Enhanced Clinical Decision Support Artifact Based on Pilot Experience

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

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Table of Contents

[1. Introduction 4](#_Toc497386268)

[2. Initial Definition of the Statin Use Artifact 4](#_Toc497386269)

[3. Artifact Enhancements 5](#_Toc497386270)

[3.1 Enhancements Made During Initial Discussions with Alliance 5](#_Toc497386271)

[3.2 Enhancements Made During Integration Development and Testing 6](#_Toc497386272)

[3.2.1 Conditions 6](#_Toc497386273)

[3.2.2 Procedures 8](#_Toc497386274)

[3.2.3 Medications 8](#_Toc497386275)

[3.2.4 Laboratory Tests 10](#_Toc497386276)

[3.3 Enhancements Made During Implementation Testing and the Live Pilot 10](#_Toc497386277)

[4. Lessons Learned and Broader Implications 12](#_Toc497386278)

[4.1 Coding variations 12](#_Toc497386279)

[4.1.1 Conditions 12](#_Toc497386280)

[4.1.2 Procedures, Tests, and Measured Observations 12](#_Toc497386281)

[4.1.3 Medications 12](#_Toc497386282)

[4.2 Clinical variations 13](#_Toc497386283)

[4.2.1 Parameter variation 13](#_Toc497386284)

[4.2.2 Facility variation 13](#_Toc497386285)

[4.2.3 Disease variation 13](#_Toc497386286)

[4.2.4 Evidence level 14](#_Toc497386287)

[5. Conclusion 14](#_Toc497386288)

[References 15](#_Toc497386289)

[Acronyms 16](#_Toc497386290)

# Introduction

In service to Agency for Healthcare Research and Quality’s (AHRQ’s) mission to make health care safer, higher quality, more accessible, equitable, and affordable, the Clinical Decision Support (CDS) Connect project created several artifacts for widespread adoption by clinicians and healthcare organizations across the United States. The artifacts are free and openly available on the CDS Connect Repository, and can be accessed at <https://cds.ahrq.gov/>.

To enhance and inform the CDS Connect artifact development process, one artifact (i.e., Statin Use for the Primary Prevention of Cardiovascular Disease [CVD] in Adults)was selected for clinical pilotingby a healthcare organization, AllianceChicago (hereinafter Alliance).Alliance, a centralized electronic health record (EHR) operator for a network of Federally Qualified Health Centers (FQHCs), facilitated collaboration with one of their network FQHC clinics to pilot the CDS in their facility. The pilot organization and clinical setting provided real-time feedback throughout the design, development, testing, and piloting of the artifact, which led to an enhanced artifact that informed and enhanced subsequent CDS Connect artifacts.

After an artifact was selected for pilot testing, Alliance and MITRE teams worked together over the course of 6 months to:

1. Ensure proper integration of the CDS specifications.
2. Test the reliability and validity of CDS responses.
3. Support a live pilot of the implemented artifact.

The pilot activity was conducted at a rural FQHC located in the western region of the United States from July 6, 2017, to August 6, 2017. Alliance facilitated pilot testing and implementation of the artifact as the hosting organization of the site’s GE Centricity EHR. Findings that arose during integration development and testing, implementation of the specifications, and the live pilot activity informed and enhanced artifact specifications, leading to a richer expression of the clinical intent and underlying logic. These enhancements are outlined in Section 3 of this document.

# Initial Definition of the Statin Use Artifact

The initial definition of the Statin Use artifact was influenced by several sources.

The core logical structure and workflow were extracted from the U.S. Preventive Services Task Force (USPSTF) guideline, Statin Use for the Primary Prevention of Cardiovascular Disease in Adults: Preventive Medication, published in November 2016. While this guideline provides some concrete boundaries (e.g., age), many of the elements are discussed with insufficient detail to author discrete, computable definitions. This is the first point where the need for interpretation and definition was introduced.

