

**Clinical Decision Support System for Chronic Pain Management in Primary
Care: Usability Testing**

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Care: Usability Testing**

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A Thesis Submitted to the School of Graduate Studies in Partial
Fulfillment of the Requirements for the Degree

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ABSTRACT

Chronic low back pain is the second most prevalent chronic condition in Canadian primary care settings. The treatment and diagnosis of chronic pain is challenging for primary care clinicians. Their main challenges are lack of knowledge and their approach toward assessing and treating pain. Evidence based guidelines have been developed for neuropathic pain and low back pain.

CDSSs for chronic diseases are becoming popular in primary care settings as a mean to implement CPGs. A CDSS prototype for diagnosis and treatment of chronic, non-cancer pain in primary care was developed at McMaster University. It is evident that poor usability can hinder the uptake of health information technologies.

The objective of this study was to test the usability of Pain Assistant using think aloud protocols with SUS scores in 2 iterations. In this study 13 primary care providers including family physicians, nurse practitioners and residents used Pain Assistant to complete 3 different patient case scenarios. Participants were asked to comment on both barriers and facilitators of usability of Pain Assistant. Additionally time to complete patient case scenarios was calculated for each participant. A comparison questionnaire gathered user preference between introducing CPGs in paper format and computerized decision support system.

This study showed that iterative usability testing of the Pain Assistant with participation of real-end users has the potential to uncover usability issues of the Pain Assistant. Problems of user interface were the main usability barrier in first testing iteration following by problems of content. Changes were made to system design for second round based on the issues came up in the first iteration. However, because of time constrains not all the changes were implemented for second round of testing. Most of the refinements were to resolve user interface issues. In the

second iteration, the problems with the content of Pain Assistant were the major barrier. The changes to the system design were successful in resolving user interface problems since the changed issues did not come up again in second round. Pain Assistant had an above the average usability score however no significant changes seen in SUS score. The time needed to complete tasks remained identical in both iterations. In addition, participants preferred to have CPGs in electronic formats than paper. Further study after implementing all the system changes needed to determine the effectiveness of system refinements.

This thesis is dedicated to my dear parents

Nahid and Mostafa

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List of Abbreviations

CLBP- Chronic Lower Back Pain

CDSS- Clinical Decision Support System

CPG- Clinical Practice Guideline

EMR- Electronic Medical Records

PCP- Primary Care Provider

SUS- System Usability Scale

1 Introduction

Chronic low back pain (CLBP) is the second most frequent chronic condition in primary care settings.(1;2) Available statistics indicate that approximately 95% of Canadians experienced acute low back pain at least once in their lifetime. Generally, 10% to 40% acute low back pain cases will develop into CLBP.(1;3) Several sequelae have been attributed to chronic pain including lost jobs, drop in productivity, decreased quantity and quality of sleep, eating disorders, impaired mood, mental health problems and even suicide.(4;5) Apart from health effects, CLBP also places a major strain on the economy; although statistics specific to CLBP are not available, it has been estimated that, in Canada, chronic pain results in per capita expenditure of \$14,700, and 6 billion dollars annually in direct health costs, a figure projected to be at least 10 billion annually by 2025.(5;6)

In Canada, Primary Care Practitioners (PCPs) are the first point of contact with the health system for persons affected by CLBP.(5;7;8) It is estimated that on an average, PCPs see 37 CLBP cases every month. PCPs act as gatekeepers performing the important function of regulating referrals to specialists.(9) This is very important because recent data indicates that the wait time to see a pain specialist in Canada averages 6 months, even extending to 18 months in many cases.(3;10) Therefore the importance of PCPs being able to manage a significant volume of CLBP pain patients by themselves, reserving referrals to specialists for the more complex cases cannot be over emphasized.(8;11)

Management of CLBP is challenging for PCPs as the approach to the management and workout of chronic pain by family physicians and other PCPs is inconsistent.(11) Results of a survey pointed out little consensus among physicians regarding effective treatment approaches for management of chronic pain.(9) Failure to recognize the cause of pain and lack of clinical knowledge in pain diagnosis and treatment are amongst the main barriers in management of chronic pain in primary care settings.(1;9;11) Additionally, recurrent visits to multiple health care providers, monitoring of the CLBP and changing the behavior of the patient are other barriers in management of CLBP.(5;9;12) Evidence based guidelines for diagnosis and treatment of chronic pain are available.(13-15) However, integrating the clinical guidelines into the routine clinical practice remains a challenge.(16)

Clinical decision support systems (CDSSs) are applications that provide clinicians with patient specific clinical recommendations bringing together data from patient charts and data elements from clinical practice guidelines (CPGs).(16;17) It is reported that CDSSs can potentially be effective tools to implement CPGs with the potential to improve the care process of diagnosis and treatment of chronic disease.(17;18) Most of the CDSSs available today for ongoing care are focused on chronic conditions, especially diabetes and cardiovascular diseases.(19) Very few CDSSs are available to assist physicians with managing CLBP.(17)

A CDSS for management of chronic back pain is being developed at McMaster University as a module within OSCAR, an open source Electronic Medical Record

(EMR)(20;21) which is also being developed and maintained at the Department of Family Medicine, McMaster University. The primary aim of the McMaster CDSS is to help PCPs in diagnosis and treatment planning for CLBP and neuropathic pain. The CDSS accomplishes this by offering patient specific recommendations based on CPGs.

Like any other health information technology intervention, the success of a CDSS is dependent on many factors, usability being one of the most important.(22;23) Usability refers to ease of use and is a quality attribute that assesses the easiness of using the applications' user interface.(23;24) In order to improve the usability of the CDSS before release of the final version of the pain CDSS, two rounds of testing were planned and these are the subject of this thesis. The objectives of this study are to test the usability of the designed CDSS and compare the results of usability testing before and after system design changes. It was expected that this iterative testing would help us improve the usability of the final product, potentially resulting in greater uptake by clinicians.(25)

The thesis proceeds as follows. The next chapter summarizes the literature review related to this study. Then, the third chapter delineates the methodology of the study and usability testing followed by presentation of the results in the fourth chapter. Finally, the discussion and interpretation of the results is argued in Chapter 5.

2 Literature Review

2.1 Chronic Pain

The International Association for Study of Pain defines pain as an “unpleasant sensory and emotional experience primarily associated with tissue damage or described in terms of such damage”.(2;7) Traditionally, pain is divided into two broad categories: acute and chronic. Acute pain is usually of sudden onset, is sharp and lasts less than 3 months while chronic pain lasts longer than 3 months.(26) Acute pain is usually associated with ongoing tissue damage whereas chronic pain is generally associated with long term diseases.(1;7) The term chronic, non-cancer pain is used to denote pain unrelated to cancer that remains after the usual course of disease or injury.(7;27)

Neuropathic pain and CLBP are two of the most important types of chronic pain.(28;29) Neuropathic pain is defined as pain that occurs as a result of damage to or disease of the nervous system.(30) Results of a study have demonstrated that between 2% to 3% of the population of developed countries suffer from neuropathic pain.(30) Translating these data to Canadian conditions, it can be assumed that 1 million Canadians are suffering from neuropathic pain.(3) Tissue damage is the most common sign of neuropathic pain.(29) The diagnoses and treatment of neuropathic pain is a multi-factorial process with several variations and hence is complex for clinicians to manage.(29) In many instances, establishing the cause of the pain might prove to be challenging because of the large number of possible etiological factors.(28)

Low back pain is the second most common chronic condition in Canada after non-food allergies.(3;30) Low back pain is defined as a pain that occurs at any point along the spinal cord. Approximately 28% of adults experience low back pain.(9;28) According to Statistics Canada, between the years of 2007 and 2008, more than 2 million Canadians aged 12 to 44 reported lower back pain.(3) This type of pain is more prevalent in women than men, respectively 17% and 14%.(3) The incidence of low back pain increases with age.(9;26) The lower back is more prone than other spinal regions to injury and hence pain because it bears most of the weight and physical stress.(12)

CLBP refers to a type of low back pain that lasts for longer than 12 weeks.(31) CLBP is more prevalent between the ages of 30 to 50 with equal frequency in men and women.(1;27) Indeed, in nearly 85% to 90% of CLBP cases no specific cause of pain can be identified thereby making its management a difficult proposition.(11) The diagnosis of non-specific CLBP is challenging, this leading to inconsistency in management of this type of pain.(5;32)

A large number of studies have reported that management of chronic pain is challenging.(1;30-32) Clinicians find the assessment and treatment of chronic pain challenging because chronic pain is extremely subjective in nature and classification patterns often conflict with one another.(8;28;30) Both CLBP and neuropathic pain have distinct assessments and treatments.(12) Generally, the treatment strategies of CLBP is not effective in neuropathic pain and occasionally neuropathic pain gets worse instead of better over time and can even lead to serious disability in some cases.(33)

Physical examination and interviewing the patient are the most important basic methods used by clinicians to diagnose chronic pain.(30;31) The primary goal of chronic pain treatment is to control rather than cure the pain.(26) Generally, instead of treating CLBP or neuropathic pain, it is recommended to focus on improving the patients' symptoms, such as pain intensity, physical functions and eventually, quality of life first and then treat the underlying cause of pain.(5;9;26)

A disease condition as widespread as chronic pain can have significant negative effects on the economy of any nation. A survey conducted by the Canadian Pain Society in 2011 found that nearly one third of the Canadian population (32%) who have severe to moderate chronic pain have reported lost productivity and absenteeism.(3) These people have experienced lost income and even loss of jobs.(4;32;34) Chronic pain is a burden on the health care system too. A Canadian health population survey estimated that management of chronic pain costs the Canadian economy \$14,744 per person per year. In 2004, the annual direct cost of health care related to chronic pain was estimated to be \$6 billion dollars in total.(5;6)

Aside from the cost of managing chronic pain, patients' private lives and their families are also affected by chronic pain.(4) People with chronic pain usually assess their quality of life negatively.(4) Chronic pain can also lead to other conditions such as deprivation of sleep, fatigue and eating problems.(35) Chronic pain is also reported to be linked to absence from school,(34) missing social activities, and taking days off work which can

result in lost or changed jobs.(36;37) Eventually, chronic pain can compromise mental health, create anxiety, cause depression and even contribute to suicidal tendencies.(38)

Despite the overall expenditure associated with CLBP and neuropathic pain, little improvement in patient outcomes has occurred.(12;39) Results of studies have shown that chronic pain is often undermanaged, and many healthcare professionals do not optimally manage chronic pain.(9;12) The poor management of pain may be caused by failure of use of appropriate medications, dosage problems or medication side effects and moreover, insisting on medication therapy as the only modality in chronic pain management.(26;31) Given the substantial number of patients with chronic pain that each PCP works with, another issue that could cause mal-management of chronic pain is the limited training that PCPs receive in regard to chronic pain.(10)

To address the large population experiencing CLBP and neuropathic pain and the limited training PCPs receive regarding pain management, specialized pain clinics have developed.(5;10) However, only between 0.5 and 2% of patients with chronic pain have access to these clinics and the wait time for being admitted to these clinics is very long.(5) In Canada wait time to attend pain clinics is reported to be between 6 to 18 months.(5;27) More visits do not seem to be the answer to pain management either, as frequent and prolonged pain visits usually lead to poor clinical outcomes and dissatisfaction of patients.(5;27) Result of a survey showed that delivering outstanding clinical care needs high quality education and knowledgeable staff.(17)

A national study has found that educating either PCPs or patients can improve clinical outcomes and decrease pain.(8) It was also reported that if PCPs were provided with appropriate knowledge, they could more effectively manage patients with chronic pain and eventually reduce the number of referrals to a pain specialist.(9;26)

Chronic pain is more often identified as a manageable condition than one that can be cured. Dealing with chronic pain needs collaboration between patients and the clinical team.(12;32) Pain management also necessitates frequent visits, evaluations and medication adjustments.(12) Following CPGs is one way to support the decision making process of clinicians and improve patient outcomes.(1;30) A study on compliance with diabetes CPG has revealed that three years after the introduction of simple, accessible interventions in a primary care clinic, the level of clinicians' adherence to guidelines and patient outcomes both were improved.(40) Hopefully a similar benefit could occur with CPGs for chronic pain.

