Safer Decisions Save Lives: Usability, Functionality, and Utility Testing of a Prototype Clinical Decision Support System 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 results of usability, functionality, and utility evaluation of a prototype clinical decision support system (CDSS) designed to support the opioid prescribing process.

The CDSS outlined here is designed for prescribers who use an electronic medical record (EMR) system. The SDSL initiative recognizes that not all prescribers use electronic medical records; SDSL has also developed guidance for non-EMR practices, which can be found on the ISMP Canada Opioid Stewardship website: https://www.ismp-canada.org/opioid_stewardship/. The paper based version was not formally evaluated.

Derivation and development of the CDSS is described in the document **Safer Decisions Save Lives: Functional Specifications for Clinical Decision Support Systems to Enhance Opioid Prescribing**, available at https://www.ismp-canada.org/opioid_stewardship/.

HumanEra is an applied human factors research team based at the Institute of Health Policy, Management and Evaluation (University of Toronto) and the Centre for Research and Innovation (North York General Hospital), and also is affiliated with the Centre for Global eHealth Innovation at UHN.

HumanEra's approach focuses on holistically capturing the *interactions* between people, technology, the environments in which they work, and the processes they facilitate. The team engages with the full spectrum of stakeholders (from front-line staff to patients, support workers, and organizational/policy decision-makers) by using methods such as clinical observations and in-situ and laboratory based simulations. As a result, HumanEra: captures the complexity of day-to-day operations; designs interventions that are informed by and supported by those most affected; quantifies improvements in rigorous simulation; and maximizes the probability of intervention uptake, an ongoing challenge facing the health system today.

For more information, visit www.humanera.ca.

The Institute for Safe Medication Practices Canada (ISMP Canada) is an independent national not-for-profit agency committed to the advancement of medication safety in all healthcare settings. ISMP Canada works collaboratively with the health care community, regulatory agencies and policy makers, provincial, national and international patient safety organizations, the pharmaceutical industry and the public to promote safe medication practices.

ISMP Canada's mandate includes collection, review and analysis of medication incident and near-miss reports, identifying contributing factors and causes and making recommendations for the prevention of harmful medication incidents. Information on safe medication practices for knowledge translation is published and disseminated.

Additional information about ISMP Canada, and its products and services, is available on the website: www.ismp-canada.org.

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Disclaimer
This document has been prepared for use for the Safer Decision Save Lives project and is provided as a service to others.

Not all evidence, knowledge, or advice may have been available or taken into account when preparing this document and not all possible practices informing safe opioid prescribing may have been considered or presented. Any person seeking to apply or consult the report is expected to use independent judgement in the context of individual circumstances. ISMP Canada and HumanEra make no representation or guarantee of any kind regarding the use or application of the report content.

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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.

The evidence addressing the use of CDSSs in medication safety or prescribing behavior is sparse[1], and the literature evaluating CDSS use in general with improved patient outcomes is conflicting[2].

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 evaluated in this document.

[1] Pengli Jia and colleagues, The Effects of Clinical Decision Support Systems on Medication Safety: An Overview. http://journals.plos.org/plosone/article?id=10.1371/journal.pone.0167683

[2] Roshanov PS and colleagues, Features of effective computerised clinical decision support systems: meta-regression of 162 randomised trials. http://www.bmj.com/content/346/bmj.f657

Description of the CDSS Prototype- The Pain Check In

CDSS Prototype Components

The demonstration CDSS consisted of the following components:

1. Electronic Medical Record: Practice Solutions Suite (Telus)[3]
2. Patient Form Software: OCEAN (CognisantMD) [4]
3. Tablets for patients to complete forms: Android tablets

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)[5] (17 items) – measuring elements of opioid misuse, replaced by Prescription Opioid Misuse Index (POMI)[6]- measuring elements of opioid misuse
- Patient Health Questionnaire (PHQ-9)[7] (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)[8] – short form (15 items) –measuring pain and function

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

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

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

[6] Knisely JS and colleagues, Prescription Opioid Misuse Index: a brief questionnaire to assess misuse.

https://www.ncbi.nlm.nih.gov/pubmed/18657935

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

[8] 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

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

CDSS Prototype 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**.

