Implementation Guide

USPSTF Aspirin Use to Prevent Cardiovascular Disease: Preventive Medication

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(23)-0007-5-EF
Updated August 2023

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

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Suggested Citation

CMS Alliance to Modernize Healthcare (The Health FFRDC). USPSTF Aspirin Use to Prevent Cardiovascular Disease: Preventive Medication Implementation Guide. Prepared under Contract No. 75FCMC18D0047. AHRQ Publication No. 18(23)-0007-5-EF. Rockville, MD: Agency for Healthcare Research and Quality; Updated August 2023.

Acknowledgments

Specifically, we want to thank and recognize:

- Agency for Healthcare Research and Quality (AHRQ) leadership team, including Dr. Mario Terán, Dr. Edwin Lomotan, Steve Bernstein, Roland Gamache, James Swiger, and Mary Nix
- AHRQ U.S. Preventive Services Task Force (USPSTF) Leadership Team
- Clinical Decision Support (CDS) Connect Work Group members
- Patient-Centered Clinical Decision Support Learning Network
- MITRE CDS Connect Project Team

Record of Implementation Guide Changes

Date	Action	Notes
October 2017	Published *Implementation Guide*	
January 2020	Updated the *Implementation Guide* based on annual CDS 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 semi-structured representation of the artifact to Appendix A, and updated a small portion of the decision log.
April 2021	Updated the *Implementation Guide* based on annual CDS 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.
September 2022	Updated the *Implementation Guide* based on annual CDS artifact updates	The Background and Introduction were edited for clarity. The content was reorganized under new headings to make navigation more intuitive. Minor wording changes were made to improve clarity.
August 2023	Updated the *Implementation Guide* based on April 2022 USPSTF guideline and resulting CDS artifact updates	All sections were edited to remain consistent with the updated 2022 USPSTF guideline. Minor wording changes were made to improve clarity.

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Background

Clinicians today face an unending stream of new research findings, new or updated clinical practice guidelines, and best practices defined by authoritative professional societies that they must incorporate into daily practice. Transforming these guidelines and best practices 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. Sharing CDS expressions enhances efficiency by removing the need for 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.

Introduction

Beginning in 2016, the MITRE CDS Connect multidisciplinary project team has facilitated AHRQ's vision to move patient-centered outcomes research (PCOR) evidence into practice by supporting implementers, clinicians, and technology vendors in developing CDS tools that are shareable, standards-based, publicly available, and person-centered. CDS Connect has created the following resources, which are described in greater detail later in this document:

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

An important feature of CDS Connect is that it supports the use of CQL, an interoperable format that eases integration with health IT systems. The use of CQL in CDS Connect development and CDS systems provides the ability to express logic that is human-readable yet structured enough to process a query electronically. CQL allows logic to be shared between CDS artifacts—and eventually with electronic clinical quality measures (eCQMs)—in support of improving healthcare quality.

CDS artifacts are classified by a "Knowledge Level"[1] that indicates the degree to which a computer can interpret the information. The four categories of Knowledge Levels are defined as:

1. Narrative – Descriptive text created by a guideline or CQM developer.
2. Semi-Structured – Human-readable text that organizes in a logical sequence the recommendations for implementation in CDS.
3. Structured – Organized or patterned code that is interpretable by a computer (includes data elements, value sets, logic).
4. Executable – Code that is interpretable by a CDS system at a local level (and will vary for each particular site).

Some artifacts developed by the MITRE project team (or other teams) 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 insights outlined in the report to inform their implementation.

CDS 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 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.

The CDS Connect Repository hosts and shares CDS artifacts across a wide array of clinical topics. The Repository provides contributors with more than 40 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 when creating the artifact. It also enables contributors to upload the coded logic expression and test data, technical files, and reports.

The CDS Authoring Tool provides a user-friendly interface to guide the creation of standards-based CDS logic using simple input 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 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 two prototype tools: one facilitates CQL testing (CQL Testing Framework); the other 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 expression. Vendors and integrators may also choose to use the CQL Testing Framework to test any site- or product-specific modifications to an 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.

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 logic expression can be used to improve patient care and 2) to provide information on how to transform the logic expression into interoperable logic code and integrate the CDS logic with a health IT system.

Various audiences may find the information in this guide helpful, including:

1. Clinicians and Quality Leaders at healthcare organizations and primary care practices who wish to implement, test, and execute CDS related to this topic in their health IT tools.
2. Healthcare Systems interested in promoting patient experience beyond traditional brick-and-mortar care to facilitate patient engagement and a patient's ability to manage their health, while enabling value-based care and quality.
3. Employers and Payers who want to manage their cost and quality through patient-facing CDS and health management tools.
4. CDS Developers and Informaticists who may use components of this CDS logic as a foundation for other preventive health CDS, or who want to use well-developed, structured logic and CQL in their own work.
5. Organizations or Individuals interested in developing their own patient-facing CDS artifacts who may employ this document as a resource for the process by which clinical guidelines are translated into mature CQL artifacts.

