Safer Decisions Save Lives: Functional Specifications for Clinical Decision Support Systems to Enhance Opioid Prescribing

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Summary

In March 2015, the Institute for Safe Medication Practices Canada began the *Safer Decisions Save Lives* (SDSL) initiative, supported by a two-year grant by Health Canada. The overarching goal of the initiative is to improve adherence to clinical practice guidelines when opioids are prescribed to patients. This may support efforts to reduce the misuse and/or abuse of opioids in Canada.

This document shares the functional specifications for a clinical decision support system (CDSS) designed to support the opioid prescribing process. It also describes a CDSS prototype where these specifications were implemented to the degree possible within the scope of the project.

The specifications outlined here are designed for prescribers who use an electronic medical record (EMR) system. SDSL recognizes that not all prescribers use electronic medical records; as a result, it has also developed guidance for non-EMR practices, which can be found on the ISMP Canada's Opioid Stewardship Website: https://www.ismp-canada.org/opioid_stewardship/.

The functional specifications described in this document were formulated from:

- Best practices identified from available guidelines and literature regarding optimal opioid prescribing and management;
- Feedback from an expert panel of Canadian experts on opioid prescribing[1], and
- Availability of software and technical support to develop a working test model of the specifications in Ontario.

The specifications are intended to be vendor agnostic (e.g., non-proprietary), and reflective of an ***idealized*** version of a CDSS. At the present time, we are not aware of any system that has the capability of supporting prescribers in the manner described in this document. Furthermore, our CDSS prototype has highlighted multiple limitations with currently available technology that may highlight areas of future work.

[1] Safer Decisions Save Lives: Proceedings of the Expert Panel on Community Opioid Prescribing; www.ismp-canada.org/download/publication-position/SDSL-Proceedings-Community-Opioid-Prescribing-2016.pdf and Safer Decisions Save Lives: Key Opioid Prescribing Messages for Community Practitioners; www.ismp-canada.org/download/safetyBulletins/2016/ISMPCSB2016-08-OpioidPrescribing.pdf

Purpose of the Functional Specifications

The Functional Specifications are intended to be used as a guide to Electronic Medical Record vendors, software developers, and other interested parties who wish to create or learn about clinical decision support systems to assist in opioid prescribing. These specifications are but one method of using technology to influence prescribing behavior.

Persons, vendors, or organizations wishing to develop their own CDSS products are encouraged to modify or adapt any of these specifications to better suit their needs or capabilities and to learn from this project's experience in creating a CDSS for community opioid prescribing.

CDSS Definition

Clinical decision support systems (CDSSs) refer to a broad spectrum of tools that can support clinician decision-making. For some, a CDSS may refer to an advanced software solution that integrates directly with existing electronic health records to integrate information from an individual patient's health record with leading evidence based recommendations about diagnosis and treatment. For others, simple reminders or alerts related to the patient's allergies, or a look-up table for drug interactions may constitute a CDSS.

In this document, we define CDSS as a process that uses a set of pre-made forms designed to collect and amalgamate specific information from the patient in order to enhance a clinician's ability to prescribe opioids in line with current best practices. Our CDSS has both an electronic version and a manual paper-based version; the electronic version has expanded capabilities because of its ability to rapidly compile statistics on pain patients enrolled in the electronic health record. The electronic version is described in detail in this document.

Overview of CDSS

The CDSS described in this document facilitates two processes: patient visits and periodic reporting.

Patient Visits

For patient's visiting prescribers (e.g., a family physician, pain specialist) for a reason related to pain, the CDSS generates an electronic questionnaire (hereafter referred to as a "*form*") with information pre-populated from the patient's electronic medical record (EMR). The patient then completes the form, and may receive additional questions from the CDSS depending on the patient's answers or as pre-determined by the prescriber. When the questionnaire has been completed, the patient's answers are immediately viewable in the EMR with notable risk factors flagged. At no point does the CDSS generate alerts or notifications that interrupt the prescriber; the information is simply made available for the prescriber to review if they choose, either in advance of the patient visit, during the visit, or not at all.

Good practice principles addressed by this function include:

- standardization of a patient's pain-related visit by facilitating the routine and consistent assessment of important patient and medication-related characteristics, thereby allowing for improved evaluation and comparison over time;
- review and reconciliation of current pain medications;
- routine collection of data on pain characteristics (location, intensity, frequency) and day-to day function
- evaluation of opioid misuse risk; and
- periodic assessment of co-morbidities (e.g., anxiety, depression).

The presentation and flagging of collected data in the clinical note section of the EMR supports prescriber review of current medications, determination of risk of misuse, evaluation of mood, coping, and function, and monitoring of safe opioid use by (if possible and applicable) determining date of last urine drug screen and expected run-out dates of current prescriptions.

