A. Cover Page:

Title: **Incorporating Patient Preferences into Decisions about Chronic Pain Management**

Grant ID 20063933

Main collaborators**:** American Chronic Pain Association (ACPA), Maine Medical Association (MMA), University of New England.

Abstract

We seek to understand the preferences, goals, and perspectives of patients with chronic pain and their health care providers (HCPs) to create a patient-centered decision support tool. This tool, aimed at patients and HCPs, should improve patient-provider communication and chronic pain management. Our long-term goal is to improve the quality of life of patients with chronic pain. We target adults with chronic unremitting pain and HCPs who manage patients with chronic pain, including primary care providers and pain specialists.

We propose to develop a shared decision making (SDM) platform, *Pain-APP* (Assessing Patient Preferences) that will assess a patient's level of pain, preferences, and concerns and communicate these to their HCPs using individualized SDM reports. The SDM platform should improve patient-provider communication and decisions about pain treatment plans by stimulating and facilitating dialogue. We will assess patient and HCP preferences using a cognitive mapping approach, including nominal group technique (NGT) meetings, and use these findings to develop the SDM tool. Formative evaluation will include usability testing and beta-testing with approximately 35 patients and HCPs. We will then measure the impact of the platform on patient-provider communication, pain, and physical function in a randomized, controlled trial (n=50). Because this project is nested within a larger vision for improving the pain management, it is likely to be adopted throughout the state of Maine as part of a new pain management policy; funding from a PCORI grant (under review) will enable us to further measure its impact longitudinally in a comparative effectiveness trial.

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C. **Reviewer Comments**:

Strengths: *"Interesting and innovative----will develop a shared decision making platform"*
"The LOI employs a <u>strong patient preference assessment process</u> that accounts for the patient experience and perspectives via Pain-APP that elicits the patients' goals and concerns and transmits them to their HCP."

Weaknesses: *"The project appears to only focus upon one side of the equation: the patient. The input to develop their communication platform, and each of their listed processes is patient-centric, which is very good, but there doesn't seem to be any acknowledgment of inclusion of the clinician in the development, implementation, or outcomes of the project."*

<u>Response</u>: We concur about the importance of targeting both patients and clinicians and regret our failure to adequately communicate this in our Letter of Intent. The PI is a primary care physician who pioneered patient-specific decision support tools that target HCPs and patients[1] and has written extensively on this framework[2] and on the importance of interprofessional education about shared decision making (SDM) in primary care.[3] Of note, we partner with the Maine Medical Association (MMA), which has deep ties to all 600+ primary care practices throughout the state of Maine, a strong commitment to improving pain management, and many strong connections to the key stakeholders in Maine who are engaged in managing chronic pain, including Maine Department of Health and Human Services (DHHS). We partner with the largest Multidisciplinary Pain Clinic in the state (see letter of support, Dr. Hull), which receives referrals from throughout the state, as well as with a high-volume solo-practitioner primary care internist who is involved in several pain initiatives in the state (see letter of support, Dr. Braun). These clinician partners will be involved in all stages of development, implementation, and outcomes assessment. Specifically, we will conduct cognitive interviews among clinicians to pretest the nominal group technique (NGT) questions, we will conduct NGTs among clinicians, we will address clinical implementation as a key question, and we include clinicians in all of our formative and summative evaluations, including usability testing, beta-testing, and the RCT. We will rigorously assess the impact of the SDM platform on clinicians and explore different approaches to integrate the SDM platform into clinical care. Several clinicians will serve on our Advisory Panel and as anchors for recruitment. All activities conducted among patients will have parallel counterparts among HCPs.

D. Proposal

1. Overall Goal and Objectives: The overall goal of this project is to create a truly patient-centered decision support tool that patients and health care providers (HCPs) can use together to support informed, preference-based approaches to chronic pain management, Pain-APP (Assessing Patient Preferences). Our long-term goal is to improve the quality of life of patients with chronic pain.

Our **key objectives** are to:

- Understand the treatment goals, preferences, and values of patients with chronic pain;
- Improve patient-provider communication;
- Stimulate patients to think about their treatment goals, preference, and values and how these relate to a treatment decision ("values clarification");
- Help HCPs be aware of the patient's level of pain, treatment goals, preferences, values, and concerns as they relate to a treatment plan;
- Improve interprofessional communication among HCPs about a patient's goals and understanding of their condition;
- Measure the impact of *Pain-APP* on patient-provider communication and other outcomes in a randomized controlled trial (RCT).

Alignment of goals with the focus of the RFP: Our goals are aligned with the focus of the RFP, addressing four areas of interest: we will develop and make a freely available online resource that supports HCP and interprofessional skill development by eliciting patient preferences and concerns and communicating them to their HCPs **(#1)**; engage less activated patients to help them become more engaged and improve their self-efficacy by facilitating communication about what's important to them **(#1 and #2);** develop resources that analyze patient-reported information and linking that to physiological phenomena, using a shared decision making (SDM) framework **(#3)**, and enable future collaborative patient centered research and implementation efforts by developing a generalizable approach and study design **(#4)**.

