Implementation Guide

Factors to Consider in Managing Chronic Pain: A Pain Management Summary

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Prepared by:

CMS Alliance to Modernize Healthcare (The Health FFRDC)

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Record of Implementation Guide Changes

Date	Action	Notes
September 2018	Published Implementation Guide	
April 2020	Updated the Implementation Guide based on annual CDS artifact updates	Updated the Implementation Guide to introduce and describe 2020 logic updates and additions in the Artifact Manifest content, updated the Artifact Relationship Diagram to also reflect the HL7 FHIR R4 artifact, and updated the semistructured representation of the artifact in Appendix A, concept definitions and decision log.
September 2021	Updated the Implementation Guide based on annual CDS artifact updates	Revised language to clarify use beyond chronic or opioid treated pain. Updated technical details to reflect CQL updates for FHIR 4.0.1 and to provide additional information regarding artifact testing.
September 2022	Updated the Implementation Guide based on annual CDS artifact updates	Edited the background and introduction for clarity. Reorganized content under new topic headings to make navigation more intuitive. Minor edits to improve clarity. Updated the CQL section to reflect new CQL library names and versions.

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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. Semistructured – 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 while creating the artifact. It also enables contributors to upload the coded logic expression, test data, technical files, and reports.

The CDS Authoring Tool provides a user-friendly interface 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: to provide insight on how the logic expression can be used to improve patient care, and 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

Description and Purpose of the Artifact

This artifact provides relevant information to consider when managing a patient's pain to inform the care decision-making process. The information is presented to the clinician as a Pain Management Summary that provides a variety of key "factors" for clinicians to consider when assessing the history and status of a patient's pain. The key factors include subjective and objective findings, along with recorded treatments and interventions to support shared decision making on treatment moving forward. Although designed primarily for care of patients with chronic pain, it may be useful for decision making for patients with acute or recurring pain.

Summary of the Clinical Statement

Although inspired by the Centers for Disease Control and Prevention's (CDC's) Guideline for Prescribing Opioids for Chronic Pain,[2] this artifact is not directly derived from any one recommendation statement. Instead, it is meant to complement several of the 12 recommendation statements within the CDC guideline by providing a consolidated view of the patient's pain experience and the management of their condition. Additionally, this artifact expands the utility of the CDC recommendations by adding information on nonopioid medications and nonpharmacologic treatments. Ultimately, the populated Pain Management Summary is intended to promote discussion between the patient and the provider regarding the effectiveness of existing treatments and the benefits and risks of potential future interventions, while considering the use of nonopioid and/or nonpharmacologic treatment when possible.

For contextual awareness, examples of CDC recommendations (which are limited to opioid prescribing for chronic pain) that the summary data indirectly support include the following:

- **Recommendation 3:** Before starting—and periodically during—opioid therapy, clinicians should discuss with patients known risks and realistic benefits of opioid therapy and patient and clinician responsibilities for managing therapy (recommendation category: A, evidence type: 3).
- **Recommendation 8:** Before starting—and periodically during—opioid therapy, clinicians should evaluate risk factors for opioid-related harms. Clinicians should incorporate into the management plan strategies to mitigate risk, including considering offering naloxone when factors that increase risk for opioid overdose (e.g., history of overdose, history of substance use disorder, higher opioid dosages—≥ 50 morphine milligram equivalents [MME]/day—or concurrent benzodiazepine use) are present.
- **Recommendation 10:** When prescribing opioids for chronic pain, clinicians should use urine drug testing before starting opioid therapy and consider urine drug testing at least annually to assess for prescribed medications as well as other controlled prescription drugs and illicit drugs.
- **Recommendation 11:** Clinicians should avoid prescribing opioid pain medication and benzodiazepines concurrently whenever possible.

Primary Use Cases

In the primary use cases, the artifact is intended for use by clinicians delivering care in an outpatient setting. The clinical use cases are particularly relevant to clinicians specializing in primary care, family medicine, internal medicine, geriatrics, and/or pain management.

The artifact presents a patient-specific Pain Management Summary that displays clinical concepts that a clinician might consider before making a treatment decision, including using shared decision making, regarding chronic pain. (Note that the specific method used to trigger the display of the Pain Management Summary is dependent on local implementation decisions. Refer to the section on Integration with the Health Information Technology). Typical scenarios include the following:

- When deciding whether to initiate, continue, modify, or discontinue nonopioid pharmacologic treatment for chronic pain:
    - Dr. Alpha is currently reviewing the record of Ms. Bravo, a scheduled patient with a history of chronic hip pain. Dr. Alpha reviews the Pain Management Summary for Ms. Bravo. She compares Ms. Bravo's medication history, self-reported pain levels, and functional status, noting that while her condition initially improved on a low dose of a nonopioid medication, her improvement has since plateaued. Dr. Alpha decides to recommend increasing the dose of the nonopioid pain medication to attempt to achieve further improvements in functional status.
- When deciding whether to initiate, continue, modify, or discontinue nonpharmacologic treatment for chronic pain:
    - Dr. Charlie is currently reviewing the record of Mr. Delta, a scheduled patient with a complaint of low back pain. Dr. Charlie reviews the Pain Management Summary for Mr. Delta. She reviews Mr. Delta's self-reported pain levels and functional status, noting that his pain functional status has been unacceptably low, and his pain level remained elevated over the past 6 months. Dr. Charlie notes that no nonpharmacologic treatments have been ordered for Mr. Delta in the past 6 months. Dr. Charlie decides to recommend physical therapy to Mr. Delta to help improve his functional status, as well as acupuncture to reduce his level of pain.
- When deciding whether to initiate, continue, modify, or discontinue opioid pharmacologic treatment for chronic pain:
    - Dr. Alpha is currently reviewing the record of Ms. Echo, a scheduled patient with a history of chronic pain currently treated with opioid therapy. Dr. Alpha reviews the Pain Management Summary for Ms. Echo. She reviews Ms. Echo's opioid risk assessments since inception of opioid therapy, noting that she was initially judged low risk for opioid abuse or diversion. Ms. Echo's subsequent risk assessments show no elevated risk factors for opioid misuse or abuse. Dr. Alpha reviews her urine drug screening results for the past 6 months, noting no aberrant findings; however, the most recent result suggests use of the opioid Ms. Echo was prescribed at this office in addition to another opioid that she was not prescribed at this office. Dr. Alpha then decides to review the local Prescription Drug Monitoring Program (PDMP) database externally to determine whether Ms. Echo received prescriptions for this or other

medications of concern from another medical professional. Dr. Alpha engages in further dialogue with Ms. Echo to assess whether her use of an additional opioid is related to misuse, pseudo addiction, diversion, or other underlying conditions, to help her determine whether opioid therapy should be continued or modified.

Additional Use Cases

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

- Identification of care gaps:
    - Dr. Charlie's practice is running a quarterly quality screen to evaluate the care of patients with chronic pain. The CDS inclusion logic for this artifact is run as a report for all patients in the practice to identify all patients with known or suspected chronic pain or recent opioid medication or adjuvant analgesic recorded. The CDS logic is extended and run as a modified report to determine what care gaps exist (e.g., overdue for Urine Drug Screening, no nonpharmacologic therapies ordered). Recommendations are compiled into an overall report that is reviewed by the provider or other care management staff in the practice. Additionally, recommendations appropriate to a given patient could display on each patient's individual to-do list or as a message or alert to the responsible provider.
- Identification of patient safety issues:
    - Dr. Alpha's practice is running a quarterly quality screen to identify patients with potential safety issues. The CDS inclusion logic is run as a report for all patients in the practice, to identify all patients with known or suspected chronic pain or recent opioid medication or adjuvant analgesic recorded. The CDS logic of this artifact could be extended and run as a modified report to determine what red flags (e.g., exceeds total recommended dose of opioids or coprescription of benzodiazepine) exist. Recommendations appropriate to a given patient could display on each patient's individual to-do list, as a message or alert to the responsible provider, or compiled into an overall report that is reviewed by the provider or other care management staff in the practice.

