations pertinent to the Aspirin Therapy artifact include the following:

1. Recommendations for aspirin use in appropriate patients. In keeping with the guideline, the recommendation is stronger for patients age 50 – 59 than those 60 – 69, and encourages shared decision making between the provider and patient.
2. Suggested action: order aspirin.
3. Suggested action: document use of aspirin in the patient’s record.
4. Educational interventions: link to the USPSTF guideline and share decision-making and patient education tools.
5. Exception: document why the provider and patient have decided on a management strategy differing from the recommendation.
6. Suggested exceptions could include (assuming these exceptions were not picked up by the algorithm):
 - a. Patient has history of gastrointestinal or intracranial bleeding.
 - b. Patient has thrombocytopenia.
 - c. Patient has a bleeding risk of another type, including bleeding disorders and liver disease.
 - d. Patient has end-stage renal disease.
 - e. Patient is on another anticoagulant.
 - f. Patient has allergy or intolerance to aspirin.
 - g. Patient has less than a 10-year life expectancy.
 - h. Patient understood the recommendation but elects not to take aspirin.

Evidence Source for Artifact Development

The Aspirin Therapy artifact is derived from the Aspirin Use for the Primary Prevention of CVD and CRC: USPSTF Recommendation Statement. At a high level, the recommendation states:

- The USPSTF recommends initiating low-dose aspirin use for the primary prevention of CVD and CRC in adults aged 50 to 59 years who have a 10 percent or greater 10-year CVD risk, are not at increased risk for bleeding, have a life expectancy of at least 10 years, and are willing to take low-dose aspirin daily for at least 10 years.² (Grade B Recommendation).

- The decision to initiate low-dose aspirin use for the primary prevention of CVD and CRC in adults aged 60 to 69 years who have a 10 percent or greater 10-year CVD risk should be an individual one. Persons who are not at increased risk for bleeding, have a life expectancy of at least 10 years, and are willing to take low-dose aspirin daily for at least 10 years are more likely to benefit. Persons who place a higher value on the potential benefits than the potential harms may choose to initiate low-dose aspirin.² (Grade C Recommendation).

Note: This artifact supports care that aligns with Grade B and Grade C recommendation statements to provide options to future implementers. Potential implementers can elect to integrate one or both of the recommendations, expressed as logic statements, in their health IT system. Grades are assigned based on the Levels of Certainty Regarding Net Benefit (LOC).

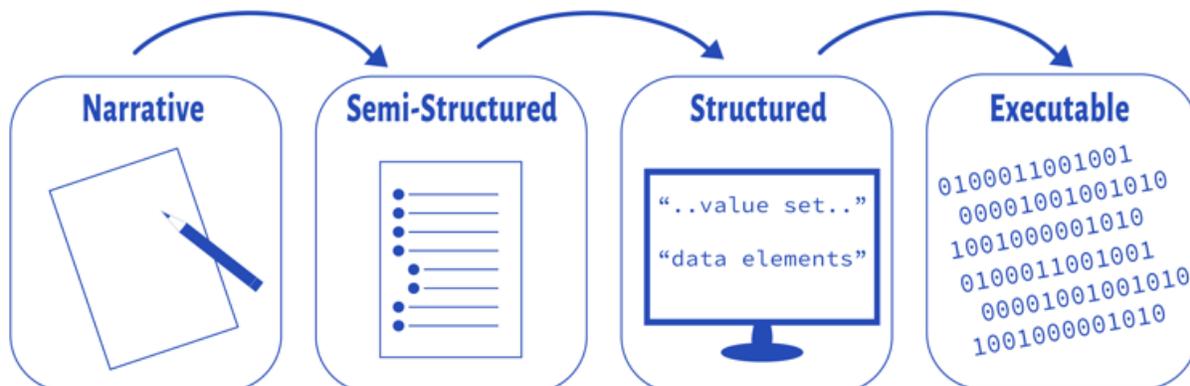
- Grade B recommendations reflect a High LOC, meaning the available evidence usually includes consistent results from well-designed, well-conducted studies in representative primary care populations. Additional information is available at [USPSTF Grade Recommendations](#).³
- Grade C recommendations 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 Recommendations](#).³

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 1**:

Figure 1. CDS Artifact Maturity Process



1. **Narrative** text created by a guideline or 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 (SMEs). It serves as a common understanding of the clinical intent; 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 following information as suggested “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 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 in the following 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 information technology 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 identifying 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) 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 (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. Many competing value sets 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, 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 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 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 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 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 that authors and implementers may find 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 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, as previous teams can be reused 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 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

The Aspirin Therapy artifact is derived from the Aspirin Use for the Primary Prevention of CVD and CRC: USPSTF Recommendation Statement, which includes the following Grade B and Grade C Statements:

Grade B Recommendation Statement: The USPSTF recommends initiating low-dose aspirin use for the primary prevention of CVD and CRC in adults aged 50 to 59 years who have a 10 percent or greater 10-year CVD risk, are not at increased risk for bleeding, have a life expectancy of at least 10 years, and are willing to take low-dose aspirin daily for at least 10 years.²

Grade C Recommendation Statement: The decision to initiate low-dose aspirin use for the primary prevention of CVD and CRC in adults aged 60 to 69 years who have a 10 percent or greater 10-year CVD risk should be an individual one. Persons who are not at increased risk for bleeding, have a life expectancy of at least 10 years, and are willing to take low-dose aspirin daily for at least 10 years are more likely to benefit. Persons who place a higher value on the potential benefits than the potential harms may choose to initiate low-dose aspirin.²

This text, the information provided in the full recommendation statement, and insight provided by the Cholesterol Management Work Group informed the following semistructured inclusion and exclusion logic and examples of CDS interventions.