2. Technical Approach:

a. Current assessment of need:

Challenges associated with managing chronic pain: Chronic pain affects over 100 million Americans and costs nearly $635 billion annually.[4] About 31% of Americans experienced chronic pain in 2010.[5] Chronic pain can affect anyone at any stage of life.[6] It can arise from genetic predisposition, as part of another chronic disease, as a complication of surgery, after an injury, from obesity, or aging. Pain and its treatment are associated with numerous comorbidities including depression and posttraumatic stress disorder (PTSD); it can impair function and common pharmacological treatments can cause dependency (e.g., opioids) and organ toxicity (e.g., non-steroidal anti-inflammatory drugs or NSAIDs and acetaminophen). Pain can interfere with patients' capacity for decision-making, managing other chronic diseases,[7] and communicating with health care providers (HCPs).[8]

Opioids became the mainstay of chronic pain treatment in recent decades. When properly

Abbreviations Used:		
• **ACPA:** American Chronic Pain Association	•**MMA:** Maine Medical Association	•**RCT:** Randomized controlled trial
• **FDA:** Food & Drug Administration	•**NGT:** Nominal Group Technique	•**SDM:** Shared decision making
• **HCP**: health care provider	•**Pain-APP:** Pain: Assessing Patient Preferences	•**UAB:** University of Alabama at Birmingham
• **IOM**: Institute of Medicine	•**PCP:** Primary Care Provider	•**UNE:** University of New England
	•**PI:** Principal Investigator	

used, opioid therapy can improve patients' quality of life, decrease healthcare costs, and promote work productivity. However, misuse and abuse of prescription opioids has reached epidemic proportions.[9] From 1991 to 2009, prescriptions for opioid analgesics nearly tripled, and over 12 million people abused or misused prescription pain relievers in 2009.[10] Factors that drove the overuse of opioids were misinformation about its benefits and harms,[11] inadequate training of HCPs in pain management, too little clinic time spent with complex patients, and too few multidisciplinary treatment programs.[12,13] Yet pain remains undertreated among those most in need. **Today's prescription drug crisis reflects a broad failure in managing pain.**

The importance of patient-centered care: Pain can only be understood through the patients' perspectives by taking into account their perceptions, values, beliefs, social context, illness behaviors, and personal experiences. Yet pain management is far from being patient-centered. Patients with chronic pain are often stymied by the complexity of the health choices they face. Patients' preferences for pain treatments differ from those of HCPs. Patients tend to place more importance on interventions that improve quality of life and function with the least disruption in their daily life. In contrast, physicians place less importance on quality of life,[14] focus on minimizing mortality risks, and choose time-consuming interventions that may provide additional health benefits.[15]

> "Primary care doctors often don't know how to do a good intake for pain."   --Internist in ME

Challenges for clinicians: For clinicians, managing chronic pain is typically time consuming, costly, and often ineffective. Physicians routinely neglect to assess patient goals and values;[16] patient preferences rarely guide treatment plans. Primary care providers (PCPs) often consider pain management as being "frustrating" and "overwhelming".[17] Most (75%) VA PCPs considered chronic pain a "major source of frustration."[18] Analysis of patient-provider communication patterns for patients who requested opioids revealed substantial interpersonal tension and discomfort.[19] PCPs often view patients with chronic pain as "difficult patients."[18,19] As a result, many patients feel stigmatized and misunderstood[20] and report being labeled as hypochondriacs or drug seekers.[21]

Patient–provider communication is critically important in pain management and predicts patient satisfaction better than actual

> The effectiveness of pain treatments depends greatly on the strength of the clinician–patient relationship"
> --IOM, Relieving Pain in America

decreases in reported pain.[22,23,24,25] The need to improve patient-provider communication is compelling. For example, patients with low back pain are less likely to seek additional and often unnecessary or harmful medical interventions from an outside provider if they perceive their pain concerns have been adequately addressed by their HCPs.[26] Most HCPs are neither taught how to assess or manage chronic pain nor how to involve patients in SDM. While patients seek more involvement in their care, patients often do not understand that they have a decision to make, why they are asked to be involved in decision-making, nor how to use their preferences and values to choose a treatment.[27,28] These barriers interfere with collaborative relationships.[29] Helping patients make better treatment choices by improving patient-provider communication should improve quality of life of people with chronic pain. **Our SDM platform is designed to improve patient-provider communication and make it easier for HCPs to care for these patients. Pain-APP will elicit patients' goals, preferences and concerns and transmit this critical information to their HCPs.**

<u>One-size-fits-all approaches do not work</u>: Many studies treat pain conditions as if they were homogenous conditions. Treatment guidelines, such as the 3-step ladder for pain management (ascending from non-opioid treatments to strong opioids),[30] match the intensity of the pain with the potency of the analgesic. Yet <u>different</u> <u>subgroups may respond differently</u> to a treatment, have <u>different treatment goals</u>, or <u>value outcomes differently</u>. Factors other than the specific diagnosis often determine appropriate treatment choice and outcomes.

Our SDM platform will elicit relevant patient information about their condition, goals , and circumstances, transmit this to their HCPs, and tailor the information to the HCP's needs to help promote patient-centered care and help HCPs better manage patients with chronic pain.

Figure 1. Conceptual Model

<u>A national mandate</u>: Improving the management of pain is a **top national priority**. The Institute of Medicine (IOM) concluded: "even existing knowledge [about pain] is not always used effectively, and thus substantial numbers of people suffer unnecessarily."[1] The American Academy of Pain Medicine called for more education for HCPs and patients. The FDA issued an open letter to all HCPs urging them "to take advantage of educational programs designed to...promote responsible opioid prescribing, improve pain management, and minimize prescription drug abuse and diversion."[31] There are wider geographic variations in opioid prescribing than for all classes of medications combined (23-fold differences across states).[32]

<u>Challenges in Maine</u>: Maine has the highest percentage of residents seeking treatment for addiction to prescription narcotics[33] and more prescription drug deaths than traffic fatalities.[34] Maine's former U.S. Attorney called prescription pain-pill abuse "the greatest criminal problem and possibly the greatest social problem facing Maine."[35] Most (56%) painkiller prescriptions in Maine were given to patients who had filled another prescription for pain from the same or different providers within the past month. Among Medicaid recipients in Maine, 10-15% were receiving daily doses that greatly exceed recommended upper limits (>300 milligrams per day).