After the visit, the prescriber has an opportunity to print a check-out form which summarizes the patient's visit. This form will include a list of drugs prescribed at the visit, suggested resources for the patient (e.g., pamphlets, online information or activities), expected date of run out of medications, and recommendation for when the follow up appointment should occur. This function acknowledges and highlights the role of the patient in pain management, provides a review of medications prescribed, encourages the patient to play an active role in pain management by engaging outside resources, and reinforces the need for planned follow-up.

Periodic Reporting

On a regular basis (e.g., quarterly), the CDSS compiles a report for all opioid patients in the prescriber's practice and highlights statistics related to opioid risk (e.g., patients who have been prescribed opioids for over 90 days, patients with concomitant benzodiazepine use). This report is available to prescribers on a set schedule, but can also be generated on an ad hoc basis if interim statistics are desired.

Good practice principles addressed by this function include:

- awareness of current opioid prescribing practices;
- identification of patients requiring further assessment; and
- identification of patients who may require medication tapering or change (e.g., above watchful dose, concomitant benzodiazepine prescriptions).

The specifications outlined in this document are written as broadly as possible, leaving flexibility in how they are implemented. They also represent an idealized CDSS that has capabilities beyond any system of which we are currently aware. The CDSS prototype described later in this document provides some examples of how some of these specifications can be operationalized, but owing to technical limitations, project scope limitations, and the manner in which EMR clinical information is generated and stored, we were not able to meet all the specifications outlined.

Table 1 summarizes idealized CDSS specifications based on the work done by the project team.

Table 1. Idealized Clinical Decision Support System (CDSS) Specifications

#	Specifications
1	The CDSS will provide forms to patients either on a desktop computer, mobile device or tablet. A tablet is recommended so that the patient can carry it from a waiting room to a consultation room with the prescriber; the prescriber may trigger additional forms during the consultation. Tablets provide a larger screen size for legibility compared to a mobile phone, and may simplify data entry (e.g., touch screen typing). Email or remote access to the forms within 24 hours prior to the appointment may improve participation by some patients.
2	The CDSS will pre-populate forms administered to patients with information from the EMR (e.g., current prescriptions and dosages, previous diagnoses, demographics, contact information (e.g., email address).

#	Specifications
3	The CDSS will allow prescribers to select the default forms and assessments that are to be completed by the patient. Additionally, the CDSS can be configured to automatically add additional forms for the patient to complete, within the same interaction session with the form device (e.g. tablet), based on any of the following three factors: • patient's responses, • as manually pre-determined by the prescriber for that patient, or • based on defined criteria that is automatically applied to all patients (e.g., if last known mood disorder assessment was greater than 1 year ago, add a mood disorder screening form).
4	The CDSS will allow prescribers to manually trigger new forms for the patient to complete, instantaneously, from within the EMR interface (e.g., during the patient's appointment, the prescriber decides the patient needs to complete additional forms).
5	The CDSS will transfer patient's responses to the EMR instantaneously upon completion.
6	The CDSS will format EMR notes to flag specific patient answers if they meet select criteria (e.g., if patient's total morphine equivalent dose (MED) higher than 90, highlight for prescriber), and where possible, providing potential interpretations of scores and responses.
7	The CDSS will display trends on measures of interest between patient visits (e.g., display values of pain score for each visit on a table or provide a visual trend across appointments) to facilitate prescribers' ability to review patient's progress.
8	The CDSS will automatically display the MED as the prescriber writes opioid prescriptions. The MED should be displayed prior to the prescriber finalizing the prescription, and the total MED prescribed to the patient should also be visible (e.g., sum MED of all prescribed medications).
9	The CDSS will produce a patient "check-out" PDF based on information from the patient's EMR notes and other calculated values (e.g., expected run-out date of prescription based on prescription duration). Prescribers' will be able to select desired attachments to accompany the PDF (e.g., exercise advice, opioid storage advice, information about chronic pain and depression).
10	The CDSS will email patients or print the "check-out" PDF either: a. automatically, based on configuration set by prescriber, and/or b. when manually triggered by prescriber.
11	The CDSS will compile a periodic report of all patients prescribed opioids and calculate specific measures (e.g., duration of opioid therapy, total morphine equivalent dose) on: a. a set schedule configured by the prescriber (see requirement #14) b. an ad hoc basis when desired by the prescriber, initiated from within the EMR interface.
12	The CDSS will generate the periodic report electronically or printed as requested by the prescriber
13	The CDSS will allow prescribers to adjust the frequency at which the periodic report is generated.
14	The CDSS will allow prescribers to select the default schedule on which the periodic report is automatically generated (no less than every 6 months, no more often than once a month); this does not apply to ad hoc triggering of the report, which can be done at any time.