Recommendations and Suggested Actions

The populated Pain Management Summary intervention provided by this CDS artifact can be found under Technical Details. The structured representation of this artifact supports the following:

1. Determine whether the patient is within the inclusion criteria (greater than [>] or equal to [=] 18 years of age AND [a condition associated with chronic pain OR one or more opioid medications were ordered or recorded within the past 180 days OR one or more adjuvant analgesic medications were ordered or recorded within the past 180 days]).
2. Display the heading "Pertinent Medical History" and populate it with the following items:
    a. Patient's condition(s) associated with chronic pain including the status, start date, stop date, and recorded date.
    b. Patient's risk factors (such as depression or liver disease) for opioid-related harms including the name, status, start date, stop date, and recorded date. If the identified risk factor is provided through the visit information, the name of the risk factor and visit date are included.
3. Display the heading "Pain Assessments" and populate it with the following items:
    a. Patient's pain assessment data including the name of the assessment tool, the score, and the date of the assessment. (Note that the assessment tools expressed in this artifact are those that were implemented in the pilot organization's EHR [i.e., Wong-Baker FACES Rating Scale; Pain intensity, Enjoyment of life, General activity (PEG) Pain Scale; Keele STarT Back Screening Tool]. See the Decision Log in Appendix A: Decision Log for additional information on this approach.)
4. Display the heading "Historical Pain-Related Treatments" and populate it with the following items:
    a. Any treatments found in the patient's record related to opioid or nonopioid pain medications ordered or recorded within the last 2 years, including the name, type (statement or order), start, and end dates.
    b. Nonpharmacologic treatments ordered, or referrals made for the patient within the last 2 years, including the name, type (procedure, procedure request, or referral), and date.
    c. Stool softeners and laxatives ordered or recorded for the patient within the last 6 months, including the name, type (statement or order), and start and end dates.
5. Display the heading "Risk Considerations" and populate it with the following items:
    a. Patient's most recent opioid MME date (if available and calculated externally to the CDS artifact).
    b. Patient's urine drug screening dates and results within the last year, including the name, result, interpretation (if available), and date.

c. Benzodiazepine medications ordered or recorded for the patient within the last 2 years, including the name, type (statement or order), and start and end dates.

d. Naloxone medications ordered or recorded for the patient (ever).

e. Patient's risk screenings that are relevant to pain management with their overall scores and dates for the past year.

6. Suggested Action: Discuss the information displayed on the Pain Management Summary with the patient, including the patient's pain management goal and potential interventions and treatments.
7. Suggested Action: Document the patient's pain management goal and the outcome of the shared decision-making discussion.
8. Suggested Action: Determine next followup appointment.

Guideline Interpretation and Clinical Decisions

It is often necessary to interpret or adjust clinical guidelines to make them suitable for computation. Although inspired by the CDC Guideline for Prescribing Opioids for Chronic Pain, this artifact is not directly derived from any one recommendation statement. Instead, it is meant to supplement several recommendation statements within the guideline by providing a consolidated view of the patient's pain experience and the management of their condition. Ultimately, the populated Pain Management Summary is intended to promote discussion between the patient and the provider regarding the effectiveness of existing treatments and the benefits and risks of future interventions, while considering the use of nonopioid and/or nonpharmacologic treatment when possible.

Throughout the development of this artifact, the team made decisions regarding the structured artifact representation, as well as integration with the pilot site EHR. Decisions outlined in Appendix A: Decision Log detail how source content informed development and how representations were defined during artifact creation. Some of the key interpretations and decisions include the following:

- The artifact was developed to align with the CDC guideline's intended population (i.e., the guidelines are intended for individuals 18 years of age or older with chronic pain, excluding patients in active cancer treatment, palliative care, and end-of-life care). Because the artifact can be trigged for any patient who has received an opioid or nonopioid pain medication, it can be used to support a broader population of patients such as those with any kind of pain. Future implementers may choose to support patients younger than 18.

- The CDC exclusion criteria (active cancer treatment, palliative care, and end-of-life care) were not encoded in this artifact, primarily because of the lack of structured electronic data across primary care settings to accurately determine if the patient is undergoing end-of-life care, palliative care, or cancer treatment. To ensure clinicians were aware of the CDC exclusion guidelines during the pilot implementation of this artifact, a notification displays at the top of the Pain Management Summary in the SMART on FHIR application to alert them to this exclusion.
- The Pain Management Summary CQL retrieves relevant information to consider when managing a patient's pain. A web-based SMART on FHIR application invokes the CQL and displays the results to the clinician as a Pain Management Summary. The SMART on FHIR application enables the provision of alerts and/or notifications reinforcing specific CDC guidelines, along with potential contraindications or patient safety warnings related to the data that is displayed.
- The specific method used to trigger the Pain Management Summary CDS and present the SMART on FHIR application is dependent on EHR integration options and subsequent implementation decisions made at each site. For the initial pilot site, the Pain Management CDS was triggered when a clinician clicked on a "Pain Summary Information" link found within a specific patient record in the EHR. Additional information on the pilot integration of the Pain Management Summary is described in the CDS Connect Pilot Final Report.

Information for Clinicians When Using the CDS

The information in this section provides context on aspects of patient-centered care and shared decision making related to pain management. The section also discusses additional references and perspectives regarding the most effective use of the Pain Management Summary to facilitate shared decision making and engage the patient via the CDS.

Pain Management

Successful treatment of chronic pain requires consideration of the patient's previous medical care, biology and genetics, individual behavior, physical environment, and social circumstances. The scope and complexity of data needed by the care team (patient, caregivers, and clinicians) to relieve pain and improve health and wellness are staggering. Relevant data can be fragmented and difficult to find, share, and interpret. Though not all-encompassing, the Pain Management Summary CDS artifact compiles and displays available and relevant information for the care team to use when treating and managing pain. This information informs the care team while they determine the most appropriate actions and plan of care.

The following information provides background material on patient-centered care and shared decision making. Both concepts are crucial to effective pain management. Subsequent sections provide information on use of the CDS artifact to provide patient-centered care and other areas of consideration related to patient-centered chronic pain management.

Patient-Centered Care

In patient-centered care, the patient and clinicians partner to plan and manage the patient's treatment and care. This includes identifying expectations, setting goals to treat medical problems and reach best health, finding service providers, collaborating with others to develop a plan to meet the goals and expectations, and learning what works and doesn't work. Planning and managing also includes tracking status and progress across settings, while considering the financial impact of treatment and service. Planning and managing often includes a care partner.

Patient-centered care compels the clinician and healthcare team to understand the patient behind the symptoms and interact in a way that affirms the patient's vitality and attends to the stresses and life circumstances of the patient.

Patient-centered clinical decision support informs and facilitates care for *specific* patients by their caregivers/care teams. Thus, it includes knowledge (evidence-based research); data (patient-generated health data, patient-reported outcomes and preferences, and/or patient-specific social/environmental/genetic/cultural factors as they affect individual patient health); and tools for patient (and/or caregiver) involvement in informed decision making.[3] It supports holistic care of the patient and the concept of "slow medicine"—one that deviates from the "fast" healthcare model of today to that of recognizing the value of taking time to listen to patients—and working to create a structure in which this process can be supported.[4]

Facilitating Shared Decision Making

Shared decision making is one component of patient-centered care. It allows an individual and their healthcare provider together to determine the most appropriate treatment or care choices.[5] When implemented effectively, CDS can facilitate this objective.

