CDS Connect Pilot Final Report

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

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

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- Pilot site leadership and clinician end users
- MITRE CDS Connect Project Team

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Introduction

The Agency for Healthcare Research and Quality (AHRQ) has elected to sponsor a project (CDS Connect) to generate a systematic and replicable process for transforming patient-centered outcomes research (PCOR) findings into shareable and standards-based clinical decision support (CDS) artifacts. A CDS artifact is the template for defining how decision support is provided for a given clinical situation, often including triggers, logic, operations, 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 health care record (EHR).

Background

The overall scope of the CDS Connect work includes generating a systematic and replicable process for transforming PCOR findings into shareable, health information technology (IT) standards-based, and publicly available CDS, including developing the prototype tools that facilitate such a process of transformation. This document focuses on the key task of piloting a MITRE-developed PCOR CDS artifact in a live clinical setting. The primary objective of the pilot is to demonstrate the feasibility of implementing an evidence-based CDS artifact hosted on the CDS Connect Repository and share lessons learned to inform future implementers via the Web-based Repository. To achieve this, MITRE enabled:

1. Development of systematic and replicable processes for CDS creation and implementation, honed through a pilot study in a live clinical health care environment, that can be undertaken by other CDS developers and implementers
2. Successful hosting and sharing of CDS artifacts on production-level infrastructure (i.e., the AHRQ CDS Connect Repository)
3. Integration of a CDS Connect-developed standards-based, interoperable artifact in an EHR system and implementation of the CDS in a clinical setting
4. Sharing of insights from the overall project and specifically the clinical pilot, from the pilot site and the MITRE team, to support others in adopting, sharing, and implementing CDS

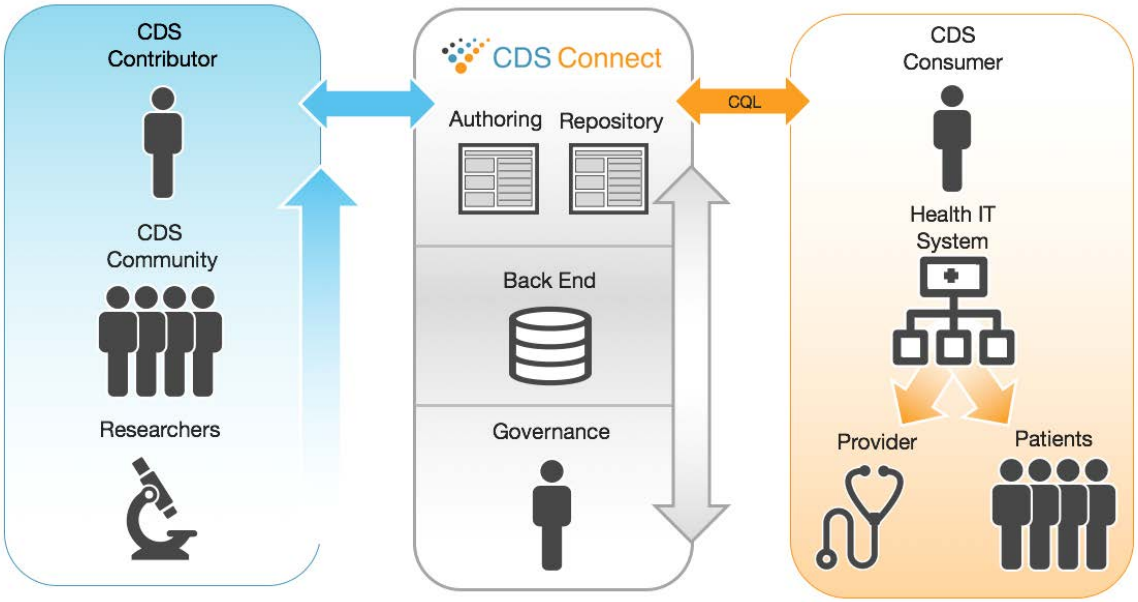
During the current period of performance, CDS artifact development centered on pain management and opioid use. Development of the CDS was informed by the Centers for Disease Control and Prevention (CDC) *Guideline for Opioid Prescribing for Chronic Pain.*[1] The CDS is not a direct representation of any one recommendation statement within the guideline. Instead, the CDS compiles clinical concepts mentioned throughout the guideline in one consolidated view

(i.e., a pain management summary) for clinician review. This resulting artifact, *Factors to Consider in Managing Chronic Pain: A Pain Management Summary* (hereinafter, Pain Management Summary or Summary), 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 dashboard developed as a Substitutable Medical Applications, Reusable Technologies (SMART) on Fast Healthcare Interoperability Resources (FHIR) application (SMART on FHIR app or app) that provides a variety of key factors for clinicians to consider when assessing the history of a patient's chronic pain. The key factors include subjective and objective findings along with recorded treatments and interventions to support shared decision making on treatment moving forward.

MITRE was tasked with executing a feasibility pilot to demonstrate the CDS Connect Concept of Operations (see Figure 1), including retrieval of the artifact from the CDS Connect Repository; integration of the artifact into the clinical site's EHR system; and the clinical demonstration, user experience, and outcomes of the implemented CDS artifact. The findings of the pilot are documented in this Pilot Report. In addition, findings regarding possible enhancements to the Pain Management Summary CDS artifact are documented in the report "CDS Artifact Enhancement Based on Pilot Implementation."

Figure 1 provides a visual depiction of the CDS Connect Concept of Operations. It portrays the Repository and Authoring Tool as central, key facilitators to developing and sharing evidence-based CDS, and a diverse group of individuals using the systems as contributors and end users of the CDS (where the CDS is integrated in EHR systems and presented to clinicians and other targeted individuals).

Figure 1. CDS Connect Repository Concept of Operations



Pilot Goals and Scope

The primary goals of the feasibility pilot included: 1) developing and demonstrating the feasibility of a self-service CDS environment that encourages development, implementation, evaluation, and dissemination of PCOR-based CDS; 2) providing evidence-based and value-add resources for inclusion in the CDS Connect Repository to be used by clinical organizations interested in implementing CDS artifacts; 3) informing and enhancing the specification of the piloted artifact based on integration test results and implementation findings; and 4) gaining an understanding of pilot stakeholder views as they experience pilot activities.

The pilot included the following activities:

1. **Design:** Developing a process or case study that aligns with the *Analytic Framework for Action*[2] and *5 Rights Framework*[3] for implementing CDS in a live clinical setting that accounts for clinical outcomes, operations, and technical efforts.
2. **Implement:** Implementing the Pain Management Summary CDS in a live clinical setting, validating that artifacts perform as expected, and storing the piloted artifact and reports in the CDS Connect Repository.
3. **Measure:** Conducting qualitative and quantitative measurements across clinical outcomes, operations, and technical efforts to provide holistic evaluation of the development and implementation of the Pain Management Summary CDS.
4. **Iterate:** Supporting and documenting a responsive process for evaluating the Pain Management Summary CDS performance and updating the Pain Management Summary CDS (i.e., versioning) based on stakeholder feedback.
5. **Document:** Documenting all pilot activities and establishing a process for disseminating pilot artifacts on the CDS Connect Repository.