2.2 Clinical Practice Guidelines

CPGs are one of the most prominent means of implementation of evidence based medicine in clinical practice settings.(41) Ideally, CPGs are derived using strong clinical research (e.g., meta-analyses and large randomized controlled clinical trials) incorporating good clinical practice, while some of the CPGs result from clinician focus groups and expert opinion.(41-43) Large numbers of clinical guidelines pertaining to various disease conditions have been published over the past years. The U.S. Agency for Healthcare Research and Quality (AHRQ) has reported 2616 published individual

guidelines for diseases, treatments and health services administration by 2013.(43) The sheer numbers of CPGs make their incorporation into everyday clinical practice a challenge for clinicians. It is difficult for clinicians to search for, select and incorporate appropriate guidelines which fulfill their practice needs from the many published CPGs. Additionally, it is a challenge to make sure the implemented CPG is offering high quality and reliable information because of the high number of available guidelines.(44;45)

As well, the numbers of CPGs regarding effective treatment strategies continue to increase and the practice of medicine is lagging behind in CPG implementation. Clearly, integrating CPGs into routine daily clinical practice has proven to be difficult.(46)

Studies have been conducted on the application of published CPGs in clinical practice settings. Lomas et al found that the implementation of CPGs into clinical practice is at least 5 years behind.(47) Furthermore, many studies have also claimed that even the broadly accepted CPGs are not often followed in routine clinical practice.(41;44-46;48) For example, a study published in 2004 reported a low adherence of PCPs in Ontario to CPGs in acute low back pain treatment.(49) This report showed that approximately 78% of patients with acute back pain did not receive subsequent treatments as was necessitated in the CPG.(49) Another study conducted in Canada to assess PCPs' adherence to guidelines for the diagnosis and management of type 2 diabetes, reported compliance of PCPs with CPGs for type 2 diabetes in rural areas to be low.(50) Despite the availability of the resources and CPGs, only 10% of patients with type 2 diabetes received proper

tests, and only 22% of patients were prescribed medications according to CPG recommendations.(50)

Different CPGs are developed and published by governmental groups and professional organizations for specific diseases.(43;51) Efforts have been made to synthesize and summarize the diverse literature on the evaluation and management of CLBP and neuropathic pain. One of the accepted CPGs for managing neuropathic pain in Canada is the Canadian guideline on pharmaceutical management of neuropathic pain.(13) Also, the guidelines for opioid management(15), neuropathic pain(13) and low back pain published by Toward Optimize Practice (TOP)(14) are currently the working CPGs in assessment and treatment of chronic back pain in primary care settings. The primary objective of developing the CPGs was to increase the use of evidence based medicine principles in assessing the literature on the prevention, diagnosis and treatment of chronic pain in primary care.(14) Additionally, promoting justified referrals to pain specialists, and patient engagement in the process of care were the objectives for developing related CPGs.(17)

Studies have proved that traditional medical journals or textbooks are not effective ways of transferring knowledge at the point of care.(17;41;48) Paper-based educational materials are limited in their use and application of the content to a specific current patient problem. Traditional continuing medical education has been demonstrated not to be very effective in changing clinicians' behavior toward pain management and reportedly did not help to increase the application of CPGs into practice.(44) Despite the

fact that CPGs can optimize and standardize clinical care, their implementation into the routine practice remains challenging. Common barriers include lack of awareness toward the CPGs and the belief that guidelines cannot be effectively implemented.(47;51)

It is believed that CDSSs integrated into EMRs may provide the needed CPG recommendations for clinicians at the point of decision making. The next section will briefly provide an overview the CDSS technology.(16)

2.3 Clinical Decision Support Systems

The American Medical Informatics Association (AMIA) defines CDSSs as computer-based applications that “provide clinicians, staff, patients or other individuals with knowledge and person specific information, intelligently filtered or presented at appropriate times, to enhance health and health care.”(52) Wyatt defined CDSSs as "active knowledge systems which use two or more items of patient data to generate case-specific advice".(53) CDSSs generally use knowledge databases combined with patient information to make individual patient recommendations.(54) In other words, these computer-based applications present clinical recommendations based on data from the patient’s chart and relevant CPGs applicable to that particular situation. The main objective of any CDSS is to generate case-specific advice.(55)

CDSSs are promising tools to facilitate the effective implementation of CPGs, reduce errors in diagnosis and treatment of diseases and even to some extent, improve clinical

outcomes.(18) A study conducted by Sim et al. presented recommendations for accelerating the adoption of CDSSs for the practice of evidence based medicine.(55) They found that CDSSs are effective means to improve adherence to guidelines and drug dosing accuracy.(55) Also a recent systematic review that studied published journal articles on the effects of CDSSs on practitioner performance and patient outcomes stated that CPGs or expert physician opinion usually formed the knowledge base for CDSS.(56)

Most of the studies in the realm of CDSSs for chronic disease management in primary care have been concentrated on diabetes and cardiovascular diseases(19); a recent review demonstrated that CDSSs slightly improved the management of chronic conditions particularly with respect to the process of care and the selection of appropriate patient therapy strategies.(18) Only 51% of the studied CDSSs improved the process of care.(19) One study highlighted that CDSSs could have a positive effect either on process of care or patient outcomes in diabetes management.(57) In this study a web-based CDSS for diabetes monitoring in adults in primary care was used to evaluate the influences on the process of diagnosis and treatment as well as patient outcomes. The results confirmed that the 61.7% of patients with diabetes received excellent care provided by clinicians who used CDSS, in comparison to 42.6% of patients who visited clinicians who did not have access to the CDSS.(57) Despite the fact that the CDSS improved the process of care, not all the clinical outcomes were significantly changed. The CDSS helped to improve patient outcomes; blood pressure, and glycated hemoglobin were effectively controlled.(57)

Evidence regarding effectiveness of CDSSs is still emerging.(58) A randomized control trial was conducted to study the effect of the use of CDSS in planning for patient weight loss in comparison to paper based planning for patients.(59) This study showed that after 1 year of study, 32% of patients in the trial group that received the CDSS weight loss recommendations successfully lost 6 or more pounds in comparison to 18% in the control group that only received paper based recommendations.(59) In contrast, a CDSS that was used to implement CPGs in treatment of patients with hypertension in general practice(60) did not affect patient outcomes in any clinically significant way. In this clinical trial, two groups of patients were studied with the goal of reducing their cholesterol levels.(60) The intervention group who had received recommendations from the CDSS showed a reduction in their level of cholesterol in blood serum on average to 6.6 mmol/l. In comparison the patients in the control group had on average a 6.7 mmol/l of cholesterol in their blood serum. The study concluded that the CDSSs had not significantly improved the clinical outcomes.(60)

Only a few studies have assessed the use of CDSSs in management of chronic pain.(61) A study conducted in 2001 by Knab et al(17) stated that the use of CDSSs may facilitate PCP's management of chronic pain and may reduce the number of referrals to pain specialty clinics. This study tested a CDSS that was designed to help PCPs in the management of chronic pain. The content and recommendations provided by this CDSS were based on academically reviewed CPGs. It was shown that the use of a CDSS after a year decreased the number of patient referrals to pain specialists by 75%.(17)

Ease of use, functioning according to strong CPGs and their ability to fit into the clinical practice workflow are attributes of an effective CDSS.(52) Poor usability has shown a major barrier in uptake and success of any health information technologies. Traditionally, CDSSs have lacked usability testing before final implementation and this could be one reason for the lack of uptake.(22)

2.4 Usability of Health Information Technologies

Neilson explains usability as “A quality attribute that assesses how easy user interface are to use. It also may refer to methods of improving ease of use during the design process”.(24)

In addition, the International Standard Organization delineates usability as the “extent to which a product can be used by specific users to achieve specified goals with effectiveness, efficiency and satisfaction in a specified context of use”.(62) Usability applies to the aspects of the system with which users work.(63;64) Usability is considered to have five components: learnability, efficiency, memorability, errors and users’ satisfaction.(24;64) Two major methods to measure the usability of a system are usability testing and usability evaluation. While usability evaluation methods involve a group of experts using the product who identify usability problems quickly, usability testing methods involve current or potential users of the system.(63-65) Watching real users, who perform typical tasks with a system, can help uncover problems and areas to be improved. Continuous usability improvement and system refinement can be achieved by collecting users’ feedback and performing usability tests throughout the design process.(24;66)

Usability can be tested at different stages of system development and implementation. Iterative usability evaluation during the process of system development is shown to be a very effective strategy to elevate the level of usability of a system.(67;68) Additionally, the involvement of end-users early in the system design process can influence the usability of a system.(65;69)

Exploratory usability tests are valuable usability engineering methods.(64) Exploratory tests are usually conducted at early stages of system design and require extensive interactions between the test users and researcher or developer.(64) Exploratory testing methods are used to specify the functional aspect of the system and examine the effectiveness of preliminary system design.(63;64) In this method, the observers work with test users to gather first impressions of participants about the design or functionality of product. This technique allows observers to ask follow-up questions in a collaborative manner.(65;67) During the exploratory usability testing, participants will be asked to perform a series of predefined tasks while using Think Aloud protocols(66;70), verbalizing their thought process and actions. Think Aloud protocols are substantial techniques of data gathering for exploratory usability tests.(23;66)

2.5 Usability Testing Methods

For complicated applications such as EMRs, the exploratory method of usability testing would typically involve a mockup of the product that represents its layout, organization of functions, and high-level operations.(64)

Think Aloud is a dominant usability testing technique.(23;67) Think Aloud helps to understand how users see the application, while analysis of the interaction between the user and the system can provide an explicit list of usability problems confronted by end users.(25;68) A list of barriers and areas for improvements can also be generated from this type of testing. Usually this list is used to modify the product before the next usability testing cycle or final product release. Two cycles of Think Aloud usability testing normally yield the most significant issues to resolve.(67;70)

The basic principle of the Think Aloud usability testing method involves a test subject verbalizing her or his thought process and actions while using the system.(23;70) The process of Think Aloud usability testing is fully covered in section 3.7.2.

One of the objectives of usability testing is measuring the users' satisfaction with system design.(23;67) Several tools have been developed for this purpose.(23;25) One of the most accepted and applied type of tools for measuring user's satisfaction is the System Usability Scale (SUS) (Appendix C).(71) The SUS, developed by John Brooke, is a valuable subjective evaluation tool.(64;71) SUS is comprised of a 10 item, Likert scale questionnaire that gives an assessment of the usability of a system or electronic product. Each item is presented to participants on a 5-point scale, ranging from 1 for strongly disagree to 5 for strongly agree.(25;64;71) SUS has also been used to measure the learnability and usability of a system. SUS items are presented in Table 1. Items 1 and 4 correspond to the learnability of the system and the remaining 8 items correspond to its usability.(71-73) The method of scoring the SUS is discussed in section 2.5.1.

A personal health record that was developed for monitoring chronic diseases was tested with Think Aloud protocols to identify usability barriers.(74) Two iterations of Think Aloud usability testing were conducted. The findings of the Think Aloud testing were categorized into four different themes: components that worked well, components that did not work well, unnecessary functions and desired enhancements. Think Aloud protocols were successful in finding problems for novice users of a pediatric portal.(74) Changes that were made to the system design for the second iteration of Think Aloud usability testing. This second iteration showed decreased time for task completion and increased user satisfaction score.(74)

A recent study was conducted to test the usability of a CDSS for opioid therapy for chronic, noncancer pain by PCPs.(75) Think Aloud protocols in combination with other methods of usability testing such as SUS, interviews and log-files were used to test the usability of this opioid CDSS. Two rounds of testing also yielded barriers experienced by the PCPs. System design was improved based on the users' feedback on the aspects of usability. The system alterations positively changed the users' satisfaction and helped to improve the graphical user interface.(75) A large number of usability testing studies have used Think Aloud protocols as an important and valuable method of usability testing.(67)

Additionally, usability of a prototype of a CDSS for secondary stroke prevention in a veterans' healthcare facility was studied by involvement of end-users during the early stages of system development.(76) In this study, family physicians, residents, nurse practitioners and physician assistants participated in the process of usability testing. Think

Aloud protocols in combination with open ended interviews were used to collect data. Participants' comments were categorized into facilitator and barrier categories. The findings of usability testing were also used to refine the CDSS.(76) The refinements helped to improve the user interface. The main functionality and key user interface problems were identified using usability testing of the prototype of the Pain Assistant. The results of this usability testing indicated that the developed CDSS prompted clinicians on using guidelines and facilitated comprehensive documentation.(76)

2.5.1 SUS Scoring

SUS yields a single number representing the overall usability of the system. Individual items are not meaningful on their own. The range of SUS score is between 0 to 100. A score above 68 is considered as a good, or above, average score.(71;72;77)

To calculate SUS score, for the items 1,3,5,7, and 9 the item score is the scale position subtracted by 1. For even items, 2,4,6,8, and 10 the item score is 5 minus the scale position. Multiplying the sum of the scores by 2.5 yields the overall value of SUS.(71;72;77)

Table 1. List of SUS Items

#	SUS Item
1	I think that I would like to use this system frequently
2	I found the system unnecessarily complex
3	I thought the system was easy to use

#	SUS Item
4	I think that I would need the support of a technical person to be able to use this system
5	I found the various functions in this system were well integrated
6	I thought there was too much inconsistency in this system
7	I would imagine that most people would learn to use this system very quickly
8	I found the system very cumbersome to use
9	I felt very confident using the system
10	I needed to learn a lot of things before I could get going with this system

In summary, Think Aloud usability testing has been shown to be an effective way to integrate users in the development process of software and other applications.(78) As well, other methods of usability testing are used concurrently with Think Aloud methods. The SUS process is one of the frequently used methods to quantifying users' satisfaction.(73) The present study aims to incorporate these usability testing methods into the development of a chronic pain CDSS.

3 Methods

This section starts with a list of the research questions and then describes the study design, research ethics board approval, participant recruitment, software testing method and data collection and analysis methods.

3.1 Study Questions

This study addresses the following research questions:

1. What usability problems are experienced by PCPs while using the McMaster chronic pain CDSS, known as Pain Assistant, for diagnosis and treatment of chronic low back pain and neuropathic pain?
2. What usability facilitators are experienced by PCPs while using McMaster chronic pain CDSS, known as Pain Assistant, for diagnosis and treatment of chronic low back pain and neuropathic pain?

3.2 McMaster Pain Assistant

A prototype of a CDSS called McMaster “Pain Assistant” was designed to function as a clinical decision support tool for diagnosis and treatment of CLBP and neuropathic pain.

It was designed to function within the OSCAR EMR(20;21) system.

Pain Assistant incorporates content from the Canadian guidelines on low back pain(14) and neuropathic pain(13) and opioid management(15). Pain Assistant aims to help clinicians in making diagnosis and treatment decisions (both pharmacologic and non-pharmacologic) for patients with chronic pain disorders. Pain Assistant also provides the ability to monitor pain and responses to treatment over time. To this end, validated pain-screening tools for CLBP and neuropathic pain are imbedded into Pain Assistant: the Brief Pain Inventory® (BPI®)(79); Douleur Neuropathique 4 (DN4)(80); Patient Health Questionnaire-4 (PHQ-4)(81); Primary Care- Post Traumatic Stress Disorder (PC-PTSD)(82); and Pain and Sleep Questionnaire three-item index (PSQ-3)(83). Additionally, this application provides suggestions on medication prescription and resources for patient education. Short descriptions of the tools follow.