CDS and decision aids can be used before, during, or after a clinical encounter to enable patients to become active, informed participants.[6] Success depends on establishing a trusting relationship, so that information is shared, and patients are supported to express their preferences and views and participate in the decision-making process.

Elwyn et al. propose a model of how to employ shared decision making. The model has three steps: 1) introducing choice; 2) describing options, often by integrating the use of patient decision support; and 3) helping patients explore preferences and make decisions. This model rests on supporting a process of deliberation and on understanding that decisions should be influenced by exploring and respecting what matters most to patients as individuals, and that this exploration in turn depends on them developing informed preferences.[7]

Use of Summaries to Facilitate Care

Treating patients with pain, especially chronic pain, is extremely complex. Treatment requires the consideration of multiple factors, such as psychiatric comorbidity (e.g., depression, suicidality), a variety of pharmacological treatments for chronic pain (opioids as well as nonopioid medications), and nonpharmacological treatments proven to be effective such as yoga, acupuncture, and meditation.[8,9] The National Pain Strategy (2016) highlights the importance of improving "physician education on pain management practices and team-based care in which multiple treatment options are offered—moving away from an opioid-centric treatment paradigm."[10] The CDC Guideline for Prescribing Opioids for Chronic Pain highlights the importance of nonpharmacologic therapy and nonopioid pharmacologic therapy for the treatment of pain, as well as additional complex factors to consider, such as the MMEs currently prescribed for the patient and risk factors for opioid therapy.

The challenge for clinicians is to appropriately collect, distill, and interpret patient information, critical to the clinical decision-making process, from a variety of sources and formats while separating important clues from background noise.[11] The way the information is structured and presented to clinicians can profoundly influence their decision making. An accurate, well-designed, and context-specific Pain Management Summary can potentially save time, improve clinical accuracy, and reduce potential errors in both outpatient and inpatient care.[12] The complexities of pain management require bringing together all the items that are relevant to the decisions about care into one comprehensive summary format so the clinician and patient can systematically address each factor.

Studies have evaluated the effectiveness of summaries and determined they are a valuable resource to clinicians. Summaries facilitate enhanced communication, have low implementation costs, and significantly improve physician performance in certain diseases, such as disease management for diabetes.[11]

This Pain Management Summary combines key subjective and objective factors in pain management, including pertinent medical history, pain assessments, historical treatments, and risk factors and assessments to create a comprehensive view of key data for facilitated patient and clinician decision making.

Providing Patient-Centered Care Using the Pain Management Summary CDS

The Pain Management Summary CDS presents a variety of key factors for patients and clinicians to consider when assessing the history of a patient's chronic pain and determining the next step in care. Although presented to the clinician via a link in the EHR during the MITRE pilot of this work, the summary data provide valuable information to share with patients, too.

Patients will likely need some orientation to the summary and why each component is relevant. Each individual patient is unique in their readiness, interest, and ability to process the information in the summary; a single standard approach on how to introduce the information is not possible or advised. Likewise, a multitude of factors impact how a clinician receives information in the Pain Management Summary and how they engage patients with the information. Patients, caregivers, and clinicians use clinical decision support evidence and tools in the context of the patient's changing life and health circumstances, clinician experience, and community standards. Consider the following factors when using this CDS summary:

- History of injury and/or disease leading to pain (including acute, genetic, chronic conditions).
- Determinants of health impacting the patient: personal characteristics and behavior, their physical environment, and social and economic circumstances.
- Resources available to the patient for assistance and support (e.g., availability of family or caregivers, the cost of care).
- Effectiveness of previous pain treatments (medical and nonmedical, medication and nonmedication).
- History of functional status changes (baseline pre-disease/injury through recent past).
- Patient preferences and attitudes toward pain management.
- Settings used for pain management (e.g., home, street, clinics, emergency departments, hospitals, pharmacies).
- Degree of life disruption for patient, caregivers, and clinician caused by pain and pain management.
- Clinician experience and training in pain management.
- Community/agency standards for pain management.

Opportunities to address some of these dynamics include educating clinicians and patients to take a holistic approach to managing care; facilitating clinician-provider interaction outside of visits; developing more-collaborative, trusting relationships; building electronic tools for

tracking assessments, comments, and communication; authorizing personal information sharing across settings and time; and designing clinic workflow and reimbursement so patients and their clinicians have sufficient time together to make informed decisions.

Additional development for this CDS might further foster patient-centered care by providing access to the information via a patient portal, allowing the patient or clinician to edit entries, and integrating commonly used pain and risk assessments with the tool, along with the capability to query and display information from a patient's pain journal.

Technical Details Regarding Artifact Implementation

The Pain Management Summary artifact is composed of several files written in CQL. The primary focus of the software files is to allow any healthcare organization to properly identify patients who may require pain management, and to provide relevant patient-specific information that could be considered when choosing interventions to manage the patient's pain.

The following sections provide technical details useful for those implementing this artifact in their health IT system. After providing background information on CQL (as the programming language used to write the logic for the artifact), the document presents a listing (or manifest) of the main CQL files included in the artifact, discusses the relationships among the files, and describes the testing activities.

General Information About CQL

The Pain Management Summary artifact is composed of several files, with the primary focus of the artifact being the introduction of providing CQL representations of the CDS logic. CQL is a data standard governed by Health Level 7® (HL7) that is currently a Mixed Normative/Standard for Trial Use (STU) specification.[13] CQL expresses logic in a human-readable document that is also structured enough for electronic processing of a query. It can be used within both the CDS and eCQM domains.

The following links provide additional information on CQL:

- HL7 CQL Specification
- CQL on the Electronic Clinical Quality Information (eCQI) Resource Center
- CQL Tools (e.g., CQL-to-ELM Translator) on GitHub
- CQL Execution Engine (JavaScript) on GitHub
- CQL Evaluation Engine (Java) on GitHub

Artifact Library Manifest

The Factors to Consider in Managing Chronic Pain: A Pain Management Summary artifact provides two distinct versions of the logic files.

- **FactorsToConsiderInManagingChronicPainFHIRv102_v2.0.0_CQL.zip**: The most recently updated FHIR DSTU2-based CQL logic files. These updates are primarily related to changes in terminology. This version was not piloted in a clinical setting but is largely based on the initial piloted version.
- **FactorsToConsiderInManagingChronicPainFHIRv401_v2.0.0_CQL.zip**: The FHIR R4-based CQL logic files were compiled using the CQL 1.5.x translator. This version was not piloted. Although the intent of the logic remains the same as the most recently updated FHIR DSTU2-based version (listed above), changes in the FHIR specification (from DSTU2 to R4) required corresponding changes to the CQL logic.

Detailed descriptions of the changes in the two most recent versions can be found in the **FactorsToConsiderInManagingChronicPain_Change_Log.txt** file attached to this artifact in the CDS Connect Repository.

Each of these packages is comprised of three distinct libraries listed in **Table 1** according to their file names. Although the file names and purposes may be the same across multiple versions (e.g., FHIRHelpers), the technical content of the files varies from version to version.

Each library is represented in two formats containing the same information but formatted for different purposes. The CQL format is human readable; the JavaScript Object Notation (JSON) format is machine readable and is generated from the CQL using the CQL-to-ELM translator.[14] The six software files that comprise the artifact are listed in Table 1.