The scope of the pilot included engaging with a designated clinical site to implement the Pain Management Summary CDS used by designated clinical providers and appropriate patients for a multi-week intervention period.

Pilot Partnership

Pilot Partner Requirements

For the pilot, MITRE sought a collaborator with both technical readiness and a suitable clinical environment to pilot the MITRE-developed CDS. There were several key factors that influenced the selection of the pilot site. Identifying a pilot site that was invested in supporting their providers' decision-making process via CDS was critical. In addition, the clinical domain (i.e., chronic, nonmalignant pain management and proper opioid prescribing) needed to resonate with the organization. Ideally, pain management was already identified as a high-value quality

improvement (QI) imperative, and the idea of gaining well-specified CDS via a pilot partnership was viewed as an optimal opportunity to gain a "leg up" on executing a QI initiative in this domain.

These additional preferred characteristics of a pilot organization were identified:

1. Ambulatory practice, with preference for a Federally Qualified Health Center (FQHC)
2. Appropriate medical specialty (e.g., internal medicine, family medicine)
3. Required structured data captured in the site's EHR system
4. Availability and support of clinical, operational, and technical staff
5. Technical capability to implement the Pain Management Summary CDS
6. Pain Management Summary CDS can be used operationally, based on the organization's clinical operations
7. Organizational commitment and operational resources to meet pilot needs before, during, and after implementation, including:
    a. Provision of clinical workflow materials and/or guidance on current process
    b. Consultation on the Pain Management Summary CDS and its placement into the clinical workflow
    c. Ability to perform site-based training and scheduling as needed
    d. Institutional Review Board (IRB) approval and support of the pilot process
    e. Commitment of designated point(s) of contact for technical, clinical, and operational domains

Pilot Partner Selection

The MITRE team collected background information on potential pilot sites through discussions and email conversations with each site, and general impressions were captured in a working document. Along with the previously defined characteristics and factors necessary to consider for selecting the pilot, it was deemed critical to select a pilot partner capable of maintaining standard operations while engaging in the pilot.

After evaluating several potential pilot partners, OCHIN was selected in collaboration with and by approval of AHRQ. OCHIN met all the defined pilot partner criteria and is one of the largest health information and innovation networks in the United States. OCHIN serves hundreds of organizations by providing health IT software, support, and services as well as providing resources and support for research, analytics, and other supportive capabilities.[4] OCHIN partners with Epic and NextGen to provide EHR products to their member organizations, who consist of inpatient and outpatient facilities that receive Federal assistance to provide care to underserved

populations. OCHIN was awarded a subcontract through the MITRE Corporation for the performance period of March 1, 2018, through August 31, 2018.

Initial Pilot Outcome Definition

Prior to beginning the pilot, the MITRE team identified several high-level outcomes of the evaluation of the Pain Management Summary CDS Implementation that were important to pilot success:

1. The pilot site can incorporate the Pain Management Summary CDS into their EHR system.
2. The Pain Management Summary CDS launches when appropriate and evaluates information as designed.
3. Clinicians use the Pain Management Summary CDS when appropriate and believe it adds clinician and patient value.
4. The MITRE team gains information from the pilot site to document and evaluate the Pain Management Summary CDS development, implementation, and dissemination process, along with integration requirements, testing results, required enhancements to the specifications, and outcomes from the pilot experience.

In addition to the high-level pilot outcomes, MITRE created research questions across the three domains—technology, people, and process—that could be investigated during the pilot. The research questions shown in Table 1 were used to structure the measurement techniques, evaluation methods, and final focus group content for the pilot.

Table 1. Research Questions

Domain	Research Questions Regarding the Pilot CDS Artifact
Technology	Are the resource requirements needed to implement CDS feasible (e.g., FTE, skill mix, hours of labor, new equipment, training)?
Technology	Can a clinical site, such as a FQHC, integrate CDS Connect artifacts with their EHR? Could the CDS implementation process be replicated in the future?
Technology	Does the CDS identify a component of patient care that could have been missed or a subset of a previously undetected population in need?
People	Do clinicians gain greater insight into a patient's health or risk when using the CDS, and does this influence the care plan?

Domain	Research Questions Regarding the Pilot CDS Artifact
People	Are clinicians and patients receptive to and ready to use CDS in general? Do clinicians use any resulting visualizations or tools during the patient encounter? Do clinicians and patients believe there is greater patient engagement when using the CDS?
People	Is the CDS user-friendly? Do clinicians, staff, or patients value the CDS? Does CDS reduce cognitive burden for clinicians?
Process	Do clinicians or clinical staff require training to use the CDS? If yes, how much and what kind, and what is the cost to the organization?
Process	Does the clinical workflow require adjustment given the CDS? If yes, what and how extensive are the adjustments? Do the adjustments outweigh the value of the CDS?
Process	Did the CDS improve the quality of patient care in the pilot facility (e.g., identify risk, inform treatment plan or prescribing practices, improve followup treatment)?

The CDS Connect project approach is grounded in agile development, which, for the purposes of outcome measurement, translates into an ongoing, iterative, as-needed model for discussing findings and ways to enhance the work to ensure outcomes, to the extent possible, are met.[5] This approach also supports the collection of both formal and informal information and data that can be both qualitative and quantitative, and incorporates these lessons learned into a feedback loop that improves the CDS artifact and benefits the broader community of users.

Throughout the pilot period, MITRE and OCHIN engaged in collaborative communication, discussions, and activities that provided both qualitative and quantitative information and data to inform ongoing evaluation and outcome assessment. This included weekly technical and management conference calls, weekly generation of analytical reports, and a virtual focus group discussion with the pilot site clinicians at the end of the pilot period. These activities are detailed further in the remainder of this report.

Institutional Review Board Approval

Given the research and evaluation nature of the work and the project's goal to provide both specific and generalizable knowledge to a broad community of stakeholders, the CDS Connect project team engaged in the IRB process to ensure compliance with applicable human subject protection policies.

On February 19, MITRE initiated contact with a MITRE IRB representative and began completing the required application forms and supplementary materials. The application included a description of the research effort, the proposed implementation and evaluation process, and an assessment of risk as well as a clear statement that outlined if and how patients might be engaged in the research. MITRE submitted the completed application along with a Research Consent Form, a list of study staff, and a draft of the Focus Group discussion topics. On March 19, the MITRE IRB provided an official response, granting the project exempt status and providing their approval.

