CDS Artifact Enhancement Based on Pilot Implementation

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

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Introduction

The Agency for Healthcare Research and Quality (AHRQ) has elected to sponsor the Clinical Decision Support (CDS) Connect project to generate a systematic and replicable process for transforming patient-centered outcomes research (PCOR) findings into shareable and standards-based CDS artifacts. A CDS artifact is the template for defining how decision support is provided for a given clinical situation, often including triggers, logic, operations, interventions, and supporting evidence. The CDS Connect Repository was created to host and share CDS artifacts, and the CDS Authoring Tool enables CDS developers to create CDS using a standard expression language and terminologies. Both systems contribute to AHRQ's mission of advancing evidence-based research into clinical practice using CDS artifacts, ultimately integrated with a clinical site's electronic healthcare record (EHR).

Background

CDS specifications undergo numerous iterations from the moment an artifact is conceived through development, integration, testing, and implementation of the CDS in a clinical environment. Iterations and enhancements are key to the artifact's use and effectiveness. This document outlines changes made to the semi-structured and structured representations of the *Factors to Consider When Managing Chronic Pain: A Pain Management Summary* CDS artifact (hereinafter, Pain Management Summary or Summary), during engagement with Oregon Community Health Information Network (OCHIN), the organization that piloted the artifact.

OCHIN is one of the largest health information and innovation networks in the United States, serving hundreds of organizations by delivering health information technology support and services[1]. From March 2018 through August 2018, MITRE and OCHIN partnered on the implementation of the Pain Management Summary CDS in OCHIN's Epic EHR environment. Both organizations collaborated on refinements to the CDS during every stage of the partnership to improve the accuracy and usefulness of the CDS. Changes were made based on:

- subject matter expert (SME) feedback
- organizational initiatives, process, and policy
- data structure and availability
- technical findings
- integration constraints
- test results
- clinician feedback.

Details in this document were recorded to provide transparency on the fine-tuning required to implement CDS specifications in a clinic site's EHR. CDS developers working to express similar

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[1] We are OCHIN. About Us. Accessed on August 8, 2018 at: https://ochin.org/about-us/.

clinical concepts may find this information instructive, and future "implementers" may value the breakdown by data element and logic specification to pinpoint where they might like to adjust or enhance the artifact further.

Revisions and improvements to the CDS specifications are outlined in the **Artifact Enhancement** section of the document.

Scope

This document catalogs all enhancements made to the clinical quality language (CQL) code during the pilot partnership. It does *not* include enhancements to the CQL integration engine (i.e., the Substitutable Medical Applications, Reusable Technologies [SMART] on Fast Healthcare Interoperability Resources [FHIR] application), which also enabled the user interface (UI) for the CDS. The CDS Connect Pilot Report provides detailed information with regards to the CQL integration engine.

Initial Definition of the Pain Management Summary Artifact
Description and Purpose of the Artifact

The Pain Management Summary artifact provides relevant information to consider when managing a patient's pain; not only eliminating the need to navigate to and from the problem list, medication list, lab results, etc., for information, but also filtering all the entries in a patient record to only display concepts related to pain management. The populated 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 non-opioid and/or non-pharmacologic treatment when possible.

Initial Semi-Structured Representation of the CDS Logic

Development of the Summary CDS was informed by the Centers for Disease Control and Prevention (CDC) *Guideline for Opioid Prescribing for Chronic Pain*. The CDS is not a direct representation of any one recommendation statement within the guideline. Instead, the CDS compiles clinical concepts mentioned throughout the guideline in one consolidated view (i.e., the Summary) for clinician review. The CDS was developed by a multi-disciplinary team of clinicians, informaticists, and engineers. At no point during the life cycle of the CDS were rules included in the CQL to provide guidance on how to act upon the compiled information (e.g., alerts). Effective use of the CDS requires clinician training on the CDC guidelines, the scope of the CDS, and where clinical judgement is required.

Table 1 outlines the initial representation of the inclusion and exclusion logic, and Table 2 outlines the initial representation of the interventions generated by the CDS code.