The Maine Medical Association (MMA) recently (2014) adopted a goal of reducing the dispensing of opioid medications for chronic pain in Maine by 25% through advocating for the use of other evidenced-based treatments and shifting the goal of pain treatment from being pain-free to maximizing function.[36]

<u>The communication gap in Maine</u>: We first were made aware of a gap in patient-provider communication concerning pain when members of the local Chronic Pain Support Group of
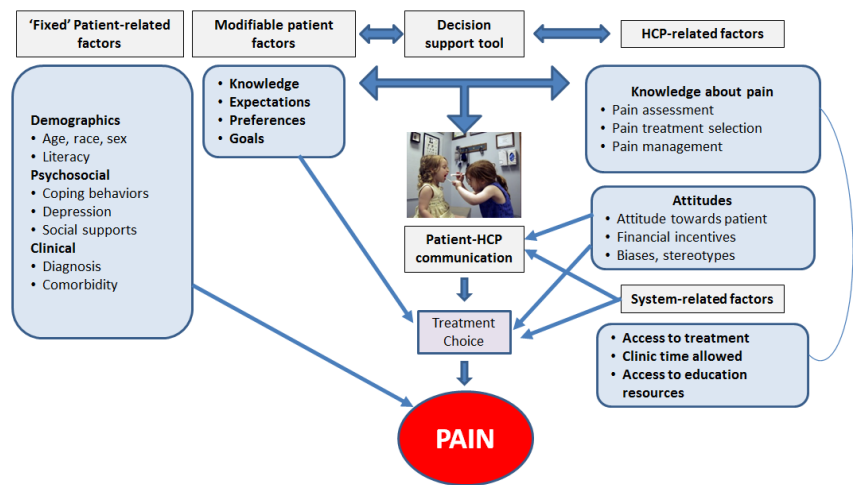
Southern Maine contacted us requesting help communicating with their HCPs, citing numerous communication challenges. We have worked closely with this support group to craft programs and solutions to meet their needs. Led by collaborator Ernie Merritt, patients requested that we pair medical students with patients to accompany them to their clinic visits, helping them to advocate on their own behalf, to find answers to their unanswered questions about their health, and to explain their doctor's advice. This request triggered a series of structured meetings of the PI, other collaborators, and medical students with this patient group. These led to the development of an online tool to assess patients' health questions, which was pretested with patients with chronic pain. After IRB review and approval, this survey was distributed to the patients and used to collect patient data. We have also worked with medical and other HCP students and faculty at the University of New England (UNE) to explore the feasibility of the support groups requests and to explore a range of solutions. This also spurred several structured group discussions with HCPs, including PCPs and pain specialists at Mercy Pain Center (the Interdisciplinary Pain Group) to explore gaps and solutions from providers' perspectives. We have conducted a nominal group technique (NGT) meeting among interdisciplinary HCPs to prioritize HCP's concerns (findings are available upon request).

<u>Our Solution</u>: We partner with engaged patients, HCPs, policy makers, scientists, and educators to develop a shared decision making platform that accounts for the patient experience and perspectives via Pain-APP, elicits the patients' goals and concerns, and transmits them to their HCP. We will assess its acceptability, feasibility, and impact on patients and HCPs. Our study has high potential to **improve patient-provider communication** about pain management and in doing so, to improve how chronic pain is managed and ultimately, the **quality of life** of patients with chronic pain.

<u>The larger context of this proposal</u>: The present proposal fits into a larger plan for improving the management of pain. Maine's Medicaid program recently disseminated a comprehensive Pain Management Program to help prescribers distinguish between acute and chronic pain, identify evidence-based treatments, establish clinically appropriate limits on doses, and identify when second opinions are needed. Since this program began in 2013, the number of opioids dispensed for Medicaid recipients decreased by 45%, prescriptions are for shorter durations, and daily dosing has decreased. After this success with Maine's Medicaid recipients, plans are underway to disseminate this program to patients with other insurance types in Maine. However, the program is not patient-centered and its impact on pain, function, quality of life, and patient-provider communication is unknown. To fill this gap, the project team in collaboration with other partners (VA Maine) submitted a proposal to Patient-Centered Outcomes Research Institute (PCORI) to improve this program and make it patient-centered and HCP-friendly by coupling it with patient and HCP resources that support patient-centered care and facilitate patient-provider communication. That PCORI proposal would fund state-wide dissemination (in 2017), creation of a pain hotline for HCPs, and evaluation of its effectiveness using time series analyses. Our letter of intent (targeting *Improving Health Care Systems*) was selected for a full proposal, which is presently under review. The present proposal dovetails with that PCORI application, developing and testing the web-based SDM platform before it is coupled with the state-wide Pain Management Program. The two projects are complementary and synergistic, but either can stand on its own.

Table 1. Gaps addressed

Identified Gap/Challenge	Feature of Pain-APP
HCP lack of skill in assessing patient preferences	Assess patient goals, values, and preferences and communicate this information to HCP
Patients intimidated by doctors, forget to ask questions	Elicit patient questions and transmit to HCP
HCP inexperience or insufficient time to assess pain	Elicit patient's pain history (onset, severity, character, timing) and functional level; transmit to HCP
Issues in literacy, doctor-speak vs. patient-speak	Assess literacy and transmit to HCP, develop scripted messages to facilitate SDM
Poor patient-provider communication	Customize communication using a SDM framework and individualized SDM reports
Poor Inter-professional communication	Patient can share preferences and concerns with all involved HCPs using SDM reports
Challenges integrating decision support tools into clinical practice	Designed to address integration barriers