Pilot Implementation Planning

Pilot Work Plan and Kick-Off Meeting

MITRE began drafting the initial work plan early in the pilot planning process to clearly define the sequential work efforts required by both the MITRE team as well as the pilot partner. The initial work plan established the proposed timeline and implementation details, as well as the critical path activities and risks. MITRE submitted the plan to AHRQ as a formal project deliverable.

Once OCHIN was selected and agreed to be the CDS Connect pilot, the pilot subcontracting process was initiated. OCHIN and MITRE met once in advance of the executed contract to begin discussion of the clinical concepts defined in the draft Pain Management Summary CDS. The meeting focused on the availability and accuracy of the required concepts within the OCHIN EHR system. As a result of the meeting, it was determined that the data to populate several concepts, such as patient goals and opioid medication information from a prescription drug monitoring program (PDMP), were not available in the EHR and were removed from the artifact. In addition, access to a patient's morphine milligram equivalents (MME) was planned but not yet implemented in the OCHIN EHR, so was deemed tentative.

Once the pilot subcontract was finalized, the OCHIN and MITRE project teams began planning additional implementation details. OCHIN identified key personnel that would be engaged in the pilot and help ensure a successful implementation. This included the key resources to function as the project lead/manager, the clinical lead, and the technical lead.

A 2-day virtual kick-off meeting was conducted in mid-April with the key OCHIN and MITRE team members that accomplished the following objectives:

1. Review of the pilot scope and work plan
2. Review and refinement of the clinical aspects of the Pain Management Summary CDS
3. Determination of the most optimal method for integration of the Pain Management Summary CDS code within the OCHIN EHR
4. Development of the process to evaluate data availability and the need for mapping

5. Development of the initial pilot analytic plan
6. Discussion of the clinical pilot site selection, engagement, and training

Communication and Collaboration

To maintain ongoing situational awareness and communication, CDS Connect project leadership held a weekly management call with the OCHIN project lead from mid-April through August. Additionally, a weekly technical call was also facilitated, where both organizations' operational, clinical, and technical leadership could address technical questions regarding the integration and implementation of the Pain Management Summary CDS and any implications on clinical execution and, ultimately, pilot outcomes and goals. Throughout the pilot period of performance, OCHIN and MITRE leadership were readily available to address questions or issues as needed.

Pilot Analytic Plan

The MITRE team developed an Analytic Plan in collaboration with OCHIN, with the objective of providing quantitative data to evaluate the effectiveness, accuracy, usefulness, and impact of the Pain Management Summary CDS. The plan outlined the specific reporting to be done at predetermined intervals (e.g., pre-pilot site implementation, during the pilot, and after the pilot conclusion). The data originated from both the Epic EHR and the Pain Management Summary SMART on FHIR app.

The data and results of the analysis are detailed further in the Pilot Findings and Lessons Learned section of this report.

Clinical Pilot Site Selection

OCHIN facilitated the process of identifying one or more clinical sites to pilot the Pain Management Summary CDS. To support this process, MITRE developed a one-page CDS Connect Pilot Partnership document that described the project, the pilot objectives, the focus of the CDS, and the pilot site activities. This information enabled OCHIN to recruit a member organization—a nonprofit community health center located in California, which agreed to pilot the CDS. The community health center employs approximately 20 physicians and six mid-level clinicians (e.g., nurse practitioners and physician assistants) and is in the process of creating a pain management program. OCHIN selected this site because of their interest in pain management, and it has a patient population that includes a large number of patients that meet the inclusion criteria for the Pain Management Summary CDS.

Clinical Pilot Site Onboarding and Training

The MITRE clinical team developed a training plan to provide the pilot site clinicians information on the overall project, the pilot objectives, and the Pain Management Summary CDS. The team also created materials to support clinician training at the pilot site, including a

training PowerPoint presentation and a Pain Management Summary "Quick Start Guide." Both documents are available on the CDS Connect Repository within the Pain Management Summary artifact.

In conjunction with the OCHIN clinical lead, MITRE delivered the training remotely via a WebEx webinar on June 14. The training content included the following information:

- Presentation via a PowerPoint slide deck on CDS Connect background information, pilot objectives, and timeline
- Review of the evidence-based guidance related to opioid prescribing and chronic pain management
- Demonstration of the Pain Management Summary SMART on FHIR app
- Discussion on engaging patients with the Summary to facilitate shared decision making

The attendees were also provided copies of the training materials. OCHIN recorded the webinar to be used by other pilot site clinicians who were not able to attend the initial training.

On June 20, clinicians at the OCHIN pilot site began using the Pain Management Summary to support patient care.

Pain Management Summary Technical Integration

Integrating specific CDS capabilities or artifacts into an existing system requires a significant amount of planning and often requires custom development and configuration. The current landscape of health IT is such that sufficient CDS standards exist, and many vendors plan to support them, but most have not yet implemented full support. MITRE developed CQL logic to collect and organize relevant data to inform the decision-making process when managing a patient's pain, but other technology to present the data to clinicians and patients was necessary. The MITRE team worked with OCHIN to elicit their input regarding the design and technical integration details of the Pain Management Summary CDS. To integrate the Pain Management Summary CDS within the OCHIN Epic EHR, both organizations' technical teams developed or customized software.

Beginning in March 2018, MITRE CDS Connect project members met with OCHIN to discuss CDS definition and how the CDS might be implemented and displayed within the current EHR environment to the clinicians. MITRE had considered using the Synopsis template, but since the template is designed to pull data from an Epic database, MITRE could not identify an implementation approach that would successfully leverage the clinical quality language (CQL) used by the CDS to populate the template. Since this approach was not feasible, MITRE researched alternative approaches with OCHIN, such as using Epic's Best Practice Advisory Web services, CDS Hooks, or a SMART on FHIR app. While CDS Hooks provided a plugin framework for custom CDS and seemed like a good approach, it was not supported in Epic.

SMART on FHIR provided a standards-based, plugin framework for custom apps and was supported by Epic. Although OCHIN had never implemented a SMART on FHIR app, they felt it was feasible for the pilot implementation, and it was agreed that this would be the method used to integrate the Pain Management Summary CDS with the Epic EHR.