Table 1. Initial semi-structured inclusion and exclusion logic

Inclusions	Exclusions

• Conditions associated with chronic pain (confirmed, active or recurring status, onset date)
 	
• OR Opioid pain medication
    ○ *Orders (active, completed, or stopped within past 180 days)*
    ○ *Statements (active or completed within past 180 days)*
 	
• OR Non-opioid pain medication
    ○ *Orders (active, completed, or stopped within past 180 days)*
    ○ *Statements (active or completed within past 180 days)*
	None.

Table 2. Initial semi-*s*tructured CDS intervention logic

POPULATE Pain Management Summary
Pertinent Medical History (unrestricted lookback): • Conditions associated with chronic pain (confirmed, active or recurring status, onset date)
Pain Assessments (lookback of 2 years): • Wong-Baker FACES Assessment (score, interpretation, date) • Pain Enjoyment General Activity (PEG) Assessment *(total score, interpretation, date)*

Historical Treatments (lookback of 2 years):
 	
• Opioid pain medication
    ○ *Orders (date, active, completed, or stopped within past 180 days)*
    ○ *Statements (date, active, or completed within past 180 days)*
 	
• Non-opioid pain medication
    ○ *Orders (date, active, completed, or stopped within past 180 days)*
    ○ *Statements (date, active, or completed within past 180 days)*
 	
• Non-pharmacologic treatment
    ○ *Orders (date, accepted, in progress, or completed)*

POPULATE Pain Management Summary

Risk Considerations:
 	
• Morphine milligram equivalent (MME) calculation (most recent, verified, value [as quantity], date in past 6 months)
 	
• Urine drug screen (verified, result, interpretation, date in past 1 year)
 	
• Benzodiazepines medication
    ○ *Orders (date, active, completed, or stopped in the past 2 years)*
    ○ *Statements (date, active, or completed in the past 2 years)*
 	
• Naloxone medication
    ○ *Orders (date, active, completed, or stopped)*
    ○ *Statements (date, active, or completed)*
 	
• Risk assessments relevant to pain management (total score, range, interpretation, date in past 6 months)

DISPLAY link to the *CDC Guideline for Opioid Prescribing for Chronic Pain*

Artifact Enhancements

The Pain Management Summary specifications were enhanced by the MITRE team at three different points of the pilot partnership. Changes occurred during the "planning," "integration," and "testing" stages of the pilot. Each set of enhancements led to a richer, more informed and effective artifact. This section of the report outlines the list of changes made to the logic.

Enhancements Made During Pilot Planning Sessions

Implementation of CDS in a clinical setting requires a significant amount of planning and coordination—especially when the CDS was developed outside the clinical organization where it is piloted. Vendor systems vary in the structured fields that they offer, and documentation practices vary by clinical site. Each implementation instance is bound to require small adjustments to the coded logic to accommodate these differences.

The changes in this section resulted from discussions attended by clinicians, informaticists, engineers, data analysts, and SMEs from CDC, OCHIN, and MITRE, during which the intent of the CDS, the logic, and each data requirement was thoroughly examined in comparison to how the data is captured in OCHIN's system and provider workflow in a primary care encounter.

Enhancements Informed by CDC Knowledge Stewards and OCHIN Clinicians and System Engineers

Since UI display of the Summary CDS via the SMART on FHIR app incorporates "flags" to draw the clinician's eye to entries of concern based upon CDC recommendations, the CDC knowledge stewards urged alignment to components of their guidelines that were not formerly expressed in the CDS logic to ensure accurate translation of their evidence. The clinical concepts, concerns, enhancements, and commentary are outlined in Table 3.