One of the most used and validated questionnaires for noncancer pain is the Brief Pain Inventory®. The purpose of this questionnaire is to assess the severity of pain and the impact of pain on the patient's daily function.(79) The Patient Health Questionnaire-4 which is a short self-report questionnaire that includes four items. PHQ-4 is designed for assessing depression and anxiety.(81) The PC-PTSD is designed for use in primary care settings to evaluate the post-traumatic stress disorders.(82) In addition, PSQ-3 is a standard validated screening tool that measures the impact of chronic noncancer pain on patient sleep.(83)

3.3 Study Design

A sequential exploratory mixed method(84) approach was selected as the research design of the study. This design was selected because as a composite method it uses both qualitative and quantitative data collection and analysis procedures. Additionally, the method aligned with project goals and available resources.

In the first step, a qualitative approach was employed to examine the activities and comments regarding usability problems by observing clinicians using the system. The goal of the qualitative phase was to gather an in-depth understanding of the issues related to the usability of the system. Think Aloud protocols(66) were used for this purpose. In the second stage, a quantitative approach was used to capture users' satisfaction scores using the SUS.(24;66;71) Additionally, descriptive analysis methods were employed to determine task completion time.

3.4 Participants

Research Ethics Board clearance was obtained from the Hamilton Integrated Research Ethics Board (REB#: 13-136). Family physicians, residents and nurse practitioners were selected as research participants because of their different perspectives in their approaches to the diagnosis and treatment of CLBP and neuropathic pain. The study took place at the McMaster Family Practice and Stonechurch Family Health Center, Hamilton, Ontario.

Study investigators selected the potential participants based on availability and ensuring representation from family physicians, residents and nurses. Participants were contacted by the research assistant to confirm the time and date of test sessions. The target was to recruit from 3 to 8 participants for each iteration of the study, with no less than 5 participants for each round. This consideration of numbers was based on conventional standards for usability testing. Recruited participants who took part in the study on their own time (i.e. not clinical time) were eligible to receive a \$100 honoraria.

3.5 Usability Testing Procedure

In order to achieve the goals of this study, 2 iterations of usability testing were performed, one before and, and one after system revisions. During each iteration, participants were given three different patient case scenarios (Appendix A) one each for medication renewal, diagnosis of CLBP and monitoring neuropathic pain. Each patient case scenario included a number of different tasks as presented in Appendix A.

3.6 First Iteration

In the first round of usability testing, each participant used Pain Assistant for 45 minutes to 1 hour while reviewing 2 to 3 patient cases.

A prototype of Pain Assistant was used, which was an actual version of Pain Assistant but ran on a demo server. It used a real patient chart and gave the participant the ability to write, alter and save information on the patient chart without being saved to a real patient

chart. The system had 1 patient chart for each of the 3 cases. All participant interactions with Pain Assistant were screen captured and responses plus Think Aloud verbalizations were audio recorded.

The process of the study was as follows:

3.7 Testing Process

3.7.1 Study Explanation and Obtaining Consent

The study procedures were explained to the participants on the test day. The explanations were given face-to-face by the author. Each participant was given information on the Think Aloud process. He or she was told that this might seem like an unnatural process but would yield important information for the study team. Participants had the opportunity to ask any questions regarding the usability testing and data acquisition methods. The participant was then asked to read and sign the study consent form and if eligible, the honoraria form.

3.7.2 Perform Tasks and Think Aloud

The participant was asked to start using the Pain Assistant prototype while reviewing the given patient case scenario and Think Aloud. The author, a clinical advisor and a computer programmer who observed participant interactions with the Pain Assistant took notes. An observation note sheet (Appendix B) was designed for each patient case scenario. This observation note sheet included a list of tasks which each participant was expected to perform. The order of the patient case scenarios was changed for each

participant to minimize the learning effect, as participants would be more familiar with the Pain Assistant in later patient case scenarios than with the first patient case scenario.

Participants were encouraged to Think Aloud about their thought process as much as possible. Prompts on tasks were given when the participant was unable to complete the expected subtasks. Participants had the opportunity to ask questions about the system and offer ideas about how to improve areas after completing the main tasks and subtasks.

3.7.3 Subjective Questionnaires

Immediately after the Think Aloud session, each participant was asked to fill out the SUS (Appendix C) and the user preference questionnaire (Appendix D). To avoid any influence by the observer comments, questionnaires were filled out before the debriefing discussion.

3.7.4 Debriefing the Session

During the debriefing, users were asked 5 open ended questions and were also asked to comment on any other particular issues that happened during the test session regarding the usability that needed more discussion or action. A list of the debriefing questions is presented in Appendix E.

3.7.5 Task Completion Time

During the study, each participant's interaction with the Pain Assistant was screen captured. The screen recordings were reviewed and the total time of participant's

interaction with the Pain Assistant was calculated with an electronic stopwatch on the computer screen.

3.7.6 Data Collection

A list of collected data, with data collection and analysis methods are presented in Table 2 below.

Table 2. Data Collection and Data Analysis Methods

	Data Collection Strategy	Data Analysis Methods
1	Demographic data	Descriptive analysis
2	Think Aloud protocols	Directed content analysis, qualitative analysis of transcribed audio recordings
3	SUS	Descriptive analysis for each of 10 SUS items and sub-factors of usability and learnability
4	User preference data	Descriptive analysis
5	Timing data	Descriptive analysis on programmatically calculated time interacting with the system

A combination of qualitative and qualitative analysis methods were used to analyze the data collected during the usability testing.

3.7.7 First Iteration Data Analysis

An identifier code was used to label participants' collected data. No specific identification information was collected and stored during the data collection and analysis. The sum, mean and median for time taken to do each task were calculated.

Microsoft excel was used to calculate the average, mean and median of the SUS scores and time needed to complete each task.

Data analysis was done in the 4 weeks after the first iteration of usability testing. For this purpose, all voice recordings were transcribed. Directed content analysis(85), which is a qualitative analysis, was used to pinpoint the usability issues of the Pain Assistant. A codebook with categories of barriers, suggestions for improvement and facilitators of usability was developed by the author who coded the transcripts. The number of occurrences of the codes was used to generate a priority list for system revision. The programming team tried to resolve the issues with a high number of occurrences before the second round of usability testing. The results of the data analysis of the first usability iteration are presented in Chapter 4.

3.8 Second Iteration

Based on the results of the first round of usability testing, some changes were made to the Pain Assistant. Usability testing in the second iteration was performed by using the changed version of the Pain Assistant.

In the second round of the study, new participants were recruited. Similar to the first iteration, family physicians, nurse practitioners and residents were invited to take part in the study. The 3 patient case scenarios and e-Charts were unchanged. The intention of using the same patient case scenarios and e-Charts was to have the ability to compare the results of the 2 iterations of usability testing.

Think Aloud protocols and SUS were used to measure usability of the prototype of Pain Assistant. All participant interactions with the Pain Assistant were again screen captured and responses were audio recorded.

The process of the study was similar to the first usability iteration except for changes in prompts on subtasks. Unlike the first round of testing, the verbal prompts of subtasks were included in the case scenario instructions.

The same five types of data (demographics, Think Aloud protocols, SUS, user preference and timing data) were collected as in the first round of usability testing.

3.8.1 Second Iteration Data Analysis

The same process was used for data analysis in iteration 2 and in iteration 1. Similarly, a list of barriers, comments for improving confusing areas and facilitators with the number of occurrence of each item was generated. Results from this round are also presented in Chapter 4.

4 RESULTS

As described in the previous section, we conducted 2 rounds of usability testing of the Pain Assistant system. This chapter outlines the results from both rounds of testing. It also details the changes made to the system design between the 2 rounds.

4.1 Participant Demographics

The first iteration of usability testing was conducted on April 17th and 18th, 2013 at McMaster Family Practice and Stonechurch Family Health Center. Seven participants, comprising of 3 family physicians, 3 nurse practitioners and 1 resident were recruited to take part in this round. For the second iteration conducted on May 27th and 29th at the previously mentioned sites, a new group of 6 participants, consisting of 3 family physicians, 2 nurse practitioners and 1 resident was recruited.

4.2 First Iteration Results

The first iteration of testing was expected to provide baseline data regarding the usability of the Pain Assistant system so as enable the research team to effect appropriate changes in the system based the results.

The participant's voice recordings were transcribed and coded and the major themes were defined by directed content analysis. Prior to analysis , coding categories were selected for characterizing the system usability following the work of Graham et al(86). The

author read the transcriptions and coded them verbatim. In the first round 7 participants commented on different aspects of the Pain Assistant.

4.2.1 Types of Usability Barriers

Broadly, two types of usability barriers were defined at baseline: 1) internal and 2) external. The term internal barrier is used to indicate those issues that were within the purview of system designers and could potentially be resolved by them. Examples of internal barriers were problems with user interface, content of the CDSS. The term external barrier is used in this thesis to denote such issues that were beyond the control of system designers as for example systemic barriers or changes in policies.

Within both of these broad categories (internal and external) systemic issues, user interface issues, technical problems and content problems have been categorized. The categories were developed based on prior studies. The definition of each category follows.

Only 1 category of external barrier, a systemic barrier was identified at baseline. The term systemic barrier is used to denote the features of the system dictated by policies, regulations and operational demands of the healthcare system. On the other hand, three types of internal barriers were identified, user interface issues, technical problems, content problem.

The term user interface is used to indicate the graphical presentation of the content of Pain Assistant. Generally, the characteristics of layout of Pain Assistant attributed to data

entry, provision of too much information, presentations of the items on the screen and the ease of navigation of the content or semantic issues. Additionally, the term technical problem was presenting the issues with computer functions that were not relevant to formatting or clinical content of Pain Assistant (e.g. ability to save or broken links between pages). Finally, the term content is used to denote the clinical items in Pain Assistant or any utility attributed to clinical content. This category included comments with clinical content (e.g. the content of medication list not included desired information) or clinical decision support (e.g. ability to flag patients).

These items were tabulated and sorted based on their frequency. In the tables below, the name of the category of each item is shown in the right hand column by using an abbreviation.

4.2.2 Usability Barriers

Table 3 presents the usability barriers of using the Pain Assistant experienced by participants in the first iteration of usability testing.

Table 3. List of Usability Barriers of the Pain Assistant, First Usability Testing Iteration

	Item	Frq. out of 7	CA T
1	Participants' lack of knowledge regards pain screening tools.	7	SY
2	Participants' lack of knowledge regards interpretations of the pain screening scores.	7	SY
3	Date, dosage, and the name of medication prescriber not existed in the medication list.	7	CF

	Item	Frq. out of 7	CAT
4	It was hard to recognize the current tab.	7	UI
5	Pain Assistant does not present any history of pain diagnosis. (referrals, consultant notes, specialist notes, results of examinations), diagnostic images and social history	6	CF
6	Measures are not linked to empty and previously filled questionnaires in main page.	4	TP
7	Locating patient education resources in encounter guides was not easy.	4	UI
8	The amount of text on “info about meds” boxes was overwhelming.	4	UI
9	The amount of text in boxes of “info about scores” is overwhelming.	3	UI
10	Going through the whole list of guidelines in CDSS need more time than a clinical standard visit.	3	SY
11	The medication list is inconsistent, not clear whether presents only pain medications or lists all the medications.	2	CF
12	The title of "info about meds" is not clear. (Does it present advice on medication prescribing or the medications patient is currently on?)This statement is not clear to me.	2	UI
13	Locating tools (e.g encounter guides and questionnaires) was not easy.	2	UI
14	Empty fields added clutter to the main page.	2	UI
15	Color coding is not intuitive in OSCAR EMR generally.	2	UI
16	Does the title of "resources" mean record of previous history of the patient or it presents empty new resources?	1	UI
17	Pain Assistant did not save automatically.	1	TP
18	Long list of opened questionnaire in the encounter guides added clutter to the page.	1	UI
19	The external resources (YouTube videos and patient handouts) were opened in the current window.	1	TP

List of abbreviations used in the table

Frq.: Frequency CAT: Category SY: Systemic Issue UI: User Interface Issue
 CF: Content Problems TP: Technical Problem

In the first round of usability testing, user interface issues emerged as the single most frequent theme commented on by the participants. Forty five percent of all comments (28 instances out of the total of 64 instances) at this stage were related to user interface issues of Pain Assistant. Systemic issues were the next most important area that participants were concerned about, with the occurrence of 16 instances translating to 25% of all the comments. Additionally, 23% of all the comments were regarded to content of Pain Assistant. Only 6 instances that translated to 7% of issues were technical problems.

4.2.2.1 User Interface Problems

According to the study participants, lack of an intuitive interface was the main user interface design related barrier of the Pain Assistant. Participants mainly noted difficulties in navigating the items on the screen, user interface impairments (e.g. cluttered pages) and semantic issues. Some examples of the participants' comments follow.

A number of participants declared the amount of text in the information boxes (e.g. “info about meds” and “info about scores”) added clutter to the page.

Another main challenge in usability of the Pain Assistant was navigating the tools. A number of participants declared that finding the items and tools on the Pain Assistant was difficult. For example, it was hard for participants to locate patient handouts or clinical encounter guides. Additionally, several clinicians stated vagueness in the coloring of the

tabs. They believed the tab color did not clearly define an open tab and caused confusion. They felt that colouring to indicate openness was not explicit and needed to be clearer. For example, a clinician articulated: *“I don’t know what really is open. I see I am in there [Pain Assistant] but if it could be highlighted, it would be nice.”* Since the gray tab color meant that there was no chronic pain diagnosis for the patient, and the opened tab was marked with an asterisk sign beside it. It was remarked that the asterisk sign was not prominent enough to be easily noticed.