Primary audiences targeted: We target: 1) adults with a diagnosis of a chronic musculoskeletal or neurologic pain disorder, present experience with persistent pain lasting >1 year, excluding those whose pain is primarily gastrointestinal, genitourinary, or cardiac in origin; 2) HCPs with > 2 years of clinical experience who manage patients with chronic pain, focusing on primary care providers (physicians, nurses, and physician assistants (PAs)) and pain specialists (physiatrists, anesthesiologists, psychiatrists, psychologists, social workers, and physical therapists).
Who is expected to benefit: We expect that patients with chronic pain and HCPs who manage chronic pain will benefit from the SDM platform. **Our SDM platform is designed to improve patient-provider communication, which should improve patient outcomes and make it easier for HCPs to care for patients with chronic pain.**
b. Project Design and Methods: The proposed project will consist of 4 phases: 1) Formative work (preparation, needs assessment); 2) Development and refinement of *Pain-APP*; 3) Evaluation in a RCT on a representative sample of 50 patients with chronic pain and their HCPs; and 4) Dissemination. To accomplish our stated goals and meet the identified needs, a mixed methods study is proposed, using cognitive mapping to obtain robust data about the goals and strategies of patients and HCPs. We will conduct NGT meetings with patients and HCPs to identify and prioritize goals and strategies. These prioritized goals and strategies will then inform our preference assessment tools, which will be embedded into the SDM platform using previously validated SDM templates[37] to summarize and communicate elicited preferences to HCPs. A multidisciplinary Advisory Panel (including patients and HCPs) will guide the project. We target diverse patients with chronic unremitting pain, recruiting chronic pain support group leaders across the country through the ACPA and HCPs across the state of Maine through our HCP partners, including the Maine Medical Association (MMA).

We propose to:

1. Conduct NGTs to identify and prioritize patient goals, strategies to improve patient-provider communication, and strategies to integrate the platform into clinical settings (4 NGTs with 28 patients, 4 NGTs with 28 HCPs).

2. Perform card sorting tasks to examine how patients (n=25) and HCPs (n=20) organize the *goals*, *SDM strategies*, and *implementation strategies* identified in the NGT meetings.

3. Develop preference assessment tools based on these prioritized preferences (usability testing with 25 subjects).

4. Refine the interprofessional SDM reports that assess and communicate patient preferences, goals, concerns, pain, literacy, and other constructs identified as being important by patients and HCP using a SDM framework (Figure 2). Reports will be tailored to the needs of different HCPs (specialists versus primary care, usability testing, n= 25 (same subjects as #4 above).

5. Develop the SDM platform, linking the preferences to individualized SDM reports. Conduct Beta-testing on 10 subjects.

6. Evaluate Pain-APP on patients and providers to establish its feasibility, acceptability, and impact.
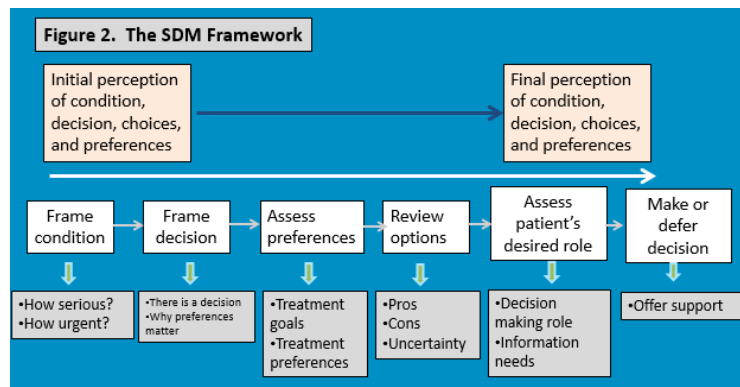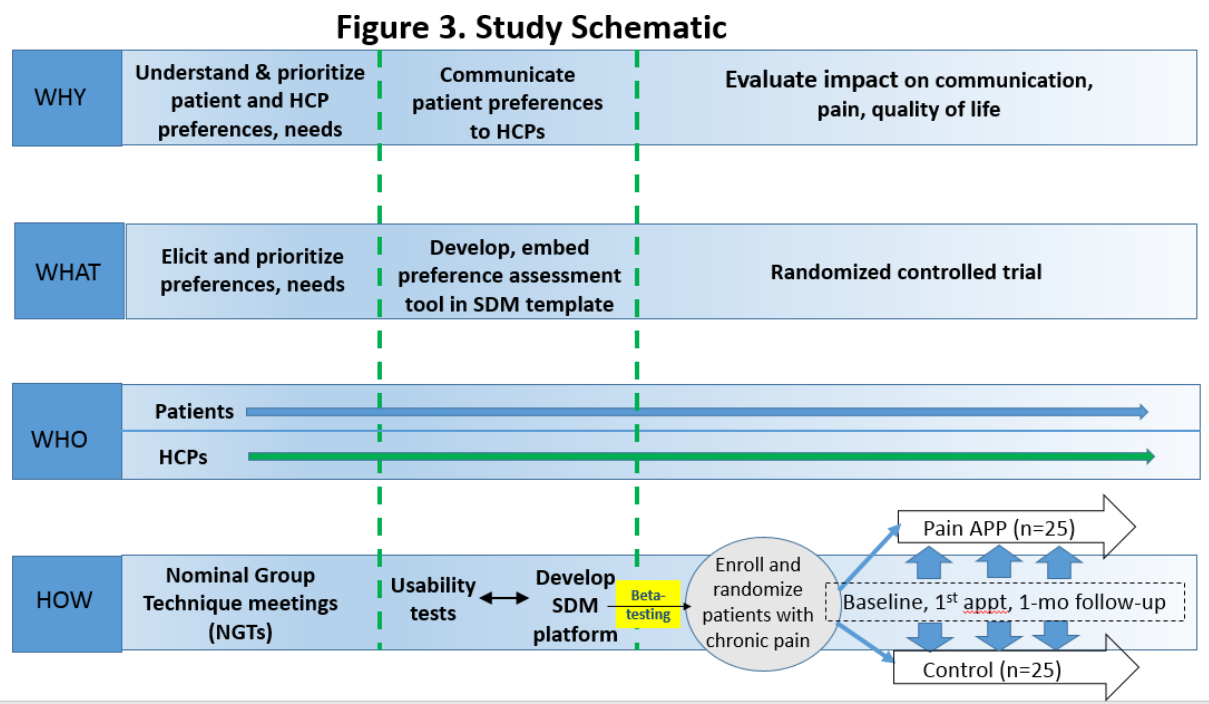
7. Disseminate Pain-APP.

Figure 2. The SDM Framework

Figure 3 summarizes the study plan.