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 if they are between 40 – 59 years old. It provides a USPSTF Grade C recommendation 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 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 electronic health record (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 Semi-Structured 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. Self-care: Patients and 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 Semi-Structured 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 created for patients aged 40 – 59 and encourages shared decision making between the provider and patient.
2. Suggested action: order low-dose aspirin if the patient elects to take it.
3. Suggested action: document use of low-dose aspirin in the patient's record.
4. Educational interventions: link to the USPSTF guideline and share decision-making and patient education tools.
5. Suggested action: document why the provider and patient decided on the selected management strategy.
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 to Prevent Cardiovascular Disease: Preventive Medication USPSTF Recommendation Statement. At a high level, the recommendation states:

- The USPSTF recommends individualizing the decision to initiate low-dose aspirin use for the primary prevention of CVD in adults aged 40 to 59 years who have a 10 percent or greater 10-year CVD risk, are not at increased risk for bleeding, and are willing to take low-dose aspirin daily (Grade C Recommendation). [2]

Note: This artifact supports care that aligns with a Grade C recommendation statement. A Grade D recommendation (USPSTF recommends against initiating low-dose aspirin for individuals age 60 years and older) is not included in this artifact. Additionally, a recommendation to recommend low-dose aspirin for risk reduction in colorectal cancer (CRC) found in the 2016 version of this guideline was removed in this 2022 recommendation, based on new research findings. Additional information is available at USPSTF Grade Recommendations.[3]

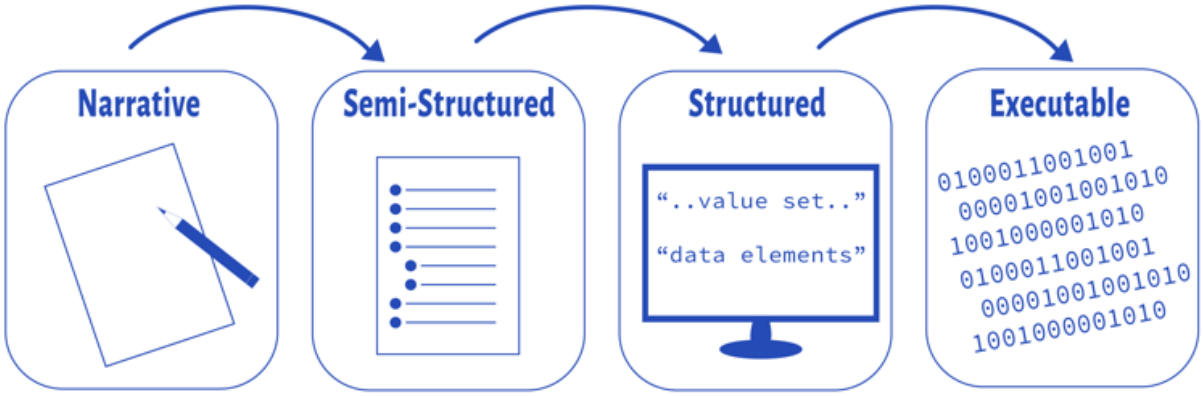
- Grade C recommendations reflect a Moderate Level of Certainty Regarding Net Benefit (LOC), meaning available evidence is sufficient to determine the effects of the preventive service on health outcomes, but that confidence in the estimate is constrained by certain factors. Additional information is 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

As noted in the Introduction, Boxwala et al. developed a multilayered knowledge representation framework for structuring guideline recommendations as they are transformed into CDS artifacts (see Figure 1 for a summary of the process).[1]

Figure 1. CDS Artifact Maturity Process



The CDS Connect team suggests the following "best practices" for developing semi-structured logic representations of evidence:

- Review this document and this artifact's entry in the CDS Connect repository 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 this semi-structured CDS artifact.

For the next step in CDS evolution—advancing logic in a semi-structured format to a structured format—the CDS Connect team recommends following the activities described in the next section.

Form a Cross-Functional Team

Translating this semi-structured 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, including:

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 individual codes that can be used to represent the clinical concepts in the semi-structured artifact. For example, if a semi-structured 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, as well as many created by independent organizations. If a clinical concept in the semi-structured 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 convey the same clinical concepts in VSAC. Investigate the alternatives and decide on value set usage based on the context of the clinical guideline. Part of the reason for using standard value sets is that they are maintained and keep up with changing usage patterns; nevertheless, 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.
    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.