Altogether, the components, pain check-in forms and output into the EMR comprise the **Pain Check In (PCI).**

Intended usage of the Pain Check In

The usage of the PCI 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 (prescription is active)
2. All patients on opioids and benzodiazepines (prescriptions are active)
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 PCI in the last 90 days

Part II – Patient Visit

Patients identified as potentially benefiting from use of the PCI (as in Part I above) are preselected to have the PCI activated at the next appropriate visit. The CDSS then automatically initializes 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. COMM (Current Opioid Misuse Measure)/POMI – Prescription Opioid Misuse Index
4. BPI- Brief Pain Inventory
5. PHQ9 – Patient Health Questionnaire (Depression, anxiety, coping)
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 PCI

The PCI is expected to produce a number of outcomes:

1. Pain related visits will acquire a structured and consistent approach to information gathering incorporating routine data elements and measures.
2. Prescribers will have better information with which to assess patients and engage in collaborative decision making with the patient. Where possible, concerning responses will be highlighted (e.g., not using medications as prescribed, feelings of self-harm) for further exploration.
3. The standardized approach of the PCI with patients on chronic opioid therapy will allow for longitudinal evaluation of pain management in individuals, but also assessments within practices and comparisons across practices.
4. Patients will also feel they have a stronger role in their own management by both self-assessment and by improving communication with their prescriber.
5. Self-audit of practices related to opioids can highlight areas in need of improvement

Purpose of the Usability, Functionality, and Utility Testing

The PCI was initially created in a software development environment in a non-clinical setting. Although clinicians were involved in the development of the product and walkthroughs and field-testing were completed, real-use testing was required to assess the product under actual clinical conditions. The product employs the relatively novel use of electronic tablets for patient use that integrate with the patient's medical record. Usability and acceptability perspectives are critical given the wide range of comfort with electronic devices on the part of patients; this particular CDSS has a significant reliance on patient inputted data. Additionally, given the wide variability in adoption and use of EMRs by clinicians, it is important to understand their perceptions of these tools, their comfort with patient derived data, their ability to comprehend the formatted and partially interpreted data displayed in the EMR, the changes in workflow that the PCI produces, and their thoughts on the utility and capacity of this information to help them make better decisions about opioid prescribing.

Feedback was collected to understand the barriers and facilitators of adopting CDSSs in general, and of this PCI in particular. Of keen interest were the perceptions of clinicians on the ability of this product or other similar systems to improve opioid prescribing. Ultimately, analysis of the feedback may support further iterations of the product and be used to add to the body of knowledge about clinical decision support systems.

Usability Testing of Demonstration CDSS

Usability tests were conducted with primary care physicians and pain patients, separately. The usability tests took place at a family practice/walk-in clinic in Ontario. The clinic receives both walk-in patients, and patients who return for regular visits with their family physician. The clinic is staffed with 5 full-time and 9 part-time physicians, who see approximately 35 000 patients annually.

Methods

Physician usability tests were conducted as a quality improvement study for the clinic, while patient usability testing was reviewed and approved as a research study by the North York General Hospital research ethics board (REB #16-0069).

One at a time, each physician was asked to review the responses to the PCI form from two fictional patients, one at high risk of opioid abuse, and another at low risk. It was explained that the patients' regular physician had been called away and therefore the appointment was to provide coverage in the meantime. The physician would then meet with a patient actor playing the role of each fictional patient. Physicians were asked to conduct a clinic appointment as they usually would, and come to a decision about how to proceed. The mock appointments would end when the physician had made a decision about the appropriate course of action, and a semi-structured debrief and questionnaire would be administered to collect their feedback.