Pain Management Summary SMART on FHIR Application

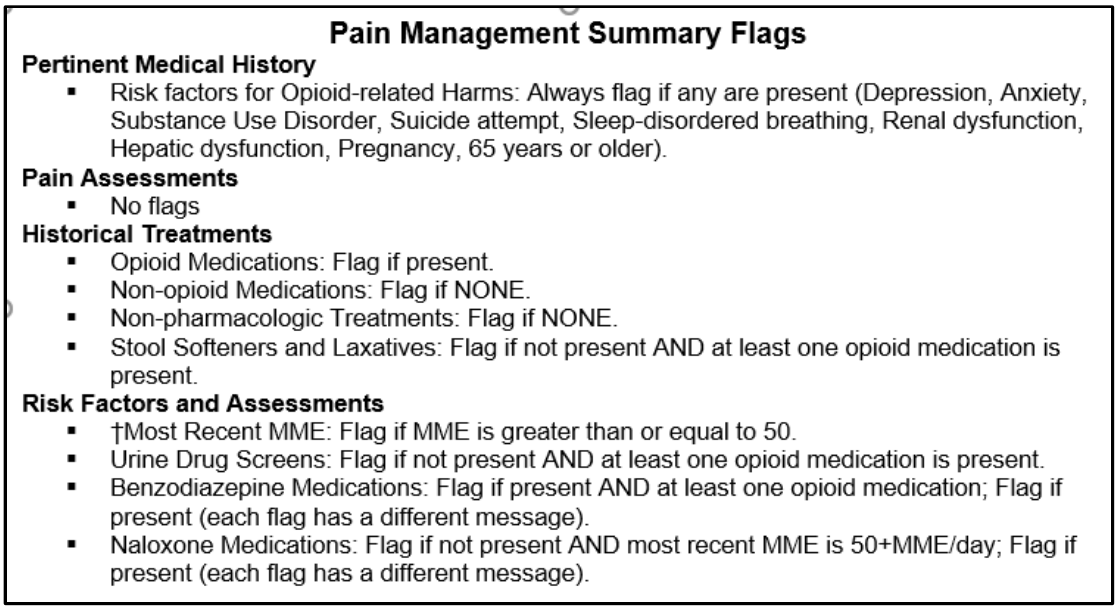
This section provides a user-friendly explanation of the Pain Management SMART on FHIR app, including the user interface (UI). Additional technical information can be found in the *AHRQ CDS Connect System Document*. Open source code for the SMART on FHIR app is planned to be released on GitHub in September 2018.

The Web-based SMART on FHIR app was developed to support the OCHIN pilot of the Pain Management Summary. The information the Pain Management Summary provides is presented to the clinician as a Pain Management Summary "dashboard." The logic used to query and return data for display in the Pain Management Summary dashboard is expressed in CQL. The SMART on FHIR application enables the integration of the CQL logic and results with the Epic EHR via the SMART on FHIR application programming interface (API). (Additional details regarding the technical integration can be found in the *Implementation Guide: Factors to Consider in Managing Chronic Pain: A Pain Management Summary* Technical details for the SMART on FHIR API can be found on the SMART Health IT website.)

Rules were embedded in the user interface of the SMART on FHIR app to display notifications such as flags, counts, and additional information to further contextual awareness for the individuals viewing the Pain Management Summary dashboard.

Figure 2 displays a list of the flags implemented to alert the clinician to an entry of potential concern based on the CDC guidelines.

Figure 2. 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 app user interface includes the following:

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

Integration of the Pain Management Summary App Within Epic Workflow

For the initial pilot of the Pain Management Summary, OCHIN elected to invoke the Summary when a clinician clicks on a "Pain Summary Information" link found within each patient record in the EHR. A decision was made to include the link for ALL patients for several reasons. First, it was determined that including the link for only those patients who were within the inclusion criteria would be technically challenging, especially given the short timeline for the pilot (with the burden being on the pilot technical staff to implement). In addition, the pilot clinical lead felt that having the link always available would be agreeable to the pilot site clinicians.

Pain Management Summary App Screenshots

The Pain Management Summary app is a single-page application that provides a clean, modern user interface with data organized in a consistent way. The relevant data are divided into four major sections: Pertinent Medical History, Pain Assessments, Historical Pain-related Treatments, and Risk Considerations. Each section contains entries (and potentially flags) related to the section topic. Users can navigate through the application by using the table of contents on the left-hand side or by scrolling up and down.

The following series of screenshots show different portions of the app that can be navigated by scrolling or via the navigation shortcuts on the left-hand side of the page. For these screenshots, a synthetic patient was constructed to exercise each of the sections of the Summary. In this regard, this synthetic patient is not intended to be clinically accurate but demonstrate the different capabilities of the Summary.

