Implementation Guide

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

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# Introduction

The Agency for Healthcare Research and Quality (AHRQ) has sponsored 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 this Implementation Guide

This document is intended to provide information about the generation, implementation, and routine operation of the U.S. Preventive Services Task Force (USPSTF)Aspirin Therapy for the Prevention of Cardiovascular Disease and Colorectal Cancerartifact. 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 EHRs and other health information 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 structured logic and Clinical Quality Language (CQL) 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 mature CQL artifacts.

# Implementing and Using This Artifact

## Description and Purpose of the Artifact

This artifact helps providers and patients decide on the use of aspirin therapy for adults 50-69 years old to mitigate a patient’s risk of developing cardiovascular disease (CVD) and/or colorectal cancer (CRC).2

## Summary of the Clinical Statement

The USPSTF recommendation served by this artifact states:

1. 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% 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 (Grade B Recommendation).[[1]](#footnote-1)6
2. 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% 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.(Grade C Recommendation).[[2]](#footnote-2)7

Additional reference information can be found in the **Textual Metadata** section of the artifact in the CDS Connect Repository.

## 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 (i.e., a common alert, reacting to an event). Typical scenarios include:

1. **Data-driven screening, when a new 10-year ASCVD risk score is documented**

Ms. Epsilon, a 55-year-old African-American nondiabetic 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 HDL fraction went down from 60 to 50. This changed her estimated ASCVD risk from 8.3% to 10.9%. The CDS executed automatically when the test was performed and, with the change in risk, now issues a recommendation that she start on aspirin therapy. Recommendations and suggested actions (RSAs) are made available as a message to the provider’s general In-Box and to the To-Do section of the patient chart.

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 aspirin based on her risk factors. The relevant 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 aspirin. When the CDS logic determines that a patient merits an aspirin 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.

## Recommendations and Suggested Actions

The recommendations, warnings, and interventions 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 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 for aspirin.
3. Suggested action: document use of aspirin in the patient’s record.
4. Educational interventions: links to the USPSTF guideline, shared decision-making tools 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):
	1. Patient has history of GI or intracranial bleeding.
	2. Patient has thrombocytopenia.
	3. Patient has a bleeding risk of another type, including bleeding disorders and liver disease.
	4. Patient has end-stage renal disease.
	5. Patient is on another anticoagulant.
	6. Patient has allergy or intolerance to aspirin.
	7. Patient has less than 10-year life expectancy.
	8. Patient has understood the recommendation but elects not to take aspirin.

# 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 A explain, in detail, how source content text was interpreted and representations were defined during artifact creation.

 Some of the more meaningful interpretations and decisions:

1. Provide for local adjustment of the upper age limit for the artifact, allowing implementing organizations to decide whether they want to include the age 60-69 recommendation (i.e., Grade C statement)
2. Provide a notification when the patient has not had an updated ASCVD risk score assessment in the last 6 years.
3. Remove the exclusion for upper GI pain—one of the exclusions mentioned in the original source—because of the difficulty of capturing that information.
4. Defer the threshold values for lab tests that indicate increased bleeding risks, such as INR and platelet count, to each implementation due to local lab variations.

# Artifact Development Plan

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 **semi-structured** representation of medical knowledge that contains Boolean logic statements.

Figure : CDS Artifact Maturity Process



To continue the maturation of this artifact to the structured stage, several steps need to be taken:

## 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:

1. A clinical background that includes working knowledge of the underlying clinical guideline and its application in medical practice.
2. Familiarity with clinical code sets (e.g., ICD-10, SNOMED-CT, RxNorm, etc.) and their implementation in health information technology products
3. The ability (or willingness to learn how) to develop code in several languages, at a minimum CQL and one other language, to be used for the execution of test scripts.