A convenience sample of clinic pain patients were recruited to participate in the usability study. Those that were due for an upcoming appointment with their physician, experiencing pain related symptoms, and taking pain medications were queried for their interest in the research study by clinic receptionists during the scheduling process. Patients that expressed interest in the study were then contacted by the research team to explain the study further and determine whether the patient could come to their regularly scheduled appointment early to take part in the study; all patients that expressed interest in the study consented and participated.

Currently, clinic patients who are flagged for a demographics update or who are pre-selected to undertake a tablet-based form, receive a tablet device upon registration to confirm their demographic information, or to complete the form. Therefore, not all patients were familiar with the tablet when participating in the study.

Upon arriving, patients were met by the study coordinator and then consented. Participants were then asked to complete a brief demographic questionnaire and then complete the forms required by the PCI on a touch-screen tablet while "thinking aloud" (e.g., providing ongoing commentary regarding their goals, expectations and current actions). The study coordinator observed the participant and the tablet to capture any other interactions of note. The consent process and usability test occurred in a private room for privacy and confidentiality reasons. When the PCI tablet forms were completed, a semi-structured debrief and questionnaire were administered and the patient continued to their regular clinic appointment as usual.

Of note, during the study, the project encountered permission-to-use limitations on the COMM. As a result, the COMM was replaced with the Prescription Opioid Misuse Index (POMI) instrument, which serves a similar purpose. All physician participants viewed the COMM score in the CDSS' EMR output, however some patient participants encountered the POMI assessment.

Results: Physician Usability Testing

Five physicians participated in the usability study. Demographic information is summarized in Table 1.

Table 1. Demographic Information for Physician Participants (N = 5)

Question	Responses	n	%
Gender	Male	1	20
	Female	4	80
Age	18-29	1	20
	30-39		
	40-49	2	40
	50 or over	2	40
How many years experience do you have working as a family physician	Less than 1 year	1	20
	1-9 years		
	10-19 years	2	40
	20 years or more	2	40

Question	Responses	n	%
How many years have you worked at this clinic?	Less than 1 year	1	20
	1-3 years		
	4 years or more	4	80
How many years have you used the Telus PS Suite EMR	Less than 1 year	1	20
	1-2 years		
	3-5 years		
	6 years or more	3*	60

*One abstention; participant was uncertain how long the EMR has been in use at the clinic.

Overall, physician feedback on the tool was positive. Table 2 summarizes the physician's ratings on the debrief questionnaire.

Table 2. Count of Physician Responses to Debrief Questionnaire (N = 5)

Question	Strongly Disagree	Disagree	Neither Agree or Disagree	Agree	Strongly Agree
I would use this new system in my practice				2	3
The information that is added to my EMR from the patient is useful				2	3
The way the information is displayed is easy to understand				4	1
I would like to review the information added to the EMR before I consult with the patient			1		4
The information added to the EMR is something that would enhance my decision making				1	4

Subjective feedback from physicians regarding the information provided by the PCI was positive. All physicians reviewed the data in the EMR and used it to guide their discussion with the patient, at times using it to ask specific questions about their daily habits. In the usability testing scenarios, physicians commonly asked about, or reviewed several aspects of the patient's activities and daily life. Table 3

summarizes the degree to which the PCI addressed some of the information they commonly requested from the patient.

Table 3. Physician Information Requirements from Usability Test

Information Requested by Physicians	Information Provided by CDSS in the EMR Output	Additional Requests from Physicians
The reason for the patient's visit	The BPI provides a diagram of the pain, but the CDSS assumes that the patient's overall condition is, or will be, described elsewhere.	None.
A review of the medications being taken, time since last visit, count of remaining medications	Patient's confirm which pain specific medications that have been previously prescribed are currently being taken.	Some physicians requested more explicit information be included, such as: • the prescribing instructions (e.g., how much to take and when) • the expected amount of medications remaining based on the date of last prescription/visit and the prescribed rate of use • the self-reported average daily or weekly dose taken of each medication by the patient • the total time the patient has been taking a specific medication Additionally, one physician indicated that the status of the urine drug screen would be useful (e.g., date of last screen, result)
Description of the pain, its frequency of onset, duration etc.	The BPI captures the average worst, least and average pain of the last 24 hours, and the current pain level.	Some physicians desired a more comprehensive description of the frequency of the pain episodes (e.g., frequency of migraines, severity).
A general timeline of the patient's medication use and its correlation to their pain (e.g., when do you take your medications, how effectively does it reduce pain)	The BPI includes a measure of the pain relief offered from analgesics in the past 24 hours. Additionally, the pain check in asks patients if they are experiencing any side effects or problems with their medications.	It may be helpful if patients are asked to self-report on their medication use on a typical day or week.