Table 1. Artifact Manifest

Filename	Purpose	Author(s)
FactorsToConsiderInManagingChronicPainFHIRv102.cql (FHIR DSTU2 only) or FactorsToConsiderInManagingChronicPainFHIRv401.cql (FHIR R4 only)	CQL representation of Factors to Consider in Managing Chronic Pain: A Pain Management Summary, specifying the necessary logic to query and return structured summary information pertaining to the relevant factors a clinician may consider when managing a patient's pain	Chris Moesel, David Winters, Sharon Sebastian

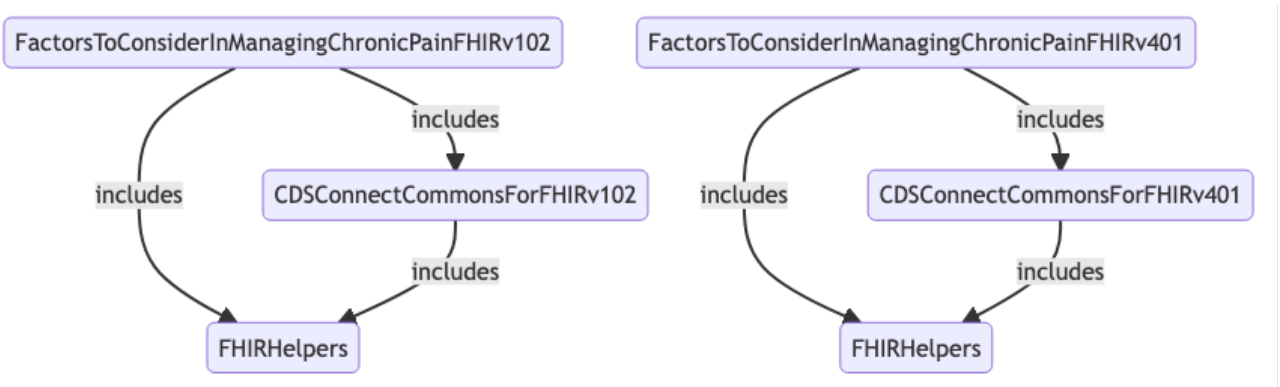
Filename	Purpose	Author(s)
FactorsToConsiderInManagingChronicPainFHIRv102.json (FHIR DSTU2 only) or FactorsToConsiderInManagingChronicPainFHIRv401.json (FHIR R4 only)	JavaScript Object Notation (JSON) representation of Factors to Consider in Managing Chronic Pain: A Pain Management Summary, specifying the necessary logic to query and return structured summary information pertaining to the relevant factors a clinician may consider when managing a patient's pain	Chris Moesel, David Winters, Sharon Sebastian
CDSConnectCommonsForFHIRv102.cql (FHIR DSTU2 only) or CDSConnectCommonsForFHIRv401.cql (FHIR R4 only)	Common CQL functions that may be called by CDS Connect artifacts	Julia Afeltra, Chris Moesel, David Winters
CDSConnectCommonsForFHIRv102.json (FHIR DSTU2 only) or CDSConnectCommonsForFHIRv401.json (FHIR R4 only)	JSON representation of common CQL functions that may be called by CDS Connect artifacts	Julia Afeltra, Chris Moesel, David Winters
FHIRHelpers.cql	Common CQL functions used to convert CQL data elements to FHIR and back again for FHIR DSTU2[15] and FHIR R4[15]	Bryn Rhodes
FHIRHelpers.json	JSON representation of common CQL functions used to convert CQL data elements to FHIR and back again	Bryn Rhodes

Library Relationship Diagram

The project team encourages CQL developers to refactor commonly used functions into separate software files called libraries.[16] The use of libraries allows better flexibility and reusability compared to placing all CDS logic into a single, unique file for that one artifact. **Figure 1** shows the relationships between this artifact's main library file and the two supporting libraries.

When implementing this artifact, ensure that all files listed in **Table 1** in the previous section are present and that the filenames have not been modified.

Figure 1. Artifact Relationship Diagram



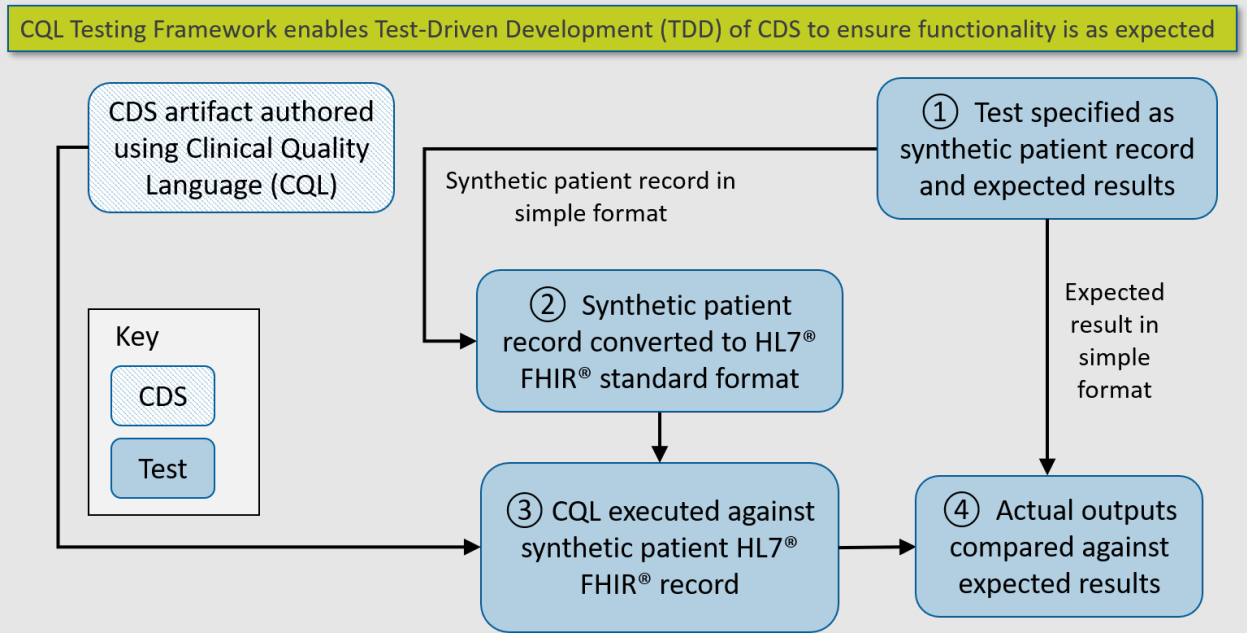
Artifact Testing

The project team developed the Factors to Consider in Managing Chronic Pain: A Pain Management Summary artifact using a test-driven development (TDD) approach.[17] TDD is important for development since it has been shown to produce software that is more robust and to contain fewer bugs.[14] With TDD, developers create a battery of test cases that define the expected functionality of the software, in this case the Pain Management Summary CQL. The project team leveraged an automated CQL testing framework developed under funding by AHRQ to enable the TDD approach for this artifact. Referred to as the "CQL Testing Framework," this tool accepts test cases specified in YAML Ain't Markup Language (YAML) files, executes the artifact against each test case, and reports the success or failure of each test case.[18]

The diagram in **Figure 2.** Testing Approach Diagram depicts the TDD approach using the CQL Testing Framework. In the first step, before any CQL is written, developers define at least one test that specifies both the input to the CQL and the desired output. When using the CQL Testing Framework, developers specify the test input in terms of a synthetic patient record containing the pertinent FHIR resources. For example, test input for the Pain Management Summary artifact might contain prescribed pain medications for the synthetic patient, which is one of the data

inputs used by the artifact. An example of the desired output might be that the CQL should list that medication in the appropriate section of the summary. Once developers have specified a test in this way, they update the artifact's CQL until the test passes, demonstrating that the CQL works appropriately in that specific case. The process continues as the developer iteratively creates tests and authors logic, line by line, and clinical concept by clinical concept. The author of the CQL may not proceed to writing or updating the next portion of the code until all existing tests pass.