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

## Identify Appropriate Value Sets and Codes

Generation of a structured CDS artifact begins with the identification of existing value sets or codes that can be used to represent the clinical concepts in the semi-structured artifact. For example, if a semi-structured artifact mentions “Diabetes” as part of its logic, there are many SNOMED-CT, ICD-9, and ICD-10 codes that could be used to represent a patient with an active condition of “Diabetes” in an EHR. Implementers should review the Value Set Authority Center (VSAC) to determine whether existing value sets are sufficient to express each clinical concept in an artifact. VSAC provides a website and an application programming interface (API) with access to all official versions of vocabulary value sets contained in Centers for Medicare and Medicaid Services (CMS) electronic Clinical Quality Measures (eCQMs). If a clinical concept in the semi-structured artifact cannot be expressed using existing value sets, implementers may create their own value sets through VSAC (e.g., a value set for “Familial Hypercholesterolemia”[[3]](#footnote-3) was created as part of MITRE’s work for another artifact posted on the CDS Connect Repository).

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

1. Many value sets are missing purpose statements, or the existing purpose statements are vague and don’t include any additional meaning beyond the value set title. Be prepared to inspect the value sets to determine their fitness for purpose.
2. There are many competing value sets for what appear to be the same clinical concepts in VSAC. Investigate the alternatives and decide on value set usage based on the context of the clinical guideline. While part of the reason for using standard value sets is that they are maintained and keep up with changing usage patterns, it would also be prudent to validate the chosen value set against codes that are in use at the implementation site(s).
3. The VSAC does not show whether a value set is actively maintained or deprecated. For example, a value set last updated in 2014 may or may not be current. To infer whether a value set is current, one must determine if the value set is used in any of the latest eCQMs, and if not, why:
	1. The eCQM itself may have been removed/retired. It is unclear what happens to the value sets in this scenario.
	2. The value set has been harmonized or replaced by a similar value set in the eCQM. This information is noted in the eCQM release notes (if one can find the version where the change was made) but is not carried over to the VSAC.

## Review Existing CQL Libraries and Develop CQL

In developing CQL code, implementers should follow the lead of the semi-structured 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 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:

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

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

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

Implementers may face challenges due to the current lack of tooling available for development and testing of CQL code. More mature languages tend to have multiple tools associated with them, but CQL is an emerging language. MITRE is currently developing a CDS Authoring Tool that allows users unfamiliar with CQL syntax and structure to create CQL with a graphical user interface. At the time of publication, this tool has not been released to the public.

## Review and Test Developed CQL

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

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

### Automated Execution of Test Cases

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

1. a synthetic patient generator, to allow for the CQL execution service to receive properly formatted patients.
2. an orchestration module that accepts test data (patient data and expected results) as raw input and then–
	1. calls the synthetic patient generator to generate patient records,
	2. sends that patient data to the execution service,
	3. receives and interprets the response from the execution service, and
	4. compares the actual results against the expected results and generates a report.

### Manual Review of the Artifact

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

During review, the team should match up the semi-structured artifact to the developed CQL code to identify any gaps between the two items. Specifically, implementers should be wary of naming conventions; code commenting conventions; and inclusion, exclusion, and subpopulation filters. This review may also be useful to determine gaps in the semi-structured artifact. If patients fall into multiple categories in the CQL code based on the semi-structured guidelines, 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. Based on pilot efforts, the item with the largest amount of uncertainty and longest lead time (and thus the driver of the project timeline) has been the identification and build process for proper value sets to be used in an artifact.

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

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

Appendix A: Decision Log

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 initiating low-dose aspirin use for the primary prevention of CVD and CRC in adults aged 50 to 59 years who have a 10% 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.