Table 3. Enhancements made to align with the CDC guideline

Clinical Concept	Concern and Enhancement	Comments
Age >=18 years (Inclusion logic)	The CDC guideline explicitly states that it applies to patients aged >= 18 years. Applying the recommendations outside that population is not evidence-based. **Implementation Decision:** Add to logic statement.	The MITRE team chose to implement this criteria in the inclusion logic (i.e., >=18 years old), as opposed to the exclusion logic (e.g., < 18 years old), since there are no other exclusion statements in the logic.
End-of-life care (Exclusion potential)	The CDC guideline does not apply to patients receiving end-of-life care (also described as hospice care and palliative care). **Implementation Decision:** Display a Notice at the top of the summary that reminds clinicians that the CDS does not apply to individuals undergoing end-of-life care and ensure proper training regarding this Notice. *The Notice reads: "Take Notice: This summary is not intended for patients who are undergoing end-of-life care (hospice or palliative) or active cancer treatment."*	This concept was considered as a potential exclusion; however, system engineers and clinicians at the pilot site conveyed that evidence of this care (e.g., performed care, an order, or referral) is not routinely available in their system. Therefore, including the concept in CDS logic would likely generate interventions that are not appropriate for the patient. With CDC agreement, the cross-organizational team determined that displaying a Notice in the heading of the summary was the best way forward.

Clinical Concept	Concern and Enhancement	Comments
Active cancer treatment (Exclusion potential)	The CDC guideline does not apply to patients receiving active cancer treatment. **Implementation Decision:** Display a Notice at the top of the summary that reminds clinicians that the CDS does not apply to individuals undergoing end-of-life care and ensure proper training regarding this Notice. *The Notice reads: "Take Notice: This summary is not intended for patients who are undergoing end-of-life care (hospice or palliative) or active cancer treatment."*	This concept was considered as a potential exclusion; however, system engineers and clinicians at the pilot site conveyed that evidence of active cancer treatment (e.g., completed treatments, an order for cancer treatment) is not available in their system. Including "active cancer treatment" in the logic might generate inappropriate interventions for the patient since the logic cannot evaluate data captured at clinical sites outside of the pilot organization. With CDC agreement, the cross-organizational team determined that displaying a Notice in the heading of the summary was the best way forward.
Risk factors for opioid-related harms (Intervention logic)	Several CDC recommendations include the need to evaluate for risk factors prior to initiating opioid therapy. Risk factors outlined in the guideline include: depression, anxiety, substance use disorder, suicide attempt, sleep-disordered breathing, renal dysfunction, hepatic dysfunction, pregnancy, age >=65. Including evidence of this information in the Summary would provide great value, since prescribing opioids to these individuals could increase their risk for harm. **Implementation Decision:** Add to the intervention logic.	MITRE chose to incorporate these concepts in the following way: • A new data element was added to the intervention logic (i.e., risk factors for opioid-related harms) • The data element was expressed as a union of value sets defining each of the Conditions (e.g., depression, anxiety), with additional logic to express age >=65. • This new data element was added to the Pertinent Medical History category of the Summary.

In addition, the CDC program office responsible for the guideline suggested including a list of stool softeners and laxatives in the Historical Treatment section of the Summary to assist clinicians in managing constipation, a common side effect of opioid therapy. OCHIN concurred with this suggestion, and MITRE added logic to express this concept and display the results to the Historical Treatment section of the CDS.

Many refinements were made to the CDS logic and coded expression of clinical concepts during planning sessions held at the outset of pilot collaboration. The clinical concepts, concerns, and rationale for CDS specification changes are outlined below in Table 4.

Table 4. Enhancements made in collaboration with the pilot site

Clinical Concept	Concern and Enhancement	Comments
Add "asserted date" and "abatement date" elements to all Conditions (Inclusion and intervention logic)	The CDS logic originally queried for and displayed the "onset date" for all Conditions; however, often the "onset date" reflects the date the Condition was *entered* in to the patient record, as opposed to the date the patient was *diagnosed* with a Condition. Adding the "asserted date" (i.e., recorded date) provides context to the "onset date." "Abatement date" was included as additional information and to balance the UI in the SMART on FHIR app across all the data elements. **Implementation Decision:** Add the "asserted date" and "abatement date" to logic statements.	Accurate, structured capture of the diagnosis date is a common constraint across many healthcare organizations and EHR implementations. The "onset date" does not routinely reflect the date of diagnosis. Note: The MITRE team used the "proper" FHIR element as described in this section but renamed each element in the SMART on FHIR app UI to provide clarity for providers. As such: • The CQL specifies "onset date," but the app displays "Start Date." • The CQL specifies "asserted date," but the app displays "Date Recorded." • The CQL specifies "abatement date," but the app displays "Stop Date."