As a start in determining the proper discrete representation of these guideline elements, existing electronic Clinical Quality Measures (eCQMs) were consulted. CMS347: Statin Therapy for the Prevention and Treatment of Cardiovascular Disease demonstrated data element representations already in use in popular government-led clinical quality programs. These helped inform how to represent broad concepts (e.g., CVD) and narrower concepts (e.g., breastfeeding) in ways that are both robust and more likely supported by health information technology (IT) vendors. Many of the initial value sets used in the CDS logic were borrowed from these eCQMs.

The CDS Connect Cholesterol Management Workgroup was also consulted, particularly in the determination of how more complex or ambiguous elements should be interpreted and defined. With strong participation from active clinicians and clinical leaders, this group of subject matter experts provided the skills and experience necessary to validate clinical appropriateness and feasibility and recommend additional implementation details.

To ensure the artifact performed as expected, it was piloted in a live clinical environment. In support of this pilot work, our technical and clinical partner, Alliance, conducted several integration and testing activities and shared their findings. These activities and key learnings served as another source of input for determining the artifact’s final representation. These collective knowledge sources, along with the clinical and health IT experience of the authors, produced the initial implementation of the Statin Use for the Primary Prevention of CVD in Adults (hereinafter “Statin Use”) artifact.

# Artifact Enhancements

The Statin Use artifact was enhanced by the MITRE team based on Alliance feedback. Updated specifications were tested during pilot integration and implementation activities.

## Enhancements Made During Initial Discussions with Alliance

The primary enhancement made during initial discussions with Alliance involved determining which aspects of the USPSTF recommendation statement to pilot. More specifically, the USPSTF recommendation statement provides various recommendation “grades”[[1]](#footnote-1) (e.g., a “B” and “C” grade), and while the CDS Connect artifact included expression logic for both the Grade B and Grade C grade recommendations, organizational policy at Alliance allows only for implementation of Grade A and Grade B recommendations.

To align implementation of the Statin Use artifact to organizational guidelines, a parameter was added to “disable” logic associated with a graded recommendation (i.e., the Grade C recommendation). Thus, the local implementers of the artifact disabled the Grade C recommendation and only implemented the Grade B recommendation to comply with policy.

Grade parameters will likely be included in all subsequent CDS Connect artifacts to allow implementers this flexibility.

## Enhancements Made During Integration Development and Testing

During integration development to align the organization’s coded data and the CDS specifications, several “disconnects” were identified between how data was captured in Alliance’s EHR and how the data concepts were expressed in the Statin Use artifact. Based on these findings and in collaboration with Alliance, MITRE implemented several enhancements to the piloted artifact across four high-level Quality Data Model (QDM) data categories. The enhancements ultimately ensured robust data evaluation and the delivery of accurate CDS interventions. The data categories are:

* Conditions (i.e., Pregnancy, Breastfeeding, Familial Hypercholesterolemia, and Hypertension)
* Medications (i.e., Low, Moderate and High Intensity Statins)
* Laboratory tests (i.e., LDL-C and HDL-C results)
* Procedures (i.e., Dialysis)

Artifact enhancement details are outlined in Sections 3.2.1 – 3.2.4.

### Conditions

EHRs allow a patient’s health conditions (“Conditions”) to be expressed in numerous ways (e.g., as an ICD-10 code for claims data, as a SNOMED-CT code captured on a problem list). Building off best practices used by eCQM developers, the initial representation of the Statin Useartifact defined each Condition as a grouped value set comprised of a vast number of ICD-9, ICD-10, and SNOMED-CT codes to accommodate an array of data.