Inclusion logic:

Patient is ≥ 50 years of age and ≤ 69 years of age

AND the MOST RECENT 10-Year CVD risk score ≥ 10 percent in the past 6 years

Exclusion logic:

Diagnosis of CVD

OR diagnosis of colorectal cancer

OR currently receiving aspirin (at any dose)

OR ordered for or receiving palliative care

OR aspirin allergy

OR evidence of increased risk of bleeding, represented by:

Diagnosis of active gastrointestinal (GI) bleed

OR diagnosis of active GI ulcers

OR diagnosis of bleeding disorders

OR diagnosis of end stage renal disease (ESRD)

OR dialysis within the past 7 days

OR diagnosis of cirrhosis

OR MOST RECENT alanine transaminase (ALT) result is > 150

OR diagnosis of thrombocytopenia

OR currently receiving an anticoagulant

OR currently receiving non-steroidal anti-inflammatory medications (NSAIDs)

OR MOST RECENT systolic blood pressure (SBP) \geq 160 millimeters/mercury (mmHg)

Examples of the CDS intervention:

Notify the clinician that aspirin therapy is recommended:

If CVD Risk score > 10 percent and patient age 50-59: Discuss oral aspirin 81 milligram (mg) daily if patient is not at high risk for bleeding.

If CVD Risk score > 10 percent and patient age 60-69: Consider oral aspirin 81 mg daily if patient is not at high risk for bleeding.

Concept Definition Decision Log

Table 1 defines many 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 by or derived from text in the evidence-based source.

Table 1. Concept Definition Decision Log

Recommendation Statement	Concept	Definition and/or Rationale
Grade B and C	“for the primary prevention”	Excludes individuals who already have CVD
Grade B and C	“CVD”	The USPSTF recommendation refers to CVD as “CVD including myocardial infarction (MI) and stroke” and “non-fatal MI and stroke.” Implementers might consider representing CVD as a grouped value set that includes diagnosis and procedure concepts to 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).
Grade B and C	“colorectal cancer”	Cancer of the colon and rectum
Grade B	“in adults aged 50 to 59”	Adults who are 50 years old based on their date of birth (DOB) at the time of calculation through 59 years old based on their DOB at the time of calculation
Grade B and C	“10 percent or greater 10-year CVD risk”	≥10 percent ASCVD risk using the American College of Cardiology (ACC)/American Heart Association (AHA) pooled cohort equation (as outlined in the USPSTF full recommendation)

Recommendation Statement	Concept	Definition and/or Rationale
Grade B and C	“are not at increased risk for bleeding”	<p>The USPSTF full recommendation statement lists the following conditions as signifying increased risk for bleeding:</p> <ul style="list-style-type: none"> Current aspirin use (at higher dose or for “long” duration) OR diagnosis of GI bleed OR diagnosis of GI ulcers OR diagnosis of bleeding disorders OR diagnosis of renal failure (i.e., ESRD) OR diagnosis of severe liver disease OR diagnosis of thrombocytopenia OR other factors that increase risk: <ul style="list-style-type: none"> Concurrent use of anticoagulant medication OR concurrent use of NSAIDs OR uncontrolled hypertension represented by SBP ≤ 160
Grade B and C	“have a life expectancy of at least 10 years”	<p>Exclude individuals who have palliative care ordered or are receiving palliative care. Remainder of this determination will be left to provider discretion.</p>
Grade B and C	“are willing to take for at least 10 years”	<p>Provider will initiate shared decision making with the patient, to include a review of the benefits and harms of aspirin therapy (this is included as an intervention).</p>

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.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
Verify Completeness	Exclusion: diagnosis of CVD	Aspirin therapy is recommended for primary prevention of CVD/ASCVD. If the patient has CVD/ASCVD, then a different treatment may be indicated. Additionally, a 10-Year ASCVD risk score is not indicated for individuals who already have ASCVD.
Verify Completeness	Exclusion: diagnosis of CRC	Aspirin therapy is recommended for primary prevention of CRC. If the patient has CRC, then a different therapy may be indicated.
Verify Completeness	Exclusion: currently receiving aspirin (at any dose)	If an individual is already receiving aspirin (at any dose), then a CDS recommendation to initiate low-dose aspirin therapy is not indicated.
Verify Completeness	Exclusion: aspirin allergy	Aspirin should not be prescribed to an individual that is allergic to the medicine.
CDS Adaptation	Allow upper age limit to be adjusted	Enables CDS implementer to determine whether to incorporate the Grade B, Grade C or both recommendations.

Decision Category	Concept	Rationale
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 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).
Verify completeness	Look back of 6 years for 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. 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 an update.
Consider completeness	Upper GI pain as an Exclusion	Although mentioned in the USPSTF guideline text as an exclusion, this is a very difficult concept to represent as a set of codes in a value set. Due to the vague, broad nature of this concept, the Cholesterol Management Work Group recommended not to specify this in the exclusions.
Consider completeness	Lab values to represent increased risk of bleeding as an Exclusion	Usually, lab values are flagged in the EHR (either by the lab or by the EHR system itself) as being above normal or outside of the normal range. The Cholesterol Management Work Group recommends that each implementer set lab thresholds based on their unique system; otherwise, divergence could exist between a CDS message/logic and flag markings of abnormal lab(s). Considerations for future lab value specifications include (1) international normalize ratio (INR) > 1.2, (2) elevated partial thromboplastin time (PTT) to represent bleeding disorder (>40 seconds), or (3) platelets <100,000 to represent thrombocytopenia. Note: look-back periods should be specified for each lab value to ensure that the lab result is clinically relevant to the patient's current condition.

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.
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3. Force USPST. Grade Definitions. <https://www.uspreventiveservicestaskforce.org/Page/Name/grade-definitions>. Accessed October 7, 2019.
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.