Clinical Concept	Concern and Enhancement	Comments
Adjuvant analgesic medications (Inclusion logic)	The "Non-opioid pain medication" data element in the inclusion logic may be too broad since it includes medications used as primary *and* secondary treatments for pain (e.g., anti-convulsant and anti-depressant medications in addition to analgesics). **Implementation Decision:** The "Non-opioid pain medication" value set was replaced with the "Adjuvant analgesic medications" value set to constrain results to patients receiving a medication for the *primary* treatment of pain.	This was a subjective decision that weighed populating the Summary for as many patients with chronic pain as possible, while not populating the Summary for individuals who might be experiencing very mild, acute pain. Future implementers may choose to refine the logic to best serve their providers and patient population.
Lookback of 180 days (Inclusion criteria)	The expression was included to define how far back the logic should look for evidence of an opioid or adjuvant analgesic medication (otherwise *any* evidence of a medication in the past would have qualified the patient). **Implementation Decision:** OCHIN concurred with the 180-day lookback period; however, this concept was expressed as a parameter, so subsequent implementers could adjust the period as needed.	This was another subjective decision that allowed a reasonable number of patients to evaluate positively against the logic. Provider feedback after the pilot may inform potential adjustments to this lookback period moving forward (e.g., include duration of the prescription in the logic, along with the lookback).
Evaluate Encounter diagnosis as a secondary way of capturing "Risk factors for opioid-related harms" Conditions (Intervention logic)	OCHIN staff mentioned some Conditions listed in the "Risk factors for opioid-related harms" data element may be best captured as an encounter diagnosis. **Implementation Decision:** Add logic to evaluate for evidence of encounter diagnosis for "Risk factor" Conditions also and include "visit date."	This ensured that all relevant data was populated in the Summary. This addition may not be necessary in other healthcare settings. Note: "onset date," "abatement date," and "recorded dates" are included in the result structure of this concept, but are always empty since encounters don't carry those dates.

Clinical Concept	Concern and Enhancement	Comments
Pregnancy as an Observation (Intervention logic)	Some providers record Pregnancy as an Observation, as opposed to a Condition. OCHIN confirmed that this was a valid "back-up" approach to evaluate pregnancy status. **Implementation Decision:** This logic was retained.	This was a "lessons learned" from the pilot partnership last year with a health center affiliate of Alliance (formerly AllianceChicago).
PEG Activity Tool – question scores (Intervention logic)	Since the PEG is comprised of questions that evaluate three very distinct aspects of a patient's pain experience, there is value in displaying each individual response, along with the total score. **Implementation Decision:** Add code to query for and display the individual scores.	Note: The same approach was not taken for the STarT Back Screening Tool, since that has nine questions, and responses would have overwhelmed the Summary UI. In addition, proprietary (i.e., local) codes were used for all aspects of these assessments since Logical Object Identifier Names and Codes (LOINC) codes do not currently exist. Ideally, a LOINC code would be used to represent each assessment, their individual questions, and their total scores. MITRE submitted applications for LOINC codes to be assigned. LOINC representatives estimate that the new codes will be available in the December LOINC release.

Clinical Concept	Concern and Enhancement	Comments
Goals (Intervention logic)	Capturing patient goals and making decisions that help patients achieve their goals is tremendously important. It was not initially modeled in the logic since standard codes are not readily available to express the required information. If goal-related data was available in OCHIN's system, local codes could have been used in the logic expression. **Implementation Decision:** Do not include logic to express goals.	OCHIN staff conveyed that patient goals are rarely captured by clinicians in a structured format, at present. This is a challenging clinical concept to evaluate across other organizations also. OCHIN shared that a quality improvement initiative is underway to facilitate regular structured capture of this information. Future enhancements in this area may be beneficial once the data are routinely available.
Lookback of 1 year for risk assessments (Intervention logic)	Initially the lookback was defined as 6 months; however, OCHIN's CDS Physician Lead suggested expanding the lookback due to clinical practice, so as not to miss relevant assessment results. **Implementation Decision:** Change code to specify a 1-year lookback.	This value set represents varied assessments to screen for depression, anxiety, opioid risk, alcohol use, and substance use.
Alcohol and Drug Screen single questions (Intervention logic)	OCHIN has two commonly used screening questions related to alcohol and drug use that are valid indicators of risk. **Implementation Decision:** Add both screening questions to the logic.	Note: Both questions are represented by proprietary (i.e., local) codes, along with MME since standard codes are not currently available. Once standard codes are issued for the concepts above, future implementers can update the CDS logic with the standard codes.