Alliance-generated test results uncovered additional variations and opportunities for refinement of the following Conditions:

* **Pregnancy**

|  |  |
| --- | --- |
| Initial Definition | Grouped Pregnancy value set, OID: 2.16.840.1.113883.3.526.3.378 |
| Test Result | Primary care providers at the clinical site often capture pregnancy as an Observation, as opposed to a formal diagnosis with an affiliated ICD-9, ICD-10, or SNOMED-CT code. These Observations were being missed by the initial representation of pregnancy. |
| Enhanced Definition | CQL specifications were updated to check for an active pregnancy Condition *or* evaluate each patient record for the presence of LOINC 82810–3 (to indicate pregnancy status) and SNOMED-CT 77386006 (to indicate currently pregnant) with an “effectiveDateTime,” “effectivePeriod,” or “issued date” within the past 42 weeks. |

* **Breastfeeding**

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| --- | --- |
| Initial Definition | Grouped Breastfeeding value set, OID: 2.16.840.1.113762.1.4.1047.73 |
| Test Result | Primary care providers at the pilot site often capture breastfeeding as an Observation with a “yes/no” answer. These Observations were being missed by the initial representation of breastfeeding. |
| Enhanced Definition | CQL was updated to check for an active breastfeeding Condition *or* if the most recent Observation with LOINC code 63895-7 (“Breast feeding [PhenX]”) had answer LA33-6 (“Yes”) within the past year. |

* **Familial Hypercholesterolemia**

|  |  |
| --- | --- |
| Initial Definition | Grouped Familial Hypercholesterolemia value set, OID: 2.16.840.1.113762.1.4.1032.15 |
| Test Result | CQL code was not evaluating a valid ICD-10 code (i.e., E78.01). |
| Enhanced Definition | CQL was updated to check for an active familial hypercholesterolemia Condition (i.e., code within the designated OID) *or* E78.01. Note: per Value Set Authority Center (VSAC) best practices, a value set should not include one code. Since there is only one ICD-10 code that represents familial hypercholesterolemia (i.e., E78.01), the creation of a new ICD-10 value set was not appropriate. Instead, CQL code was updated to check for the designated OID *or* E78.01. |

* **Hypertension**

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| --- | --- |
| Initial Definition | Grouped Hypertension value set that expressed essential and secondary hypertension,OID: 2.16.840.1.113762.1.4.1032.9 |
| Test Result | Pilot site clinicians utilize a broader range of ICD-10 codes to express hypertension (i.e., I10-I16). Several of the utilized codes were not included in the initial value set. |
| Enhanced Definition | The initial value set (OID: 2.16.840.1.113762.1.4.1032.9) was expanded to include a broader range of ICD-10 codes, including non-essential/non-secondary hypertension conditions. Note: I16 codes were not added to the value set since they need to be paired with an I10-I15 code for billing purposes. Pregnancy-related hypertensive conditions were not added either, since pregnancy is a strong exclusion for statins. |

### Procedures

Procedures are included in the Statin Use expression logic to more fully describe certain Conditions. For example, a history of CVD might be evidenced by a CVD diagnosis *or* the occurrence of a coronary artery bypass graft in the past. Procedures are considered alternate ways to represent a Condition, since procedures may not be captured in an outpatient primary care EHR unless the procedure was performed by that practice.

* **Dialysis**

|  |  |
| --- | --- |
| Initial Definition | Union of 3 grouped dialysis value sets that represent renal and peritoneal dialysis, vascular access and outpatient services related to dialysis (i.e., OID: 2.16.840.1.113883.3.464.1003.109.12.1013,2.16.840.1.113883.3.464.1003.109.12.1011,2.16.840.1.113883.3.464.1003.109.12.1014) |
| Test Result | In rare instances, dialysis was captured as a Condition (i.e., “dependence on renal dialysis,” ICD-10 z99.2). This code was not considered by CQL specifications as representing dialysis in the past 7 days.  |
| Enhanced Definition | The testing timeline did not allow time to research and build a grouped value set to include all indicated codes for each standardized terminology (i.e., ICD-10, ICD-9, and SNOMED-CT) to represent “dependence on dialysis.” Instead, a disclaimer notification was added to the user interface to convey that the condition “dependence on renal dialysis” is not currently recognized or acted upon by CQL specifications. |

### Medications

The Centers for Medicare and Medicaid Services (CMS) Blueprint recommends eCQM medication value sets contain only semantic clinical drugs (SCDs), since changes made to branded identifiers occur throughout the year, and eCQMs are only updated annually. The initial representation of medications in the Statin Useartifact followed the same methodology, and statins were defined using value sets created by Quality Insight of Pennsylvania’s (QIP) for CMS347: Statin Therapy for the Prevention and Treatment of Cardiovascular Disease.