Semantic problems were also identified by participants. Not all the titles were explicit to participants. For example, the title of “info about meds” implied the pain medications that the patient had taken previously. Another semantic complication identified by participants was the title of resources. While the resources section provided tools and guides for clinicians, it also conveyed the idea to some clinicians that it contained the record of patients.

4.2.2.2 Systemic Issues

Two systemic issues were identified in the first iteration of usability testing; knowledge and time. Participants commented that they were not familiar with the pain management tools used in the system and that they felt that they were likely to be unable to fit using the complete Pain Assistant within the duration of the usual clinical appointment. Participants indicated that perhaps they might have to select the tools or content they want to use rather than use all available guides.

Several participants reported problems toward the aspects of pain management that seemed not to be correctable by Pain Assistant. Firstly, not all participants' were familiar with the embedded standard pain screening tools. For example, one clinician stated: *"what is the DN4 ?"* or *"What is BPI ? I never used that before"* And another participant declared, *"So these are various questions I am asking the patient with the pain. But, I don't typically use these[pain screening tools] in regular practice."*

4.2.2.3 Content Problems

Participants highlighted some crucial barriers in using the content of the Pain Assistant. The main barrier was that the Pain Assistant did not give information regarding the date of the prescription or the dosage of the medications. As a result, participants had to go back to the main patient e-Chart to check the list of prescribed medications. As an example, a participant said, *"So then I want to know if these medications have been renewed in the past. Is there a way finding this out? Because I see a list of it, but not when they were prescribed. So I just need to go back to the old [prescription] module."*

Another content related issue that came up several times was the display of history of pain in the Pain Assistant. Test subjects stated that they wanted more details of previous diagnoses, referrals and diagnostic notes to be accessible within the Pain Assistant system. A clinician stated, *"I don't see any [history of pain]. I would want to know if this pain was similar to what he had before, and, I would want to know also what was done"*

for him before or if there was any investigations, x-rays? Or MRIs done, And how long did it [pain] last?”.

One more problem that was identified regarding the content of Pain Assistant was inconsistency in the presentation of the listed medications. It was observed that, in some instances, only pain medications were presented for some patients while a complete list of all medications was presented in other cases. Participants requested a consistent list of pain-related medications to be presented for all patients.

4.2.2.4 Technical Problems

Some technical problems also hindered the use of Pain Assistant. Participants stated that previously filled questionnaires were not linked to the pain screening scores. Therefore, the details of scores were not clear.

A participant stated that Pain Assistant does not save automatically. This can lead to loss of already entered information. Users can potentially lose information while browsing tabs or when accidentally closing the tool.

Another technical issue that raised concerns amongst participants was that the external resources (e.g. YouTube videos or patient handouts) and tools (e.g. BPI®) opened in the current window. Therefore, if they did not save the measures they were working on when opening one of these external resources, they would need to re-enter this information.

4.2.3 Features Requested to Be Added to Pain Assistant

Changes or suggestions for improving usability of Pain Assistant are presented in Table 4.

Table 4. List of Suggested Features or Changes of the Pain Assistant, First Usability Testing Iteration

	Item	Frq. out of 7	CA T.
1	Initial doses and list of covered medications to “info about meds” boxes.	5	CF
2	Write prescriptions directly from Pain Assistant	5	CF
3	Information regarding pain screening tools.	3	SY
4	Flagging patients on narcotics and indicate the refill date.	3	CF
5	Add patient handouts in easily printable formats (e.g. PDF).	2	CF
6	Form to document medication's effectiveness and side effects.	2	CF
7	Functionality to sort the measurements and scores by visit/date.	2	UI
8	Link to videos for patient handouts in easily printable formats (e.g. PDF).	1	CF
9	Reminder or flags to differentiate between types of pain, if several types of pain are present.	1	CF
10	More space in the Brief Pain Inventory® tool for text.	1	CF
11	Auto save and minimize functionality for tools.	1	TP
12	Pharmacy information into Pain Assistant	1	CF

List of abbreviations used in the table

Frq.: Frequency CAT: Category SY: Systemic issues Solution
 UI: User Interface Addition CF: Content Addition TP: Technical Problem Solution

During the usability testing, participants were given the opportunity to talk about the features that they thought would increase the utility of the Pain Assistant. An overview of the participants’ comments showed that 78% of all the comments were suggestions regarding clinical content of Pain Assistant. Twelve percent of all the comments were

demanding improvements the systemic barriers. Not surprisingly, only 7% of comments were about improving user interface, because most of the comments about user interface were given in the form of barriers and not suggestions to improve the interface. Moreover, 3% of comments were representing the need to recover technical problems. The results are listed in Table 4, and some of the suggested features to be added to Pain Assistant are presented here.

4.2.3.1 Content Additions

The majority of comments were regarding the content of the Pain Assistant. Because traditionally primary care clinicians are not very familiar with pain management strategies(5;75), elaborations on the content were requested by participants.

Several participants needed more information on the initial dosage of medication to be presented to support their pharmacological treatment strategies. Also, participants stated it would be more convenient for them to write prescriptions within Pain Assistant rather than going to the patient e-Chart and prescribe from the main prescription module. They believed the presence of this feature would help them as it takes fewer mouse clicks.

Clinicians also requested additional features for Pain Assistant to improve the utility of the content. One main concern in dealing with chronic pain patients was monitoring patients for narcotics abuse and clinicians wanted the Pain Assistant to flag patients with narcotic contracts and alert the clinician regarding the date that the patient would run out of opioids.

4.2.3.2 Systemic Issue Solutions

Another addition that participants asked for was information on tools. No information was provided about imbedded tools in the Pain Assistant and participants were clearly unfamiliar with the imbedded tools. A number of participants suggested that an explanation of the tool would help them to have a better understanding of the tools.

4.2.4 Usability Facilitators

During the usability testing participants also commented on the aspects of system design that helped them in interaction with the Pain Assistant. Table 5 lists the facilitators experienced by PCPs who participated in first iteration of usability testing of Pain Assistant.

Table 5. List of Usability Facilitators of Pain Assistant, First Usability Testing Iteration

	Item	Frq. out of 7	CAT.
1	The imbedded pain screening tools and pain encounter guides simplified chronic pain visit.	7	CF
2	All the pain pertinent information from patient chart was presented in one screen.	7	CF
3	Plotted trend of changes in pain scores, helped to identify pattern of pain.	5	CF
4	Patient handouts/educational materials will be an asset in changing the expectations of patient.	4	CF
5	The visual presentations (i.e. size and style of font and color) of Pain Assistant were pleasing.	4	UI
6	Auto calculation of the scores.	4	TP
7	Well-designed workflow prevented jumping around patient chart/going back and forth between Pain Assistant and patient e-Chart.	4	CF
8	Pain Assistant populates patient information from chart to Pain Assistant and vice versa.	2	TP

	Item	Frq. out of 7	CAT.
9	It was easy to complete questionnaires with check marks without the need to write things (yes/no answers).	2	UI
10	Presented a big picture of pain management (diagnosis, screening and treatment) rather than only focusing on medication therapy.	2	CF
11	Titles across the top distributed different items very nicely (easy access to different items).	1	UI

List of abbreviations used in the table

Frq.: Frequency CAT: Category SY: Systemic Facilitator
 UI: User Interface Facilitator CF: Content Facilitator TP: Technical Facilitator

The total number of facilitator instances was 44. Participants believed that the content of Pain Assistant facilitated its use. This observation was repeated in 70% of all the comments. User interface items as facilitators in using the Pain Assistant were repeated in 16% of all instances.

4.2.4.1 Content Facilitator

Participants' comments reflected that Patient Assistant was equipped with the essential pain-screening tools. Subjects believed that all the imbedded tools helped make the treatment and assessment of chronic pain better. Additionally, patient handouts in Pain Assistant would give clinicians access to the latest version of educational materials with few clicks.

4.2.4.2 User Interface Facilitators

Additionally, the font size and color of the items in the Pain Assistant were also seen as facilitators in the use of the Pain Assistant. Participants stated that filling out the pain questionnaires was very easy as questions were in yes or no format.

4.3 System Design Changes

In response to the usability barriers and comments for improvements that came up in the first round of usability testing changes were made to the Pain Assistant system. The changes are listed in the Table 6. Because of the time constraints, not all changes requested could be performed as the system was in an ongoing development stage. Therefore even some changes with lower frequency were prioritized over others because they were more in alignment with the progress of Pain Assistant development. The implementation of changes was delayed because the prototype of Pain Assistant was running on a demo server and it took time to be implemented on the server. The last column of the Table 6 shows the changes implemented for the second round of testing.

Table 6. List of Suggestions and Changes Made to Pain Assistant after the First Iteration of Usability Testing and before the Second Iteration

Item	Change/Revision	CAT.	Changes made
1	Patient name and demographics were added to the header of each page.	UI	+
2	Coloring of the tab was changed and an underline was added to indicate the current tab	UI	-
3	Bigger text input dedicated to the text area in Brief Pain Inventory®.	UI	+
4	Resources title reworded as it was not as descriptive.	UI	+
5	The title “info about meds” changed to “suggestions on medications”.	UI	+
6	Implemented the ability to make all questionnaires collapsible by default and added the + sign beside it to indicate that the questionnaire could expand.	UI	+
7	Suggestions on medications were updated to make first line more visible and the rest of text changed to an expandable field.	UI	+
8	A link to YouTube videos for patient handouts in printable format was implemented.	CF	+

Item	Change/Revision	CAT.	Changes made
9	Pain score correlated to medications functionality was added to the Pain Assistant to help clinicians identify the effectiveness of medications.	CF	+
10	History of the pain referrals, diagnostic images and pain diagnosis were added to the Pain Assistant in different tabs.	CF	-
11	Patient psychological SMART goals section added to both pain guidelines.	CF	+
12	The ICD9 codes displayed when “Add a Diagnosis” warning is displayed (only a list of specific chronic pain codes were shown).	CF	+
13	New tools added to resources: Opioid Manager, Narcotic Note, Narcotic Contract and Workplace Safety and Insurance Board (WSIB) form 8.	CF	+
14	Explanations were added to questionnaires; (i.e. titles, purpose, and how to fill out information).	SY	+
15	Explanations were added to each score.	SY	+
16	External resources (e.g. YouTube links) to be opened in a new window rather than the same patient e-Chart window.	TP	+
17	Measures linked to completed questionnaires.	TP	+

List of abbreviations used in the table

Frq.: Frequency CAT: Category SY: Systemic Changes
 UI: User Interface Addition CF: Content Addition TP: Technical Problem Solution

4.3.1.1 User Interface Changes

Because usability was reported as a major barrier in use of Pain Assistant, efforts were made to resolve some of the usability problems. A number of participants reported items as not being explicit, Titles (e.g., “Info about meds” and “resources”), and these were changed to clarify the purpose and content of each item.

Additionally, expandable fields were added to decrease the amount of text on the screen and in information boxes. To decrease the amount of text presented in “info about meds”

boxes, the design team planned to prioritize the visible information and condense the rest of the text under an expandable field for the next iteration. Therefore, only recommendations on the first line of medications would be visible and the rest of the items were hidden under an expandable button. Also actions were devised to resolve the problem of long lists of questionnaires in the clinical guidelines. The Pain Assistant programmer changed opened questionnaires to collapsible by default and added a plus (+) sign beside each questionnaire to indicate that the questionnaire could expand.

Participants reported unclear coloring of the tabs in the first iteration of usability testing. The opened tab was marked by an asterisk sign but because the sign was not clear enough, the programming team decided to try to resolve the issue by using underlining of the opened tab rather than marking it with an asterisk.

4.3.1.2 Content Changes

Besides the changes to the user interface, some new content was added to the Pain Assistant for the second iteration of usability testing. New embedded tools consisted of opioid therapy specialized tools and work injury claim forms. Clinicians in the design team decided to add these tools as the Pain Assistant was supposed to function in opioid management. Moreover, to involve patients in the process of care, patient SMART¹ goals were also added as a new content for the Pain Assistant.

¹ Specific, Measurable, Attainable, Relevant, Time Bound.

One major change requested by participants was adding history of pain to Pain Assistant. This issue was resolved by adding a history of pain diagnosis during the next revision. Information on previous diagnostic imaging, referrals to specialists, physiotherapist's consultation notes, and previously filled pain screening scores were planned to be added to the second revision of Pain Assistant.

4.3.1.3 Systemic Additions

In response to participants' requests to add information to imbedded tools, descriptions were added to tools and the scores. The explanations were about how and when to use the tool, and interpretation of scores. Also some information was added to each tool description for clarification. All these additional explanations were shown when users would hover the mouse on items or tools in the encounter guide or the face page of Pain Assistant.

4.3.1.4 Technical Problem Solutions

Technical problems with the Pain Assistant were also attempted to be resolved. In the first iteration some test users lost their information while browsing new tabs. Therefore, all of the new tools were programmed to be opened in new windows rather than the previous one.

In addition, participants commented that the date of entry and who entered the measures were not clear. Thus, to form a better understanding of measurements, previously filled questionnaires were linked to measures.

4.4 Second Iteration Results

The purpose of conducting the second round of usability testing was to assess whether the implemented changes to system design were effective and to identify other usability issues.

Similar to the first phase of usability testing, Think Aloud protocols were used to study the usability of the Pain Assistant system. Similarly, all the voice recordings of the participants working with the Pain Assistant were transcribed. The transcriptions were coded in a similar manner to the first usability iteration by the author. The number of occurrences of each usability category was calculated. Tables for barriers and facilitators were created and items were sorted based on the number of occurrences of the item. The results of the second iteration of Think Aloud protocols are presented in Tables 7, 8 and 9.