Enhancements Made During CDS Integration

Integration of CDS in an EHR system is a large undertaking, often requiring custom development and configuration. For the purpose of this document, integration is scoped to efforts taken to identify how the required data is captured in OCHIN's system versus how the data is used in the CDS. MITRE instituted enhancements when disconnects were identified between the logic expression and the EHR data to ensure robust data evaluation and the delivery of accurate CDS interventions.

Enhancements that occurred during this stage of the pilot effort are outlined in Table 5.

Table 5. Enhancements made during CDS integration

Clinical Concept	Concern and Enhancement	Comments
Assessment result ranges (Intervention logic)	Assessment tool authors often include an interpretation of assessment scores to provide context to the numeric score (e.g., a score of 4 may be interpreted as moderate pain). Although the CDS logic queries for the interpretation of each score, the interpretation was generally not present in the data returned through the FHIR interface; therefore, it would not display in the SMART on FHIR app. As a workaround to this problem, MITRE proposed adding the score ranges to the CQL code, to provide context to the score (e.g., a score of 4 on a scale of 0–10). **Implementation Decision:** Add assessment score ranges to the logic.	Note: MITRE investigated developing code to convert a numeric score to the author's interpretations of that score; however, legal counsel determined that intellectual property permissions were required to implement this approach, and the pilot timeline could not afford this delay (therefore, the approach was not implemented). Future implementers may choose to further investigate this approach.

Clinical Concept	Concern and Enhancement	Comments
Non-pharmacologic treatments – Referrals (Intervention logic)	Non-pharmacologic treatments are very difficult to identify in a structured format in EHRs. For instance, the treatment itself (e.g., physical therapy, yoga) does not occur in a primary care setting. Secondly, treatment orders are only placed for care that *requires* an order, putting structured data capture of the treatment in jeopardy (e.g., a physician is unlikely to order "stretching," or yoga). As a result, query results likely include a fraction of the care discussed with a patient. OCHIN technical staff identified an opportunity to evaluate referrals as evidence of non-pharmacologic treatments, improving the odds of displaying relevant treatments. **Implementation Decision:** Relevant referrals in OCHIN's system were mapped to non-pharmacologic codes in the MITRE-created value set.	Moving forward, implementers may choose to create a referral value set if standardized codes are available to express the indicated concepts.
Wong-Baker FACES Assessment (Intervention logic)	This assessment usually supports pain intensity ratings on a scale of 0–10. However, OCHIN provides the assessment with a scale of 0–5. Clear communication of the range is imperative to provide the clinician with the right interpretation context. **Implementation Decision**: A unique branch of the CQL code was created for the OCHIN pilot to define the range as 0–5.	The branch of the codes released to the public includes the published 0–10 range. Future implementers should double check their systems to ensure alignment to the ranges defined in the CQL.

Enhancements Made During CDS Testing

Robust testing is integral to release accurate, reliable, valid CDS. Testing is conducted after integration of the CDS is complete, using first synthetic data and later "real" patient data. OCHIN's synthetic records tested all logic phrases, attributes, and value sets, and included positive and negative testing. Only one issue identified during testing on the development server required a change to the CDS specification (outlined in Table 6). Testing on production with live patient data did not elicit the need for additional enhancements.

Table 6. Enhancements made during CDS testing in the EHR system

Clinical Concept	Concern and Enhancement	Comments
Conditions associated with chronic pain (Inclusion and intervention logic)	Testing revealed missing International Classification of Disease 10 (ICD10) codes in this value set (e.g., pain in "unspecified" knee). **Implementation Decision**: Additional, indicated codes were added to the value set.	No additional concerns were raised about the value set definition.