Figure 3. Pain Management Summary - Header and Pertinent Medical History

Figure 4. Pain Management Summary - Pain Assessments

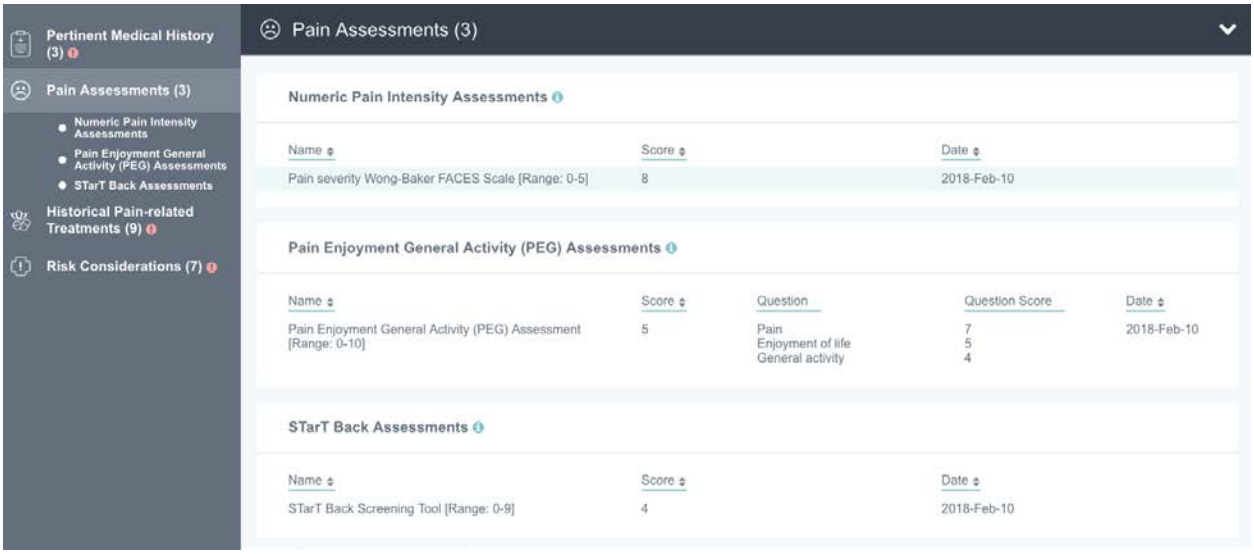


Figure 5. Pain Management Summary – Historical Pain-Related Treatments

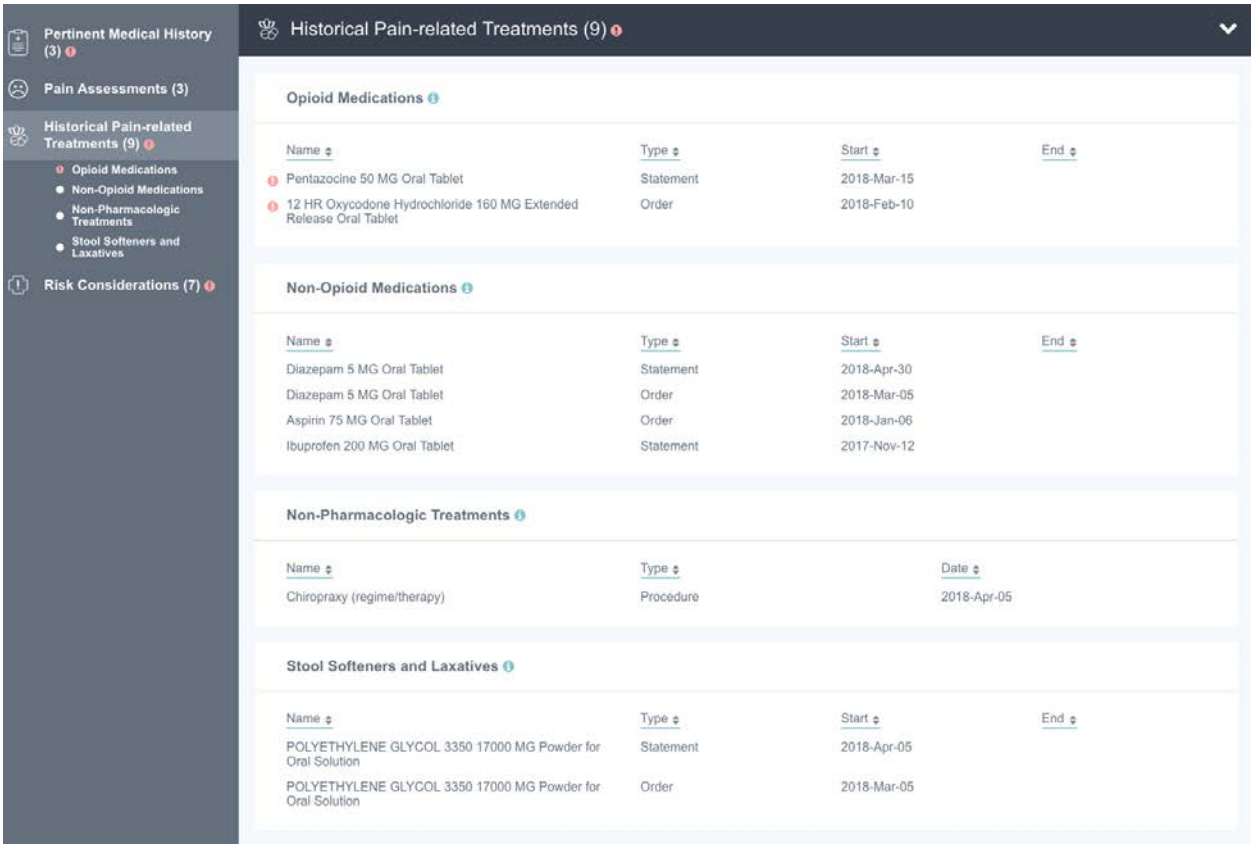
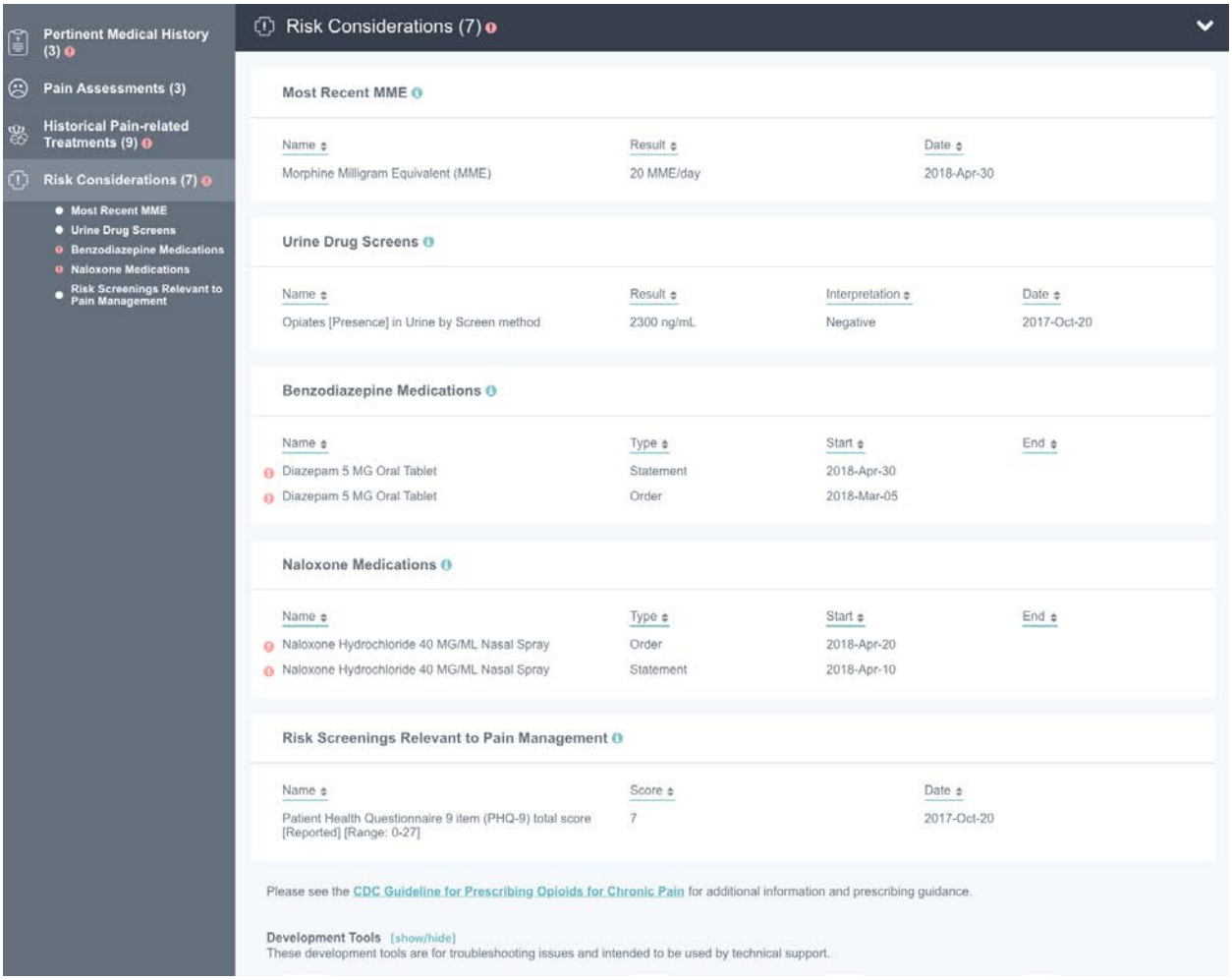


Figure 6. Pain Management Summary – Risk Considerations



Pain Management Summary Enhancements

Artifact Enhancements

This section discusses the enhancements made to the Pain Management Summary SMART on FHIR app during the pilot partnership. It does *not* include enhancements to the CQL code for the Pain Management Summary artifact. The *CDS Artifact Enhancement Based on Pilot Implementation* document provides detailed information on the artifact and CQL enhancements.