In December 2022, the VSAC published a new functionality[4] for comparing published value sets, documenting its review/maintenance status, and providing the ability to track changes. When these functions enter common use, the problems described in the previous list will decrease.

Review Existing CQL Libraries and Develop CQL

In developing CQL code, implementers should follow the lead of the semi-structured artifact. Begin by establishing the inclusion and exclusion criteria for the artifact in CQL. For artifacts

that provide only one recommendation, provide the recommendation based on the inclusion and exclusion criteria. For artifacts that provide multiple recommendations, model subpopulations that will contribute to the various recommendations laid out in the semi-structured 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
- HL7 FHIR Clinical Guidelines Implementation Guide
- CQL on the Electronic Clinical Quality Information (eCQI) Resource Center
- CQL Tools (e.g., CQL-to-ELM Translator) on GitHub
- CQL for VS Code

CQL code from other artifacts have been developed to enact specific clinical guidelines, but portions of that code may be helpful for developing CQL for similar guidelines:

1. The CDSConnectCommonsForFHIRv102, CDSConnectCommonsForFHIRv401, FHIRHelpers, and CDSConnectConversions 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. Authors who are familiar with CQL can use the open-source CQL extension for Visual Studio Code ("CQL for VS Code") to more efficiently author and test CQL.

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. CQL for VS Code also provides a mechanism for defining and executing automated tests.

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 semi-structured 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 the semi-structured 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 semi-structured artifact. If patients fall into multiple categories in the CQL code based on the semi-structured guidelines, then the semi-structured artifact may need to be revisited.

Expected Timeline

Implementers should expect the first translation of a semi-structured 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 Semi-Structured Logic

The Aspirin Therapy artifact is derived from the Aspirin Use to Prevent Cardiovascular Disease: Preventive Medication: USPSTF Recommendation Statement, which includes the following Grade C Statement.

Grade C Recommendation Statement: The decision to initiate low-dose aspirin use for the primary prevention of CVD in adults aged 40 to 59 years who have a 10 percent or greater 10-year CVD risk should be an individual one. Evidence indicates that the net benefit of aspirin use in this group is small. Persons who are not at increased risk for bleeding and are willing to take low-dose aspirin daily for at least 10 years are more likely to benefit.[2]

This text, the information provided in the full recommendation statement, insight provided by the Cholesterol Management Work Group, and careful consideration of the options for Grade D and I presented by the updated evidence informed the following semi-structured inclusion and exclusion logic and examples of CDS interventions.

Inclusion logic:

Patient is >=40 years of age and <= 59 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 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) >= 160 millimeters/mercury (mmHg)

Examples of the CDS intervention:

Notify the clinician that aspirin therapy may be considered:

If CVD Risk score > 10 percent and patient age 40 – 59: Discuss oral aspirin 81 milligram (mg) daily if patient is not at increased risk for bleeding.

Concept Definition Decision Log

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

Table 1. Concept Definition Decision Log

Concept	Definition and/or Rationale
"for the primary prevention"	Excludes individuals who already have CVD
"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).
"in adults aged 40 to 59"	Adults who are 40 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
"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)

Concept	Definition and/or Rationale
"are not at increased risk for bleeding"	The USPSTF full recommendation statements (2016 and 2022 together) named the following conditions as carrying an increased risk for bleeding. All are reproduced here: Current aspirin use (at higher dose or for "long" duration) OR recent bleeding OR history of peptic ulcer disease 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 medical condition" OR use of medications that increase bleeding risk: Concurrent use of anticoagulant medication OR concurrent use of NSAIDs OR concurrent use of corticosteroids OR uncontrolled hypertension represented by SBP <=≤160
"are willing to take low-dose aspirin daily "	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).

Artifact Development Decision Log

The Artifact Development Team made several decisions when translating the evidence and developing the semi-structured 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
Add explanation	Revisions to the recommendation	On April 26, 2022, the USPSTF published an updated recommendation for deciding whether to initiate low-dose aspirin use for the primary prevention of CVD in adults aged 40 – 59 years, replacing the 2016 recommendation. This new guideline changes the inclusion age range to 40 – 59; the CVD prophylaxis recommendations to Grade C and Grade D; and aspirin for CRC prevention to Grade I. The CDS artifact has been updated to change the inclusion age range, revise the recommendation for the new age range to Grade C, and remove recommendations for CRC. Patients aged 60 – 69 now have a Grade D recommendation (recommend against) for low-dose aspirin therapy. That recommendation was not included as a separate recommendation because of the risk of clinician alert fatigue (given the variety of uses for aspirin) and because low-dose aspirin is generally prescribed over-the-counter and may not be captured through the EHR.
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: 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.
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).

Decision Category	Concept	Rationale
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	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

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