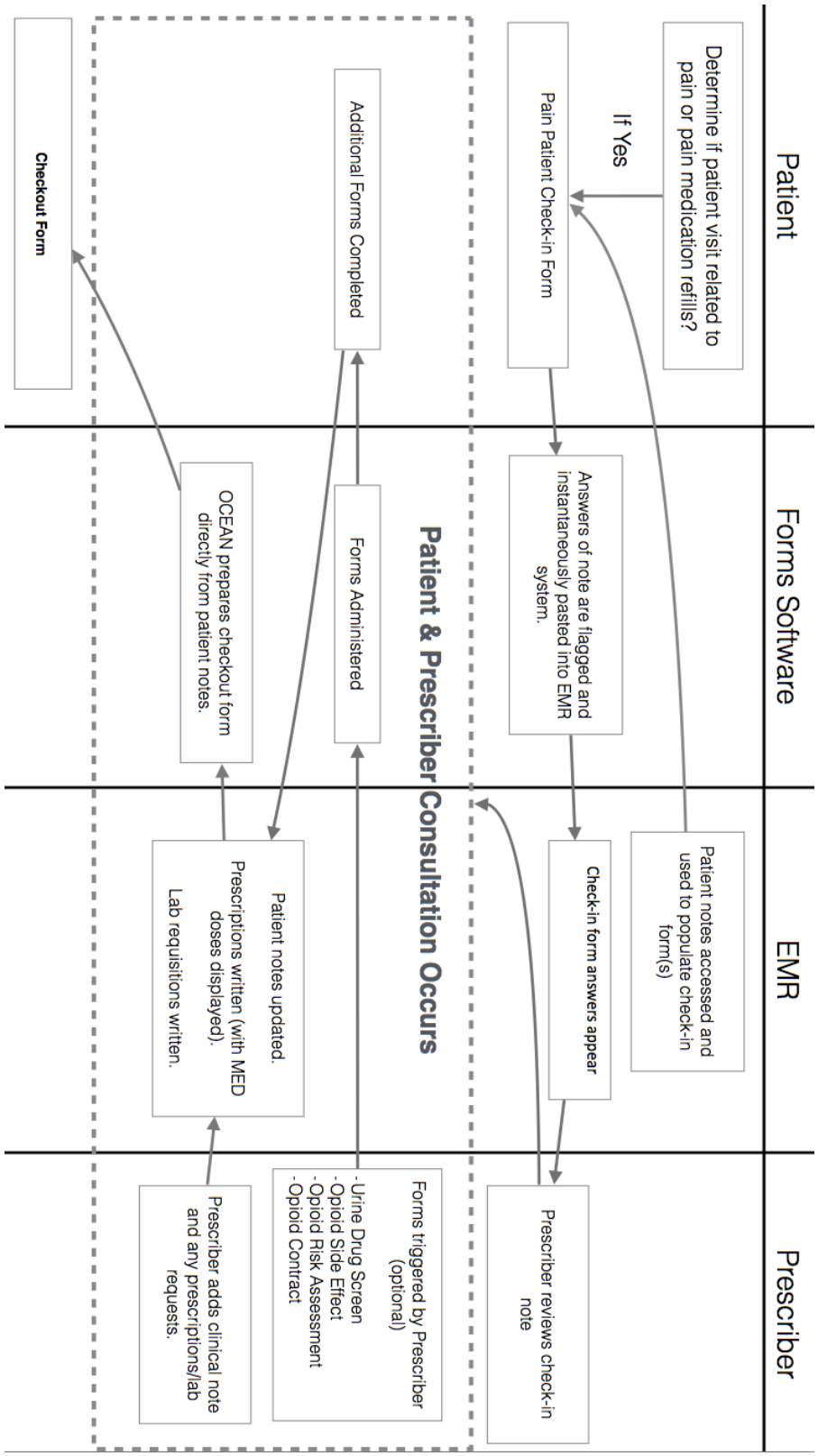
Specifications: Patient Visit

The patient's visit with their prescriber can be divided into four phases:

1. Collecting information from the patient
2. Displaying collected information for prescriber review
3. Facilitating prescriber decision making
4. Producing a summary document for the patient

Each of these phases will be described in the sections below. Figure 1 provides an overview of the various activities that accompany the patient's visit.

Figure 1. Clinical Decision Support System Workflow of Patient Visit



Phase 1 – Collect Information from the Patient

The CDSS is only relevant if patients are visiting because of pain, or because they require a refill of pain medication; the prescriber's usual processes should apply for visits motivated by other reasons.