Information Requested by Physicians	Information Provided by CDSS in the EMR Output	Additional Requests from Physicians
What impact the pain or prescribed medications have, if any, on: • The patient's ability to fall or stay asleep • Ability to work • Other daily activities	The BPI captures interference with function on multiple categories, including sleep, normal work, relations with other people etc. Additionally, the PHQ-9 captures the frequency of patients' sleep difficulties.	None.
Amount of alcohol use, smoking, or other recreational substances	Not provided by pain check in form.	May be worth asking about the timing and frequency of alcohol use, smoking and other substances in the future. One physician expressed that medical marijuana may become another important question in the future.
Family history (e.g., addiction risk)	Not provided by pain check in form.	None.
Comorbidities (e.g., blood pressure, cholesterol)	Not provided by pain check in form.	None.
Patient's social support system (e.g., living alone?)	Not provided by pain check in form.	None.
Patient's emotional status and mood (e.g., suicidal ideation, self harm)	PHQ-9 provides an overall perspective of risk of depression.	Two physicians indicated a desire to include the use of the generalized anxiety disorder (GAD-7) questionnaire, either as a mandatory component of the pain check in form, or an easily accessible follow-up form that can be triggered, to further assess the patient's status.
Other treatments attempted or other clinicians visited (e.g., pain specialists).	The pain check in form asks the patient to identify if they have seen a pain specialist, or if they have used any other treatments for pain.	None.

In addition to physician's feedback on several information requirements above, additional themes emerged from their comments and the study coordinator's observations of the appointments including:

- **Value of collecting information ahead of time:** Physicians appreciated that the form collected useful information outside of the appointment, increasing their ability to maximize use of limited in-person consultation time with the patient. One physician asked if the pain check-in could conceivably be completed by the patient from home; this may allow for the form to be more

extensive and/or increase the amount of time physicians have to review the information prior to seeing the patient in person. Physicians who worked as walk-in clinic physicians found the additional information helpful in rapidly understanding patients for whom they otherwise have no history.

- **Pain Check In supports difficult conversations:** Some of the questions in the pain check in can lead to defensive or evasive responses from patients. By being asked to complete the questionnaire on a tablet ahead of time, outside of a direct face-to-face conversation, there may be a lowered probability of this reaction and a sense that such a line of questioning is standard. Additionally, the questions allow for more specific questioning than is typically possible face to face due to time constraints.
- **Obligation to address all information provided:** Some physicians noted that they feel more compelled to act on issues presented by the form, as flagged items suggest problem areas that must be addressed (e.g., problematic scores on individual COMM questions may require further investigation). This may lead to longer appointment times as physicians attempt to better characterize and understand the issues raised by the form, prior to making a decision about how to proceed. One physician suggested that the PCI may not be ideal to use for every pain patient appointment, but rather as an annual assessment of the patient's pain management.
- **Confusion regarding the assessment instruments:** Some physicians were not familiar with the COMM score and the questions it asked, but there was a unanimous sense that it provided useful information. One physician felt that it was not particularly sensitive enough to detect risk of abuse in one of the fictional patients, but the physician may have misunderstood the purpose of the COMM score as measuring multiple forms of substance abuse (in this case, alcohol), rather than opioids abuse specifically. One physician was confused by the BPI "interference with function" score, because the final score was displayed as an average of 7 items, instead of a total count out of 90 (this is from a different version of the assessment with which they were more familiar).
- **Information density:** Physicians commented that while the overall amount of information was acceptable, it could be formatted to better support rapid review. For example, the questions displayed in the COMM score table could be grouped by topic (medication related versus mood related questions). Key items including, but not limited to, the COMM score, the BPI's "interference with function score", the PHQ 9, or other flagged items could be pulled out into the left-hand margin so they are immediately eye catching summary information. If desired, physicians could then review the more detailed sub-questions that contributed to the summary information by looking at an indented section farther to the right.
- **Lack of interpretation or action oriented suggestions:** Physicians suggested that there was minimal guidance on how to integrate the information provided by the patient check-in. This