Figure 2. Testing Approach Diagram



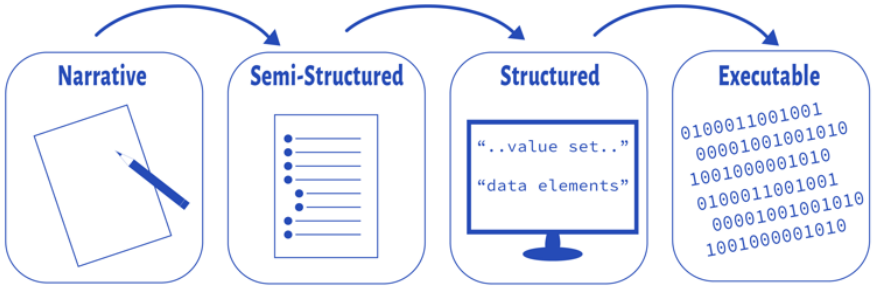
The development team created test cases to investigate efficacy for basic expected functionality and to test the expected inclusion criteria and results (the summary). The entire set of test data resides in zip files attached to the CDS artifact in the Repository. One zip file provides test cases in the FHIR DSTU2 format, while the other provides test cases in the FHIR R4 format. Implementers should review their organizational priorities and develop a similar testing framework (and test cases) prior to implementation in a production system.

Implementation Checklist

As noted in the Introduction, Boxwala et al. developed a multi-layered knowledge representation framework for structuring guideline recommendations as they are transformed into CDS artifacts (see **Figure 3** for a summary of the process).[1]

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

Figure 3. CDS Artifact Maturity Process



The CDS Connect team suggests the following "best practices" for including third-party CDS into an existing health IT system:

- Analyze the purpose, clinical statement, and use case sections of this document to ensure that your organization understands and agrees with the intended goals of the clinical guideline on which this artifact is based.
- Review the Guideline Interpretation and Clinical Decisions section of this document (including the cited Decision Log in Appendix A: Decision Log) to ensure that your organization understands and agrees with the decisions made during the process to convert the underlying clinical guideline to a structured, computable CDS artifact.
- Technical staff should read through each of the files in the artifact manifest to understand their respective purposes and how they can be successfully incorporated into a clinical IT system. At the time of publication, many commercial off-the-shelf EHR systems are unable to use CQL files natively and require a separate application to convert CQL code such that it can be used in those EHR systems. Implementers should work with vendors of their respective health IT products to understand their readiness to implement CQL code and any potential adverse impacts to existing functionality. In the pilot of this artifact, the CQL execution was embedded in a SMART on FHIR application, allowing for EHR integration via the standard SMART on FHIR API. In other pilot settings, developers have worked around existing EHR limitations by implementing a web service wrapper around a CQL execution engine. This is a nontrivial amount of work with two primary components:
    - A CQL execution engine with a Representational State Transfer (RESTful) web service designed to accept requests for CQL execution and to respond with the calculated results.

    - Modifications to the EHR system such that it will:
        - Trigger RESTful events to call the CQL execution engine.
        - Interpret the response.
        - Reflect the CQL-generated recommendations and suggested actions in the EHR user interface.
- After incorporation into a development environment, the artifact should be exhaustively tested by the implementer against predefined test cases. Additionally, testing by the implementer should be conducted to ensure that implementation of the artifact has no adverse effect on the processing efficiency of the health IT system.
- Documentation and training materials for clinical staff should be drafted and distributed. These training materials should include descriptions of modified functionality, directions for interacting with CDS rules (if different than in the current system), and contact information for assistance if functionality does not meet expectations.

Potential Reuse Scenarios

CQL code within this artifact was developed to display a Pain Management Summary, but there are portions of the CQL code that are expected to be useful for other purposes.

- The three libraries—CDSConnectCommonsForFHIRv102, CDSConnectCommonsForFHIRv401, and FHIRHelpers—included in the artifact define commonly used functions in CQL files and are not specific to the Pain Management Summary artifact. They may be used with any other CQL file that could benefit from those functions.
- Selected code blocks from the Pain Management Summary could be copied and reused in other CQL files. For example, some might be interested in reusing the logic to query across multiple resource types to gather relevant opioid-related risk factors.

Integration with the Health Information Technology

The Pain Management Summary artifact provides relevant information to consider when managing a patient's pain. The information is presented to the clinician as a Pain Management Summary, implemented as a web-based SMART on FHIR application. The application serves as a CQL integration engine to enable integration of the CQL logic and results with an EHR (such as Epic and Cerner) via the SMART on FHIR API. Implementers should work with their EHR vendor to determine the steps necessary to register and integrate a SMART on FHIR application within their EHR. Technical details regarding the SMART on FHIR API can be found on the SMART Health IT website.

Taking steps to ensure accessibility by the widest range of users, an accessibility subject matter expert performed a review of the application, enumerated issues found, and provided recommended remediations. In addition to the recommendations, the Mozilla ARIA Accessibility (https://developer.mozilla.org/en-US/docs/Web/Accessibility/ARIA) reference was used to address issues. The application was then manually tested using accessibility tools including JAWS, VoiceOver, and the WebAIM Contrast Checker (https://webaim.org/resources/contrastchecker/).

The specific method used to invoke the Pain Management Summary CDS and present the SMART on FHIR application is dependent on implementation decisions made at each site. For the initial pilot of this artifact, the site elected to invoke the Pain Management Summary CDS when a clinician clicks on a "Pain Summary Information" link found within a specific patient record in the EHR.

As discussed previously, the logic used to query and return data for the Pain Management Summary is expressed in the CQL. However, it is important to note that the CQL code does not enact any alerts and/or notifications to reinforce specific CDC guidelines, potential contraindications, or patient safety warnings related to the data that are displayed. Instead, rules were embedded in the SMART on FHIR application to enact notifications displayed as flags, counts, and additional information to further contextual awareness of where a CDC recommendation statement intersects with the displayed data. Future implementers may opt to include the notifications in the CQL; others may opt to expand the notifications in the app. Iterations will likely be informed by capabilities, modules, and the user interface of the EHR, among many other considerations. **Figure 4** displays the first portion of a populated Pain Management Summary. The alert flags display as an exclamation point within a red circle to alert the clinician to an entry of potential concern based on the CDC guidelines. The Pain Management Summary can be navigated by scrolling or via the navigation shortcuts on the left-hand side of the page.