4.4.1 Usability Barriers

A list of usability impediments in using Pain Assistant by participants in round 2 are presented in Table 7.

Table 7. List of Usability Barriers of Pain Assistant, Second Usability Testing Iteration

	Item	Frq. Out of 6	CAT
1	Participants' lack of knowledge regarding interpretation of pain screening scores.	6	SY
2	The medication list is inconsistent, not clear whether it represents only	6	CF

	Item	Frq. Out of 6	CAT .
	pain medications or lists all the medications.		
3	Pain Assistant does not present any history of pain diagnosis (referrals, consultant notes, specialist notes, results of examinations), diagnostic images and social history.	6	CF
4	Date, dosage, and the name of medication prescriber do not exist in the medication list.	6	CF
5	The information on scores is not explicit to everyone.	5	UI
6	Locating patient education resources in encounter guides is not easy.	4	UI
7	It was difficult to recognize the current tab.	4	UI
8	Empty fields added clutter to the main page.	4	UI
9	Going through the whole list of guidelines in Pain Assistant requires more time than a clinical standard visit.	3	SY
10	The image requisition form in the Pain Assistant will result in over ordering the diagnostic images; this contradicts the new policy of Ministry of Health of Ontario does not pay for imaging for chronic back pain.	3	SY
11	Too many acronyms were used in Pain Assistant.	3	UI
12	When clicking on tools in Pain Assistant, the new pages are big and not resizable.	2	TP
13	The amount of text in “Suggestions on Medications” boxes is overwhelming; small font size and too many numbers added clutter to these information boxes.	2	UI
14	The imbedded opioid contract form is not the latest version.	1	CF
15	Numeric ICD-9 Codes were not explicit.	1	CF

List of abbreviations used in the table

Frq.: Frequency

CAT.: Category

SY: Systemic Issue

UI: User Interface Issue

CF: Content Problems

TP: Technical Problem

In the second round of usability testing 48 issues were raised in all the categories. The number of barriers in user interface decreased by 10% from 45% to 35% for all the

barriers. Not surprisingly, more barriers were reported regarding the content of the Pain Assistant in the second round since almost no changes were made to improve the content of Pain Assistant. In this round, 41% of all the comments stated new or repeated barriers about Pain Assistant content. The changes made to the system design therefore seemed to have been successful in solving some systemic barriers. The proportion of systemic barriers decreased to 18% of all the problems. Also, a slight reduction in the number of technical problems was seen. In the second usability iteration, the issue of technical problems with system design accounted for only 4% of all the comments.

To explain the results of the second round of usability testing analysis, some examples of user's comments on content, user interface problems, systemic barriers and technical problems are presented.

4.4.1.1 Content Problems

Some of the changes that listed in Table 7 were in response to the need to improve the content of Pain Assistant. In some items, the implemented changes were helpful in improving the usability of Pain Assistant while some of the other changes were reported inadequate. Additionally, most of the problems on content of Pain Assistant were carried forward from the first iteration of usability testing, because few substantial modifications took place to resolve issues in this section. Inconsistency in the medication list, and lack of history of pain diagnosis were the two top barriers in content of Pain Assistant identified by participants in both two iterations.

As mentioned before, new tools were added to the Pain Assistant. Some participants highlighted that the imbedded opioid contract tool was not the latest version and therefore, needed to be changed during the next system design revision.

The programming team decided to add a list of International Classification of Diseases-9 codes to Pain Assistant to simplify the process of adding patients with chronic pain to the disease registry. While numeric codes were shown, a number of participants stated that these numbers were not identifiable to them. They wanted to change the numeric list of codes to actual descriptive codes for easier recognition of the diagnosis.

Because no changes were made to the Pain Assistant medication module, not surprisingly all the barriers identified in the first round were identified in the second iteration as well. For example, several users in the second round of testing noticed inconsistencies in the list of medications. Participants felt that from the list of medications it was unclear whether the intent was to display only pain medications or all the prescribed medications. Notably, clinicians' disagreed with each other with regarding suggestions to resolve this problem. Some of them wanted only the pain medications to be displayed while others wanted other medications also to be presented on the list of medications. For example a clinician stated that *"I like all the medication to be reflected here, not only the pain ones."* In contrast to that, one other clinician commented that *"If it is pain specific module, I would want to see only pain medications"*.

4.4.1.2 User Interface Problems

While there were many similar issues were identifies in both rounds of usability testing, some new concerns were raised. These concerns were related to the system changes. It was clear that as some issues were resolved, new issues became apparent.

Problems of user interface design were among the top barriers in using Pain Assistant. To remove barriers in the design of user interface, some actions were taken after the first iteration of usability testing.

Titles were changed to be clear and self-explanatory for the second iteration. But a resident stated that too many acronyms and abbreviations in Pain Assistant is a big issue especially for learners.

Some efforts were made to tidy the pages and decrease the clutter on the face page of Pain Assistant and information boxes. For this purpose a (plus) + sign was added next to each tool to expand and minimize the questionnaires or other text fields. Participants stated that this added feature helped to organize the encounter guides. However, the problem on the information boxes persisted. Even after changes to the system design, participants reported clutter on information boxes. They believed small font size and too many numbers made the boxes overwhelming.

4.4.1.3 Systemic Issues

A new issue which came up several times was having the medical imaging requisition form within the Pain Assistant front page. Several participants commented that the existence of the medical imaging requisition form on the main page of Pain Assistant would lead to over ordering of imaging in an environment where chronic back pain medical images are not supported by evidence and will not be covered under the Ontario Health Insurance Plan. They believed that this imaging order form should be removed from the front page of Pain Assistant.

Study subjects in the second iteration of usability testing recognized the added feature of information on pain screening tools as being very helpful. They declared explanations on the tools helped them to understand what the tool was about.

Despite the fact that the explanation of scores was added to each measure, study participants reported that the explanations were not explicit enough. They wanted to have more details and information on scores and their interpretation to be added to the explanations of the scores. A clinician stated that *“I don’t know what these scores mean. It would be better to have their range beside it.”*

Similar to the first iteration of usability testing, in the second phase clinicians were concerned about the time constraints that may limit their use of the Pain Assistant. While participants believed that the content and tools imbedded in the Pain Assistant could facilitate diagnosis and treatment planning, and would support their clinical decisions, the

limited clinical time they have for each patient may prevent them from using the Pain Assistant comprehensively. For example a participant stated *“I think there are good aspects of it, but may not be applicable to our 15 minutes appointments”*.

4.4.1.4 Technical Problems

A new issue related to a technical problem came up in the second iteration. This issue was the result of change to the Pain Assistant system design. Pain Assistant was changed to open tools and guides in a new window. A number of participants reported these new windows were big and not resizable. Even scrolling through these windows was not easy, as the scroll bar was hidden on the side of the window that was not visible.

No other technical issues came up in the second round of usability testing.

4.4.2 Features Requested to Be Added to Pain Assistant

Similar to the first round of testing, participants were asked to give their ideas about how to improve system design or the content of Pain Assistant. Table 8 lists participants' suggestions of features or changes to system design. Some of the suggestions or requests of change the system design are similar to what was raised in Round 1.

Table 8. List of Suggested Features or Changes of the Pain Assistant, Second Usability Testing Iteration

	Item	Frq. out of 6	CAT.
1	Add the ability to write prescriptions directly from Pain Assistant, and see other current medications while in the Pain Assistant.	5	CF
2	Add medication side effects and drug-drug interactions to the medication suggestion section.	2	CF
3	Move the important measures to the top of the page for easier follow up, move the height/weight or barely used measures under the scroll bar.	2	UI
4	The ability to add a new questionnaire from either the menu, encounter guide or the "add" button in the scores list.	2	UI
5	Add a printable version of questionnaires (such as BPI®) to the patient handouts.	2	CF
6	To grab more attention, allergy tab color should be changed if any allergies existed.	1	UI
7	Add a tab for opioid management that includes opioid guidelines, prescribed opioids with dates and dosage, the medication refill date and due date of the opioids.	1	CF
8	Add a submit button at the end of each questionnaire as well as one at the end of encounter guide.	1	TP
9	Add pharmacy information into Pain Assistant.	1	CF

List of abbreviations used in the table

Frq.: Frequency CAT: Category SY: Systematic Issue Solution

UI: User Interface Solution CF: Content Addition TP: Technical Problem Addition

4.4.2.1 Content Additions

A number of test subjects had difficulties in locating and using handouts. Subjects highlighted that they want to have patient handouts readily accessible on the Pain Assistant face page rather than going to the clinical guides. Also the patient handout section led them to website URLs that did not provide PDF or printable files. Participants stated that they wanted the handouts in printable format and not as links to websites.

4.4.2.2 User Interface Solutions

Subjects also highlighted the need for organizing the pain screening measurements. In the testing phase several participants stated that too many empty fields and boxes in measurements added clutter to the page and reduced its utility.

Participants also provided input on the solutions to be applied in subsequent design revisions, particularly regarding the level of details on the face page of the Pain Assistant. They wanted to have most commonly used features and information to be visible on the Pain Assistant face page and all other measures be hidden under the scroll bar to avoid a cluttered page.

Moreover, new features were requested to be implemented for the next system revision. For example participants were looking for the ability to add questionnaires from the menu, encounter guide or the “add” button in the scores list.

4.4.2.3 Technical Problems

During the second iteration of usability testing, a family physician reported that there was only one save button in the list of tools. This participant suggested having a save button at the end of each questionnaire. Having this option would make the saving process easier.

4.4.3 Usability Facilitators

Facilitators in using Pain Assistant in second iteration of usability testing are presented in Table 9 below.

Table 9. List of Usability Facilitators of Pain Assistant, Second Iteration

	Item	Frq. out of 6	CAT.
1	Having different pain screening tools and encounter guides embedded in the Pain Assistant made it a comprehensive package and fruitful resource for chronic pain management.	6	UI
2	Presents all the pain management sources in one spot, it prevents jumping around patient e-Chart to gather information or searching over the internet for the screening tools or handouts.	6	CF
3	The feature of having a timeline that correlates the measures and medications will make a better understanding of the effectiveness of the treatments.	6	CF
4	Pain Assistant offers different management strategies for different types of pain rather than only medication therapies.	5	CF
5	Pain Assistant provides a standard method of chronic pain management which consequently will improve team work and quality of care.	4	CF
6	Explanations on tools found to be very helpful.	4	SY
7	Ability to enlarging and minimizing questionnaires in encounter guides found to be helpful.	4	UI
8	The ability to auto populate the scores in different places in Pain Assistant and patient e-Chart	4	UI
9	The ability to fill the WSIB form 8 through Pain Assistant will save clinical time.	3	UI

10	Pain Assistant serves as a self-learning tool, which collects data in forms of pain screening numbers versus patient narrative data.	3	CF
11	Helpful suggestions for medication prescription with evidences provided.	2	CF
12	The SMART goals for patient could positively reinforce patients and have the potential of motivation and treatment plan reminders for clinicians.	2	CF

List of abbreviations used in the table

Frq.: Frequency CAT: Category SY: Systematic Issue
 UI: User Interface Issue CF: Content TP: Technical Problem

Facilitators related to content were the main facilitators for using the Pain Assistant, with 68% of all the comments related to these 2 categories. User interface design was experienced as the next most common facilitator in using the Pain Assistant with 30% of all the comments.

4.4.3.1 Content Facilitators

Although not all of the clinicians were aware of the pain screening tools contained in the Pain Assistant, having the range of different pain screening tools was seen as a positive feature of the Pain Assistant. Participants believed that having all the standard pain screening questionnaires imbedded in the Pain Assistant would improve the documentation of assessment and treatment of chronic pain. They also expected the Pain Assistant to facilitate better teamwork by providing a common approach to pain management. Also, CPGs that were presented in the form of clinic visit guides, helped clinicians to make decisions with confidence by providing details about where to begin, and recommendations of medications and other modalities of treatment.

Additionally, a section with patient SMART goals was devoted to psychological aspects of pain management. This section was seen as very useful content which could assist clinicians and patients to collaborate in an effective way to manage chronic pain. Participants stated that they usually forget to talk about patient goals during a clinical visit. Therefore, having a separate goals section would likely be a good reminder for clinicians to discuss goals with patients. SMART goals were also commented on as functioning as a positive reinforcement for patients. A clinician stated that “*SMART goals, Well, You know I always struggle with that. I don’t even have time to ask. That is something I would like myself personally to have somewhere handy.*”

Moreover, several participants commented that the suggestions on prescribing medications facilitated decision making. This suggestion section provided the usual dosage, the drug adverse effect, titration and comments about pain medications. All of this added information was found to be helpful.

The added feature of a timeline that correlated the medication to pain screening scores was highly appreciated by the participants as a facilitator. Participants felt that this feature could be helpful as they could track the changes of pain scores based on changes in medications. In other words, medication effectiveness could be assessed by this feature longitudinally.

The system also received endorsement from nurse practitioners who usually do not deal with many patients with chronic pain. A nurse practitioner stated, *“It means a lot when you can show a person that what the first line medication is.”*

4.4.3.2 User Interface Facilitators

One other user interface facilitator was that Pain Assistant gathered all the pain pertinent information from the patient’s e-Chart in one place in the Pain Assistant that was specialized for chronic pain. In this regard, one participant stated that *“I like the fact that it (is) divided into different types of pain, and that within [the Pain Assistant] you have so many tools that otherwise you will be searching for.”* Centralizing all the pain assessment and screening tools eliminated the need for clinicians from having to look at different flowsheets, or different locations to find forms and information.