Figure 3. Study Schematic

Task 1: Conduct NGTs: The NGT is a data collection strategy that imposes structure on focus group meetings.[38] It is intended to foster creativity and help group members articulate meaningful disclosures in response to a single question. The structured framework of the NGT minimizes power differentials that may exist among group members or between the group members and the moderator. By promoting even rates of participation and equally weighting the input from all group members, the ordinal data generated by this process provide a valid and an easily interpretable representation of the implicit prioritized views held by a representative group.

NGT meetings with different groups of patients and HCPs will be conducted to identify their treatment goals, strategies that they think will improve SDM and patient-provider communication, and implementation strategies for integrating the SDM platform into their practice. Participants will be asked to frame their responses around one of the following draft questions:

> **Goals:** What do you specifically hope to achieve (or avoid), now and in the future, when you choose ways to manage your chronic pain?
>
> **SDM Strategies:** What sort of things would help you and your HCP/patient make informed treatment decisions?
>
> **Implementation strategies:** How would you integrate this into your clinical practice?

Formulating the specific questions: Our Advisory Panel will refine the candidate questions for NGT meetings. The actual questions will be specified only after they have been shown to elicit meaningful responses in **cognitive interviews**. These interviews will evaluate how they are understood from the perspective of participants (2-3 per question) by trained project staff following a written protocol. The interviewer will read and show the question to the subject, asking: 1) what they perceive the question is asking, 2) if the question is clear, and 3) what responses immediately come to mind. Interviews last about 20 minutes. Responses will be qualitative and recorded for refinement of the questions.

NGT meetings: To increase the likelihood of obtaining a comprehensive and representative array of patient and HCP responses, each of the final questions will be addressed in 2 NGT meetings with each target audience. We propose to convene 8 separate NGT meetings with 40-56 participants (total) stratified in terms of participant group (patient vs provider), question focus, and NGT type (Table 2).

Table 2. NGT meeting and sampling plan			
NGT Questions:	Patients	HCPs	Total
Goals	2		2
SDM strategies	2	2	4
Implementation strategies		2	2

Each meeting will consist of 5-9 different patients or HCPs, conducted by Dr. Col, in person or online, lasting 60-90 minutes. Barriers for patients and HCPs are well studied.[39,40] We will use patient and HCP perceived barriers from the literature to stimulate participants to generate strategies to overcome barriers. To expand reach beyond Maine, we will hold online NGT meetings, recruiting patient subjects through the ACPA. The online NGT meetings will be conducted using an asynchronous internet-

based virtual NGT forum using long-distance teleconference technology (i-Meet). This program has been developed and used by Dr. Col for a study about multiple sclerosis. Participants will access the virtual NGT forum via a unique link to the study website that includes brief videos explaining each step of the process. During each in-person NGT meeting, participants first will be asked to work independently and silently to generate ideas in response to one open-ended question. A round-robin approach will be used to elicit a single idea from each participant in each round. Every idea will be recorded and projected in plain view of the participants and the process continues until participants are unable to generate more ideas. At that point, the group will be invited to participate in a discussion to focus or clarify, but not to criticize or otherwise evaluate, the responses. Each participant then will be instructed to rank or prioritize 5-9 of what they perceive to be the most important of the responses. Finally, the individual rankings will be aggregated across all members of the group and the aggregated results presented to the group for their final comments.[41],[42]

Given the small number of NGT participants, comparisons of the responses generated by the different groups will be descriptive only. We will aggregate the prioritized responses across groups to ensure that the responses convey similar meanings across groups.

Based on previous experience, we expect that NGT participants will nominate between 30-45 responses to each question, that about one third of these will be endorsed by the group, and there will be considerable overlap and generalizability of the responses across groups, and the final, refined lists will each consist of approximately 20-25 non-redundant responses that convey similar meanings across all groups. By combining only the prioritized responses across the patient and HCP groups we will ensure that the most important issues are specified, by including only those issues ranked as important by at least one group effectively eliminates idiosyncratic or tangential responses.

Task 2: Conduct card sorting: We will develop a card sorting task to examine how patients (n= 25) and HCPs (n=20) cognitively organize the separate sets of *goals*, *SDM strategies*, and *implementation strategies* identified in the NGT meetings. For each card sorting task,

participants will be shown a shuffled deck of individually labeled cards and asked to use their own criteria to sort the cards into an unspecified number of card stacks containing any number of perceptually similar cards.

Task 3: Building the SDM platform: We partner with PMI, a leading non-profit in relationship education, who we selected because they


Figure 4. The SDM Platform
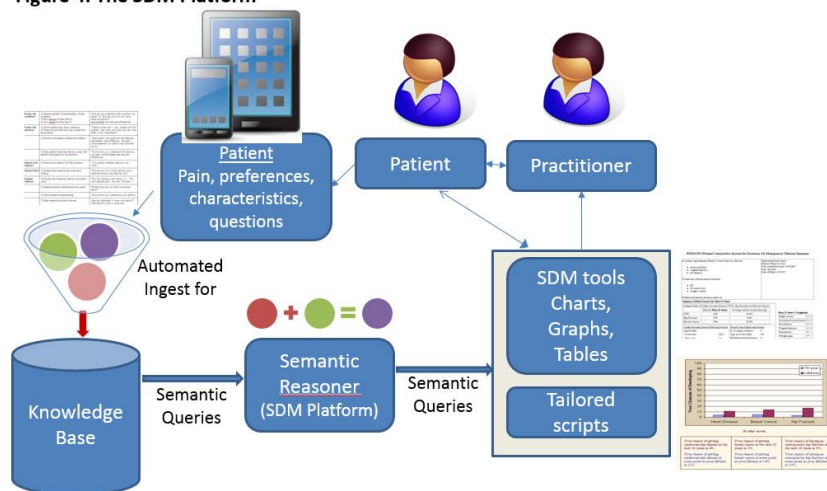
developed and manage the leading website for patients with chronic pain, the American Chronic Pain Association, which includes user-friendly health management tools and apps.[43] Steps in the development process include:

1) **Develop user interface constructs** (Figure 4) to:
   - Allow patients to input preferences and other data
   - Tailor the presentation of information to users
2) **Develop a semantic reasoner** to translate patient data into knowledge and to map stated preferences to tailored scripts
3) **Develop visualization constructs** to illustrate and compare key constructs (e.g., level of pain, function)
4) **Develop short demonstration videos** to help new users navigate the site, enter information, and interpret feedback.