Assuming the patient's visit is related to pain, the patient should receive a form (or series of forms) aimed at gathering the following information (or verifying if fields in the EMR can be used to pre-populate the form):

1. Name and dosage of medications they are currently taking
2. Current diagnoses
3. Visits to other pain specialists (date and specialists' name)
4. Assessments of the prescriber's choice or as triggered by defined criteria:
    a. A pain assessment tool (e.g., brief pain inventory[2])
    b. Emotion/mood assessment (e.g., PHQ9[3])
    c. Opioid Side Effect Assessment (if on opioids)
    d. Opioid use risk assessment (e.g., COMM[4], POMI[5])
    e. Triggered forms (e.g., mood disorder screening if not done in last year, updating treatment plan or opioid contract on a yearly basis)
    f. Other assessments (at the discretion of the prescriber)

Ideally, the forms will be pre-populated whenever possible, with information from the EMR. For example, if the patient is known to be taking benzodiazepines, the form will list the names of the benzodiazepine medications and their dosages, and then ask the patient to confirm or correct the information on file.

Phase 2 – Display Collected Information for Prescriber Review

The patient's answers are formatted and inserted into the patient's EMR file immediately upon completion. The format should be reviewed with prescribers prior to any technical solutions being developed, to ensure they are as user friendly as possible.

Table 2 describes notable data that may benefit from being flagged (i.e., made more salient) to increase the likelihood that the prescriber will consider this information.

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[2] Cleeland CS, The Brief Pain Inventory. http://www.rygforskning.dk/sites/default/files/files/skemaer/BPI_UserGuide.pdf

[3] Spitzer RL and colleagues, http://www.phqscreeners.com/sites/g/files/g10016261/f/201412/PHQ-9_English.pdf

[4] https://www.painedu.org/index.asp and http://www.opioidprescribing.com/documents/09-comm-inflexxion.pdf

[5] Knisely JS and colleagues, Prescription Opioid Misuse Index: a brief questionnaire to assess misuse. https://www.ncbi.nlm.nih.gov/pubmed/18657935

Table 2. Data Fields to be flagged in EMR

Data Fields	Rationale
Name of opioid medications currently being taken	Although opioids can be effective in the treatment of pain, it is widely recognized that this class of medications can cause harm. The ability to recognize and highlight prescribed opioids is the basis of mitigating risks.
Presence of a fentanyl prescription	High potency opioids have a heightened risk of harm.
Presence of concomitant opioid and benzodiazepine prescriptions	Increasingly, evidence points to the harm of combining opioids and benzodiazepines.
Days since opioid was first prescribed	Opioids are ideally used for short-term pain relief- there is little evidence that shows these medications are effective for longer term pain control. Patients who are on opioids for longer than one month are at high risk of being on very long term opioid therapy and being exposed to the increased risk of harm.
Morphine equivalent dose (MED) of each opioid taken	The use of MED increases prescriber comprehension of the strength of each prescription by providing a common reference unit. The risk of harm increases with increasing MED.
Total MED of the patient; additional flags of increasing severity if MED is larger than 50, 90 or 200	These levels of MED prescribing represent "watchful doses" where practitioners should re-evaluate opioid treatment or refer patients to pain specialists.

When standardized instruments are used, scoring and interpretation should be automated as much as possible, with scores or responses of concern highlighted for further review.

As patient's check-in responses accrue through multiple visits, the CDSS should be able to facilitate comparisons between visits (e.g., the prescriber should be able to monitor how the pain/function score has changed between visits 1, 2, and 3). This may be accomplished by different mechanisms (e.g., quick line graphs that demonstrate trends for specific measures or a custom table that plots key measures against each visit date so that all measures can be reviewed rapidly at once).

Phase 3 – Facilitate Prescriber Decision-Making

In the course of reviewing the information from the forms, or in speaking with the patient face to face, the prescriber may require additional assessments to be performed (e.g., if the patient is a candidate for opioids, the prescriber may desire an opioid risk assessment, urine drug screen and/or an opioid agreement/contract). Therefore, the prescriber should be able to identify and select additional forms, assessments or forms they would like the patient to complete electronically and send them directly to the patient's device for instant completion, within the appointment session. Ideally this option should be available from within the EMR, so as to minimize the number of steps the prescriber must take to select the forms that should appear on the device that the patient uses to view them.

Additionally, functionality should be built into the EMR such that the morphine equivalent dose of any opioid prescriptions written is immediately displayed during the prescription ordering workflow. Doses that exceed the threshold levels of 50, 90, or 200 should be highlighted, or require acknowledgement via a warning box.

Phase 4 – Produce a Summary Document for the Patient

Once the prescription has been written, and the appointment concluded, the CDSS should output a patient "check-out" form, which includes:

1. Date of the appointment
2. The medication instructions (e.g., dosage, how/when to take)
3. Expected run-out date of prescription
4. Recommended date of next appointment
5. Referrals to any other pain specialists, if required
6. Additional handout information (e.g., information about sleep apnea, benzodiazepines) as determined by the prescriber.

Specifications: Periodic Reporting

The CDSS, on a frequency dictated by the prescriber, but no less than twice a year (i.e., at least every 6 months), will report the following information.