Figure 4. Pain Management Summary – Header and Pertinent Medical History

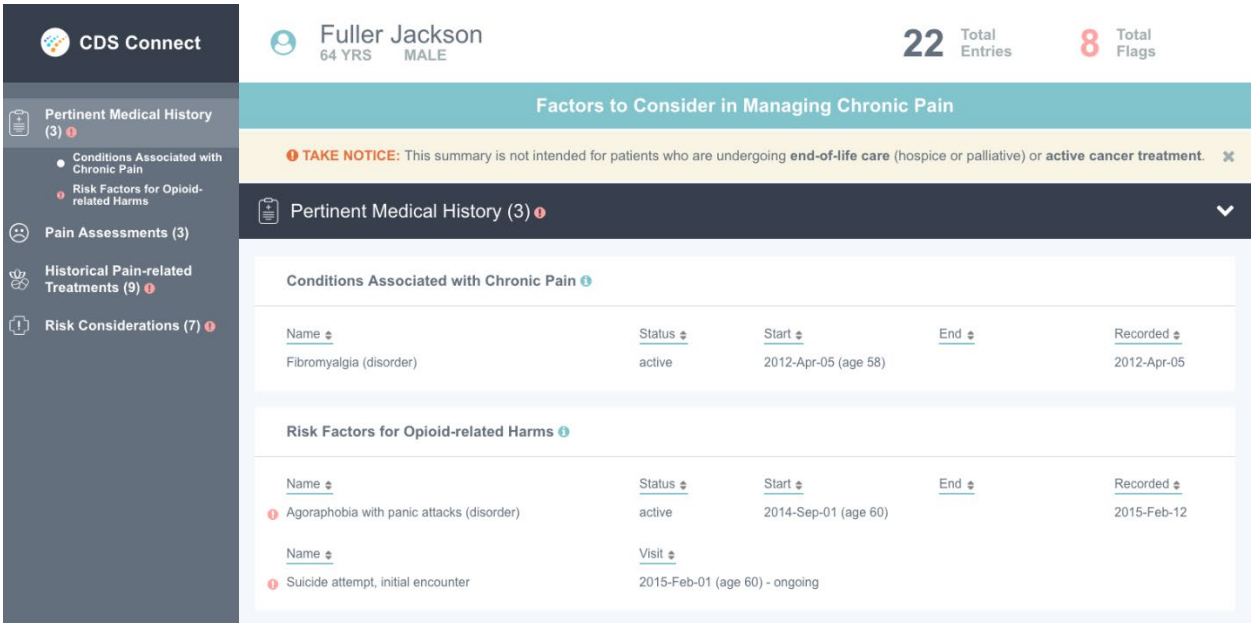


Figure 5 displays a list of the flags implemented in the SMART on FHIR app, along with the description of the flag logic.

Figure 5. Pain Management Summary Flags

Pain Management Summary Flags

Pertinent Medical History

- Risk factors for Opioid-related Harms: Always flag if any are present (Depression, Anxiety, Substance Use Disorder, Suicide attempt, Sleep-disordered breathing, Renal dysfunction, Hepatic dysfunction, Pregnancy, 65 years or older).

Pain Assessments

- No flags

Historical Treatments

- Opioid Medications: Flag if present.
- Non-opioid Medications: Flag if NONE.
- Non-pharmacologic Treatments: Flag if NONE.
- Stool Softeners and Laxatives: Flag if not present AND at least one opioid medication is present.

Risk Factors and Assessments

- †Most Recent MME: Flag if MME is greater than or equal to 50.
- Urine Drug Screens: Flag if not present AND at least one opioid medication is present.
- Benzodiazepine Medications: Flag if present AND at least one opioid medication; Flag if present (each flag has a different message).
- Naloxone Medications: Flag if not present AND most recent MME is 50+MME/day; Flag if present (each flag has a different message).

Additional information provided by the SMART on FHIR application user interface includes the following:

- Counts: Indicates the number of patient clinical entries, as well as flagged entries.
- Tooltips: Provide additional information about why the entry was flagged.
- Information icons: Provide information on what data were pulled to populate the summary and references.
- Uniform Resource Locators (URLs): Provide links to guidelines and additional references.

Open source code for the SMART on FHIR app is located on GitHub via the following URL: https://github.com/AHRQ-CDS/AHRQ-CDS-PAIN-MANAGEMENT-SUMMARY.

Appendix A: Decision Log

Artifact Semistructured Logic

This artifact specifies inclusion criteria that outlines when the Pain Management Summary should be populated and displayed. The semistructured logic criteria are as follows:

Age >= 18 years

AND

Conditions associated with chronic pain (confirmed, active or recurring status, onset date, asserted date, abatement date)

OR Opioid pain medication

Orders (date, active, completed, or stopped within the past 180 days)

Statements (date, active, or completed within the past 180 days)

OR Adjuvant analgesic medication

Orders (date, active, completed, or stopped within the past 180 days)

Statements (date, active, or completed within the past 180 days)

If a patient meets this logic criteria, the Pain Management Summary CDS 1) displays a link to the CDC Guideline for Prescribing Opioids for Chronic Pain (i.e., https://www.cdc.gov/mmwr/volumes/65/rr/rr6501e1.htm), 2) displays a "notice header" (i.e., TAKE NOTICE: This summary is not intended for patients who are undergoing end-of-life care (hospice or palliative) or active cancer treatment."), and 3) populates and displays the Pain Management Summary with the following:

Pertinent Medical History (unrestricted lookback):

- Conditions associated with chronic pain (confirmed, active or recurring status, onset date, asserted date, abatement date)
- Risk factors for opioid-related harm
  - Risk Conditions (represented by a union of value sets) – (confirmed, active or recurring, onset date, asserted date, abatement date)

    - Encounter Risk Diagnosis (represented by a union of value sets) – (name, visit date, onset date, abatement date, and recorded date)
    - Pregnancy Diagnosis or Observation in the past 42 weeks
    - Age >= 65 years

Pain Assessments (lookback of 2 years):

- Wong-Baker FACES Assessment (score, interpretation, date)
- PEG Assessment (question response and total score, date)
- STarT Back Screening Tool (total score, date)

Historical Treatments (lookback of 2 years for all except stool softeners, which is 6 months):

- Opioid pain medication
    - Orders (date, active, completed, or stopped)
    - Statements (date, active, or completed)
- Nonopioid pain medication
    - Orders (date, active, completed, or stopped)
    - Statements (date, active, or completed)
- Nonpharmacologic treatment
    - Orders (date, accepted, in progress, or completed)
    - Referrals (date)
- Stool softener and laxative
    - Orders (date, active, completed, or stopped)
    - Statements (date, active, or completed)

Risk Considerations:

- Age >= 65 years

- MME calculation (most recent, verified, value [as quantity], date in past 6 months)
- Urine drug screen (verified, result, interpretation, date in past 12 months)
- Benzodiazepine medication
  - Orders (date, active, completed, or stopped)
  - Statements (date, active, or completed)
- Naloxone medication
  - Orders (date, active, completed, or stopped)
  - Statements (date, active, or completed)
- Risk assessments relevant to pain management (represented by a value set) – (total score, range, interpretation, date in the 12 months)
  - Verified "single question related to alcohol use" Observation
  - Verified "single question related to drug use" Observation

It is important for implementers and clinicians to understand that this CDS presents a summary of several pertinent clinical and psychosocial factors to consider when managing pain and considering opioids. Data populated in the summary may reveal contraindications to opioid therapy. At present, the CQL does not provide alerts and/or notifications to reinforce the contraindications. Instead, the notifications (via flags generated by coded rules) are embedded in the SMART on FHIR app used to integrate the CQL with the pilot site EHR. Future implementers of this artifact may choose to include alerts reinforcing specific CDC or other authoritative entity guidelines directly into the CQL code based on available templates and modules in the EHR. Clinician training is imperative so they have the knowledge and resources to interpret and act upon the summary data (e.g., modify benzodiazepine medications and/or opioid medications so they are not administered simultaneously).

Concept Definitions from the Semistructured Logic

Table 2 provides definitions of many of the terms used in the semistructured representation of the CDS logic to ensure clarity and provide awareness of how and why each data element was defined as they are.