User centered development process: The system will undergo extensive usability testing and debugging to ensure that its information is accurate and useful. We will then conduct "think aloud" usability tests on **patients and HCPs**, revising after 2-3 tests (n=10-12). We will begin online **beta testing** through our local and national partners.

We apply a user centered-development process, the **Technology Acceptance Model (TAM)**,[44] which posits that user perceptions are formed after minimal exposure to the system; perceived ease of use, value (in enhancing decision making), and trust determine a person's intention to use the system (Figure 5).[45]

Figure 5. Technology Acceptance Model (TAM)
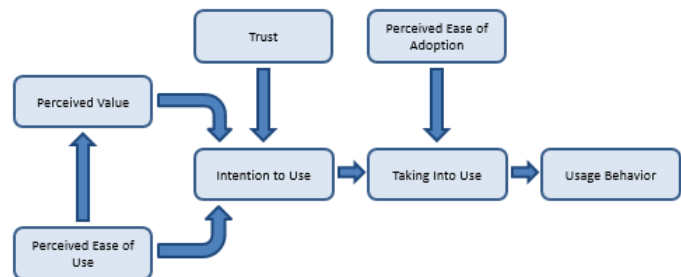
Criteria for success: We will evaluate the perceived value of Pain-APP using TAM constructs (value, trust, ease of use, etc.). Users will be asked their gender, age, race, and education and to rate their overall impressions of the site and suggestions for improvement using a short questionnaire. Beta-testing (using online questionnaires on the website) will continue until at least 80% of users in each target demographic group find it usable and informative. We estimate n=10 Beta-testers (including patients and HCPs).

The SDM platform will be built using the latest available version of Microsoft's .NET Framework and SQL Server along with the best patterns and practices for HTML, CSS, Javascript. The design template for the SDM feedback pages will be draw from the SDM framework (Figure 2) and previous personalized health IT applications that summarized patient-

specific information to their HCP (Chart).

Innovation: Our innovations include our methods (online NGTs) to identify and prioritize patient preferences about pain and use of an SDM framework to help patients and HCPs convey their preferences to guide decisions and promote coordination among the HCPs involved in a patient's care. Our platform will be the first to elicit and convey patient preferences and other patient-centered information about chronic pain to HCPs using an interprofessional SDM framework.[46] Pain-APP should improve patient-HCP communication by **changing the focus of the clinical encounter from data gathering to SDM,** stimulating discussion about desired outcomes and personal values.

c. Evaluation Design: <u>Overview</u>: We include extensive formative and summative (outcome) evaluations. Our formative evaluations include semi-structured cognitive interviews, iterative usability testing, and beta-testing, assessing the impact of each component of the SDM platform (the intake questionnaire, patient output, HCP output) on its intended audience. These evaluations will ensure that the information transmitted through Pain-APP is accurate, valid, uniformly understood, and useful to patients and HCPs. After we achieve satisfactory evaluations from at least 90% of our beta testers**,** we will conduct a small RCT in a representative sample of our intended audience, including 50 patients and 5-15 HCPs. Eligible patients will be enrolled online, and after informed consent, randomized online to either Pain-APP or the control group, which will consist of online educational materials (*Managing Chronic Pain: A Guide for Patients).[47]* Patients in both groups will be assessed before, immediately after the index clinic visit, and 1 month later. Patient-reported outcomes will include patient-provider communication, pain intensity and interference, physical function, depression, and catastrophizing, using validated scales (See Table 3). We also include qualitative patient evaluations on a random sampling (20%) of patients (in both groups) in order to capture the full range of its impact and to explore potential mechanisms of action. Structured phone interviews including open-ended questions will assess patient perceptions of the platform, perceptions about how it affected communication and decisions making about treatments, trust in their HCP, and self-efficacy.

HCPs will be surveyed shortly after the patient encounter to assess acceptability of the tool, its perceived utility, and its impact on clinical efficiency. Additionally, quality of the patient encounter, ease of assessing patients with pain and of making decisions regarding treatments to manage that patient's pain will be evaluated using previously developed instruments. We hope to measure its impact longitudinally through a separate PCORI grant (pending 11/1/2015).

<u>**Our Main Hypothesis**</u>: Compared to control, patients assigned to Pain-APP will have better patient-HCP communication.

<u>**Outcome measures:**</u>
<u>**i) Determining if the practice gap was addressed for the target group**</u>: All of our identified gaps in patient-provider communication (Table 1) are measured by the validated COMRADE scale. This patient self-report scale measures communication and decision-making effectiveness, satisfaction with HCP communication, and confidence in the decision made.[48,49,50] Patient-provider communication - the most important factor mediating health outcomes for patients

with chronic pain—is <u>our primary outcome measure.</u> We will separately evaluate the HCP's perceived impact of Pain-APP on communication and other outcomes.

<u>Secondary outcome measures include</u> pain intensity and interference, physical function, and mental health (depression, catastrophizing). Other measures are described in Table 3.

<u>Pain and interference</u>: The Brief Pain Inventory (BPI) rates the severity and location of pain and the degree to which it interferes with daily function. It is the most widely used tool for assessing clinical pain caused by a wide range of clinical conditions; a change of 1 point is considered to be clinically important.[51,52] Cronbach alpha reliability ranges from 0.77 to 0.91.