1. The number and percentage of patients on opioids out of the total clinic population
2. The opioid load (MED) over their pain patients, and over their total clinic population
3. A list of all patients in their practice on opioids and the following information for each patient
    a. The opioids they have been prescribed, along with dosages
    b. The presence of fentanyl and/or any long acting opioids
    c. Total MED
    d. The duration of opioid therapy
    e. The presence of concomitant benzodiazepines
    f. Percentage of change in the MED between their two latest visits, including new opioid starts (from a zero value to a non-zero)
    g. Out of date urine drug screen (flag if over 180 days since last urine drug screen)
    h. Out of date pain/function score (flag if over 180 days since last assessment)
    i. Duration since last visit (flag if last visit over 90 days ago)

The CDSS will generate a report for the practice. The report can be printed or delivered electronically, such as via email.

Limitations of Current EMR Systems

Limitations influencing the ability of current EMR systems to fully implement the specifications fall into two main categories: technological limitations and practice limitations.

Technological Limitations

Technological limitations are constraints inherent in the software, hardware, or data storage methods of EMR systems. A subset of these shortcomings is outlined as follows:

1. Inaccessible data: Certain EMR systems store data in a way that is difficult to retrieve and manipulate for the purposes of analysis. This may be due to EMR proprietary restrictions, storing data as a non-extractable portable document file or picture file, or other non-searchable method.
2. Non-standard data elements: The relationship between related data elements may be obscured by the manner in which they are stored in the electronic record. For example, drug and dose may be stored as two discrete elements ("morphine" and "5") or as one element containing both drug and dose ("morphine 5mg") or as contractions ("mrph5"). This variability significantly obstructs reliable extraction and analysis of the data.
3. Limitations in standard data fields: Some data elements (e.g., medication instructions), may be too complex for standardized data fields, or the standard data field does not provide the flexibility required for the instructions.
4. Restricted search functions: Although most EMR systems have a search function, this ability to search and identify desired data elements or components is restricted to the fields and logic capabilities provided by the EMR vendor. Searches are significantly hampered by limitation #2 described above.
5. Proprietary considerations: Most EMR software is guarded intellectual property and thus the ability to implement modifications independent of the software owners is extremely limited.
6. Interoperability and interconnectivity gaps: The multiple software systems that form a part of the health care system do not automatically or easily share information, or do not communicate with each other at all. Changes made to the medication regimen by one practitioner are not reflected in the EMRs of other practitioners in the patient's circle of care.
7. Developmental history of EMR systems: EMR systems are designed for storage of the patient's health record and have, in general, been conceptually and functionally analogous to the paper chart. Consequently, the ability to search, manipulate, and analyze the information contained with the record has not been a priority.

Practice Limitations

Practice limitations are constraints in clinical practice that affects EMR users. Often, time pressures or a lack of standardization and/or forcing functions lead to deviations from optimal workflow. A selection of these shortcomings is outlined as follows:

1. Incomplete adoption of EMRs: Although most practitioners use some kind of EMR, the degree to which practitioners employ the capability of the EMR varies. For example, a clinician may use an EMR to keep track of appointments, laboratory results, and medications, but continue to write encounter notes on a paper chart.
2. Use of short forms, acronyms, and variability in terminology: Users may describe illnesses in multiple ways. For example, "coronary artery disease", "vasculopathology", "MI", "CAD", "vascular disease", "heart attack" may all refer to the same disease process. Likewise "morphine", "Statex", "MS", "morph" may all refer to the same medication.
3. Use of free text fields rather than standard data fields: Most EMRs allow users to input data either in standardized fields, in free text fields, or in a combination of both fields. Practitioners may choose to preferentially enter data in the free text fields or may only partially fill standardized fields. This may be related to the limitations in standard data fields as outlined above.
4. Transfer/updating of information or into EMR: Healthcare continues to rely, at least in part, on paper based information transfer. Practitioners may not input this paper based information into the EMR in a timely manner. Consequently, patient information may not be up to date or may be erroneous.
5. Modifications of computer generated data: Once a form or prescription is produced by the software, subsequent modifications to that data are not necessarily reflected in the EMR. For example, a practitioner may make handwritten changes to a computer-generated prescription. These changes are not automatically captured by the EMR.

CDSS Prototype

This section will describe the CDSS developed by SDSL as an example of how the functional specifications might be implemented. It describes which of the functional specifications were addressed by our prototype.

Specifications Addressed by CDSS Prototype

This pilot system represents only one possible implementation of the specifications and should **not** be viewed as an optimal implementation. There are several specifications we were unable to achieve. Our CDSS prototype is matched against the idealized functional specifications in Table 3.