may, in part, be due to the information density. For example one physician did not notice the final COMM score until after the mock appointments were complete, and then it was unclear what the value represented. Another physician asked for the synopsis of the PHQ9 to be bolded so that it is more noticeable.

- **Patient data entry:** One physician suggested that the "other comments" question may lead to some patients writing an excessive amount of information, and recommended it be removed. Another physician expressed possible concerns for patients who speak English as a second language, or elderly patients who may not be familiar or comfortable with using the tablet.

Results: Patient Usability Testing

Four patients participated in the usability study. The responses to the demographic questionnaire are summarized in Table 4.

Table 4. Demographic Information for Patient Participants (N = 4)

Question	Responses	N	%
Gender	Male	4	100%
	Female		
	Other		
Age	18-29		
	30-39	1	25%
	40-49		
	50 or over	3	75%
Generally speaking, do you feel comfortable using technology?	Yes	3	75%
	No	1	25%
In general, how often do you use touch-screen technology (e.g., iPad, smart phone, etc.)?	Never		
	Rarely		
	Fairly often (i.e., daily)	2	50%
	All the time (i.e., multiple times per day)	2	50%
How long have you been a	Less than 1 year		
	1-5 years		

Question	Responses	N	%
patient at the clinic?	More than 5 years	4	100%
On average, how often do you visit the clinic for pain-related appointments?	Less than once per month	4	100%
	1-2 times per month		
	3 times a month or more		

Patient responses on the debrief questionnaire (Table 5) showed that the tool was generally well received.

Table 5. Count of Patient Responses to Debrief Questionnaire (N = 4)

Question	Strongly Disagree	Disagree	Neither Agree or Disagree	Agree	Strongly Agree
It is easy to read the information on the form				2	2
I understand the terminology and symbols on the form				2	2
Entering information into the form is easy			1		3
I would like to fill out this information every time I have a visit related to pain		1	1	1	1
This form helps communicate how I feel about my pain			2	2	
I think my physician will make better decisions about my pain based on my responses on the form				2	2

Note several participants expressed a desire to answer "between" categories (e.g., between agree or strongly agree). These answers have been "rounded down" for consistency and to present the most conservative subjective response to the CDSS forms.

Direct observations and subjective feedback were grouped into several themes, each described in more detail below.

Navigation and Data Entry

Patients were able to complete the questionnaire with minimal guidance, likely owing to their familiarity with technology (Table 4). However, there were occasional issues with the navigation that impeded their anticipated use of the tablet.

Scrolling

The need to scroll to view all questions on the tablet presented some unexpected challenges for patients. First, the PCI forms do not require scrolling for the first several questions, all appearing in a single view and being answered by the patient prior to proceeding to the next page. However, after several screens, this format changes and patients are required to scroll; this change is jarring for some users. This was particularly noticeable on a screen where the option to proceed to the next screen is not enabled until the patient has scrolled to the bottom of the screen. Most patients were momentarily unable to determine their next steps at this point, with one patient being particularly confused that bottom question was slightly obscured "off screen". At one point, the PCI form provided a prompt to the user to scroll down by dragging the screen "upwards" with their finger, but it happened too quickly for the patient to register.