<u>Physical Function</u>: The PROMIS Physical Function (Adult 10-item version) assesses one's ability to carry out activities that require physical actions, ranging from self-care to more complex activities that require a combination of skills.

<u>Depression</u>: The Center for Epidemiologic Studies Depression (CES-D) scale measures the severity of depressive symptoms. The 20-item self-administered questionnaire has established reliability and validity.[59,60]

<u>The Pain Catastrophizing Scale (PCS)</u> is a validated patient-reported 13-item scale.[61]

<u>We will pre-test the intake survey and preference assessment tool/s</u>: The sample will include 6-12 patients recruited from the Southern Maine Chronic Pain Support groups. We will enact recruitment procedures, informed consent, baseline data collection, and follow-up data reporting. These subjects will also pretest the structured needs assessment

Table 3. Outcome Measures					
Construct	**Measure**	**# items**	**T_0***	**T_1**	**T_2**
Primary outcome					
Patient-HCP communication	COMRADE[53]	20	x	x	x
Secondary Outcomes	**Self-report**				
Pain (severity, interference)	Brief Pain Inventory	8	x	x	x
Physical function	PROMIS Physical Function	10	x	x	x
Moderators / confounders					
Socio-demographics	Age, gender, race, ethnicity, partner, insurance, zip, etc.		x		
Self-efficacy	Decisional Self-Efficacy scale	11	x	x	x
Depression	CESD-R[54,55]	20	x		
Pain catastrophizing	PCS[56]	13	x		x
Literacy and numeracy	Subjective Numeracy & Literacy[57,58]	3	x		

interview. Refinements will be made and incorporated into the study's Manual of Procedures. <u>Beta-testing</u> (before the RCT is started) will also monitor how subjects use the site, time spent on different pages or features, and explore user experience (using google analytics or a comparable product, "Optimizely").

Phase I data analyses plan: Multidimensional scaling will be used to analyze the NGT and card sort data.[62,63,64,65] Hierarchical cluster analysis will be used to identify subgroups of homogenous strategies.[66,,67] Organizational frameworks (maps) reflecting different patterns of goals and SDM strategies will be developed for patients and HCPs. These analyses will help us understand how goals/strategies are viewed and organized by our stakeholders, which will directly inform the design of our SDM templates. Dr. Qu has used these approaches in her

previous studies.[68,69] We will use simple descriptive statistics (mean, variance, frequencies) to describe findings from our usability and beta tests.

Phase II data analysis plan: For the RCT, the primary outcomes analyzed will be patient-provider communication (COMM), pain (PAIN), and function (FUNCTION), all of which will be treated as continuous. We will compare Pain-APP and the control intervention. We will adhere to accepted standards.[70,71] Analysis will be done in 4 stages: We will examine 1) whether variables meet expected distributional assumptions; 2) bivariate associations between treatment arms and each outcome, and between covariates and outcomes. 3) unadjusted measures of effect and potential confounders; 4) exploratory multivariable analyses. Patients who are lost to follow-up will be treated according to their assigned group (intent to treat analysis). We will use analysis of covariance to assess differences in outcomes between assigned groups, adjusting for any baseline differences between the randomized comparison groups. Covariates will include baseline health status, moderators listed in Table 3, and prescriber characteristics. We will use linear mixed-effects models, treating scores at different points in time as repeated measures to account for inter-correlation between these measurements. We will control for patient- and HCP-level factors by including them as covariates.

ii) Quantify the amount of change expected: We expect to find, at minimum, a 20% improvement in communication, comparing the difference in communication pre- post-intervention in the Pain-APP group to that of the control group.

Power analysis: We expect a mean of 70 and a SD of 20.[72] With our sample size of 50 (25 in each arm), we estimate having an 80% chance of detecting a 20% improvement on the primary outcome COMM at time=T_1, with a type-I error rate of 0.05.

Recruitment: Patient recruitment for the cognitive interviews, NGTs and usability testing will be conducted by ACPA. HCP recruitment will be done through the MMA and our HCP partners in Maine. Online subjects will include leaders of chronic pain support groups around the country, recruited through the ACPA.

Participant recruitment in Maine: Patients will be recruited using purposeful and snowball sampling through strategically placed ads/flyers at our many participating clinics and support groups. Participating clinics and HCPs will be identified by our partnering MMA who will use their extensive networks throughout Maine to identify, reach out to, and enlist clinics, including primary care and specialty pain clinics. We already have the support of several practice sites, including Mercy Pain Center and Dr. Braun's primary care clinic (see letters of support).

Feasibility of Recruitment: We have previously implemented an online needs assessment survey for patients with chronic pain attending a support group meeting. Of the 12 who attended some part of the meeting, 9 indicated interest in participating, 8 logged into the survey, and 7 gave valid responses within 3 days of receiving the survey. The proposed online recruitment strategy is being used for an ongoing MS study with very high response and completion rates.

We do not anticipate any challenges in being able to identify and recruit 50 patients for the RCT over the span of 3 months. We could easily recruit all subjects from just one of our pain referral centers, although this is not our plan. The Pain Center (Portland, ME), directed by collaborator

Dr. Hull, sees 13,000 patients a year referred from throughout the state, including 300 new patient referrals each month (note that we do not limit our study to new referrals). About 75% of those patients have chronic pain and 60% of those are conservatively estimated to be eligible for the study, corresponding to 5,850 potentially eligible subjects a year from this site alone. In contrast, only 50 subjects are needed for this study. The MMA engages all 600 PCPs in the state, providing a convenient route to access HCPs.

iii) Determining if the target audience was fully engaged in the project: We use several approaches to determine engagement of both patients with chronic pain and HCPs. During the formative stages, we will routinely assess patient and HCP engagement through our Advisory Panel, by making this a recurring agenda topic. We will also elicit approaches to improve engagement. In our evaluation, we will assess engagement by monitoring how Pain-APP is used, and asking testers to provide feedback on their level of engagement with the tool. During the RCT, we will monitor interest (initial and sustained) in the study, and monitor drop-outs. During our qualitative sampling of 20% of our RCT subjects, their level of engagement will be assessed.

iv) Plans for broad dissemination: Our study has high potential for dissemination of both its scientific findings and its resulting product, the *Pain-APP* tool-kit. Our findings will be disseminated through publication in high profile scientific journals, national presentations, national workshops and seminars at national meetings, newsletters and mailings through our national partners the VA, consumer websites (ACPA) and newsletters, and social networks (i.e., ResearchGate, LinkedIn), targeting groups such as "Effective Decision Making in the Midst of Complexity Group Members <group-digests@linkedin.com", listserves Shared@EACH - Shared Decision Making Network, professional societies such as Society for Medical Decision newsletters, and national societies addressing pain management. We will leverage stakeholders on our Advisory Panel and disseminate through their affiliated networks.