Table 2. Semistructured Logic Concept Definitions

Location in CDS Logic	Concept	Definition and/or Rationale
Inclusion, Intervention	“conditions”	Diagnoses.
Inclusion, Intervention	“Conditions associated with chronic pain”	List of diagnoses that often cause or imply chronic pain. The list was informed by peer-reviewed research (i.e., “Using Electronic Health Records to identify patients with chronic pain in a primary care setting” by Tian, T. Y., Zlateva, I & Anderson, D. R. in 2013. Accessible at https://www.ncbi.nlm.nih.gov/pubmed/23904323).
Inclusion, Intervention	“medication”	A drug or other substance used to treat disease or injury; a medicine.
Inclusion, Intervention	“orders”	A prescription by a physician, dentist, nurse practitioner, or other designated health professional for a medication, treatment, procedure, etc.
Inclusion, Intervention	“statement”	Verbal acknowledgment by the patient. A statement could be related to a treatment, whether it was ordered by a different provider or initiated by the patient independently (e.g., “I take ibuprofen 600 mg every 6 hours as needed for pain”).
Inclusion	“Past 180 days”	Occurring within 180 calendar days of the CDS trigger (e.g., clicking on the link to the Pain Management Summary CDS). Note: This concept is expressed as a parameter in the CQL code so future implementers can adjust the time, if preferred.
Inclusion, Intervention	“Opioid pain medication”	Opiate and opioid medication classes derived from descendants of the following terms “opioids,” “opioid analgesics,” “opioid agonist,” “narcotics,” and “analgesics, opioids.”
Inclusion	“Adjuvant analgesic medication”	Nonopioid medications that have a primary indication for chronic pain. Medications that have a primary indication for a “nonpain” condition, but are occasionally used to treat pain, are not included (e.g., serotonin-norepinephrine reuptake inhibitors for depression). This constrained definition of a nonopioid pain medication is intended to populate the summary for the most appropriate group of individuals.
Intervention	“Pertinent Medical History”	Category heading in the summary that provides context to the listed conditions (whether that be conditions associated with pain or conditions that may complicate or impact pain treatment).

Location in CDS Logic	Concept	Definition and/or Rationale
Intervention	“Risk factors”	A medication, calculation, assessment result, lab result, etc., that elevates the degree of danger or harm to an individual.
Intervention	“Risk factors for opioid-related harms”	Health conditions (along with age > 65) that may elevate the level of risk for harm to a patient if an opioid is prescribed. The conditions include depression, anxiety, substance use disorder, suicide attempt, sleep-disordered breathing, renal dysfunction, hepatic dysfunction, and pregnancy. This list is outlined in the CDC guidelines as an outcome of evidence-based research. Each condition is represented by a distinct value set. The object identifier for each value set is included in the CQL code.
Intervention	“Date of onset”	Date of diagnosis. This is a challenging data concept to accurately evaluate due to the way it is captured in EHRs (i.e., the date displayed in a patient record is often the date that is it entered in the EHR). Most clinicians are aware of this limitation, but it should be reinforced during pilot training.
Intervention	“Pain Assessment”	Category heading in the summary that groups together pain intensity and multidimensional assessment scores. A lookback of 2 years enables the provider to determine trends over time and the effectiveness of previous treatments. **Note:** Each of the three pain assessments listed in the next three rows are expressed individually in the CQL code as direct reference codes (as opposed to being expressed as a group of standardized codes in a value set) because the PEG and STarT Back tools were not represented by Logical Observation Identifiers Names and Codes (LOINC) codes when this CDS was originally created. A much larger number of evidence-based pain assessments could have been included in this section, had they been represented by LOINC codes. The assessments below were selected because they are available in the pilot site’s EHR and clinicians at the pilot location utilize the three assessments.
Intervention	“Wong-Baker FACES Assessment”	A pain intensity rating tool that enables patients to quantify the intensity of their pain. The score is usually reported on a scale of 0 – 10.
Intervention	“Pain Enjoyment General Activity (PEG) Assessment”	A multi-dimensional tool that enables patients to quantify their average pain intensity, and the degree to which pain interferes with enjoyment of life and general activity. Since ratings for each of these components is informative to managing pain, the CQL queries for the response to each question, along with the total score.

Location in CDS Logic	Concept	Definition and/or Rationale
Intervention	"STarT Back Screening Tool"	A multidimensional tool that assesses and screens primary care patients with low back pain using nine questions. Since displaying the response to all nine questions would have taken up too much space in the summary presentation, only the final score is included in the CQL query.
Intervention	"Historical treatments"	Category heading in the summary that lists pharmacologic and nonpharmacologic pain treatments, along with stool softeners and laxatives (which are often required to manage constipation if a patient is on long-term opioid therapy). A lookback of 2 years for pain treatments provides reference information that can be evaluated against pain ratings to determine the effectiveness of treatment. A lookback of 6 months for the stool softeners and laxatives was considered adequate to provide information on the patient's recent constipation treatments.
Intervention	"Nonopioid medications"	Medications with analgesic effects that may provide therapeutic benefit in treating chronic pain (including aspirin, acetaminophen, nonsteroidal anti-inflammatory drugs, anticonvulsants, antidepressants, muscle relaxants, and topical analgesics)
Intervention	"Nonpharmacologic treatments"	Nonmedication procedures and therapies employed to treat pain (e.g., physical therapy, massage, yoga, acupuncture). Treatments included in this value set were compiled from pain management systematic reviews. **Note:** It is often challenging to query for these types of treatments in a patient record, since they are usually captured as unstructured "free text." Additionally, patients may seek self-treatment, which may not be entered into the patient's record. Despite these limitations, this is an important concept (e.g., it should often be the first line of treatment); therefore, all available nonpharmacologic treatments should be displayed.
Intervention	"Referrals"	A way to direct a patient to specialized care (e.g., a pain management specialist or counseling). This was added to the logic as an additional way to identify treatments not captured as an order.
Intervention	"Stool softeners and laxatives"	Although the CDC guidelines do not offer guidance on managing constipation (a common side effect of opioid therapy), these medications were included in the summary because they are relevant to managing pain and treatment selection.

Location in CDS Logic	Concept	Definition and/or Rationale
Intervention	“Risk Considerations”	A contextual category that lists additional risks not expressed in the “Risk factors for opioid-related harm” value set. Concepts in this category include: MME amount, urine drug screen results, evidence of benzodiazepine or naloxone medications, and risk assessment results. These items were informed by the CDC guideline and should be considered by the clinician prior to making a pain management decision (e.g., the patient is already receiving 50 MMEs/day; the patient has a positive urine screen for an opioid that was not ordered by the clinical practice where they are being seen).
Intervention	“MME”	The total amount of MMEs (in mg) that the patient is receiving in 1 day. This is calculated by determining the total daily amount of each opioid the patient takes, converting each medication to MMEs, and adding the amounts together. Ideally, this would include medications prescribed outside of the primary care setting where the patient is being seen. It is important for clinicians to know whether the calculated amount is based upon prescriptions from their practice only, or includes opioids prescribed from other providers. The CQL queries for the “most recent” calculated amount. **Note:** The CQL does not include a coded algorithm to calculate MMEs. Instead, it queries the patient record for the calculated amount (i.e., the EHR must have a calculator embedded in the system that stores the amount in a discrete field). In addition, there is not a LOINC code to express MME; therefore, a local code (unique to the EHR in which it was implemented) was used. For CDS that calculates MME, see the following resource available on the CDS Connect Repository: https://cds.ahrq.gov/cdsconnect/artifact/recommendation-5-lowest-effective-dose.
Intervention	“Urine drug screens”	Per the CDC guidelines, a urine drug screen should be conducted before initiating opioid therapy and at least once/year when prescribing long-term opioid therapy to evaluate for the risk of misuse or opioid-related harms. Standardized codes in this value set evaluate for adherence to prescribed therapy, diversion of prescribed medications, and misuse of illicit or prescribed medications in the context of chronic pain management. The lookback period is expressed as 1 year to align with the recommendation.
Intervention	“Benzodiazepine medications”	Per CDC guideline information and U.S. Food and Drug Administration guidance, opioids should not be prescribed if a patient is on a benzodiazepine medication since it may further depress the central nervous system, potentially leading to life threatening symptoms. The CQL looks back 2 years for evidence of a benzodiazepine to provide historical perspective.