Smart on FHIR Application and UI Enhancements

The initial SMART on FHIR app was developed to integrate with the Pain Management Summary CQL requirements and was enhanced throughout the planning, integration, and testing phases of the pilot. MITRE frequently conducted collaborative work sessions with the OCHIN

pilot team and other stakeholders that included demonstrations of the SMART on FHIR app and user interface. Feedback from each session was incorporated into modifications to the Pain Management Summary CQL, app software, and user interface, which led to a richer, more informed, and user-friendly experience. This section of the report outlines the summary of changes made to the SMART on FHIR app software and user interface over the course of the pilot.

App Enhancements Made During Integration and Testing

During the integration phase of the pilot, refinements made to the SMART on FHIR app software were primarily a result of enhancements to the CDS artifact or address issues found during pilot integration. Some of these enhancements that impacted the app software included:

- Addition of an end date to conditions to facilitate the display in the user interface
- Modifications to the MedicationStatement/MedicationOrder queries to specify "status" parameters (to return other statuses in addition to "active")
- Modifications to the format of some of the queries to use commas (",") instead of ("|") to enumerate different values
- Modifications to better handle large query results that span across multiple pages of response data
- Modifications to better support Internet Explorer 11 browsers
- Modifications to capture data from the app required for reports defined in the Analytics Plan
- Updates to the value set for "Conditions associated with chronic pain," which required an update to the app

App Enhancements Made During the Live CDS Pilot

During the live pilot, one update was made to the SMART on FHIR app software to address latency in the display of the Summary after clicking on the link (a finding of the pilot clinicians). To improve the performance time, changes were made to decrease the volume of data being processed. This resulted in filtering several clinical concepts to include only data that were required to display in the app. The updated app included additional filtering for the following clinical concepts:

- Observations are filtered to only those with category: laboratory, survey, or therapy.
- MedicationOrders are filtered to only those with status: active, completed, or stopped.
- MedicationStatements are filtered to only those with status: active or completed.

User Interface Enhancements

The initial user interface was developed to align with the Pain Management Summary CQL requirements. Refinement of the user interface was ongoing throughout the iterative development process, prior to the testing phase of the pilot. Some changes resulted from enhancements made to the CQL as a result of further refinement and discussion with the CDC, CDS Connect Work Group members, and OCHIN clinicians. In addition, MITRE demonstrated the Pain Management Summary app to several pain management experts, clinicians, usability experts, and other stakeholders, and invited feedback on the user interface. Table 2 documents the most significant changes made to the user interface.

Table 2: User Interface Enhancements

UI Area	Concerns and Enhancements	Comments
Flags	Refinement of the logic and display of the flags presented in the UI were suggested in several meetings with MITRE clinicians, usability experts, and OCHIN. These updates were made over the course of the development period prior to the final app delivery to OCHIN for the pilot.	The flags are intended to draw the clinician's attention to an entry of potential concern, based on the CDC guidelines. Refinement was done to reduce "over-alerting" of entries and ensure accuracy. (Figure 2 displays the final list of flags)
Counts	As a result of user experience expert review, the location of the counts was modified to prevent any confusion on the part of the end user.	The counts indicate the number of patient clinical entries, as well as flagged entries.
Information Icons	Initially, the URLs were hyperlinks in the information text. Because of a limitation on the OCHIN EHR side, the URLs were updated to be fully specified text.	The information icons provide information on the data pulled to populate the summary and references, including URLs.
Order and Grouping of Display of Clinical Concepts	The order in which the clinical concepts displayed, as well as the grouping of the concepts was modified over the course of the development of the app to present a more logical and clinician-friendly flow.	Several clinicians provided feedback to help ensure that the layout of the clinical information supported decision making and logical work flow.

UI Area	Concerns and Enhancements	Comments
Notice Displayed at the Top of the Clinical Information	The CDC guideline specifies excluding patients receiving active cancer care or end-of-life care (also described as hospice care and palliative care), as well as patients under the age of 18. **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."* It was decided that the age criteria would be added to the inclusion logic, so that the app displayed only for patients 18 years and older.	Including this exclusion criteria in the artifact logic was considered; however, system engineers and clinicians at the pilot site conveyed that evidence of active cancer treatment or end-of-life care (e.g., performed care, an order, or referral) is not routinely available in their system. Therefore, including the concept in the 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, as well as specifying age in the inclusion criteria.

UI Area	Concerns and Enhancements	Comments
Notice Displayed at the Top of the Clinical Information	It was determined early in the pilot integration planning process that in the EHR, the link to the Summary would display for ALL patients, not just patients that meet the inclusion criteria defined in the CQL. Once the link is selected, the inclusion logic can be invoked within the Summary. **Implementation Decision:** If the link to the Summary is clicked and the patient does not meet the inclusion criteria, display a Notice at the top of the Summary that alerts the clinician that the patient does not fall within the inclusion criteria. In addition, no patient clinical information is displayed. The Notice reads: *"Warning: This summary applies to patients 18 years or older who meet at least one of the following criteria:* • *Has a condition likely to indicate chronic pain* • *Has an active opioid medication in the last 180 days* • *Has an active adjuvant analgesic medication in the last 180 days"*	As mentioned previously, the decision was made early in the pilot integration discussions to display the link to the Summary for ALL patients instead of trying to determine how to display it only for those patient that met the inclusion criteria for several reasons. With CDC agreement, the team agreed that displaying the Notice for patients that were not within the inclusion criteria was a reasonable solution in order to inform clinicians.
Other miscellaneous changes	• In the left-hand navigation bar, white dots display to the left of sub elements. If the element was flagged, the dot was changed to red. Because of concern over potential color-blind users, an exclamation point was added to the red dots to indicate a flagged item.	

Pilot Implementation and Testing

As mentioned previously, the integration and implementation of the Pain Management Summary CDS required both MITRE and OCHIN to develop or customize software. While MITRE was

responsible for developing the CQL logic for the Pain Management Summary artifact as well as for the SMART on FHIR app, OCHIN was responsible for integrating the app within the Epic environment. This required a significant level of coding and mapping from OCHIN.

Although Epic supported the SMART on FHIR platform, it was determined that there were additional modifications necessary to support Epic's specific requirements and limitations. For example, Epic's FHIR API did not support FHIR Encounters, but the CQL needed to query "Encounters" for encounter diagnoses. Similarly, Epic's implementation of FHIR Observation supported only lab data, vitals, and smoking status, but the CQL needed to query "Observations" for pain assessments as well. To support this, OCHIN developed a proxy API in front of the Epic FHIR API. This proxy API handled FHIR queries that Epic did not support and passed through the queries that Epic did support.