Within Maine, the MMA will utilize its electronic newsletter (Maine Medicine Weekly Update) published every week to share information on this initiative with every practice in the state. Dr. Hull has access to the extensive network of Eastern Maine Healthcare System (EMHS). ACPA has access to all members of its support group network in Maine.

Our *Pain-APP* toolkit will be designed for rapid dissemination and broad reach. It will be available online through the study website. Thus dissemination can be accomplished by including links to our website on partners' websites, including the ACPA. We will notify the various pain consortia in which the team members are involved (e.g., Pain Research Working Group) and present our study and its findings as a cyber-seminar (e.g., the VA (HSR&D Cyber-seminar).

We will also disseminate our findings by presenting our work at a meeting of the *Initiative on Methods, Measurement, and Pain Assessment in Clinical Trials* (IMMPACT),[73] which develops consensus reviews and recommendations for improving the design, execution, and interpretation of clinical trials of treatments for pain.

Our SDM platform has specific features that enhance its potential for dissemination, including:
1. Web-based: simplifies access to patient and HCP educational and training materials. The website will contain resources that can be printed by a practice and distributed to patients; it will also include printable screening tools that can be used in lieu of online screeners for those who lack Internet access.

2. Online training videos will depict how to navigate and use the toolkit; videos demonstrating actual patient-provider encounters using resources included in the toolkit will be included.

Features that promote broad implementation:
- Addressing obstacles to implementation (work flow, HCP ennui, demonstrated value)
- Low costs of implementation and dissemination
- Ensuring that the content is transparent and trustworthy to users.

Features that promote it long-term sustainability:
One of the greatest challenges to the sustainability of any type of educational decision support tools is that the evidence base is constantly evolving, making content updates costly. Web-based programs are easier to update, but require specialized expertise. By collaborating with other organizations that share our goals (e.g., MMA, ACPA) and tapping into the altruistic nature of people, we promote our long-term sustainability after study completion.
We plan to make the toolkit available on media that are accessible to vulnerable populations. We will make the tool-kit available as a 'hybrid app' that works on multiple platforms, including mobile phone, such as the free pre-paid cell phones that are routinely issued by Medicaid (e.g., Safelink[74] or Assurance wireless phones[75]).

d. Detailed Work Plan:
1. Prepare for kick-off meeting
2. Complete core training of staff
3. Develop formal study protocol and obtain IRB approval
4. Develop draft NGT questions for each target audience: first with advisory panel, then with cognitive interviews
5. Adapt the online NGT survey for this application, embedding inclusion/exclusion criteria and informed consent into the online program.
6. Recruit subjects for NGT (create panels of subjects, from the ACPA and MMA)
7. Conduct NGTs to identify and prioritize patient goals, strategies to improve patient-provider communication, and strategies to integrate the platform into clinical settings
8. Perform card sorting tasks to examine how patients and HCPs organize the *goals*, *SDM strategies*, and *implementation strategies* identified in the NGT meetings.
9. Draft and refine preference assessment tools based on these prioritized preferences through usability testing.
10. Draft and refine SDM templates (interprofessional SDM reports) that assess and communicate patient preferences, goals, concerns, etc to HCPs, through usability testing
11. Develop the SDM platform, linking the preferences to individualized SDM reports
12. Beta-test the platform (Pain-APP)
13. Develop and pretest intake screeners and outcome measures for the RCT
14. Embed intake screening, consent, randomization, and baseline measures into the RCT survey software (Qualtrics)
15. Identify recruitment sites for the RCT
16. Recruit patients and HCPs into the RCT
17. Implement the RCT to evaluate the impact of Pain-APP on patients and HCPs.
18. Analyze results from the RCT
19. Broadly disseminate Pain-APP through our advisory Panel and partners (ACPA, MMA).

E. Project Timeline

Activities	Year 1 (2015 / 2016)												Year 2 (2016-2017)									
	S	O	N	D	J	F	M	A	M	J	J	A	S	O	N	D	J	F	M	A	M	J
Kick-off meeting	x																					
Develop IRB protocol	x	x	x																			
Recruit subjects			x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x			
Cognitive Interviews			x																			
Conduct NGTs, analyses			x	x	x	x	x															
Conduct card sorts								x	x													
Draft Preference tools					x	x	x	x	x													
Draft SDM templates							x	x	x	x	x	x	x	x								
Design digital platform				x	x	x	x	x	x	x	x	x	x	x	x	x	x	x	x			
Usability testing								x	x	x	x	x	x	x	x							
Beta-testing														x	x							
Conduct RCT																x	x	x	x	x		
Preparation of papers, reports																			x	x	x	x

Table 4. Deliverables Schedule:

Deliverable	Date
Kick-off meeting	9/30/15
IRB approval	11/15/15
Complete NGT reports (patients)	3/15/16
Complete NGT reports (HCPs)	3/31/16
Complete card sort (report)	5/31/16
Complete usability testing of preference assessment tool	8/31/16
Complete usability testing of digital platform & SDM templates	10/31/16
Complete beta-testing	12/31/16
Complete RCT	4/30/17
Complete final report	6/30/17

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