**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% 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.

Decision Logs

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

| **Recommendation Statement** | **"Atomized" Word/Phrase** | **Interpretation** |
| --- | --- | --- |
| 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 MI and stroke" and "Non-fatal MI and stroke." For the purposes of this artifact, CVD is defined by the value set created by QIP to represent ASCVD, as evidenced by the following conditions and procedures:"Diagnosis: "Ischemic Vascular Disease" "Diagnosis: Myocardial Infarction" "Procedure, Performed: CABG Surgeries" "Procedure, Performed: PCI" "Procedure, Performed: Carotid Intervention"  |
| 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% or greater 10-year CVD risk" | >= 10% ASCVD risk using the ACC/AHA pooled cohort equation (as outlined in the USPTF full recommendation) |
| Grade B and C | "are not at increased risk for bleeding" | The USPSTF full recommendation statement lists the following conditions as signifying increased risk for bleeding: Current ASA 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 (ESRD) OR Diagnosis of severe liver disease OR Diagnosis of thrombocytopenia OR "other factors that increase risk include:"Concurrent use of anticoagulant medicationOR Concurrent use of NSAIDsOR Uncontrolled Hypertension represented by SBP <=160 |
| Grade B and C | "have a life expectancy of at least 10 years" | Exclude individuals who have palliative care ordered or are receiving palliative care. Remainder of this determination will be left to provider discretion. |
| Grade B and C | "are willing to take for at least 10 years" | Provider will initiate shared decision making with the patient, to include a review of the benefits and harms of ASA therapy (this is included as an intervention). |

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  | Exclusion: Diagnosis of CVD | ASA therapy is recommended for primary prevention of CVD/ASCVD. If the patient has CVD/ASCVD 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 Colorectal Cancer (CRC)  | ASA therapy is recommended for primary prevention of CRC. If the patient has CRC a different therapy may be indicated. |
| Verify Completeness  | Exclusion: Currently receiving ASA (at any dose)  | If an individual is already receiving aspirin (at any dose) a CDS recommendation to initiate low-dose ASA therapy is not indicated.  |
| Verify Completeness  | Exclusion: Aspirin Allergy |  ASA 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 if they want to incorporate the Grade B, Grade C or both recommendations.  |
| 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 | 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 > 6 years old a notification warning or error will be presented to the provider to provide awareness and prompt an update.  |
| **Exclusions that were considered, but not included in CDS logic at this time** |
| 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 sets lab thresholds based on their unique system, otherwise there could be divergence between a CDS message/logic and flag markings of abnormal lab(s). Considerations for future lab value specifications include: - INR > 1.2 OR elevated PTT to represent bleeding disorder (>40 seconds) - Platelets <100,000 to represent thrombocytopeniaNote: 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: 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 Resources |
| 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 |

Reference List

[1] Osheroff J, Teich J, Middleton B, et al. A Roadmap for National Action on Clinical Decision Support. J Am Med Inform Assoc. 2007 Mar-Apr;14(2):141–5. doi: 10.1197/jamia.M2334

[2] [Bibbins-Domingo K](https://www.ncbi.nlm.nih.gov/pubmed/?term=Bibbins-Domingo%20K%5BAuthor%5D&cauthor=true&cauthor_uid=27064677); [U.S. Preventive Services Task Force](https://www.ncbi.nlm.nih.gov/pubmed/?term=U.S.%20Preventive%20Services%20Task%20Force%5BCorporate%20Author%5D).Aspirin Use for the Primary Prevention of Cardiovascular Disease and Colorectal Cancer: U.S. Preventive Services Task Force Recommendation Statement.[Ann Intern Med.](https://www.ncbi.nlm.nih.gov/pubmed/27064677) 2016 Jun 21;164(12):836-45. doi: 10.7326/M16-0577.

[3] Boxwala AA, Rocha HB, 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:i132-9. doi:10.1136/amiajnl-2011-000334.

[4] Tso G, Tu SW, Oshiro C, et al. Automating Guidelines for Clinical Decision Support: Knowledge Engineering and Implementation. AMIA Annu Symp Proc. 2017; 2016:1189–98. PMCID: PMC5333329

[5] Shiffman RN, Michel G, Essaihi A, Thornquiest E. Bridging the Guideline Implementation Gap: A Systematic, Document-Centered Approach to Guideline Implementation. J Am Med Inform Assoc 2004; 11(5):4-18-26.

[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 Recommendations](https://www.uspreventiveservicestaskforce.org/Page/Name/grade-definitions#grade-definitions-after-july-2012) [↑](#footnote-ref-1)
2. 7 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](https://www.uspreventiveservicestaskforce.org/Page/Name/grade-definitions#grade-definitions-after-july-2012) [↑](#footnote-ref-2)
3. <https://vsac.nlm.nih.gov/valueset/2.16.840.1.113762.1.4.1032.15/expansion> [↑](#footnote-ref-3)