* **Low Intensity Statin**

|  |  |
| --- | --- |
| Initial Definition | Low intensity statin semantic clinical drugs (SCD) and semantic generic clinical drug packs (GPCK) RxNorm value set, OID: 2.16.840.1.113762.1.4.1047.107 |
| Test Result | Low intensity semantic branded drugs (SBD) and semantic branded drug packs (BPCK) captured in the pilot organization’s EHR were not being evaluated by the CQL code. |
| Enhanced Definition | A new value set was created to represent low intensity statin SBDs and BPCKs (i.e., OID: 2.16.840.1.113762.1.4.1032.16) and the concept was re-defined as the union of the original OID and the new OID. |

* **Moderate Intensity Statin**

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| --- | --- |
| Initial Definition | Moderate intensity SCD and GPCK RxNorm value set, OID: 2.16.840.1.113762.1.4.1047.98 |
| Test Result | Moderate intensity SBDs and BPCKs captured in the pilot organization’s EHR were not being evaluated by the CQL code. |
| Enhanced Definition | A new value set was created to represent moderate intensity statin SBDs and BPCKs (i.e., OID: 2.16.840.1.113762.1.4.1032.17) and the concept was re-defined as the union of the original OID and the new OID. |

* **High Intensity Statin**

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| --- | --- |
| Initial Definition | High intensity SCD and GPCK RxNorm value set,OID: 2.16.840.1.113762.1.4.1047.97 |
| Test Result | High intensity SBDs and BPCKs captured in the pilot organization’s EHR were not being evaluated by the CQL code. |
| Enhanced Definition | A new value set was created to represent high intensity statin SBDs and BPCKs (i.e., OID: 2.16.840.1.113762.1.4.1032.18) and the concept was re-defined as the union of the original OID and the new OID. |

### Laboratory Tests

Laboratory tests have numerous dates and times associated with them (e.g., order date, drawn date, result date, posted date). The label that each distinct EHR and laboratory system assigns to these dates and times can vary widely, making generalized attribute definition very challenging.

* LDL-C Laboratory Test

|  |  |
| --- | --- |
| Initial Definition | CQL code looked for the “effectiveDateTime” (i.e., the date the lab was drawn) and “effectivePeriod” (i.e., the period that the lab draw was in effect), represented by LOINC value set (i.e., OID: 2.16.840.1.113883.3.464.1003.198.11.1029) |
| Test Result | The pilot organization’s EHR captures the “issued date,” as opposed to the “effectiveDateTime” or “effectivePeriod,” so the result was not being evaluated by the CQL code. |
| Enhanced Definition | CQL code was updated to look for the “effectiveDateTime,” “effectivePeriod,” *or* the “issued date” affiliated with an LDL-C test. |

* HDL-C Laboratory Test

|  |  |
| --- | --- |
| Initial Definition | CQL code looked for the “effectiveDateTime” (i.e., the date the lab was drawn) and “effectivePeriod” (i.e., the period that the lab draw was in effect), represented by LOINC value set (i.e., the union of OID:2.16.840.1.113883.3.464.1003.104.12.1012,2.16.840.1.113883.3.600.875) |
| Test Result | The pilot organization’s EHR captures the “issued date,” as opposed to the “effectiveDateTime” or “effectivePeriod,” so the result was not being evaluated by the CQL code. |
| Enhanced Definition | CQL code was updated to look for the “effectiveDateTime,” “effectivePeriod,” *or* the “issued date” affiliated with an HDL-C test. |

## Enhancements Made During Implementation Testing and the Live Pilot

End-to-end implementation testing of the Statin Use artifact occurred over the course of 13 days (i.e., from June 23, 2017, to July 5, 2017). Due to the enhancements listed above, testing demonstrated consistently valid and reliable CDS execution. Furthermore, no additional enhancements were required during the live pilot of the CDS artifact, which occurred from July 6, 2017, to August 6, 2017.