4.4.3.3 Systemic Facilitator

Explanations of tools that were added to Pain Assistant in the second iteration of usability testing were reported as one of the valuable additions to the system. The displayed information included some explanations on how and when to use each measure. As participants mentioned, the short explanations helped them to have a clear image of the purpose of the tools. Furthermore, this additional feature improved Pain Assistant as a self-learning tool.

4.5 SUS Score

All participants completed the SUS usability questionnaire (Appendix C) immediately after using the Pain Assistant in both usability testing rounds. The mean and SD of each SUS item and the overall mean is calculated. The comparison of SUS scores between two iterations are presented in Table 10.

Table 10. Comparison of the SUS Scores between First and Second Usability Testing Iterations

#	Item	Round One, n=7 Mean (SD)	Round Two, n=6 Mean (SD)
1	I think that I would like to use this system frequently.	4.85 (0.35)	4.17 (0.75)
2	I found the system unnecessarily complex.	2.00 (0.76)	2.33 (0.81)
3	I thought the system was easy to use.	4.42 (0.49)	3.66 (0.51)
4	I think that I would need the support of a technical person to be able to use this system.	1.71 (0.70)	1.83 (0.40)
5	I found the various functions in this system were well integrated.	3.42 (1.05)	4.00 (0.63)
6	I thought there was too much inconsistency in this system.	1.71 (0.70)	1.83 (0.75)
7	I would imagine that most people would learn to use this system very quickly.	4.42 (0.49)	3.33 (0.81)
8	I found the system very cumbersome to use.	1.57 (0.73)	1.66 (0.81)
9	I felt very confident using the system.	3.85 (0.64)	3.16 (0.75)
10	I needed to learn a lot of things before I could get going with this system.	1.57 (0.49)	2.50 (0.83)
	SUS Score	81.10 (12.02)	70.40 (6.78)

The overall SUS score decreased from 81.10 (± 12.02) out of 100 possible points in phase 1, to 70.40 (± 6.78) in phase 2. Although this decrease seems large, the difference between the 2 groups was not statistically significant ($P= 0.86$).

The scores pertaining to usability and learnability sub-scales were determined and are given in Table 11.

Table 11. Comparison of SUS Sub-Scales of Learnability and Usability of First and Second Usability Testing Iteration

SUS Item #	Sub-Scale	Round 1 Mean (SD)	Round 2 Mean (SD)	P Value
1,4	Learnability	3.57 (SD= 1.72)	3.16 (SD=1.34)	0.78
2,3,5,6,7,8,9,10	Usability	3.16 (SD=1.40)	2.73 (SD= 1.06)	0.69

Both sub-scales of learnability and usability of SUS decreased in the second round of usability testing. The 2 rounds were conducted using different groups of clinicians, which could account for some of the differences in scores.

4.6 Timing Data

In each of the usability testing rounds, not all of the participants could finish all three patient case scenarios because of time constraints. However, every participant finished at least 2 patient case scenarios. Additionally, timing for each scenario was difficult because different participants performed the subtasks in different orders at various stages in the workflow. Therefore, only the total time to do each task was calculated.

Participants spent an average of 7:56 minutes working with Pain Assistant in the first testing round, and 7:28 minutes in the second usability testing iteration. Time to complete each patient case scenario varied (Table 12).

Table 12. Comparison of Total Time Taken for Completing Task Scenarios

Case Scenario	Round One Mean minutes (SD, number of completed scenarios)	Round Two Mean minutes (SD, number of completed scenarios)	P value
Medication refill	7:48 (SD=4.50, n=5)	7:18 (SD=3.40, n=5)	0.79
Diagnosis of CLBP	8:06 (SD=3.01, n=6)	7:43 (SD=1.81, n=6)	0.83
Visit for neuropathic pain	7:33 (SD=4.10, n=7)	7:25 (SD=3.30, n=5)	0.87
Average of all three tasks	7:56 (SD= 3.70, n=18)	7:28 (SD= 2.86, n=16)	0.86

In both iterations, participants spent more than 7 minutes to complete each patient case scenario. There was no statistically significant difference between the times needed to complete each patient case scenario in the both iterations. Partly because of low numbers analysis showed no statistically significant difference between times needed to complete case scenarios.

4.7 Preference Data

One standalone question asked of all the participants was about their preference for the format of the CPGs. An overall comparison of users' preference about format of CPGs is given below in Table 13.

Table 13. Participants' Preference on the Format of CPGs

	Would prefer to use guidelines for neuropathic and lower back pain in paper format	Would prefer to use guidelines for neuropathic and lower back pain in electronic format
Family Physician (n=6)	0	6
Nurse Practitioner (n=5)	2	3
Residents (n=2)	0	2

Among all 13 participants, only 2 nurse practitioners preferred to have the CPGs in paper format. The rest of the participants preferred the CPGs in an electronic format.

5 Discussion

The present study was conducted to evaluate the usability of a prototype of Pain Assistant, a CDSS being developed at McMaster University, Department of Family Medicine, to assist PCPs in assessment and treatment of chronic lower back and neuropathic pain. As part of the study, two rounds of usability testing were done employing Think Aloud usability protocols(24) as well as SUS scores(71). Think Aloud protocols were selected as they are the most widely used methods of usability testing for the prototype of the applications or applications in the development cycle.(64;69) Results of this study provided important pointers in identifying major barriers and facilitators in usability of the prototype of Pain Assistant.

Using Think Aloud usability testing with PCPs who were unfamiliar with Pain Assistant, we found problems with a) content, b) user interface c) systemic features and d) technical aspects. Some of the issues were resolved by changes being made to the system design for the second testing phase. Despite the difficulties PCPs encountered, they had many positive comments about the system. Task completion time and system usability scores were also calculated.

In the first iteration, 45% of all the barriers were pertaining to the user interface, while in the second iteration, barriers related to content of Pain Assistant with 42% of the comments were predominant. The decrease in percentage of user interface problems

between the first and second iterations could be interpreted as due to improvements in system design.

The terminology used in the Pain Assistant was a significant barrier for participants; which could be because of ambiguity of the titles for some resources. This finding is consistent with that of Saleem et al, who reported that the terminology used in a clinical reminder as a user interface barrier identified by clinicians.(87) We attempted to reduce the unclear titles during development for the second phase of testing. Our second testing cycle demonstrated that this issue was largely resolved.

Participants in both iterations stated that navigation of imbedded tools was not easy. This finding was in agreement with findings of Graham et al(86) who found that participants had difficulties in navigating the system. In this study the usability of a web-based CDSS designed to help emergency physicians in prescribing medications for pneumonia was tested. Fifty seven percent of all the barriers in this study were in regards to navigational problems of the CDSS.(86) In this thesis, we attempted to resolve the system navigation issue by adding tabs to the Pain Assistant to divide the tools evenly into different tabs. However, because of the time constraints, this feature could not be implemented for the second iteration of testing. Similar to our results, other studies have also demonstrated that allocating items under different tabs can be an effective way to reduce the clutter on pages and lead to easier navigation of the system.(74;86)

Participants reported an overwhelming amount of text on the screen. This problem seems to be a common challenge in user interface design of the CDSS, as the main objective of development of any CDSS is providing supportive information to the care provider.(88) The strategy to resolve this obstacle involved making an abstract of the text visible and the rest of the text to be hidden under an expandable field. The same strategy was selected to elucidate the problem of a long list of questionnaires in clinical encounter guides. Participants were provided with the option to expand and collapse the questionnaires. The results of other studies also have demonstrated these strategies as helpful methods to reduce the amount of text on the screen and organize the pages better.(76;88)

The organization of the measures was emphasized more in the second round of testing. Participants wanted to have frequently used tools (e.g. BPI® and other patient specific measures) to be visible on top of the page, rather than having blood pressure, height and weight which were at the top of the page at the time. These comments helped to clarify the detail and level of the information presented on the first page. This finding is consistent with that of a study which tested usability of an opioid management CDSS.(75) The study reported that participants had difficulties in recognizing and locating specific information. Another solution presented in the Trafton et al. Study was to highlight specific information.(75)

The results of testing the usability of the Pain Assistant exhibited issues with content. These issues were the most predominant problems in system design of the Pain Assistant. Similar content barriers were reported in both the rounds of usability testing, because no

changes were implemented in these problematic areas between iterations, owing to time and technical constraints. Presentation of the history of the pain, inconsistency in the medication list and missed information on the medication list were seen as consistent issues in both iterations.

Participants reported the same problems in the medication module of the Pain Assistant in both testing iterations. Comments identified problems with basic issues such as lacking date and dosage of the prescribed medication were impeding the usability of the CDSS. To resolve the issue some changes need to take place in the medication module as it is one of the most important aspects of pain management. This finding is in agreement with results of study of Graham et al.(86) that showed that poor usability of a web-based medication CDSS has the potential to end in mistakes in medication prescription. Five serious medication prescription issues were occurred during the course of testing as the result of poor usability of medication CDSS.(86) Therefore, this issue should be prioritized in next iterations of system revisions.

The finding of this study revealed some systematic barriers in using the Pain Assistant CDSS in the chronic pain visit. Participants stated that following all the CDSS recommendations is very time consuming. This systematic issue could not be resolved with changes in the system design of Pain Assistant, as the following CPG recommendations in practice takes time and the clinical visit time in primary care is usually limited to a 15 minute appointment. Results of other studies also highlighted that while CDSSs are beneficial applications to implement CPGs into clinical practice, their

main burden is that following all the CDSS recommendations consume time that may need to be used for other clinical activities.(75;89)

Another barrier in terms of content was the lack of the participants' knowledge regarding the pain screening tools. This concern came up in both iterations of testing and confirmed that PCPs need the support of the CDSS in chronic pain management. Explanations of the tools were added to them to help participants have a better understanding of the purpose and use of the imbedded tools. In the second iteration, participants found this added information very helpful to recognize the purpose and usage of the measurements. One of the main objectives of the CDSS was to serve as a self-learning tool. The results of this study were in alignment with the results of a study that evaluated the effect of CDSS recommendations for PCPs in improving depression care. Their CDSS was shown to be an effective self-learning tool for PCPs.(90)

Participants also articulated the convenience of pain screening tools and fitting into workflow as key positive attributes of the Pain Assistant, a finding that echoes the previous research.(61;75) Participants also cited as benefits easier documentation of pain care and suggestions on medications as strong facilitators of the system. In addition to liking the convenience of the system, participants liked the added feature of explanation of the tools. Knowing about the imbedded tools is very important to care providers and will likely play a positive role in uptake of the Pain Assistant.

System design changes between iterations seemed successful, as in the second iteration more comments were regarding the content and tools than user interface. It is likely that the Pain Assistant could help to increase clinicians' knowledge regarding chronic pain management.

Participant's satisfaction score of system usability was measured by SUS in both usability iterations. SUS scores above 68 are considered above the average.(72) The SUS scores were above average in both the rounds implying satisfaction with the system. The average SUS score in the first round of testing was 81 versus 70 in the second iteration (no statistically significant difference in scores). However, although it was expected to see an increase in SUS after changes in system design, this measure decreased non-significantly in the second usability testing iteration. One explanation for the observed decrease in SUS score could be that some critical changes were not made to the system, so the same issues came up in both iterations. Also the decrease in SUS score could be attributed to have participants with less technological proficiency in second round as a new group of clinicians participated in the second iteration. This non-significant difference is likely attributable to the small sample sizes as well. The results of this study may not be generalizable due to the small number of participants with diverse clinical backgrounds and differences in computer skills. The mean learnability and usability sub-factor scores in the second iteration declined. This sub score presents the ease of learning and using the system and scales for values range from 0 to 4, where 4 represents the most positive response.(72) The mean of learnability scores in the first and second iterations were 3.57 and 3.16 respectively. The mean of usability scores were 3.16 and 2.73 correspondingly.

Pain Assistant was perceived as a more learnable than usable system in both iterations, however these differences were not statistically significant.

The mean of task completion time for all three case scenarios was over seven minutes in both iterations. However the task completion time decreased in the second round of testing; the changes were not statically significant. No other similar study could be found which reported task completion time by care providers. It was assumed that identical calculated times were due to participants being observed and followed completing the requested list of tasks in a research setting. Furthermore, during the usability test, participants were requested to Think Aloud about the Pain Assistant and often asked questions as they worked through the task. This created challenges with interpreting timing of each task and subtask. Efforts were made to only include time used interacting with the CDSS. Further studies of task completion time for each task during actual use of Pain Assistant may help to clarify this issue. Another explanation could be that an inadequate number of changes to system design were made before the second iteration of testing. Despite the fact that the changes that were made to the system could potentially resolve the correspondent barrier, the number of changes were not sufficient to demonstrate a difference between SUS scores and time to complete tasks.

Participants preferred the CLBP and neuropathic pain CPGs implemented into practice in electronic rather than paper format. Only nurse practitioners preferred paper based guidelines over any electronic format. One explanation for this preference is that nurse practitioners usually do not assess patients with chronic pain and do not prescribe opioids.

Therefore, they will not need to use the CDSS as a means of decision support as often as other clinicians will. This finding is in disagreement with a study that questioned residents and medical students' regarding their preference for syncope clinical guidelines in paper format or on mobile applications.(91) The study reported that the majority of participants preferred CPGs in paper formats.

5.1 Limitations

There were a number of limitations to this study. This study was limited to two rounds of testing with a small number of participants.

We also noted that having different participants for each round of usability testing could be perceived as both a strength and weakness. This sampling methodology decreased the potential for biased comments regarding Pain Assistant problems. On the other hand, it raised the concern that it is not feasible to follow up on issues after implementing changes based on feedback from the first iteration with different participants.

This study was also limited in terms of the short period of time elapsed during the development process of the Pain Assistant between iterations of testing. Since there was a short time window between two iterations of usability testing, not all the barriers that came up in the first round of testing could be resolved before the second iteration of usability testing. Additionally, because the application was running on a live demo server, even some already implemented changes were not available to participants in the second iteration.