Second, scrolling complicated the process of identifying questions that had been unanswered. One patient had accidentally overlooked a question and attempted to proceed. An error prompt informed the patient that a question had been missed, which the patient understood, but when they dismissed the prompt they could not determine which question they had missed, as all the questions on screen at the time had been answered. It did not immediately occur to them that they might need to scroll to view other questions on the page.

Finally, in the process of scrolling, the observer noticed that participants sometimes inadvertently changed their answers. By placing their finger on the screen and dragging it upwards, the scale from 1-10 they had used to answer a question sometimes spontaneously adjusted to their finger position and patients were sometimes unaware of this, continuing to the next screen without correcting the change.

Misleading Page and Question Numbering

At the conclusion of the brief pain inventory, but prior to the administration of the PHQ9, one patient assumed the PCI forms were complete. This may have been supported by the page numbering, as the PCI form indicated that they had reached "page 10/10" in the page footer. Notably, none of the other patients noticed or made comments about this, or the variable question number (e.g., after the COMM instrument and the brief pain inventory, the question numbers restart at 1).

Exiting the On-Screen Keyboard

The use of the keyboard was straightforward in most cases, but some patients found it difficult to eliminate the keyboard when their data entry was complete. Given that these patients were comfortable with technology; this may present issues for other less technology savvy patients.

Undoing Accidental Markings on the Pain Diagram

One question in the PCI forms requires patients to indicate where they are experiencing pain in a diagram of the human body. Two views of the body are presented (anterior, posterior). Patients found the use of the diagram to indicate where in their body they felt pain to be intuitive and straightforward. However, when accidental markings were placed (e.g., patient intended to mark the wrist but marked the elbow instead), patients were initially unsure if this could be removed and appeared to be ready to move on without attempting to correct the error. When prompted to consider ways to undo the error, the thought of pressing the mark again to remove it occurred to some patients, which successfully removed the accidental marking.

Mismatch Regarding Question Answer Categories and Patient's Preferred Response

All patient participants expressed at least one comment of frustration or difficulty with the answer categories provided by the PCI form. The comments between patients were, at times, contradictory:

- One participant felt there was insufficient granularity in the possible responses (e.g., wanted to answer a question with a response of 5.5, rather than 5 or 6). In contrast, a different patient felt that they preferred to answer with a range (e.g., 4-7) rather than a specific value (e.g., 5). This, in their opinion, was a better reflection of the variability in the experience. Additionally, in the PHQ9, one patient felt that the questions grouped vastly different phenomenon (e.g., "trouble falling or staying asleep, or sleeping too much"), and as a result did not communicate a clear picture of their issues to their physician.
- The instructions for how to use the answer categories are unclear to some patients due to being in tablet form. For example, the question format for the brief pain inventory asks patients to "Please rate your pain by choosing the box beside the number that best describes your pain on *average*."). In the original paper format, each number on a scale from 1 to 10 has an individual box that can be marked. However, in the digital version created for the CDSS forms, a "sliding scale" is utilized. This discrepancy in question wording and answer format led to some confusion on how to proceed on the part of one patient.
- In question 7 of the brief pain inventory, the PCI form was modified to provide some typical complementary treatments patients might be using to treat their pain (e.g., massage, physiotherapy). This was done to reduce the amount of text entry patients might encounter while

using the tablet. One patient expressed that they did not understand what homeopathy was, so was unsure whether to select it. The patient also indicated they were looking for a "none" option, and a "self-help" option in reference to their self-care activities. When they selected "other", they were surprised by the appearance of a text field requesting for them to type what other treatments they were using. They indicated they would have preferred to see this text entry field from the beginning.

- Two participants found question 8 of the brief pain inventory confusing (i.e., In the last 24 hours, how much relief have pain treatments or medications provided? Please choose the box with the percentage that most shows how much relief you have received) and suggested it either be reworded, or remove the use of percentages in favour of a simple 1 to 10 scale as used in previous questions.
- One participant was confused about the default answer category in the drop-down menu for questions in the PHQ9, and suggested that the form might keep the same sliding scale format as in previous questions. This participant attempted to select the appropriate answer by pressing the radial button to the right of the answer, but often accidentally "exited" the drop down menu, as the radial buttons are close to the edge of the answer categories; this resulted in an experience of not understanding why their answer was not being registered.