Table 3: Prototype Clinical Decision Support System's Adherence to Functional Specifications

#	Specifications	Achieved in CDSS Prototype
1	The CDSS will provide forms to patients either on a desktop computer, mobile device or tablet. A tablet is recommended so that the patient can carry it from a waiting room to a consultation room with the prescriber; the prescriber may trigger additional forms during the consultation. Tablets provide a larger screen size for legibility compared to a mobile phone, and may simplify data entry (e.g., touch screen typing). Email or remote access to the forms within 24 hours prior to the appointment may improve participation by some patients.	Achieved. Forms are available for patients to complete using electronic tablets.
2	The CDSS will pre-populate forms administered to patients with information from the EMR (e.g., current prescriptions and dosages, previous diagnoses, demographics, contact information (e.g., email address).	Partially achieved. Demographic information, contact information, prescriptions for opioids and benzodiazepines can be accessed. Accurate extraction of other information is prevented by non-standard data entry and technological limitations.

#	Specifications	Achieved in CDSS Prototype
3	The CDSS will allow prescribers to select the default forms and assessments that are to be completed by the patient. Additionally, the CDSS can be configured to automatically add additional forms for the patient to complete, within the same interaction session with the form device (e.g. tablet), based on any of the following three factors: • patient's responses, • as manually pre-determined by the prescriber for that patient, or • based on defined criteria that is automatically applied to all patients (e.g., if last known mood disorder assessment was greater than 1 year ago, add a mood disorder screening form).	Partially achieved. The CDSS always provided 3 forms (COMM (POMI), PHQ9, BPI). Additional forms can be queued for the patient to complete by the prescriber. However, we did not program logic to: • check for other criteria (e.g., administer additional forms if assessments were missing or out of date), or • provide additional forms depending on the patient's responses.
4	The CDSS will allow prescribers to manually trigger new forms for the patient to complete, instantaneously, from within the EMR interface (e.g., during the patient's appointment, the prescriber decides the patient needs to complete additional forms).	Not achieved. In our prototype, prescribers can add additional forms prior to the visit, but not during.
5	The CDSS will transfer patient's responses to the EMR instantaneously upon completion.	Achieved.
6	The CDSS will format EMR notes to flag specific patient answers if they meet select criteria (e.g., if patient's total morphine equivalent dose (MED) higher than 90, highlight for prescriber), and where possible, providing potential interpretations of scores and responses.	Partially achieved; for specific fields. Standardized instruments were able to be scored and interpreted. We could not flag MED, given difficulties in accurately extracting doses from free-text prescriptions in the EMR.
7	The CDSS will display trends on measures of interest between patient visits (e.g., display values of pain score for each visit on a table or provide a visual trend across appointments) to facilitate prescribers' ability to review patient's progress.	Partially achieved. Capabilities inherent in the EMR can graph a number of scores over time. Consideration of a table that would add a new column of measures for each patient visit could not be met within the project timeline.
8	The CDSS will automatically display the MED as the prescriber writes opioid prescriptions. The MED should be displayed prior to the prescriber finalizing the prescription, and the total MED prescribed to the patient should also be visible (e.g., sum MED of all prescribed medications).	Not achieved. We could not achieve this given the difficulty in accurately interpreting prescriber's free-text prescriptions.

#	Specifications	Achieved in CDSS Prototype
9	The CDSS will produce a patient "check-out" PDF based on information from the patient's EMR notes and other calculated values (e.g., expected run-out date of prescription based on prescription duration). Prescribers' will be able to select desired attachments to accompany the PDF (e.g., exercise advice, opioid storage advice, information about chronic pain and depression).	Not achieved. This capability was explored, but technical considerations limited the amount of useful information that could be harnessed into a "check out". Thus this feature was not prioritized for the project.
10	The CDSS will email patients or print the "check-out" PDF either: c. automatically, based on configuration set by prescriber, and/or d. when manually triggered by prescriber.	Not achieved. See above.
11	The CDSS will compile a periodic report of all patients prescribed opioids and calculate specific measures (e.g., duration of opioid therapy, total morphine equivalent dose) on: c. a set schedule configured by the prescriber (see requirement #14) d. an ad hoc basis when desired by the prescriber, initiated from within the EMR interface.	Partially achieved. The report can be generated manually on an ad hoc basis. Reports can be generated outlining all practice patients on opioids, all patients co-prescribed opioids and benzodiazepines, patients who have not had a urine drug screen in greater than 180 days, patients on opioids who have not had completed elements of the CDSS in greater than 3 months Regularly scheduled reports were not developed as part of the CDSS prototype. We could not report on morphine equivalent dose, opioid usage, percentage change in MED between visits, or the specific dosages of any opioids prescribed. This is largely due to the inaccuracies of extracting information from free-text prescriptions.
12	The CDSS will generate the periodic report electronically or printed as requested by the prescriber	Partially achieved. The reports generated above can be displayed within the EMR or printed.
13	The CDSS will allow prescribers to adjust the frequency at which the periodic report is generated.	Partially achieved. The reports generated above can be generated on an on-demand basis.