5.2 Future Work

A more advanced study of usability of the Pain Assistant with all the changes made to the system design could be an expansion to this study. One other round of usability testing may facilitate a better understanding of the usability issues after further system redesign and may also allow a SUS during a pilot study with a larger number of end-users and more time to work with the system.

The presented research used Think Aloud usability testing protocols as the main usability methods. Further studies could also use heuristic evaluations simultaneously with the Think Aloud method to include heuristics of usability in the system design process. Usability heuristics are 10 general principles for interface design.(23;67)

Additionally, a greater time frame between two iterations would allow the programming team to try to resolve more issues or implement changes before the next iteration of testing. Again, changes should be made to the system design to resolve most frequent barriers before the next round of testing.

This study tried involvement of Software developers and a business analysis team in both iterations of usability testing of Pain Assistant. Involvement of software developers and a business analysis team helped to have an elaborated direct understanding of the problems faced by end-users. Using this methodology allowed the software development team to make system revisions in collaboration with end-users.

5.3 Conclusion

CDSSs for chronic diseases are becoming popular in primary care settings. The objective of this study was to test the usability of a CDSS for chronic pain management, the Pain Assistant. This study showed that iterative usability testing of the CDSS with participation of real-end users has the potential to uncover usability issues of the Pain Assistant during the system design and development cycle. Although changes to the system design were successful in resolving user interface problems since the changed issues did not come up again in second round. But not enough changes were made to system design for the second round of usability testing to be able to demonstrate improvement in system usability (for example significant increase in SUS score or significant decrease in task completion time). Moreover, content played an important role in the usability of tools that are providing new knowledge. The usability testing with PCPs revealed that the Pain Assistant had an above the average usability score and was considered as a learnable and usable system. Further studies are needed to determine the effect of changes to system design of Pain Assistant.

Reference List

- (1) Schopflocher D, Taenzer P, Jovey R. The prevalence of chronic pain in Canada. *Pain Res Manag.* 2011;16(6):445-50.
- (2) Gureje O, Von Kroff M, Simon GE, Gater R. Persistent pain and well-being: a World Health Organization study in primary care. *JAMA.* 1998;280(2):147-51.
- (3) Ramage-Morin PL, Gilmour H. Chronic pain at ages 12 to 44. 4[82-003-XPE]. 2010. Toronto, Statistics Canada.
- (4) Schultz SE, Kopec JA. Impact of chronic conditions. *Health Rep.* 2003;14(4):41-53.
- (5) Lynch ME. The need for a Canadian pain strategy. *Pain Res Manag.* 2011;16(2):77-80.
- (6) Jacobs P, Golmohammadi K. The cost of low-back pain : a review of the literatyre. Health Quality Council of Alberta. 2003 Available from: <http://publications.hqca.ca/preview/49>.
- (7) Canadian Institute for The Releif of Pain and Disability. What is chronic pain? <http://www.cirpd.org/painmanagement/chronicpain/pages/default.aspx>. 2013.
- (8) Forster PK M, Clark AJ, Speechley M, Moulin D. Attitudes toward opioid use for chronic pain: a Canadian physician survey. *Pain Res Manag.* 2003;8(4):189-94.
- (9) Boulanger A, Clark AJ, Squire P, Cui E, Horbay G. Chronic pain in Canada: have we improved our management of chronic noncancer pain? *Pain Res Manag.* 2007;12(1):39-47.
- (10) Forster PK M. Tomorrow and tomorrow and tomorrow: wait times for multidisciplinary pain clinics in Canada. *Can J Anaesth.* 2007;54(12):936-8.
- (11) Upshur C, Luckmann R, Savageau J. Primary care provider concerns about management of chronic pain in community clinic populations. *J Gen Intern Med.* 2006;21(6):652-55.
- (12) Smith BH, Torrance N. Management of chronic pain in primary care. *Curr Opin Support Palliat Care.* 2011;5(2):137-42.
- (13) Moulin D, Clark AJ, Gilron I, Ware MA, Watson CPN, Sessle BJ, et al. Pharmacological management of chronic neuropathic pain - consensus statement and guidelines from the Canadian Pain Society. *Pain Res Manag.* 2007;12(1):13-21.

- (14) Toward Optimized Practice (TOP) low back pain clinical practice guidelines. Toward optimized practice. 2013 Available from: http://www.topalbertadoctors.org/cpgs.php?sid=65&cpg_cats=90.
- (15) Canadian guideline for safe and effective use of opioids for chronic non-cancer pain. National Opioid Use Guideline Group. 2010 Available from: <http://nationalpaincentre.mcmaster.ca/opioid/>.
- (16) Rrush JE, Radford MJ, Krumholz HM. Integrating clinical practice guidelines into the routine of everyday practice. *Crit Pathw Cardiol*. 2005;4(3):161-7.
- (17) Knab JH, Wallace SM, Wagner RL, Tsoukatos J, einger MB. The use of computer-based decision support system facilitates primary care physicians management of chronic pain. *Anesth Analg*. 2001;93(3):712-20.
- (18) Garg AX, Adhikari NK, McDonald H, Rosas-Arellano MP, Devereaux PJ, Beyene J, et al. Effects of computerized clinical decision support systems on practitioner performance and patient outcomes a systematic review. *JAMA*. 2005;293(10):1223-38.
- (19) Roshvanov P, Misra S, Cgerstein H, Garg AX, Sebaldt RJ, Mackay JA, et al. Computerized clinical desicion support systems for chronic disease management: a decision-maker-researcher partnership systematic review. *Implement Sci*. 2011;6(92) doi: 10.1186/1748-5908-6-92.
- (20) OSCAR Canada User Society. What is OSCAR EMR? OSCAR Canada. 2013 [cited 2013]; Available from: http://www.oscarcanada.org/about-oscar/brief-overview/index_html#what-is-oscar.
- (21) OSCAR McMaster. OSCAR McMaster customers. OSCAR McMaster. 2013 [cited 2013 Jan 25]; Available from: http://oscarmcmaster.org/?page_id=27.
- (22) Viitanen J, Hypponen H, Laaveri T, Vanska J, Reponen J, Winblad I. National questionnaire study on clinical ICT systems proofs: physicians suffer from poor usability. *Int J Med Inform*. 2011;80(10):708-25.
- (23) Yen PY, Bakken S. Review of health information technology usability study methodologies. *J Am Med Inform Assoc*. 2012;19(3):413-22.
- (24) Neilsen J. *Uability Engineering*. 1st ed. Cambridge: Elsevier.; 1994.p 25-34
- (25) Horsky J, McColgan K, Pang JE, Melnikas AJ, Linder JA, Schnipper JL, et al. Complementary methods of system usability evaluation: surveys and observations during software design and development cycles. *J Biomed Inform*. 2010;43(5):780-90.
- (26) O' Sullivan P. Diagnosis and classification of chronic low back pain disorders: maladaptive movement and motor control impairments as underlying mechanism. *Man Ther*. 2005;10(4):242-55.

- (27) Mailis- Gagnon A, Yegneswaran B, Lakha SF, Nicholson K, Steiman AJ, Ng D, et al. Pain characteristics and demographics of patients attending in university- affiliated pain clinic in Toronto, Ontario. *Pain Res Manag.* 2007;12(2):93-9.
- (28) AHRQ Publication. what is pain? understanding your body. Agency for Healthcare Research and Quality. 2013 [cited 2013 Dec 7];Available from: <http://www.ahrq.gov/patients-consumers/prevention/understanding/bodysys/edbody11.html>.
- (29) Haanpää ML, Backonja MM, Bennett MI, Bouhassira D, Cruccu G, Hansson PT, et al. Assessment of neuropathic pain in primary care. *Am J Med.* 2009;122(10):S13-21.
- (30) Baer PA, Bissonnette A, Peck J. A novel therapeutic approach to chronic low back pain. *Can J Diag.* 2010;43-50.
- (31) Fourney DR, Andersson G, Arnold PM, Dettori J, Cahana A, Fehlings MG, et al. Chronic low back pain: a heterogeneous condition with challenges for an evidence-based approach. *Spine.* 2011;36(21):S1-9.
- (32) Brreivik H, Collett B, Ventafridda V, Cohen R, Gallacher D. Survey of chronic pain in Europe: prevalence, impact on daily life, and treatment. *Eur J Pain.* 2006;10(4):287-333.
- (33) Torrance N, Smith BH, Bennett MI, Lee AJ. The epidemiology of chronic pain of predominantly neuropathic origin. Results from a general population survey. *J Pain.* 2006;7(4):281-9.
- (34) Roth-Isigkeit A, Thyen U, Stoven H, Schwarzenberger J, Schmucker P. Pain among children and adolescents: restrictions in daily living and triggering factors. *Pediatrics.* 2005;115(2):e152-62.
- (35) Karoly P, Ruhlman LS. Psychosocial aspects of pain-related life task interference: an exploratory analysis in a general population sample. *Pain Med.* 2007;8(7):563-72.
- (36) Cote P, Kristman V, Vidmar M, Van Eerd D, Hogg-Johnson S, Beaton D, et al. The prevalence and incidence of work absenteeism involving neck pain: a cohort of Ontario lost-time claimants. *J Manipulative Physiol Ther.* 2009;32(2):S219-26.
- (37) Stewart WF, Ricci JA, Chee E, Morganstein D, Lipton R. Lost productive time and cost due to common pain conditions in the US workforce. *JAMA.* 2003;290(18):2443-54.
- (38) Ratcliffe GE, Enns MW, Belik SL, Sareen J. Chronic pain conditions and suicidal ideation and suicide attempts: an epidemiologic perspective. *Clin J Pain.* 2013;24(3):204-10.
- (39) Institute of Medicine. *Relieving Pain in America: A blueprint for transforming prevention, care, education and research.* Washington DC: National Academies Press.; 2011.

- (40) Lin D, Hale S, Kirby E. Improving diabetes management: structured clinic program for Canadian primary care. *Can Fam Physician*. 2007;53(1):73-7.
- (41) Kastner M, Estey E, Bhattacharyya O. Better guidelines for better care: enhancing the implementability of clinical practice guidelines. *Expert Rev Pharmacoecon Outcomes Res*. 2011;11(3):315-24.
- (42) Aigner W, Kaiser K, Miksch S. Visualization methods to support guideline-based care management. Amsterdam: IOS Press.; 2008. p. 140-59.
- (43) Agency for Healthcare Research and Quality. National guidelines clearinghouse. AHRQ. 2013 Available from: <http://www.guideline.gov/browse/by-topic.aspx>.
- (44) Cabana MD, Rand CS, Powe NR, Wu AW, Wilson MH, Abboud PA, et al. Why don't physicians follow clinical practice guidelines? a framework for improvement. *JAMA*. 1999;282(15):1458-65.
- (45) McKinlay JB, Link CL, Freund KM, Marceau LD, O'Donnell AB, Lutfey KL. Sources of variation in physician adherence with clinical guidelines: results from a factorial experiment. *J Gen Intern Med*. 2007;22(3):289-96.
- (46) Brindis RG, Sennett C. Physician adherence to clinical practice guidelines: does it really matter? *Am Heart J*. 2003;145(1):13-5.
- (47) Lomas J, Sisk JE, Stocking B. From evidence to practice in the United States, the United Kingdom, and Canada. *The Milbank Quarterly*. 1993;71(3).
- (48) Waddell C. So much research evidence, so little dissemination and uptake: mixing the useful with the pleasing. *Evid Based Ment Health*. 2001;4(1):3-5.
- (49) Iron K, Jaakimainen L, Rothwell D, Li P, Laupacis A. Investigation of acute lower back pain in Ontario: are guidelines being followed? 2004. Toronto, ICES.
- (50) Toth EL, Majumdar SR, Guiguis LM, Lewanczuk R, Lee TK, Johnson JA. Compliance with clinical practice guidelines for type 2 diabetes in rural patients: treatment gaps and opportunities for improvement. *Pharmacotherapy*. 2003;23(5):659-65.
- (51) Timmermans S, Mauck A. The promises and pitfalls of evidence-based medicine. *Health Aff*. 2005;24(1):18-28.
- (52) Bates DW, Kuperman GJ, Wang S, Gandhi T, Kittler A, Volk L, et al. Ten commandments for effective clinical decision support: making the practice of evidence-based medicine a reality. *J Am Med Inform Assoc*. 2003;10(6):523-30.
- (53) Decision support systems. *Open clinical*. 2006 [cited 2013 Jan 9]; Available from: <http://www.openclinical.org/dss.html#wyatt1991>.