In addition, mapping was required in several areas to ensure capture of the appropriate data. Some of the mapping was required to work around data requirements that Epic did not support. In addition, because some of the required data used local codes rather than a standard terminology to codify each data element, mapping of the local code to a standard terminology was required. Mapping is a resource intensive process and can impact the implementation timeline. MITRE and OCHIN held collaborative weekly meetings for approximately 10 weeks prior to the pilot launch date. Integration issues were debugged and resolved during these meetings.

Pain Management Summary Validation and Testing

Robust testing is integral to release accurate, reliable, valid CDS. MITRE tested the Pain Management Summary CDS and SMART on FHIR app throughout the development cycle using a comprehensive set of test cases and synthetic patient data. This testing provided assurance that the CQL logic was sound before beginning the pilot implementation and testing. MITRE also created a "Hello World" app to assist OCHIN in testing their FHIR server and interface.

After integration of the Pain Management Summary app in the OCHIN environment was completed, OCHIN quality assurance (QA) personnel began formal testing. MITRE contributed to the testing by providing sample data to test each area within the Pain Management Summary, as well as sample testing scenarios.

Using the sample data as a guide, the QA analyst built a series of test patients to exercise the testing scenarios and began the testing process. As issues were identified, the analyst documented them in an Issues Log to ensure capture and resolution and shared the Log with both OCHIN technical resources and MITRE to facilitate rapid resolution. Once all outstanding issues were resolved in the development environment, the same set of testing scenarios were executed in the live, or production, environment using real patient data.

Pilot Findings and Lessons Learned

Pilot Objectives

The objectives established during the initial pilot planning for the CDS Connect project were largely met by the pilot activities. Through their collaborative efforts, OCHIN and the MITRE CDS Connect team incorporated the pilot CDS into the OCHIN EHR system, achieving a successful technical integration. Through the artifact development and validation and technical testing activities, MITRE confirmed that the Pain Management Summary app launched when appropriate and captured and shared information as designed by the artifact logic and CQL integration engine.

Through both the weekly pilot touch point meetings and the clinician focus group, OCHIN and the CDS Connect team learned that the clinicians using the CDS found the information provided by the app was valuable to patient care and pain management.

Through the pilot work, the CDS Connect team gained valuable information from OCHIN and the clinical pilot site to support the CDS Connect Concept of Operations and enhance and validate the pilot CDS moving forward. The feedback and experiences of the OCHIN pilot team provided valuable input to the ongoing CDS Connect project from both a CDS consumer and contributor perspective.

Focus Group Findings

MITRE conducted two virtual focus group meetings at the end of the pilot to learn about the pilot site clinicians' experiences and opinions regarding the Pain Management Summary app. The combined pilot site attendees included the Chief Medical Officer and Clinical Champion, the Chief Information Officer and Chief Quality Officer, a physician who had been using the Pain Management Summary, and a physician's assistant (PA) who recently began working at the pilot site and was very interested in the topic of pain management. Several members of the OCHIN project team also attended.

To prepare for the focus group, MITRE developed a discussion guide to provide a meeting framework and ensure that important topics with appropriately structured, open-ended questions were included, while allowing for a naturalistic, conversational discussion.

MITRE had previously learned that several clinicians included in the pilot training elected not to participate in the pilot use of the Pain Management Summary app; therefore, the feedback provided was from a limited number of clinicians. However, the feedback from these clinicians provided valuable information to inform the research questions created during the initial pilot planning process.

Usefulness and Usability

Generally, the clinicians felt that the app was a useful tool and included beneficial information to help guide the care process. They praised the user interface, describing it as "simple and

intuitive" and "can be clicked through quickly." They remarked that the information needed was right there and felt it informed decision making.

One clinician was a little confused by the flags, as some seemed to have additional information when you hover over them, and some did not. He did not seem aware of the "Quick Start Guide" and the recorded training video that would have provided information to explain the flags. Another clinician found the flags useful, but mentioned that she found the "counts" (number of data occurrences in each section) distracting and did not see any value to them, as they did not add to her understanding of the patient's current clinical status. As a "lessons learned," it may be helpful to schedule additional touchpoints with the clinicians to respond to questions and provide support, although this could be challenging to schedule given the typical demands on clinician time.

Reduced Provider Burden

The clinicians were asked about their usual process for reviewing patient information related to pain management when not accessing the app. They responded that their typical workflow consisted of accessing the PDMP; tabbing through the patient encounters; and looking up medications, labs, and other treatments, and described this as "clunky." When using the Pain Management Summary, they felt that the ease of accessing the information was "wonderful." When asked what made them determine when to click on the link to the Summary, they explained it might be due to the complexity of the patient, or a high opioid dosage identified, or if the patient was seeing other providers.

In future implementations of the Pain Management Summary app, the ability to launch the app automatically on appropriate patients should be explored, to improve clinician workflow and patient efficacy. This was considered during the pilot integration but determined not feasible due to technical constraints.

Role of the Patient

When asked if they shared the Summary with a patient, one clinician responded that he might verbally describe the information, especially lab results, and would be more likely to show it to some patients than others. He also commented that he does show the CURES report (the report generated from the PDMP) to some patients to "jog their memory." Another clinician has not shared the Summary with a patient, as she references it either before or after the patient visit.

Barriers

There were several barriers mentioned to using the Summary more frequently. One major barrier was the lag time in the app display once the link is selected. One clinician commented that it consistently took 15 seconds. There were also concerns voiced about inconsistent display of urine drug screen results and non-pharmacologic treatments. The display of the MME was also reported as inconsistent, even if present in the Epic EHR. The clinicians were reminded by the

OCHIN clinical lead that to troubleshoot any of these issues, they needed to enter a JIRA ticket with patient examples, which unfortunately did not occur during the pilot period.

Several important lessons came from this exchange. Additional troubleshooting and debugging were needed to help resolve the issues identified, but as noted previously, the ability for MITRE to support debugging and performance testing was limited due to restrictions on access to the test and live environment. In addition, the clinicians did not have a specific resource at the pilot site that could provide direct support and assistance in resolving or logging issues, and the Clinical Champion unexpectedly left the organization soon after the pilot kicked off. Communication from the pilot site clinicians to the OCHIN project team was limited, with some of this due to the unique partnership OCHIN has with its member organizations. Improved support, communication, and troubleshooting capabilities are all areas to consider in future implementations.

Recommendations

When asked about recommendations for enhancements, one clinician claimed it would be "magical" if the Summary automatically displayed the latest CURES report from the PDMP. Another clinician agreed they would find this very valuable. He also mentioned possible integration with a new feature OCHIN is implementing, medMATCH[6], that indicates if the patient's lab results are consistent with the prescribed medication.