Question Design

The PCI form is largely designed with validated instruments; however some patients indicated that the questions were not ideal for the purposes of sharing information with their physician. For example:

- Patients had contradictory ideas about the appropriate time frame that should be queried. One patient felt that describing the variation in their pain in the last 24 hours was short sighted, and that a longer time frame should be used. This patient also felt that there were significant trends or variations over the month when responding to some of the questions, and this was not being reflected in their communication with their physician. Another patient however, when addressing questions about the past 30 days, laughed and indicated they could barely remember the day prior.
- Some of the questions in the COMM were considered difficult to answer. For example, questions about the patient's memory, or the frequency of arguments they have had in the last 30 days, were met with questions about confounding variables (e.g., "age is a factor too", "I had mortgage issues this month").
- One patient felt that the terminology was slightly too advanced, and that the questions could often be simplified.

- Two patients felt that question 9 of the PHQ9 was insensitive (i.e., Thoughts you would be better off dead, or of hurting yourself in some way).
- One participant expressed confusion about why the brief pain inventory diagrams showed both the front and back of an individual (e.g., if the knee hurts, does it need to be indicated whether it is front or back?).
- While the response to the questionnaire was positive, as was the patients' assessment of its value, some patients felt that it was too long to use for each pain related appointment. One patient inquired as to whether it could be done from home, and another worried they would feel rushed to complete it.

Incomplete Capture and/or Review of Medications or Medical Substances

Through the debrief interview, it was discovered that patients were prescribed multiple pain medications, but the PCI form was not displaying all of them. The PCI is able to extract active opioid and benzodiazepine prescriptions appearing in the EMR. Other medications used for pain, medications prescribed by other physicians (and not entered in the EMR), as well as opioids or benzodiazepines marked as inactive would not be identified. Additionally, one patient indicated that they use medical marijuana to assist with pain control and falling asleep, and that this was a notable omission from the PCI forms.

In what may have been an unintentional deployment of the PCI forms prior to the usability testing, one patient had indicated they had already answered these PCI forms, and noticed that the medications listed on the PCI were incorrect. The patient had attempted to correct the medications listed in their record with their physician on this prior visit. However, the same discrepancies appeared to them during the current usability test.

Readability and Privacy

Patients were all asked about the legibility, visibility and readability of the PCI forms, and patients unanimously felt that the forms were easy to view. Patients indicated that filling the forms out in the waiting area would be acceptable, although one patient expressed concern about being rushed given the length of the questionnaire.

Value of Documentation and Perception Management

Patients felt that the PCI forms would facilitate a more complete review of their situation by physicians, and also would facilitate tracking of the information over time. Some patients expressed their awareness that the questions and their answers may be framing their situation in a certain way and were acutely aware of the potential of being perceived as drug abusers. As a result, patients were sometimes thoughtful

about how they would respond to some questions, neither wanting to appear too dependent on their medications, but also concerned about being unable to secure the pain support they required. One patient indicated they felt the form would help broach topics they would be unlikely to raise themselves.

Limitations

The limitations of the usability tests are the relatively small sample sizes, and the restriction of testing to a single clinic. In particular, the demographics of the patient population were relatively homogeneous (e.g., older men who were long term patients at the clinic and relatively familiar with technology). It is unclear if patients less familiar with technology, women, or younger patients might face different challenges or concerns when using the PCI forms.

The change in the design of the PCI forms (i.e., the substitution of POMI for the COMM instrument) may address some of the concerns expressed by patients that participated earlier in the study. This is because the POMI is shorter, and has questions that are phrased differently. Similarly, some of the ambiguity in the interpretation of the COMM score, which some physicians were unfamiliar with, may be reduced. However, the fewer questions in the POMI compared to the COMM may reduce the number of insights physicians may be able to generate from the PCI forms.