Enhancements Made During the Live CDS Pilot

Concerns that arose during the live pilot (e.g., latency) did not involve the CDS specifications. No additional enhancements were made to the artifact during live use of the CDS in a primary care setting.

Semi-Structured Representation of the Enhanced Artifact

The final semi-structured representation of the Pain Management Summary artifact incorporates all enhancements discussed in this document. Table 7 contains the inclusion and exclusion statements, and Table 8 contains the intervention logic.

Table 7. Final semi-structured inclusion and exclusion logic

Inclusions	Exclusions

Age >=18 years
AND
 	
• OR 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 past 180 days)*
    ○ *Statements (date, active, or completed within past 180 days)*
 	
• OR Adjuvant analgesic medication
    ○ *Orders (date, active, completed, or stopped within past 180 days)*
    ○ *Statements (date, active, or completed within past 180 days)*
	None.

Table 8. Final semi-structured CDS intervention logic

POPULATE Pain Management Summary

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 status, 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 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, interpretation, date) • STarT Back Screening Tool (total score, interpretation, date)

POPULATE Pain Management Summary

Historical Treatments (lookback of 2 years for all except stool softeners, which is 6 months):
 	
• Opioid pain medication
   o *Orders (date, active, completed, or stopped)*
   o *Statements (date, active, or completed)*
 	
• Non-opioid pain medication
   o *Orders (date, active, completed, or stopped)*
   o *Statements (date, active, or completed)*
 	
• Non-pharmacologic treatment
   o *Orders (date, accepted, in progress, or completed)*
   o *Referrals (date)*
 	
• Stool softener and laxative
   o *Orders (date, active, completed, or stopped)*
   o *Statements (date, active, or completed)*

Risk Considerations:
 	
• MME calculation (most recent, verified, value [as quantity], date in past 6 months)
 	
• Urine drug screen (verified, result, interpretation, date in past 1 year)
 	
• Benzodiazepines medication
   o *Orders (date, active, completed, or stopped in the past 2 years)*
   o *Statements (date, active, or completed in the past 2 years)*
 	
• Naloxone medication
   o *Orders (date, active, completed, or stopped)*
   o *Statements (date, active, or completed)*
 	
• Risk assessments relevant to pain management (represented by a value set) - (total score, range, interpretation, date in past year)
   o *Verified "single question r/t alcohol use" Observation*
   o *Verified "single question r/t drug use" Observation*

DISPLAY link to the *CDC Guideline for Opioid Prescribing for Chronic Pain*
DISPLAY Notice header: "TAKE NOTICE: This summary is not intended for patients who are undergoing **end-of-life care** (hospice or palliative) or **active cancer treatment**."

Potential Future Enhancements of the CDS Artifact

Pain Management Summary CDS specifications enabled reliable and accurate delivery of CDS interventions to the intended population of patients at the pilot site. The specifications can be implemented at any time in other settings and EHRs (given successful integration and test results). Nevertheless, there are numerous ways that the specifications might be enhanced by developers and implementers in the future. Suggestions include:

- Develop a value set to represent non-pharmacologic treatment referrals to eliminate the need for mapping to the non-pharmacologic treatment value set.
- Develop value sets that represent a broader range of pain intensity assessments, multi-dimensional pain assessments, and opioid risk assessments once LOINC codes are available for the evidence-based assessments.
- Develop logic to express patient goals and pertinent attributes once the FHIR resource for Goals is more mature, transfer of goal-related data can pass through the FHIR interface, and standard terminology codes (e.g., LOINC and Systematized Nomenclature of Medicine-Clinical Terms [SNOMED-CT]) are available to express goal-related questions and responses related to pain. Note: This will only work if goal-related data is routinely captured in structured fields in the EHR. In addition, ideally, goals would be associated with a Condition expressed with a standard terminology code.
- Incorporate a MME calculator in to the logic, if not already available in the EHR. CDS specifications for an MME calculator are available on the CDS Connect Repository, via this link: https://cds.ahrq.gov/cdsconnect/artifact/cdc-opioid-prescribing-guideline-recommendation-5.
- Incorporate Prescription Drug Monitoring Program (PDMP) data if legal, security and technical constraints can be addressed.
- Develop CDS logic to generate directive guidance (e.g., an order set) derived from the CDC guidelines. Note: Logic exists in the SMART on FHIR app to generate flag notifications to draw attention to concerning summary entries. Logic to generate notifications is *not* included in the CQL.
- Adjust CDS specification to generate reports that can be reviewed by medical directors and clinicians outside of an encounter.
- Incorporate end user feedback obtained through pilot focus group discussions to enhance the usability and function of the artifact.