A clinician recommended integration with the patient pain agreement, including information on the presence of a signed pain agreement, as well as a reminder if the renewal date is near. She also suggested additional pain assessment tools that measure functional status, such as the American Chronic Pain Association Quality of Life Scale, as well as the Pain Disability Index.

The MITRE team had initially considered integration with the State PDMP, but because of the variation of technical capabilities as well as legal considerations, it was not included in the initial development effort. Future implementations should consider the feasibility of implementing this enhancement, as most States now require PDMP access, or are on the path to require it.

Analytic Report Findings

As mentioned previously in the Pilot Implementation Planning section of this document, the MITRE team developed an Analytic Plan in collaboration with OCHIN, with the objective of providing quantitative data to help evaluate the effectiveness, accuracy, usefulness, and impact of the Pain Management Summary. The plan included pulling specified data into formatted reports at predetermined intervals (e.g., pre-pilot site implementation, during the pilot, and after the pilot conclusion) during the pilot process.

Pre-pilot Site Implementation

The initial objective of the pre-pilot data analytics was to confirm that the pilot site had a sufficient number of patients that met the inclusion criteria for the Pain Management Summary

and, for those patients, to gain an understanding of the availability of data within each section of the Summary. Additional reporting provided a sample of patients used by the OCHIN QA analyst to manually validate the accurate display of the Summary for each patient prior to actual use by the pilot site clinicians.

During the Pilot

During the pilot, data were collected to ensure the Pain Management Summary was working as expected, including capturing how many times the link to the Pain Management Summary in the EHR was "clicked on" (selected) by a clinician. In addition, data were generated by the Pain Management Summary app each time the Summary was launched for a patient, and the data stored for future reporting. The data included whether the patient was within the inclusion criteria, the total number of entries, and the number of entries for each data element or clinical concept populated in the Summary.

Pilot Conclusion

The reports created by OCHIN at the pilot conclusion utilized the data that originated from both the Epic EHR as well the Pain Management Summary app. The MITRE team performed further analysis of the reports with the following high-level findings:

1. During the 8-week clinical pilot, clinicians clicked on the link for the Pain Management Summary a total of 85 times, or an average of 10.6 times each week.
2. Availability of clinical data to populate the Pain Management Summary was evident, as shown in the report displayed in Figure 7.

Figure 7. Total of Summary Clinical Entries - July

Section/Clinical Entries	Sum
HistoricalTreatments	**252**
NonOpioidMedications	130
NonPharmacologicTreatments	8
OpioidMedications	109
StoolSoftenersAndLaxatives	5
PainAssessments	**104**
NumericPainIntensityAssessments	104
PainEnjoymentGeneralActivityAssessme	0
STarTBackAssessments	0
PertinentMedicalHistory	**73**
ConditionsAssociatedWithChronicPain	32
RiskFactorsForOpioidRelatedHarms	41
RiskConsiderations	**866**
BenzodiazepineMedications	38
MostRecentMME	6
NaloxoneMedications	9
RiskScreeningsRelevantToPainManagem	4
UrineDrugScreens	809
Grand Total	**1295**

Of note, MITRE learned that clinicians at the pilot location did not use the PEG or STarT Back assessments to support patient care; therefore, the count of entries is "0." As expected, the count of non-pharmacologic treatments is relatively low due to the lack of structured capture of this data.

Given the relatively short duration of 8 weeks of the actual use of the Summary by the pilot clinicians, the ability to draw any conclusive findings on the actual impact to patient care or outcomes was not feasible.

Post-Pilot Plans for the CDS

While OCHIN expressed positive feedback on their participation in the Pain Management Summary pilot, they do not plan on continued use or further roll out of the Summary at this time. The primary reason cited was the lag time experienced by the clinicians in the launch of the Summary for each patient. Additional reasons include the need for further piloting due to the limited number of pilot site users, concern that the OCHIN technical resources necessary to support troubleshooting and ongoing use are not available due to other priorities, as well as the lack of MITRE resources to implement any enhancements suggested by the pilot clinicians (e.g., integration with PDMP systems used at their member sites).

The Pain Management Summary artifact along with supporting documentation will be posted on the CDS Connect Repository for access by all stakeholders. In addition, MITRE and AHRQ plan to release the Pain Management Summary SMART on FHIR application as Open Source software using the Apache 2.0 license. Potential enhancements to the Pain Management

Summary (whether performed by MITRE or others) might include performance optimizations, addition of other related concepts, built-in MME calculation, and/or integration with PDMPs.

Key Lessons Learned and Future Recommendations

Throughout the pilot process, several valuable lessons were learned that both impacted the current pilot activities and work, as well as provided critical information to use when planning for the CDS Connect project's third year. Some of these are incorporated into other areas of the pilot report, but the key recommendations include:

1. **Pilot CDS integration**: Integration of the CDS at the pilot site required engineering efforts from OCHIN and the CDS Connect project team. The CDS Connect team did not have direct access to testing or production pilot systems, making debugging and performance testing very difficult. In future pilot efforts, access to testing environments (even if supervised) can likely make integration more efficient. If this is not feasible, then additional methods to support debugging and performance testing should be explored for each pilot site.
2. **Pilot FHIR support**: While the Epic EHR provided a FHIR API, several of the concepts that the CDS needed were not exposed through the FHIR API. This was especially true of pain assessments, which were captured in structured data, but were not available in the FHIR API. This required OCHIN's custom development. In future pilot efforts, these limitations should be considered during the technical evaluation and planning.
3. **Early engagement of key resources:** While the initial pilot planning and launch included the key members of the OCHIN pilot team, other pilot team members would have benefitted from earlier involvement. For example, the QA analyst was not introduced to the project until she was needed to begin the testing process, and she needed significant orientation and assistance to create an effective test plan and validate the results. In addition, at the end of the pilot period the CDS Connect team learned that the pilot site had an IT system resource available on site, and having that person involved in the initial clinician training could have provided an additional level of support to the pilot clinicians.

Conclusion

This feasibility project achieved the goal of developing, refining and verifying that the MITRE developed Pain Management Summary CDS performed as expected in a live clinical setting. The objectives established during the initial pilot planning for the CDS Connect project were met by the pilot activities, including successful integration with the EHR system, validation of the Pain Management Summary app design and content, and agreement by the pilot site clinicians that the information provided was valuable and contributed to patient care.

Through collaboration with OCHIN, MITRE benefitted from OCHIN's technical, clinical, and operational expertise. Through the pilot work, the CDS Connect team gained valuable information to support the CDS Connect Concept of Operations and enhance and validate the pilot CDS moving forward. The feedback and experiences of the OCHIN pilot team provided valuable input to the ongoing CDS Connect project from both a CDS consumer and contributor perspective.

Appendix B: References

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