Location in CDS Logic	Concept	Definition and/or Rationale
Intervention	"Naloxone medications"	Medications used to reverse the toxic effects of opioid overdose. Evidence of a naloxone medication in the past indicates potential misuse of an opioid or a history of receiving a high MME dosage. Awareness of the presence or absence (in some cases) of these meds is important when considering opioid therapy; therefore, the lookback period is unrestricted.
Intervention	"Risk assessments relevant to pain management"	A variety of risk assessment tools that evaluate for factors that may convey opioid-related harms (e.g., depression and anxiety screening, the risk of opioid misuse). The CQL queries for the result of all assessments completed in the past year.

Artifact Development Decision Log

Decisions were made by the Artifact Development Team while translating the CDC clinical practice guideline and developing the structured representation of this artifact. **Table 3** provides insight on those decisions, along with where the coded representation might be expanded in the future.

Table 3. Artifact Development Decision Log

Decision Category	Concept	Rationale
Add explanation	Revisions to the guidelines	The CDC released draft updates to the 2016 guidelines on February 10, 2022. After 60 days of public comment, the CDC will begin the process to finalize the updated guidelines which are expected to be released by the end of 2022. Readers can follow the process at: https://www.cdc.gov/opioids/guideline-update/index.html.

Decision Category	Concept	Rationale
Inclusion logic/ Disambiguate	Acute versus chronic pain	Although the clinical data and notifications displayed in the summary may be informative for a broader a set of patients than expressed in the inclusion logic (e.g., individuals with acute pain), the “Conditions associated with chronic pain” value set was included in the logic to align more closely to the CDC opioid prescribing guidelines and populate the summary for the most relevant group of patients. Future implementers may choose to remove this criterion or expand the inclusion logic.
Inclusion logic/ Verify completeness	Age >= 18 years old	The CDC guidelines apply to individuals over the age of 18 years old, based on researched evidence. Although earlier versions of the logic did not exclude younger patients, the age requirement was added after CDC guideline stewards counseled for exact alignment on this concept. Future implementers should be aware that expanding the age may not align with the evidence base for any contextual notifications that are enabled in the user interface of this summary.
Inclusion logic/ Verify completeness	Active cancer treatment, palliative care, end-of-life care	The CDC guidelines do not apply to individuals undergoing active cancer treatment or receiving palliative care/end-of-life care/hospice care since these individuals may appropriately require high-dose opioid therapy to manage pain. Please note that these concepts are not expressed in the CQL because the availability of this data in a structured format in a primary care setting EHR is very low, thus impacting the ability to present information that a provider can rely upon as complete. After consultation with CDC guideline stewards, MITRE decided to display a notification at the top of the summary display in the SMART on FHIR app that serves as the CQL engine, which reads: “TAKE NOTICE: This summary is not intended for patients receiving end-of-life care or cancer treatment.” In addition, this approach was discussed with pilot site clinicians during training, so they clearly understood the context of the notice and the CDC guideline.
Standards limitation/Map terminology	Use of local codes for clinical concepts	MITRE identified a gap in the availability of LOINC codes to represent frequently used evidence-based pain and risk assessment questions, tools, and scores. As a result, local codes were initially used for many of these concepts. MITRE submitted applications in 2018 to have all aspects of the PEG and STarT Back tools represented by LOINC codes and updated the CQL code in 2020 to include the new LOINC codes for these tools. As LOINC codes become available for additional concepts, future implementers may want to consider developing a value set to express these concepts. As of April 2020, MME is still expressed using a local code since a standardized (i.e., LOINC) code is not yet available for this concept.

Decision Category	Concept	Rationale
Data limitations	Encounters	Some risk factors for opioid-related harms may exist only as encounter diagnoses (as opposed to entries on a problem list). For this reason, the CQL logic queries encounters for the presence of these diagnoses. Some EHRs do not yet support retrieval of encounters via the FHIR API, and as a result, these encounter diagnoses will be missed. In the pilot of this artifact, the piloting organization worked around this issue by implementing custom code to extend its EHR's FHIR API to support encounters.
Data limitations	Assessments and Screenings	Much of the data in the Pain Management Summary is comprised of assessments and screenings (i.e., Wong-Baker Family Adaptability and Cohesion Scale [FACES]; Pain, Employment, General Activity [PEG]; Patient Health Questionnaire [PHQ-9]). Many EHRs, however, do not yet support returning assessments and screenings via the FHIR API. As a result, these critical data may be missing from the Pain Management Summary when using only “out-of-the-box” FHIR functionality in EHRs. In the pilot of this artifact, the piloting organization worked around this issue by implementing custom code to extend its EHR's FHIR API to support returning assessments and screenings as FHIR Observations.
Data limitations	Goals	Patient goals related to their pain should inform every decision while managing pain. Ideally, patient goals would have been expressed in the CQL and prominently displayed in the user interface of the summary; however, patient goals are rarely captured in a structured format, and often goals are not “tied” to a specific condition in the patient record (potentially causing query results to be outside the context required). This concept was not expressed in the CQL since this information was not available in a discrete field of the pilot site’s EHR, and a LOINC code to represent a pain goal has not yet been created. Inclusion of patient-reported goals would be a valuable enhancement to this artifact in the future for sites that record goal-related responses in a structured format.
Technical limitations	PDMP	Integration of PDMP data would be valuable and ideal to include in this summary; however, this would have required a significant amount of coding that was unique to the EHR and the pilot site’s implementation, involved legal and security approvals, and needed a significant amount of time to develop. Therefore, this was deemed outside the scope of this artifact. Because cross-state PDMP data expand and EHRs provide integrated access to PDMP databases, inclusion of these data should strongly be considered for future iterations of this artifact.

Decision Category	Concept	Rationale
Verify completeness	Value set creation	Thirteen new value sets were created during the development of this artifact. Many are very robust and may ultimately need revision (e.g., the urine drug screen value set includes over 1,200 LOINC codes). Future implementers may want to compare how the required data are captured in their EHR to the codes in each value set and either edit the value set or just use a subset of the codes. In the 2021 update, three robust literature reviews commissioned by AHRQ covering opioid medication for chronic pain, nonopioid medication, and nonpharmacologic therapies were reviewed. Based on new findings from those reviews, all value sets were reviewed and updated to include new medications, lab tests, and one additional risk scale. In addition, please be aware that the medication value sets were developed to query for all medications in the desired class, as opposed to only those that are legal to prescribe in the United States. They may need to be adjusted to support other use cases (e.g., integration with Computerized Prescription Order Entry systems in the United S. to generate an order set).
Adapt CDS to a local EHR	Wong-Baker FACES Assessment	The pilot organization's EHR accepted a numeric pain intensity response of 0 – 5, as opposed to 0 – 10 (the published range); therefore, a unique branch of the CQL was created for the pilot only.

Appendix B: References

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