Lessons Learned and Broader Implications

Many of the findings outlined in this document have implications beyond the scope of the Pain Management Summary CDS artifact, impacting other CDS and electronic Clinical Quality Measurement (eCQM) developers and implementers as well. Approaches taken to address some of the constraints encountered during the pilot of the Summary CDS may inform other efforts and highlight opportunities for community engagement and effort in the future.

Availability of Standard Codes

Standards-based, interoperable CDS is dependent upon the availability of standardized codes to express the clinical data elements required in the logic. Terminologies such as LOINC, SNOMED-CT, ICD10 and RxNorm provide a wealth of codes for CDS developers to use in their CDS expression. If codes are not available for the express need of a concept, developers are forced to use local codes to express the concept, lessening the interoperability of the final coded artifact.

Developers can submit applications for codes to be assigned to required concepts. MITRE did this for the PEG and STarT Back screening tools and anticipates that LOINC codes to express each aspect of these tools will be released in the December 2018 LOINC update. LOINC representatives are currently expanding representation of pain and opioid risk assessments as LOINC codes, and welcome community involvement in this effort.

Intellectual Property Constraints

Many pain and risk assessments have intellectual property (IP) restrictions governing how their body of work may be used. Expression of their work as CDS and assignment of standard terminology codes to their work requires expressed permission. CDS developers should be aware of this requirement and respect IP regulations.

Application for new terminology codes (at least using the LOINC terminology), requires IP approval from the author of the assessment. LOINC representatives are willing to assist with author engagement to facilitate approval.

Evaluating EHR Data for Evidence of Procedures and Treatments in a Primary Care Setting

Procedures and treatments rarely occur in a primary care setting; therefore, evidence of the treatment being performed or completed is usually not available in their EHR. Alternative approaches, such as looking at orders or referrals, can help identify some evidence of these concepts; however, limitations exist with this approach also (i.e., some treatments do not require an order or referral, such as "stretching" or "exercise").

CDS developers and implementers should evaluate data availability and accuracy constraints before undertaking an effort and clearly convey the limitations of the CDS interventions to their end users for appropriate interpretation of the presented information.

Need for Mapping

The need to map local codes to standard terminologies is likely to persist for the foreseeable future. As mentioned above, evaluation of *if* and *how* data is captured in a structured format in an EHR is one of the first steps in determining the feasibility of developing reliable CDS. If the required data is routinely captured in a structured field, but not recorded using a standard terminology, mapping the local code to the standard code expressed in the CDS is required. Implementation efforts should include an investigation of how the required data is captured in

their system to inform the implementation timeline and identification of staff resources to assist with any mapping.

Date of Diagnosis Accuracy

EHRs consistently capture the date that a new diagnosis is entered in the system. Often, that date is displayed and stored as the "onset date," which *may* be a misrepresentation of the date. This is a significant limitation for CDS logic that evaluates the "onset date" of a Condition to provide guidance on an evidence-based treatment. Caution is required when evaluating this concept. Including the "asserted date" in the CDS provides context to the date presented as the "onset date."

Conclusion

Pilot implementation of a CDS artifact in a live clinical setting provides valuable opportunities to enhance the CDS specifications—not just for the distinct pilot implementation, but also for subsequent end users. Enhancements to the CDS occur along the entire continuum of pilot implementation, enabling iterations of the artifact to improve the reliability, validity, and usefulness of the CDS. The information in this document provides transparency on the findings, decisions, and lessons learned during the pilot use of the Pain Management Summary CDS specifications to inform future CDS development, enhancement, and implementation efforts.