- (54) Kawamoto K, Houlihan CA, Balas EA, Lobach DF. Improving clinical practice using clinical decision support systems: a systematic review of trials to identify features critical to success. *BMJ*. 2005;330(7494).
- (55) Sim I, Gorman P, Greenes RA, Haynes RB, Kaplan B, Lehmann H, et al. Clinical decision support systems for the practice of evidence-based medicine. *J Am Med Inform Assoc*. 2001;8(6):527-34.
- (56) Sahota N, Lloyd R, Ramakrishna A, Mackay JA, Prorok JC, Weise-Kelly L, et al. Computerized clinical decision support systems for acute care management: a decision-maker-researcher partnership systematic review of effects on process of care and patient outcomes. *Implement Sci*. 2011;6(91) doi: 10.1186/1748-5908-6-91.
- (57) Holbrook A, Thabane L, Keshavjee K, Dolovich L, Bernstein B, Chan D, et al. Individualized electronic decision support and reminders to improve diabetes care in the community: COMPETE II randomized trial. *CMAJ*. 2009;181(1-2):37-44.
- (58) Hunt DL, Haynes RB, Hanna SE, Smith K. Effects of computer-based clinical decision support systems on physician performance and patient outcomes: a systematic review. *JAMA*. 1998;280(15):1339-46.
- (59) Christian JG, Myers TE, Christian KK, Goldstein MG, Cook BC, Sesslen DH. Clinic-based support to help overweight patients with type 2 diabetes increase physical activity and lose weight. *Arch Intern Med*. 2008;168(2):141-6.
- (60) Hetlevik I, Holmen J, Krüger O. Implementing clinical guidelines in the treatment of hypertension in general practice. Evaluation of patient outcome related to implementation of a computer-based clinical decision support system. *Scand J Prim Health Care*. 1999;17(1):35-40.
- (61) Lin L, Hu PJ-H, Liu Sheng OR. A decision support system for lower back pain diagnosis: Uncertainty management and clinical evaluations. *Decision Support Systems*. 2006 Nov;42(2):1152-69.
- (62) Usability - ISO 9241 definition. International Standard Organization. 2013 [cited 2013 Jan 9]; Available from: <http://www.w3.org/2002/Talks/0104-usabilityprocess/slide3-0.html>.
- (63) Gulliksen J, Goransson B, Boivie I, Blomkvist S, Persson J, Cajander A. Key principles for user-centred systems design. *BIT*. 2003;22(6):397-409.
- (64) Rubin J, Chisnell D. *Handbook of Usability Testing*. 2 ed. Indianapolis: Wiley Publishing Inc.; 2008.
- (65) Johnson CM, Johnson TR, Zhang J. A user-centred framework for redesigning healthcare interfaces. *J Biomed Inform*. 2005;38(1):75-87.

- (66) Krahmer E, Ummelen N. Thinking about thinking aloud: A comparison of two verbal protocols for usability testing. *Transactions for Professional Communications*. 2004;47(2):105-17.
- (67) Bastien CJ. Usability testing: a review of some methodological and technical aspects of the method. *Int J Med Inform*. 2010;79(4):e18-23.
- (68) Jaspers MW. A comparison of usability methods for testing interactive health technologies: methodological aspects and empirical evidence. *Int J Med Inform*. 2009;78(5):340-53.
- (69) Carroll C, Marsden P, Siden P, Naylor E, New J, Dornan T. Involving users in the design and usability evaluation of a clinical decision support system. *Comput Methods Programs Biomed*. 2002;69(2):123-35.
- (70) Li AC, Kannry JL, Kushniruk A, Chrimes D, McGinn TG, Edonyabo D, et al. Integrating usability testing and think-aloud protocol analysis with "near-live" clinical simulations in evaluating clinical decision support. *Int J Med Inform*. 2012;81(11):761-72.
- (71) Brooke J. SUS - A quick and dirty usability scale. *Usability evaluation in industry*. 1996.
- (72) Bangor A, Kortum P, Miller J. Determining what individual SUS score mean: Adding an adjective rating scale. *Journal of Usability Studies*. 2009;4(3):114-23.
- (73) Sauro J. Measuring usability with the System Usability Scale (SUS). *Measuring Usability*. 2011 [cited 2013 Jan 18]; Available from: <http://www.measuringusability.com/sus.php>.
- (74) Britto MT, Jimson HB, Muanfo JK, Wissman J, Rogers ML, Hersh W. Usability testing finds problems for novice users of pediatric portals. *J Am Med Inform Assoc*. 2009;16(5):660-9.
- (75) Trafton J, Martins S, Michel M, Lewis E, Wang D, Combs A, et al. Evaluation of the acceptability and usability of a decision support system to encourage safe and effective use of opioid therapy for chronic, noncancer pain by primary care providers. *Pain Med*. 2010;11(4):575-85.
- (76) Anderson JA, Willson P, Peterson NJ, Murphy C, Kent TA. Prototype to practice: Developing and testing a clinical decision support system for secondary stroke prevention in a veterans healthcare facility. *Comput Inform Nurs*. 2010;28(6):353-63.
- (77) Borsci S, Federici S, Lauriola M. On the dimensionality of the System Usability Scale: a test of alternative measurement models. *Cogn Process*. 2000 Sep;10(3):193-7.
- (78) Lewis RJ, Sauro J. *Quantifying the user experience: practical statistics for user research*. 1 ed. Cambridge: Morgan Kaufmann; 2012.

- (79) Cleevland CS. The Brief Pain Inventory (BPI). MD Anderson. 2013 [cited 2013 Jan 9]; Available from: <http://www.mdanderson.org/education-and-research/departments-programs-and-labs/departments-and-divisions/symptom-research/symptom-assessment-tools/brief-pain-inventory.html>.
- (80) Perez C, Galvez R, Huelbes S, Insausti J, Bouhassira D, Diaz S, et al. Validity and reliability of the Spanish version of the DN4 (Douleur Neuropathique 4 questions) questionnaire for differential diagnosis of pain syndromes associated to a neuropathic or somatic component. *Health Qual Life Outcomes*. 2007;5(66).
- (81) Kroenke K, Spitzer RL, Williams JB, Löwe B. An ultra-brief screening scale for anxiety and depression: the PHQ-4. *Psychosomatics*. 2009;50:613-21.
- (82) Prins A, Ouimette P, Kimerling R, Cameron RP, Hugelshofer DS, Shaw-Hegwer J, et al. The primary care PTSD screen (PC-PTSD): development and operating characteristics. *Prim Care Psychiatry*. 2003;9(1):9-14.
- (83) Ayearst L, Harsanyi Z, Michalko KJ. The Pain and Sleep Questionnaire three-item index (PSQ-3): a reliable and valid measure of the impact of pain on sleep in chronic nonmalignant pain of various etiologies. *Pain Res Manag*. 2012;17(4):281-90.
- (84) Tashakkori A, Teddlie C. *Advanced Mixed Methods Research Design. Handbook of Mixed Methods in Social and Behavioral Research*. CA: SAGE Publications; 2003. p. 209-40.
- (85) Hsieh HF, Shannon SE. Three approaches to qualitative content analysis. *Qual Health Res*. 2005;15(9):1277-88.
- (86) Graham TA, Kushniruk A, Bullard M, Holroyd B, Meurer D, Rowe BH. How usability of a web-based clinical decision support system has the potential to contribute to adverse medical events. *AMIA Ann Symp Proc.*; 2008 p. 257-61.
- (87) Saleem JJ, Patterson ES, Militello L, Render ML, Orshansky G, Asch SM. Exploring Barriers and Facilitators to the Use of Computerized Clinical Reminders. *J Am Med Inform Assoc*. 2005 Jul;12(4):438-47.
- (88) Giguere A, Legare F, Grad R, Pluye P, Rousseau F, Haynes RB, et al. Developing and user-testing Decision boxes to facilitate shared decision making in primary care--a study protocol. *BMC Med Inform Decis Mak*. 2011;11(17) doi: 10.1186/1472-6947-11-17.
- (89) Karsh BT. *Clinical practice improvement and redesign: how change in workflow can be supported by clinical decision support*. Rockville, Maryland: Agency for Healthcare Reserach and Quality; 2009. Report No.: AHRQPublication No. 09-0054-EF.
- (90) Kurian BT, Trivedi MH, Grannemann BD, Classen CA, Daly EJ, Sunderajan PA. A computerized decision support system for depression in primary care. *J Clin Psychiatry*. 2009;11(4):140-6.

- (91) Mathew DA. A Mobile Tablet App for Clinical Evaluation and Medical Education: Development and Usability Evaluation. Hamilton: McMaster University; 2012.

Appendix A: Case Scenarios

Scenario 1: I just need my meds refilled please.

You have not met this woman before, but she is booked with you because your colleague is away. You do not have the patient with you for this exercise, you only have her chart. (This chart has been opened on a demo server so you can click and add anything you want without this being saved to the real chart.)

The patient walks into the clinic with a walker and from the look on her face you suspect she is quite uncomfortable. She tells you she has had pain for many years since an accident. Her medications are all running out and she just needs a refill. She has an appointment with her regular physician in 2 weeks to discuss doing some new tests and really does not want to waste your time with this today.

Task:

Complete the following tasks using Pain Assistant.

Please think out loud. Explain to the observer what you are looking for, what you are doing, and what you are thinking about as you use each feature of the **Pain Assistant in Health Tracker.**

1. Review history of the pain.
2. Review the medications list.
3. Locate opioid manager in Pain Assistant.
4. Locate narcotic note.
5. Locate narcotic contract in Pain Assistant.
6. Write prescription.
7. Any other tasks you would typically do for this patient.

Scenario 2: I have a new back pain.

This man is not your patient, but comes to you because his doctor is away. You do not have the patient with you for this exercise. You do not have the patient with you for this exercise, you only have his chart. (This chart has been opened on a demo server so you can click and add anything you want without this being saved to the real chart.)

He tells you he has had back pain for 8 weeks, since he pulled on a heavy lever on a machine at work. He has continued to work with increasing difficulty, and the pain in his back is now in his left leg as well.

Task:

Complete the following tasks using Pain Assistant.

Explain to the observer what you are looking for, what you are doing, and what you are thinking about as you use each feature of the **Pain Assistant in Health Tracker**.

1. Review history of the pain.
2. Review medications list.
3. Use the low back pain encounter guide.
 - a. Complete Red Flags. (use make up responses)
 - b. Complete PTSD.
4. Locate WSIB forms.
5. Prescribe medications.
6. Give handouts to the patient.
7. Any other tasks you would typically do for this patient.

Scenario 3: My feet hurt.

This man is not your patient, but comes to you because his doctor is away. You do not have the patient with you for this exercise. You only have his chart. (This chart is opened on a demo server so you can click and add anything you want without this being saved to the real chart.)

He tells you that both of his feet hurt and he wonders if there is anything he can do about this. He wonders if it might be related to his diabetes, but whatever it is, he wants to have something to help the pain.

Task:

Complete the following tasks using Pain Assistant.

Explain to the observer what you are looking for, what you are doing, and what you are thinking about as you use each feature of the **Pain Assistant in Health Tracker**.

1. Review history of the pain.
2. Review medications list.
3. Use the neuropathic encounter guide in Pain Assistant.
 - a. Fill BPI (use make up responses)
 - b. Fill DN4
4. Prescribe medications.
5. Give handouts to the patient.
6. Any other tasks you would typically do for this patient.

Appendix B: Observation Notes

Scenario 1 observer notes **Time to complete the task.**_____

Subtask	Done	Comments from observation or prompting
Found date last prescription written for opioids and whether the meds are due		
Used opioid manager		
Calculated morphine equivalent dose.		
Looked for narcotic note.		
Looked for narcotic contract.		
Looked for diagnosis of the pain.		
Looked for any problems or side effects with opioids the patient has been taking.		
Used questionnaires in pain assistant. (which ones)		
Looked for co-morbidities (eg depression, anxiety, sleep trouble) in CPP or chart notes		
Wrote prescription.		
Gave patient info		
Others:		

Scenario 2 observer notes

Time to complete the task. _____

Subtask	Done	Comments from observation or prompting
Used red flag tool		
Used yellow flag tool		
Looked for past history of pain diagnosis.		
Looked for past back imaging.		
Looked for past WSIB forms.		
Looked for a new WSIB form to complete.		
Looked for current meds.		
Found resources for patient.		
Used encounter guide questionnaires (which ones)		
Used info about prescribing meds.		
Gave patient info.		
Others:		

Scenario 3 Observer notes

Time to complete the task. _____

Subtask	Done	Comments from observation or prompting
Looked for past history of DM and details of DM control.		
Looked for medications.		
Could find a past history of pain diagnosis.		
Used DN4 questionnaire		
Used other questionnaires		
Used opioid manager		
Looked for information to give to patient		
Used info about prescribing meds.		
Gave patient info.		
Other:		

Comments:

Appendix C: System Usability Scale

Instructions: Please mark the response that best captures your agreement with each statement.

	Strongly disagree	Disagree	Neutral	Agree	Strongly agree
1. I think that I would like to use this system frequently	1	2	3	4	5
2. I found the system unnecessarily complex	1	2	3	4	5
3. I thought the system was easy to use	1	2	3	4	5
4. I think that I would need the support of a technical person to be able to use this system	1	2	3	4	5
5. I found the various functions in this system were well integrated	1	2	3	4	5
6. I thought there was too much inconsistency in this system	1	2	3	4	5
7. I would imagine that most people would learn to use this system very quickly	1	2	3	4	5
8. I found the system very cumbersome to use	1	2	3	4	5
9. I felt very confident using the system	1	2	3	4	5
10. I needed to learn a lot of things before I could get going with this system	1	2	3	4	5

Appendix D: User Preference Questionnaire

Please answer the following questions:

- 1- What is your role in patient care?
 - Family Physician
 - Nurse Practitioner
 - Resident
 - Other (please explain): _____

- 2- Do you currently access guidelines for neuropathic pain in paper format?
 - Yes No
- 3- Do you currently access guidelines for neuropathic pain electronically on a website?
 - Yes No
- 4- Do you currently access guidelines for low back pain either in paper format?
 - Yes No
- 5- Do you currently access guidelines for low back pain either electronically on a website?
 - Yes No

If yes, would you prefer to use:

Neuropathic pain

- Electronic within the McMaster Pain Assistant
- Stay with my usual access to the CPG

Low back pain

- Electronic within the McMaster Pain Assistant
- Stay with my usual access to the CPG

Appendix E: Debrief Guide

McMaster Pain Study, Usability testing

The debriefing topic guide:

1. How did you feel about the tone of the CDSS? did you find it easy to use?
2. Do you see yourself using this CDSS? (if no, what made them not to use)
3. A) What did you like best?

B) What did you like least?
4. What are the additional features that would make this CDSS more useful for you? What were the features you think should be presented differently?
5. What was missing from the CDSS?