Focus group discussions were held in late August 2017 to gather feedback from clinical users of the CDS. Based on their experience with the CDS, additional enhancements may be considered in the future.

# Lessons Learned and Broader Implications

The findings and discussions that arose during the development and testing phases of the Statin Use pilot activity provide good examples of key points to consider, as well as local variations that could commonly be requested or applied to a CDS artifact. They do not suggest an error in the original artifact; rather, they demonstrate areas where differences in local health patterns, clinical policy, or common practice dictate modest differences in CDS data elements and logic. Feedback about these variations can be used to make the original artifact more widely applicable, as well as inform the development of future artifacts.

## Coding variations

Overall, the existence of local variation suggests that CDS artifacts should contain relatively inclusive definitions of data elements, thus containing the diverse expressions that may be used at different sites. Additionally, consistency and maintenance requirements suggest that standard value sets (or combinations of standard value sets) from QIP, National Committee for Quality Assurance (NCQA), and other organizations should be used wherever possible.

### Conditions

Published guidelines and rules are often written using non-coded generic Condition terms such as “diabetes.” Value sets successfully translate these terms into computable data elements, but legitimate variations among posted standard value sets exist. Codes that express a diagnosis are found within ICD-9, ICD-10, SNOMED-CT, and LOINC terminologies as both Conditions and Observations, and include many values that overlap. By using value sets that are inclusive of these terminologies and code variations, CDS authors can provide more robust expressions that easily allow for local institutions to find or include codes used by their organization.

### Procedures, Tests, and Measured Observations

Procedures, tests, and Observations that are measured (i.e., gestational age) can be challenging concepts to capture in structured, uniform formats across EHR and clinical systems. Adding to this complexity is the large number of ways that each concept can be described using standardized terminologies. As above, more inclusive value sets allow for more local usage variations. Note that in choosing such values, it is still important to stay within the intent of the guideline; thus, codes for “urinary potassium” should not be included in a value set for “serum potassium.”

### Medications

As noted in Section 3.2.3, specifying a recommendation statement that calls for a statin order or evaluates for evidence of an anti-hypertensive medication presents challenges in inclusiveness as well as in granularity, as different guidelines may recommend a medication at the RxNorm Ingredient level (e.g., all drugs containing atorvastatin), Clinical Drug Component (e.g., all drugs containing atorvastatin 20mg), Clinical Dose Form Group (e.g., atorvastatin/amlodipine oral forms), or Clinical Drug level (e.g., atorvastatin 20mg/amlodipine 10mg oral tablet).

Branded forms might best be avoided in CDS artifacts because of their frequent changes; however, if an institution does not have an easy mapping from their formulary to RxNorm or to a generic terminology, it may be necessary to build and maintain value sets with branded items.

## Clinical variations

In some cases, varying clinical practice decisions and local conditions may call for variations in the CDS artifact. In general, artifacts downloaded from the CDS Connect Repository could be modified locally; however, it may also be that CDS contributors should recognize parameters and elements that are likely to vary locally and annotate coded specifications for easy identification and access.