#	Specifications	Achieved in CDSS Prototype
14	The CDSS will allow prescribers to select the default schedule on which the periodic report is automatically generated (no less than every 6 months, no more often than once a month); this does not apply to ad hoc triggering of the report, which can be done at any time.	Not achieved.

CDSS Components

The CDSS prototype consisted of the following components:

1. Electronic Medical Record: Practice Solutions Suite (Telus)[6] deployed on a private clinic network using desktop computers running Microsoft Windows.
2. Patient Form Software: OCEAN (CognisantMD)[7]
3. Tablets for patients to complete forms: Android tablets connected to the private clinic network via WIFI

Pain Check-in Form

The Pain Check In form (PCI) has several components. First, it extracts active opioid and benzodiazepine prescriptions in the patient's file and asks patients to confirm what medications they are taking. Patients are also asked whether they are experiencing problems with the medications, if they have seen a pain specialist, and if they have any comments about their pain and/or pain management via free-text data entry. However, the core of the PCI is the administration of 3 assessment tools. The assessment tools in the prototype were administered in the following order:

- **Current Opioid Misuse Measure (COMM)[8] (17 items) – measuring elements of opioid misuse, replaced by Prescription Opioid Misuse Index (POMI)[9]- measuring elements of opioid misuse
- Patient Health Questionnaire (PHQ-9)[10] (10 items) – measuring mood, anxiety, and coping, with a subset of questions activated if a patient endorses thoughts of self-harm
- Brief Pain Inventory (BPI)[11] – short form (15 items) –measuring pain and function

Screenshots of the patient-facing tool are available in Appendix A.

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[6] https://www.telushealth.co/health-solutions/electronic-medical-records/products/ps-suite-emr/

[7] https://www.cognisantmd.com/

[8] https://www.painedu.org/index.asp and http://www.opioidprescribing.com/documents/09-comm-inflexxion.pdf

[9] Knisely JS and colleagues, Prescription Opioid Misuse Index: a brief questionnaire to assess misuse. https://www.ncbi.nlm.nih.gov/pubmed/18657935

[10] Spitzer RL and colleagues, http://www.phqscreeners.com/sites/g/files/g10016261/f/201412/PHQ-9_English.pdf

[11] Cleeland CS, The Brief Pain Inventory. http://www.rygforskning.dk/sites/default/files/files/skemaer/BPI_UserGuide.pdf

** The COMM was replaced by the POMI during usability testing owing to permission-to-use limitations

CDSS Output in the EMR

The output of the patient pain check-in form, when complete, appears in the EMR in four sections, in the following order:

1. Pain related medications and the patient's self report of whether each medication is, or is not, currently being taken
2. Patient's responses for each item in the PHQ9 and the total score (along with a legend contextualizing the score)
3. Table that displays the patient's responses to each item in the COMM/POMI and BPI
4. A field for the physician to add notes adjacent to a diagram of the patient's pain

Screenshots of the physician-facing tool are available in Appendix B.

Intended Usage of the CDSS Prototype

The usage of the CDSS prototype can best be thought of as two parts:

Part I – Periodic Reporting

Periodic reporting can increase awareness of opioid prescribing behavior, and can also identify patients who may benefit from using the tools. The EMR has a number of search capabilities. In this demonstration, search scripts were created to identify:

1. All patients on opioids (i.e., active prescriptions)
2. All patients on opioids and benzodiazepines (i.e., active prescriptions)
3. All patients on opioids who have no urine drug screen in the last 180 days
4. All patients on opioids who have not completed a The CDSS in the last 90 days

Part II – Patient Visit

Patients identified as potentially benefiting from use of the CDSS (as in Part I above) are preselected to have the CDSS activated at the next appropriate visit. The CDSS is then initialized on the tablet when patient arrives for next appointment and the following steps are completed by the patient while waiting for the start of the visit:

1. Confirmation of opioid and benzodiazepine prescriptions
2. Question about side effects or problems
3. Current Opioid Misuse Measure (COMM) or Prescription Opioid Misuse Index (POMI)
4. Brief Pain Inventory (BPI)
5. Patient Health Questionnaire (PHQ9)
6. Question about visit to pain specialist
7. Question about other comments from patient

Information collected from the patient prior to the visit is formatted and presented in the EMR as a note before the patient-physician encounter. Standardized tools are scored and where applicable, possible interpretations are presented. Potential flags and/or discussion points are flagged.

Outcome Goals of the CDSS Prototype

The CDSS is expected to produce a number of outcomes:

1. Pain related visits will acquire a structured and consistent approach to information gathering by incorporating routine data elements and measures.
2. Prescribers will have standard information with which to assess patients and engage in collaborative decision making with the patient, and will benefit from automatic highlighting of concerning responses (e.g., not using medications as prescribed, feelings of self-harm), promoting targeted exploration with the patient.
3. The standardized approach of the CDSS with patients on opioid therapy will allow for longitudinal evaluation of pain management in individuals, but also assessments within practices and comparisons across practices.
4. Patients will feel they have a stronger role in their own management by both self-assessment and by improving communication with their prescriber. By moving standard data collection into the waiting room, the in-person consultation between physicians and patients will focus on communication and discussion rather than rote data gathering.
5. Physicians and their practices can self-audit their practice as it relates to opioids, and identify areas in need of improvement.