Conclusions

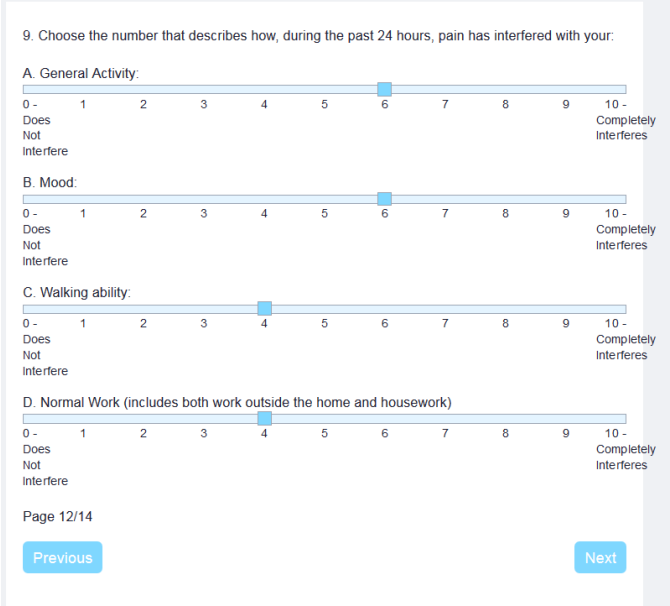
Overall, both physicians and patients reacted positively to the PCI. Participants felt that it facilitated valuable information transfer, saving time and enhancing the quality of the in-person visit between physician and patient. Several usability concerns were relayed with regards to how information was displayed and interpreted, for both user groups. There was mention of some additional functionality that may benefit users, such as the ability to complete the forms at home, and the option to use other standardized instruments. Both patients and prescribers agreed on the high degree of utility of the PCI, believing it would help improve decision-making around opioids. Future work will be required to determine the appropriate design interventions to address the concerns identified here, and further usability testing with a broader diversity of physicians and patients is recommended to determine if such changes lead to a reduction in usability issues for future iterations of the PCI.

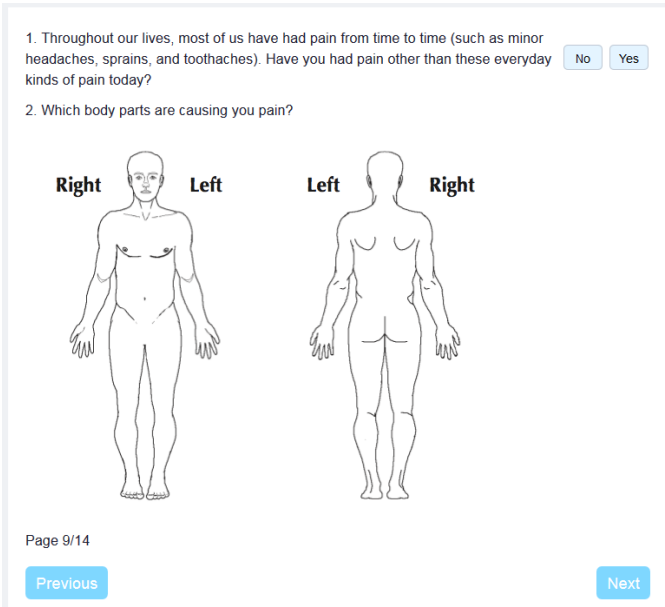
Further larger scale longitudinal studies are required to determine the impact of CDSSs in general, and the PCI in particular on actual long term prescribing behaviours.

The current (May 2017; Version35) release of the PCI is available through the CognisantMD Ocean website: www.cognisantmd.com. Further information, including a paper-based version, is available through ISMP Canada's Opioid Stewardship website at www.ismp-canada.org/opioid_stewardship/

Appendix A

Sample screenshots of demonstration patient facing tool (on tablet)





Appendix B

Sample screenshots of demonstration physician-facing tool (on EMR)