### Parameter variation

Practice differences lead clinicians and healthcare organizations to set different parameters for certain guidelines, and thus for the resulting CDS, such as:

* **Test values**: The threshold for actionable Hemoglobin A1C, hemoglobin threshold for transfusion, optimal INR endpoints, and other parameters often differ somewhat in different settings, in the absence of a hard-and-fast evidence-based cutoff.
* **Demographics**: Guidelines, particularly for invasive procedures and long-term therapies, may have an unspecified or soft age limit, which can be interpreted differently from one setting to another. The American College of Cardiology/American Heart Association guideline for statin use acknowledges lesser benefit above age 75, which could cause some organizations to choose higher or lower age thresholds around this point in their CDS logic.
* **Timing**: Acute-care treatments, such as for thrombolysis in myocardial infarction and stroke, have rapidly tapering benefit-risk ratios as time elapses after symptoms start. Institutions may wish to have different time thresholds for recommending thrombolysis, based on their experience and other therapeutic options.

### Facility variation

Available tests and treatments may vary across clinical settings and healthcare organizations. For example, management of suspected pulmonary embolism in pregnancy may vary based on availability of CT scanning, nuclear medicine scanning, and other tests. Availability can even vary by the day of the week and time of day. CDS should adapt accordingly to be best tailored to local availability.

### Disease variation

Epidemiologic variations can alter CDS recommendations. For example, regional or even institution-specific infectious disease prevalence and resistance differences can change the preferred order of antibiotic treatment specified in a CDS artifact (i.e., an order set).

### Evidence level

Clinical guidelines may feature multiple recommendations, some with higher and lower strength of evidence and strength of recommendation. Organizations may fairly differ about which strength of evidence is strong enough to merit a recommendation, particularly when it results in an alert. Thus, CDS that provides multiple recommendations and suggested actions, based on evidence of different strength levels, might also allow local sites to incorporate only the stronger recommendations.

# Conclusion

Partnering with Alliance to pilot the Statin Use artifact provided a valuable opportunity to evaluate the CDS in a clinical setting. As described above, each healthcare organization is likely to have local variations in how they define and capture clinical concepts. A total of 10 concepts were more effectively expressed based on discussions with the pilot organization and testing that occurred during the pilot process. As other organizations implement the Statin Use artifact, they may identify additional local variations that can be added to the specifications, thus enhancing the artifact even further.

CDS is a powerful tool that can be utilized to improve the quality and safety of care provided to each patient. The CDS Connect Repository aims to allow for a virtual, asynchronous, and more widespread level of collaboration leading to mature, well-expressed CDS. Pilot implementation of developed artifacts enhances their specification and ultimately enriches the effectiveness of the artifact and its ability to impact patient care.

References

1. Grade Definitions. U.S. Preventive Services Task Force. June 2016.
https://www.uspreventiveservicestaskforce.org/Page/Name/grade-definitions

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 |
| eCQM |  | Electronic Clinical Quality Measure |
| EHR |  | Electronic Health Record |
| FAR |  | Federal Acquisition Regulation |
| FFRDC |  | Federally Funded Research and Development Center |
| FHIR |  | Fast Healthcare Interoperability Resources |
| FQHCs |  | Federally Qualified Health Centers |
| HDL |  | High-Density Lipoprotein |
| HHS |  | Department of Health and Human Services |
| HIT |  | Health Information Technology |
| HL7 |  | Health Level 7 |
| ICD |  | International Statistical Classification of Diseases and Related Health Problems |
| IT |  | Information Technology |
| LDL |  | Low-Density Lipoprotein |
| LOINC |  | Logical Observation Identifiers Names and Codes |
| NCQA |  | National Committee for Quality Assurance |
| OID |  | Object Identifier Descriptor |
| ONC |  | Office of the National Coordinator for Health Information Technology |
| PCOR |  | Patient-Centered Outcomes Research |
| PCORI |  | Patient-Centered Outcomes Research Institute |
| QDM |  | Quality Data Model |
| QIP |  | Quality Insight of Pennsylvania |
| SNOMEDCT |  | Systematized Nomenclature of Medicine-Clinical Terms |
| USPSTF |  | U.S. Preventive Services Task Force |
| VSAC |  | Value Set Authority Center |

1. 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. 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 https://www.uspreventiveservicestaskforce.org/Page/Name/grade-definitions#grade-definitions-after-july-2012 [↑](#footnote-ref-1)