Usability and Performance of the CDSS Prototype

The CDSS prototype was tested in a clinic setting by mock physicians and patients, as well as by real physicians and patients in actual clinical encounters. The Periodic Reporting search functions identified patients as intended and were used to preselect patients for the Patient Visit forms. The tablet component of the CDSS and the display of collected information functioned as intended. No issues of software or system instability were encountered, and only minimal change in normal workflow of clinic staff and prescribers was reported. The CDSS prototype was, in general, acceptable to patients as well.
Further usability and performance evaluation can be found in Safer Decisions Save Lives: Usability, Functionality, and Utility Testing for a Clinical Decision Support System to Enhance Opioid Prescribing available through: https://www.ismp-canada.org/opioid_stewardship/

The Future of, and Feedback on, the Functional Specifications and CDSS Prototype

Clinical decision support systems hold great promise in health care practice improvement. Although the project accomplished a number of intended goals, the limitations of both technology and typical practice proved to be difficult barriers. Expanded functionality and enhanced data manipulation of EMR software must be coupled with more standardized language and terminology when inputting data. The wide variety of both EMR systems and EMR users pose particularly complicated challenges.

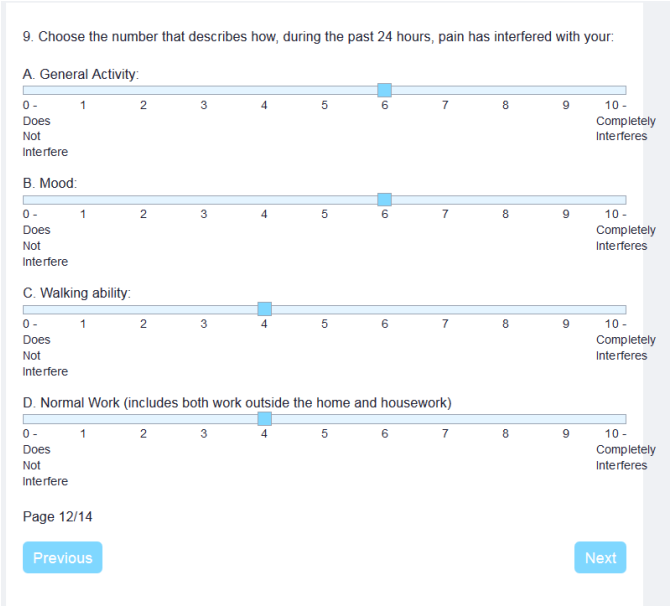
The Functional Specifications are intended to be used as a resource to Electronic Medical Record vendors, software developers, and other interested parties who wish to create or learn about clinical decision support systems to assist in opioid prescribing. Modifications or adaptations to any of these specifications or processes are encouraged.

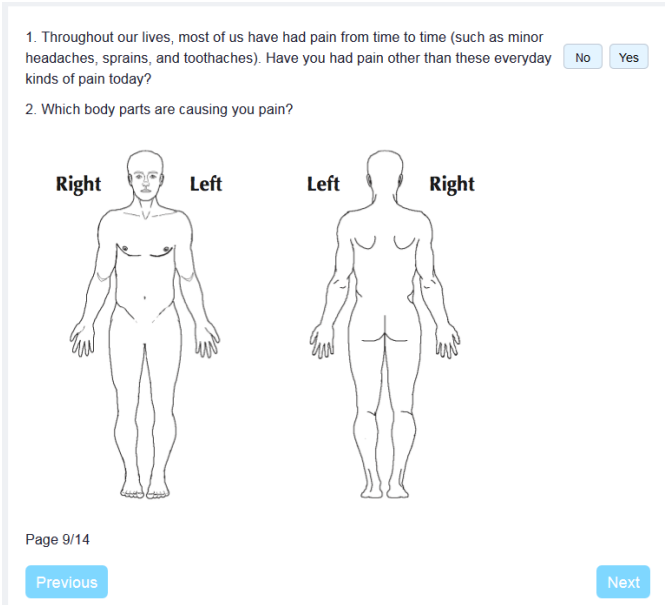
Feedback is welcome on the content or process outlined herein. Persons, vendors, or organizations wishing to develop their own CDSS products are encouraged to share their experience and ideas.

Comments can be sent to info@ismp-canada.org.

Appendices

Appendix A - Sample screenshots of CDSS prototype patient facing tool (on tablet)





Appendix B - Sample screenshots of CDSS prototype physician-facing tool (on EMR)